

CLINICAL EVALUATION SUMMARY - CES SIL L01

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.

SILIPOS DURAGEL LINER

WARRANTY PERIOD – 6 Months
WEIGHT LIMIT – Not applicable



EVALUATION SUMMARY

There seems to have been general agreement that this liner is easy to don and, provided the correct size has been ordered, comfortable to wear. The fairly soft gel can breakdown over high pressure areas and the liner is not ideal when used with a pin, performing better when used as a cushion liner.

Like the Silipos LA liner, the gel of this liner seems to be very gentle on the skin and doesn't irritate existing conditions.

Whilst, on occasions it has been used as a direct replacement for an Alpha, as with Patient 4, this can cause early deterioration of the liner and a socket produced specifically for use with the Duragel is recommended.

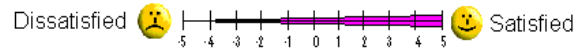
INDICATIONS	CONTRAINDICATION
On patients with skin problems, such as psoriasis	Moderate to high activity users who prefer pin suspension
Low to moderate activity patients with bony residual limbs	Moderate to high activity users with bony residual limbs, thereby producing highly loaded areas
Existing Alpha users requiring a slightly softer and more flexible liner	
Ease of donning	
Comfort	

EVALUATION PATIENTS

PATIENT DETAILS

Patient 1	Transtibial	93 kg	49 year old female	Unemployed	Sigam E
Patient 2	Transtibial	56 kg	62 year old female	Retired	Sigam F
Patient 3	Transtibial	85 kg	50 year old male	Storeman	Sigam F
Patient 4	Transtibial	64 kg	76 year old female	Retired	Sigam E
Patient 5	Transtibial	73kg	47 year old male	Unemployed	Sigam E
Patient 6	Transtibial	66 kg	66 year old male	Unemployed	Sigam F

EVALUATION RESULTS



CURRENT PRESCRIPTION

Patient 1	Polypropylene PTBSC, with Blatchfords Multiflex foot & ankle
Patient 2	Polypropylene PTBSC, with CPI Tribute foot
Patient 3	I/R TSB laminate socket with shuttlelock, clear liner and Ossur Sureflex foot
Patient 4	Laminate socket with Icelock 600 smooth pin lock, Alpha liner and Quantum foot
Patient 5	Laminate socket with Icelock 600, Medipro Sensitive 6 liner, Blatchfords Multiflex foot.
Patient 6	Polypropylene PTBSC, with Blatchfords Multiflex foot and ankle

PROSTHETIST'S COMMENTS

Patient 1 – The patient had been struggling with popliteal cysts caused by the PTB socket. It was hoped that the use of a gel liner with a pin would reduce this problem and also provide a more positive suspension. The prosthetist found the liner easy to don and a good fit and cast using a vacuum system.

At the diagnostic socket stage, slight modifications were needed to prevent socket rotation, but at the delivery stage he was delighted with the fit, suspension and cosmetic appearance **4**. When reviewed 6mths later, the liner was showing signs of wear, but the patient's residual limb had improved **5**.

Patient 2 – It was decided to try a gel liner with pin on this patient due to the pain being experienced when using her current socket. The prosthetist became concerned that a neuroma had developed and this is currently being investigated.

Patient 3 – Though the prosthetist found the wide range of dimensions apparently covered by each liner created a problem deciding which to choose, the eventual choice proved a good fit and was easy to don. A hand cast was taken using a lanyard to provide some distension. Despite this, distension of the liner in the swing phase did cause concern, though in every other respect it scored **4**.

Patient 4 – Sent out to the patient to trial as a direct swap for the Alpha liner. A second one was requested after several months, and at the last review was still being used, alternating with the Alpha.

Patient 5 – The patient was chosen because his very short residual limb had reduced in volume and the fibula had abducted. This had created a very sensitive area just below the fibula head which, it was hoped, this softer liner would relieve. The socket was produced with an additional Icx pad built in.

Patient 6 – In the early stages of his rehabilitation, this patient's short residual limb had decreased significantly in volume, giving discomfort around the fibula head. It was hoped that this liner would give relief in this area. The socket was produced with an additional Icx pad built into this area.

PATIENT'S COMMENTS

Patient 1 – Having scored her current prosthesis **2**, because of the problems with the socket, she scored the new socket system a tentative **0** at the fitting stage. At the review 6 months later she scored it **5**, declaring that, though it had taken a while to get used to, it was "the best leg I have had", having been an amputee for 16 years.

Patient 2 – Due to her current socket problems, the current set up only scored **-3**, but although she did feel better using the gel liner, scoring it **2** at the delivery, the development of a neuroma revealed itself to be the main cause of the pain in her residual limb and further investigations into this problem are ongoing.

Patient 3 – Though the patient scored his current socket at **3** when walking, the discomfort caused when sitting scored **-3**. The Duragel liner increased the patient's comfort, especially when sitting, this being the main reasons for the good score given **4**. Though the score was maintained at the review stage, the patient did comment on the "bungee" feeling when walking, especially when wearing a heavy boot.

Patient 4 – Early reactions to the liner were favourable, scoring **3**, and despite the liner rolling down at the top edge and a skin irritation in that area, she continues to score it **4**. The skin irritation was also caused by the Alpha liner which she'd attempted to ease with the use of Vaseline, but which has now been resolved by the use of a section of soft thin sock under the top edge.

Patient 5 – Initially the Duragel had felt very comfortable, but when he returned at the review stage it was discovered that he had decided to wear the liner with the front turned to the back. He declared that it felt better that way around, but on examination the tibia, which is also very prominent was not adequately off-loaded and the liner had started to disintegrate distally. He had also resorted to using the Medipro liner more often than not and therefore a new socket was produced for that liner.

Patient 6 – Initially this seemed very good and for some time he made excellent progress, but then presented with significant problems over the distal end of the residual limb. Eventually this was resolved by taking the patient off of a pin liner and using a Silipos LA cushion liner instead, The "milking" effect created by the extension of the gel pin liner being the cause of the problem.