



Clinical Evaluation Summary

CES CPI F03

College Park - Truststep Foot

Warranty period - 3 Years

(18 Months over 136kg)

(6 Months Foot shell)

Weight Limit - 136kg

(160kg on Exoskeletal build)

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 foot already had a deservedly good reputation as a compliant, effective and reliable product. The evaluations that have been carried out, have served only to reinforce that reputation, even surprising those involved. The patient's comments really speak for themselves, but the Indications and Contraindications listed below may help clarify the most appropriate application of the Truststep foot.

Indications

Sigam mobility grade C to F
College Park activity level 2 to 5
Patient regularly walks or runs on uneven ground
Patient regularly encounters undulating, or hilly terrain
Patients who wish to take part in sport, such as badminton, golf, hill walking or tennis
Those who would, for reasons other than those already given, benefit from shock absorption at heel strike, energy return at toe off, axial rotation or inversion/eversion

Contraindication

Mobility or activity levels outside those specified

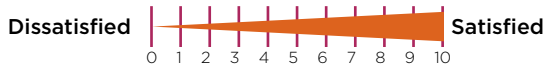
Where a low build height is required
Patients who wish to wear footwear requiring a split toe option
Where a light build is of more importance than extremes of function
Where a high definition cosmetic cover is to be used (the action of the foot destroys them rather quickly)

Evaluation Patients

Patient Details

Patient 1	Transtibial	81kg	57 year old male	Retired	Sigam F	CPI 3
Patient 2	Bilateral Transtibial	72kg	39 year old male	Unemployed	Sigam F	CPI 2
Patient 3	Transtibial	87kg	36 year old male	Accountant	Sigam F	CPI 5
Patient 4	Transtibial	77kg	49 year old male	Labourer	Sigam F	CPI 4
Patient 5	Transtibial	106kg	50 year old male	Diver	Sigam F	CPI 5
Patient 6	Transfemoral	100kg	44 year old male	Teacher	Sigam F	CPI 3

Evaluation Result



Current Prescription

Patient 1	Laminate socket with suction valve and Sureflex foot
Patient 2	Alpha liner socket with pin and Multiflex foot and ankle
Patient 3	Laminate socket, liner with pin and Multiflex foot and ankle
Patient 4	Icross liner with pin and Quantum foot
Patient 5	Icross liner with pin and Multiflex foot and ankle
Patient 6	A polypropylene 'H' suction socket, SFESK, IP+ and Seattle Voyager foot

Prosthetist's Comments

Patient 1 - The Truststep foot was chosen for this patient because he was constantly breaking the Sureflex feet due to the activity level he'd achieved, playing football, badminton and basketball. The prosthetist was very pleased with the ease of assembly and adjustment, and with the end result 5.

Patient 2 - The patient had been having a problem with uneven ground and the Truststep was chosen to try to overcome this. Easily aligned and adjusted 5, with no problems obtaining a good cosmesis, the end result was good, but both foot shells split within a year 3.

Patient 3 - The patient had attempted to run on the Multiflex foot, but the energy return was inadequate. In general the prosthetist was satisfied with the product and scored it an average of 4 for ease of use, cosmetic appearance and durability, commenting only that the foot shell had worn out within 10mths and the ankle gaiter was stiff, but not durable enough.

Patient 4 - A hill walker and golfer, this foot was chosen for its compliance. Again scoring an average of 4 for the set up and finishing, but again experienced some problems with the cosmesis around the ankle gator. The overall result was good and functionally scored 5.

Patient 5 - This very active individual was chosen because he frequently needed to walk on uneven ground and slopes. The prosthetist, having found the alignment more difficult on this patient 3, was satisfied with the function, and ease of adjustment 5, but the patient split the foot shell, lowering durability to 4. The function of the foot also found to change with wear 3. Cosmesis was acceptable 4, though a wider foot shell would have been better in this case.

Patient 6 - Again scoring an average of 4 for the set up and finishing, and also for durability, despite having some problems with the interface of the cosmesis and foot. "An excellent foot for this hill walker - he is able to walk without conscious thought" 5

Patient's Comments

Patient 1 - Rating his current foot at 3, this patient scored the Truststep at 5 throughout the evaluation, but his comments became more and more enthusiastic as time went by. Wishing he'd had the foot sooner, he comments on the "excellent ground compliance", the fact that it doesn't require "conscious thought" when walking, and seems to make him less tired.

Patient 2 (Bilateral) - Because he found the Multiflex feet awkward on uneven ground, he scored them 0. His initial response to the Truststep was that they "feel more comfortable", a theme that continued throughout the evaluation 5. He experienced no problems with the feet, even attempting "a bit of running". He wasn't quite so sure about the appearance 3.

Patient 3 - Finding the response from the Multiflex slow, especially when attempting to run, he scored it -2. His response to the Truststep was initially good, but a cautious 4, until he'd tried it "on different terrains", when he declared himself to be "very impressed" 5. Having needed only some "minor adjustments" and repairs, he scored durability 4.

Patient 4 - Relatively satisfied with the Quantum foot, though not so good on some surfaces, he scored it 2. Finding the Truststep increased the "ease of walking" he gave it 4. The appearance of it at delivery was obviously not as good as he'd like 3, but a round of golf or two later and the score had crept up to 5, with his final comment being "I don't want to be without it".

Patient 5 - This patient's back discomfort caused, in his opinion, by the stiffness of the Multiflex foot and the problems he experienced when walking on uneven ground, resulted in a score of -5. From day one on the Truststep, the increased comfort, ease of walking and stability had caused him to score it at the other extreme 5. Despite the fact that the foot shell was too small, the ankle gaiter came adrift and the foot shell wore out too quickly, he continued to score it at 5.

Patient 6 - This transfemoral patient, a keen hill walker, found the Seattle Voyager foot "didn't provide any particular benefit" and scored it 2. Scoring the Truststep 4 at the fitting and delivery, he commented on its flexibility and greater movement when walking. At the first review date he scored it 5 and makes comments such as "significant feedback", "great stability on sloping and uneven ground", "increased confidence" and "less conscious thought". On a visit to the Falklands he walked over some very hilly and rough ground "in a way I had previously been unable to do". He continues to use the foot, preferring it as his "all round, day to day foot". Durability, he states, has been good.

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