steeper
Creating life's turning points, together

Clinical Evaluation Summary

CES **CPI** F09

College Park- Celsus Foot

Warranty period - 1 Year (Footshell 6 months)

Weight Limit - 136kg (Depending on foot size)

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

This fairly low profile and lightweight foot is aimed at the low impact K2 community ambulator.
It provides a smooth and stable heel strike to toe off action, which has proved to be softer and more compliant than the Trés foot, giving an action that is similar to that of a soft Tribute foot, without the adjustability, but also without the maintenance it requires. This makes it ideal for transtibial patients with residual limb, knee or hip joint pain, who would benefit from a reduction in the foot reaction forces and resultant socket pressures, or for transfemoral amputees, especially those with reduced hip extension. The simplicity of the design makes for a product which the prosthetists have found simple to align and set up, and which the patients find comfortable to use. The Celsus can be directly swapped out for the Trés or the Tribute, with a build height of just 64mm. This allows the opportunity to easily assess the function of one against another.

Indications

K2 ambulators, up to 136kg Patients who would benefit from -

- a lightweight foot
- a smooth and stable heel strike to toe off action
- a reasonably soft and compliant action
- a fairly low build height
- a reduction in transtibial socket pressures

Contraindication

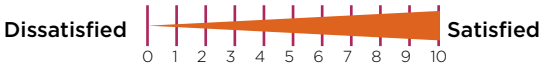
Patients outside the weight or activity level
Patients requiring a foot with a very low build height

Evaluation Patients

Patient Details

Patient 1	Transtibial	80kg	52 year old male	Unemployed	Sigam D
Patient 2	Transtibial	65kg	76 year old male	Retired	Sigam F
Patient 3	Transtibial	64kg	58 year old male	Salesman	Sigam F
Patient 4	Transfemoral	100kg	70 year old male	Retired	Sigam D
Patient 5	Transfemoral	65kg	59 year old male	Unemployed	Sigam D
Patient 5	Transtibial	70kg	53 year old male	Unemployed	Sigam F
Patient 5	Transtibial	68kg	82 year old male	Retired	Sigam D

Evaluation Result



Current Prescription

Patient 1	Laminate socket, Absolute pin liner and CPI Trés foot
Patient 2	Laminate socket, Silipos LA liner and CPI Tribute foot
Patient 3	Polypropylene PTB socket with Contex Gel suspension sleeve, Trés foot and OB torque absorber
Patient 4	Quadrilateral laminate socket with Silesian belt suspension, OB 3R32 knee and 1D10 foot
Patient 5	Quadrilateral socket with soft suspension belt, Ossur Total knee and OB Dynamic SACH foot
Patient 6	Laminate socket, Silipos LA liner and Contex Gel sleeve and Freedom WalkTek foot
Patient 7	Laminate socket with Pelite liner, Iceross Original with pin and CPI Trés foot

Prosthetist's Comments

Patient 1 – The patient has problems with his sound side leg and hip, using his stick to provide support for that side, rather than for his amputated side. Because of this, though he is a reasonable walker, he lacks sufficient "attack" in his gait to get the best from the Trés foot and, as a result, finds it too stiff. Fitting the Celsus was simple and the results very evident, with a softer roll over being achieved.
Patient 2 – This active gentleman, who walks better than many much younger patients, was finding his Tribute foot slightly too stiff over the forefoot. A softer bumper was requested, along with the Celsus foot, in an attempt to define which would be most appropriate for him. At the fitting he walked both the Celsus and the Tribute, with the softer bumper, very well. He thought the Celsus was possibly slightly better, but chose to stay with the Tribute. The build heights of the two feet are functionally identical and the Celsus was easily aligned and set up.
Patient 3 – The foot originally requested for Patient 2 was reallocated to this gentleman. Despite being only 5 months into his rehabilitation and having a transmetatarsal amputation on the other side, he was walking very well. He had been prescribed a soft Trés foot, but was finding it a little stiff, so the Celsus was fitted and despite it being a medium stiffness, it seemed to provide a softer rollover. It was also hoped that this would be better when he was on the golf course.
Patient 4 – Since the patient was feeling unsteady and unsafe on his current set up, rating it at 0, the Celsus was fitted in the hope that it would provide greater compliance, stability and patient safety. Whilst the technical information seemed limited, it proved to be sufficient and setting it up was easy.
Patient 5 – The patient had several falls with his current knee and foot set up and the prosthetist prescribed the Celsus foot as part of a package, including a Medi NOP4 knee, to try and reduce the number of falls. Initial results were very promising, though there were some socket issues.
Patient 6 – This gentleman, though not very active in terms of impact, does walk a fair amount and likes to go fishing as often as he can. The Kinetic foot had worked fairly well, but his gait is such that he always seems to need more action from the forefoot than it can give. A WalkTek was provided to see if this would offer the support required, but he had found that too stiff (see WalkTek CES). The Celsus was issued to try and provide a solution, which it appeared to do, even before it had been critically aligned.
Patient 7 – With very little soft tissue covering over the cut end of tibia, this patient regularly developed a painful bursa in this area and the prosthetist had decided to try an Inception pin liner and a Celsus foot, in an attempt to offload some of the stresses on the residual limb.

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 – The patient immediately felt more comfortable on the Celsus, with less undue pressure on his residual limb. He also thought that it reduced the problems on his sound side, making the whole experience of walking less painful.
Patient 2 – On delivery of his new socket, the forefoot bumper in the Tribute was changed for a soft and he felt this was probably better. The Celsus (25 medium) was also tried and though he thought this may be slightly better, he was not sufficiently sure as to want to take it, preferring to stay on the Tribute.
Patient 3 – On being provided with the foot originally ordered for Patient 2, his initial reaction was very positive, finding it more comfortable when standing still, as well as rolling smoothly from heel strike to toe off. At his first review his concerns were regarding the socket and he had to be pressed to comment on the foot, though he agreed that this would be a satisfactory foot for use on the new prosthesis being produced.
Patient 4 – At the delivery stage the patient immediately stated that it felt "smoother and safer". At the first review he commented that he "preferred this foot and its smoother to walk with" and at the second review he was walking more, with increased independence and mobility. He rated this set up at 3.
Patient 5 – The prosthetist found the foot easy to align and set up and initial results looked very promising, with an obvious improvement in stability and gait, but the socket issues persisted and were still ongoing when the evaluation had to be concluded. Note! Despite the disappointing outcome of this evaluation, it does serve to show that the compliance of this foot, its soft heel strike and easy planterflexion do make it very appropriate for transfemoral users.
Patient 6 – The patient's reaction to this foot was very enthusiastic. He stated that "it was the nearest I've ever felt to having my own leg back" and he left saying that I wouldn't see him again for a year, because he was convinced that this had resolved his problems. Some months have past and he has not yet returned.
Patient 7 – Whether the change in prescription will reduce problem with the bursa in the long term remains to be seen, but what was very evident to the patient was the reduction in the stresses to his residual limb as a result of the softer roll over of the Celsus foot. He felt the prosthesis to be lighter, but the weight of the feet is similar.