Lower Limb Prosthetic Components
Clinical Support Manual

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Clinical Support Manual

Welcome to the Clinical Support Manual. The aim of this manual is to provide you with the sort of information that it would be impossible to include within the Lower Limb Components Catalogue, but which will help you make better use of those products. To that end, it contains Clinical Evaluation Summaries on many of the products that can be found in our catalogue.

Clinical Evaluation Summaries

These are summaries of a few simple evaluations of each product, carried out by the Clinical Support Group. Though these evaluations are clearly not exhaustive studies, they will help avoid the inappropriate application of products, provided the Indications and Contraindications are observed. They are also available to download from our website, along with some other information regarding maintenance, alignment and assembly.

Clinical Support Group

This group consists of several experienced Prosthetists who aim to evaluate the products that the company intends to bring to the UK market. These products, manufactured by our partners in Germany, France and America, come to us with recommendations regarding their application, but the group aim to confirm these and to define them as accurately as possible. They also aim to provide as much clinical support as is needed to ensure the most appropriate application of these products.

Note: All the Össur products evaluated were supplied by Medi at the time of the evaluation.

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Clinical Evaluation Summary

CES **CPI** F01

College Park - Tres Foot

Warranty period - 1 Year

Weight Limit - 100kg (125kg for sizes 25cm and above)

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

From the responses of the prosthetists and patients alike, this is a foot that appears to function very well, being fairly compliant, but also reasonably dynamic. This is achieved in a foot that is light, even competing with many of the lightweight sach feet, but with the added advantage of a lower build height. It was evaluated, with equal success, on patients with transfemoral and transtibial amputations, but would probably be useful on patients with any level of amputation, possibly even some with Symes amputations, due to the relatively low build height.

In comparison with other feet from this manufacturer, such as the Trustep, it has less inversion/eversion and no significant torsional rotation, but this really doesn't seem to be a significant factor for the patient group it is aimed at. To get the best from the foot it is important to refer to the College Park activity levels and not to over prescribe in terms of the foot stiffness (yellow/red/blue).

Indications

Sigam mobility grade C to F
College Park activity level low to moderate
Patient would benefit from a lightweight foot, but still requires it to be reasonably dynamic and compliant
Where a fairly low build height is required

Contraindication

Mobility or activity levels outside those specified
Patients over 100kg(21cm to 24cm) or over 125kg (25cm to 31cm)

Evaluation Patients

Patient Details

Patient 1	Transfemoral	96kg	49 year old male	Machine operator	CPI low	Sigam F
Patient 2	Transtibial	63kg	76 year old male	Retired	CPI low	Sigam Dd
Patient 3	Transfemoral	83kg	59 year old male	Retired	CPI low	Sigam Dd
Patient 4	Transtibial	56kg	77 year old male	Retired	CPI low	Sigam E
Patient 5	Transtibial	78kg	62 year old male	Retired	CPI low	Primary
Patient 6	Transtibial	54kg	68 year old male	Retired	CPI low	Sigam Db

Evaluation Result

Dissatisfied — Satisfied

0 1 2 3 4 5 6 7 8 9 10

Current Prescription

Patient 1	'H' Socket with dspb suspension, Blatchfords ESK/PSPC, Multiflex foot & ankle
Patient 2	Polypropylene PTBSC, with Blatchfords Super Sach foot
Patient 3	Quadrilateral socket with TES, Blatchfords ESK/PSPC/MKL and Multiflex foot & ankle
Patient 4	Polypropylene PTBSC, with Sureflex foot
Patient 5	Primary amputee, issued with a PTB, with a cuff suspension and the Trés foot
Patient 6	Polypropylene PTBSC, with Otto Bock 1D10 foot

Prosthetist's Comments

Patient 1 – The Trés foot was chosen to attempt to improve the dynamic response of the foot. Assembly was simple and it was easy to align 5. There were no problems with the cosmesis and the product seemed durable, functioning well 5.

Patient 2 – Walks with one stick, but is an energetic man for his age and it seemed he would benefit from a livelier foot. The foot shell appeared a bit narrow and a larger size may have been slightly better. Easily set up and aligned 5. After 4 months use there was no sign of wear 5.

Patient 3 – The foot chosen since this patient is moderately active, wanting a lighter set up. The planter flexion seemed too stiff at heel strike and the shoe was difficult to don 3.

Patient 4 – The prosthetist commented that the foot was easy to assemble and align. He felt the inversion/eversion of the foot was limited, being disappointing in comparison with other CPI feet, scoring it 2 at that stage. He liked the low build height and after 3 months use saw no sign of any wear and with a very positive response from the patient, now scored 5.

Patient 5 – The comments of the prosthetist involved were favourable. He thought it was a compliant, but reasonably dynamic foot. Based on his experience with other CPI feet he was anticipating it being durable, with few maintenance problems. The cosmetic appearance was considered reasonable.

Patient 6 – Chosen in an attempt to improve the patient's stability throughout the stance phase, the clinician observed that it allowed a "steady roll over, with fair compliance". With only small issues regarding the cosmetic finishing, he scored it 2 initially, improving to 3 by the end.

Patient's Comments

Patient 1 – The patient scored his current prosthesis at 4, but negotiating slopes problematic. From the start he rated the new foot highly, using expressions such as, less tiring, less painful, more flexible and shock absorbing, increased confidence and less effort. He claims his walking distance has increased 100% and gradients are much more easily negotiated 5.

Patient 2 – It was hard getting any measurable response from this patient since everything always seems good to him, but he does appear to be very pleased with the Trés foot.

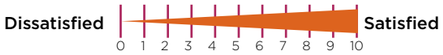
Patient 3 – The patient's comments were very difficult to decipher, but he seems happy with the function 4, despite the prosthetist's initial concerns, but unhappy with the foot size, finding it too wide for his shoes.

Patient 4 – Having scored his current prosthesis at 5, it was hard to see how the Trés foot was going to improve on that prescription. At the delivery stage he felt it was "comfortable and light" walking it well in the fitting room. At the first review he commented that it was " excellent for dancing and a big improvement on his previous leg", scoring it 5 he added "it inspires confidence to stride out". Three months after delivery he was still raving about its qualities, especially for dancing, being able only to fault it slightly when on "uneven surfaces". He attempted to cheat the scoring system then by awarding a 5+.

Patient 5 – The limited experience of this patient meant that his responses were not always about the foot itself, but about his rehabilitation in general. He seemed very pleased with his progress however and made no negative comments about the action of the foot.

Patient 6 – The patient having scored his current foot at 0, rated the Trés foot at 2 to 3 from start to finish. He felt it provided the stability he required, twice describing it as "consistent". Saying that it felt like a "real" foot, he felt more confident on it.

Supporting Information



Static Alignment

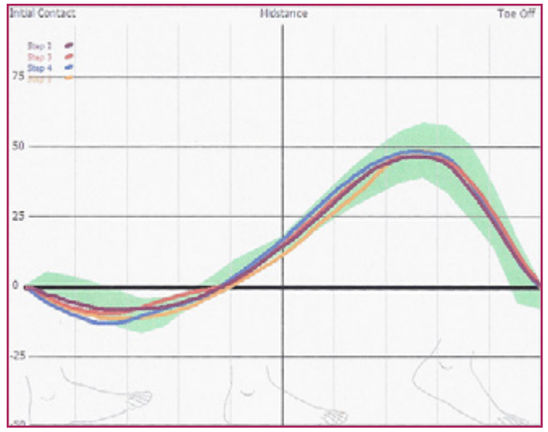
Have the patient stand with equal weight on both feet. Adjust alignment to achieve even weight distribution on the forefoot and heel. Check load line to determine if it is close to the recommended starting point.

For transtibial users, A should be 33% of B and 30% for transfemoral users. Now proceed with your normal dynamic alignment techniques. Please see the catalogue or website for ordering information.

Compas Results

COMPAS is a Computerized Alignment System produced by Orthocare Innovations. Whilst it can be useful in assisting the clinician with the alignment of a prosthesis, it is the data that it produces as part of that process that is of interest to us when evaluating the function of prosthetic feet.

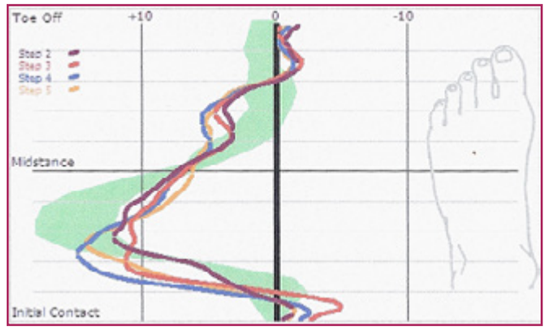
The graphs show the forces recorded of the second to fifth steps in a sequence of six, superimposed over a shaded area that has been produced by collating the results of data recorded from prostheses that have been carefully aligned using conventional methods,
but supported by gait analysis.



As can be seen from the anterior/posterior graph, the heel strike to toe off pattern for the Trés foot shows four very consistent traces that fall very close to this norm, with a smooth transition from heel strike, right through to toe off.

Equally the medial/lateral graph also shows fairly consistent patterns, though with a slight increase in lateral thrust soon after midstance, just as the toe load begins to reach its maximum. This would indicate reasonable inversion/eversion compliance.

The rotational position of the foot has a significant effect on this and it maybe that the patient walked with the sound foot very straight and with the prosthesis aligned to match it, there is a slight lateral thrust created as a result, especially as the anterior/posterior graph shows no indication of an unusual load at that point.



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Clinical Evaluation Summary

CES **CPI** F09

College Park- Celsus Foot

Warranty period - 1 Year (Footshell 6 months)

Weight Limit - 136kg (Depending on foot size)

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

This fairly low profile and lightweight foot is aimed at the low impact K2 community ambulator.
It provides a smooth and stable heel strike to toe off action, which has proved to be softer and more compliant than the Trés foot, giving an action that is similar to that of a soft Tribute foot, without the adjustability, but also without the maintenance it requires. This makes it ideal for transtibial patients with residual limb, knee or hip joint pain, who would benefit from a reduction in the foot reaction forces and resultant socket pressures, or for transfemoral amputees, especially those with reduced hip extension. The simplicity of the design makes for a product which the prosthetists have found simple to align and set up, and which the patients find comfortable to use. The Celsus can be directly swapped out for the Trés or the Tribute, with a build height of just 64mm. This allows the opportunity to easily assess the function of one against another.

Indications

K2 ambulators, up to 136kg Patients who would benefit from -

- a lightweight foot
- a smooth and stable heel strike to toe off action
- a reasonably soft and compliant action
- a fairly low build height
- a reduction in transtibial socket pressures

Contraindication

Patients outside the weight or activity level
Patients requiring a foot with a very low build height

Evaluation Patients

Patient Details

Patient 1	Transtibial	80kg	52 year old male	Unemployed	Sigam D
Patient 2	Transtibial	65kg	76 year old male	Retired	Sigam F
Patient 3	Transtibial	64kg	58 year old male	Salesman	Sigam F
Patient 4	Transfemoral	100kg	70 year old male	Retired	Sigam D
Patient 5	Transfemoral	65kg	59 year old male	Unemployed	Sigam D
Patient 5	Transtibial	70kg	53 year old male	Unemployed	Sigam F
Patient 5	Transtibial	68kg	82 year old male	Retired	Sigam D

Evaluation Result

Dissatisfied — Satisfied

0 1 2 3 4 5 6 7 8 9 10

Current Prescription

Patient 1	Laminate socket, Absolute pin liner and CPI Trés foot
Patient 2	Laminate socket, Silipos LA liner and CPI Tribute foot
Patient 3	Polypropylene PTB socket with Contex Gel suspension sleeve, Trés foot and OB torque absorber
Patient 4	Quadrilateral laminate socket with Silesian belt suspension, OB 3R32 knee and 1D10 foot
Patient 5	Quadrilateral socket with soft suspension belt, Ossur Total knee and OB Dynamic SACH foot
Patient 6	Laminate socket, Silipos LA liner and Contex Gel sleeve and Freedom WalkTek foot
Patient 7	Laminate socket with Pelite liner, Iceross Original with pin and CPI Trés foot

Prosthetist's Comments

Patient 1 – The patient has problems with his sound side leg and hip, using his stick to provide support for that side, rather than for his amputated side. Because of this, though he is a reasonable walker, he lacks sufficient "attack" in his gait to get the best from the Trés foot and, as a result, finds it too stiff. Fitting the Celsus was simple and the results very evident, with a softer roll over being achieved.
Patient 2 – This active gentleman, who walks better than many much younger patients, was finding his Tribute foot slightly too stiff over the forefoot. A softer bumper was requested, along with the Celsus foot, in an attempt to define which would be most appropriate for him. At the fitting he walked both the Celsus and the Tribute, with the softer bumper, very well. He thought the Celsus was possibly slightly better, but chose to stay with the Tribute. The build heights of the two feet are functionally identical and the Celsus was easily aligned and set up.
Patient 3 – The foot originally requested for Patient 2 was reallocated to this gentleman. Despite being only 5 months into his rehabilitation and having a transmetatarsal amputation on the other side, he was walking very well. He had been prescribed a soft Trés foot, but was finding it a little stiff, so the Celsus was fitted and despite it being a medium stiffness, it seemed to provide a softer rollover. It was also hoped that this would be better when he was on the golf course.
Patient 4 – Since the patient was feeling unsteady and unsafe on his current set up, rating it at 0, the Celsus was fitted in the hope that it would provide greater compliance, stability and patient safety. Whilst the technical information seemed limited, it proved to be sufficient and setting it up was easy.
Patient 5 – The patient had several falls with his current knee and foot set up and the prosthetist prescribed the Celsus foot as part of a package, including a Össur NOP4 knee, to try and reduce the number of falls. Initial results were very promising, though there were some socket issues.
Patient 6 – This gentleman, though not very active in terms of impact, does walk a fair amount and likes to go fishing as often as he can. The Kinetic foot had worked fairly well, but his gait is such that he always seems to need more action from the forefoot than it can give. A WalkTek was provided to see if this would offer the support required, but he had found that too stiff (see WalkTek CES). The Celsus was issued to try and provide a solution, which it appeared to do, even before it had been critically aligned.
Patient 7 – With very little soft tissue covering over the cut end of tibia, this patient regularly developed a painful bursa in this area and the prosthetist had decided to try an Inception pin liner and a Celsus foot, in an attempt to offload some of the stresses on the residual limb.

The max build height using a female adapter is 21-24cm = 41.1cm, and 25-26cm = 41.5cm.
At the finishing stage, he found it a little difficult to totally hide the transition between the ankle cosmesis and soft foam transfemoral cosmetic fairing. Its ground compliance proved good and it required no maintenance.

Patient's Comments

Patient 1 – The patient immediately felt more comfortable on the Celsus, with less undue pressure on his residual limb. He also thought that it reduced the problems on his sound side, making the whole experience of walking less painful.
Patient 2 – On delivery of his new socket, the forefoot bumper in the Tribute was changed for a soft and he felt this was probably better. The Celsus (25 medium) was also tried and though he thought this may be slightly better, he was not sufficiently sure as to want to take it, preferring to stay on the Tribute.
Patient 3 – On being provided with the foot originally ordered for Patient 2, his initial reaction was very positive, finding it more comfortable when standing still, as well as rolling smoothly from heel strike to toe off. At his first review his concerns were regarding the socket and he had to be pressed to comment on the foot, though he agreed that this would be a satisfactory foot for use on the new prosthesis being produced.
Patient 4 – At the delivery stage the patient immediately stated that it felt "smoother and safer". At the first review he commented that he "preferred this foot and its smoother to walk with" and at the second review he was walking more, with increased independence and mobility. He rated this set up at 3.
Patient 5 – The prosthetist found the foot easy to align and set up and initial results looked very promising, with an obvious improvement in stability and gait, but the socket issues persisted and were still ongoing when the evaluation had to be concluded. Note! Despite the disappointing outcome of this evaluation, it does serve to show that the compliance of this foot, its soft heel strike and easy planterflexion do make it very appropriate for transfemoral users.
Patient 6 – The patient's reaction to this foot was very enthusiastic. He stated that "it was the nearest I've ever felt to having my own leg back" and he left saying that I wouldn't see him again for a year, because he was convinced that this had resolved his problems. Some months have past and he has not yet returned.
Patient 7 – Whether the change in prescription will reduce problem with the bursa in the long term remains to be seen, but what was very evident to the patient was the reduction in the stresses to his residual limb as a result of the softer roll over of the Celsus foot. He felt the prosthesis to be lighter, but the weight of the feet is similar.

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Issue Date - 26 Nov 2009

Clinical Evaluation Summary

CES **CPI** F02

College Park - Tribute Foot

Warranty period - 18 Months

(6 Months Foot shell)

Weight Limit - 100kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

Interestingly, all the evaluation patients found the Tribute foot more responsive than those they had been using and that it made it easier to ascend an incline. The weight of the foot was commented on by one patient, it being significantly better than the Multiflex foot and ankle, especially in the smaller sizes, though the difference decreases as the size increases. The only problem with the finished cosmesis seems to have been the lack of a split toe option and the edge of the foot shell showing through the cover. All the prosthetists found some small problems with aligning the foot with the foot shell on, but that it was more difficult to remove the foot shell, make the adjustment and then replace it. Adjusting the stride control was less of a problem, until a full cosmesis was fitted. Obtaining a good function and alignment was reasonably simple. Changing the foot rubbers was easy once the foot shell had been removed, but it was not found necessary to adjust more than the stride control and the only time the foot rubbers were changed they were then changed back to the original set up.

Indications

Sigam mobility grade C to F
College Park activity level low to moderate
Daily activity or specific activity involving ascending and descending inclines
The ability to easily adjust the foot action as the patient's gait changes

Contraindication

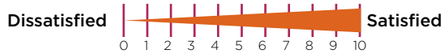
Mobility or activity levels outside those specified
Patients over 100kg

Evaluation Patients

Patient Details

Patient 1	Transtibial	69kg	37 year old male	Butcher	CPI low/mod	Sigam F
Patient 2	Transtibial	83kg	55 year old male	Retired	CPI low	Sigam Db
Patient 3	Transtibial	74kg	72 year old male	Retired	CPI low	Sigam Dd
Patient 4	Transtibial	40kg	68 year old female	Retired	CPI low	Sigam Dd
Patient 5	Transtibial	61kg	42 year old female	None	CPI low	Sigam F
Patient 6	Transtibial	80kg	60 year old male	Driving Examiner	CPI low/mod	Sigam F

Evaluation Result



Current Prescription

Patient 1	Blatchfords Multiflex foot & ankle
Patient 2	Otto Bock 1D10
Patient 3	Blatchfords Multiflex foot & ankle
Patient 4	Otto Bock 1D10
Patient 5	Quantum Truestep
Patient 6	Quantum Truestep

Prosthetist's Comments

Patient 1 – The prosthetist found it slightly difficult to apply the foot-shell and scored it -1 for ease of adjustment (with the foot shell on). The ease of achieving a cosmetic appearance scored 0.

Patient 2 – The prosthetist scored ease of alignment 5, ease of adjustment 1, ease of achieving a satisfactory cosmetic appearance -2.

Patient 3 – The squared edge of the foot shell showing through the cover. Ease of achieving cosmetic appearance scored 4, ease of alignment 3, ease of adjustment 3 and durability 5.

Patient 4 – Ease of alignment and adjustment scored at -1 (in comparison with 1D10 Dynamic SACH).

Patient 5 – Ease of understanding instructions was scored at 3, ease of alignment 5, ease of adjustment 4, ease of obtaining an acceptable cosmetic appearance 4 and durability 5.

Patient 6 – This prosthetist scored ease of understanding the instructions at 3, ease of alignment 5, ease of adjustment 4, ease of obtaining a good cosmetic appearance 4 and durability 5.

Patient's Comments

Patient 1 – The patient scored his current foot at -3, but stated that the new foot was "very springy". He scored the affect on cosmetic appearance 0, but the overall effectiveness of the new foot +3.

Patient 2 – In comparison with previous component he scored the Tribute 2, but after 3 weeks increased it to 5. He found it much easier to go up slopes, felt more natural – "could feel the foot moving". He stated that it has improved his quality of life – "less pain and greater mobility".

Patient 3 – This patient rated all factors 4 to 5, finding that it improved manoeuvrability. The comparative weight advantage felt greater than anticipated (considering the actual weight is only slightly better).

Patient 4 – Her initial reaction was restrained, but she felt an immediate improvement in balance and momentum. Her elation at the ease with which she could walk up a slope, previously almost impossible, made it hard to make a reasoned judgement. She scored it 5 on all factors other than cosmesis where a split toe would have been preferred to allow Skinergy to be used with sandals. She has found it has made rail journeys easier and only uses a stick on uneven ground.

Patient 5 – She rated the Tribute at 3 as a comparison with her previous foot, but scored the overall effectiveness of the foot as 4.

Patient 6 – Rated at 4 as a comparison with previous foot, he then scored the overall effectiveness of the Tribute foot as 5, commenting on the ease of negotiating hills and slopes.

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Clinical Evaluation Summary

CES **CP1** F03

College Park - Trustep Foot

Warranty period - 3 Years

(18 Months over 136kg)

(6 Months Foot shell)

Weight Limit - 136kg

(160kg on Exoskeletal build)

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Evaluation Summary

This foot already had a deservedly good reputation as a compliant, effective and reliable product.
The evaluations that have been carried out, have served only to reinforce that reputation, even surprising those involved. The patient's comments really speak for themselves, but the Indications and Contraindications listed below may help clarify the most appropriate application of the Trustep foot.

Indications

Sigam mobility grade C to F
College Park activity level 2 to 5
Patient regularly walks or runs on uneven ground
Patient regularly encounters undulating, or hilly terrain
Patients who wish to take part in sport, such as badminton, golf, hill walking or tennis
Those who would, for reasons other than those already given, benefit from shock absorption at heel strike, energy return at toe off, axial rotation or inversion/ eversion

Contraindication

Mobility or activity levels outside those specified

Where a low build height is required
Patients who wish to wear footwear requiring a split toe option
Where a light build is of more importance than extremes of function
Where a high definition cosmetic cover is to be used (the action of the foot destroys them rather quickly)

Evaluation Patients

Patient Details

Patient 1	Transtibial	81kg	57 year old male	Retired	Sigam F	CPI 3
Patient 2	Bilateral Transtibial	72kg	39 year old male	Unemployed	Sigam F	CPI 2
Patient 3	Transtibial	87kg	36 year old male	Accountant	Sigam F	CPI 5
Patient 4	Transtibial	77kg	49 year old male	Labourer	Sigam F	CPI 4
Patient 5	Transtibial	106kg	50 year old male	Diver	Sigam F	CPI 5
Patient 6	Transfemoral	100kg	44 year old male	Teacher	Sigam F	CPI 3

Evaluation Result

Dissatisfied 0 1 2 3 4 5 6 7 8 9 10 **Satisfied**

Current Prescription

Patient 1	Laminate socket with suction valve and Sureflex foot
Patient 2	Alpha liner socket with pin and Multiflex foot and ankle
Patient 3	Laminate socket, liner with pin and Multiflex foot and ankle
Patient 4	Iceross liner with pin and Quantum foot
Patient 5	Iceross liner with pin and Multiflex foot and ankle
Patient 6	A polypropylene 'H' suction socket, SFESK, IP+ and Seattle Voyager foot

Prosthetist's Comments

Patient 1 – The Trustep foot was chosen for this patient because he was constantly breaking the Sureflex feet due to the activity level he'd achieved, playing football, badminton and basketball. The prosthetist was very pleased with the ease of assembly and adjustment, and with the end result 5.

Patient 2 – The patient had been having a problem with uneven ground and the Trustep was chosen to try to overcome this. Easily aligned and adjusted 5, with no problems obtaining a good cosmesis, the end result was good, but both foot shells split within a year 3.

Patient 3 – The patient had attempted to run on the Multiflex foot, but the energy return was inadequate. In general the prosthetist was satisfied with the product and scored it an average of 4 for ease of use, cosmetic appearance and durability, commenting only that the foot shell had worn out within 10mths and the ankle gaiter was stiff, but not durable enough.

Patient 4 – A hill walker and golfer, this foot was chosen for its compliance. Again scoring an average of 4 for the set up and finishing, but again experienced some problems with the cosmesis around the ankle gator. The overall result was good and functionally scored 5.

Patient 5 – This very active individual was chosen because he frequently needed to walk on uneven ground and slopes. The prosthetist, having found the alignment more difficult on this patient 3, was satisfied with the function, and ease of adjustment 5, but the patient split the foot shell, lowing durability to 4. The function of the foot also found to change with wear 3. Cosmesis was acceptable 4, though a wider foot shell would have been better in this case.

Patient 6 – Again scoring an average of 4 for the set up and finishing, and also for durability, despite having some problems with the interface of the cosmesis and foot. "An excellent foot for this hill walker – he is able to walk without conscious thought" 5

Patient's Comments

Patient 1 – Rating his current foot at 3, this patient scored the Trustep at 5 throughout the evaluation, but his comments became more and more enthusiastic as time went by. Wishing he'd had the foot sooner, he comments on the "excellent ground compliance", the fact that it doesn't require "conscious thought" when walking, and seems to make him less tired.

Patient 2 (Bilateral) – Because he found the Multiflex feet awkward on uneven ground, he scored them 0. His initial response to the Trustep was that they "feel more comfortable", a theme that continued throughout the evaluation 5. He experienced no problems with the feet, even attempting "a bit of running". He wasn't quite so sure about the appearance 3.

Patient 3 – Finding the response from the Multiflex slow, especially when attempting to run, he scored it -2. His response to the Trustep was initially good, but a cautious 4, until he'd tried it "on different terrains", when he declared himself to be "very impressed" 5. Having needed only some "minor adjustments" and repairs, he scored durability 4.

Patient 4 – Relatively satisfied with the Quantum foot, though not so good on some surfaces, he scored it 2. Finding the Trustep increased the "ease of walking" he gave it 4. The appearance of it at delivery was obviously not as good as he'd like 3, but a round of golf or two later and the score had crept up to 5, with his final comment being "I don't want to be without it".

Patient 5 – This patient's back discomfort caused, in his opinion, by the stiffness of the Multiflex foot and the problems he experienced when walking on uneven ground, resulted in a score of -5. From day one on the Trustep, the increased comfort, ease of walking and stability had caused him to score it at the other extreme 5. Despite the fact that the foot shell was too small, the ankle gaiter came adrift and the foot shell wore out too quickly, he continued to score it at 5.

Patient 6 – This transfemoral patient, a keen hill walker, found the Seattle Voyager foot "didn't provide any particular benefit" and scored it 2. Scoring the Trustep 4 at the fitting and delivery, he commented on its flexibility and greater movement when walking. At the first review date he scored it 5 and makes comments such as "significant feedback", "great stability on sloping and uneven ground", "increased confidence" and "less conscious thought". On a visit to the Falklands he walked over some very hilly and rough ground "in a way I had previously been unable to do". He continues to use the foot, preferring it as his "all round, day to day foot". Durability, he states, has been good.

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Clinical Evaluation Summary

CES **CPI** F06

College Park- Soleus Foot

Warranty period - 3 Years (6 Months Foot shell)

Weight Limit - 21 – 24cm: 100kg
25 – 26cm: 113kg
27 – 30cm: 125kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

The College Park Trustep foot, which has been available since 1997, features excellent ground compliance as the main characteristic of its design. The design of the Soleus also appears to incorporate the same characteristic, though with a more significant energy return. The gentle nature of the compliance and energy return have been commented on, particularly the way it seems to reduce any feeling of jarring through the residual limb and eases the problems of ascending or descending slopes. Initial concerns regarding the durability of the Soleus have proved unfounded, with none of the feet showing any signs of deterioration, even on the most active users. Indeed, the only negative comments so far, are with regard to the problem of creating a good cosmetic finish, due to the size of the four bolt mounting. Whether in the gold or silver finish, it is unusual, but it does allow for a greater range of build options.

Indications

Moderate to high impact activity level
Sporting activities, especially involving running on uneven ground
Any activity requiring good ground compliance, but with energy return
Where there is a need to decrease undue forces on a transtibial residual limb, or knee joint, or the prosthetic knee of a transfemoral prosthesis, especially ascending or descending slopes

Contraindication

A very low activity user
A patient above the product weight/impact limit
Limited clearance below the socket
Where cosmetic appearance is a high priority

Evaluation Patients

Patient Details

Patient 1	Transtibial	80kg	49 year old male	Antique Dealer	Sigam F CPI 3
Patient 2	Transtibial	99kg	32 year old male	Production Worker	Sigam F CPI 3
Patient 3	Transfemoral	94kg	40 year old male	Unknown	Sigam F CPI 2
Patient 4	Bilateral Transtibial	75kg	30 year old male	Unemployed	Sigam F CPI 2
Patient 5	Transfemoral	59kg	18 year old male	Unemployed	Sigam F CPI 2
Patient 6	Bilateral Transtibial	98 kg	41 year old male	Salesman	Sigam F CPI 2

Evaluation Result

Dissatisfied 0 1 2 3 4 5 6 7 8 9 10 Satisfied

Current Prescription

Patient 1	TSB TEC Socket with suction valve and suspension sleeve. Freedom Renegade foot
Patient 2	TSB socket with pin liner and CPI Trustep
Patient 3	ICS suction socket, Otto Bock 3R80 and Variflex foot
Patient 4	TSB sockets with Contex Gel liners, sleeves and suction valves. Freedom Renegade feet
Patient 5	End-bearing socket with Seal-In liner, to Endolite KXO6 and Freedom 1000 (Sierra) foot
Patient 6	TSB socket with Ossur Synergy Wave pin liners and Otto Bock C walk feet

Prosthetist's Comments

Patient 1 – The patient is a very active man and regularly runs, cycles and swims. He has been very satisfied with his Renegade foot and, knowing we needed a demonstration patient to show it off at BAPO, he volunteered to come along. Whilst there, it was suggested that he may like to try the Soleus foot, since an appropriate one was available. Having agreed, it was fitted and the patient used it all day.

Patient 2 – This young man enjoys walking and playing football. Having fractured components in his Trustep foot, the Soleus foot was supplied in the hope that it would provide the same degree of compliance, but would enable him continue to run, whilst achieving greater durability.

Patient 3 – A fairly big and active D.I.Y enthusiast, the patient was chosen to try and make a comparison with the Variflex foot he had been using and, hopefully, to improve his gait. The prosthetist felt that this was achieved, but that the foot function was compromised by the knee prescription and the fact that the socket was slightly loose. No problem had been experienced with fitting the Soleus, though the prosthetist didn't like the cosmetic appearance.

