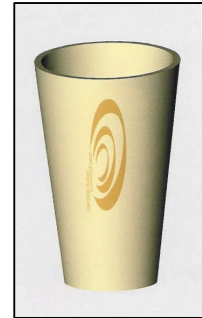


CLINICAL EVALUATION SUMMARY - CES STR S01

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.

STREIFENEDER CONTEX GEL SLEEVE

WARRANTY PERIOD – Not applicable
WEIGHT LIMIT – Not applicable



EVALUATION SUMMARY

This sleeve appears to have provided most of the patients evaluated with a comfortable and long lasting suspension sleeve option. Some patients and prosthetists had difficulty donning the sleeves and whilst this was partly due to the sticky surface, it may also have been because of an incorrect donning technique*. The only other criticisms have been about the colour and the logo, which peels after a short period of time. Though some patients and prosthetists failed to provide a score, and some initial comments expressed doubts regarding durability, sizing and ease of donning, the comments at the end of the evaluation were all positive and durability was no longer an issue. One patient, who was initially critical, went on to score it highly, finding it “secure and strong”.

Since this evaluation summary was first produced in Feb 2006, the production method has changed and the logo no longer causes a problem. Streifeneder have also introduced a grey version, which some patients prefer. 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.

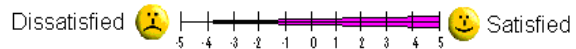
INDICATIONS	CONTRAINDICATION
Suction socket sleeve.	Poor dexterity or reduced hand function.
Secondary suspension sleeve.	Allergies to polyurethane.
Where a water tight seal is required.	
Where a full range of flexion is important.	
Where longevity is an issue.	

EVALUATION PATIENTS

PATIENT DETAILS

Patient 1	Transtibial	88 kg	52 year old male	Retired	Sigam F
Patient 2	Transtibial	97 kg	68 year old male	Retired	Sigam F
Patient 3	Transtibial	70 kg	44 year old male	Engineer	Sigam F Very Active
Patient 4	Transtibial	93 kg	32 year old male	Banker	Sigam F
Patient 5	Transtibial	85kg	54 year old male	Businessman	Sigam F
Patient 6	Transtibial	75 kg	36 year old male	Unemployed	Sigam F
Patient 7	Transtibial	76 kg	60 year old male	Engineer	Sigam F Very Active

EVALUATION RESULTS



CURRENT PRESCRIPTION

Patient 1	Polypropylene socket with a Variflex foot and Blatchfords neoprene susp sleeve
Patient 2	PTB supracon on a beach activity limb with a neoprene suspension sleeve
Patient 3	Tec liner with a Vass sleeve and valve. Freedom Renegade foot
Patient 4	Tec Custom liner with a Prolink sleeve and valve. Reflex VSP foot
Patient 5	Laminate socket with Alpha liner, Iceflex balance sleeve and Endolite DR2 foot
Patient 6	Laminate socket with suction valve, Iceflex balance sleeve and Tribute foot
Patient 7	Laminate socket with suction valve and Alps sleeve

PROSTHETIST'S COMMENTS

Patient 1 – Donning was easy using the same technique as suggested for the Iceflex Endurance sleeve **4**. 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 sleeve was chosen to try and provide a more water tight seal on a beach activity limb.

Patient 3 – 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 4 – The Contex Gel sleeve was trialled on this patient to provide a direct comparison with the Prolink sleeve. There were Initial problems putting the sleeve on the prosthesis, partly due to the sticky gel surface **3**. The prosthetist scored durability **2**, but the sleeve was still intact at the end of the evaluation.

Patient 5 – 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 6 – 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 7 – 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***.

*** Overall new product score.**

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 – The patient liked the feel of the sleeve and initially felt it was better, but quickly developed, what appeared to be an allergic skin reaction. It may have been due to poor donning technique creating tissue tension, but it was abandoned before it could be investigated further.

Patient 3 – This very active patient has found the sleeves to be the most comfortable and longest lasting of all the sleeves he has tried.

Patient 4 – Patient had a problem with the sizing of the sleeves, finding the X Large too big, but the Large too small and both too short. He did feel the sleeve comfortable in use, more secure and stronger than the Prolink sleeve **4**.

Patient 5 – 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 6 – 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 7 – 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**.