

CLINICAL EVALUATION SUMMARY - CES SIL 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.

SILIPOS DURAGEL SLEEVE

WARRANTY PERIOD – Not applicable
WEIGHT LIMIT – Not applicable



EVALUATION SUMMARY

In brief, the non reinforced versions of this sleeve, whilst slightly softer than the Streifeneder Contex Gel sleeves, are still remarkably durable when used on patients who do not use them in such a way as to put them under impact, such as kneeling, or where there's a risk of knocking them against hard surfaces.

The reinforced versions are more durable in such circumstances, but are consequently slightly more bulky and less elastic. Whilst this did not present a problem for the particular patient chosen for evaluation, it may make sizing the sleeve more critical.

The range of sizes, since they include tapered (Med+ and Large+) versions, appears to make this product particularly useful for patients with tapering thighs, where the rather parallel shape of some sleeves causes them to roll down, or to be constrictive proximally.

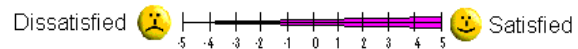
INDICATIONS	CONTRAINDICATION
Suction socket sleeve.	Patients with poor manual dexterity.
Secondary suspension sleeve.	Allergy to the sleeve material.
Where a water tight seal is required.	Impact situations such as kneeling or crawling – <i>though the use of the reinforced version may help.</i>
Where a full range of flexion is important.	
Patients with tapered thighs – <i>use + sizes.</i>	Poor hygiene – <i>especially the reinforced version.</i>
Where longevity is an issue.	

EVALUATION PATIENTS

PATIENT DETAILS

Patient 1	Transtibial	92 kg	28 year old male	Estate Agent	Sigam F
Patient 2	Transtibial	92 kg	28 year old male	Estate Agent	Sigam F
Patient 3	Transtibial	96 kg	56 year old female	Retired	Sigam D
Patient 4	Transtibial	77 kg	42 year old female	Unemployed	Sigam F
Patient 5	Transtibial	76kg	76 year old female	Retired	Sigam D
Patient 6	Transtibial	70 kg	70 year old female	Retired	Sigam D

EVALUATION RESULTS



CURRENT PRESCRIPTION

Patient 1	TEC Harmony system socket and Otto Bock 1D35 foot
Patient 2	TEC Harmony system socket and Otto Bock 1D35 foot
Patient 3	Polypropylene PTBSC, with Iceflex Balance sleeve, Multiflex foot & ankle
Patient 4	Polypropylene PTBSC, with Juzo suspension sleeve, Multiflex foot & ankle
Patient 5	Silicone Self Suspending Socket with pin, Multiflex foot & ankle
Patient 6	Cushion liner, suction socket with valve, silicone suspension sleeve and Elation foot

PROSTHETIST'S COMMENTS

Patient 1 – Being a user of the Harmony negative pressure socket system, the patient needs a suspension sleeve which retains its integrity for a reasonable length of time. Currently he uses the Streifeneder Contex Gel sleeve which lasts approximately 8 weeks. The prosthetist experienced no problems in the application of the product, having chosen a large non-reinforced version initially.

Patient 2 – The same patient was also provided with the reinforced version to trial.

Patient 3 – Insufficient suspension from the current sleeve and difficulty rolling it on prompted the trial of the Silipos Duragel sleeve. The prosthetist found it easy to size and don the sleeve, also commenting on the “better colour”. After about a month, the sleeve was still going well, scoring **3**.

Patient 4 – The prosthetist was hoping for increased suspension whilst retaining good flexibility, since his patient likes to ride a bicycle. He found the non tacky gel and the smooth fabric cover made it easy to don, though the fabric was easily snagged.

Patient 5 – Not liking the pulling effect created by the liner and pin, the patient was offered the option of trying a suction socket and sleeve. The prosthetist found the sleeve easy to don and durable, at least for the short time she used it, rejecting the system as a whole after about a month.

Patient 6 – Since the patient was having some problems with premature wear of her current suspension sleeves, her prosthetist chose to trial the Duragel sleeve on her. The appearance and function of the sleeve were acceptable **3**. There were no instructions or size chart with the sleeve, but the size available, Medium+, fitted the prosthesis easily. On this individual the durability has been excellent, with little sign of wear that would affect the function, even after 6 months **5**.

PATIENT'S COMMENTS

Patient 1 – This patient, not liking flesh coloured sleeves, would have preferred a different colour, but initially found the sleeve functioned well and was comfortable, scoring **4**. The outer cover of the sleeve soon started to “bobble” and in less than 2 weeks it had torn. This may be partly due to the patient’s activities, but makes this an inappropriate product for this particular individual.

Patient 2 – Whilst on the same patient as above, the reinforced version of the liner felt as comfortable **4** as the non-reinforced and lasted longer, he did manage to pinch it when working and a small hole may have resulted, since he felt there was a slight reduction in the suction effect of the Harmony system. However, he still thought it was the best he’d had to date **4**.

Patient 3 – The patient commented that the sleeve was “soft and flexible” and better than the previous sleeve, scoring it **3**.

Patient 4 – The sleeve seemed to work well at first, but sweating increased causing the sleeve to slip down and it then became trapped under the edge of the socket. This created severe discomfort **-1**.

Patient 5 – The patient clearly found the silicone liner and pin uncomfortable, especially due to the pulling effect on the distal end of her residual limb, scoring it at **-5**. She found the suction system with sleeve much better scoring it **3**. These scores relate to the system as a whole and, since she had never used a silicone suspension sleeve before, her satisfaction with the comfort of the sleeve and the fact that it had no bearing on her decision to abandon this system, are the only things that can be drawn from this.

Patient 6 – Having not been particularly happy with the durability of the sleeve she had been using, she scored this one **3** for comfort and function from day one, increasing to **5** after 6 months. She particularly commented that the sleeve did not roll down and felt that it functioned as well at the end of the evaluation as it had at the start.