Patient 4 – At the point where it was decided to produce a pair of limbs with Soleus feet, the patient was having some socket problems and was also suffering with a cyst on his right side. He had managed well on his Renegade feet, but had not achieved as much as they would allow him to due to these issues. The problem of producing new sockets and swapping them as day jobs aggravated these problems, so it was agreed that a second pair of limbs be produced and the Soleus feet were chosen to try and reduce the forces on his residual limbs, without reducing his function. They proved relatively easy to set up and have been reliable.

Patient 5 – This young man was chosen by his prosthetist to evaluate the Soleus, since he was currently using a foot that was thought to have similar properties and was a good user of a transfemoral prosthesis. The prosthetist had no criticism of the Soleus, apart from the proximal dimension; especially should a foam cosmesis have been required.

Patient 6 – An active user, involved in various sports, he was not satisfied with the energy return he was getting from his C walk feet. Discussions regarding the available options included Renegade, as well as the Soleus and Trustep. The Soleus was chosen since early reports indicated that they provide compliance with energy return.

Patient's Comments

Patient 1 – Having scored his current prosthesis at 5, he gave himself a problem, scoring the Soleus 5+++ for his initial impression. He then requested to take it for a run outside and returned even more delighted than when he left. Since he wouldn't let us have it back, he was allowed to take it. At the first review over a month later, he stated "it just gets better". He had continued with all his normal activities, including his daily run. Over a month after that, the foot having proved to be 100% reliable, he declared it to be "a fantastic bit of kit – absolutely top grade". The only negative was the cosmesis, which both he and his prosthetist felt to be unacceptable.

Patient 2 – The patient felt the Trustep to be a good foot, but the activities he likes to engage in, adversely affected its durability, causing him to score it 2. Having used the Soleus for 2 months he scored it 4, finding it requires less effort to walk and jog, even on uneven ground. He felt it assists his gait, driving him forward, making the limb feel more a part of him, so that his daily activities are easier to achieve, as well as his more energetic activities.

Patient 3 – Scoring his current prosthesis 0, he liked the Soleus foot as soon as it was fitted, scoring it 4 and after 2 months he stated that it had made his gait feel smoother and faster. Still pleased with the foot a month later, he felt it had improved his quality of life. It had also proved completely reliable, though he judged the cosmetic appearance as OK, rather than good

Patient 4 – Given all the issues this individual has been coping with; it has been difficult for him to define the benefits he finds from these feet. Added to which, he is already on a very high quality pair of feet, so it was not expected that he would notice extreme differences between them. He feels that they are softer and more compliant, making them more comfortable to use in everyday situations, but isn't currently able to push them too hard, so can't be sure how they compare when used more vigorously.

Patient 5 – Obviously very satisfied with his current prosthesis, he scored it 4, stating that he found the Soleus "strange, but ok". He didn't feel it was as "natural" initially, especially the heel action, though he declared that it "looks awesome". After a period of use he commented that running was "more comfortable, specifically heel strike" and even "walking is easier and easier to vary speed", though he also commented that the Freedom 1000 (Sierra) was also very good.

Patient 6 – The response of the patient to the Soleus feet was very positive. He found that they provided a smooth roll over, making it easier to walk, but with sufficient energy return for the sports he gets involved in. His only concern was the problem of achieving a satisfactory cosmetic shape, which is so important to him that he has requested to trial a pair of Trustep feet.

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Issue Date - 26 Nov 2009

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Clinical Evaluation Summary

CES **CPI** F14

College Park- Odyssey K2 Foot

Warranty period - 2 Years

Weight Limit - 100kg (21 - 24 cm)
136kg (25 - 30 cm)

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

The Odyssey foot from College Park has a hydraulic ankle with independent adjustment of dorsiflexion and plantarflexion resistances. There is a total of 12^0 of hydraulically controlled movement and the foot should be aligned to allow 1^0 of dorsiflexion in stance. This, along with compliance of the composite keel, provides sufficient dorsiflexion, with the rest of the hydraulic range being used to provide the plantarflexion required when descending slopes. The build height, at around 80mm, is low for this style of foot, as is the weight at 744g for a size 26cm.

Indications

Patients of an activity as defined by College Park activity levels.

A patient who would benefit from a foot that
- Improves gait when ascending or descending slopes
- Increases stability and safety on inclines
- Reduces forces on the residual limb on undulating ground
- Improves stability when standing on slopes

Contraindication

Patients whose activity level is outside those outlined by College Park.
A patient above the product weight/impact limit
Where a lightweight prosthesis is critical
Where the foot is small and a slender ankle/ forefoot cosmesis is required.

Evaluation Patients

Patient Details

Patient 1	Transtibial	52kg	66year old female	Retired	Sigam E
Patient 2	Transtibial	55kg	70year old female	Retired	Sigam F
Patient 3	Transfemoral	60kg	36year old female	Civil Servant	Sigam F
Patient 4	Transtibial	87kg	51year old male	Unemployed	Sigam E
Patient 5	Transtibial	97kg	46year old female	Office Worker	Sigam E
Patient 6	Transtibial	67kg	45year old female	Hotel Receptionist	Sigam E

Evaluation Result

Dissatisfied — Satisfied
0 1 2 3 4 5 6 7 8 9 10

Current Prescription

Patient 1	TSB laminate socket, Ossur 100 lock and Elation foot
Patient 2	TSB laminate socket – silicone self-suspending, CPI Trustep foot
Patient 3	Quadrilateral socket – silicone pin liner, Endolite KX06 knee and CPI Tribute foot
Patient 4	TSB laminate socket with Pelite liner and Iceross pin liner, Endolite Multiflex foot and ankle
Patient 5	TSB laminate socket – silicone pin liner, Otto Bock 1D10 Dynamic SACH foot
Patient 5	TSB laminate socket, Icelock 600 shuttlelock, Össur Sensitive 6 liner and CPI Celsus foot

Prosthetist's Comments

Patient 1 – Keen to be more active and feel more stable on uneven ground, especially when out with her dog, she agreed to trial the Odyssey foot. The prosthetist had no problems setting up the foot, though it did take a bit of time to get it just right. It was noted that the hydraulics did create a slightly unusual shape around the dorsal aspect. The prosthetist also observed a "smooth descent to foot-flat and tibial progression".

Patient 2 – This very active retired lady had requested a second Trustep, but was willing to trial the Odyssey as part of the assessment process, the prosthetist thinking that it would provide a good comparison between a compliant foot that accommodates uneven ground and one that is designed to accommodate slopes. The prosthetist had no problem setting up the foot and felt the instructions were "clear and concise". The raised area on the dorsum of the foot was again commented on.

Patient 3 – This active patient enjoys walking over a variety of terrains and has had some experience with the Echelon foot. However, with this knee, since she is very short, she needs a foot with a lower build height, which is why the Odyssey was chosen. Alignment was easily achieved and the technical literature easily understood.

Patient 4 – Since the patient was wanting greater compliance to cope with slopes and even on the flat suffered with discomfort during tibial progression, the prosthetist decided that the Odyssey may well resolve the issues.

Patient 5 – The prosthetist was keen to improve the patient's gait pattern. It was noted that there was currently marked hyperextension at the knee and that the patient had difficulty with slopes, especially when ascending them. The prosthetist commented that at the delivery of the Odyssey the patient felt some "instability", which improved a little with an adjustment to the angle of the foot. This had improved still more by the second review.

Patient 6 – The prosthetist chose to trial this patient on the Odyssey K2 in an attempt to reduce the socket forces and improve stability when in standing stance and when negotiating slopes, or undulating ground. It was easy to swap out for the current Celsus foot, especially as the patient does not have a cosmetic cover.

Patient's Comments

Patient 1 – The patient initially commented that it felt a strange sensation, but that she quickly got used to it and felt it reduced the pressures on her residual limb. The foot shape couldn't be padded out to match her rather wide sound foot, since the "bulge" created by the hydraulics wouldn't allow room in the shoe. Five months later and she was continuing to enjoy the comfort in everyday walking about and felt more confident when walking the dog. She stated that it had increased her enjoyment of walking the hills and cycling

Patient 2 – The patient initially felt the foot was comfortable, but with extended use started to have some problems. She felt that this was due to surgery that had been done on her knee many years before, leaving it prone to becoming easily irritated. Though she felt the function of the foot extremely good, she always felt that she was walking with a "lump" under the heel. Clearly the extreme compliance of the Trustep suited her better.

Patient 3 – At delivery the patient seemed very pleased with the foot and two weeks later reported that it made it much easier to negotiate ramps and slopes, even on grass. Five months later she stated that it was still working well and that she was now able to walk further; over uneven terrain; up and down slopes and through the woods.

Patient 4 – The patient commented at delivery that the walk was smoother and "felt more like other leg". Three months later he stated that his confidence when trying new activities had increased and that slopes and hills were easier to cope with.

Patient 5 – The initial comments from the patient were that she liked the action of the foot and was keen to try it out on slopes. At first review she stated that "I feel my walking has improved. Slopes are easier, though I sometimes feel a bit unsteady when standing up from a chair, but I feel less pressure on my knee cap when going up slopes".

Patient 6 – The patient's response at delivery was that "it felt like a 'normal' walk". At the first review though, she seemed less sure, stating "it is better, but not as good as expected". She went on to say that "In flats or no shoes the foot does nothing. In boots it has the initial 'whoosh', but nothing after that". At the final review she did agree that it had improved things for her in her daily activities.

Clearly, if the patient was under the impression that this foot would automatically accommodate different heel heights, from bare foot to heeled boots, her disappointment is understandable. If it had been set up with her walking barefoot, it would have accommodated a shoe with a fairly small heel, certainly much better than the Celsus foot would do, but that is not the main purpose of this type of foot.

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Issue Date - July 2015

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Clinical Evaluation Summary

CES **CPI** F04

College Park- Accent IP Foot

Warranty period - 2 Years

Weight Limit - 100kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

The requirement for a patient adjustable foot to allow the use of footwear with various heel heights, has always presented a challenge. Previous designs have either been heavy, prone to play developing in the adjustment, difficult to adjust, un-cosmetic in the ankle and forefoot, or lacking function in the gait. In designing the Accent foot, College Park have succeeded in producing a patient adjustable foot that, from the evaluations we have carried out, is cosmetically very good, whilst also providing a very responsive action when walking. There are a number of factors that will affect whether a user manages to cope with the adjustment of the foot, but in general, the evaluations show that the Accent is easy to adjust. Patients also commented on the lightness of the foot. Since the weight of the foot, though it is fairly light, is not significantly less than that of the Elation foot, for example, it must be concluded that the responsive function of the foot increases the impression of lightness.

Indications

Any patient requiring an adjustable heel height foot, especially if they also require,

- a foot with a degree of energy return,
- a good cosmetic appearance,
- a lightweight prosthesis.

Contraindication

A very high activity user
A patient above the product weight limit
A very low activity patient, where the use of anything other than "flat" shoes is contraindicated*
A patient whose cognitive ability is such that they are unable to determine the appropriate foot position*
Poor hand function*

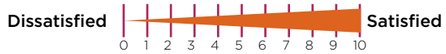
* These are issues that need to be considered when prescribing any patient adjustable foot

Evaluation Patients

Patient Details

Patient 1	Transtibial	91.5kg	68 year old female	Retired	Sigam F
Patient 2	Transfemoral	65kg	43 year old female	Unemployed	Sigam F
Patient 3	Transtibial	77kg	57 year old female	Unknown	Sigam F
Patient 4	Transtibial	82kg	48 year old male	Development Control Officer	Sigam F
Patient 5	Transfemoral	66kg	50 year old female	Unemployed	Sigam F

Evaluation Result



Current Prescription

Patient 1	Laminate socket with Ossur Icelock 600, Iceross liner and Elation foot
Patient 2	Polypropylene quadrilateral socket with TES, Blatchfords ESK/PSPC and MFFA
Patient 3	Laminate socket with Ossur Icelock 600, smooth pin, Iceross liner and Elation foot
Patient 4	Laminate socket with Ossur Icelock 600, Iceross liner and Elation foot
Patient 5	Northvene suction socket with laminate outer, Otto Bock 3R80 knee and Elation foot

Prosthetist's Comments

Patient 1 – A long time user of patient adjustable feet, this patient was chosen in the hope that she would provide useful feedback. The foot was easy to fit and to adjust. Though initially thinking that it may not have as much inversion/eversion as some CPI feet, in practice compliance to the ground surface was good. For this patient the foot shell was too narrow and had to be built up, though the ankle fairing made it easy to produce a good finish. Some problems were experienced with the ankle failing to lock effectively, possibly as a result of pressure on the button from the strap of a particular shoe.*

Patient 2 – The patient had an Elation foot on one of her prostheses. On her second prosthesis, she had begun using an Accent foot, which she preferred, but being very active, may benefit from the energy return of the DP version. Similar concerns were expressed regarding the cutting of the shin tube, as with Patient 1. Though the pylon had to be cut fairly short, the prosthetist was surprised at the responsiveness of the remaining section. The foot shell was too narrow for this patient and had to be built up to suit the shoes.

Patient 3 – Being an Elation foot user already and wanting a similar, adjustable heel height foot on her second prosthesis, her prosthetist requested we trial her on the Accent. He had no problems fitting the foot, the instructions being easily understood. His only concerns were the narrowness of the foot shell and the tension the ankle cosmesis was under when in full planter-flexion. He noticed that the application of the Skinergy cover did initially appear to compromise the effectiveness of the ankle lock, due to the increased pressure on the button.*

Patient 4 – Since this patient has been a good user of an Elation foot and a keen rambler, it was considered that he would give the Accent foot a very thorough comparative trial. The prosthetist had no problems fitting and adjusting the foot, his only concern being the effectiveness of the ankle cosmesis should the patient not match the fairing provided. In practice the technician found it easy to achieve a good cosmetic appearance for this patient.

Patient 5 – This lady was in the process of having a second prosthesis produced. Having complained about the dead feeling in the heel of her Elation foot, as well as problems with the cosmetic finish, the Accent foot was chosen in the hope of improving things for her.

Patient's Comments

Patient 1 – This patient had found the Elation foot a little "inflexible", though otherwise "the best she had ever had". She commented on this and the weight when scoring her current prosthesis at 3. She noted that the Accent foot felt more "flexible" and walked "normally", especially feeling the benefit when going uphill – scoring it at 5. She also liked the cosmetic appearance despite the foot shell width being too small.

Patient 2 – Though critical of the degree of control she had over the knee and the cosmetic appearance of her current prosthesis she still scored it 3. Her initial impressions of the Accent foot were that it was "heavier, but more springy" than her current Endolite Multiflex, but as compliant on uneven surfaces. She was not impressed by the cosmetic appearance, stating that it looked "clumsy". At the review stage, initial problems with finding the operating button had diminished with practice, but she had found the foot too deep in the mid third section, creating footwear problems, though the benefit of being able to change heel height outweighed those to a large degree. Compared with her current foot she scored it 3, though stating that it was "better for all social circumstances and activities".

Patient 3 – Scoring her current prosthesis at -1, commenting that it wasn't easy to adjust and was "not smooth" to walk on, she was much more positive about the Accent foot at the fitting stage. She felt it was "very easy to walk on" and she could "feel the ground better". At the review she said "it's just got better for walking on" and had "reduced the effort going upstairs" 4. She also commented on the narrowness of the foot, though with the Skinergy cover on, it did look very good indeed. At a review appointment it was noted that there was some play at the ankle joint. *

Patient 4 – The patient had expressed no problems with the Elation, apart from locating the release button, but immediately commented that the Accent felt easier to walk on, being "more flexible". The cosmetic appearance was also good, in this case using an RPVC cover. At the review, as well as stating that he'd found it much easier to adjust, he also enthused about its effectiveness when rambling because of improved energy return, giving him a "spring in the step". Three months after the delivery his opinion of the foot remained positive, with no maintenance required in that period and no signs of wear or play in the ankle. At the next appointment it was noted that there was some play at the ankle joint. *

Patient 5 – Though unfortunately the patient has not yet taken delivery of this foot, due to problems with the socket at fitting stage, her initial comments were very helpful. She immediately felt the foot was lighter than the Elation and commented on the "springiness" at heel strike and toe off. Her only negative comment was to do with having to hold in the adjustment button whilst adjusting the foot position, something she didn't need to do with the Elation, though she was prepared to find a way around this to gain the benefits of the function and the feeling of lightness.

* Evaluation Results - Though on some of the feet used in the evaluation the adjustment button was found to be too sensitive and some developed play at the ankle, CPI have addressed these issues and, to date less than 3% of the redesigned versions have needed to be returned under warranty, for any reason.

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Issue Date - 26 Nov 2009

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Clinical Evaluation Summary

CES **CPI** F05

College Park- Accent DP Foot

Warranty period - 2 Years

Weight Limit - 100kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

In designing the Accent foot, College Park succeeded in producing a patient adjustable foot that, from the evaluations we carried out, is cosmetically very good, whilst also providing a very responsive action when walking. The Accent Dynamic Pylon foot is aimed at providing a patient adjustable foot, but which also accommodates those patients who require and would benefit from, an even greater degree of responsiveness from the foot. The foot and ankle are the same as the standard Accent (see CES CPI F04) and this evaluation was carried out in an attempt to define the effectiveness of the Dynamic Pylon. From the results obtained there appears to be a significant increase in function, even from a relatively short section of pylon. The limitations created by there being no alignment function directly above the foot did affect one patient who wanted to use a shoe with a slightly higher heel than the foot itself would allow.

Indications

Any patient requiring an adjustable heel height foot, especially if they are also fairly active and therefore require,

- a foot with a good degree of energy return,
- a good cosmetic appearance,
- a lightweight prosthesis,
- with improved proprioception.

Contraindication

A very high activity user
A patient above the product weight/impact limit
Limited clearance below the socket
A patient with a very low cadence
A very low activity patient, where the use of anything other than "flat" shoes is contraindicated*
A patient whose cognitive ability is such that they are unable to determine the appropriate foot position*
Poor hand function*

* These are issues that need to be considered when prescribing any patient adjustable foot

Evaluation Patients

Patient Details

Patient 1	Transtibial	55kg	46 year old female	Nurse	Sigam F CPI 2
Patient 2	Transtibial	80kg	70 year old female	Retired hotel manager	Sigam F CPI 2
Patient 3	Transtibial	53kg	50 year old female	Housewife	Sigam F CPI 2
Patient 4	Transfemoral	72kg	52 year old female	Housewife	Sigam F CPI 1
Patient 5	Transfemoral	54kg	58 year old female	Primary School Assistant	Sigam F CPI 2

Evaluation Result

Dissatisfied — Satisfied

0 1 2 3 4 5 6 7 8 9 10

Current Prescription

Patient 1	PTB supracondylar socket, with CPI Trustep foot
Patient 2	Silicone pin liner to laminate socket, with Elation foot and standard Accent on her other prosthesis.
Patient 3	Iceross pin liner to laminate socket, with CPI Venture foot.
Patient 4	Seal-In liner socket, OB knee with Elation foot.
Patient 5	Iceross pin liner with clutchlock in polypropylene socket, to knee with Catech and Accent foot.

Prosthetist's Comments

Patient 1 – This patient was chosen in an attempt to provide a very active lady with a foot that gives the function she needs, but also meets her need to use shoes with varying heel heights. Cutting the pylon to length leaves no room for error, though there are "oops" adaptors available. Fitting the top adaptor also required considerable force, with concerns regarding the effect this may have on the foot, since the pylon is integral to the foot. There also appears to be very little inversion/eversion, though this didn't cause the patient any problem.

Patient 2 – The patient had an Elation foot on one of her prostheses. On her second prosthesis, she had begun using an Accent foot, which she preferred, but being very active, may benefit from the energy return of the DP version. Similar concerns were expressed regarding the cutting of the shin tube, as with Patient 1. Though the pylon had to be cut fairly short, the prosthetist was surprised at the responsiveness of the remaining section. The foot shell was too narrow for this patient and had to be built up to suit the shoes.

Patient 3 – Cutting the pylon to length and the force needed to hammer home the adaptor were the concerns of this patient's prosthetist. She was a good user of the CPI Venture foot, but wanted something that would adjust to different heel heights. The foot shell was too narrow and had to be built up.

Patient 4 – Needing a second patient adjustable foot in order to make progress with a change of knee prescription and alignment on the patient's second prosthesis, the Accent DP was chosen. The male pyramid top was chosen to allow a long stump adaptor to be used directly into the knee, thereby keeping the longest possible pylon section. The problem encountered was the patient's request to use a shoe with a heel height that was slightly higher than the foot would allow (even though the Elation foot coped with it), there being no alignment adjustment directly above the foot. The foot appeared to function well and the pylon could be seen to be flexing, as a consequence of it being longer than would be possible in any transtibial application.

Patient 5 – The prosthetist decided to use an OB 3R95=1 knee, to maximize the length of the DP and to reduce the weight of the prosthesis, since she didn't use the yield element of the Catech and found it heavy. He commented that, when trying to work out what components to use and what length the pylon was to be, no mention of a maximum length could be found in the literature.

The max build height using a female adapter is 21-24cm = 41.1cm, and 25-26cm = 41.5cm.
At the finishing stage, he found it a little difficult to totally hide the transition between the ankle cosmesis and soft foam transfemoral cosmetic fairing. Its ground compliance proved good and it required no maintenance.

Patient's Comments

Patient 1 – Rating her current prosthesis 4, her main complaints were that it wasn't adjustable for different shoes and didn't have a split toe. She also commented that the Trustep was so compliant it felt a little like walking on a "balloon". At the delivery she scored the Accent DP at 5, feeling it gave greater control as she progressed to toe off, with "less rebound or jarring" on her knee. She also found it easy to adjust the foot position. The narrowness of the footshell, in comparison with that of the Trustep foot of the same size did present a problem with her shoes and several attempts had to be made to improve the cosmesis to fit them. At work she found she could walk further, with less effort. She felt the benefits of being able to change heel height were significant.

Patient 2 – Rating the Elation foot at 3 and the Accent at 4, she was very pleased that the Accent DP achieved yet another improvement for her. The increased flexibility and spring made the prosthesis feel lighter, to the extent that she said "I forget I'm wearing a false leg; I can do more around the house; I go out more and have even been dancing". It has given her the confidence to choose shoes with a greater range of heel heights and even to walk backwards! She was so pleased she gave it "top marks" 5.

Patient 3 – She rated the Venture foot at 4, but aside from the ability to adjust the heel height, said of the new foot "It's more flexible and cushioned, like wearing a comfy shoe, yet I could feel the ground under me better". Despite a short episode of pain in her residual limb, which proved to be unrelated to the change of foot, she scored it 5. She walks further on it, but feels it's slightly stiffer than the Venture when going up an incline.

Patient 4 – The patient was perhaps trying to cope with too many changes at once and couldn't really give the sort of feed back hoped for, but the slight lack of forefoot support caused by the alignment didn't help.

Patient 5 – The patient seemed more positive than her prosthetist about the Accent DP. She had been an amputee for over 40 years and commented on the greater "bounce" in the foot, which had enabled her to walk further, giving her greater freedom, without the need to "plan when to rest".

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Issue Date - 26 Nov 2009

Clinical Evaluation Summary

CES CP F 11

College Park- Breeze Foot

Warranty period - 2 Years (footshell 6mths)

Weight Limit - 100 to 125kg

(size dependent)

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

The Breeze foot from College Park is a cost effective option, aimed at the Dynamic SACH foot market, with the additional benefit of being water resistant, with an optional drain hole in the removable foot-shell.
The gait function of the foot appears to be good, but the original foot-shell tended to hold the water and not allow it to drain away. A redesign of the foot-shell was undertaken and this issue has now been resolved, making it an ideal option for a water activity of shower limb, which is also capable of being used for everyday activites.

Indications

Patients of a Low to Moderate activity as defined by College Park activity/impact levels.

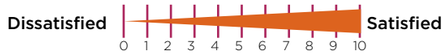
A patient with a positive gait who would benefit from a foot that is
- Simple and durable
- Smooth in its heel strike to toe off action
- Water resistant
- Relatively low in build height and weight

Contraindications

Patients whose activity level is outside those outlined by College Park.
- A patient above the product weight/impact limit
- Where a high degree of compliance is required
- Users who have a very vigorous gait
- Users who have a very passive gait

Patient 1	Transtibial	60kg	20 year old female	Student	Sigam E CPI Low
Patient 2	Transtibial	98kg	68 year old female	Retired	Sigam C CPI Low
Patient 3	Transtibial	95kg	22 year old female	Student	Sigam E CPI Low
Patient 4	Transtibial	103kg	59 year old male	Unemployed	Sigam F CPI Low
Patient 5	Transtibial	76kg	70 year old male	Retired	Sigam D CPI Low/Med
Patient 6	Transtibial	109kg	40 year old female	Unemployed	Sigam F CPI Low/Med

Evaluation Result



Current Prescription

Patient 1	PTB with suspension sleeve and Otto Bock 1D10 foot
Patient 2	PTB Supracondylar with Très foot
Patient 3	TSB Laminate socket, Medi pin liner and CPI Accent foot
Patient 4	PTB socket, with pin liner, conventional build and Otto Bock 1D10 SACH foot
Patient 5	PTB Supracondylar with suspension sleeve (foot not known)
Patient 6	PTB socket with Otto Bock Berma ProFlex sleeve and Senator foot

Prosthetist's Comments

Prosthetist 1 – The patient had been coping reasonably well with the 1D10, but it had worn badly and when replaced like for like, the new foot seemed too stiff and was causing instability at the knee. The Breeze was chosen as one of two options, mainly because the design criteria were aimed at producing a foot to compete with the 1D10.

Prosthetist 2 – Because the patient needed to be able to bathe independently, but also mobilise on a water activity limb with the same degree of confidence that he has on his standard prosthesis, the prosthetist felt the Breeze would provide the best solution. There was no problem setting it up and the patient walked well on it.

Prosthetist 3 – Finding the Accent foot slightly heavy and its heel height adjustment seldom used, the prosthetist decided to trial the Breeze, in the hope of providing a cost effective option for her everyday use. He had no problem setting up the foot. At the review stage he noted that "the foot shape creates a very pronounced rollover". From the patient's comments this seems to be a positive feature, though on more vigorous walkers, the prosthetist felt that it may not provide sufficient resistance at toe-off.

Prosthetist 4 – The prosthetist's aim was to provide the user with a prosthesis with "a robust, all in one foot". The patient disliked the fact that the current water activity limb didn't work well enough for him to then use it anywhere else, so had to swap limbs. Alignment was slightly awkward due to the low profile of the foot making access to the screws a bit difficult. Compliance was not particulary good, but the profile allowed a good roll over.

Prosthetist 5 – Since the patient wanted to be able to use his main prosthesis to go swimming, shower and go and do whatever he wanted, without having to swap to a different prosthesis, the Breeze seemed like an obvious choice. The prosthesist found the posterior adjustment screw awkward, since its partly covered by the footshell, which he felt was rather too narrow.

Prosthetist 6 – This limb was prescribed specifically as a water activity limb, to be used alongside the patient's everyday walking limb. The prosthetist had no problem with the set-up and alignment of the foot. It wasn't expected that the Breeze would compare with the Senator foot that was on that limb, after five months of use, the prosthetist was surprised by her preference for it over the Senator and there have been no issues with it at all.

Patient's Comments

Patient 1 – The patient found that the action of the foot was similar to that of the 1D10, unfortunately creating the same feeling of instability in the knee. She preferred the softness of the Trulife Kinetic foot, with soft bumpers to allow a good range of plantarflexion at heel strike and a comfortable progression through foot-flat, to toe off.

Patient 2 – The patient walked well enough, but found that the foot shell filled with water and despite the drain hole in it, the prosthesis had to be removed to drain the water out. The spectra sock would also not dry out without removing the footshell, which was too hard for the patient to do for himself. This didn't stop him using the prosthesis and at the second review he stated there were "no issues with the function of the foot" and that he was "able to bath independently". (Note! This was using the original foot-shell design)

Patient 3 – At delivery it took the patient a little while to get used to the action of the foot, since it felt softer than the Accent. She commented that it felt smooth and easy to walk on. Four months later she she'd got used to its action. She was clearly making efforts to be more active and by nine months, with no issues with the foot at all, she stated "I can definitely walk further - though I am more active and fitter, and I have a better balance now. The foot has kept pace with my improvement".

Patient 4 – Initally scoring his current limb **6**, at the delivery of the new limb, he scored it **7**, finding it "not to bad" when walking. After going on holiday he stated "it has enabled me to walk comfortably all day, every day when on holiday no need for another limb". He liked it for its better function and appearance and because he only needed to take one limb with him on holiday.

Patient 5 – The patient's only critism was the fact that the footshell was rather narrow, but also that it was little short, so maybe it would have been possible to go up a size, which may have improved things a bit. Despite this, the fact that he could now go swimming without have to use a different prosthesis caused him to score **10**.

Patient 6 – She scored the Breeze on **8** against the Senator at the delivery, even though she wasn't particulary happy with the cosmetic appearance of the footshell, still wanting it to be slimmer and more feminine. Five months later and she states that she can now walk with an improved gait and for a greater distance. Surprisingly, she prefers its soft action to that of the Senator and uses it as her main prosthesis, as well as water activities.

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Clinical Evaluation Summary

CES **FRE** F01

Freedom - Senator Foot

Warranty period - 2 Years (6 months Foot shell)

Weight Limit - 136kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

It is essential, when considering the application of this foot, to refer to the Freedom activity levels and to note that even the low impact activity level includes light jogging. From this evaluation the Senator foot certainly appears to be of most benefit to those patients who will walk it with some vigour. It is also important not to over-estimate the activity level of the patient when selecting the foot category. What surprised all those involved in this evaluation was the level of activity achievable from what is a relatively low priced foot. Even against the College Park Trustep foot, on fairly flat ground it competed very well, only being outdone over uneven terrain. The fact that five of the six patients involved were currently using the Blatchfords Multiflex foot serves to demonstrate the continued popularity of that product, particularly for the low to moderate activity patients, rather than to suggest that they are directly comparable products, this being reinforced by the evaluation results and the product price.

Indications

Most suited to low to moderate impact activity level patients, as defined by the Freedom impact activity levels.

Where a patient requires a foot which can be used for their routine activities, but which will also allow them to participate in some sports.

For activities where smooth energy return between heel strike and foot flat, and from foot flat to toe off, would be beneficial.

Where a robust, low maintenance foot is required.

Contraindication

Patients of less than, or at the very low end of the low impact activity, as defined by the Freedom impact activity levels.

Patients whose weight fluctuates frequently to any significant degree, or who are over the weight limit.

Where uneven ground and/or frequently undulating ground has to be negotiated regularly.

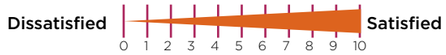
Patients requiring a very high level of cosmetic appearance, especially if they are of a slim build.

