

CLINICAL EVALUATION SUMMARY - CES MED L 02

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 SOFT C LINER

WARRANTY PERIOD – 6 months
WEIGHT LIMIT – Not applicable

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	CONTRAINDICATION
Patients with a transtibial amputation	Patients with poor cognitive function
Sigam mobility grade C to F	Patients with a poor standard of hygiene
MEDI Mobility classes 1, 2, 3 and 4	Patients with poor manual dexterity
Where ease of donning is important	Excessive residual limb volume fluctuation
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	

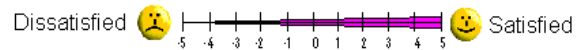
Note! The Contraindications shown are true for all transtibial pin liners, not just the Medi Soft C liner, though there are some Indications specific to it, which would suggest that some of the Contraindications may be reduced.

EVALUATION PATIENTS

PATIENT DETAILS

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

EVALUATION RESULTS



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, Medi 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 Medi 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 Medi 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 Medi First liner and finds the Soft C just as easy, but that the cover has made it significantly more durable.