

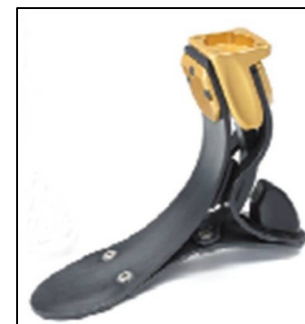
CLINICAL EVALUATION SUMMARY - CES CPI F 07

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 SOLEUS

WARRANTY PERIOD – 3 YEARS (footshell 6 mths)

WEIGHT LIMIT
 21 – 24cm: 100kg
 25 – 26cm: 113kg
 27 – 30cm: 125kg



EVALUATION SUMMARY

The College Park Trustep foot, which has been available since 1997, features excellent ground compliance as the main characteristic of its design. The design of the Soleus also appears to incorporate the same characteristic, though with a more significant energy return. The gentle nature of the compliance and energy return have been commented on, particularly the way it seems to reduce any feeling of jarring through the residual limb and eases the problems of ascending or descending slopes.

Initial concerns regarding the durability of the Soleus have proved unfounded, with none of the feet showing any signs of deterioration, even on the most active users. Indeed, the only negative comments so far, are with regard to the problem of creating a good cosmetic finish, due to the size of the four bolt mounting. Whether in the gold or silver finish, it is unusual, but it does allow for a greater range of build options.

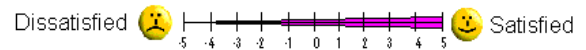
INDICATIONS	CONTRAINICATION
Moderate to high impact activity level	A very low activity user
Sporting activities, especially involving running on uneven ground	A patient above the product weight/impact limit
Any activity requiring good ground compliance, but with energy return	Limited clearance below the socket
Where there is a need to decrease undue forces on a transtibial residual limb, or knee joint, or the prosthetic knee of a transfemoral prosthesis, especially ascending or descending slopes	Where cosmetic appearance is a high priority

EVALUATION PATIENTS

PATIENT DETAILS

Patient 1	Transtibial	80kg	49 year old male	Antique Dealer	Sigam F CPI 3
Patient 2	Transtibial	99kg	32 year old male	Production Worker	Sigam F CPI 3
Patient 3	Transfemoral	94kg	40 year old male	Unknown	Sigam F CPI 2
Patient 4	Bilateral Transtibial	75kg	30 year old male	Unemployed	Sigam F CPI 2
Patient 5	Transfemoral	59kg	18 year old male	Unemployed	Sigam F CPI 2
Patient 6	Bilateral Transtibial	98 kg	41 year old male	Salesman	Sigam F CPI 2

EVALUATION RESULTS



CURRENT PRESCRIPTION

Patient 1	TSB TEC Socket with suction valve and suspension sleeve. Freedom Renegade foot
Patient 2	TSB socket with pin liner and CPI Trustep
Patient 3	ICS suction socket, Otto Bock 3R80 and Variflex foot
Patient 4	TSB sockets with Contex Gel liners, sleeves and suction valves. Freedom Renegade feet
Patient 5	End-bearing socket with Seal-In liner, to Endolite KXO6 and Freedom 1000 (Sierra) foot
Patient 6	TSB socket with Ossur Synergy Wave pin liners and Otto Bock C walk feet

PROSTHETIST'S COMMENTS

Patient 1 – The patient is a very active man and regularly runs, cycles and swims. He has been very satisfied with his Renegade foot and, knowing we needed a demonstration patient to show it off at BAPO, he volunteered to come along. Whilst there, it was suggested that he may like to try the Soleus foot, since an appropriate one was available. Having agreed, it was fitted and the patient used it all day.

Patient 2 – This young man enjoys walking and playing football. Having fractured components in his Trustep foot, the Soleus foot was supplied in the hope that it would provide the same degree of compliance, but would enable him continue to run, whilst achieving greater durability.

Patient 3 – A fairly big and active D.I.Y enthusiast, the patient was chosen to try and make a comparison with the Variflex foot he had been using and, hopefully, to improve his gait. The prosthetist felt that this was achieved, but that the foot function was compromised by the knee prescription and the fact that the socket was slightly loose. No problem had been experienced with fitting the Soleus, though the prosthetist didn't like the cosmetic appearance.

Patient 4 – At the point where it was decided to produce a pair of limbs with Soleus feet, the patient was having some socket problems and was also suffering with a cyst on his right side. He had managed well on his Renegade feet, but had not achieved as much as they would allow him to due to these issues. The problem of producing new sockets and swapping them as day jobs aggravated these problems, so it was agreed that a second pair of limbs be produced and the Soleus feet were chosen to try and reduce the forces on his residual limbs, without reducing his function. They proved relatively easy to set up and have been reliable.

Patient 5 – This young man was chosen by his prosthetist to evaluate the Soleus, since he was currently using a foot that was thought to have similar properties and was a good user of a transfemoral prosthesis. The prosthetist had no criticism of the Soleus, apart from the proximal dimension; especially should a foam cosmesis have been required.

Patient 6 – An active user, involved in various sports, he was not satisfied with the energy return he was getting from his C walk feet. Discussions regarding the available options included Renegade, as well as the Soleus and Trustep. The Soleus was chosen since early reports indicated that they provide compliance with energy return.

PATIENT'S COMMENTS

Patient 1 – Having scored his current prosthesis at 5, he gave himself a problem, scoring the Soleus 5+++ for his initial impression. He then requested to take it for a run outside and returned even more delighted than when he left. Since he wouldn't let us have it back, he was allowed to take it. At the first review over a month later, he stated "it just gets better". He had continued with all his normal activities, including his daily run. Over a month after that, the foot having proved to be 100% reliable, he declared it to be "a fantastic bit of kit – absolutely top grade". The only negative was the cosmesis, which both he and his prosthetist felt to be unacceptable.

Patient 2 – The patient felt the Trustep to be a good foot, but the activities he likes to engage in, adversely affected its durability, causing him to score it 2. Having used the Soleus for 2 months he scored it 4, finding it requires less effort to walk and jog, even on uneven ground. He felt it assists his gait, driving him forward, making the limb feel more a part of him, so that his daily activities are easier to achieve, as well as his more energetic activities.

Patient 3 – Scoring his current prosthesis 0, he liked the Soleus foot as soon as it was fitted, scoring it 4 and after 2 months he stated that it had made his gait feel smoother and faster. Still pleased with the foot a month later, he felt it had improved his quality of life. It had also proved completely reliable, though he judged the cosmetic appearance as OK, rather than good.

Patient 4 – Given all the issues this individual has been coping with; it has been difficult for him to define the benefits he finds from these feet. Added to which, he is already on a very high quality pair of feet, so it was not expected that he would notice extreme differences between them. He feels that they are softer and more compliant, making them more comfortable to use in everyday situations, but isn't currently able to push them too hard, so can't be sure how they compare when used more vigorously.

Patient 5 – Obviously very satisfied with his current prosthesis, he scored it 4, stating that he found the Soleus "strange, but ok". He didn't feel it was as "natural" initially, especially the heel action, though he declared that it "looks awesome". After a period of use he commented that running was "more comfortable, specifically heel strike" and even "walking is easier and easier to vary speed", though he also commented that the Freedom 1000 (Sierra) was also very good.

Patient 6 – The response of the patient to the Soleus feet was very positive. He found that they provided a smooth roll over, making it easier to walk, but with sufficient energy return for the sports he gets involved in. His only concern was the problem of achieving a satisfactory cosmetic shape, which is so important to him that he has requested to trial a pair of Trustep feet.