



Clinical Evaluation Summary

CES OSS 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

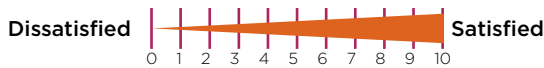
Note! The Contraindications shown are true for all transtibial pin liners, not just the Sensitive liner, though the Indications specific to it, would suggest that some of the Contraindications may be reduced in this case.

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



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 Truststep 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 Truststep 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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