Evaluation Patients

Patient Details

Patient 1	Transtibial	88 kg	44 year old male	Retired Police Officer	Sigam F
Patient 2	Transtibial	104 kg	60 year old male	Unemployed	Sigam F
Patient 3	Transtibial	60 kg	37 year old male	Unemployed	Sigam F
Patient 4	Transtibial	76 kg	60 year old male	Retired	Sigam F
Patient 5	Transtibial	63kg	47 year old male	Unemployed	Sigam F
Patient 6	Transtibial	58 kg	58 year old male	Unemployed	Sigam F

Evaluation Result



Current Prescription

Patient 1	Laminate Iceross socket and College Park Trustep foot
Patient 2	Polypropylene PTBSC socket with Blatchfords Multiflex foot.
Patient 3	Laminate socket with Icelock 600 and Össur liner, Blatchfords Multiflex foot.
Patient 4	Laminate socket, Iceross with Icelock 600 and Blatchfords Multiflex foot.
Patient 5	Polypropylene PTBSC socket with Blatchfords Multiflex foot.
Patient 6	Laminate socket, Iceross with Icelock 600 and Blatchfords Multiflex foot.

Prosthetist's Comments

Patient 1 – The Senator foot was chosen because the patient was seeking greater energy return from the foot. Instructions, ease of assembly and alignment scored well 4 & 5. In finishing the cosmesis the foot function can be compromised. Durability and function scored 4.

Patient 2 – Anticipating a more dynamic gait, this foot was chosen and found to be easy to assemble 4, though extremes of alignment with cosmesis may be awkward to achieve. The cosmetic appearance, whilst not as good as the Multiflex foot, was satisfactory and better than other similar feet 4.

Patient 3 – This recent amputee, wanting to "run a bit", was provided with this foot and when aligned to the instructions provided, it needed no further adjustment 5. Cosmesis was alright and the function excellent 5. Durability seems good, though spectra sock worn through in 2 months.

Patient 4 – Having lost a lot of weight recently and become much more mobile as a result, it was decided to trial two alternative feet, this and the OB Trias. Both were set up using the recommended alignment, but this patient is very susceptible to alignment change and the Senator, being less compliant was more difficult to get right.

Patient 5 – This foot was chosen because a more reactive foot was required. The prosthetist found it easy to adjust and align 4 and after 3 months there was no sign of wear.

Patient 6 – The patient, despite his age wanted to get back to doing some running, and this was seen as a cost effective method of trying to make progress for him.

Patient's Comments

Patient 1 – Whilst rating his current prosthesis at 4, he felt he needed more energy return, which he felt he got from the Senator, but still rated it 4. Walked it faster and smoother, but found it unforgiving over rough ground and the lack of inversion/eversion dropped the score to -1, though on smooth ground and slopes he found it "brilliant" scoring 5.

Patient 2 – Scoring his current prosthesis 2 and "good", he found it a little slow. On starting to use the Senator he stated "I feel like I can walk forever" and scored it 5, his opinion remaining unchanged after a month of constant use.

Patient 3 – Though he scored his current prosthesis at 4, he says "I tried running on it, but it doesn't work". The Senator "feels lighter" and lively on the toe 4. On returning 2 months later he said he'd started running again, about 2km every day and started playing a bit of football 5.

Patient 4 – In comparison with the Trias foot that he trialled first, the Multiflex foot on his current prosthesis scored 0, the Senator scored 4, but he preferred the compliance of the Trias foot and it was agreed that it seemed to be the more appropriate prescription.

Patient 5 – The patient rated his current limb at 2, but once the Senator foot had been fitted the score rose to 5 and has stayed there. He found it good when riding his bike, playing football with his children and jogging. Says he's not found the limitations of the foot yet.

Patient 6 – The patient was happy enough with his original prosthesis, but the foot was not responsive enough for running. At the review stage, having spent the last few weeks abroad, had got back to jogging and was very pleased with the foot, but was limited by a slight socket problem 5.

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Clinical Evaluation Summary

CES **FRE** F02

Freedom - Sierra (F1000) Foot

Warranty period - 3 Years (6 months Foot shell)

Weight Limit - 166kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

This retrospective evaluation of the Freedom F1000 foot, whilst it demonstrates the effectiveness of the foot, also majors on one particular failing of the original design, namely the poor cosmetic shape that could be achieved, which was caused by the anterior positioning of the pyramid mount and the width of the spring at the posterior curve. Whilst the position of the pyramid made alignment easy, the resultant undesirable cosmetic shape did create such an adverse reaction that some modifications to the design were clearly necessary. Freedom have since redesigned the foot and the cosmetic appearance that can be achieved, has been significantly improved, without any noticeable reduction in the function. To help with this they have also produced a two-part foam, already cut out to accommodate the ankle and shin tube and only requiring to be ground out to take the socket, glued together and shaped to match the patient's sound side.

Indications

Most suited to the moderate and high activity categories, as defined by the Freedom activity levels.

Where a patient requires a foot which can be used for their routine activities, but which will also allow them to participate in sports.

For activities where smooth energy return between heel strike and foot flat, and from foot flat to toe off, would be beneficial.

Where a robust, low maintenance foot is required.

Contraindication

Patients of low activity or less, as defined by the Freedom activity levels.

Patients whose weight fluctuates frequently to any significant degree, or who are over the weight limit.

Where uneven ground and/or frequently undulating ground has to be negotiated regularly.

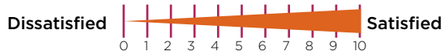
Patients requiring a high level of cosmetic appearance, especially if they are of slim build.

Evaluation Patients

Patient Details

Patient 1	Transtibial	96 kg	39 year old male	Engineer	Sigam E
Patient 2	Transtibial	74 kg	33 year old male	Unknown	Sigam F
Patient 3	Transtibial	90 kg	31 year old male	Unemployed	Sigam F
Patient 4	Transtibial	70 kg	26 year old male	Property Developer	Sigam F
Patient 5	Transtibial	60 kg	42 year old male	Sheetmetal Worker	Sigam F
Patient 6	Transtibial	111 kg	63 year old male	Hospital Porter	Sigam F

Evaluation Result



Current Prescription

Patient 1	Laminate Condylar Bearing Munster socket with Variflex foot replaced
Patient 2	Laminate socket, Iceross with Icelock 600 shuttlelock
Patient 3	Laminate Iceross socket
Patient 4	Laminate socket, Iceross with Icelock 600 shuttlelock
Patient 5	Laminate socket, Iceross with Icelock 100 shuttlelock with Variflex foot replaced
Patient 6	Laminate PTB Supracondylar socket with Variflex foot replaced

Since this is a retrospective evaluation summary, the build includes the Sierra (F1000) foot, but where applicable comparisons with any previous build are included in the comments.

Prosthetist's Comments

Patient 1 – No problems with the instructions 4. Easy to assemble and set up, but experienced some problems with noise from the split toe sections rubbing together. The cosmesis was very poor (old style foot), both the overall shape and the foot shell -5. Durability and function have been good however scoring 5 and 4 respectively.

Patient 2 – The patient was supplied with this foot because he had found previous feet had restricted his activity in the gym. He has not returned to the centre for over 18 months.

Patient 3 – This foot was chosen because of the high activity sport this patient is involved in. The foot needed to be replaced after 2 years, though the prosthetist had hoped for greater durability.

Patient 4 – This ex-soldier, was provided with an Elation foot on his first limb, but needed a foot on his second limb that would enable him to get back to playing football, cricket and running, amongst other things. The cosmetic shape, if important to the patient, would clearly be a problem (old style foot). Easy to set up from recommended bench alignment 4.

Patient 5 – This active guy was supplied with this foot because of the level of his activity.

Patient 6 – Despite his age, this fairly heavy patient is still a very active user, but was having problems with the Variflex foot that had previously been supplied.

Patient's Comments

Patient 1 – The patient has been wearing this foot for nearly 3 years and still finds the function good, but thinks the cosmetic shape poor, even though not "fussed too much" by it.

Patient 2 – On eventually attending the centre, over 18 months since delivery, he rated everything about the foot at 5. It was still in good condition despite his having used it for numerous gym activities including running.

Patient 3 – This young man gets involved in motocross and simply states that he is satisfied with the foot, rating it at 5.

Patient 4 – Attending for a fitting on a new socket for this limb, he says the socket has recently prevented him from using the limb, but until then had played numerous sports on it. He feels there is a slight dead spot at mid stance, but otherwise feels it is very springy. Alignment of the new socket may help reduce the dead spot feeling. It is still in good condition after over 2 years of use. He is not bothered about the cosmetic shape.

Patient 5 – This patient serves to demonstrate one of the contraindications for this foot. He found it walked well on level ground, but felt it gave little help on steep hills or uneven ground, scoring it at -1.

Patient 6 – The patient uses the foot to walk long distances and also to ride a motorcycle. He describes it as "brilliant" and "better than the Variflex", with a "smooth action". He does state that it took a bit of effort to fine tune it in order to get the best from it. He was not bothered at all by the cosmetic appearance.

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Clinical Evaluation Summary

CES **FRE** F07

Freedom Dynadapt Foot

Warranty period - 3 Years

Weight Limit - 166kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

The Dynadapt has clearly been produced to compete against the current Ossur Variflex foot. The evaluations show that it is indeed possible to use it as a direct swap out for that product, since its build height and alignment are the same and the function is very similar, though the usual design features of the Freedom products do seem to provide greater energy return, a slightly smoother roll over and improved compliance.

To limit it to that role though would be to overlook both the effectiveness of the design and the benefits of the subtle improvements that Freedom has made to it. Whilst the build height is greater than that of the Sierra, for example, the longer spring gives even better energy return and makes it easier to produce a good ankle cosmesis for those patients where the build height can be accommodated.

Indications

Patients that would benefit from a foot:

- Lightweight for its activity level
- Smooth in its roll over action
- Reasonably compliant with good energy return
- Slender at the ankle to allow a good cosmesis
- Has a sandal toe option

Contraindication

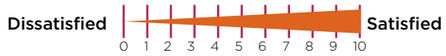
Patients outside the weight limit of the foot
Low activity patients (below Freedom's low).
Long residual limb, due to build height
Where high levels of compliance are required.

Evaluation Patients

Patient Details

Patient 1	Transtibial	116kg	60 year old male	Engineering Inspection	Sigam F	Freedom 4
Patient 2	Transfemoral	75kg	34 year old male	Unemployed	Sigam F	Freedom 3
Patient 3	Transtibial	100kg	69 year old male	Retired	Sigam E	Freedom 3
Patient 4	Transfemoral	85kg	25 year old male	Personal Trainer	Sigam F	Freedom 4
Patient 5	Transtibial	79kg	56 year old male	Office Worker	Sigam E	Freedom 4
Patient 6	Transtibial	115kg	41 year old male	Unemployed	Sigam E	Freedom 3

Evaluation Result



Current Prescription

Patient 1	Laminate TSB socket, silicone pin liner and Ossur Variflex foot
Patient 2	Laminate socket, silicone pin liner, Freedom Plié knee and Highlander foot
Patient 3	Laminate socket, silicone pin liner and Freedom Senator foot
Patient 4	Ischial containment socket with pin liner, Endolite KXO6 knee and Ossur Variflex foot
Patient 5	Laminate TSB socket, Össur Soft C liner, Ossur 600 lock and CPI Trés foot
Patient 6	PTB supracondylar socket, with Juzo sleeve and CPI Trés foot

Prosthetist's Comments

Patient 1 – Since this gentleman was already a good user of a Variflex which now needed to be replaced, opportunity was taken to trial the Dynadapt. The prosthetist found no problems swapping out the feet and setting up the alignment, and there were no issues in producing the cosmesis.

Patient 2 – This young man was supplied with the Dynadapt in an attempt to measure its effectiveness against the Highlander, especially in a transfemoral application, where Freedom has always promoted that product. He has found the Highlander to be an effective foot, though his prosthetist had always felt that it seemed a little too stiff for him, possibly contributing to the lateral rotation he experiences at heel strike.

Patient 3 – The Dynadapt foot was provided for this active gentleman, since he found the Senator foot a little too stiff, especially when walking down a slope. The prosthetist had no problem setting it up, finding that very little adjustment was required from the bench alignment. At a later review the prosthetist commented that the foot seemed to have a "lovely smooth roll over", with no problems or noises, declaring it to be "a great foot".

Patient 4 – Since the patient was finding the Variflex a bit too stiff, the prosthetist decided to replace it with a Dynadapt. The hope was that it would be a little softer, but would still give energy return. It proved easy to set up with the comment at the final review, that "it is a really nice foot, compliant, smooth roll over, with no dead spot" and that "the patient seems to like it better than the Variflex".

Patient 5 – Three years into his rehabilitation, this active gentleman was struggling to achieve the level of activity he wanted, so was trialled on the Medi Panthera CF1 and the Dynadapt. The prosthetist had no problem setting up either foot, but understandably felt the Dynadapt provided the higher level of dynamic response, which the patient seemed to want. It still seemed "flexible and responsive" though "more dynamic than compliant".

Patient 6 – The prosthetists was looking for a more compliant foot, with a smoother roll over that would help reduce the socket forces. It needed to be able to tolerate a wet environment, have a full length toe lever and energy return, with good support in standing stance. The prosthetists found no problem in setting up and aligning the prosthesis.

Patient's Comments

Patient 1 – The patient immediately commented on the increased "springiness" of the foot and nearly three months later stated that this seemed to have made walking a "little easier". He wasn't so sure that it provided a level of compliance that was greater than the Variflex, but did remark that the "foot feels flatter to the ground".

Patient 2 – At delivery, he immediately noticed the increased benefit of the longer spring in the Dynadapt, both in terms of its energy return and its compliance and has continued with it since then, though the rotation at heel strike has only reduced very slightly.

Patient 3 – The patient's initial comment was simply that it "seems much better than the old one" and even after 3 months his only comment was that it had made some activities "a little easier". At a later review the prosthetist noted that "the patient is very happy".

Patient 4 – At the delivery stage the patient declared the foot to be easy to walk on, with "more movement than the old foot". At the review stage, whilst it had not enabled him to take up any new activities, he did feel that there was more movement in the foot which made some things easier.

Patient 5 – The response of the patient to the change of foot was very positive. Rating his previous set up 3, he increased it to 4 with the Dynadapt. Though not involved in any sporting activities, he was now doing more walking, finding the foot significantly better going up and down hills.

Patient 6 – Wanting to get back to doing some sporting activities, the patient was pleased to report that he'd been able to make progress in that direction since getting the Dynadapt. He'd also found it easier when walking his children to school and when walking uphill. He'd lost some weight on account of his increased activity level and was looking forward to getting back to the gym and the pool.

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Issue Date - 29 March 2015

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Clinical Evaluation Summary

CES **FRE** F05

Freedom - Kinterra Foot

Warranty period - 3 Years (6 months Foot shell)

Weight Limit - 125kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

The hydraulic ankle unit of the Kinterra is designed to "yield" into planterflexion at heel strike, to accommodate any down slope and then "yield" into dorsiflexion, to provide the necessary support at toe off. The rate of yield for both can be independently adjusted to suit the patient's gait. A return spring lifts the toe quickly enough to avoid catching the toe at mid swing, should the slope have levelled out. From our evaluation results it would appear to achieve all this very successfully and, despite its low profile, the split carbon fibre element seems to provide a good degree of compliance with a soft, comfortable heel strike, smooth progression to foot flat and good energy return at toe off, but with sufficient deflection to accommodate the up hill slopes. Prosthetists have found it easy to set up, thanks to the wide range of adjustment available.

Indications

Suited to patients in the low to medium impact categories, as defined by the Freedom activity levels

Patients who would benefit from
- An energy storing foot
- Controlled planterflexion and dorsiflexion to aid descending slopes
- Compliant split keel to accommodate uneven ground
- Subsequent decreased socket pressures and stress on the knee, hip and back

Contraindication

Patients whose activity categories fall below or above those outlined in the Freedom activity levels

Patients who are over the product weight limit, or whose weight fluctuates to such a degree that the foot function, or safety is compromised

Evaluation Patients

Patient Details

Patient 1	Transtibial	115 kg	35 year old male	Unemployed	Sigam F	Freedom 3
Patient 2	Transtibial	80kg	47year old male	IT Support	Sigam F	Freedom 3
Patient 3	Transtibial	111kg	59year old male	Unemployed	Sigam F	Freedom 2
Patient 4	Transtibial	88kg	54year old male	Unemployed	Sigam F	Freedom 2
Patient 5	Transtibial	105kg	50year old male	Farmer	Sigam F	Freedom 3
Patient 6	Transtibial	50kg	15year old female	Schoolgirl	Sigam F	Freedom 3

Evaluation Result

Dissatisfied — Satisfied

0 1 2 3 4 5 6 7 8 9 10

Current Prescription

Patient 1	Laminate socket with silicone pin liner and Endolite Echelon foot
Patient 2	Laminate socket with silicone pin liner and Endolite Echelon foot
Patient 3	Laminate socket with silicone pin liner and CPI Trés foot
Patient 4	Total Contact socket over TEC liner and suspension sleeve, with Endolite MFFA
Patient 5	Total Contact socket with Iceross X5 Seal In, Endolite MFA on Seattle Lightfoot
Patient 6	Total Contact socket with Iceross X5 Seal In and OB1D10

Prosthetist's Comments

Patient 1 – The patient was offered a chance to try the Kinterra in an attempt to improve his comfort when walking on uneven terrain. The prosthetist found the foot easy to fit and align, thanks to the clear instructions.

Patient 2 – The patient was selected to evaluate this foot since they were already a good user of the Echelon foot and capable of giving good feedback. The prosthetist stated that the instructions were concise and easy to follow. It was also easy to fit and align, thanks to the fitting guidelines provided. He thought the foot was most suited to medium impact activity levels, since the ankle unit seems to function best at moderate to fast walking speeds, and that medial/lateral compliance was less than that of the Echelon and certainly not as good as the Trustep.

Patient 3 – Only a year into his prosthetic rehabilitation, this patient was keen to improve his gait when taking part in his favourite pastime – hill walking. He was briefly given the opportunity to try a CPI Trustep, as well as the Kinterra. The prosthetist found the foot easy to fit and align and in the 3 months that the patient has had the foot, it has needed no attention.

Patient 4 – The prosthetist chose the Kinterra in the hope that it's compliance on slopes would help reduce pressures on the patient's scarred residual limb. The patient lives in a hilly area and likes to walk his dog across country.

Patient 5 – The patient was prescribed the Kinterra foot in the hope of helping reduce his back pain and to improve the longevity of the foot ankle components.

Patient 6 – This young lady was only 5 months into her prosthetic rehabilitation, having had an elective amputation after several surgical procedures to try and correct a severe club foot had left her with a fixed and painful ankle. The other foot and ankle, though affected, were much better. Having progressed well with what had been provided so far, it was decided that a foot with a yielding ankle would help prevent any undue forces on her knee and the other ankle, especially when descending slopes.

Patient's Comments

Patient 1 – The patient stated that he found the new foot a lot better than his old one, commenting that "it does not hamper me when going up and down hills".

Patient 2 – Initial comments were that the foot felt good to walk on, with good energy return. The dorsiflexion assist spring helped when transitioning from a down slope to the flat or an up slope, but reduced his sense of balance when standing on a slope. At the review he stressed again the better energy return of the Kinterra, but also noted that the smaller amount of dorsiflexion improved his balance on flat ground, but gave him a feeling of coming up against the forefoot too soon. He therefore found it harder to stand on an uphill slope and ascending slopes and stairs slightly more difficult, due to the reduced toe clearance. He went back to the Echelon for a few days, but then requested the Kinterra be refitted, finding the positives outweighed the negatives. Note! Other prosthetists that had seen this patient before, confirmed that, due to his other injuries, the patient tends to allow knee flexion on his prosthetic side at mid to late stance, riding the dorsiflexion yield of the Echelon to the end of its range of movement. This may explain, to some degree, why he found the reduced range of dorsiflexion on the Kinterra slightly problematic.

Patient 3 – From day one this gentleman rated the Kinterra very highly. He'd scored his previous prescription -2, due to the difficulty he had going up and down hills. At the end of the evaluation he rated the Kinterra set up at 5.

Patient 4 – Rating his current prosthesis at 3, he immediately commented "brilliant on slopes uphill" and at the first review that it was 100% better than his previous foot, despite a residual limb problem that had been hampering his progress. He felt that the foot was helping to overcome this issue. When contacted by phone over a month later, he stated that a slight noise had developed on rollover, but the foot function was unchanged. The reason for the noise could not be determined over the phone!

Patient 5 – This hardworking farmer had rated his current prosthesis at -3, since he found the foot uncomfortable to walk on. He was immediately impressed with the Kinterra and at the review stage, reported that he'd been able to repair the roof of a farm building, finding it good when walking along it. At the second review he was still as pleased with it and was able to wear it for 18 – 20 hours a day, with no chafing to his residual limb and no backache. Rating it at 4+, he stated "it's the best leg I've ever had" and "I've forgotten I have a false leg".

Patient 6 – Though the transition from the fairly basic foot she'd been initially supplied with, to the Kinterra, was always going to provide her with a significant improvement in her gait, she was thrilled by just how much it achieved for her and very soon wanted to know if she'd "be able to run on it and would it be ok to play football with it?". The benefit to her when descending slopes was very obvious. Though no problems were reported regarding the foot, she has since progressed so much that an alternative foot has now been issued, in order to better accommodate the activities she now wants to get involved in.

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Issue Date - 11 Jan 2014

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Clinical Evaluation Summary

CES **FRE** F04

Freedom - Renegade Foot

Warranty period - 3 Years (6 months Foot shell)

Weight Limit - 166kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

Whilst it is clear that this is a foot intended for use by more active individuals, it is surprising how it manages to be so readily usable in lower activity situations. This is born out by the fact that at least two of the patients in the evaluation use it as their only prosthetic foot. It is also very compliant for this type of foot, and though other feet may be more appropriate where compliance is the major issue, their energy return is inevitably less effective than the Renegade. * It has been reported that, when running over rough ground, soft sand, or severely undulating ground, the foot accommodates the unevenness without compromising the energy return. Available in standard and low profile versions, neither have a very low build height, but selecting the lower profile has little effect on the function, except at higher activity levels.

Indications

Suited to patients in the low to very high activity categories, as defined by the Freedom activity levels

Where a foot is required which can be used for routine activities, but which will also enable participation in sport to a reasonably high level

For activities where very smooth energy return between heel strike and foot flat, and from foot flat to toe off, would be beneficial

Where a robust, high activity, low maintenance foot is required

Contraindication

Patients whose activity categories fall below those outlined in the Freedom activity levels

Patients who are over the weight limit, or whose weight fluctuates to such a degree that the foot function, or safety is compromised

Where walking over very uneven or severely undulating ground make foot compliance the most important function of the foot *

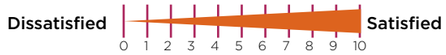
Patients requiring a high level of cosmetic appearance, especially if they are of slim build

Evaluation Patients

Patient Details

Patient 1	Transtibial	70 kg	45 year old male	Importer	Sigam F
Patient 2	Transtibial	85 kg	26 year old male	Transport Planner	Sigam F
Patient 3	Transtibial	96 kg	54 year old male	Senior Manager	Sigam F
Patient 4	Transtibial	79 kg	58 year old female	Artist	Sigam F
Patient 5	Transfemoral	80kg	35 year old male	Unemployed	Sigam F
Patient 6	Transtibial	68 kg	19 year old male	Student	Sigam F

Evaluation Result



Current Prescription

Patient 1	Laminate socket with valve and TEC liner, with Reflex VSP foot
Patient 2	PTBSC socket and Variflex foot – replaced first with F1000 and then Renegade
Patient 3	Laminate socket with TEC profile liner and valve, Flex Modular 3
Patient 4	Laminate socket with Iceross Dermo locking liner and Endolite Dynamic Response 2 foot
Patient 5	Seal-In liner suction socket with an Ossur Total knee and Venture foot
Patient 6	Laminate socket with Ossur 600 shuttlelock, Össur pro liner and Otto Bock 1D10 foot

Prosthetist's Comments

Patient 1 – This very active Triathlete, who trains for 3 hours every day, had destroyed every type of foot he'd been given. The Renegade was issued, more in desperation than expectation. Though it has proven to be effective and durable, some initial problems were experienced and he currently uses a foot rated 2 categories above that which his weight and activity level would indicate. This is now very effective, having lasted over 18mths with minimal attention, apart from worn foot shells and a broken titanium adaptor.

Patient 2 – This active individual was prescribed this foot because his current foot did not meet his needs. Easily assembled, it proved initially difficult to align dynamically, though reference to the documentation provided solved the problem 4. Like the above patient he chose not to bother with a cosmetic cover.

Patient 3 – A lacrosse player who, despite his amputation, played for Great Britain, this patient's Flex Modular 3 had eventually cracked and since he was no longer playing, a more appropriate foot was required for use in the gym and as a back up for his other prostheses. The foot was easy to set up and align 4. He has required minimal maintenance apart from two foot shells in as many years.

Patient 4 – The patient had been having problems with the DR2 foot making noises and was also looking for a more responsive foot. Whilst the prosthetist had no problem setting up the foot, and found it had a satisfactory cosmetic appearance, he concluded at the end of the evaluation that it was more appropriate to the high activity patients. He was also uncertain of the compliance of the foot over uneven ground. On reflection he suggested that, whilst he had chosen the foot module based on the table provided, the weight and activity level were both borderline and the patient may have benefited from using a "softer" unit.

Patient 5 – This young and very active patient with a transfemoral amputation, whilst already making good use of a CPI Venture foot, needed a second prosthesis and it was felt that this would be a good opportunity to evaluate the Renegade foot. The prosthetist found the foot easy to fit and align. He also thought it had reasonable inversion and eversion, as well as vertical compliance. No attempt has yet been made to fit a cosmesis.

Patient 6 – Whilst this patient was a fairly recent amputee, he had made very good progress and it was felt that a more responsive foot was clinically appropriate. The Low Profile version of the Renegade was chosen since, though very active, he wasn't involved in activities that involved running.

Patient's Comments

Patient 1 - The patient rated the function of his VSP at 5, but from day one rated the Renegade at 5+++ The durability he's experienced has only added to that. He declares it "brilliant" and "the best high activity foot I have experienced". This patient participated in the gruelling "Beyond Boundaries" program, taking a spare foot with him just in case, but despite the extreme conditions, he didn't need to make use of it.

Patient 2 – He had found his previous foot rather "flat" when he jogged on it, but despite the time it took to set it up, he initially scored the Renegade at 4, increasing it to 5 when he'd had the opportunity to try running on it, stating "the more I put in the more I get out". He also found it easier for balancing on a ladder!

Patient 3 – Having used the Flex Modular 3 for several years of competitive lacrosse, his only negative comment was to say that it caused problems on uneven ground and required effort on his part before it gave back the performance he needed. No longer playing, but still wanting to keep fit, a more compliant energy storing foot was required, one that could possibly also be used on a day to day basis. He was delighted with it at the fitting stage, immediately running on it, even in the confines of the fitting room. He is still impressed by it, using it every day as his preferred prosthesis, as well as at the gym or jogging round the countryside with his dog. "If only I'd had this when I was seventeen, who knows what I could have achieved", was probably his most telling comment.

Patient 4 – Rating her current limb with the DR2 foot at between 2 & 3, her initial criticisms of the Renegade were that "roll over" was more difficult. She also felt the limb was shorter, even though it was set up at the same length. She disliked the rather "thick" ankle and would have preferred a split toe option. She wasn't happy with the finished shape and after a months use, requested her Endolite DR2 be refitted, feeling that her activity level had been significantly reduced, her score of 1 reflecting this.

Patient 5 – Scoring the Venture foot at a fair 2 to 3 despite commenting that it felt like an "entry level starter leg", he scored the Renegade 4, since it "flexed more, giving a more natural step". He immediately felt that he may be able to run on it and has since started playing badminton and jogging again. His every day activities have not been affected detrimentally and no wear noted over the short time he's had the foot.

Patient 6 – Scoring his current prosthesis at 1, he acknowledged that, as a first issue prosthesis, it was OK. The compliance and responsiveness of the Renegade noted by the prosthetist, was expressed by the patient as "it rolls better". At the review he stated that he was "able to walk more briskly and jog, if required", though perhaps his most telling comment was, "I don't have to think about using the leg as the foot responds as I want it to" 3.

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Clinical Evaluation Summary

CES **FRE** F09

Freedom - Thrive Foot

Warranty period - 3 Years

(6 Months Foot shell)

Weight Limit - 166kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

This foot utilizes a dual-keel design incorporating a full-length primary keel and a secondary, load-activated keel. When an additional load (up to 30% of the user's body weight) is carried, the primary keel progressively comes into contact with the upper, secondary keel, providing incremental support.

This allows the user to achieve a normal gait pattern when not carrying a load, but to safely pick up a significant weight, and to walk with it, whilst maintaining a normal gait pattern.

Indications

Suited to patients in the low to very high activity categories, as defined by the Freedom activity levels
Patients who regularly carry loads of up to 30% of their body weight, but who require to foot to remain functional when not carrying a load.

Contraindication

Patients whose activity categories fall below those outlined in the Freedom activity levels
Patients who are over the weight limit, or whose weight fluctuates to such a degree that the foot function, or safety is compromised.

Evaluation Patients

Patient Details

Patient 1	Transtibial	90 kg	41 year old male	Joiner/Bricklayer	Sigam F Moderate
Patient 2	Transtibial	129kg	45 year old male	Publican/Brewer	Sigam F Moderate
Patient 3	Transtibial	139kg	39 year old male	Home Dad	Sigam F Moderate
Patient 4	Transtibial	83kg	17 year old male	Fisherman	Sigam F Moderate
Patient 5	Transtibial	89kg	52 year old male	Fork Lift Truck Driver	Sigam F Moderate
Patient 6	Transtibial	84kg	30 year old male	Ambulance Crew	Sigam F Moderate

Note! When selecting the activity level for your patient, do not select Moderate based on the need to carry heavy loads alone, unless the loads regularly exceed 30% of the patient's body weight. Doing so will make the action of the foot feel unnecessarily firm.

Freedom Moderate: More active, such as fast jogging, carrying heavy loads; engaging in tennis, golf, light jogging or hiking on uneven surfaces on a regular basis.

Evaluation Result

Dissatisfied 0 1 2 3 4 5 6 7 8 9 10 Satisfied

Current Prescription

Patient 1	Laminate socket with valve and TEC liner, with Reflex VSP foot
Patient 2	Laminate TSB socket and Ossur Ceterus foot – replaced by Reflex Shock
Patient 3	Laminate TSB socket, TEC liner, with Derma Pro Flex sleeve and Trulife Cat 9 foot
Patient 4	TSB socket over PUR cushion liner, suction sleeve and valve, and CPI Soleus foot
Patient 5	PTB Supracondylar socket, with Juzo suspension sleeve and Endolite DR2 with MFA
Patient 6	TSB socket with silicone pin liner. (He had trialled numerous feet whilst at Headley Court)

Prosthetist's Comments

Patient 1 – This active family man, who suffered the loss of his limb in an RTA, has managed to return to work as a Joiner and Bricklayer. He also competes in Motorcycle races and therefore, in both work and leisure, he often needs to carry significant loads. His current foot was proving inadequate for purpose and he was therefore chosen to trial the Thrive.

