

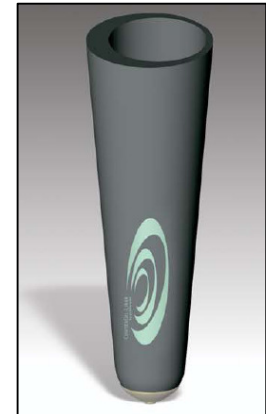
## CLINICAL EVALUATION SUMMARY - CES STR L 02

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 LINER - WITH MATRIX

**WARRANTY PERIOD – 6 months**  
**WEIGHT LIMIT – Not applicable**

#### EVALUATION SUMMARY



Having tried several gel liners from various suppliers the Clinical Support Group were aware that, when using the pin options, many patients found the benefits of the gel were outweighed by the elasticity of the liner allowing the socket to piston creating discomfort and a “milking” effect in the distal end of the residual limb.

The advent of this version, with 10cm of integral matrix, seems to have provided the benefits of a gel liner, but with dramatically reduced distension and increased durability.

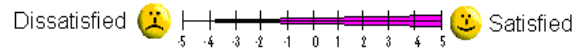
INDICATIONS	CONTRAINDICATION
Appropriate for all levels of activity from very low to very high	Poor manual dexterity
Patients who require a greater degree of protection for their residual limb	
Patients who are allergic to silicone liners	
Patient prefers shuttlelock and pin suspension, but distension would cause problems	The residual limb is too short to avoid the matrix enclosing the fib head
The residual limb requires improved circumferential containment, even for cushion liner option	<i>Only the Indications and Contraindications shown in black are specific to the matrix version of the liner</i>
Where liner durability is important	

#### EVALUATION PATIENTS

##### PATIENT DETAILS

<b>Patient 1</b>	Transtibial	95kg	28 year old male	IT Support Technician	Sigam F
<b>Patient 2</b>	Transtibial	118kg	68 year old male	Retired	Sigam F
<b>Patient 3</b>	Bilateral Transtibial	75kg	30 year old male	Unemployed	Sigam F
<b>Patient 4</b>	Transtibial	106kg	51 year old male	Voluntary worker	Sigam F
<b>Patient 5</b>	Transtibial	45kg	88 year old female	Retired	Sigam E

# EVALUATION RESULTS



## CURRENT PRESCRIPTION

<b>Patient 1</b>	Polypropylene socket with Alpha pin liner, with Freedom 1000 foot
<b>Patient 2</b>	Laminate socket with Icelock 600 ratchet lock, Contex Gel (non matrix) and Freedom F1000 foot
<b>Patient 3</b>	Laminate sockets with fib head apertures, Icelock 600 locks and Freedom Renegade feet
<b>Patient 4</b>	TSB socket with ratchet shuttlelock, Alpha liner and Freedom Renegade foot
<b>Patient 5</b>	PTB/TSB socket with ratchet shuttlelock, Silipos Duragel liner and CPI Tribute foot

## PROSTHETIST'S COMMENTS

**Patient 1** – Needing a refit of his spare prosthesis and an upgrade of the foot, this active young man was chosen to evaluate the new version of this liner. A laminate socket was produced and a Freedom Senator foot fitted. At the delivery stage no issues were forthcoming.

**Patient 2** – This active individual had been using the standard Contex Gel liner for the previous 6 months and had found it better than any previous liner he'd been provided with. The new matrix version was provided to try and minimize any pistoning and increase the durability even further.

**Patient 3** – Having initially been fitted with standard silicone liners, some problems with liner distension aggravating a scar, Silipos LA cushion liners were prescribed and, as the patient's ability improved, Duragel liners were prescribed. With his residual limb well healed, he requested the option of returning to pin liners, for the sake of the convenience when donning and doffing.

**Patient 4** – This very active patient, who sails, plays tennis and badminton, was chosen in an attempt to find a more durable alternative to the Alpha liner. The prosthetist had no problems when issuing the liner, the instructions being clear and the liner easy to don. It seemed to meet the patient's needs for improved comfort and suspension. Durability also appears to have been proven, since the patient took delivery of the liner and promptly embarked on a Trans-Atlantic sailing adventure, returning with the liner after 7 months, now showing signs of wear over the anterior cut end of the tibia.

**Patient 5** – The patient's prosthetist chose to try the Streifeneder Contex Gel liner on this lady in an attempt to provide her with a socket system in which she was comfortable, several alternatives having already been tried. The current option, though the most comfortable to date, allows distension in swing phase and tends to fail too soon. The prosthetist commented that donning was initially fairly difficult, but easier after it had been pre-stretched. Distension was dramatically reduced by the matrix in the liner and several months after delivery was still in good condition, having "exceeded expectations".

## PATIENT'S COMMENTS

**Patient 1** – There were no negative comments at the delivery stage, but equally, no particularly positive ones either. After a small socket adjustment at the review stage, the patient continued to wear the limb and at the point where he was due to go on an extended adventure holiday, he requested a spare liner of the same type.

**Patient 2** – The patient felt the new liner definitely reduced the pistoning, but after a few days presented with a small sore over the fib head, above the top of the matrix. The application of a small amount of lubricant cream resulted in this healing within a few days and there was no recurrence until a new liner was provided many months later, when exactly the same thing occurred again.

**Patient 3** – The patient felt the liners were easy to don and comfortable. At the delivery stage he experienced no problems. Having been on these liners for 2 months, the residual limb volumes had again decreased and new sockets were required. He had once again experienced some problems as a result of wearing pin liners, the "milking" effect having opened a small open sore over the cut end of the tibia on the right side. Though, for this reason, he requested we return to cushion liners, there was no sign of any wear on the liners and we agreed to use Contex Gel cushion liners with the new sockets.

**Patient 4** – The patient was delighted with the liner from the outset, finding it easy to don and that the matrix reduced the pistoning. He had no reaction to the gel and stated that it had improved the socket comfort, such that engage in new activities such as sailing and white water rafting and, more importantly he has been able to return to work full time, something he wouldn't have been able to do before.

**Patient 5** – The patient felt she had never had a comfortable prosthesis and scored her current prosthesis 0. She found it more difficult to don than the Duragel, though this improved with use. She immediately found the liner improved her comfort, though, in fairness, the Duragel it replaced was worn out. However, two months later, she still felt it was still comfortable and scored it 2. Admittedly she was a very low activity user and two months further on, was in hospital, having fractured her hip.