

CLINICAL EVALUATION SUMMARY - CES MED SOCK

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.

MEDI NIGHT CARE SOCK

WARRANTY PERIOD – Not applicable
WEIGHT LIMIT – Not applicable



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, **Medi do refund the cost of the sock should it prove to be ineffective for whatever reason (see website or catalogue).**

INDICATIONS	CONTRAINDICATION
Any patient suffering from “phantom pain”, with no other cause or source of the pain.	Patients not suffering from pain, or whose pain cannot be defined as a “phantom pain”.

Note! If the Relax Night Care sock does prove effective, it is of course possible to proceed to the production of a socket for use with the Relax Liner, with greater assurance of success.

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 RESULTS

PAIN SCALE: 0 = no pain, 10 = intolerable pain

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 Medi. 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 score**1**) ---- 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**.