Patient 2 – Since this gentleman regularly carries and manoeuvres barrels weighing up to 50kg, it was thought prudent to find a foot that would accommodate that without unduly compromising his gait when not carrying any weight. The prosthetist chose a slightly higher category keel than required for the patient's weight, in order to accommodate a maximum 30% of body weight load a little nearer to the 50kg that some barrels can weigh.

Patient 3 – This very tall, well-built gentleman, whilst moderately active by Freedom Activity Levels, is far more active than most. Living on a farm, with quad biking, shooting, diving and going to the gym listed as his hobbies and sports, he often carries bags weighing at least 30% of his body weight and frequently gets his foot wet. The prosthetist chose the Thrive, in an attempt to accommodate all the patient's requirements. With a category 9 keel, the foot function in walking was suitable for his 139kg body weight, with the secondary keel just coming into play to allow up to 30% above body weight, 47kg, to be carried.*

Patient 4 – Since the patient regularly works on his dads fishing boat, with the inevitable contact with salt water and regularly carrying loads of 25kg and also rides Quad Bikes and Mountain Bikes, it was felt that the Thrive would offer a better all-round solution than the comfortable and compliant Soleus. There were no problems with setting up the foot.

Patient 5 – Regularly needing repairs to the MFA, due to the nature of his job, the prosthetist felt that the Thrive may provide a more durable solution for him.

Patient 6 – Whilst at Headley Court, this young man was retrained to work as Ambulance Crew and since this involved regularly carrying loads, often whilst manoeuvring backwards, many different feet were trialled, but when selected taking in account the loads being carried, none worked well, so the Thrive was chosen to try and satisfy his requirements.

***Note!** 30% above the 166kg maximum for the category 9 keel, at 220kg, would actually allow this 139kg patient to lift and carry up to 80kg. Where weights above 30% of body weight are being carried, ensure the patient is at the lower end of the range for the keel, or increase the cat of keel to ensure that they are.

Patient's Comments

Patient 1 – He was delighted with the action of the foot, both when carrying a load and when not.

Patient 2 – The patient reported that, despite the slight compromise in keel category, the foot still felt smooth and flexible when not carrying a load and had no issues when he was. He also felt that the foot was much lighter than any of the alternatives he'd tried.

Patient 3 – Whilst he rated his Catalyst 9 foot at 4, he was always anxious about getting it wet and thereby causing it to fail. The patient found the function of the Thrive to be really good when not carrying a load, but equally as good when he was. He rated it 5, stating that it "lets me get on with life". The only maintenance required has been to regularly wash the foot out with fresh water.

Patient 4 – The patient felt "more balanced" when carrying heavy loads, making it easier to use when working on the boat. It was also durable, only needing a new footshell after a year.

Patient 5 – Initially "looking promising", the patient had some other issues which kept him from wearing it for a while, but 7 months later he felt that it had had a positive effect on his life, with no repairs having been necessary.

Patient 6 – At the point of swapping to the Thrive the patient was using an Endolite Echelon, but from day one he rated the Thrive **9** for its functionality, comfort and ease of use. He stated that he'd "tried lots of other feet, but this out performed all of them". He also commented that he can "feel the second keel working when walking backwards downstairs carrying a patient". Since it is water proof, he also uses for his various water sports, such as windsurfing and it enables him to maintain his active lifestyle, as well as feeling secure in the knowledge that it won't fail him at work.

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Clinical Evaluation Summary

CES **FRE** F08

Freedom Catapult Foot

Warranty period - 12 Months

Weight Limit - 166kg Jogger

- 147kg Runner

- 116kg Sprinter

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

Building on their experience with the Nitro running blade, Freedom developed the Catapult, with the aim of providing the user with a running blade that could be tuned, so as to make it adaptable for different applications, or to keep up with improvements in the users' ability. Each foot is supplied with three secondary Power Springs, appropriate in strength to that of the main C spring, which is based on the patient's activity level and weight. Swapping the springs is not as simple as trying a different running shoe, but can be achieved by the user and does appear to increase the energy return and also to make the foot function adjustable. The Power Springs also increase medial/lateral stability, making it excellent when used on an even surface, but slight less so when running on very uneven terrain, such as trail running.

Indications

Patients who would benefit from a running foot that:

- Gives high energy return
- Can be adjusted suit different activities
- Can be adjusted to keep up with improved ability
- Provides good medial/lateral stability
- Goes to a high weight limit

Contraindication

Low and moderate activity patients

Patients outside the weight limits of the foot

Users who want to run on uneven terrain

Patients with long residual limbs, due to build height of the foot

Evaluation Patients

Patient Details

Patient 1	Transtibial	75kg	49 year old male	Director	Sigam F	Freedom 5
Patient 2	Transtibial	85kg	50 year old male	Electronics Engineer	Sigam F	Freedom 4/5
Patient 3	Bilateral TT	62kg	25 year old female	BBC Journalist	Sigam F	Freedom 4
Patient 4	Transtibial	66kg	39 year old male	Phychologist	Sigam F	Freedom 5
Patient 5	Transtibial	59kg	31 year old female	Quality Surveyor	Sigam F	Freedom 3/4
Patient 6	Transtibial	86kg	55 year old male	Builder	Sigam F	Freedom 4

Evaluation Result

Dissatisfied — Satisfied

0 1 2 3 4 5 6 7 8 9 10

Current Prescription

Patient 1	Lam socket, Össur Protect 3C Cushion liner, Contex Gel sleeve and Freedom Renegade
Patient 2	Laminate socket, Alps Liberty liner and Ossur Flexrun foot
Patient 3	Laminate TSB socket, TEC vacuum system and Freedom Sierra feet
Patient 4	Laminate TSB socket, TEC vacuum system and Ossur Flexrun foot
Patient 5	Laminate TSB socket, with silicone pin liner and Ossur Elation foot (no running foot to date)
Patient 6	Laminate TSB socket, Iceross pin liner and CPI Trustep foot

Prosthetist's Comments

Patient 1 – The patient had started to increase the frequency and lengths of his runs and had started to take part in 10k events. He wanted to improve his performance and, although he felt that his current prosthesis was very good, scoring it 4, wanted to see if a dedicated running prosthesis would help him achieve more. Set up was easy and the only fault was with the sole tread, which wore rather quickly. A trainer sole was glued on instead and this proved more effective.

Patient 2 – A keen runner, entering events from 5k to marathons, he has found his Flexrun fine for longer distances, but too firm over short distances. Wanting to see if the Catapult would enable him to "tune" the foot to suit, he was given the opportunity of a three week trial. There were no problems with the set-up, though the sole tread did have to be glued back after a short period.

Patient 3 – Already running 100m in 17secs, she was advised by her coach that running blades would be needed to help her make further progress. The Catapults were chosen since the additional springs increase the medial/lateral stability, as well as allowing the feet to be adjusted to suit the running style. Freedom recommended cat 5 springs and the secondary spring was left unchanged at the fit/delivery stage. The prosthetist expressed some concern regarding achieving the alignment shown in the diagram provided with the feet, but felt that the feet were functioning correctly and "look the business".

Patient 4 – Already running significant distance and, unusually for this type of foot, across fells and trails, he was given the opportunity to trial the Catapult, to see how it would compare with the Flexrun, especially has he has used both versions of that product. There were no problems with the set-up, though, due to the type of running he normally participates in and the fact that it was a trial foot, he had to limit the trial slightly.

Patient 5 – Having been keen on running prior to her injuries, regularly running 6 to 9 miles (10km to 15km), this young woman was keen to get going again. The prosthetist was interested in trying the Catapult and exploring its features, in an attempt to find the optimum set up for the patient. Though the patient was very light the prosthetist was impressed by the maximum weight limit available and also by the lower build height compared with other similar feet. Set-up and alignment proved to be easily achieved.

Patient 6 – Keen on keeping fit by attending a gym, cycling and running, this gentleman felt that he needed a foot more appropriate for running. His prosthetist chose the Catapult to allow the opportunity to customize its function to the patient's ability. No problems were encountered in set-up or alignment.

Patient's Comments

Patient 1 – He liked the appearance of the foot and apart from the sole tread issue, has had no problems with it. Whilst has not taken up any new sporting activities, he states that he now finds running easier, he runs more and has increased his activity level.

Patient 2 – The ability to swap the springs and "tune" the foot was found to be a very positive feature of the foot, but after some time using it he felt that the main spring, cat 6, was too stiff. His schedule didn't allow him to try a softer spring at this stage, but he wanted to take up that option when possible.

Patient 3 – The patient was delighted with the feet and was soon bouncing around on them and was confident enough to take them without any further training. Unfortunately her job took her out of the catchment area for the centre and therefore further feedback has not been possible.

Patient 4 – He stated, even after a fairly short trial period, that he felt that the Catapult feel somewhere between the 1st and 2nd generation versions of the Flexrun, though lighter than either of them. He felt that the addition of the secondary spring made the foot feel too stiff for his liking, causing the energy return to come too soon, creating a jarring sensation. He also felt that it prevented the primary blade from "loading" completely and also prevented inversion/eversion, making it harder on uneven ground or tight turns. Given the type of running he does this is an understandable issue, but a lower category primary spring may have been better, as for Patient 2.

Patient 5 – Though the patient gave no direct feedback, suffice to say that, though a private patient, she chose to purchase the foot following a trial period.

Patient 6 – The patient gave little initial feedback, other than to state that it was easy to walk on, good to run on and pleasing to look at. At the review he added very little, but added that he'd increased his sporting activities and that it had, thereby improved the quality of his life. It had needed no attention and he felt it was a reliable product.

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Issue Date - 29 March 2015

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Clinical Evaluation Summary

CES FRE F10

Freedom - Maverick Extreme & AT Foot

Warranty period - 36 mths (footshell 6mths)

Weight Limit - 166kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

For many years Freedom have produced feet that were designed around the energy returning qualities of carbon fibre. Where required, the energy storage and return that can be achieved is very beneficial to the user, but for many amputees compliance is more important and many carbon fibre feet include design features that try to provide that. More recently there has been a trend back to glass fibre based composites. This material seems to provide good compliance, with sufficient energy return, but with a gentler progression. They have also been found to be very durable.

Freedom have produced two versions, both based on the Dynadapt spring shape. The Maverick Extreme AT has a split keel for increased inversion/eversion, whereas the Maverick Extreme does not, making it more suitable for users who need less compliance and more mediolateral stability. Both are waterproof.

Indications

Patients that would benefit from a foot that is:

- Lightweight for its activity level.
- Very smooth in its roll over action.
- Compliant with reasonably good energy return.
- Slender at the ankle to allow a good cosmesis.
- Very durable.
- Has a sandal toe option.

Contraindications

- Patients outside the weight limit of the foot.
- Low activity patients (below Freedom's low).
- Long residual limb, due to build height.
- Where high levels of energy return are required.

Evaluation Patients

Patient Details

Patient 1	Transtibial	98kg	44 year old male	Driver	Sigam F Freedom Mod
Patient 2	Transtibial	80kg	56 year old male	Railway office worker	Sigam F Freedom Mod
Patient 3	Transtibial	68kg	38 year old male	Unemployed	Sigam F Freedom High
Patient 4	Transtibial	80kg	37 year old male	Cycle mechanic	Sigam F Freedom High
Patient 5	Transtibial	73kg	35 year old male	Roof tiler/slater	Sigam F Freedom High
Patient 6	Transtibial	118kg	42 year old male	Ambulance driver	Sigam F Freedom High

Evaluation Result

Dissatisfied 0 1 2 3 4 5 6 7 8 9 10 Satisfied

Current Prescription

Patient 1	Supracondylar PTB socket, Contex Gel suspension sleeve and CPI Trés foot
Patient 2	Supracondylar PTB socket, Contex Gel suspension sleeve and Freedom Kinetic or Sierra
Patient 3	PTB socket with pin liner and clutchlock and Össur Variflex foot
Patient 4	PTB socket with pin liner and clutchlock and Ortho Europe Pathfinder foot
Patient 5	Laminate PTB socket with gel sleeve and Flex-Foot XC (tried Rush foot for work)
Patient 5	Laminate TSB socket with pin liner and Icelock 600, Ottobock Triton Vertical Shock foot

Prosthetist's Comments

Prosthetist 1 – The patient had heard good reports of the Rush foot from other users, especially for hiking and had requested one, specifically because of the compliance and durability. The prosthetist had always been impressed by the Dynadapt's flexibility, shock absorption and smooth roll over and suggested trialling the Maverick Extreme AT. It proved easy to set up and align. It was obviously compliant, but has shown no sign of stress issues in the keel to date.

Prosthetist 2 – The patient has previously broken a Sierra foot and the prosthetist was hoping that the Maverick would provide greater durability, without increasing the stiffness of the foot, but rather, with the possibly of a softer action. Set up was easy, since it was very similar to the familiar Dynadapt foot.

Prosthetist 3 – Wanting to try and keep up with his patient's increased activity level and to provide a waterproof prosthesis, the prosthetist chose the Maverick AT. He hoped that this version would provide the best ground compliance. He found it easy to set up and align.

Prosthetist 4 – Requiring a high activity foot that is waterproof, since he enjoys Wakeboarding, but also wanting greater shock absorption, the patient agreed to trial a Maverick AT. The prosthetist found it easy to set up and align.

Prosthetist 5 – This very active and busy man has managed to break every foot that's been provided. He currently uses a Flex-Foot XC that has a keel with a weight limit above his body weight, on which he plays football. He tried a Rush foot, but didn't find it active enough, though he liked the action when walking. The prosthetist therefore decided to trial the Maverick in the hope of finding a solution that would be robust, compliant and provide sufficient energy return, without having to increase the keel category. He was very impressed with the result, stating "it's a fantastic, active, waterproof foot".

Prosthetist 6 – Keen on athletics (throwing disciplines) and fitness, this active man has been regularly breaking his Triton foot, so was swapped to the Maverick in the hope of increasing durability without compromising his activities. The prosthetist found the foot easy to set up, since it is so similar to the Dynadapt he was familiar with. By the end of the four month trial period, the prosthetist was clearly satisfied that the Maverick had not only achieved but exceeded his expectations for his patient.

Patient's Comments

Patient 1 – After just two months of use the patient stated that "The new foot has improved the way I walk in general, but the greatest improvement has been in being able to walk more easily over uneven ground and up and down slopes".

Patient 2 – After four months use, the patient reported that he'd had no issues with the foot at all; that his walking ability had increased. He'd had less visits to the limb centre with the foot being more durable for gym use.

Patient 3 – Though the patient made very few comments, he clearly liked the foot, finding it "light and very comfortable for running, walking and also very good for playing football", which is one of his main interests. He commented to his prosthetist that, because it compresses more than the Variflex, it made the limb feel slightly short, which had to be corrected.

Patient 4 – Although he'd not had much time in the first month to trial it for his leisure activities, he reported that it had already reduced the soreness on his residual limb, even though he's been very busy in his place of work. This improvement has allowed him to wear his residual limb for longer periods of time.

Patient 5 – He scored his Flex-Foot XC at **8**, but at the delivery of the Maverick he scored that at **9** and stated that it felt better than the Rush foot, using terms like, bouncy, responsive, comfortable and smooth. When walking he felt it was much the same as the Flex-Foot, giving a lot back at toe off. He was not keen on the shape of the cosmetic footshell, but found the foot easier to wash after swimming than the Flex-Foot, thanks to the lack of black dust.

Patient 6 – Scoring his current prescription at **8**, with no major issues, he added that he found it limited for running and water activities, but not least by the durability issues, his current foot being his third in 12 months. At the delivery of the Maverick he immediately felt that it was better to walk with and "looks great". At the end of the delivery appointment he stated "so much better – it feels like I have my own foot back". At the first review two months later, he reported that there had been no change in the foot's function, despite using it when swimming, running and unlimited walking. A further two months saw no change, other than "greatly improved activity and opportunity" and he's now running as a regular part of his athletics training, which was previously "difficult and limiting as a thrower".

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Clinical Evaluation Summary

CES **SEA** F03

Trulife - Kinetic Foot

Warranty period - 2 Years (6 Months Foot shell)

Weight Limit - 166kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

Supplied in three versions, these feet have a great range of dorsiflexion and planterflexion from the main bumper, with some inversion, eversion and slight rotation from the flexible pivot bushes. The main bumper has five durometer options for all three versions, with one of two keel options for the Light and one of five for the Edge being automatically chosen, dependant on the patient's weight. The keel and ankle are integral with the footshell, with plugs to allow access for the removal of the pivot and bumper, using a special tooling kit (not essential). Since the original evaluations of the Kinetic, the ankle has been redesigned to increase the durability.

The Kinetic has a female pyramid receiver and is supplied complete with a shin tube with bonded male pyramid. This makes it easier to adjust the alignment, but still allows a build height of just 70mm.

The Kinetic Light is not supplied with a shin tube, since it has a more conventional male pyramid adaptor. This arrangement makes for a more conventional way of aligning the foot, but only increases the build height by about 3mm. Both feet are fairly lightweight, yet they seem to allow gentle, rapid planterflexion and an easy, smooth transition to toe off, ideal for patients of low to moderate activity.

The Kinetic Edge is very similar to the Kinetic Light, but has a removable footshell*, with an increased roll over to the forefoot and a moderate activity level.

Indications

Patients of low to moderate activity
Any patient requiring, or benefiting from
- easy, rapid and compliant planterflexion
- a fairly lightweight functional foot
- exchangeable ankle bumpers, either to adjust the foot function, or for ease of maintenance
- a relatively low build height
- a good cosmetic foot shell*(see Edge)

Contraindication

Patients above moderate activity or 166kg
Where energy storage and return would be of greater importance than compliance
Where lightness is more necessary than function

Evaluation Patients

Patient Details

Patient 1	Transfemoral	75kg	65 year old male	Retired	Sigam E
Patient 2	Transtibial	85kg	36 year old male	Dentist	Sigam F
Patient 3	Transtibial	67kg	55 year old male	Unemployed	Sigam E
Patient 4	Transtibial	126kg	36 year old male	Unemployed	Sigam D
Patient 5	Transtibial	139kg	27 year old female	Hairdresser	Sigam E
Patient 6	Transtibial	70kg	55 year old female	Retired	Sigam D

Evaluation Result

Dissatisfied **Satisfied**

0 1 2 3 4 5 6 7 8 9 10

Current Prescription

Patient 1	Seal-In liner socket, Endolite ESK and Esprit foot
Patient 2	Supracondylar/Suprapatella PTB with corset and side steels Variflex foot
Patient 3	Icecross to a laminate socket with Icelock 600 shuttlelock and Endolite DR2 foot
Patient 4	PTB socket with Contex Gel sleeve and CPI Trés foot
Patient 5	Supracondylar PTB, Dermo Pro Flex sleeve and Kinetic Light foot
Patient 6	PTB socket with OB sleeve and CPI Trés foot

Prosthetist's Comments

Patient 1 – Prosthetist stated that he had some initial concerns relating to his experiences with the Cadence foot (Also produced by Trulife and similar in appearance). It was noted that the posterior tendon contributed to a far smoother forward progression during stance phase and that it also contributed in preventing "drop off" in the forefoot by reducing the forward deflection of the upper element of the "s" shaped pylon. Donning and doffing of the foot shell was stated to be difficult and the Prosthetist outlined some difficulty in selecting the correct heel wedge (required to ensure neutral alignment in the chosen footwear) and then donning the foot shell over the glued wedge. It was noted that the patient had considerable experience with a range of prosthetic feet and that this foot had performed exceptionally well.

Patient 2 – The Prosthetist highlighted that the foot functioned well with smooth forward progression. He encouraged the patient to evaluate the foot performance on a gradient and noted that when descending slopes the foot plantar flexed rapidly, in preparation for the next step.

Patient 3 –The Prosthetist noted that the foot had provided good planter flexion motion and compliance and recommended that this foot would be suitable for impact activities at work and leisure.

Patient 4 – The Prosthetist noted that this patient had trialled a number of prosthetic feet but had been able to find a "flaw or undesired property" in each. He reported that the foot appeared smooth with a controlled heel strike and a plantar flexion action comparable to the contra-lateral limb. The Prosthetist also noted that the foot worked well "in tandem with a Mauch unit".

Patient 5 – The Prosthetist reported that this patient had been an amputee for a little over two years but could "walk on anything". The patient also had a history of oil leakages from hydraulic units suggesting a high level of activity and impact. The Prosthetist reported that although this gentleman already had a good gait that there was a marked improvement at heel strike and toe off. The Prosthetist reported that he had not seen the patient for over 5 months and that this was the longest period over which the patient had not required any further appointments.

Patient 6 – With his current prescription under review, it was decided to trial the NOP5 knee and, since he is still a relatively young and active man, who likes to play golf and travels a good deal, to upgrade the foot accordingly by supplying the Catalyst 9. The prosthetist found that there was a knack to donning the foot shell, but that it was tricky initially, especially when trying to determine which heel wedge was most appropriate for the footwear, prior to gluing on the wedge. Once this had been achieved, setting up the foot proved very simple indeed and clearly enhanced the function of the knee unit

Patient's Comments

Patient 1 – The patient found that this foot functioned exceptionally well and that he did not experience a "dead spot" at mid stance. Upon two subsequent reviews the patient stated that he had been very impressed with the performance of the foot throughout all of his regular daily activities which included cycling, gym work and dog walking. He requested that he be allowed to keep the foot upon completion of the evaluation.

Patient 2 – Patient noted that had previously had to descend slopes by side stepping, but that he could now descend step over step. The patient also noted that he was able to wear his prosthesis for a longer period throughout the day. He also noted that he had previously experienced discomfort and reddening over the patella tendon and that this had reduced.

Patient 3 – The patient stated that with his previous prescription he had "no compliance on uneven ground and poor balance on cambers" and that it was good "when walking". He also added that he had been able to complete an 18 mile charity walk due to its good compliance. On the final review the patient noted that "less thought was required" during walking and that the foot had allowed him to "get on with his life without having to pre-plan journeys".

Patient 4 – The patient felt that the action was smooth and that the foot felt "nice and springy at the end of stance". The patient also commented that "the foot helped activate the knee into swing phase."

Patient 5 – The patient felt that the foot was more stable on the ground and was surprised at the amount of movement that the foot afforded. He also appreciated the cosmetic appearance of the foot shell.

Patient 6 – The patient was very impressed with the new prescription as a whole, but found it difficult to separate out which of the benefits he was experiencing was due to the knee and which to the foot. The ease of transition into the swing phase was clearly helped by the foot function and the soft heel strike and rapid planterflexion also helped maintain the stability of the knee in the stance phase, especially when ascending or descending slopes.

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Clinical Evaluation Summary

CES **SEA** F04

Trulife - Seattle LP Foot

Warranty period - 3 Years (6 Months Foot shell)

Weight Limit - 136kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

Trulife have developed this foot as a low profile version of the Catalyst 9, though it is not low profile in comparison with many other feet on the market. The split keel seems to provide good inversion/eversion of the forefoot. The C spring provides the heel strike shock absorption and returns energy to propel the user to foot flat, at which point the posterior link prevents any further extension of the C spring, bringing the forefoot springs into play, storing energy that is then released at toe off Whilst in this low profile format it cannot give the level of torsional rotation of the Catalyst 9, it does appear to perform very well, providing, not only a lower build, but also a cost effective option for the active user, who may want to walk briskly, jog, or participate in recreational sport, but who also needs a foot that is compliant enough for their everyday activities.

Indications

Sigam mobility grade E to F
Trulife activity level moderate to high*
Patient would benefit from a foot, with a smooth heel strike to toe off action, with reasonable inversion/ eversion compliance and energy storage and return
Where a fairly low build height is required

Contraindication

Mobility or activity levels outside those specified
Patients over 136kg

* Wherever possible, for higher activity patients, the group would suggest the use of the Catalyst 9

Evaluation Patients

Patient Details

Patient 1	Transfemoral	75kg	27 year old male	Voluntary Worker	Mod/High	Sigam F
Patient 2	Transtibial	92kg	47 year old male	Factory Worker	Mod/High	Sigam F
Patient 3	Transtibial	120kg	33 year old male	Engineer	Mod/High	Sigam F
Patient 4	Transtibial	89kg	62 year old male	IT Consultant	Mod	Sigam E
Patient 5	Transtibial	62kg	20year old male	Unemployed	Mod	Sigam F
Patient 6	Transtibial	85kg	29year old male	Shopkeeper	Mod	Sigam E

Evaluation Result

Dissatisfied — Satisfied

0 1 2 3 4 5 6 7 8 9 10

Current Prescription

Patient 1	Quadrilateral socket with Silesian belt, Total Knee and Streifeneder Dynamic SACH foot.
Patient 2	PTB with cuff suspension and CPI Trés foot
Patient 3	TSB socket with silicone pin liner and Renegade LP foot
Patient 4	TSB socket with silicone pin liner and Endolite Multiflex foot
Patient 5	PTB Supracondylar socket with CPI Trés foot
Patient 6	PTB Supracondylar socket with CPI Trés foot

Prosthetist's Comments

Patient 1 – The prosthetist prescribed this foot since the patient was routinely breaking the Streifeneder Dynamic SACH, having achieved an activity level which took it beyond its appropriate application. The prosthetist found everything about the foot easy, except for achieving a good cosmetic appearance due to the low position of the ankle and would have preferred the footshell to have come a little higher (the footshells now provided are higher). They also felt that medial/lateral compliance at heel strike could be better, though there was some evident and the action was "even". At the review the prosthetist stated that it had fulfilled their expectations, scoring it +5.

Patient 2 – The patient had developed to a point where he was above the recommended activity level for his current prescription and was wearing out the Trés feet too regularly. He was prescribed the Seattle LP in the hope that this would meet his needs, with improved durability. The prosthetist found it easy to fit and align, with a satisfactory cosmetic appearance.

Patient 3 – This active young man was issued with the Seattle LP to try and provide a more cost effective, but usable option for his spare prosthesis. The prosthetist ordered with a spring category that was in line with the information provided. There was no problem with fitting it and it was easy to align and set up. At the final review, nearly two years later, it had started to delaminate (in hindsight, it would have been better to make use of the available trial period and to have ordered a foot with a stiffer spring).

Patient 4 – The patient had requested a foot that would give more movement, since he found his current foot "unreliable and rigid, like walking on a brick". The prosthetist chose the Seattle LP in the hope that it would give the sort of movement that the patient required, whilst still being cost effective. Due to the limited knee flexion that the patient has, the prosthetist was pleased with the relative ease with which a satisfactory alignment was achieved. They were also impressed by the function of the foot, though thought it more appropriate for moderate activity, rather than high activity patients.

Patient 5 – This young man was supplied with a Trés foot as part of a new limb prescription when he was just 15 years old. Over 4 years after taking delivery he finally attended again, with the foot totally wrecked. It was clear that his level of activity had increased and he was issued with the Seattle LP, which he walked well. Attending 8 months later for an emergency repair, with a lot of play in the foot, it became clear that he'd sheared the pin in the dorsiflexion stop and had already worn through the footshell, both of which were replaced.

Patient 6 – Initially most concerned about socket comfort, he was prescribed a new limb with a Trés foot, but then declared that he wanted to be able to run. With this in mind, it was agreed that he should be supplied with the Seattle LP, though several refits later he is still struggling with socket discomfort issues and has not started running. He is, however, satisfied with the function of the foot.

Patient's Comments

Patient 1 – The patient found the foot easy and smooth to walk on and was happy with the cosmetic appearance. Though he made no further comment, the prosthetist felt, at the review stage, that this was the appropriate prescription for the patient scoring it +5.It had required no repairs.

Patient 2 –The patient seemed very pleased with the foot, finding it comfortable to walk on, particularly commenting that it was better on uneven terrain, such as fields. He walks for pleasure and also cycles. He has found it to be more durable and states that he has "less back pain", the roll over being very smooth.

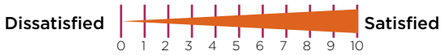
Patient 3 – From day one the patient felt that the foot was too soft and that it was "very spongy" when he jogged on it. As a Rugby Coach he often runs on soft ground and stated that in such conditions he didn't "have much confidence in it". At a later review he commented that, whilst he found it fine for cycling, it wasn't stiff enough for jogging and had started to become softer.

Patient 4 – At the delivery the patient commented that "it's much springier – with much more movement" and at the final review, over a year later, he stated that it was "more reliable" and that he could "walk further, do more and not get as tired".

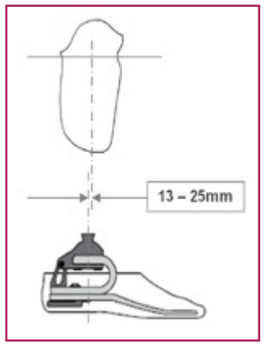
Patient 5 – Being a lad who has very little to say for himself and who seems capable of walking on anything, he contributed little in the way of feedback, but both the Trés and the Seattle LP had clearly been "well used", with little care being taken. The failure of the LP was disappointing, but was relatively easily repaired, with no loss of function.

Patient 6 – English not being his first language has sometimes made it difficult to get quality feedback from this patient, but he does seem to find the function of the foot to be good and his fairly long residual limb does not leave room for some of the alternatives.

Supporting Information



Static Alignment



With the footwear on and taking into account the amount of flexion, adduction or abduction required by the patient, the anterior/posterior midline of the socket; at the mid patella tendon level should fall between 13 and 25mm anterior to the centre of the pyramid. The medial lateral midline should be 6mm lateral to the centre of the pyramid.

The more active the patient, the greater the need will be to preload the forefoot, either by decreasing the socket flexion or increasing planterflexion at the ankle.

In transfemoral applications, it is advised that preloading the forefoot by planterflexing the foot by 2o to 3o from the static alignment would provide the best, before starting the dynamic alignment.

Compas Results

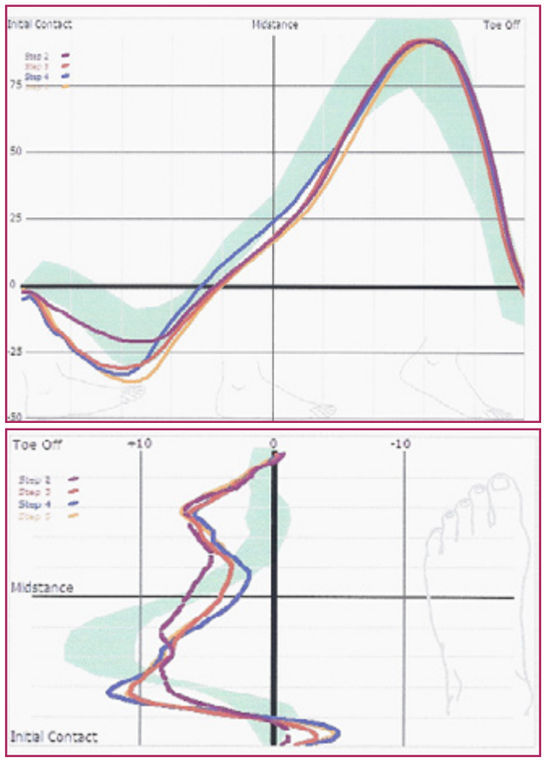
COMPAS is a Computerized Alignment System produced by Orthocare Innovations. Whilst it can be useful in assisting the clinician with the alignment of a prosthesis, it is the data that it produces as part of that process that is of interest to us when evaluating the function of prosthetic feet.

