



Clinical Evaluation Summary

CES CPI F04

College Park- Accent IP Foot

Warranty period - 2 Years

Weight Limit - 100kg

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 requirement for a patient adjustable foot to allow the use of footwear with various heel heights, has always presented a challenge. Previous designs have either been heavy, prone to play developing in the adjustment, difficult to adjust, un-cosmetic in the ankle and forefoot, or lacking function in the gait. In designing the Accent foot, College Park have succeeded in producing a patient adjustable foot that, from the evaluations we have carried out, is cosmetically very good, whilst also providing a very responsive action when walking. There are a number of factors that will affect whether a user manages to cope with the adjustment of the foot, but in general, the evaluations show that the Accent is easy to adjust. Patients also commented on the lightness of the foot. Since the weight of the foot, though it is fairly light, is not significantly less than that of the Elation foot, for example, it must be concluded that the responsive function of the foot increases the impression of lightness.

Indications

Any patient requiring an adjustable heel height foot, especially if they also require,

- a foot with a degree of energy return,
- a good cosmetic appearance,
- a lightweight prosthesis.

Contraindication

A very high activity user

A patient above the product weight limit

A very low activity patient, where the use of anything other than "flat" shoes is contraindicated*

A patient whose cognitive ability is such that they are unable to determine the appropriate foot position*

Poor hand function*

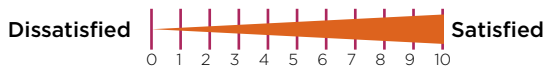
* These are issues that need to be considered when prescribing any patient adjustable foot

Evaluation Patients

Patient Details

Patient 1	Transtibial	91.5kg	68 year old female	Retired	Sigam F
Patient 2	Transfemoral	65kg	43 year old female	Unemployed	Sigam F
Patient 3	Transtibial	77kg	57 year old female	Unknown	Sigam F
Patient 4	Transtibial	82kg	48 year old male	Development Control Officer	Sigam F
Patient 5	Transfemoral	66kg	50 year old female	Unemployed	Sigam F

Evaluation Result



Current Prescription

Patient 1	Laminate socket with Ossur Icelock 600, Iceross liner and Elation foot
Patient 2	Polypropylene quadrilateral socket with TES, Blatchfords ESK/PSPC and MFFA
Patient 3	Laminate socket with Ossur Icelock 600, smooth pin, Iceross liner and Elation foot
Patient 4	Laminate socket with Ossur Icelock 600, Iceross liner and Elation foot
Patient 5	Northvene suction socket with laminate outer, Otto Bock 3R80 knee and Elation foot

Prosthetist's Comments

Patient 1 – A long time user of patient adjustable feet, this patient was chosen in the hope that she would provide useful feedback. The foot was easy to fit and to adjust. Though initially thinking that it may not have as much inversion/eversion as some CPI feet, in practice compliance to the ground surface was good. For this patient the foot shell was too narrow and had to be built up, though the ankle fairing made it easy to produce a good finish. Some problems were experienced with the ankle failing to lock effectively, possibly as a result of pressure on the button from the strap of a particular shoe.*

Patient 2 – The patient had an Elation foot on one of her prostheses. On her second prosthesis, she had begun using an Accent foot, which she preferred, but being very active, may benefit from the energy return of the DP version. Similar concerns were expressed regarding the cutting of the shin tube, as with Patient 1. Though the pylon had to be cut fairly short, the prosthetist was surprised at the responsiveness of the remaining section. The foot shell was too narrow for this patient and had to be built up to suit the shoes.

Patient 3 – Being an Elation foot user already and wanting a similar, adjustable heel height foot on her second prosthesis, her prosthetist requested we trial her on the Accent. He had no problems fitting the foot, the instructions being easily understood. His only concerns were the narrowness of the foot shell and the tension the ankle cosmesis was under when in full planter-flexion. He noticed that the application of the Skinergy cover did initially appear to compromise the effectiveness of the ankle lock, due to the increased pressure on the button.*

Patient 4 – Since this patient has been a good user of an Elation foot and a keen rambler, it was considered that he would give the Accent foot a very thorough comparative trial. The prosthetist had no problems fitting and adjusting the foot, his only concern being the effectiveness of the ankle cosmesis should the patient not match the fairing provided. In practice the technician found it easy to achieve a good cosmetic appearance for this patient.

Patient 5 – This lady was in the process of having a second prosthesis produced. Having complained about the dead feeling in the heel of her Elation foot, as well as problems with the cosmetic finish, the Accent foot was chosen in the hope of improving things for her.

Patient's Comments

Patient 1 – This patient had found the Elation foot a little “inflexible”, though otherwise “the best she had ever had”. She commented on this and the weight when scoring her current prosthesis at 3. She noted that the Accent foot felt more “flexible” and walked “normally”, especially feeling the benefit when going uphill – scoring it at 5. She also liked the cosmetic appearance despite the foot shell width being too small.

Patient 2 – Though critical of the degree of control she had over the knee and the cosmetic appearance of her current prosthesis she still scored it 3. Her initial impressions of the Accent foot were that it was “heavier, but more springy” than her current Endolite Multiflex, but as compliant on uneven surfaces. She was not impressed by the cosmetic appearance, stating that it looked “clumsy”. At the review stage, initial problems with finding the operating button had diminished with practice, but she had found the foot too deep in the mid third section, creating footwear problems, though the benefit of being able to change heel height outweighed those to a large degree. Compared with her current foot she scored it 3, though stating that it was “better for all social circumstances and activities”.

Patient 3 – Scoring her current prosthesis at -1, commenting that it wasn't easy to adjust and was “not smooth” to walk on, she was much more positive about the Accent foot at the fitting stage. She felt it was “very easy to walk on” and she could “feel the ground better”. At the review she said “it's just got better for walking on” and had “reduced the effort going upstairs” 4. She also commented on the narrowness of the foot, though with the Skinergy cover on, it did look very good indeed. At a review appointment it was noted that there was some play at the ankle joint. *

Patient 4 – The patient had expressed no problems with the Elation, apart from locating the release button, but immediately commented that the Accent felt easier to walk on, being “more flexible”. The cosmetic appearance was also good, in this case using an RPVC cover. At the review, as well as stating that he'd found it much easier to adjust, he also enthused about its effectiveness when rambling because of improved energy return, giving him a “spring in the step”. Three months after the delivery his opinion of the foot remained positive, with no maintenance required in that period and no signs of wear or play in the ankle. At the next appointment it was noted that there was some play at the ankle joint. *

Patient 5 – Though unfortunately the patient has not yet taken delivery of this foot, due to problems with the socket at fitting stage, her initial comments were very helpful. She immediately felt the foot was lighter than the Elation and commented on the “springiness” at heel strike and toe off. Her only negative comment was to do with having to hold in the adjustment button whilst adjusting the foot position, something she didn't need to do with the Elation, though she was prepared to find a way around this to gain the benefits of the function and the feeling of lightness.

* Evaluation Results - Though on some of the feet used in the evaluation the adjustment button was found to be too sensitive and some developed play at the ankle, CPI have addressed these issues and, to date less than 3% of the redesigned versions have needed to be returned under warranty, for any reason.

For almost 100 years, we have broken boundaries in healthcare to create fundamental, positive turning points that enhance lives. Contact us today on customerservice@steepergroup.com to find out more about our products and services.