31st August 2010

CLINICAL EVALUATION SUMMARY - CES **SEA** F 02

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.

SEATTLE CATALYST 9 FOOT

WARRANTY PERIOD – 3 YEARS (footshell 6 mths)
WEIGHT LIMIT – 166kg

EVALUATION SUMMARY

The Seattle Catalyst 9 is described as a dynamic foot, consisting of a unique carbon fibre "S" shaped pylon connected to a split keel. Control of the movement of these two sections relative to each other is provided by a posterior link connecting the alignment pyramid block through the heel of both the split keel sole plate and the "S" shaped pylon. The foot is designed for use with moderate to high activity patients (K3 – K4).
Feedback from both the prosthetists and the patients has substantiated the Trulife claim. The feet used for the evaluation were found to be suited to situations where foot compliancy to uneven terrain is required combined with high energy storage and return. Prosthetists noted that they were particularly impressed with the rapid plantar flexion of the foot at heel strike and the smooth progression of compliance to "toe off" throughout stance phase. It was found that application and fixing of the appropriate heel wedges had caused some minor difficulties.

INDICATIONS	CONTRAINDICATION
Moderate to high impact activities requiring good compliance.	Low activity levels.
Amputees requiring enhanced energy storage and return.	Patients over 166Kg
Patients requiring a high degree of anterior-posterior compliance (e.g. Bilateral and transfemoral amputees)	Patients with small ankle circumferences requiring a good level of cosmetic compliance.

EVALUATION PATIENTS

PATIENT DETAILS

Patient 1	Transtibial	76kg	46 year old male	Importer	Sigam F
Patient 2	Transfemoral	70kg	42 year old male	Foster Parent	Sigam F
Patient 3	Transfemoral	77kg	49 year old male	Keen cyclist and walker	Sigam F
Patient 4	Transfemoral	76Kg	41 year old male	I.T Consultant	Sigam F
Patient 5	Transfemoral	83Kg	28 year old male	Student	Sigam F
Patient 6	Transfemoral	97kg	55 year old male	Company Director	Sigam F

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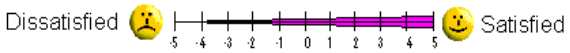
EVALUATION RESULTS



CURRENT PRESCRIPTION

Patient 1 TSB TEC Socket with suction valve and suspension sleeve. Freedom Renegade foot
Patient 2 Custom TEC liner, with TSB socket and one way valve, College Park Trustep foot
Patient 3 PTBSC socket with College Park Tres Foot
Patient 4 Polyurethane ICS Seal-In socket, Black Max Knee and Eschelon foot .
Patient 5 Quad Suction socket, Black Max knee and Senator foot.
Patient 6 Polypropylene Quadrilateral socket with DSPB, Endolite ESKPSPC, Multiflex foot/ankle

PROSTHETIST'S COMMENTS

Patient 1 – Prosthetist stated that he had some initial concerns relating to his experiences with the Cadence foot (Also produced by Trulife and similar in appearance). It was noted that the posterior tendon contributed to a far smoother forward progression during stance phase and that it also contributed in preventing "drop off" in the forefoot by reducing the forward deflection of the upper element of the "s" shaped pylon. Donning and doffing of the foot shell was stated to be difficult and the Prosthetist outlined some difficulty in selecting the correct heel wedge (required to ensure neutral alignment in the chosen footwear) and then donning the foot shell over the glued wedge. It was noted that the patient had considerable experience with a range of prosthetic feet and that this foot had performed exceptionally well.
Patient 2 – The Prosthetist highlighted that the foot functioned well with smooth forward progression. He encouraged the patient to evaluate the foot performance on a gradient and noted that when descending slopes the foot plantar flexed rapidly, in preparation for the next step.
Patient 3 –The Prosthetist noted that the foot had provided good planter flexion motion and compliance and recommended that this foot would be suitable for impact activities at work and leisure.
Patient 4 – The Prosthetist noted that this patient had trialled a number of prosthetic feet but had been able to find a "flaw or undesired property" in each. He reported that the foot appeared smooth with a controlled heel strike and a plantar flexion action comparable to the contra-lateral limb. The Prosthetist also noted that the foot worked well "in tandem with a Mauch unit".
Patient 5 – The Prosthetist reported that this patient had been an amputee for a little over two years but could "walk on anything". The patient also had a history of oil leakages from hydraulic units suggesting a high level of activity and impact. The Prosthetist reported that although this gentleman already had a good gait that there was a marked improvement at heel strike and toe off. The Prosthetist reported that he had not seen the patient for over 5 months and that this was the longest period over which the patient had not required any further appointments.
Patient 6 – With his current prescription under review, it was decided to trial the NOP5 knee and, since he is still a relatively young and active man, who likes to play golf and travels a good deal, to upgrade the foot accordingly by supplying the Catalyst 9. The prosthetist found that there was a knack to donning the foot shell, but that it was tricky initially, especially when trying to determine which heel wedge was most appropriate for the footwear, prior to gluing on the wedge. Once this had been achieved, setting up the foot proved very simple indeed and clearly

PATIENT'S COMMENTS

Patient 1 – The patient found that this foot functioned exceptionally well and that he did not experience a "dead spot" at mid stance. Upon two subsequent reviews the patient stated that he had been very impressed with the performance of the foot throughout all of his regular daily activities which included cycling, gym work and dog walking. He requested that he be allowed to keep the foot upon completion of the evaluation.
Patient 2 – Patient noted that had previously had to descend slopes by side stepping, but that he could now descend step over step. The patient also noted that he was able to wear his prosthesis for a longer period throughout the day. He also noted that he had previously experienced discomfort and reddening over the patella tendon and that this had reduced.
Patient 3 – The patient stated that with his previous prescription he had "no compliance on uneven ground and poor balance on cambers" and that it was good "when walking". He also added that he had been able to complete an 18 mile charity walk due to its good compliance. On the final review the patient noted that "less thought was required" during walking and that the foot had allowed him to "get on with his life without having to pre-plan journeys".
Patient 4 – The patient felt that the action was smooth and that the foot felt "nice and springy at the end of stance". The patient also commented that "the foot helped activate the knee into swing phase."
Patient 5 – The patient felt that the foot was more stable on the ground and was surprised at the amount of movement that the foot afforded. He also appreciated the cosmetic appearance of the foot shell**.**
Patient 6 – The patient was very impressed with the new prescription as a whole, but found it difficult to separate out which of the benefits he was experiencing was due to the knee and which to the foot. The ease of transition into the swing phase was clearly helped by the foot function and the soft heel strike and rapid planterflexion also helped maintain the stability of the knee in the stance phase, especially when ascending or descending slopes.