The COMPAS results show that the heel strike is fairly firm, but not excessively so and the graph follows the expected norm fairly accurately, with a good toe load.

There seems to be minimal deviation in the medial/lateral plane.

The patient seems to prefer the foot rather straight since there is some medial load at heel strike and some lateral thrust towards the toe off.

The progression from maximum heel load to maximum toe load is smooth, which was confirmed by the comments of the patients.



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Clinical Evaluation Summary

CES **SEA** F02

Trulife - Catalyst 9 Foot

Warranty period - 3 Years (6 Months Foot shell)

Weight Limit - 166kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

The Seattle Catalyst 9 is described as a dynamic foot, consisting of a unique carbon fibre "S" shaped pylon connected to a split keel. Control of the movement of these two sections relative to each other is provided by a posterior link connecting the alignment pyramid block through the heel of both the split keel sole plate and the "S" shaped pylon. The foot is designed for use with moderate to high activity patients (K3 – K4).

Feedback from both the prosthetists and the patients has substantiated the Trulife claim. The feet used for the evaluation were found to be suited to situations where foot compliancy to uneven terrain is required combined with high energy storage and return. Prosthetists noted that they were particularly impressed with the rapid plantar flexion of the foot at heel strike and the smooth progression of compliance to "toe off" throughout stance phase. It was found that application and fixing of the appropriate heel wedges had caused some minor difficulties.

Indications

Moderate to high impact activities requiring good compliance.
Amputees requiring enhanced energy storage and return.
Patients requiring a high degree of anterior-posterior compliance (e.g. Bilateral and transfemoral amputees)

Contraindication

Low activity levels.
Patients over 166Kg
Patients with small ankle circumferences requiring a good level of cosmetic compliance.

Evaluation Patients

Patient Details

Patient 1	Transtibial	76kg	46 year old male	Importer	Sigam F
Patient 2	Transtibial	70kg	42 year old male	Foster Parent	Sigam F
Patient 3	Transtibial	77kg	49 year old male	Keen cyclist and walker	Sigam F
Patient 4	Transfemoral	76Kg	41 year old male	I.T Consultant	Sigam F
Patient 5	Transfemoral	83Kg	28 year old male	Student	Sigam F
Patient 6	Transfemoral	97kg	55 year old male	Company Director	Sigam F

Evaluation Result

Dissatisfied 0 1 2 3 4 5 6 7 8 9 10 Satisfied

Current Prescription

Patient 1	TSB TEC socket with suction valve and suspension sleeve and Freedom Renegade foot
Patient 2	Custom TEC, TSB socket and one way valve, suspension sleeve, CPI Trustep foot
Patient 3	PTBSC socket with College Park Tres Foot
Patient 4	Polyurethane ICS Seal-In socket, Black Max Knee and Eschelon foot
Patient 5	Quad Suction socket, Black Max knee and Senator foot
Patient 6	Polypropylene Quadrilateral socket with DSPB, Endolite ESKPSPC, Multiflex foot/ankle

Prosthetist's Comments

Patient 1 – Prosthetist stated that he had some initial concerns relating to his experiences with the Cadence foot (Also produced by Trulife and similar in appearance). It was noted that the posterior tendon contributed to a far smoother forward progression during stance phase and that it also contributed in preventing "drop off" in the forefoot by reducing the forward deflection of the upper element of the "s" shaped pylon. Donning and doffing of the foot shell was stated to be difficult and the Prosthetist outlined some difficulty in selecting the correct heel wedge (required to ensure neutral alignment in the chosen footwear) and then donning the foot shell over the glued wedge. It was noted that the patient had considerable experience with a range of prosthetic feet and that this foot had performed exceptionally well.

Patient 2 – The Prosthetist highlighted that the foot functioned well with smooth forward progression. He encouraged the patient to evaluate the foot performance on a gradient and noted that when descending slopes the foot plantar flexed rapidly, in preparation for the next step.

Patient 3 –The Prosthetist noted that the foot had provided good planter flexion motion and compliance and recommended that this foot would be suitable for impact activities at work and leisure.

Patient 4 – The Prosthetist noted that this patient had trialled a number of prosthetic feet but had been able to find a "flaw or undesired property" in each. He reported that the foot appeared smooth with a controlled heel strike and a plantar flexion action comparable to the contra-lateral limb. The Prosthetist also noted that the foot worked well "in tandem with a Mauch unit".

Patient 5 – The Prosthetist reported that this patient had been an amputee for a little over two years but could "walk on anything". The patient also had a history of oil leakages from hydraulic units suggesting a high level of activity and impact. The Prosthetist reported that although this gentleman already had a good gait that there was a marked improvement at heel strike and toe off. The Prosthetist reported that he had not seen the patient for over 5 months and that this was the longest period over which the patient had not required any further appointments.

Patient 6 – With his current prescription under review, it was decided to trial the NOP5 knee and, since he is still a relatively young and active man, who likes to play golf and travels a good deal, to upgrade the foot accordingly by supplying the Catalyst 9. The prosthetist found that there was a knack to donning the foot shell, but that it was tricky initially, especially when trying to determine which heel wedge was most appropriate for the footwear, prior to gluing on the wedge. Once this had been achieved, setting up the foot proved very simple indeed and clearly enhanced the function of the knee unit

Patient's Comments

Patient 1 – The patient found that this foot functioned exceptionally well and that he did not experience a "dead spot" at mid stance. Upon two subsequent reviews the patient stated that he had been very impressed with the performance of the foot throughout all of his regular daily activities which included cycling, gym work and dog walking. He requested that he be allowed to keep the foot upon completion of the evaluation.

Patient 2 – Patient noted that had previously had to descend slopes by side stepping, but that he could now descend step over step. The patient also noted that he was able to wear his prosthesis for a longer period throughout the day. He also noted that he had previously experienced discomfort and reddening over the patella tendon and that this had reduced.

Patient 3 – The patient stated that with his previous prescription he had "no compliance on uneven ground and poor balance on cambers" and that it was good "when walking". He also added that he had been able to complete an 18 mile charity walk due to its good compliance. On the final review the patient noted that "less thought was required" during walking and that the foot had allowed him to "get on with his life without having to pre-plan journeys".

Patient 4 – The patient felt that the action was smooth and that the foot felt "nice and springy at the end of stance". The patient also commented that "the foot helped activate the knee into swing phase."

Patient 5 – The patient felt that the foot was more stable on the ground and was surprised at the amount of movement that the foot afforded. He also appreciated the cosmetic appearance of the foot shell.

Patient 6 – The patient was very impressed with the new prescription as a whole, but found it difficult to separate out which of the benefits he was experiencing was due to the knee and which to the foot. The ease of transition into the swing phase was clearly helped by the foot function and the soft heel strike and rapid planterflexion also helped maintain the stability of the knee in the stance phase, especially when ascending or descending slopes.

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Clinical Evaluation Summary

CES TRU F02

Trulife - Triumph Foot

Warranty period - 36 mths (footshell 6mths)

Weight Limit - 160kg medium activity

125kg high activity

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

When reorganising their product range, Trulife chose to consolidate the Catalyst foot options, only retaining the Catalyst 9, but renamed the Triumph. It retains the same features, except for the removal of the optional heel height wedges which, according to the original CES, often caused "some minor difficulties".

Described as a dynamic foot, it consists of a unique carbon fibre "S" shaped pylon connected to a split keel. Control of the movement of these two sections relative to each other is achieved by a posterior link connecting the alignment pyramid block through the heel of both the split keel sole plate and the "S" shaped pylon. The foot is designed for use with moderate to high activity patients (K3 – K4), and provides significant torsional rotation within the keel construction.

Feedback from both the prosthetists and the patients has confirmed that the Triumph is just as effective as the original Catalyst 9, such that the evidence previously provided is still applicable. The feet were found to be suited to situations where foot compliancy to uneven terrain is required combined with high energy storage and return. Prosthetists were particularly impressed with the rapid plantar flexion of the foot at heel strike and the smooth progression of compliance to "toe off" throughout stance phase.

Indications

Patients requiring a foot that:

- Allows moderate to high impact activities, especially when they require good compliance.
- Provides good energy storage and return.
- Offers a significant torsional rotation and a high degree of anterior-posterior compliance.

Contraindications

- Low activity levels.
- Patients over 160kg.
- Patients with small ankle circumferences requiring a good level of cosmetic appearance.

Evaluation Patients

Patient Details

Patient 1	Transtibial	80kg	59 year old male	Retired	Sigam F
Patient 2	Transtibial	70kg	42 year old male	Foster parent	Sigam F
Patient 3	Transtibial	77kg	49 year old male	Keen cyclist and walker	Sigam F
Patient 4	Transfemoral	76kg	41 year old male	I.T. Consultant	Sigam F
Patient 5	Transfemoral	83kg	28 year old male	Student	Sigam F
Patient 6	Transfemoral	97kg	55 year old male	Company director	Sigam F

Evaluation Result

Dissatisfied 0 1 2 3 4 5 6 7 8 9 10 Satisfied

Current Prescription

Patient 1	Supracondylar PTB with Juzo sleeve and Trulife Catalyst 9 foot
Patient 2	Custom TEC, TSB socket and one way valve, suspension sleeve, CPI Trustep foot
Patient 3	PTBSC socket with College Park Trés foot
Patient 4	Polyurethane ICS Seal-In socket, Black Max knee and Echelon foot
Patient 5	Quad Suction socket, Black Max knee and Senator foot
Patient 5	Polypropylene Quadrilateral socket with DSPB, Endolite ESKPSPC, Multiflex foot/ankle

Prosthetist's Comments

Prosthetist 1 – Having already used the Catalyst 9 for several years, when it eventually needed to be replaced, the Triumph was the obvious option. An enthusiastic Squash player and walker, he had found the original foot to be very effective and the prosthetist was pleased to discover that the Triumph provided exactly the same degree of functionality.

Prosthetist 2 – The Prosthetist highlighted that the foot functioned well, with smooth forward progression. He encouraged the patient to evaluate the foot performance on a gradient, and noted that when descending slopes the foot plantar flexed rapidly in preparation for the next step.

Prosthetist 3 – The Prosthetist noted that the foot provided good planter flexion motion and compliance and recommended that this foot would be suitable for impact activities at work and leisure.

Prosthetist 4 – It was noted this patient had trialled a number of prosthetic feet, but had been able to find a "flaw or undesired property" in each. He reported that this foot appeared smooth with a controlled heel strike and a plantar flexion action comparable to the contra-lateral limb. The Prosthetist also noted that the foot worked well "in tandem with a Mauch unit".

Prosthetist 5 – The Prosthetist reported that this patient had been an amputee for a little over two years, but could "walk on anything". The patient also had a history of oil leakages from hydraulic units suggesting a high level of activity and impact. Although this gentleman already had a good gait, the Prosthetist commented that that there was a marked improvement at heel strike and toe off. He also reported that he had not seen the patient for over 5 months and that this was the longest period in which the patient had not required any further appointments.

Prosthetist 6 – With his current prescription under review it was decided to trial the NOP5 knee, and since he is still a relatively young and active man who likes to play golf and travels a good deal, to upgrade the foot accordingly. The prosthetist found that there was a knack to donning the foot shell, but that it was tricky initially, especially when trying to determine which heel wedge was most appropriate for the footwear, prior to gluing on the wedge (no longer an issue, since these wedges are no longer supplied). Once this had been achieved, setting up the foot proved very simple indeed and clearly enhanced the function of the knee unit.

Patient's Comments

Patient 1 – The patient found that he could feel no difference between his original foot and the new Triumph, and he continues to use it when playing squash and walking in the countryside, and for all his day to day activities.

Patient 2 – Patient noted that had previously had to descend slopes by side stepping, but that he could now descend step over step. The patient also noted that he was able to wear his prosthesis for a longer period throughout the day. He also noted that he had previously experienced discomfort and reddening over the patella tendon and that this had reduced.

Patient 3 – The patient stated that with his previous prescription he had "no compliance on uneven ground and poor balance on cambers" and that it was good "when walking". He also added that he had been able to complete an 18 mile charity walk due to its good compliance. On the final review the patient noted that "less thought was required" during walking and that the foot had allowed him to "get on with his life without having to pre-plan journeys."

Patient 4 – The patient felt that the action was smooth and that the foot felt "nice and springy at the end of stance". The patient also commented that "the foot helped activate the knee into swing phase".

Patient 5 – The patient felt that the foot was more stable on the ground and was surprised at the amount of movement that the foot afforded. He also appreciated the cosmetic appearance of the foot shell.

Patient 6 – The patient was very impressed with the new prescription as a whole, but found it difficult to separate out which of the benefits he was experiencing was due to the knee and which to the foot. The ease of transition into the swing phase was clearly helped by the foot function and the soft heel strike and rapid planterflexion also helped maintain the stability of the knee in the stance phase, especially when ascending or descending slopes.

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Clinical Evaluation Summary

CES **ÖSS** K00

Össur - NOFM0 Knee

Warranty period - 3 Years

Weight Limit - 125kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

It appears from these evaluations, that this lightweight monocentric knee is easily unlocked, even when there is some weight still on the prosthesis and, on standing, locks with a very positive and audible click. This makes it ideal and very safe for the application it was designed for. When flexed, despite its slightly posterior pivot point, it only "bird-mouths" a little and the design of the upper section still provides a knee profile that allows a good cosmetic shape to be achieved.

Indications

Low activity patients. Össur I.

Primary patients who only need a lightweight SAKL, with no likelihood of progressing to a free knee.

Where there is a particular need for easy operation of the lock mechanism, to provide safe transition from standing to sitting.

Contraindication

Reasonably active patients. Above Össur I.

Patients requiring greater swing phase control, or who do no need a lock option at all.

Where a very low build height is required above the knee.

Patients above 125kg

Evaluation Patients

Patient Details

Patient 1	Transfemoral	56 kg	79 year old male	Retired	Sigam Cd
Patient 2	Transfemoral	67 kg	74 year old male	Retired	Sigam Cd
Patient 3	Transfemoral	53 kg	69 year old male	Retired	Sigam Cd
Patient 4	Transfemoral	81 kg	61 year old male	Retired	Sigam Dd
Patient 5	Transfemoral	86kg	81 year old male	Retired	Sigam Cd
Patient 6	Transfemoral	68 kg	79 year old male	Retired	Sigam Cd
Patient 7	Transfemoral	67 kg	62 year old male	Retired	Sigam Dd
Patient 8	Transfemoral	49 kg	62 year old male	Retired	Sigam Dd
Patient 9	Transfemoral	66 kg	85 year old male	Retired	Sigam Dd

Evaluation Result

Dissatisfied — Satisfied

0 1 2 3 4 5 6 7 8 9 10

Current Prescription

Patient 1	**Primary** – Quadrilateral socket, RPB suspension and SACH foot
Patient 2	**Primary** – Quadrilateral socket, TES belt suspension and CPI Trés foot
Patient 3	Ischial Containment Socket, TES belt suspension, Össur NOFM2 knee and CPI Trés foot
Patient 4	**Primary** – Quadrilateral socket, TES belt suspension and SACH foot
Patient 5	**Primary** – Quadrilateral socket, TES belt suspension and SACH foot
Patient 6	**Primary** – Quadrilateral socket, TES belt suspension and CPI Trés foot
Patient 7	**Primary** – Quadrilateral socket, TES belt suspension and CPI Trés foot
Patient 8	**Primary** – Quadrilateral socket, TES belt suspension and CPI Trés foot
Patient 9	**Primary** – Quadrilateral socket, Silesian belt suspension and OB 1G6 foot

Prosthetist's Comments

Since all the patients, except Patient 3, were being prescribed their first issue prosthesis, the Sigam Mobility Grades shown are all anticipated grades and, following examination by the Rehabilitation Consultant; assessment by the Physiotherapist and in consultation with the Prosthetist, the prescription was decided and agreed by the MDT.

Unfortunately Patient 3 did not achieve his originally anticipated level of activity and, due to his ill health and increasing frailty, was not coping with the weight of the NOFM2 knee originally prescribed. Consequently he was issued with the NOFM0 which he managed more easily.

The Össur NOFM0 knee was chosen because it is lightweight and appeared to be robust and easy to operate, though all, except Patient 9 (see Patient Comments), were set up with the Endolite thigh release lever, simply because levers are the preferred option at the centre where the patients were being rehabilitated.

With a three year warranty and a very reasonable price, the MDT agreed that it was a cost effective option.

Patient's Comments

The fact that, as primary amputees, all but one of the patients had no experience of any other prosthesis, meant that there was little they could comment on at this stage in their rehabilitation. It was therefore decided to simply canvass the opinions of the Physiotherapists, Prosthetists and Prosthetic Technicians, in an attempt to determine whether there were any significant positives or negatives with this knee, over those that had previously been issued to such patients.

The only exception to this was Patient 9 who, having been set up with the standard Össur thigh release and despite having no knowledge of the options available, asked if it could be changed for something "less bulky and easier to use". It was replaced with the Ortho Europe actuator.

The Physiotherapists were surprised at how many had been issued, but had nothing negative to report. They couldn't recall there being any issues with the knees at all, but had noted a marked change in the way they were able to teach the patients to transition from standing to sitting. They found this much easier, since there was not the need to get the patient to off load, or toe load the prosthesis in order to unlock the knee. They discourage the patients from keeping the knee loaded, but find that the knee unlocks easily, even if there is some load on it.

The Prosthetists have all found the knee easy to use, with no problems setting up the alignment. Setting up the thigh release can only be effectively done once the appropriate alignment has been achieved, but this has caused no problems.

The Technicians have had none of the knees come back with play in them, or any other problems and have found it simple to assemble and set up in the prosthesis. They have also found no problem when producing the cosmesis.

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Clinical Evaluation Summary

CES **ÖSS** K02

Össur - NOFM2 Knee

Warranty period - 3 Years

Weight Limit - 125kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

This monocentric knee, allows prosthetists the opportunity to prescribe it as a free knee, with sensitive weight activated stance stability, but with the option of adding a semi automatic (SAKL) or manual, hand operated lock (MKL/HOKL), if the progress of the patient's rehabilitation should require it.

Indications

Low to medium activity patients. Össur I and II.

Primary patients who, in the opinion of the M.D.T needs a SAKL in order to start rehabilitation, but who may progress to a free knee, providing good stability is available. The option of a manual knee lock can be retained if required.

Free knee users whose condition has deteriorated, requiring greater stability and maybe needing a HOKL or SAKL in due course. *

Where a very short build length is required. **

Contraindication

Reasonably active patients. Above Össur II.

Patients requiring greater swing phase control, or who do not need a lock option at all.

Patients who only need a lightweight SAKL, with no likelihood of progressing to a free knee

Where the patient has become dependant on some other form of stance control, such as geometric stability.

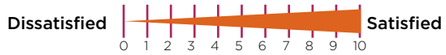
* It is imperative that the M.D.T assess very carefully the current limb use, not just the gait, but every aspect of the patient's activity before choosing to change any components.
** The total height is 115mm including the pyramid. Please see the catalogue for all the other dimensions.

Evaluation Patients

Patient Details

Patient 1	Transfemoral	74 kg	60 year old male	Unemployed	Sigam Da
Patient 2	Transfemoral	71 kg	63 year old male	Retired	Primary
Patient 3	Transfemoral	76 kg	60 year old male	Unemployed	Sigam F
Patient 4	Transfemoral	62 kg	59 year old female	Retired teacher	Sigam D
Patient 5	Transfemoral	77 kg	70 year old male	Retired	Sigam C
Patient 6	Transfemoral	72 kg	71 year old male	Retired	Primary

Evaluation Result



Current Prescription

Patient 1	Laminate socket, Icelock 600, Alphamax liner. ESK, PSPC with MKL and Multiflex foot
Patient 2	Primary prescription
Patient 3	Flexible inner socket with valve, Seal-In liner, Total knee and Seattle Lightfoot
Patient 4	Laminate socket with Seal-In liner, Otto Bock 3R49 and Variflex foot
Patient 5	Primary prescription
Patient 6	Primary prescription

Prosthetist's Comments

Patient 1 – For safety, this patient now requires an increased level of stability in stance, but still wants to try and use a free knee, although he likes to use the HOKL when standing still and may need to use it more frequently as time goes by. The very positive lock and the internal spring assist were the two features of this knee that were noted by the prosthetist. The thigh release* and rather hard terminal impact bumper were the only negative issues mentioned.

Patient 2 – Chosen as the primary prescription in order to provide good stability when used as a free knee, but with the benefits of a lock option, the prosthetist found its assembly, alignment and adjustment very easy. Good stability and smoothness of action were both noted. Though not worn for very long, the knee gave no problem.

Patient 3 – Looking for a locked knee option, with increased stability even when used as a free knee, this unit was chosen. The prosthetist found its assembly, alignment and adjustment "OK" 4. The large socket required greatly hindered the function of the lock mechanism -2, though the knee appeared to be very stable in stance and smooth in the swing phase.

Patient 4 – This patient's contralateral leg was also badly damaged in the incident which resulted in the amputation; this limits her gait and general mobility. Nonetheless she doesn't like too much stance control and doesn't require much swing phase control. The prosthetist managed to achieve the necessary balance between these two factors, providing her with the security she needed and the swing control she likes, though it took a couple of attempts to get the adjustments just right.

Patient 5 – When the knee was prescribed, this patient was a primary amputee with a predicted Sigam C mobility grade, but with uncertainty as to whether this would be achievable most safely with a fixed or a free knee. The unit has required no maintenance or adjustment, other than to convert it from a HOKL to a free knee with the lock option completely removed.

Patient 6 – This gentleman, when he presented as a primary, appeared capable of managing with a free knee and was keen to try to do so, but his contralateral limb was showing some signs of being at risk. Therefore, the NOFM2 was chosen to accommodate the possibility that it may deteriorate sufficiently for him to require a lock option.

* The original thigh release was a problem every prosthetist and patient commented on. An alternative has since been developed by Össur in response to our Clinical Evaluations and the Clinical Support Group have also produced instructions for the use of a lever type actuator, if preferred.

Patient's Comments

Patient 1 – Whilst the patient found the knee better and he felt safer on it 3, he felt the failure of the thigh release to always function as it should was problematic. The socket was also giving him problems, as was residual limb volume fluctuation. It should be noted that the prosthetist was concerned that the patient sometimes forgot to lock the knee when he really needed to and felt it would be better if he could be persuaded to have it converted to a SAKL, this being possible using the same knee unit.

Patient 2 – Though the patient found no problem with the knee unit, scoring it 4, in fairness he had nothing against which to compare it and unrelated health problems caused him to abandon his prosthetic rehabilitation a month after the delivery.

Patient 3 – Having struggled with the "lock" effect of the Total Knee, he rated it at 2. Despite the thigh release problems of the NOFM2 (see above), he scored it 4, finding the action of the knee to be smooth and stable when used as a free knee. Even the lock was declared "good" once the thigh release issues had been sorted out.

Patient 4 – The patient preferred the NOFM2 to the 3R49, once the correct set up had been achieved. Though she scored both 4, she found the NOFM2 less bulky and more reliable. It was initially too sensitive in the stance control and she found this very difficult, but once it was set up correctly, she found no functional difference between the two units.

Patient 5 – After an initial period of training the lock option was removed and the patient now uses the prosthesis with a free knee, finding the brake to be so effective that he has confidence in it, even when walking outdoors 4.

Patient 6 – Unfortunately the early expectations for this patient were not realized, due to the deterioration of his contralateral limb. Though surgery has improved the situation, he has only now begun any significant prosthetic rehabilitation and is using the knee as a SAKL at the moment. Whether he ever achieves sufficient confidence or ability to attempt to use the unit as a free knee remains to be seen.

Note! Most of the units evaluated were the original 100kg weight limit versions, but all new units are now rated at 125kg, following the introduction of an uprated version.

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Issue Date - 26 Nov 2009

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Clinical Evaluation Summary

CES **ÖSS** K01

Össur - NOFM1/NKFM1 Knee

Warranty period - 3 Years

Weight Limit - 136kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

This polycentric knee, allows prosthetists the opportunity to prescribe it as a free knee, with inherent geometric stance stability, but with the option of adding a semi automatic or manual lock, if the progress of the patient's rehabilitation should require it. It is particularly useful where a low above knee build height is also required.

Indications

Low to medium activity patients. Össur I and II.
Primary patients who, in the opinion of the M.D.T needs a SAKL in order to start rehabilitation, but who may progress to a free knee, providing good stability is available. The option of a manual knee lock can be retained if required.
Users of SAKL knees who need a low AK build height, (to improve the cosmesis or accommodate additional hardware) or who wish to progress to a free knee, whilst still retaining good stability with a lock option. *
Free knee users whose condition has deteriorated, requiring greater stability and maybe needing a SAKL in due course. *
Short build length required.
Very low AK build height required (NKFM1).

Contraindication

Reasonably active patients. Above Össur II.

Patients requiring greater swing phase control, or who do no need a lock option at all.

Patients who only need a lightweight SAKL, with no likelihood of progressing to a free knee

Where the patient has become dependant on some other form of stance control, such as weight activated.

* It is imperative that the M.D.T assess very carefully the current limb use, not just the gait, but every aspect of the patient's activity before choosing to change any components.

Evaluation Patients

Patient Details

Patient 1	Transfemoral	63.5 kg	74 year old male	Retired	Sigam E
Patient 2	Transfemoral	60 kg	82 year old female	Retired	Sigam D
Patient 3	Transfemoral	64 kg	61 year old male	Retired	Sigam D
Patient 4	Transfemoral	70 kg	61 year old male	Retired	Sigam D
Patient 5	Transfemoral	50kg	15 year old male	Schoolboy	Sigam Dc
Patient 6	Transfemoral	70 kg	44 year old male	Unemployed	Sigam C

Evaluation Result

Dissatisfied 0 1 2 3 4 5 6 7 8 9 10 **Satisfied**

Current Prescription

Patient 1	Endolite Uniaxial Knee with SAKL and Multiflex foot.
Patient 2	Iceross socket. Otto Bock 3R33 with HOKL and Multiflex foot
Patient 3	Primary
Patient 4	Quadrilateral socket with TES belt, Endolite UK SAKL and Multiflex foot
Patient 5	Iceross socket. OrthoEurope Easy Knee SAKL and Multiflex foot
Patient 6	Endolite SK with PSPC, RPB suspension and Multiflex foot, but he has been unable to wear it for some time due to various health problems.

Prosthetist's Comments

Patient 1 – NOFM1 Ease of alignment scored 4 and other adjustments 3. Due to its short build height cosmesis scored 4, with durability at 3. The thigh release was problematic -2.

Patient 2 – NKFM1 Easy to align and adjust 4. It was chosen because of the short build and manual knee lock option, with the possibility of progressing to a free knee. The thigh release proved problematic.

Patient 3 – NOFM1 Assembly, alignment and adjustment were simple enough 4, but the thigh release proved a problem -2. The patient quickly started to use the knee unlocked, finding it stable and smooth, despite only having a friction control swing phase 4.

Patient 4 – NOFM1 Patient was chosen because he has the potential to use a free knee, but should benefit from the stability of the 4 bar geometry and the MKL option. It was easy to assemble, but needed a better thigh release. Ease of alignment 4. The unit enabled the patient to walk well 5.

Patient 5 – NOFM1 chosen for this boy because he was showing the potential to progress to a free knee, despite being a Hip Disarticulation amputee on the contralateral side. No problems with general assembly 4. The thigh release had to be replaced with an alternative.

Patient 6 – NOFM1 Chosen because the current prosthesis is now unsafe for him, this knee was set up for use as a SAKL, but with the option to progress to a stable free knee.

Patient's Comments

Patient 1 – Initial comparison with the current prosthesis scored 3 and the patient was satisfied with the cosmesis and with the function of the knee when walking. The knee was completely let down by the thigh release, until an alternative was fitted. **

Patient 2 – Liked the knee from day one, but progressively improved and now has had the lock removed completely since she feels the knee is stable enough without.

Patient 3 – Since the patient was a primary he had nothing to compare the knee with, but walked it as a free knee very quickly, only using the lock when additional security was required 4. Unfortunately the patient was not recalled for 3 months and the socket was too tight to use for the last month. Once the new socket had been produced he immediately walked with a free knee again. No signs of wear at the review 4.

Patient 4 – The only comment the patient made on the questionnaire was, "Very effective, good." 5.

Patient 5 – The patient is a teenage boy and a relatively recent traumatic bilateral amputee, (Transfemoral with NOFM1 & hip disarticulation with NHM3 & NOM8) and therefore his comments on the function of the knee have been limited. His progress on them speaks for itself however. He is walking with crutches and has now progressed to walking with a free knee on both sides.

Patient 6 – Since the patient had used a free knee in the past and was now unsafe on it, he had very little positive to say about the new item. He wanted to be free of the SAKL as soon as possible. Thigh release was a real problem, both because of its bulk and because it didn't function very well either. At a later date we effectively removed the lock to see if he could cope without it. Due to the knee being very stable in stance phase he did well and scored it 4.

** The original thigh release was a problem every prosthetist and patient commented on. An alternative has since been developed by Össur in response to these Clinical Evaluations and the Clinical Support Group have also produced instructions for the use of a lever type actuator, if preferred.

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Clinical Evaluation Summary

CES **ÖSS** K04

Össur - NOP4 Knee

Warranty period - 3 Years

Weight Limit - 100kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

The original version had worked well for many patients, but the brake mechanism had sometimes proved difficult to set up, especially on slightly more aggressive walkers. This would result in "popping" at toe off. Össur redesigned the knee and revised the set up instructions. The end result is a unit that is light, with a very effective brake and smooth swing phase control, both of which are easy to set up, with no sign of the problems sometimes found in the original version.

Indications

Low to medium/high activity patients. Össur activity level I to III
Users of similar types of knees needing a lighter or more reliable unit
Users of similar types of knees who want to upgrade the swing phase control, or who require a more sensitive brake
Lower build height required*
Shorter build length required*
Primary patient, capable in the opinion of the M.D.T of using a free knee, but needing good stance control

Contraindication

Very active patients, above Össur activity level III

Patients who currently make use of, need, or prefer a yielding hydraulic or geometric stance control knee

Where a very short build height is required

*These are comparative terms. Please check the technical manual for the exact dimensions.

