



Clinical Evaluation Summary

CES CPI F05

College Park- Accent DP 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

In designing the Accent foot, College Park succeeded in producing a patient adjustable foot that, from the evaluations we carried out, is cosmetically very good, whilst also providing a very responsive action when walking. The Accent Dynamic Pylon foot is aimed at providing a patient adjustable foot, but which also accommodates those patients who require and would benefit from, an even greater degree of responsiveness from the foot. The foot and ankle are the same as the standard Accent (see CES CPI FO4) and this evaluation was carried out in an attempt to define the effectiveness of the Dynamic Pylon. From the results obtained there appears to be a significant increase in function, even from a relatively short section of pylon. The limitations created by there being no alignment function directly above the foot did affect one patient who wanted to use a shoe with a slightly higher heel than the foot itself would allow.

Indications

Any patient requiring an adjustable heel height foot, especially if they are also fairly active and therefore require,

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

Contraindication

A very high activity user A patient above the product weight/impact limit Limited clearance below the socket A patient with a very low cadence 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	55kg	46 year old female	Nurse	Sigam F CPI 2
Patient 2	Transtibial	80kg	70 year old female	Retired hotel manager	Sigam F CPI 2
Patient 3	Transtibial	53kg	50 year old female	Housewife	Sigam F CPI 2
Patient 4	Transfemoral	72kg	52 year old female	Housewife	Sigam F CPI 1
Patient 5	Transfemoral	54kg	58 year old female	Primary School Assistant	Sigam F CPI 2

Evaluation Result



Current Prescription

Patient 1	PTB supracondylar socket, with CPI Trustep foot	
Patient 2	Silicone pin liner to laminate socket, with Elation foot and standard Accent on her other prosthesis.	
Patient 3	Iceross pin liner to laminate socket, with CPI Venture foot.	
Patient 4	Seal-In liner socket, OB knee with Elation foot.	
Patient 5	Iceross pin liner with clutchlock in polypropylene socket, to knee with Catech and Accent foot.	

Prosthetist's Comments

Patient 1 – This patient was chosen in an attempt to provide a very active lady with a foot that gives the function she needs, but also meets her need to use shoes with varying heel heights. Cutting the pylon to length leaves no room for error, though there are "oops" adaptors available. Fitting the top adaptor also required considerable force, with concerns regarding the effect this may have on the foot, since the pylon is integral to the foot. There also appears to be very little inversion/eversion, though this didn't cause the patient any problem.

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 – Cutting the pylon to length and the force needed to hammer home the adaptor were the concerns of this patient's prosthetist. She was a good user of the CPI Venture foot, but wanted something that would adjust to different heel heights. The foot shell was too narrow and had to be built up.

Patient 4 - Needing a second patient adjustable foot in order to make progress with a change of knee prescription and alignment on the patient's second prosthesis, the Accent DP was chosen. The male pyramid top was chosen to allow a long stump adaptor to be used directly into the knee, thereby keeping the longest possible pylon section. The problem encountered was the patient's request to use a shoe with a heel height that was slightly higher than the foot would allow (even though the Elation foot coped with it), there being no alignment adjustment directly above the foot. The foot appeared to function well and the pylon could be seen to be flexing, as a consequence of it being longer than would be possible in any transtibial application.

Patient 5 – The prosthetist decided to use an OB 3R95=1 knee, to maximize the length of the DP and to reduce the weight of the prosthesis, since she didn't use the yield element of the Catech and found it heavy. He commented that, when trying to work out what components to use and what length the pylon was to be, no mention of a maximum length could be found in the literature.

The max build height using a female adapter is 21-24cm = 41.1cm, and 25-26cm = 41.5cm.

At the finishing stage, he found it a little difficult to totally hide the transition between the ankle cosmesis and soft foam transfemoral cosmetic fairing. Its ground compliance proved good and it required no maintenance.

Patient's Comments

Patient 1 – Rating her current prosthesis 4, her main complaints were that it wasn't adjustable for different shoes and didn't have a split toe. She also commented that the Trustep was so compliant it felt a little like walking on a "balloon". At the delivery she scored the Accent DP at 5, feeling it gave greater control as she progressed to toe off, with "less rebound or jarring" on her knee. She also found it easy to adjust the foot position. The narrowness of the footshell, in comparison with that of the Trustep foot of the same size did present a problem with her shoes and several attempts had to be made to improve the cosmesis to fit them. At work she found she could walk further, with less effort. She felt the benefits of being able to change heel height were significant.

Patient 2 – Rating the Elation foot at 3 and the Accent at 4, she was very pleased that the Accent DP achieved yet another improvement for her. The increased flexibility and spring made the prosthesis feel lighter, to the extent that she said "I forget I'm wearing a false leg; I can do more around the house; I go out more and have even been dancing". It has given her the confidence to choose shoes with a greater range of heel heights and even to walk backwards! She was so pleased she gave it "top marks" 5.

Patient 3 – She rated the Venture foot at 4, but aside from the ability to adjust the heel height, said of the new foot "It's more flexible and cushioned, like wearing a comfy shoe, yet I could feel the ground under me better". Despite a short episode of pain in her residual limb, which proved to be unrelated to the change of foot, she scored it 5. She walks further on it, but feels it's slightly stiffer than the Venture when going up an incline.

Patient 4 - The patient was perhaps trying to cope with too many changes at once and couldn't really give the sort of feed back hoped for, but the slight lack of forefoot support caused by the alignment didn't help.

Patient 5 – The patient seemed more positive than her prosthetist about the Accent DP. She had been an amputee for over 40 years and commented on the greater "bounce" in the foot, which had enabled her to walk further, giving her greater freedom, without the need to "plan when to rest".

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