

Clinical Evaluation Summary

CES CP F 11



College Park- Breeze Foot

Warranty period - 2 Years (footshell 6mths)

Weight Limit - 100 to 125kg

(size dependent)

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

The Breeze foot from College Park is a cost effective option, aimed at the Dynamic SACH foot market, with the additional benefit of being water resistant, with an optional drain hole in the removable foot-shell.

The gait function of the foot appears to be good, but the original foot-shell tended to hold the water and not allow it to drain away. A redesign of the foot-shell was undertaken and this issue has now been resolved, making it an ideal option for a water activity of shower limb, which is also capable of being used for everyday activities.

Indications

Patients of a Low to Moderate activity as defined by College Park activity/impact levels.

A patient with a positive gait who would benefit from a foot that is

- Simple and durable
- Smooth in its heel strike to toe off action
- Water resistant
- Relatively low in build height and weight

Contraindications

Patients whose activity level is outside those outlined by College Park.

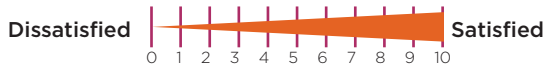
- A patient above the product weight/impact limit
- Where a high degree of compliance is required
- Users who have a very vigorous gait
- Users who have a very passive gait

Evaluation Patients

Patient Details

Patient 1	Transtibial	60kg	20 year old female	Student	Sigam E CPI Low
Patient 2	Transtibial	98kg	68 year old female	Retired	Sigam C CPI Low
Patient 3	Transtibial	95kg	22 year old female	Student	Sigam E CPI Low
Patient 4	Transtibial	103kg	59 year old male	Unemployed	Sigam F CPI Low
Patient 5	Transtibial	76kg	70 year old male	Retired	Sigam D CPI Low/Med
Patient 6	Transtibial	109kg	40 year old female	Unemployed	Sigam F CPI Low/Med

Evaluation Result



Current Prescription

Patient 1	PTB with suspension sleeve and Otto Bock 1D10 foot
Patient 2	PTB Supracondylar with Très foot
Patient 3	TSB Laminate socket, Medi pin liner and CPI Accent foot
Patient 4	PTB socket, with pin liner, conventional build and Otto Bock 1D10 SACH foot
Patient 5	PTB Supracondylar with suspension sleeve (foot not known)
Patient 5	PTB socket with Otto Bock Berma ProFlex sleeve and Senator foot

Prosthetist's Comments

Prosthetist 1 – The patient had been coping reasonably well with the 1D10, but it had worn badly and when replaced like for like, the new foot seemed too stiff and was causing instability at the knee. The Breeze was chosen as one of two options, mainly because the design criteria were aimed at producing a foot to compete with the 1D10.

Prosthetist 2 – Because the patient needed to be able to bathe independently, but also mobilise on a water activity limb with the same degree of confidence that he has on his standard prosthesis, the prosthetist felt the Breeze would provide the best solution. There was no problem setting it up and the patient walked well on it.

Prosthetist 3 – Finding the Accent foot slightly heavy and its heel height adjustment seldom used, the prosthetist decided to trial the Breeze, in the hope of providing a cost effective option for her everyday use. He had no problem setting up the foot. At the review stage he noted that “the foot shape creates a very pronounced rollover”. From the patient’s comments this seems to be a positive feature, though on more vigorous walkers, the prosthetist felt that it may not provide sufficient resistance at toe-off.

Prosthetist 4 – The prosthetist’s aim was to provide the user with a prosthesis with “a robust, all in one foot”. The patient disliked the fact that the current water activity limb didn’t work well enough for him to then use it anywhere else, so had to swap limbs. Alignment was slightly awkward due to the low profile of the foot making access to the screws a bit difficult. Compliance was not particularly good, but the profile allowed a good roll over.

Prosthetist 5 – Since the patient wanted to be able to use his main prosthesis to go swimming, shower and go and do whatever he wanted, without having to swap to a different prosthesis, the Breeze seemed like an obvious choice. The prosthetist found the posterior adjustment screw awkward, since its partly covered by the footshell, which he felt was rather too narrow.

Prosthetist 6 – This limb was prescribed specifically as a water activity limb, to be used alongside the patient’s everyday walking limb. The prosthetist had no problem with the set-up and alignment of the foot. It wasn’t expected that the Breeze would compare with the Senator foot that was on that limb, after five months of use, the prosthetist was surprised by her preference for it over the Senator and there have been no issues with it at all.

Patient's Comments

Patient 1 – The patient found that the action of the foot was similar to that of the 1D10, unfortunately creating the same feeling of instability in the knee. She preferred the softness of the Trulife Kinetic foot, with soft bumpers to allow a good range of plantarflexion at heel strike and a comfortable progression through foot-flat, to toe off.

Patient 2 – The patient walked well enough, but found that the foot shell filled with water and despite the drain hole in it, the prosthesis had to be removed to drain the water out. The spectra sock would also not dry out without removing the footshell, which was too hard for the patient to do for himself. This didn’t stop him using the prosthesis and at the second review he stated there were “no issues with the function of the foot” and that he was “able to bath independently”. (Note! This was using the original foot-shell design)

Patient 3 – At delivery it took the patient a little while to get used to the action of the foot, since it felt softer than the Accent. She commented that it felt smooth and easy to walk on. Four months later she she’d got used to its action. She was clearly making efforts to be more active and by nine months, with no issues with the foot at all, she stated “I can definitely walk further - though I am more active and fitter, and I have a better balance now. The foot has kept pace with my improvement”.

Patient 4 – Initially scoring his current limb **6**, at the delivery of the new limb, he scored it **7**, finding it “not to bad” when walking. After going on holiday he stated “it has enabled me to walk comfortably all day, every day when on holiday no need for another limb”. He liked it for its better function and appearance and because he only needed to take one limb with him on holiday.

Patient 5 – The patient’s only criticism was the fact that the footshell was rather narrow, but also that it was little short, so maybe it would have been possible to go up a size, which may have improved things a bit. Despite this, the fact that he could now go swimming without have to use a different prosthesis caused him to score **10**.

Patient 6 – She scored the Breeze on **8** against the Senator at the delivery, even though she wasn’t particularly happy with the cosmetic appearance of the footshell, still wanting it to be slimmer and more feminine. Five months later and she states that she can now walk with an improved gait and for a greater distance. Surprisingly, she prefers its soft action to that of the Senator and uses it as her main prosthesis, as well as water activities.

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