Evaluation Patients

Patient Details

Patient 1	Transfemoral	95kg	46 year old male	Unknown	Sigam F
Patient 2	Transfemoral	75kg	44 year old female	Pharmacy Assistant	Sigam F
Patient 3	Transfemoral	73kg	43 year old male	Bank Clerk	Sigam F
Patient 4	Transfemoral	85kg	54 year old male	Engineer	Sigam F
Patient 5	Transfemoral	68kg	72 year old female	Retired	Sigam E
Patient 6	Transfemoral	75kg	51 year old male	Unemployed	Sigam E

Evaluation Result

Dissatisfied 0 1 2 3 4 5 6 7 8 9 10 Satisfied

Current Prescription

Patient 1	Blatchfords ESK/PSPC
Patient 2	Original Össur NOP4 on a quadrilateral socket with Seal-In liner and a Multiflex foot
Patient 3	Original Össur NOP4 on a quadrilateral socket, TES belt and CPI Trés foot
Patient 4	Ortho Europe Sensor knee, "H" type suction socket and a Multiflex foot
Patient 5	Original NOP4 on a quadrilateral socket, with TES belt and CPI Accent foot
Patient 6	Blatchfords ESK/PSPC and a Multiflex foot

Prosthetist's Comments

Patient 1 – The prosthetist's only comments were that the knee was easy to fit, align and adjust, with easy to understand technical literature. It has required no further adjustment or maintenance in six months of use.

Patient 2 – The prosthetist had problems with the original NOP4 and had been unable to stop the brake "popping" at toe off, though he had achieved it eventually. He found the new version of the knee much simpler to adjust and feels the patient, who was already an aggressive walker, hence the problems with the old unit, was now even more aggressive, but with no sign of the problems recurring. He also found the swing phase simple to set up.

Patient 3 – The patient was chosen to trial the new version of the NOP4 since the original NOP4 he had been provided with had developed a fault after a short period of use. This was the problem of "popping" at toe off. To try and prevent this, the brake sensitivity had been reduced to the point where it was inadequate.
The new version, which had been designed to overcome this problem, was fitted, but unfortunately it developed a noise after the patient fell off a dinghy into the sea!! The knee was replaced and the socket also had to be remade and the alignment was improved at the same time. Three months later and the knee was still silent and the brake still effective, but without any "popping".

Patient 4 – A long time user of a Blatchford's ESK, this gentleman had become rather dependant on a weight activated stabilized knee and was struggling a little with the hydraulic yielding option he was currently using. The NOP4 was prescribed to redress the situation.

Patient 5 – The original NOP4 had been prescribed it as a replacement for a worn out Endolite ESK/PSPC, in an attempt to reduce the weight of the prosthesis and improve the stance stability for this long time user, who was becoming a little frailer. The unit had been sent for refurbishment, due to ML play and had been upgraded to the new version.

Patient 6 – The prosthetist was presented with a patient who had lost confidence in his current prosthesis, but seemed fit enough to be able to make use of a free knee. The NOP4 was chosen, since it was similar to what the patient had already used, but could be set up to be very stable in the stance phase. No problems were experienced in setting up the knee to provide this stability, without compromising the swing phase.

Patient's Comments

Patient 1 – The patient rated his current knee at 2. Having had the NOP4 fitted he scored it 3 immediately, and found no fault with the unit, being most pleased with the fact that it had not required any attention in six months, but its function had remained the same.

Patient 2 – The patient declined to make any comment on the knee, since she had found the original version good and hadn't noticed any improvement in her gait with the new version, though her prosthetist felt that her confidence in the prosthesis had increased.

Patient 3 – The patient was clearly disappointed with the first knee he was provided with (original NOP4) and scored it -3.
He acknowledged that the replacement functioned well and three months after the remake of the socket, said he had much more confidence in the prosthesis, stating the brake was strong and silent, with no "popping", but failed to award it a score, commenting only that his "friends had noticed an improvement in his gait".

Patient 4 – A man of few words and extremes of opinion, he stated that he found the Sensor knee too heavy and found it "hard to have faith in". He admitted he didn't like not having a stabilizing unit and therefore scored this current limb -4. He found the NOP4 lighter and he could walk further on it and scored it 5. Positive responses were made to all the questions regarding the knee's function and also the question regarding whether the knee had helped him undertake additional sporting or recreational activities, though he didn't comment as to what they were.

Patient 5 – The new version of the NOP4 has proven to be even better than the original version, since it has not required any maintenance, nor has it developed any ML play. The patient feels there is no difference in the function of the knee unit, but is finding it more difficult as her physical strength seems to be decreasing further. Her prosthetist feels that some improvements could be made and is refitting the socket to accommodate a small change in the residual limb volume and slight increase in hip flexion, incorporating the necessary anterior shift to ensure the weight line doesn't compromise the function of the knee.

Patient 6 – The patient quickly regained confidence after a couple of sessions of physiotherapy. His gait, which had become compromised by his loss of confidence and the resultant restriction of his hip mobility, hadn't improved significantly, but the patient has declared himself to be "much happier now".

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Clinical Evaluation Summary

CES **ÖSS** K07

Össur - NOP5/NKP5 Knee

Warranty period - 3 Years

Weight Limit - 125kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

By referring to the design features of the knee the Clinical Support Group decided to evaluate the knee on moderately active patients that required little stance phase control and some swing phase adjustment. Polycentric in design and is therefore geometrically stable during stance phase, the knee includes a pneumatic swing phase control cylinder, offering the ability to adjust both flexion and extension resistance. The results of the evaluation conclude that the knee is smooth in action an easy and controlled transition from geometrical stability to free swing. The knee was found to be easy to adjust requiring no maintenance for the duration of the evaluation period.

Indications

Any patient requiring a free knee with:

- A moderate amount of stance phase control typical of that offered by geometric stability
- Swing phase adjustment offered by a pneumatic cylinder
- The "fluid" swing phase with increased ground clearance at mid swing typical of a polycentric design
- Short build height with alignment (K version)
- A large degree of flexion

Contraindication

A patient of low or very high activity
A patient exceeding 125kg
Where a wide range of speeds are required
Individuals with a particularly aggressive gait

* It is imperative that the M.D.T assess very carefully the current limb use, not just the gait, but every aspect of the patient's activity before choosing to change any components.

Evaluation Patients

Patient Details

Patient 1	Transfemoral	82 kg	61 year old male	Caretaker/Groundsman	Sigam F
Patient 2	Transfemoral	90kg	56 year old male	Retired	SigamF
Patient 3	Transfemoral & Symes	83kg	50 year old male	Unemployed	Sigam E
Patient 4	Transfemoral	70kg	41 year old male	Badminton Player	Sigam F
Patient 5	Transfemoral	97kg	55 year old male	Company Director	Sigam F
Patient 6	Transfemoral	82kg	52 year old male	IT Manager	Sigam F

Evaluation Result

Dissatisfied 0 1 2 3 4 5 6 7 8 9 10 **Satisfied**

Current Prescription

Patient 1	Laminate socket with Ossur Seal-In liner 3R60 EBS Knee Multiflex foot (later converted to Trés)
Patient 2	OB 3R80 Knee
Patient 3	OB 3R106 Knee
Patient 4	Endolite Smart IP knee and Elite foot
Patient 5	Polypropylene Quadrilateral socket with DSPB, Endolite ESKPSPC, Multiflex foot/ankle
Patient 6	Polypropylene Conventional Suction socket, with a metal outer, conventional free knee, with no swing phase control and uniaxial foot

Prosthetist's Comments

Patient 1 – Easy to adjust swing phase control, a smooth and progressive swing. It appears stable at heel strike until mid-stance. Prosthetist noted that the patient was (in this instance) able to wear the trial the knee at factory setting "out of the box" and was then able to fine tune the settings according to the patients requirements. It was noted that it was not possible to discern if the addition of the cosmesis at delivery stage had altered the swing phase characteristics. The last feedbacks from the patient were taken via telephone conversations (the patient not feeling the need to attend the clinic) and it would appear that the knee has continued to perform as well as it had done after the first review appointment. (16/9/08) The Prosthetist was unable to determine if he would routinely prescribe this knee, preferring further experience with the knee before passing any conclusion.

Patient 2 – Described by the Prosthetist as a "robust gentleman" the patient "overpowered" the pneumatic cylinder and despite adjustment excessive heel rise was experienced. When compared to a knee (NOP4) manufactured by the same supplier, also with a pneumatic cylinder it was noted that it was possible with that unit to eliminate the excessive heel rise. It is thought therefore that the geometry of the knee was a feature that contributed to this experience, though his current prescription, being a hydraulic yielding knee, may also have contributed, since it allows a more aggressive gait, which was a characteristic of this gentleman's walking action.

Patient 3 – The Prosthetist noted that this gentleman preferred historically to have no swing phase control, but that it was possible to achieve good swing phase control with the NOP5, requiring little change from the initial factory setting of the pneumatic unit. Found to be a good knee when used in combination with a Trés foot.

Patient 4 – The Prosthetist was initially concerned that the lack of a weight activated stance phase control may be an issue for the patient (The Smart IP already having a weight activated stance phase control within its design) was pleasantly surprised to find that the unit performed well although the lack of stance phase control did "catch him out" once or twice. He would easily have learnt to control the knee, given more time.

Patient 5 – The Prosthetist commented that this patient was accustomed to having the sensitivity of the ESK reduced to a minimum and that he had a short residual limb. His current prescription was under review and so it was decided to trial the NOP5. It was found to be stable, but easy to transition into swing phase. He commented that the patient felt he "was in control of the point at which the transition takes place, such as when descending a slope, but that stability was retained until that point". Also he had found the technical literature easy to understand and concluded by suggesting that the knee would be appropriate for a patient requiring a medium level of stance control. Over the review period the knee needed no further alterations or maintenance.

Patient 6 – Having worn a prosthesis since suffering an accident when a child, this patient had always been reluctant to change his prosthesis, but problems with obtaining some components to service it, added to increasing back problems, possibly due to the exaggerated gait he'd developed in order to control the prosthesis, lead his prosthetist to persuade him to at least try to make a change and this knee unit seemed to be the most appropriate, based on experience with Patient 3.

Patient's Comments

Patient 1 – The patient described his opinion as being "very satisfied overall" and found the knee to be "comfortable and easy to use". He described the knee walking and stability as feeling good and "able to change from old leg to new and still be able to walk with confidence". At the last contact with the patient he described himself as being "entirely satisfied".

Patient 2 – No comments recorded.

Patient 3 – The patient benefited from the swing phase control offered but found the knee flexion angle excessive, preferring to rest onto the unit during kneeling (a stop would therefore need to be added in order to prevent this). It was noted however that the flat broad design of the knee unit made it a more stable platform when kneeling.

Patient 4 – The only note made was that the patient appeared to like the unit.

Patient 5 – The patient commented at the second review that the knee was "smoother and easier to walk with less energy required" and that he had found it easier to manage slopes, but the change in foot prescription had also contributed to the benefits he'd experienced.

Patient 6 – Though he understood the need to try and make a change to his prescription, the patient remained reluctant to do so right up to the delivery stage. He actually walked the new set up very well and this was commented on by other patients, but it wasn't until he returned to his original limb that he realized just how much better the new prosthesis was, at which point he became very enthusiastic about it.

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Issue Date - 18 Aug 2010

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Clinical Evaluation Summary

CES **ÖSS** K03

Össur - NOHP3/NKHP3 Knee

Warranty period - 3 Years

Weight Limit - 100kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

This polycentric knee design includes long side links which when combined with the high performance pneumatic cylinder results in a smooth and controlled swing phase. Stance phase stability is achieved by virtue of the geometry of the polycentric unit. The knee is available with both male pyramid and lamination adaptor distal attachments therefore making this knee suited for any level of transfemoral amputation, but especially those with long residual limbs, and knee disarticulation amputees. The knee is recommended for use with patients of mobility class 3. The results of the evaluations to date would suggest that the enhanced performance of the pneumatic cylinder combined with the geometry of the knee does indeed produce a smooth swing phase for the amputee.

Indications

Patients who would benefit from -
Stance phase control offered by the geometrical stability of the knee design.
Independent flexion and extension swing phase adjustment.
Fluid swing phase with increased ground clearance and enhanced pneumatic performance and adjustability.
Short build height with alignment (especially short with the K version)
Large knee flexion required (Max. 150º)

Contraindication

Patients who -
Are of low or very high activity
Exceed 100kg
Require very high levels of stance phase stability
Who are unable to toe load effectively at the end of stance in order to release the knee.

Evaluation Patients

Patient Details

Patient 1	Transfemoral	80kg	75 year old male	Retired	Sigam F
Patient 2	Transfemoral	102*kg	35 year old male	Stonemason	Sigam F
Patient 3	Transfemoral	74kg	37 year old male	Unemployed	Sigam F
Patient 4	Transfemoral	80kg	55year old female	Unemployed	Sigam D
Patient 5	Transfemoral	74kg	74year old male	Retired	Sigam D
Patient 6	Transfemoral	49kg	65year old female	Retired	Sigam E

Evaluation Result

Dissatisfied 0 1 2 3 4 5 6 7 8 9 10 **Satisfied**

Current Prescription

Patient 1	Laminate Quad socket Tran femoral Locking liner, KFM1 knee, Tribute Foot
Patient 2	(First prosthesis) Laminate Quad socket, NOHP3 knee, Axia foot
Patient 3	Össur AKOS liner on a polypropylene socket with Össur Imatik knee and CPI Trustep
Patient 4	No previous/current prescription.
Patient 5	No previous/current prescription
Patient 6	No previous/current prescription

Prosthetist's Comments

Patient 1 – Due to increased mobility the primary prescription was no longer appropriate. Upon supply of the changed prescription additional physiotherapy support was provided. He adjusted excellently to his knee reporting that it felt smooth. His gait improved dramatically and he achieved symmetry in swing phase. The pneumatic cylinder proved easy to adjust to achieve optimum swing, with small alterations resulting in greater changes than would normally be expected from a pneumatic cylinder.

Patient 2 – This gent became an amputee as a result of RTA prior to which he had been an active and healthy individual. This knee was prescribed because this gent appeared to fill all of the manufacturers recommended criteria. It was anticipated that this gent would be suited to the benefits of fine adjustment afforded by a hydraulic cylinder. This cylinder has proven to be adequate for this gent's gait. He walked at a varied cadence and the cylinder could be adjusted to accommodate this with small adjustments. Swing phase is very smooth in appearance.

Patient 3 – Previously prescribed Endolite IP+ and OrthoEurope Sensor knees the patient liked the speed change feature of the IP+, steps descent feature of the Sensor though neither knee achieved what he felt he needed. He'd previously benefited from the pre-launch version of the Imatik knee, so an NOHP3 loaner unit was fitted in its place. As the Imatik and the NOHP3 share the same chassis design the Prosthetist thought it would be a good opportunity to check which particular feature of the Imatik he'd benefited from most.

Patient 4 – This lady did not initially receive sufficient physiotherapy to achieve her full potential and so progress post amputation was hampered. The Prosthetist noted that the knee was easy to set up, silent in operation and that there was a good angle of knee flexion. Since fitting the knee no adjustments or maintenance have been required.

Patient 5 – This knee had been applied to a primary amputee requiring gait training. The patient had had difficulty in loading the forefoot in order to release the knee and found this difficult when away from the walking gym environment. He fell on a number of occasions and his prescription was reviewed. The knee was an inappropriate prescription for this gentleman even though the knee functioned well when used during gait training.

Patient 6 – This was the first prescription for this patient. No maintenance or further adjustment was required after initial provision. A possible need for a specific cosmesis that will "accommodate the change in dimension of the knee during swing without effecting function" was identified. This has continued to be a successful prescription for this patient who has progressed well with her rehabilitation.

Patient's Comments

Patient 1 – The patient reported that he found this knee a considerable improvement on his previous prescription. He reported that it took him a little while to adjust to. He felt that the knee action was smooth and that he had gained some freedom in mobility with this knee. He reported that the design of the knee allowed him to kneel more comfortably and he felt more stable.

Patient 2 – This patient reported that he found wearing a prosthesis easier than he expected and that the "knee felt good". He did however add that he was unable to be objective with his comments because he had no point of reference. (This was this gent's first prosthetic prescription). He also reported that the knee felt "smooth" and "easy to walk with".

Patient 3 – Though it took time for the patient to get used to the polycentric Imatik knee, he persevered with it, due to liking the "immediate and smooth change in function as he increased his speed". He found ascending hills easier, (probably due to the effective shortening at mid swing).The change to the NOHP3 was simple and though he noticed the fact that the pspc wasn't able to cover the full range of speeds he could achieve with the Imatik, it was still smooth in its action and just as effective in every other way.

Patient 4 – Being a Primary amputee this patient had no other prosthetic experience to compare the knees performance with – however the patient stated that she felt stable and secure and was generally pleased with her prosthesis as a whole.

Patient 5 – The patient noted that he had difficulty getting into his car because he was unable to unlock the knee.

Patient 6 – The patient recorded that she was happy with the function and performance of the knee. She continues to lead a full and active life.

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Clinical Evaluation Summary

CES **ÖSS** K05

Össur - NOH5/NKH5 Knee

Warranty period - 3 Years

Weight Limit - 100kg (NOH6/NKH6 – 136kg)

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

This knee appears to provide excellent geometric stability in stance phase, a smooth and controllable swing phase, good levels of durability and reliability, and a very low build height option, especially in the NKH5 form. Even in this form it is alignable. It also has an exceptionally good range of flexion, limited most often by the socket itself.

Indications

The NKH5 is particularly suited for application where a very short build is required, but where some alignment would still be desirable.
The NOH5 still provides a lower build option than many other knees.
Active users of a free knee who would benefit from a high level of geometric stability in the stance phase.
Active users of a free knee who would benefit from greater control of the swing phase.
Free knee users who would benefit from increased reliability and durability from their prosthesis.
Where a high flexion angle is required.
Cyclists*.

Contraindication

Patients whose activity level is below that where a free knee is appropriate, or who need a manual lock on occasions.

Patients who currently use a hydraulic knee with a yield facility, in order to descend stairs or steep slopes leg over leg.

*We would hesitate to suggest that this knee unit be prescribed for use on a dedicated cycling prosthesis, since it is not possible to bypass the hydraulic system and the constant effect of the hydraulics would make the action of pedalling less efficient and constant high cadence cycling for any length of time may overheat the hydraulic fluid.

Evaluation Patients

Patient Details

Patient 1	Knee Dis	67 kg	21 year old male	Police/Clerical	Sigam F
Patient 2	Transfemoral	82 kg	30 year old male	Pharmacist	Sigam F
Patient 3	Transfemoral	85 kg	26 year old male	Office Worker	Sigam F
Patient 4	Transfemoral	68 kg	27 year old male	Unemployed	Sigam F
Patient 5	Knee Dis	75kg	28 year old male	Office Worker	Sigam F
Patient 6	Transfemoral	58 kg	24 year old male	Unemployed	Sigam F

Evaluation Result

Dissatisfied — Satisfied

0 1 2 3 4 5 6 7 8 9 10

Current Prescription

Patient 1	Laminate socket with the load shared between end bearing and ischial bearing, to Total Knee 2001 and Seattle Lightfoot
Patient 2	Silicone self suspending socket with lanyard with High Activity Total Knee and OB 1D10 foot
Patient 3	Laminate socket with Iceross liner, High Activity Total Knee 2100 and Variflex foot.
Patient 4	Primary prescription
Patient 5	Laminate self suspending socket with Blatchfords 4 Bar knee with PSPC. Seattle Lightfoot
Patient 6	Primary prescription

Prosthetist's Comments

Patient 1 – Actually a young man with an extremely short congenital transtibial absence, who has always been dealt with as a knee disarticulation and who therefore requires as short a build above the knee as possible. The Total Knee had served him very well indeed, apart from the fact that the knee ball kept coming loose and making a noise. Since unit one had reached the end of its life, following a fall into the sea, the opportunity was taken to trial the NKH5 in an attempt to provide an even shorter build.

Patient 2 – The patient was chosen in an attempt to provide a more dynamic gait. The prosthetist observed that the NOH5 was easy to assemble, smoothly finished and gave a good flexion angle. The adjustment of spring assist and hydraulic swing phase control he found "tricky" 4.

Patient 3 – A good user of the Total knee, this patient's second prescription gave opportunity to trial the NOH5 knee. The prosthetist found it easy to set up 4 and did not need to change anything from the factory settings. A pivot screw came loose after 6 months, but was serviced under warranty without question.

Patient 4 – Due to the length of the residual limb, an NKH5 was prescribed as his first issue prosthesis, the prosthetist finding it easy to fit, with a wide range of alignment and swing phase control. It appears stable throughout the stance phase and has proved reliable and durable.

Patient 5 – Technically a congenital absence of the fibula, the very short tibia would not allow the use of a transtibial prosthesis. The distal section does allow the socket to be self suspending, but also present a problem since the patient likes a high degree of flexion to enable him to kneel. The Blatchfords unit allowed this, but didn't tolerate the activity level of the patient. The Total knee wouldn't allow the flexion required, so the NKH5 was chosen. The alignment wedges, though requiring a certain level of "mental gymnastics", do make it easier to align than the other units.

Patient 6 – Previously fit and active prior to his amputation, but wishing to return to full time employment and to pursue his sporting and leisure activities, the prosthetist chose the NOH5 knee in the hope of helping him achieve a smooth, natural, cadence responsive gait. There were no problems with the technical instructions, fitting and alignment, and two months after delivery, no maintenance or adjustment has been required.

Patient's Comments

Patient 1 – Initially a little unsure of the knee, since the level of stability was such that he had to be more precise in his action when flexing the knee to sit, he scored it at 3, having scored the Total Knee at 4. By the review date 3 months later, he didn't even mention this issue, commenting only that it felt more stable and safer on stairs. He particularly liked the increased flexion. After 6 months he scored the knee at 5. No durability problems to date.

Patient 2 – Though he had scored the Total Knee at 4 and we did have some problems getting the swing phase speed correct on the NOH5, he still gave it 4 as well. The first unit developed a hydraulic leak, but a loaner was provided and the refurbished unit has been fine since. He likes it for cycling especially, but still seems to want it to be faster in swing phase.

Patient 3 – The patient made very little comment, but liked the look of the unit, thought it felt lighter and more stable. He requested it rather than a second Total knee and is still using it as his preferred prosthesis.

Patient 4 – Having no other experience against which to judge the knee, the patient scored it a cautious 3, stating that "I can do everything I need to". His only difficulty was in learning to sit, at which point the excessive stability of the unit initially proved awkward.

Patient 5 – The patient has found this unit very reliable and apart from a slight noise that developed in the hydraulics, has had no need of repairs whatsoever. He also appreciates the high degree of flexion available.

Patient 6 – This enthusiastic young man, despite having nothing with which to compare his prosthesis, scored it 5 at the start and the end of the two month evaluation. He is delighted with its performance, having used it on an exercise bike, walked over uneven ground and been on nights out with his friends. He tends go down slopes by taking a diagonal route, not because the knee has ever let him down, but because he lacks confidence. He wants to start running, but he is still at an early stage in his prosthetic rehabilitation.

This picture shows the flexion angle achieved on patient 5

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Clinical Evaluation Summary

CES **OSS** K08

Össur - NOP2 Knee

Warranty period - 3 Years

Weight Limit - 125kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

Since this knee is a lightweight and slim unit, it is ideal for slim adults or children who need to progress from a paediatric to an adult's knee. The original version has been re-designed, improved and reintroduced to the range. The polycentric construction now has adjustable geometry that allows the transition from stance to swing phase to be fine-tuned. This also makes it ideal for use on Hip Disarticulation applications. Although the unit doesn't have the low build height which sometimes defines the application of a polycentric knee, its flexed profile allows a very good cosmetic shape to be achieved. The pneumatic control of the swing phase is very smooth and easily adjusted to suit the patient's gait.

Indications

K2 to medium/high K3 activity patients who would benefit from a knee that:

- Is lightweight and reliable
- Has a smooth, easily adjustable swing phase
- Has an adjustable ICR to fine-tune the stability and transition into swing phase
- Small enough to allow a slim cosmesis
- Cost-effective

Contraindication

- Very active patients, above activity level K3, or above the weight limit of the knee
- Patients who currently make use of, or need, or prefer a yielding hydraulic or weight-activated stance control knee
- Where a very short proximal build height is required

*Please refer to the Steeper Prescription Guideline: HW **P** KNE 02

Evaluation Patients

Patient Details

Patient 1	Transfemoral	46kg	37 year old female	Swimming coach & Mum	Sigam D Medi 3
Patient 2	Transfemoral	86kg	55 year old male	Unemployed	Sigam D Medi 2(3)
Patient 3	Transfemoral	60kg	41 year old male	Unemployed	Sigam D Medi 3
Patient 4	Transfemoral	75kg	64 year old male	Retired milkman	Sigam D Primary
Patient 5	Hemi-pelvectomy	80kg	67 year old male	Retired	Sigam D Medi 2(3)
Patient 6	Transfemoral	76kg	71 year old female	Retired	Sigam D Medi 2(3)

Evaluation Result

Dissatisfied — Satisfied

0 1 2 3 4 5 6 7 8 9 10

Current Prescription

Patient 1	Quadrilateral socket with Silesian belt, NOP2 knee and CPI Trés foot – Primary prescription
Patient 2	Quadrilateral socket, TES belt, NOP2 knee and CPI Trés foot - Primary prescription
Patient 3	Quadrilateral socket, TES belt, NOP2 knee and CPI Trés foot - Primary prescription
Patient 4	CADCAM Quad, TES belt, NOFM2 knee and CPI Trés foot - Primary prescription
Patient 5	Conventional socket, Quantum Hip with stride limiter and 4 bar knee, Dynamic Motion foot
Patient 6	Quadrilateral socket with Seal-in silicone liner, NOFM2 knee and CPI Trés foot

Prosthetist's Comments

Patient 1 – Since the patient was very petite and as a primary required good stability, but with the option to make it more dynamic as the patient's ability increased, the prosthetist felt that the NOP2 knee was ideal, having rejected the OB 3R90 at the initial fitting. The prosthetist had no problem setting up the knee and at the review stage commented that the knee was very stable, but released at toe off into a "lovely controlled swing phase".

Patient 2 – This primary patient has the potential ability to walk with a free knee, but at a single speed. There was no problem setting it up and at the review the prosthetist noted that the swing phase appeared smooth.

Patient 3 – This primary patient being very light, with a fairly long residual limb requiring a reasonably low build, seemed an ideal patient for the NOP2. Set up was easily achieved. One year on and the patient had not progressed as well as his prosthetist had hoped, still finding it hard to achieve a reasonable and consistent swing phase.

Patient 4 – Though a primary patient, he appeared capable of progressing easily to a free knee. For this reason the prosthetist chose the NOP2, since it is light and the ICR can be adjusted such that it would provide high stability in the early stages of the patient's rehabilitation, but could be made more dynamic as he progressed. It proved easy to set-up and align.

Patient 5 – The patient had complained that there was some lag in extension of his previous knee in swing phase, so the NOP2 was chosen to try and improve the efficiency of the gait. He found the Quick Fit Guide very handy, such that the set-up was easy. A very stable stance phase and the desired swing phase were both easily achieved.

Patient 6 – The patient had been an Ossur Total knee wearer for many years before her activity and confidence levels decreased, making a stabilised knee a more appropriate prescription. Patient has been progressing well with NOFM2, but has demonstrated she would walk more efficiently with a geometric locking knee, but is not at an activity level that requires hydraulic swing phase control. Adjustable ICR made this knee the optimum prescription for the patient

Patient's Comments

Patient 1 – Bearing in mind that the patient was a primary amputee, she quickly started to make use of the knee, finding it "much better than the other one" (3R90). A month or so later and she was obviously feeling much more confident and pleased to be walking again, stating "I haven't fallen over yet" and at the final review "I can drive again".

Patient 2 – Though the patient had nothing particular to compare the knee against, he did find he really had to concentrate to ensure that it was in extension as he transitioned into stance and did have one or two falls, though by the last review he was walking fairly well.

Patient 3 – This patient consistently found it difficult to get the knee to transition into swing phase and even after a year on it, he still found it hard to achieve consistently. Even so, he is getting about quite well, stating that he feels much more confident when walking and "can care for my kids so much better again".

Patient 4 – Whilst he had nothing with which to make a comparison, he still seemed very pleased with the knee, finding that it functioned well and provided good stability on the flat and on slopes. He gave it **8** on the satisfaction scale, but was obviously hoping for greater satisfaction as time progressed.

Patient 5 – Scoring the NOP2 **9**, his only complaint was that, due to its high level of stability, he occasionally had to move and reposition his prosthesis in order to get it to unlock.

Patient 6 – The patient made an immediate comparison with the Ossur Total knee in positive ways – stability on most surfaces and easy to initiate swing phase. The patient noticed no degradation in performance and although she commented that there were no significant increases in activity level or quality of life, she felt confidence in the knee and was happy to continue in her current activity level.

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Clinical Evaluation Summary

CES OSS K09

Össur - NO/NKPASO Knee

Warranty Period - 3 Years

Weight Limit - 136kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

This is the final outcome of a project started by Medi and evaluated by Steeper over several years. Its polycentric chassis, though improved and strengthened for the Paso, was already well proven. The pneumatic cylinder is a unique design that allows a wide range of gait speeds to be achieved, from below the suggested 2km/h to well above the advertised 7km/h, provided the user is capable of safely doing so.

Our evidence shows that there is no perceived delay as speed is increased or decreased and that the extension required to ensure stance stability is consistently achieved. The anterior/posterior shift increases or decreases the stance stability and the use of one of the two optional wedges that change the ICR, makes for a more dynamic transition into swing phase. There are no means of adjusting the pneumatic cylinder, since it self-adjusts to suit the activity of the user. Users whose current knee has no significant swing resistance, may find this a little difficult to get used to, but only two patients have rejected it on that basis.

Indications

K3 to K4 activity patients who would benefit from a knee that:

- Has a smooth self-adjusting swing phase
- Accommodates a wide range of gait speeds
- Has ICR adjustment wedges to fine tune the stability and transition into swing phase
- Has a low above knee build height**
- Has a large flexion angle
- Is robust and durable
- Is cost effective
- Is lightweight (compared with hydraulic options)

Contraindications

- Patients below activity level K3, or above the weight limit of the knee.
- Patients who currently make use of, need, or prefer a yielding hydraulic or weight activated stance control knee.*
- Patients requiring a very slim cosmesis or a very short total build height.

*Please also refer to the Steeper Prescription Guideline HW P KNE 02.
** Especially the NKPaso version.

