steeper
Creating life's turning points, together

Clinical Evaluation Summary

CES **OSS** L16

Össur - AKOS 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

The original version of this liner, as issued to the patients included in this evaluation summary, has proved to be a durable product that is easy to don and easily cleaned, as a result of it having a slip surface treatment, rather than a fabric cover. The surface treatment has since been improved, which appears to have increased its durability even further. A conical version has also been introduced, making it applicable for an even more patients. The matrix that is incorporated helps reduce longitudinal stretch, without significantly affecting the circumferential elasticity.

Indications

Patients with a transfemoral amputation
Sigam mobility grade C to F
Össur Mobility classes 1 to 4
Necessity for enhanced suspension and gait control
Auxiliary suspension is undesirable
Where durability is important
Where ease of donning is important
Where the ability to clean the liner easily is helpful

Contraindication

Patients with poor cognitive function
Patients with a poor standard of hygiene
Patients with poor manual dexterity
Long transfemoral or knee disarticulations, especially when used in conjunction with other adapters and knee joints resulting in a cosmetically unacceptable long thigh segment
Excessive residual limb volume fluctuation

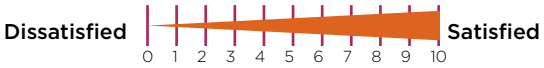
Note! The Contraindications shown are true for all transfemoral pin liners, not just the AKOS liner, though the Indications specific to the AKOS would suggest that some of the Contraindications may be reduced in this case.

Evaluation Patients

Patient Details

Patient 1	Transfemoral	95kg	71 year old male	Retired	Sigam D
Patient 2	Transfemoral	87kg	23 year old male	Unemployed	Sigam F
Patient 3	Transfemoral	76kg	51 year old male	Engineer	Sigam F
Patient 4	Transfemoral	96kg	63 year old male	Retired	Sigam E
Patient 5	Transfemoral	82kg	60 year old male	Unemployed	Sigam F
Patient 6	Transfemoral	90kg	52 year old male	Employed - Advisor	Sigam F

Evaluation Result



Current Prescription

Patient 1	Polypropylene socket with TES belt, ESK, PSPC, MKL, Multiflex foot
Patient 2	Polypropylene Quadrilateral socket with TES belt, ESK, PSPC, MKL, Multiflex foot
Patient 3	Laminate Quadrilateral socket – (no further detail supplied)
Patient 4	Quadrilateral socket with Iceross pin liner – (no further detail supplied)
Patient 5	Polypropylene and Northvene socket to hand cast, TES Suspension, ESK, PSPC, Multiflex foot
Patient 6	Bespoke silicone pin liner to flexible laminate outer, Total Knee and OB 1D10 foot

Prosthetist's Comments

Patient 1 – Patient had requested a more positive suspension, but the residual limb tissue was flaccid. Use of the AKOS liner improved the soft tissue stability and enhanced suspension. It was noted by the Prosthetist that the liner had lasted 18 months before a replacement had been required. At the final review the liner was awarded a score of 5. The Prosthetist stated that he would be prepared to routinely use this product.

Patient 2 – This patient had undergone a transfemoral amputation fairly recently, as a result of a road traffic accident. It was anticipated that he would become more active and require a regular prescription review. Upon maturation of the residual limb, it was decided by the MDT that he would benefit from a silicone suspension system. The Prosthetist awarded the liner a score of 4 suggesting that the range of sizes should be increased to accommodate a larger circumference.

Patient 3 – – The Prosthetist stated that she had prescribed the AKOS Liner with the aim of achieving positive suspension, with longitudinal stretch control. A final score of 3 was awarded however it was noted that the proximal edge of the liner had split and that this may be avoided by inclusion of a conical design within the AKOS range. **(A conical version is now available)**. This Prosthetist stated that she would routinely use this product.

Patient 4 – The Prosthetist commented that she had decided to try the AKOS Liner because the previously prescribed liner had kept falling off. The aim was to achieve a more secure attachment. The Prosthetist stated that she had found this liner to be a durable product and that it had proved to be a more successful prescription than the previously supplied liner. A satisfaction score of 3 was awarded.

Patient 5 – This Prosthetist stated that he was aiming to improve the suspension of the prosthesis and reduce socket rotation. Satisfaction scores for all aspects for performance review were between 3 & 4. It was noted that the edge of the liner was prone to tearing, however overall performance was thought to be very satisfactory.

Patient 6 – Having received compensation following the industrial accident that had caused the loss of his limb, he spent a considerable amount purchasing two prostheses, with bespoke silicone liners. On returning to the NHS, the prosthetist suggested the use of an AKOS liner and both he and the patient were impressed with the end result, though the slip surface treatment did appear to encourage small tears on the proximal edge 4. **(An improved surface treatment has since been introduced)**

Patient's Comments

Patient 1 – Although he scored his current prescription as 5 he described his previous method of suspension as "useless". Having been fitted with the AKOS liner, the benefits highlighted by the patient included improved suspension and the ability to return to horse riding. Some rotation of the residual limb within the socket had been noted when the patient "twisted violently". He scored the AKOS liner as 5.

Patient 2 – When asked about his current prescription this patient stated that he was happy with his prosthesis, but wished that his socket could be made more comfortable. He awarded a score of 3 for his current socket. Upon his final review after delivery of his new socket, incorporating the AKOS liner, he stated that the socket had become more comfortable but wished that "the rubber could be thicker in places for added comfort".

Patient 3 – This patient did not offer any details regarding his opinion of the previous socket design but stated that he was "very happy with the liner" and awarded a satisfaction score of 4.

Patient 4 – This patient stated that the AKOS liner was an improvement on his previous prescription and that it "felt much more secure". At the delivery of his new prosthesis the patient awarded a score of 4.

Patient 5 – Due to some language/communication difficulties it was not possible to collate this gentleman's comments in a written form, but it is known that he is satisfied with the results he has achieved with his AKOS liner.

Patient 6 – Having spent a considerable sum of money on privately purchased prostheses with bespoke liners, this gentleman was somewhat doubtful initially as to whether the AKOS liner would prove adequate. He was delighted with the end result however. They have proven to be durable, failing eventually around the top edge, as a result of small tears that appear to start as a result of the slip surface treatment. **(He has since been supplied with the new version, which has an improved slip surface treatment, and this appears to have improved durability even further.)**