



Clinical Evaluation Summary

CES OSS L01

Össur - First & First 3 liners

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 original version of this liner, as issued to the patients included in this evaluation summary, was easy to don and easily cleaned, as a result of it having a slip surface treatment, rather than a fabric cover. The surface treatment created a weakness in the liner, making it easy to tear if not handled carefully. Since then the surface treatment has been improved, which has made a dramatic difference to its durability, whilst retaining all the benefits outlined by the original evaluations. The surface flaking mentioned by some of the patients, has also been eliminated. Sweating and subsequently, odour problems seem to be reduced, as mentioned by some of the patients. This has been confirmed over a reasonable period of time now and two of the patients requested replacements because of that benefit alone. The First 3 version provides greater protection to the distal end of the residual limb and is directly interchangeable with the other Össur 3 liners.

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 the ability to clean the liner easily is helpful

Contraindication

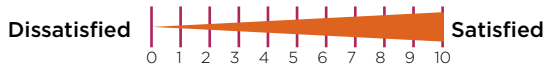
Patients with a transtibial amputation
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Evaluation Patients

Patient Details

Patient 1	Transtibial	112 kg	38 year old male	Maintenance Technician	Sigam F
Patient 2	Transtibial	70 kg	38 year old male	Fire Officer	Sigam E
Patient 3	Transtibial	73 kg	75 year old female	Retired	Sigam D
Patient 4	Transtibial	75 kg	62 year old male	Retired	Sigam D
Patient 5	Transtibial	72 kg	43 year old female	Administrator	Sigam E
Patient 6	Transtibial	67 kg	55year old male	Unemployed	Sigam E

Evaluation Result



Current Prescription

Patient 1	Laminate socket with Icelock 600 shuttlelock, Össur soft C liner and Variflex foot
Patient 2	Laminate socket with Icelock 600 shuttlelock, Össur soft C liner and Multiflex foot
Patient 3	Vacuum laminated, one shot Ossur socket with Iceross Comfort liner and SACH foot
Patient 4	Laminate socket with shuttlelock, Össur soft C liner and Otto Bock 1D10 foot
Patient 5	Laminate socket with shuttlelock, Össur soft C liner and Otto Bock 1D10 foot
Patient 6	Laminate socket over Iceross Clear liner, Icelock 600 shuttlelock and Endolite MFA

Prosthetist's Comments

Patient 1 - This patient was already on a Össur soft C liner and was simply chosen at random.

Patient 2 - This patient was already on a Össur soft C liner and was simply chosen at random.

Patient 3 - The Ossur vacuum laminated one shot socket had been a final effort by the patient's previous prosthetist, to produce a comfortable socket, but it had required a 2mm pelite liner to correct the volume, scored 0.

It was decided to return to basics and, since the residual limb had adequate soft tissue cover, it was agreed that the Comfort liner was not necessary and a Össur First liner was chosen as a cost effective way of trying to make progress. On the second attempt, triangulating the socket and adding supracondylar wings to prevent rotation the socket was deemed comfortable 3 and a CPI Très foot was added to reduce the weight and add a dynamic element to the gait.

Patient 4 - This patient was also a user of the Össur soft C liner, but was chosen with the hope of providing greater comfort and increased flexibility around the knee. Initial fears were that it may be too soft and looked likely to tear. There were no problems with the fitting, but surface cracks appeared after one month.

Patient 5 - This lady was another Össur soft C liner user, but was chosen by the prosthetist in the hope of providing an increase in patient comfort on the thigh. Though comfort did seem to have been achieved surface cracks appeared on the liner surface around the knee and the liner tore proximally.*

Patient 6 - The Iceross Clear being worn by this patient had lasted well, but was now in need of replacement. The patient tended to be overenthusiastic with the use of powder when donning and had given himself a skin problem as a result. Since the socket was also loose the prosthetist decided to recast over a Össur First liner and also take the opportunity, to upgrade the foot to a Trulife Kinetic.

Unusually very few scores were given either positive or negative.

Patient's Comments

Patient 1 - "Much better - want another one" was the response of this patient. He commented on the ease of donning, comfort, reduced irritation and odour, and durability.

Patient 2 - Despite an initial problem when the liner tore proximally, this patient persevered and reported increased comfort and ease of donning. Durability was not a problem either, provided he was careful when donning.

Patient 3 - Though the patient's dependence on her three wheeled walker had not decreased, due to problems with her sound hip, she has expressed herself very pleased with the prosthesis, if not with her progress 3. Though she found the original liner easy to don, the surface flaked away eventually* and she had to resort to using powder to don it. No such problems have been reported with the new version that has been supplied as a replacement.

Patient 4 - This patient liked the softness of the liner, finding it easier to flex the knee and more comfortable when walking. He experienced some irritation around the proximal edge of the liner and was concerned by the cracking in the liner surface.*

Patient 5 - She says the rubbing to the back of the leg, experienced with the other liner, has now gone, stating it to be "Really comfortable - doesn't feel as if I'm wearing it and not sweaty - a pleasure to wear". She also found it easy to don, though when she used a sock on the outside it did tend to slip down easily and durability was poor.

Patient 6 - Though the patient initially found the socket a little tight, he's had no problem donning the liner and has stopped using powder altogether, though the skin issue that it gave him is taking time to heal.

Unusually very few scores were given either positive or negative.

*An improved surface treatment has since been introduced.

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