Evaluation Patients

Patient Details

Patient 1	Transfemoral	85kg	53 year old male	Bookings Office	Sigam E
Patient 2	Transfemoral	95kg	36 year old female	Self Employed	Sigam F
Patient 3	Knee Dis	78kg	44 year old male	Unemployed	Sigam F
Patient 4	Transfemoral	67kg	16 year old female	Student	Sigam E
Patient 5	Transfemoral	110kg	43 year old male	Self Employed Carpenter	Sigam F
Patient 6	Transfemoral	95kg	51 year old male	Self Employed Photographer	Sigam E

Evaluation Result

Dissatisfied 0 1 2 3 4 5 6 7 8 9 10 Satisfied

Current Prescription

Patient 1	Quadrilateral socket, 4Seal liner, Medi NKFM1 knee and CPI Venture foot
Patient 2	Self-suspending end bearing socket, Medi NOH5 knee and Freedom Senator foot
Patient 3	Revision from transtibial on PTB Supracondylar socket with CPI Trés foot
Patient 4	Laminate socket, Össur Seal In liner, Medi NOFM1 knee and CPI Trés foot
Patient 5	Ischial Containment socket with silicone pin liner, Endolite KX06 (Total Knee), Proflex XC foot
Patient 6	Ischial Containment socket with Seal In liner, Össur Total knee and CPI Venture foot

Prosthetist's Comments

Patient 1 – Having started the patient on a NKF1M knee, he has progressed beyond that prescription, limiting his gait and walking speed. As a result, the Paso was chosen in the hope of providing a smoother swing phase, with the ability to walk at variable speeds.

Patient 2 – Having been a long time user of a Total Knee, he was swapped to a Medi NOH5 over three years ago. Since that knee was now showing some significant wear, it was decided to trial an alternative unit in an attempt to upgrade the swing phase action and improve durability. The prosthetist had no problem setting up and aligning the knee and a year after delivery it had required no attention.

Patient 3 – Having been a fairly active transtibial amputee, it was expected that this patient would achieve K3 activity level and Sigam F following revision to knee disarticulation. To that end he was supplied with the Paso, its 4 bar construction allowing a low build height. It was easy to fit and align, but did need to be returned for repair soon after delivery, due to a hissing noise (maybe due to it being an open pneumatic cylinder).

Patient 4 – This young patient's activity level had increased significantly, such that the swing phase of the NOFM1 no long provided adequate control. The Paso was chosen with the intention of improving the gait over a wider range of speeds, reducing gait deviations and lowering energy expenditure. Due to the age and petite build of the patient, this was an admitted risk, but one that the prosthetist felt it was worth taking. They had no problem with the set up, but commented that the knee was rather bulky for this patient, with limited adaptability to changes in speed.

Patient 5 – The prosthetist chose to trial the Paso in an effort to improve the patient's gait. The main features that influenced this choice were the fact that the Paso is lighter than the KX06 and has an auto adjustable speed range that, being pneumatic would require less effort from the patient. An A wedge had been fitted at the first review, the patient having become used to its function, to the point where he wanted it to release into swing phase more dynamically. The only negative was the fact that the knee cover had broken and it wasn't possible to obtain a replacement.

Patient 6 – Due to the fact that the patient walks quickly, with and aggressive swing phase, adjusting the knee settings himself, dependant on what activity he was about to engage in, the prosthetist that he'd be safer on the Paso. Having fitted it, which was found to be very simple to do, the prosthetist commented that, apart from the stumble recovery feature, the Paso was as effective as an MPK.

Patients' Comments

Patient 1 – The patient felt that there was a need to over-emphasise loading the toe to achieve swing, or to sit down and to extend the knee fully for stability at heel strike.

Patient 2 – The patient found it slightly difficult when descending a slope, or stairs. A year after delivery he stated that its stability and durability had allowed him to do more manual work.

Patient 3 – At delivery the patient found some issues negotiating slopes and getting it to transition into swing, or to unlock for sitting. An A wedge was fitted and this improved the situation. The patient loves walking his dogs and found that he could still manage to do so on the Paso and stated that "I can do everything I want to do", scoring it with an "I love it" comment and a 10.

Patient 4 – At the delivery the patient felt that the knee did not unlock easily and was stiff to bend due to the cosmesis, though four months later her comments were more positive, even though she still felt some limitations to mobility (it would have been good to have been able to review the situation a year or so on).

Patient 5 – The patient's main issues with the KX06 were that it felt heavy and slow and that he'd had several falls as a result of it not "being there for me". Rating the Paso at 9, he was very positive about it in every way, stating that it had improved his quality of life.

Patient 6 – Although he had used the Total knee for about ten years, rating it at 6, he stated that he found it difficult going down slopes. He had been able to run on it. The response of the patient to the Paso caused him to score it 10. He was impressed with its stability even when he walked it backwards, though more difficult on slopes (the prosthetist fitted a wedge at the review and the patient didn't mention the issue again). He says that it has allowed him to access more machines in the gym and to go further for longer on the treadmill.

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Clinical Evaluation Summary

CES **ÖSS** L01

Össur - First & First 3 Liner

Warranty period - 6 Months

Weight Limit - Not applicable

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

The original version of this liner, as issued to the patients included in this evaluation summary, was easy to don and easily cleaned, as a result of it having a slip surface treatment, rather than a fabric cover. The surface treatment created a weakness in the liner, making it easy to tear if not handled carefully. Since then the surface treatment has been improved, which has made a dramatic difference to its durability, whilst retaining all the benefits outlined by the original evaluations. The surface flaking mentioned by some of the patients, has also been eliminated. Sweating and subsequently, odour problems seem to be reduced, as mentioned by some of the patients. This has been confirmed over a reasonable period of time now and two of the patients requested replacements because of that benefit alone. The First 3 version provides greater protection to the distal end of the residual limb and is directly interchangeable with the other Össur 3 liners.

Indications

Patients with a transtibial amputation
Sigam mobility grade C to F
Össur Mobility classes 1 and 2
Where ease of donning is important
Where the ability to clean the liner easily is helpful

Contraindication

Patients with a transtibial amputation
Sigam mobility grade C to F
Össur Mobility classes 1 and 2
Where ease of donning is important
Where the ability to clean the liner easily is helpful

Evaluation Patients

Patient Details

Patient 1	Transtibial	112 kg	38 year old male	Maintenance Technician	Sigam F
Patient 2	Transtibial	70 kg	38 year old male	Fire Officer	Sigam E
Patient 3	Transtibial	73 kg	75 year old female	Retired	Sigam D
Patient 4	Transtibial	75 kg	62 year old male	Retired	Sigam D
Patient 5	Transtibial	72 kg	43 year old female	Administrator	Sigam E
Patient 6	Transtibial	67 kg	55year old male	Unemployed	Sigam E

Evaluation Result

Dissatisfied — Satisfied

0 1 2 3 4 5 6 7 8 9 10

Current Prescription

Patient 1	Laminate socket with Icelock 600 shuttlelock, Össur soft C liner and Variflex foot
Patient 2	Laminate socket with Icelock 600 shuttlelock, Össur soft C liner and Multiflex foot
Patient 3	Vacuum laminated, one shot Ossur socket with Iceross Comfort liner and SACH foot
Patient 4	Laminate socket with shuttlelock, Össur soft C liner and Otto Bock 1D10 foot
Patient 5	Laminate socket with shuttlelock, Össur soft C liner and Otto Bock 1D10 foot
Patient 6	Laminate socket over Iceross Clear liner, Icelock 600 shuttlelock and Endolite MFA

Prosthetist's Comments

Patient 1 – This patient was already on a Össur pro soft C liner and was simply chosen at random.

Patient 2 – This patient was already on a Össur pro soft C liner and was simply chosen at random.

Patient 3 – The Ossur vacuum laminated one shot socket had been a final effort by the patient's previous prosthetist, to produce a comfortable socket, but it had required a 2mm pelite liner to correct the volume, scored 0.

It was decided to return to basics and, since the residual limb had adequate soft tissue cover, it was agreed that the Comfort liner was not necessary and a Össur First liner was chosen as a cost effective way of trying to make progress. On the second attempt, triangulating the socket and adding supracondylar wings to prevent rotation the socket was deemed comfortable 3 and a CPI Trés foot was added to reduce the weight and add a dynamic element to the gait.

Patient 4 – This patient was also a user of the Össur soft C liner, but was chosen with the hope of providing greater comfort and increased flexibility around the knee. Initial fears were that it may be too soft and looked likely to tear. There were no problems with the fitting, but surface cracks appeared after one month.

Patient 5 – This lady was another Össur soft C liner user, but was chosen by the prosthetist in the hope of providing an increase in patient comfort on the thigh. Though comfort did seem to have been achieved surface cracks appeared on the liner surface around the knee and the liner tore proximally.*

Patient 6 – The Iceross Clear being worn by this patient had lasted well, but was now in need of replacement. The patient tended to be overenthusiastic with the use of powder when donning and had given himself i skin problem as a result. Since the socket was also loose the prosthetist decided to recast over a Össur First liner and also take the opportunity, to upgrade the foot to a Trulife Kinetic.

Unusually very few scores were given either positive or negative.

Patient's Comments

Patient 1 – "Much better – want another one" was the response of this patient. He commented on the ease of donning, comfort, reduced irritation and odour, and durability.

Patient 2 – Despite an initial problem when the liner tore proximally, this patient persevered and reported increased comfort and ease of donning. Durability was not a problem either, provided he was careful when donning.

Patient 3 – Though the patient's dependence on he three wheeled walker had not decreased, due to problems with her sound hip, she has expressed herself very pleased with the prosthesis, if not with her progress 3. Though she found the original liner easy to don, the surface flaked away eventually* and she had to resort to using powder to don it. No such problems have been reported with the new version that has been supplied as a replacement.

Patient 4 – This patient liked the softness of the liner, finding it easier to flex the knee and more comfortable when walking. He experienced some irritation around the proximal edge of the liner and was concerned by the cracking in the liner surface.*

Patient 5 – She says the rubbing to the back of the leg, experienced with the other liner, has now gone, stating it to be "Really comfortable – doesn't feel as if I'm wearing it and not sweaty – a pleasure to wear". She also found it easy to don, though when she used a sock on the outside it did tend to slip down easily and durability was poor.

Patient 6 – Though the patient initially found the socket a little tight, he's had no problem donning the liner and has stopped using powder altogether, though the skin issue that it gave him is taking time to heal.

Unusually very few scores were given either positive or negative.

***An improved surface treatment has since been introduced.**

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Clinical Evaluation Summary

CES **ÖSS** L02

Össur - Soft C Liner

Warranty period - 6 Months

Weight Limit - Not Applicable

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

The patients comments suggest that this liner, with its fabric cover, is easily donned and the cover and matrix together provide greater control of any distal soft tissue, with very limited distension. This reduces the socket pistoning that may be apparent when using most liners that have no cover, or the thicker, softer gel liners.
The latest version of this liner had a different fabric cover to that which it originally had and which was initially supplied to some of the evaluated patients. This appears to have improved the durability of the liner.

Indications

Patients with a transtibial amputation
Sigam mobility grade C to F
Össur Mobility classes 1, 2 , 3 and 4
Where ease of donning is important
Where there is soft residual limb tissue that needs to be controlled, either to ease donning, provide improved control, or reduce socket pistoning
Where there is little residual limb tissue, such that socket pistoning causes discomfort

Contraindication

Patients with poor cognitive function
Patients with a poor standard of hygiene
Patients with poor manual dexterity
Excessive residual limb volume fluctuation

Note! The Contraindications shown are true for all transtibial pin liners, not just the Össur Soft C liner, though there are some Indications specific to it, which would suggest that some of the Contraindications may be reduced.

Evaluation Patients

Patient Details

Patient 1	Transtibial	77kg	78 year old male	Retired	Sigam E Össur 3
Patient 2	Transtibial	108kg	70 year old male	Retired	Sigam Dd Össur 2
Patient 3	Transtibial	58kg	72 year old male	Retired	Sigam Dd Össur 2
Patient 4	Transtibial	76kg	45 year old female	Clerical Officer	Sigam F Össur 3
Patient 5	Transtibial	62kg	73 year old male	Retired	Sigam E Össur 2
Patient 6	Transtibial	81kg	44year old male	Unemployed	Sigam Dd Össur 2

Evaluation Result

Dissatisfied — Satisfied

0 1 2 3 4 5 6 7 8 9 10

Current Prescription

Patient 1	Laminate socket with Icelock 600 shuttlelock, Iceross Original liner and Otto Bock Trias foot
Patient 2	PTB Supracondylar socket and CPI Trés foot
Patient 3	Polypropylene socket with Blatchford's shuttlelock and MFA, Iceross Clear liner with matrix
Patient 4	Polypropylene socket with Icelock 100, Iceross clear liner with matrix and Endolite MFA
Patient 5	Polypropylene socket with Blatchford's shuttlelock and Iceross Original liner
Patient 6	Laminate socket with Icelock 600 shuttlelock, Össur First liner and CPI Trés foot

Prosthetist's Comments

Patient 1 – The prosthetist chose this liner in an attempt to improve the suspension and comfort of the socket, though otherwise the prescription remained unchanged. Concern was expressed regarding slight fraying of the cover, but no other problems were mentioned, the liner being easy to don and doff, with improvements in the patient's comfort and the socket suspension.

Patient 2 – The patient was chosen in an attempt to improve the quality of the fit and suspension, as well as doing away with the cuff strap. The only complaint the prosthetist had was the fact that the fabric cover tended to fray easily. The prosthetist reported that this has improved since the material used in the production has been changed and that this has increased the longevity of the liners.

Patient 3 – Having attended for a routine examination, it was clear that the patient had lost weight and was frailer than previously. The socket and liner were both too large and the patient was finding the limb too heavy. In an attempt to provide a lighter prosthesis, with a liner that the patient could don more easily, but which would also be durable, a Össur Soft C liner was prescribed, with a lightweight laminate socket, Icelock 600 and Trés foot. A new liner was issued after one year and another was ordered a year after that.

Patient 4 – The patient's residual limb had significant distal soft tissue that required stabilization (Refer to guideline number TT P SSS 01) and to that end a Soft C liner with matrix was prescribed, with a laminate socket and Icelock 600 shuttlelock, along with a CPI Accent foot and Skinergy cover. Some issues were experienced with the trim line of the socket, since the patient kneels a lot as part of her job, but a few months later the spare prosthesis was refitted to match. The liner lasted about a year before a replacement was ordered.

Patient 5 – This rather frail gentleman, with an unsteady gait, presented with a socket that was now far too big. His residual limb was now very bony and consideration was given to the option of a thicker liner, but since he was still coping with a thinner one, despite issues with socket pistoning and donning, it was agreed to try a Soft C with a laminate socket and Icelock 600.

Patient 6 – Though this patient capable of reasonable ambulation, due to his other medical conditions, it is unsafe for him to do so, since he can collapse without warning. He mostly uses a powered wheelchair. The Össur First liner was satisfactory, but since he does fall on occasions, even when transferring, the liner was too easily damaged and he was supplied with three in 11 months. Since being issued with the Soft C, with it's more durable cover, this has reduced to two in 17 months.

Patient's Comments

Patient 1 – The improvement in socket comfort and suspension were noted by the patient, as was the ease of donning, since the cover obviated the need to apply powder or lubricant, the Iceross Original being the patient's current prescription.

Patient 2 – The patient commented that the liner was easy to don and doff, had made his prosthesis more comfortable to wear, partly as a result of the improved suspension. He didn't feel that the liner had shown any serious signs of wear or breakdown.

Patient 3 – At the last review the patient declared the prosthesis "smashing" and nothing was required, though the liner looked rather worn, nearly a year after it was supplied, and a replacement was ordered.

Patient 4 – The ease of donning was commented on straight away and the socket comfort also improved as a result of the stabilization of the distal soft tissue. Though the patient noticed some changes in her residual limb shape after a while, these were accommodated by using additional socks. The spare limb was refitted to the same prescription.

Patient 5 – The patient initially struggled with a problem of pressure on his fib head. This was resolved by cutting an aperture in the socket. He now says that he is very comfortable in the socket, finding the pistoning negligible and the ease of donning a real benefit. Over two years on and only two liners have been supplied, the first having the more fragile original fabric cover. Though the second liner still had some life left in it when recently reviewed, a third liner was ordered.

Patient 6 – He had no problem donning the Össur First liner and finds the Soft C just as easy, but that the cover has made it significantly more durable.

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Clinical Evaluation Summary

CES **ÖSS** L03

Össur - Sensitive 3C and 6C Liner

Warranty period - 6 Months

Weight Limit - Not Applicable

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

The thicker, softer silicone used in these liners seems to make them ideal for those patients where the soft residual limb tissue is limited, leaving bony areas that need protection, or where the tissue is liable to be easily damaged. Whilst the gel does not have the "flow" properties claimed for urethane liners, it does appear to provide adequate cushioning to allow comfort, but with a fabric cover and matrix combination that doesn't allow significant distal distension. This reduces socket pistoning and thereby limits the discomfort it can cause. The fabric on the latest version is much more durable than on the original version and which some of the evaluated patients were originally issued with.

Indications

Patients with a transtibial amputation
Sigam mobility grade C to F
Össur Mobility classes 1 and 2
Where ease of donning is important
Where there is little residual limb tissue and greater protection is required
Where the residual limb tissue is easily damaged, due to scarring, or poor vascularity

Contraindication

Patients with poor cognitive function
Patients with a poor standard of hygiene
Patients with poor manual dexterity
Excessive residual limb volume fluctuation

Note! The Contraindications shown are true for all transtibial pin liners, not just the Sensitive liner, though the Indications specific to it, would suggest that some of the Contraindications may be reduced in this case.

Evaluation Patients

Patient Details

Patient 1	Transtibial	80kg	57year old male	Landscape Gardener	Sigam E	Össur 4
Patient 2	Transtibial	108kg	70year old male	Retired	Sigam D	Össur 2
Patient 3	Transtibial	65kg	56 year old male	Unemployed	Sigam Dd	Össur 2
Patient 4	Transtibial	58kg	64year old female	Retired	Sigam E	Össur 3
Patient 5	Transtibial	79kg	35year old male	Unemployed	Sigam F	Össur 3
Patient 6	Transtibial	82kg	48year old male	Unemployed	Sigam E	Össur 2

Evaluation Result

Dissatisfied — **Satisfied**

0 1 2 3 4 5 6 7 8 9 10

Current Prescription

Patient 1	Laminate socket with Icelock 600 shuttlelock, Össur soft C liner
Patient 2	Laminate socket with shuttlelock, Ossur original liner and Multiflex foot
Patient 3	Laminate socket with Icelock 600 ratchet lock Össur First liner and Seattle Kinetic foot
Patient 4	PTB with cuff suspension and Multiflex foot
Patient 5	Laminate socket with Icelock 600 shuttlelock, Iceross Original liner, CPI Trustep foot
Patient 6	Laminate socket Icelock 600 smooth pin lock, Iceross Original and Sureflex foot

Prosthetist's Comments

Patient 1 – Due to his work and the condition of his residual limb, though the patient managed well on the Össur Soft C liner he found he was prone to tissue breakdown. It was hoped that the much thicker and softer gel of the Sensitive 6C would provide improved comfort over a longer period, with less tissue breakdown.

Patient 2 – This elderly retired lady had managed reasonably well on the Ossur liner, but was suffering some discomfort as her skin tissue was rather fragile and easily damaged. A Sensitive 6C liner was chosen in an attempt to provide an appropriate level of protection.

Patient 3 – The patient had managed well on the Össur First liner, but due to illness and family tragedy had lost weight and the socket was now slightly too big. His fibula head and the distal end of the residual limb were becoming sore as a result. It was agreed that a new socket be made to take a Sensitive 3C liner and the liner was ordered. The Össur First liner was almost worn out by the time the patient was able to return for casting, so after the cast was taken, the current socket was tried over the Sensitive 3C liner and the patient immediately felt the benefit of the softer and slightly thicker gel. The new socket was produced with a built in pad over the fib head.

Patient 4 – Not finding the PTB with cuff strap particularly satisfactory in appearance, a self suspending socket was agreed, but due to the rather bony nature of her residual limb, the prosthetist prescribed a Sensitive 3C to provide greater protection and comfort than could be achieved with a Össur First or Soft C. This was a new limb build, so a laminate socket and Icelock 600 shuttlelock was used with a CPI Trés foot. Five liners have been issued in 3 years, but one of these was a failed attempt to improve the comfort by using a tighter liner. Ignoring this, the liners have lasted approximately 8 to 9 months each, though the new cover material has improved the average, the most recent one lasting 10 months.

Patient 5 – Originally provided with a PTB socket, cuff suspension and OB 1D10 foot, he was later provided with a Trustep foot and, at the same time, fitted with an Iceross Original liner. He had limited success with the liner since he found it made him sore. He was prescribed a Sensitive 3C liner in an effort to provide improved socket comfort. In nearly two years of use he has only been provided with one other Sensitive 3C liner.

Patient 6 – Attending for review, it was noted that the patient's weight had increased and that the Sureflex foot was now too soft. He was provided with a Freedom Senator and then, in an attempt to further improve his comfort, he was prescribed a Sensitive 3C liner. A second issue limb was later provided, to the same prescription and also a water activity limb, both with Sensitive 3C liners, but no other liners have been issued since their delivery over 8 months ago.

Patient's Comments

Patient 1 – Despite his heavy and dirty working conditions, the liner still functioned well after eight months of use and he stated that he had not had nearly as many tissue breakdown issues. He did however feel that his residual limb had reduced in volume and this may have accounted for the occasional problems that he had experienced.

Patient 2 – Although she suffered some initial problems with blistering around the proximal edge of the liner, this had passed and after nine months the liner was still functioning well, though her residual limb volume had decreased and a new socket had to be produced over a smaller Sensitive 6C liner. Her only negative comment was that, in warm weather, perspiration sometimes caused the liner to slide off slowly. She thought this liner better than her previous one though and found it easier to mobilize and to do her shopping.

Patient 3 – Despite the immediate relief experienced by using the Sensitive 3C in his original socket, at the fitting of the new socket he felt an even greater improvement and walked it without the aid of the stick that he'd taken to using because of his discomfort. By now the fabric of the original Sensitive liner was showing signs of significant damage, but the new liner provided has a new fabric cover, an improvement that has increased durability.

Patient 4 – Although it has taken the patient a little while to get used to the new socket system, she is now pleased with the set up, finding it more convenient and comfortable than the PTB.

Patient 5 – He immediately felt the benefit of this liner, finding it increased his comfort, not just because of the increased cushioning, but also because the covered liner helped reduce pistoning.

Patient 6 – Always uncertain of change, the patient took a while to settle into the new foot and liner, but once sure of them, he requested a duplicate prosthesis. He noted the improved comfort, from both the liner and the foot.

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Clinical Evaluation Summary

CES **ÖSS** L05

Össur - Protect 3C Liner

Warranty period - 6 Months

Weight Limit - Not Applicable

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

The same in profile as the Sensitive 3C, with the same soft silicone gel, this liner has the advantage of being impregnated with a lubricant formulated to protect and care for the skin and to prevent skin tension during flexion and extension. From the evaluations, it seems to provide the same level of cushioned comfort as the Sensitive 3C, but also dramatically improves comfort for those patients whose residual limb tissue is easily irritated by sweat, or by conditions such as eczema, or where the skin is readily irritated or damaged by the tension of the liner on the thigh, especially around the top edge, or over the patella. It appears to be as durable as the Sensitive liner, having the same fabric cover.

Indications

Patients with a transtibial amputation
Sigam mobility grade C to F
Össur Mobility classes 1, 2 and 3
Where ease of donning is important
Where residual limb and thigh tissue is easily damaged by tension from the liner, or is subject to conditions such as eczema, or is easily irritated
Where there is little residual limb tissue and greater protection is required
Where the residual limb tissue is easily damaged, due to scarring, or poor vascularity

Contraindication

Patients with poor cognitive function
Patients with a poor standard of hygiene
Patients with poor manual dexterity
Excessive residual limb volume fluctuation

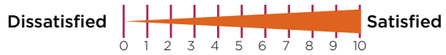
Note! The Contraindications shown are true for all transtibial pin liners, not just the Protect liner, though the Indications specific to it, would suggest that some of the Contraindications may be reduced in this case.

Evaluation Patients

Patient Details

Patient 1	Transtibial	72kg	53 year old male	IT Teacher	Sigam F	Össur 2
Patient 2	Transtibial	88kg	63 year old male	Retired	Sigam F	Össur 2
Patient 3	Bilateral TT	83kg	70 year old male	Retired	Sigam D	Össur 1
Patient 4	Transtibial	66kg	73year old female	Retired	Sigam D	Össur 1
Patient 5	Transtibial	104kg	54year old male	Security Guard	Sigam F	Össur 3
Patient 6	Transtibial	73kg	72year old male	Retired	Sigam E	Össur 2

Evaluation Result



Current Prescription

Patient 1	Polypropylene socket with Blatchford's shuttlelock, Otto Bock TEC pin liner and Multiflex foot
Patient 2	Laminate socket with Icex pads and Icelock 600 ratchet lock, Iceross clear liner, Flexwalk foot
Patient 3	Polypropylene socket with Blatchford's shuttlelock and Multiflex foot, Iceross clear liner
Patient 4	Iceross Modular socket system with Comfort liner and Kingsley SACH foot
Patient 5	Laminate socket with Iceross shuttlelock, Össur First liner and Freedom Senator foot
Patient 6	Polypropylene socket with Blatchford's shuttlelock, Iceross Original liner and Multiflex foot

Prosthetist's Comments

Patient 1 – The patient was chosen because of severe problems with blisters and open wounds to his thigh from the TEC liner he had recently been issued with. This had not been a problem with the original TEC version, but changes to the gel and cover were suspected to have caused his skin to be damaged and further irritated by his own sweat. It cleared within a few days of being issued with the Össur Protect. A new socket had been produced to accommodate the liner and at the same time the foot changed to a CPI Trustep, since he likes to play golf.

Patient 2 – Transferring from another centre, the patient was having problems with the Iceross clear liner causing tissue breakdown. A Sensitive 3C liner was originally ordered and a new socket made. Although initially the liner seemed better, his very fragile tissue again broke down over the fibula head and a Protect 3C liner was issued. Although he felt this was much better, the fibula head continued to cause problems, until a new socket was made with a Keasy foam liner with an aperture cut in the laminate socket to accommodate the fibula head.

Patient 3 – Having recently become a bilateral amputee, it was clear that his original socket was now too big, so new sockets were made for both sides, using Össur First liners. With his reduced ability to look after himself, a tendency to perspire and to scratch when irritated, it soon became clear that these liners were creating a problem for him. Though he'd started to mobilize using the prostheses, it had become such a problem that alternative socket options could not be considered until the condition of his residual limbs could be improved. Despite several attempts, this was not achieved, until the limbs were taken from him. The left side improved first and a Protect liner was ordered and supplied for use in his existing socket, to see if this could be tolerated. No problems arose and a Protect liner was confidently ordered for the other side.

Patient 4 – Having struggled for some time to make headway, her prosthetist requested help and a colleague agreed to start afresh. A laminate socket was produced with a Össur First liner and Icelock 600 and a Trés foot. Later the socket was remade to include supracondylar wings to reduce socket rotation. She was eventually persuaded to use flatter shoes and considerable improvement was slowly achieved. The provision of a new First liner increased existing skin irritation problems, since it felt tighter than the now much stretched original. A Protect liner was ordered, almost out of desperation. A second limb was produced as part of this process and this has resolved the problems.

Patient 5 – The residual limb tissue of this patient was very easily damaged and the Sensitive 3C liner was provided in an attempt to prevent the lesions he'd had as a result of wearing the PTB he'd originally been supplied with. Though he liked the socket, it didn't resolve all the problems and a Protect liner was prescribed.

Patient 6 – Attending with his residual limb in very poor condition, it was decided to prescribe this gentleman with a Protect liner, in order to give it the best chance possible to recover whilst keeping him mobile. On returning 18months later, he was struggling to don the limb due to having increased in weight, thanks to an improvement in his general health and a new socket was produced over a slightly larger liner.

Patient's Comments

Patient 1 – The patient was delighted with the improvement in his skin condition and socket comfort, as well as the improvement in his gait due to the Trustep foot. A refit of the socket was required after some time, but the liners have proved durable and have remained comfortable, long after any obvious sign of the lubricant surface inside the liner has disappeared.

Patient 2 – Even at the first attempt with the Protect liner, the patient declared that he "couldn't even feel that it was on". Since the introduction of the Keasy liner his tissue breakdowns have reduced significantly. Both limbs are now to the same prescription and the liners have proved durable. He is still wearing the third liner to have been issued in two years of use. Converting from an old Flexwalk foot to a Senator has resulted in an improved gait, with considerably less jarring through his residual limb. This has also helped reduce his problems.

Patient 3 – Having suffered badly when using Össur First liners, the Össur Protect dramatically improved his comfort, reduced any irritation and helped improve the skin condition. Delivery of the Protect liner for the other side was achieved soon after, with no sign of the skin problems returning. His only comment was that the liners tended to slip down more readily than the First liners, especially when he sweats.

Patient 4 – She has eventually come to understand that many of her problems have been due to her lack of confidence in the prosthesis and her unwillingness to compromise in things such as shoes styles, but is now much more comfortable on her prosthesis; is gaining in confidence as a result; is content with the latest prosthesis and has requested that her original limb be converted to the same prescription.

Patient 5 – Initially he didn't find any benefit from the Sensitive 3C and kept reverting to the limb with the PTB socket, until this limb failed him and he had to use the limb, now with the Protect liner. On returning to collect the repaired PTB, he stated that he now loved the limb with the Protect liner and has now used it for about 6 months.

Patient 6 – The patient seemed very pleased and his skin condition has now improved significantly.

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Clinical Evaluation Summary

CES **ÖSS** F06

Össur - AKOS Liner

Warranty period - 6 Months

Weight Limit - Not Applicable

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

The original version of this liner, as issued to the patients included in this evaluation summary, has proved to be a durable product that is easy to don and easily cleaned, as a result of it having a slip surface treatment, rather than a fabric cover. The surface treatment has since been improved, which appears to have increased its durability even further. A conical version has also been introduced, making it applicable for an even more patients. The matrix that is incorporated helps reduce longitudinal stretch, without significantly affecting the circumferential elasticity.

Indications

Patients with a transfemoral amputation
Sigam mobility grade C to F
Össur Mobility classes 1 to 4
Necessity for enhanced suspension and gait control
Auxiliary suspension is undesirable
Where durability is important
Where ease of donning is important
Where the ability to clean the liner easily is helpful

Contraindication

Patients with poor cognitive function
Patients with a poor standard of hygiene
Patients with poor manual dexterity
Long transfemoral or knee disarticulations, especially when used in conjunction with other adapters and knee joints resulting in a cosmetically unacceptable long thigh segment
Excessive residual limb volume fluctuation

Note! The Contraindications shown are true for all transfemoral pin liners, not just the AKOS liner, though the Indications specific to the AKOS would suggest that some of the Contraindications may be reduced in this case.

