



## Clinical Evaluation Summary

CES FRE F01

### Freedom - Senator Foot

Warranty period - 2 Years (6 months Foot shell)

Weight Limit - 136kg

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

It is essential, when considering the application of this foot, to refer to the Freedom activity levels and to note that even the low impact activity level includes light jogging. From this evaluation the Senator foot certainly appears to be of most benefit to those patients who will walk it with some vigour. It is also important not to over-estimate the activity level of the patient when selecting the foot category. What surprised all those involved in this evaluation was the level of activity achievable from what is a relatively low priced foot. Even against the College Park Truststep foot, on fairly flat ground it competed very well, only being outdone over uneven terrain. The fact that five of the six patients involved were currently using the Blatchfords Multiflex foot serves to demonstrate the continued popularity of that product, particularly for the low to moderate activity patients, rather than to suggest that they are directly comparable products, this being reinforced by the evaluation results and the product price.

#### Indications

Most suited to low to moderate impact activity level patients, as defined by the Freedom impact activity levels.

Where a patient requires a foot which can be used for their routine activities, but which will also allow them to participate in some sports.

For activities where smooth energy return between heel strike and foot flat, and from foot flat to toe off, would be beneficial.

Where a robust, low maintenance foot is required.

#### Contraindication

Patients of less than, or at the very low end of the low impact activity, as defined by the Freedom impact activity levels.

Patients whose weight fluctuates frequently to any significant degree, or who are over the weight limit.

Where uneven ground and/or frequently undulating ground has to be negotiated regularly.

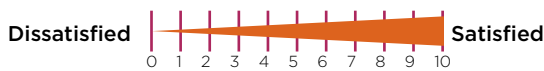
Patients requiring a very high level of cosmetic appearance, especially if they are of a slim build.

#### Evaluation Patients

##### Patient Details

<b>Patient 1</b>	Transtibial	88 kg	44 year old male	Retired Police Officer	Sigam F
<b>Patient 2</b>	Transtibial	104 kg	60 year old male	Unemployed	Sigam F
<b>Patient 3</b>	Transtibial	60 kg	37 year old male	Unemployed	Sigam F
<b>Patient 4</b>	Transtibial	76 kg	60 year old male	Retired	Sigam F
<b>Patient 5</b>	Transtibial	63kg	47 year old male	Unemployed	Sigam F
<b>Patient 6</b>	Transtibial	58 kg	58 year old male	Unemployed	Sigam F

## Evaluation Result



## Current Prescription

<b>Patient 1</b>	Laminate Iceross socket and College Park Truststep foot
<b>Patient 2</b>	Polypropylene PTBSC socket with Blatchfords Multiflex foot.
<b>Patient 3</b>	Laminate socket with Icelock 600 and Medi liner, Blatchfords Multiflex foot.
<b>Patient 4</b>	Laminate socket, Iceross with Icelock 600 and Blatchfords Multiflex foot.
<b>Patient 5</b>	Polypropylene PTBSC socket with Blatchfords Multiflex foot.
<b>Patient 6</b>	Laminate socket, Iceross with Icelock 600 and Blatchfords Multiflex foot.

## Prosthetist's Comments

**Patient 1** - The Senator foot was chosen because the patient was seeking greater energy return from the foot. Instructions, ease of assembly and alignment scored well 4 & 5. In finishing the cosmesis the foot function can be compromised. Durability and function scored 4.

**Patient 2** - Anticipating a more dynamic gait, this foot was chosen and found to be easy to assemble 4, though extremes of alignment with cosmesis may be awkward to achieve. The cosmetic appearance, whilst not as good as the Multiflex foot, was satisfactory and better than other similar feet 4.

**Patient 3** - This recent amputee, wanting to "run a bit", was provided with this foot and when aligned to the instructions provided, it needed no further adjustment 5. Cosmesis was alright and the function excellent 5. Durability seems good, though spectra sock worn through in 2 months.

**Patient 4** - Having lost a lot of weight recently and become much more mobile as a result, it was decided to trial two alternative feet, this and the OB Trias. Both were set up using the recommended alignment, but this patient is very susceptible to alignment change and the Senator, being less compliant was more difficult to get right.

**Patient 5** - This foot was chosen because a more reactive foot was required. The prosthetist found it easy to adjust and align 4 and after 3 months there was no sign of wear.

**Patient 6** - The patient, despite his age wanted to get back to doing some running, and this was seen as a cost effective method of trying to make progress for him.

## Patient's Comments

**Patient 1** - Whilst rating his current prosthesis at 4, he felt he needed more energy return, which he felt he got from the Senator, but still rated it 4. Walked it faster and smoother, but found it unforgiving over rough ground and the lack of inversion/eversion dropped the score to -1, though on smooth ground and slopes he found it "brilliant" scoring 5.

**Patient 2** - Scoring his current prosthesis 2 and "good", he found it a little slow. On starting to use the Senator he stated "I feel like I can walk forever" and scored it 5, his opinion remaining unchanged after a month of constant use.

**Patient 3** - Though he scored his current prosthesis at 4, he says "I tried running on it, but it doesn't work". The Senator "feels lighter" and lively on the toe 4. On returning 2 months later he said he'd started running again, about 2km every day and started playing a bit of football 5.

**Patient 4** - In comparison with the Trias foot that he trialled first, the Multiflex foot on his current prosthesis scored 0, the Senator scored 4, but he preferred the compliance of the Trias foot and it was agreed that it seemed to be the more appropriate prescription.

**Patient 5** - The patient rated his current limb at 2, but once the Senator foot had been fitted the score rose to 5 and has stayed there. He found it good when riding his bike, playing football with his children and jogging. Says he's not found the limitations of the foot yet.

**Patient 6** - The patient was happy enough with his original prosthesis, but the foot was not responsive enough for running. At the review stage, having spent the last few weeks abroad, had got back to jogging and was very pleased with the foot, but was limited by a slight socket problem 5.

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