

## CLINICAL EVALUATION SUMMARY - CES CPI F 06

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

### COLLEGE PARK - ONYX FOOT

**WARRANTY PERIOD – 3 YEARS**  
**WEIGHT LIMIT – 125kg**

#### EVALUATION SUMMARY



This foot is similar to the Venture foot in appearance, but with a dynamic response shin pylon. The heel rubber, forefoot bumper and pylon are selected based on the patient's weight and activity level. There is a stride control adjuster on the heel rubber and removable wedges allow the foot to be set up to suit the patient's footwear.

In general the patients found this foot effective and the prosthetists found no particular problems setting it up, or in achieving a good cosmetic finish. There is no doubt that, as with the Accent DP, the dynamic pylon is effective, even when only a relatively short section of pylon can be accommodated and the foot itself provides similar compliance to the Venture or Tribute feet. The only issue appears to be in defining its most appropriate application, especially with regard to cost effectiveness. The Indications and Contraindications below probably show something of this uncertainty, but do also outline some very positive benefits.

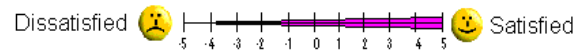
INDICATIONS	CONTRAINDICATION
Moderate to high activity patient up to 125kg	Low activity patient
Patient with an active, dynamic gait	Patients with a slow tentative gait
Patient who is particular about the cosmetic appearance (especially if they are slim)	Insufficient clearance to accommodate the components (whilst still allowing 2-3cm pylon)
Where good ground compliance is required	Very high activity patient
Transfemoral amputees, where the maximum length of pylon allows full use of its dynamic effect.	

### EVALUATION PATIENTS

#### PATIENT DETAILS

<b>Patient 1</b>	Transtibial	85kg	46 year old male	Postman	Sigam F CPI 3
<b>Patient 2</b>	Transfemoral	58kg	26 year old female	Property Management	Sigam F CPI 2
<b>Patient 3</b>	Transfemoral	75kg	38 year old female	Lecturer	Sigam E CPI 2
<b>Patient 4</b>	Transfemoral	76kg	46 year old male	Importer	Sigam F CPI 3

## EVALUATION RESULTS



### CURRENT PRESCRIPTION

<b>Patient 1</b>	Supracondylar ptb socket with Otto Bock Axtion DP (previously Springlite Gold)
<b>Patient 2</b>	ICS suction socket, Medi NOH5 and Freedom Senator foot
<b>Patient 3</b>	H socket with TES belt suspension, Mauch knee and Freedom Senator foot
<b>Patient 4</b>	TSB TEC Socket with suction valve and suspension sleeve. Freedom Renegade foot

### PROSTHETIST'S COMMENTS

**Patient 1** – The patient was supplied with the Onyx foot, since he was on a foot that appeared to have similar construction and characteristics to his current issue. This had been supplied, on the recommendation of the manufacturers, as a replacement for a foot that is now obsolete. The prosthetist had no problem setting up and aligning the foot and over the 3mths of the evaluation no problems were experienced with the foot and no adjustments were required.

**Patient 2** – Since the patient was young and fit, she was chosen to trial the Onyx in the hope that its compliance and energy return element would help her achieve her every day activities more easily. The prosthetist found it easy to set up, the literature being easy to understand and everything that was required was supplied. Concern was expressed regarding setting up the foot to achieve the appropriate heel height and the force required when fitting the proximal adaptor. Though both were achieved without undue problems, the setting up of the heel height was fiddly. The foot cosmesis met with approval.

**Patient 3** – The prosthetist chose the patient in the expectation that the Onyx would provide greater energy return. He had no problems fitting and aligning the foot, finding the literature easy to understand, and the cosmetic finish acceptable.

**Patient 4** – The prosthetist found the instructions easy to understand and fit, though the process of fitting the wedges to accommodate the shoe provided was rather tedious and not easily changed, should the patient wish the change to a new shoe with a slightly different heel. He felt that the pylon, provided it was of a reasonable length, allowed good compliance on uneven ground. The posterior bumper needed replacement and the footshell was showing signs of wear under the forefoot after just four weeks. The user is a very active individual, running approximately 5 miles every day.

### PATIENT'S COMMENTS

**Patient 1** – The only comments the patient made were that he found the Onyx “much better” than the Axion, scoring it **5** and also, unusually, that the foot shell seemed too wide. He felt it had improved his quality of life and that it worked well when he walked or jogged.

**Patient 2** – The patient was not unhappy with her current prosthesis, scoring it **4**, but on first trying the Onyx, she scored it **5**. The impression she had was of energy being stored up and then propelling her forward, requiring less effort. At the review stage 2mths later, realignment of the knee was required to increase the stability, since the foot tended to trigger knee flexion too early. At 4mths the patient reported that she still felt that less energy was required to carry out every day activities. She also thought the cosmetic appearance was better.

**Patient 3** – The patient scored his current prosthesis at a noncommittal **0**, on the basis that, since he had only had a prosthesis for about 5mths, he had nothing to compare it with. Initially he scored the Onyx at **2**, stating that it was “much more springy”, giving greater energy return. Though not particularly fussed about the cosmetic appearance, he agreed that it was good. He then started to have socket problems, but at the socket refit delivery, he requested to have the Freedom Senator foot refitted, feeling that it gave greater compliance.

**Patient 4** – The patient found the foot functioned well for all his activities, including running, though he felt there was a distinct dead spot at mid stance, especially in comparison with his Freedom Renegade.