Evaluation Patients

Patient Details

Patient 1	Transfemoral	95kg	71 year old male	Retired	Sigam D
Patient 2	Transfemoral	87kg	23 year old male	Unemployed	Sigam F
Patient 3	Transfemoral	76kg	51 year old male	Engineer	Sigam F
Patient 4	Transfemoral	96kg	63 year old male	Retired	Sigam E
Patient 5	Transfemoral	82kg	60 year old male	Unemployed	Sigam F
Patient 6	Transfemoral	90kg	52 year old male	Employed - Advisor	Sigam F

Evaluation Result

Dissatisfied 0 1 2 3 4 5 6 7 8 9 10 Satisfied

Current Prescription

Patient 1	Polypropylene socket with TES belt, ESK, PSPC, MKL, Multiflex foot
Patient 2	Polypropylene Quadrilateral socket with TES belt, ESK, PSPC, MKL, Multiflex foot
Patient 3	Laminate Quadrilateral socket – (no further detail supplied)
Patient 4	Quadrilateral socket with Iceross pin liner – (no further detail supplied)
Patient 5	Polypropylene and Northvene socket to hand cast, TES Suspension, ESK, PSPC, Multiflex foot
Patient 6	Bespoke silicone pin liner to flexible laminate outer, Total Knee and OB 1D10 foot

Prosthetist's Comments

Patient 1 – Patient had requested a more positive suspension, but the residual limb tissue was flaccid. Use of the AKOS liner improved the soft tissue stability and enhanced suspension. It was noted by the Prosthetist that the liner had lasted 18 months before a replacement had been required. At the final review the liner was awarded a score of 5. The Prosthetist stated that he would be prepared to routinely use this product.

Patient 2 – This patient had undergone a transfemoral amputation fairly recently, as a result of a road traffic accident. It was anticipated that he would become more active and require a regular prescription review. Upon maturation of the residual limb, it was decided by the MDT that he would benefit from a silicone suspension system. The Prosthetist awarded the liner a score of 4 suggesting that the range of sizes should be increased to accommodate a larger circumference.

Patient 3 – – The Prosthetist stated that she had prescribed the AKOS Liner with the aim of achieving positive suspension, with longitudinal stretch control. A final score of 3 was awarded however it was noted that the proximal edge of the liner had split and that this may be avoided by inclusion of a conical design within the AKOS range. **(A conical version is now available)**. This Prosthetist stated that she would routinely use this product.

Patient 4 – The Prosthetist commented that she had decided to try the AKOS Liner because the previously prescribed liner had kept falling off. The aim was to achieve a more secure attachment. The Prosthetist stated that she had found this liner to be a durable product and that it had proved to be a more successful prescription than the previously supplied liner. A satisfaction score of 3 was awarded.

Patient 5 – This Prosthetist stated that he was aiming to improve the suspension of the prosthesis and reduce socket rotation. Satisfaction scores for all aspects for performance review were between 3 & 4. It was noted that the edge of the liner was prone to tearing, however overall performance was thought to be very satisfactory.

Patient 6 – Having received compensation following the industrial accident that had caused the loss of his limb, he spent a considerable amount purchasing two prostheses, with bespoke silicone liners. On returning to the NHS, the prosthetist suggested the use of an AKOS liner and both he and the patient were impressed with the end result, though the slip surface treatment did appear to encourage small tears on the proximal edge 4. **(An improved surface treatment has since been introduced)**

Patient's Comments

Patient 1 – Although he scored his current prescription as 5 he described his previous method of suspension as "useless". Having been fitted with the AKOS liner, the benefits highlighted by the patient included improved suspension and the ability to return to horse riding. Some rotation of the residual limb within the socket had been noted when the patient "twisted violently". He scored the AKOS liner as 5.

Patient 2 – When asked about his current prescription this patient stated that he was happy with his prosthesis, but wished that his socket could be made more comfortable. He awarded a score of 3 for his current socket. Upon his final review after delivery of his new socket, incorporating the AKOS liner, he stated that the socket had become more comfortable but wished that "the rubber could be thicker in places for added comfort".

Patient 3 – This patient did not offer any details regarding his opinion of the previous socket design but stated that he was "very happy with the liner" and awarded a satisfaction score of 4.

Patient 4 – This patient stated that the AKOS liner was an improvement on his previous prescription and that it "felt much more secure". At the delivery of his new prosthesis the patient awarded a score of 4.

Patient 5 – Due to some language/communication difficulties it was not possible to collate this gentleman's comments in a written form, but it is known that he is satisfied with the results he has achieved with his AKOS liner.

Patient 6 – Having spent a considerable sum of money on privately purchased prostheses with bespoke liners, this gentleman was somewhat doubtful initially as to whether the AKOS liner would prove adequate. He was delighted with the end result however. They have proven to be durable, failing eventually around the top edge, as a result of small tears that appear to start as a result of the slip surface treatment. **(He has since been supplied with the new version, which has an improved slip surface treatment, and this appears to have improved durability even further.)**

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Issue Date - 26 Nov 2009

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Clinical Evaluation Summary

CES **OSS** L13

Össur - 4Seal TFS & TFC Classic Liners

Warranty period - 6 Months

Weight Limit - Not Applicable

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

Össur spent several years in the design and development of this liner, before bringing it to market and the end result is a liner with many excellent features. The most popular of these, from the patient's viewpoint, is the fact that the Easy Glide surface obviates the need for any lubricant when donning the liner, or the socket. Secondly, the very soft integral seals make for much easier donning of the liner, increasing the opportunity for patients with reduced hand function to use this type of liner and socket. The lack of a fabric cover has also been welcomed, since it makes the liner much simpler to keep clean and also more durable. The fact that the Umbrellan fabric, integrated within the silicone to provide a matrix, offers the possibility of a reduction in P hantom Pain, at no extra cost is certainly a significant benefit.

Indications

Patients with a transfemoral amputation
A long and stable residual limb
A patient who would benefit from a liner that

- Is easy to don
- Requires no lubricant to don prosthesis
- Is easily cleaned and durable
- May provide Phantom Pain relief
- That doesn't require a specific socket design

Contraindication

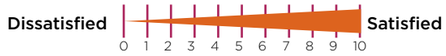
Patients with poor cognitive function
Patients with a poor standard of hygiene
Patients with very poor manual dexterity
Excessive residual limb volume fluctuation
A short or conical residual limb
Unable to tolerate a TSB socket
Unable to tolerate a suction seal liner socket

Evaluation Patients

Patient Details

Patient 1	Transfemoral	80kg	45year old female	Amputees in Action	Sigam F
Patient 2	Transfemoral	80kg	47year old female	Self Employed	Sigam F
Patient 3	Transfemoral	66kg	65year old female	Unemployed	Sigam E
Patient 4	Transfemoral	65kg	76year old male	Retired	Sigam E
Patient 5	Transfemoral	98kg	72year old female	Retired	Sigam B
Patient 6	Transfemoral	80kg	73year old male	Retired (Blind)	Sigam D

Evaluation Result



Current Prescription

Patient 1	Quadrilateral socket with Iceross Seal In liner, Össur NOFM2 knee and CPI Tribute foot
Patient 2	Quadrilateral socket with Össur 4Seal TFS liner, Mauch knee and CPI Velocity foot
Patient 3	Quadrilateral socket with Iceross Seal In liner, Össur NOFM2 knee and CPI Trés foot
Patient 4	Quadrilateral socket with Iceross Seal In liner, Össur NOP4 knee and CPI Trés foot
Patient 5	Soft Quadrilateral socket with Iceross Seal In liner, Össur NOFM0 knee and CPI Trés foot
Patient 6	Metal Quadrilateral suction socket, Endolite Smart IP knee and Multiflex foot

Prosthetist's Comments

Patient 1 – The patient had been complaining that the current liner was inclined to lose suction and the cover easily gets torn and dirty. The prosthetist had been considering an X5 Seal In liner, but when the 4Seal became available, decided to give it a try, since it also offered the benefit of having no cover. The patient prefers to roll the liner over the socket edge and though this was manageable, in this early version it was slightly short.
This has been rectified in the latest production version, making it 1cm longer than the Seal In.

Patient 2 – Having been a user of the 4Seal TFS for some time, distal residual limb volume had reduced slightly, making the TFC more appropriate. The benefits of the original liner remain just as effective, but distal containment was improved, without increasing the proximal tension. A new socket was produced to suit.

Patient 3 – Finding that the Ossur Seal In liner tended to fray the fabric cover fairly regularly, her prosthetist decided to try her on the Össur 4Seal.

Patient 4 – A long time user of the Seal In liner, when the patient attended, having lost some weight and requiring a new socket, the prosthetist decided to use the 4Seal liner, in an attempt to make donning the prosthesis easier, especially as the patient was becoming slightly more frail.

Patient 5 – Because the patient found the Seal In difficult to don, needed the spray to get into the socket, but tended to lose suction when sitting for any length of time, the prosthetist decided to try the Össur 4Seal in the hope of improving the situation. The liner proved to be easy to trim; the patient could don it herself; retention was improved and durability is good.

Patient 6 – Suffering with distal congestion as a result of wearing a metal suction socket that was no longer fitting well, the prosthetist chose the 4Seal and produced a new plastic socket as a short term solution, whilst a new metal socket was being made. The patient could don the liner himself, but being blind did struggle a bit, especially when getting into the socket. However, this enabled him to mobilize again, though he did suffer from some blisters around the top of the liner. The plan is to produce a new socket, with the advice being to trim the liner a little lower, so that the patient is not sitting on the edge of it and possibly with a sleeve to give extra protection, or a seating pad. The prosthetist also observed that it was easier to don and that it had a "nice feel" to it.

Patient's Comments

Patient 1 – At the delivery the patient commented that the liner was easier to don and though a little tight*, still comfortable. It was too lose in her current socket and a new socket was produced. At the review stage she commented that she'd had no problems with the durability of the liner, felt more comfortable and was able to wear the limb for longer. She liked that fact that there was no fabric cover, making it easier to keep clean, easier to don, with a consistent level of comfort.

Patient 2 – The patient found the new liner and socket more comfortable with improved control. At the review she stated that the new socket had made "walking better", with no rubbing or bruising and "extended walking ability". She also commented that there was no ripping at the top of the liner, which presumably had been where the TFS liner had been under greater tension and where it failed first.

Patient 3 – The patient immediately commented that it was easier to don, felt more comfortable and provided a very positive suspension, with reduced rubbing. At the review, the reduced rubbing was again mentioned, along with the ease of cleaning and care of the liner. Two months later there was no sign of wear or damage to the liner and the patient commented that she felt more confident and could walk faster on her prosthesis.

Patient 4 – Finding the liner very much easier to roll on and with the benefit of not requiring a lubricant spray when donning the prosthesis, the patient was delighted with the end result. Durability has proved to be excellent.

Patient 5 – The patient stated that the liner was easier to don and "holds on much better". At the first review she commented that it was simpler to keep it clean, since it doesn't have a fabric cover and at the final review, that "it still holds the leg on better".

Patient 6 – The patient found the liner "ok" to don and that it improved his comfort and reduced the movement of the limb on his residual limb. Though he did still feel discomfort and suffered some blistering around the top of the liner, he was very pleased to be mobile again. A new socket is currently being made to try and resolve the issues.

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Issue Date - 9 October 2014

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Clinical Evaluation Summary

CES **STR** S01

Streifeneder - Contex Gel Suspension Sleeve

Warranty period - 3 Months

Weight Limit - Not Applicable

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

This sleeve appears to have provided most of the patients evaluated with a comfortable and long lasting suspension sleeve option. Since this evaluation summary was first produced in Feb 2006, these sleeves have been redesigned and improved, and they now have a smaller permanent logo, are more durable around the knee area, with a matt surface in that area to reduce any possible tissue tension over the patella. Patients 6 and 7 were issued with the latest version of the sleeve and reflect the opinion of many other patients regarding its durability and comfort. Donning is best achieved by reflecting the bottom half of the sleeve, stretching the folded part over the socket edge and sliding the reflected section back down the shin.

Indications

Suction socket sleeve.
Secondary suspension sleeve.
Where a water tight seal is required.
Where a full range of flexion is important.
Where longevity is an issue.

Contraindication

Poor dexterity or reduced hand function.
Allergies to polyurethane.

Evaluation Patients

Patient Details

Patient 1	Transtibial	88 kg	52 year old male	Retired	Sigam F
Patient 2	Transtibial	70 kg	44 year old male	Engineer	Sigam F Very Active
Patient 3	Transtibial	85kg	54 year old male	Businessman	Sigam F
Patient 4	Transtibial	75 kg	36 year old male	Unemployed	Sigam F
Patient 5	Transtibial	76 kg	60 year old male	Engineer	Sigam F Very Active
Patient 6	Transtibial	100kg	39 year old male	Full time Dad	Sigam F
Patient 7	Transtibial	102kg	74 year old male	Retired	Sigam C

Evaluation Result

Dissatisfied — Satisfied

0 1 2 3 4 5 6 7 8 9 10

Current Prescription

Patient 1	Polypropylene socket with a Variflex foot and Blatchford's neoprene suspension sleeve
Patient 2	Tec liner with a Vass sleeve and valve. Freedom Renegade foot
Patient 3	Laminate socket with Alpha liner, Iceflex balance sleeve and Endolite DR2 foot
Patient 4	Laminate socket with suction valve, Iceflex balance sleeve and Tribute foot
Patient 5	Laminate socket with suction valve and Alps sleeve
Patient 6	PTB Socket, with Reflex rotate foot and previous version of Contex Gel Sleeve
Patient 7	TSB Laminate socket with Contex Gel Cushion liner, suction valve, Endolite MFFA and previous version of Contex Gel Sleeve

Prosthetist's Comments

Patient 1 – Donning was easy using the same technique as suggested for the Iceflex Endurance sleeve. A diagram would make the instructions clearer, perhaps. This sleeve was chosen because the patient was going through neoprene sleeves at a rate of one a month.

Patient 2 – The patient is so very active, running 5 miles daily, that he was wearing out sleeves fairly quickly and it seemed that it would be a fair trial of the Streifeneder against the Vass suspension sleeve. 4

Patient 3 – This golf fanatic had been wearing through every type of suction sleeve we had provided. He attended to be measured for an Alps sleeve, but was given this to trial as well.

Patient 4 – Until the Explorer liner was issued, his residuum broke down regularly due to the scar tissue and psoriasis, but the Iceflex Balance sleeve issued with it failed very quickly and the Contex Gel sleeve was provided to try and improve the situation 4

Patient 5 – The Alps sleeve currently being used, was comfortable and flexible, but became baggy, especially around the top edge and leaked easily. This sleeve was provided as an alternative 4.

Patient 6 – Though the patient had found the previous Contex Gel Sleeve was very good, its durability was its weakest point, hence this patient was keen to trial the new version. At the end of the evaluation, the prosthetist stated that it had "much longer than expected".

Patient 7 – The new version of the Contex Gel Sleeve was chosen in the hope that it would outlast the previous version. The prosthetist was concerned that there did not appear to be any reinforcement around the knee, but also that it had proved to be more durable and was much better aesthetically.

Patient's Comments

Patient 1 – The patient felt the sleeve to be very comfortable and that it gave better retention of the prosthesis. After eight weeks he reported that it showed no signs of wear and he was still delighted with it 4.

Patient 2 – This very active patient has found the sleeves to be the most comfortable and longest lasting of all the sleeves he has tried.

Patient 3 – He was delighted with this sleeve. He felt it was comfortable, gave him the range of movement he required, but without restriction and it was still in one piece several weeks past the time any others would have lasted.

Patient 4 – This patient's sleeves need to be flexible due to his skin condition, but he destroyed the Iceflex balance sleeves very quickly. The Streifeneder sleeve has lasted 2 months with no sign of breakdown 4.

Patient 5 – The Alps sleeve was scored at 3, but he scored the Streifeneder sleeve 5 at the delivery of it. Six weeks later he was still as impressed with it. It didn't leak at all and sweating seemed less during prolonged running. He found it comfortable, flexible and less bulky, remaining comfortable even after 18 hours of use 5.

Patient 6 – The patient found the sleeve to be just as effective and 4 months later stated that, though a little looser on his thigh, it had "not ripped" and was lasting over twice as long as the previous version. He was very pleased with it indeed.

Patient 7 – The patient liked the appearance of the new sleeve and though most of his comments were regarding problems with the suction valve, he appeared pleased with the durability and comfort of the sleeve.

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Clinical Evaluation Summary

CES **ÖSS** S01

Össur - Genu Sleeve

Warranty period - 3 Months

Weight Limit - Not applicable

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

The Genu is a soft suspension sleeve, made from a thermo plastic elastomer, which was specifically designed for use with Össur Cushion liner and valve suction systems. It is 3mm thick, with a well designed elastic outer fabric. This makes it very comfortable to wear, but unless it's used as part of a suction system, it is too easily stretched to be effective, except for particularly low activity patients, or patients who require easy flexion of the knee. As with all sleeves used in this way, care needs to be taken to protect the sleeve from damage around the socket edge and it is supplied complete with a separate protective fabric sleeve, with a silicone strip which grips to the top of the socket. The sleeve is then pulled over the knee before the Genu is rolled onto the thigh. This has proved very effective and durable. After a very short time it became clear that, though very soft, flexible and comfortable, the elasticity of the sleeve makes it unsuitable for highly active patients, but is generally best suited to low activity users, not using a suction system, or moderately active patients using a suction system. Few sleeves are being used on sockets with suction valves, on highly active patients, hence the fact that only four patients have been included in this evaluation.

Indications

Patients with a transtibial amputation
Patients who need a soft, flexible sleeve, due to general frailty, or specific weakness of knee flexors/extensors
Low activity patients who need a sleeve that is easy to don and who can cope without a suction system
Moderately active Patients who can cope with a suction system

Contraindication

Patients with poor cognitive function
Patients with poor manual dexterity
Patient activity level above moderate

Evaluation Patients

Patient Details

Patient 1	Transtibial	98kg	49 year old male	Quarryman	Sigam F	Össur 4
Patient 2	Transtibial	61kg	30 year old female	Unemployed	Sigam F	Össur 3
Patient 3	Transtibial	65kg	45 year old female	Unemployed	Sigam D	Össur 2
Patient 4	Transtibial	72kg	54 year old female	Education Advisor	Sigam E	Össur 3

Evaluation Result

Dissatisfied 0 1 2 3 4 5 6 7 8 9 10 **Satisfied**

Current Prescription

Patient 1	Laminate supracondylar PTB socket, Juzo sleeve and Freedom Sierra foot
Patient 2	Laminate TSB socket, 9mm Absolute liner, CPI Trés foot, thigh corset and side steels
Patient 3	Laminate TSB socket, TEC Custom liner, Contex Gel sleeve and valve, and Kinetic foot
Patient 4	Laminate TSB socket with Pelite liner, Ossur 600 valve, Contex Gel sleeve and Elation foot

Prosthetist's Comments

Patient 1 – Suffering contact dermatitis from the original PTB socket material, this patient was provided with a new laminate PTB socket, with a Streifederm gel sock in lieu of a Pelite liner, a suction valve and Genu sleeve. It was also hoped that this would improve the suspension and reduce the bulk around the knee, especially in the posterior knee region. The prosthetist liked the sleeve colour, its tapered shape and separate protective sleeve. She also commented on the fast delivery time. The patient has a very active lifestyle, but none of his activities were affected by the new set up and it has lasted longer than other sleeves that were initially tried, primarily due to the separate protective sleeve.

Patient 2 – This active lady was keen to get back to running and cycling. She had been hampered by the damage to her tibia, caused by the accident in which she lost her limb. This had been surgically refashioned and fixed, but a thigh corset and side steels were incorporated in the initial prosthesis to try and offload the residual limb. When the thigh corset was removed a valve and suction sleeve were provided and the Genu sleeve was supplied in an attempt to improve the ease of flexion. The prosthetist liked the sleeve colour and the flexibility of the thin gel of the sleeve.

Patient 3 – The Genu sleeve was supplied to this patient to see if it would allow a better range of movement than the Streifeneder Contex Gel, without compromising durability. The prosthetist commented that it was easy to don, but was unsure about the durability, since a small hole in it had compromised the suspension after 3 months and necessitating a replacement.

Patient 4 – The patient had been suffering with a rash due to the excessive adhesion/friction from her current suspension sleeve, though it had made the limb feel very secure. The prosthetist found it easy to fit and that it seemed to work well with the protective sleeve.

Patient's Comments

Patient 1 – The patient preferred the new set up, feeling that it provided a greater sense of security and "feedback". He tried two other types of suspension sleeve, but has found this allows easier knee flexion. Though initially concerned that it may not last well, he stated at the three month review that it was better and more durable than either of the other options that he'd tried.

Patient 2 – Although still hindered by the pain in her residual limb, on which she was due to have further surgery, and some problems with eczema, she commented that this sleeve seemed "more stretchy" than the previous sleeve she'd tried, making it more comfortable to bend the knee. She noted less irritation around the top edge and greater comfort when sitting. The first Genu issued seemed to lose its elasticity and a tighter one was issued.

Patient 3 – Finding the sleeve easier to don, neater and more flexible, the patient was initially very pleased. She stated that the suspension was positive and reliable, until the small hole appeared in the sleeve, but she requested a replacement rather than go back to the original sleeve.

Patient 4 – Initially the patient felt that the Genu sleeve provided a similar degree of security to that of the Contex Gel sleeve, whilst also making it easier to bend for climbing stairs and cycling. At the first review, five months later, she mentioned that the sleeve tends to roll down easily and wrinkle around the knee, reducing the adhesion and the limb then feels less secure. The increased mobility when walking or cycling was a definite positive though. She felt that it was beginning to wear out, especially where it's folded over when the limb is removed. A month later the sleeve was replaced with another Genu sleeve because of its benefits, even though she still felt the sleeve tended to slip down and if sitting and standing repeatedly, it can cause the sleeve to drop down sufficiently that the limb becomes less secure.

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Clinical Evaluation Summary

CES **ÖSS** SOCK

Össur - Relax Nightcare Sock

Warranty period - Not applicable

Weight Limit - Not applicable

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

With five of the six patients featured in this evaluation benefiting from significant levels of pain relief and the sixth being found to have a neuroma as the cause of their pain, this unusual product does appear to offer real hope for those patients whose sleep is regularly disturbed by the effects of phantom pain. Interestingly some patients have reported that they also seem to have benefited from a decrease in phantom pain in the daytime. This may be due to improved sleep patterns as a result of the decreased pain at night, or there may be some other factors involved, but either way the patients were very grateful for the relief of their pain. Other patients have reported that, although no other cause for their pain has been found, the sock has not given any relief from phantom pain, or not particularly significant relief. It would seem that the only way to determine which patients will be fortunate enough to enjoy the benefits experienced by those featured in this evaluation, is to "try it and see". Though care should be taken to eliminate the possibility that the pain is being caused by some other underlying problem prior to prescribing the sock, Össur do refund the cost of the sock should it prove to be ineffective for whatever reason (see website or catalogue).

Indications

Any patient suffering from "phantom pain", with no other cause or source of the pain.

Contraindication

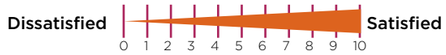
Patients not suffering from pain, or whose pain cannot be defined as a "phantom pain".

Evaluation Patients

Patient Details

Patient 1	Transtibial	68 kg	91 year old male	Retired	Sigam D
Patient 2	Transtibial	88 kg	54 year old female	Unemployed	Sigam F
Patient 3	Transtibial	78 kg	59 year old male	Unemployed	Sigam F
Patient 4	Transtibial	61 kg	77 year old male	Retired	Sigam C
Patient 5	Transtibial	65kg	66 year old male	Retired	Sigam F
Patient 6	Transtibial	47 kg	77 year old male	Retired	Sigam D

Evaluation Result



Current Prescription

Patient 1	PTB Supracondylar socket with Endolite Multiflex Foot and Ankle
Patient 2	Laminate socket with Iceross liner and shuttlelock with Ossur Variflex foot
Patient 3	PTB Supracondylar socket with College Park Tribute foot.
Patient 4	PTB Supracondylar socket with Quantum foot.
Patient 5	PTB Supracondylar socket with Flex Allurian foot and also has a Laminate socket with Relax liner and Flexwalk foot
Patient 6	Laminate socket with Silipos LA cushion liner, corset & side steels with SACH foot

Though the patient's details and current prescription have no relevance in one sense, they do show that the extent of the problem and the effectiveness of the product are not affected by these factors.

Prosthetist's Comments

Patient 1 – The patient was selected to try the sock since he suffers with Hyperaesthesia in his residual limb, with constant phantom pain.

Patient 2 – The patient has chronic pain in his residual limb and has used TENS and a mirror box in an attempt to relieve it.

Patient 3 – The patient suffers with residual limb pain that is getting worse and from which he gets no relief.

Patient 4 – When questioned this gentleman said he experiences phantom pain most evenings from about 5.00pm for anything between 5 and 12 hours on a scale between 8 and 9. He takes Co-Dydramol (paracetamol and dihydrocodeine) as required, though this only helps slightly.

Patient 5 – This energetic ex semi-professional footballer suffers with fairly severe phantom pain in short bursts at level 8 every 30mins (especially when trying to sleep or rest) despite being on Gabapentin morning and evening. He feels this drug only gives about 20% pain relief, but that this does at least make it bearable. He was supplied with a Relax liner when they were first introduced, though he never really liked that style of socket, preferring his PTB with multi-sock fit. He has however gained considerable pain relief and has taken to sitting with the liner on when he wishes to relax. Hence, when the Night Care Sock became available it was provided for him.

Patient 6 – Having recently fractured her hip, this ladies discomfort enabled her to tell her prosthetist that she has always suffered phantom pain problems, which are currently worse due to her other problems. She described her pain as starting with a tingling sensation distally which culminated in a severe "jumping" pain. This she scored at level 10, and though it quickly subsides it always wakes her, if it's allowed her to get to sleep in the first place.

Patient's Comments

Patient 1 – Scoring his pain prior to the use of the Night Care Sock at 6 and after at 0 whilst using the sock at night, with a score of 1 during the day, he said it had allowed him to sleep well at night. This had previously been a problem. He'd been impressed with the effectiveness of the product and how quickly he got results.

Patient 2 – He says he's reduced his pain medication by 40% and gets no pain at night when using the sock, finding it easier to sleep as a result. He scored his pain at an unbearable 10 prior to using the sock, reducing that to 3, in the form of an occasional twinge once a week on average, with no pain at night.

Patient 3 – The patient rated their pain as almost unbearable most of the time 9. Unfortunately the Relax Night Care Sock did not help at all and he returned it. This enabled the centre to claim a refund from Össur. The prosthetist noted that the patient had suffered Ischemic Compartment Syndrome post amputation and that it was in the same area of the residual limb that the pain seemed to originate. On further investigation it was found that a neuroma had also developed. Either of these would account for the pain, but neither would be improved by the use of the sock.

Patient 4 – Two weeks after being provided with the sock this patient states, "Since getting the sock I have hardly had any pain at all (pain score1) ---- sleeping better, cut down on my pain tablets and my life is better." Nearly 4mths later and a phone call confirmed that he was still just as satisfied, though he'd had a bad night recently. Fearing that this may be due to the deterioration of the sock, the prosthetist phoned again a week later, but there had been no reoccurrence of the problem.

Patient 5 – He has been really pleased with the effects of the Night Care Sock, rating what pain he has at no more than 2. He sleeps better, has abandoned the Gabapentin, and says that "Whoever designed that sock deserves a medal". He is on his third issue, but each has lasted approximately 5mths before becoming ineffective.

Patient 6 – Scoring her pain at 10, though in short bursts, a Relax Night Care sock was posted to her and when she attended a month later, despite the fact that she was still in some discomfort with her other problems, she was delighted with the sock. The pain had been completely relieved and she was now able to sleep. Apparently a lady of extremes, she declared the pain score to be 0.

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Clinical Evaluation Summary

College Park - Lamination Adapters

Warranty period - N/A

Image	Component	Build Height	Weight	Part Number
	**3 Prong Anchor, Rotatable** Stainless Steel	9.9mm	122g	3PA R
	**4 Prong Anchor, Rotatable** Stainlesss Steel	16.3mm	156g	4PA R

Super Set Screws

Weight Limit- 136kg

Image	Kit	Build Height	Weight	Part Number
	**3 Prong Anchor, Adapter w/ Pin Lock Hole, Rotatable** Titanium	13.1mm	159.5g	**3PA AHR T**
	**3 Prong Anchor w/ Receiver, Rotatable** Titanium	23.1mm	158.4g	**3PA RR T**
	**4 Prong Anchor, Adapter w/ Pin Lock Hole, Rotatable** Titanium	19.4mm	194g	**4PA AHR T**
	**4 Prong Anchor w/ Receiver, Rotatable** Titanium	29.5mm	193g	**4PA RR T**

Image	Kit	Build Height	Weight	Part Number
	**3 Prong Anchor, Adapter w/Pin Lock Hole, Rotatable** Stainless Steel	13.1mm	188g	**3PA AHR S**
	**3 Prong Anchor w/ Receiver, Rotatable** Stainless Steel	23.1mm	186.1g	**3PA RR S**
	**4 Prong Anchor, Adapter w/Pin Lock Hole, Rotatable** Stainless Steel	19.4mm	222g	**4PA AHR S**
	**4 Prong Anchor w/ Receiver, Rotatable** Stainless Steel	29.5mm	220.5g	**4PA RR S**

This summary has been compiled from the results of a number of returned Clinical Evaluation forms. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

College Park introduced these adapters as part of their new range of structural components. Whilst we already have a good range of such components from both APC and Trulife, there were features on these particular products that were of interest to us.
Samples were duly supplied and issued to two of our service centres and both were quick to respond positively, with great feedback from both the technicians and clinicians.

Comments were made regarding the prongs being much easier to crank and for tying materials into the adaptor, especially on the 4PA versions. College Park have stated that the deeper section on this option allows for a thicker lamination and therefore, though the weight limit remains at 136kg, it accommodates patients with a higher activity level more easily than the 3PA versions.
The 4PA versions also have one prong pre-shaped to accommodate the inevitable shift required on transfemoral sockets, making it much easier to align.

The general consensus from the technicians was that they are of a high quality and the clinicians liked the fact that Loctite was not required for the grub screws and commented that the 5mm fastening on the pinch bolt “felt” more secure than on other similar adapters, though there is no substantive evidence that this is the case.

One of the technicians commented that he did not use the provided insert for laminating as there is no groove to aid removal once the socket is laminated. He felt that it may have been hard to remove and could result in damaging the socket if it had to be forcibly removed following lamination, but again this is a matter of opinion only.

Notes

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