



Clinical Evaluation Summary

CES OSS S01

Össur - Genu Sleeve

Warranty period - 3 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 Genu is a soft suspension sleeve, made from a thermo plastic elastomer, which was specifically designed for use with Össur Cushion liner and valve suction systems. It is 3mm thick, with a well designed elastic outer fabric. This makes it very comfortable to wear, but unless it's used as part of a suction system, it is too easily stretched to be effective, except for particularly low activity patients, or patients who require easy flexion of the knee. As with all sleeves used in this way, care needs to be taken to protect the sleeve from damage around the socket edge and it is supplied complete with a separate protective fabric sleeve, with a silicone strip which grips to the top of the socket. The sleeve is then pulled over the knee before the Genu is rolled onto the thigh. This has proved very effective and durable. After a very short time it became clear that, though very soft, flexible and comfortable, the elasticity of the sleeve makes it unsuitable for highly active patients, but is generally best suited to low activity users, not using a suction system, or moderately active patients using a suction system. Few sleeves are being used on sockets with suction valves, on highly active patients, hence the fact that only four patients have been included in this evaluation.

Indications

Patients with a transtibial amputation
 Patients who need a soft, flexible sleeve, due to general frailty, or specific weakness of knee flexors/extensors
 Low activity patients who need a sleeve that is easy to don and who can cope without a suction system
 Moderately active Patients who can cope with a suction system

Contraindication

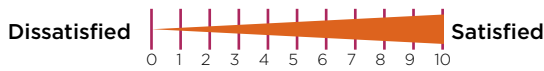
Patients with poor cognitive function
 Patients with poor manual dexterity
 Patient activity level above moderate

Evaluation Patients

Patient Details

Patient 1	Transtibial	98kg	49 year old male	Quarryman	Sigam F	Össur 4
Patient 2	Transtibial	61kg	30 year old female	Unemployed	Sigam F	Össur 3
Patient 3	Transtibial	65kg	45 year old female	Unemployed	Sigam D	Össur 2
Patient 4	Transtibial	72kg	54 year old female	Education Advisor	Sigam E	Össur 3

Evaluation Result



Current Prescription

Patient 1	Laminate supracondylar PTB socket, Juzo sleeve and Freedom Sierra foot
Patient 2	Laminate TSB socket, 9mm Absolute liner, CPI Trés foot, thigh corset and side steels
Patient 3	Laminate TSB socket, TEC Custom liner, Contex Gel sleeve and valve, and Kinetic foot
Patient 4	Laminate TSB socket with Pelite liner, Ossur 600 valve, Contex Gel sleeve and Elation foot

Prosthetist's Comments

Patient 1 – Suffering contact dermatitis from the original PTB socket material, this patient was provided with a new laminate PTB socket, with a Streifederm gel sock in lieu of a Pelite liner, a suction valve and Genu sleeve. It was also hoped that this would improve the suspension and reduce the bulk around the knee, especially in the posterior knee region. The prosthetist liked the sleeve colour, its tapered shape and separate protective sleeve. She also commented on the fast delivery time. The patient has a very active lifestyle, but none of his activities were affected by the new set up and it has lasted longer than other sleeves that were initially tried, primarily due to the separate protective sleeve.

Patient 2 – This active lady was keen to get back to running and cycling. She had been hampered by the damage to her tibia, caused by the accident in which she lost her limb. This had been surgically refashioned and fixed, but a thigh corset and side steels were incorporated in the initial prosthesis to try and offload the residual limb. When the thigh corset was removed a valve and suction sleeve were provided and the Genu sleeve was supplied in an attempt to improve the ease of flexion. The prosthetist liked the sleeve colour and the flexibility of the thin gel of the sleeve.

Patient 3 – The Genu sleeve was supplied to this patient to see if it would allow a better range of movement than the Streifeneder Contex Gel, without compromising durability. The prosthetist commented that it was easy to don, but was unsure about the durability, since a small hole in it had compromised the suspension after 3 months and necessitating a replacement.

Patient 4 – The patient had been suffering with a rash due to the excessive adhesion/friction from her current suspension sleeve, though it had made the limb feel very secure. The prosthetist found it easy to fit and that it seemed to work well with the protective sleeve.

Patient's Comments

Patient 1 – The patient preferred the new set up, feeling that it provided a greater sense of security and “feedback”. He tried two other types of suspension sleeve, but has found this allows easier knee flexion. Though initially concerned that it may not last well, he stated at the three month review that it was better and more durable than either of the other options that he'd tried.

Patient 2 – Although still hindered by the pain in her residual limb, on which she was due to have further surgery, and some problems with eczema, she commented that this sleeve seemed “more stretchy” than the previous sleeve she'd tried, making it more comfortable to bend the knee. She noted less irritation around the top edge and greater comfort when sitting. The first Genu issued seemed to lose its elasticity and a tighter one was issued.

Patient 3 – Finding the sleeve easier to don, neater and more flexible, the patient was initially very pleased. She stated that the suspension was positive and reliable, until the small hole appeared in the sleeve, but she requested a replacement rather than go back to the original sleeve.

Patient 4 – Initially the patient felt that the Genu sleeve provided a similar degree of security to that of the Contex Gel sleeve, whilst also making it easier to bend for climbing stairs and cycling. At the first review, five months later, she mentioned that the sleeve tends to roll down easily and wrinkle around the knee, reducing the adhesion and the limb then feels less secure. The increased mobility when walking or cycling was a definite positive though. She felt that it was beginning to wear out, especially where it's folded over when the limb is removed. A month later the sleeve was replaced with another Genu sleeve because of its benefits, even though she still felt the sleeve tended to slip down and if sitting and standing repeatedly, it can cause the sleeve to drop down sufficiently that the limb becomes less secure.

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