



## Clinical Evaluation Summary

CES OSS L13

### Össur - 4Seal TFS & TFC 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

Several years in design and development before being brought to market, has resulted in a liner with many excellent features and options. The most popular of these, from the patient's viewpoint, is the fact that the Easy Glide surface obviates the need for any lubricant when donning the liner, or the socket. Combined with the very soft integral seals this allows much easier donning of the liner, increasing the opportunity for patients with reduced hand function to use this type of liner and socket. The lack of a fabric cover has also been welcomed, since it makes it much simpler to keep clean and also more durable. The fact that the Umbrellan fabric, integrated within the silicone to provide a matrix in the Classic version, offers the possibility of a reduction in Phantom Pain at no extra cost, is certainly a significant benefit. Where that is not required, a slightly more flexible matrix is available in the Senso.

#### Indications

- Patients with a transfemoral amputation
- A long and stable residual limb
- A patient who would benefit from a liner that
  - Is easy to don
  - Requires no lubricant to don prosthesis
  - Is easily cleaned and durable
  - May provide Phantom Pain relief (Classic)
  - That doesn't require a specific socket design

#### Contraindication

- Patients with poor cognitive function
- Patients with a poor standard of hygiene
- Patients with very poor manual dexterity
- Excessive residual limb volume fluctuation
- A short or conical residual limb
- Unable to tolerate a TSB socket
- Unable to tolerate a suction seal liner socket

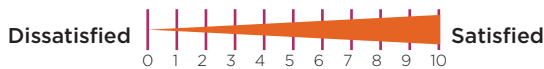
Please see Best Practice Guideline TF P SSS 01.

#### Evaluation Patients

##### Patient Details

<b>Patient 1</b>	Transfemoral	80kg	45 year old female	Amputees in Action	Sigam F
<b>Patient 2</b>	Transfemoral	80kg	47 year old female	Self Employed	Sigam F
<b>Patient 3</b>	Transfemoral	66kg	65 year old female	Unemployed	Sigam E
<b>Patient 4</b>	Transfemoral	65kg	76 year old male	Retired	Sigam E
<b>Patient 5</b>	Transfemoral	98kg	72 year old female	Retired	Sigam B
<b>Patient 6</b>	Transfemoral	53kg	49 year old female	Administrator	Sigam F
<b>Patient 7</b>	Transfemoral	61kg	67 year old female	Retired	Sigam D

## Evaluation Result



## Current Prescription

<b>Patient 1</b>	Quadrilateral socket with Iceross Seal In liner, Össur NOFM2 knee and CPI Tribute foot
<b>Patient 2</b>	Quadrilateral socket with Össur 4Seal TFS liner, Mauch knee and CPI Velocity foot
<b>Patient 3</b>	Quadrilateral socket with Iceross Seal In liner, Össur NOFM2 knee and CPI Très foot
<b>Patient 4</b>	Quadrilateral socket with Iceross Seal In liner, Össur NOP4 knee and CPI Très foot
<b>Patient 5</b>	Soft Quadrilateral socket with Iceross Seal In liner, Össur NOFM0 knee and CPI Très foot
<b>Patient 6</b>	Soft Quadrilateral socket with Ossur 4Seal (Classic), OB 3R92 and CPI Accent
<b>Patient 7</b>	Quadrilateral socket with Ossur 4Seal (Classic), Ossur NOFM2 knee and CPI Très foot

## Prosthetist's Comments

**Patient 1** - The patient had been complaining that their current liner was inclined to lose suction and the cover easily gets torn and dirty. The prosthetist had been considering an X5 Seal In liner, but when the 4Seal became available decided to give it a try, since it also offered the benefit of having no cover.

**Patient 2** - Having been a user of the 4Seal TFS for some time, distal residual limb volume had reduced slightly, making the TFC more appropriate. The benefits of the original liner remain just as effective, but distal containment was improved without increasing the proximal tension. A new socket was produced to suit.

**Patient 3** - Finding that the Ossur Seal In liner tended to fray the fabric cover fairly regularly, her prosthetist decided to try her on the 4Seal liner.

**Patient 4** - A long time user of the Seal In liner, when the patient attended having lost some weight and requiring a new socket, the prosthetist decided to use the 4Seal liner, in an attempt to make donning the prosthesis easier, especially as the patient was becoming slightly more frail.

**Patient 5** - Because the patient found the Seal In difficult to don - needing the spray to get into the socket but tended to lose suction when sitting for any length of time - the prosthetist decided to try the Medi 4Seal in the hope of improving the situation. The liner proved to be easy to trim; the patient could don it herself; retention was improved and durability is good.

**Patient 6** - Having been on the original 4Seal liner, now called the Classic, the prosthetist chose the Senso in the hope of resolving some skin breakdown issues that the patient was experiencing. Though this had been achieved, the Senso had proved to be less durable and it had required greater care to protect it around the seating area.

**Patient 7** - Since the patient was finding the 4Seal Classic a little firm and tight proximally and a little difficult to keep clean, though otherwise effective, the prosthetist decided to try her on the Senso version. Durability appears to have been better in this case, with improved patient comfort and suspension.

## Patient's Comments

**Patient 1** - At the delivery the patient commented that the liner was easier to don and though a little tight\*, still comfortable. It was too loose in her current socket and a new socket was produced. At the review stage she commented that she'd had no problems with the durability of the liner, felt more comfortable and was able to wear the limb for longer. She liked that fact that there was no fabric cover, making it easier to keep clean, easier to don, with a consistent level of comfort.

**Patient 2** - The patient found the new liner and socket more comfortable with improved control. At the review she stated that the new socket had made "walking better", with no rubbing or bruising and "extended walking ability". She also commented that there was no ripping at the top of the liner, which presumably had been where the TFS liner had been under greater tension and where it failed first.

**Patient 3** - The patient immediately commented that it was easier to don, felt more comfortable and provided a very positive suspension, with reduced rubbing. At the review, the reduced rubbing was again mentioned, along with the ease of cleaning and care of the liner. Two months later there was no sign of wear or damage to the liner and the patient commented that she felt more confident and could walk faster on her prosthesis.

**Patient 4** - Finding the liner very much easier to roll on and with the benefit of not requiring a lubricant spray when donning the prosthesis, the patient was delighted with the end result. Durability has proved to be excellent.

**Patient 5** - The patient stated that the liner was easier to don and "holds on much better". At the first review she commented that it was simpler to keep it clean, since it doesn't have a fabric cover and at the final review, that "it still holds the leg on better".

**Patient 6** - The patient noticed no difference in the quality of the suspension, but stated that the areas of skin that had previously broken down, had healed up since wearing the Senso, though the liner had not proved quite as durable. It had worn through on the seating area.

**Patient 7** - The patient reported that the new version of the liner "has helped me to walk more and is very comfortable to wear and easy to keep clean".

\*Supplied before the TFC version was available.

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