



Clinical Evaluation Summary

CES OSS 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

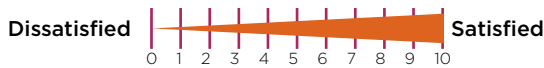
Note! The Contraindications shown are true for all transtibial pin liners, not just the Protect liner, though the Indications specific to it, would suggest that some of the Contraindications may be reduced in this case.

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 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 Truststep, 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 Truststep 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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