



Clinical Evaluation Summary

CES STR S01

Streifeneder - Contex Gel Suspension 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

This sleeve appears to have provided most of the patients evaluated with a comfortable and long lasting suspension sleeve option. Since this evaluation summary was first produced in Feb 2006, these sleeves have been redesigned and improved, and they now have a smaller permanent logo, are more durable around the knee area, with a matt surface in that area to reduce any possible tissue tension over the patella. Patients 6 and 7 were issued with the latest version of the sleeve and reflect the opinion of many other patients regarding its durability and comfort. Donning is best achieved by reflecting the bottom half of the sleeve, stretching the folded part over the socket edge and sliding the reflected section back down the shin.

Indications

Suction socket sleeve.
Secondary suspension sleeve.
Where a water tight seal is required.
Where a full range of flexion is important.
Where longevity is an issue.

Contraindication

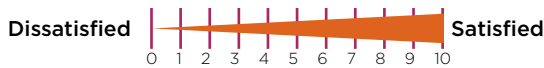
Poor dexterity or reduced hand function.
Allergies to polyurethane.

Evaluation Patients

Patient Details

Patient 1	Transtibial	88 kg	52 year old male	Retired	Sigam F
Patient 2	Transtibial	70 kg	44 year old male	Engineer	Sigam F Very Active
Patient 3	Transtibial	85kg	54 year old male	Businessman	Sigam F
Patient 4	Transtibial	75 kg	36 year old male	Unemployed	Sigam F
Patient 5	Transtibial	76 kg	60 year old male	Engineer	Sigam F Very Active
Patient 6	Transtibial	100kg	39 year old male	Full time Dad	Sigam F
Patient 7	Transtibial	102kg	74 year old male	Retired	Sigam C

Evaluation Result



Current Prescription

Patient 1	Polypropylene socket with a Variflex foot and Blatchford's neoprene suspension sleeve
Patient 2	Tec liner with a Vass sleeve and valve. Freedom Renegade foot
Patient 3	Laminate socket with Alpha liner, Iceflex balance sleeve and Endolite DR2 foot
Patient 4	Laminate socket with suction valve, Iceflex balance sleeve and Tribute foot
Patient 5	Laminate socket with suction valve and Alps sleeve
Patient 6	PTB Socket, with Reflex rotate foot and previous version of Contex Gel Sleeve
Patient 7	TSB Laminate socket with Contex Gel Cushion liner, suction valve, Endolite MFFA and previous version of Contex Gel Sleeve

Prosthetist's Comments

Patient 1 - Donning was easy using the same technique as suggested for the Iceflex Endurance sleeve. A diagram would make the instructions clearer, perhaps. This sleeve was chosen because the patient was going through neoprene sleeves at a rate of one a month.

Patient 2 - The patient is so very active, running 5 miles daily, that he was wearing out sleeves fairly quickly and it seemed that it would be a fair trial of the Streifeneder against the Vass suspension sleeve. 4

Patient 3 - This golf fanatic had been wearing through every type of suction sleeve we had provided. He attended to be measured for an Alps sleeve, but was given this to trial as well.

Patient 4 - Until the Explorer liner was issued, his residuum broke down regularly due to the scar tissue and psoriasis, but the Iceflex Balance sleeve issued with it failed very quickly and the Contex Gel sleeve was provided to try and improve the situation 4

Patient 5 - The Alps sleeve currently being used, was comfortable and flexible, but became baggy, especially around the top edge and leaked easily. This sleeve was provided as an alternative 4.

Patient 6 - Though the patient had found the previous Contex Gel Sleeve was very good, its durability was its weakest point, hence this patient was keen to trial the new version. At the end of the evaluation, the prosthetist stated that it had "much longer than expected".

Patient 7 - The new version of the Contex Gel Sleeve was chosen in the hope that it would outlast the previous version. The prosthetist was concerned that there did not appear to be any reinforcement around the knee, but also that it had proved to be more durable and was much better aesthetically.

Patient's Comments

Patient 1 - The patient felt the sleeve to be very comfortable and that it gave better retention of the prosthesis. After eight weeks he reported that it showed no signs of wear and he was still delighted with it 4.

Patient 2 - This very active patient has found the sleeves to be the most comfortable and longest lasting of all the sleeves he has tried.

Patient 3 - He was delighted with this sleeve. He felt it was comfortable, gave him the range of movement he required, but without restriction and it was still in one piece several weeks past the time any others would have lasted.

Patient 4 - This patient's sleeves need to be flexible due to his skin condition, but he destroyed the Iceflex balance sleeves very quickly. The Streifeneder sleeve has lasted 2 months with no sign of breakdown 4.

Patient 5 - The Alps sleeve was scored at 3, but he scored the Streifeneder sleeve 5 at the delivery of it. Six weeks later he was still as impressed with it. It didn't leak at all and sweating seemed less during prolonged running. He found it comfortable, flexible and less bulky, remaining comfortable even after 18 hours of use 5.

Patient 6 - The patient found the sleeve to be just as effective and 4 months later stated that, though a little looser on his thigh, it had "not ripped" and was lasting over twice as long as the previous version. He was very pleased with it indeed.

Patient 7 - The patient liked the appearance of the new sleeve and though most of his comments were regarding problems with the suction valve, he appeared pleased with the durability and comfort of the sleeve.

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