



Clinical Evaluation Summary

CES FRE F05

Freedom - Kinterra Foot

Warranty period - 3 Years (6 months Foot shell)

Weight Limit - 125kg

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

The hydraulic ankle unit of the Kinterra is designed to “yield” into planterflexion at heel strike, to accommodate any down slope and then “yield” into dorsiflexion, to provide the necessary support at toe off. The rate of yield for both can be independently adjusted to suit the patient’s gait. A return spring lifts the toe quickly enough to avoid catching the toe at mid swing, should the slope have levelled out. From our evaluation results it would appear to achieve all this very successfully and, despite its low profile, the split carbon fibre element seems to provide a good degree of compliance with a soft, comfortable heel strike, smooth progression to foot flat and good energy return at toe off, but with sufficient deflection to accommodate the up hill slopes. Prosthetists have found it easy to set up, thanks to the wide range of adjustment available.

Indications

Suited to patients in the low to medium impact categories, as defined by the Freedom activity levels

Patients who would benefit from

- An energy storing foot
- Controlled planterflexion and dorsiflexion to aid descending slopes
- Compliant split keel to accommodate uneven ground
- Subsequent decreased socket pressures and stress on the knee, hip and back

Contraindication

Patients whose activity categories fall below or above those outlined in the Freedom activity levels

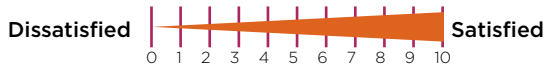
Patients who are over the product weight limit, or whose weight fluctuates to such a degree that the foot function, or safety is compromised

Evaluation Patients

Patient Details

Patient 1	Transtibial	115 kg	35 year old male	Unemployed	Sigam F Freedom 3
Patient 2	Transtibial	80kg	47year old male	IT Support	Sigam F Freedom 3
Patient 3	Transtibial	111kg	59year old male	Unemployed	Sigam F Freedom 2
Patient 4	Transtibial	88kg	54year old male	Unemployed	Sigam F Freedom 2
Patient 5	Transtibial	105kg	50year old male	Farmer	Sigam F Freedom 3
Patient 6	Transtibial	50kg	15year old female	Schoolgirl	Sigam F Freedom 3

Evaluation Result



Current Prescription

Patient 1	Laminate socket with silicone pin liner and Endolite Echelon foot
Patient 2	Laminate socket with silicone pin liner and Endolite Echelon foot
Patient 3	Laminate socket with silicone pin liner and CPI Trés foot
Patient 4	Total Contact socket over TEC liner and suspension sleeve, with Endolite MFFA
Patient 5	Total Contact socket with Iceross X5 Seal In, Endolite MFA on Seattle Lightfoot
Patient 6	Total Contact socket with Iceross X5 Seal In and OB1D10

Prosthetist's Comments

Patient 1 - The patient was offered a chance to try the Kinterra in an attempt to improve his comfort when walking on uneven terrain. The prosthetist found the foot easy to fit and align, thanks to the clear instructions.

Patient 2 - The patient was selected to evaluate this foot since they were already a good user of the Echelon foot and capable of giving good feedback. The prosthetist stated that the instructions were concise and easy to follow. It was also easy to fit and align, thanks to the fitting guidelines provided. He thought the foot was most suited to medium impact activity levels, since the ankle unit seems to function best at moderate to fast walking speeds, and that medial/lateral compliance was less than that of the Echelon and certainly not as good as the Trustep.

Patient 3 - Only a year into his prosthetic rehabilitation, this patient was keen to improve his gait when taking part in his favourite pastime - hill walking. He was briefly given the opportunity to try a CPI Trustep, as well as the Kinterra. The prosthetist found the foot easy to fit and align and in the 3 months that the patient has had the foot, it has needed no attention.

Patient 4 - The prosthetist chose the Kinterra in the hope that it's compliance on slopes would help reduce pressures on the patient's scarred residual limb. The patient lives in a hilly area and likes to walk his dog across country.

Patient 5 - The patient was prescribed the Kinterra foot in the hope of helping reduce his back pain and to improve the longevity of the foot ankle components.

Patient 6 - This young lady was only 5 months into her prosthetic rehabilitation, having had an elective amputation after several surgical procedures to try and correct a severe club foot had left her with a fixed and painful ankle. The other foot and ankle, though affected, were much better. Having progressed well with what had been provided so far, it was decided that a foot with a yielding ankle would help prevent any undue forces on her knee and the other ankle, especially when descending slopes.

Patient's Comments

Patient 1 - The patient stated that he found the new foot a lot better than his old one, commenting that "it does not hamper me when going up and down hills".

Patient 2 - Initial comments were that the foot felt good to walk on, with good energy return. The dorsiflexion assist spring helped when transitioning from a down slope to the flat or an up slope, but reduced his sense of balance when standing on a slope. At the review he stressed again the better energy return of the Kinterra, but also noted that the smaller amount of dorsiflexion improved his balance on flat ground, but gave him a feeling of coming up against the forefoot too soon. He therefore found it harder to stand on an uphill slope and ascending slopes and stairs slightly more difficult, due to the reduced toe clearance. He went back to the Echelon for a few days, but then requested the Kinterra be refitted, finding the positives outweighed the negatives. Note! Other prosthetists that had seen this patient before, confirmed that, due to his other injuries, the patient tends to allow knee flexion on his prosthetic side at mid to late stance, riding the dorsiflexion yield of the Echelon to the end of its range of movement. This may explain, to some degree, why he found the reduced range of dorsiflexion on the Kinterra slightly problematic.

Patient 3 - From day one this gentleman rated the Kinterra very highly. He'd scored his previous prescription -2, due to the difficulty he had going up and down hills. At the end of the evaluation he rated the Kinterra set up at 5.

Patient 4 - Rating his current prosthesis at 3, he immediately commented "brilliant on slopes uphill" and at the first review that it was 100% better than his previous foot, despite a residual limb problem that had been hampering his progress. He felt that the foot was helping to overcome this issue. When contacted by phone over a month later, he stated that a slight noise had developed on rollover, but the foot function was unchanged. The reason for the noise could not be determined over the phone!

Patient 5 - This hardworking farmer had rated his current prosthesis at -3, since he found the foot uncomfortable to walk on. He was immediately impressed with the Kinterra and at the review stage, reported that he'd been able to repair the roof of a farm building, finding it good when walking along it. At the second review he was still as pleased with it and was able to wear it for 18 - 20 hours a day, with no chafing to his residual limb and no backache. Rating it at 4+, he stated "it's the best leg I've ever had" and "I've forgotten I have a false leg".

Patient 6 - Though the transition from the fairly basic foot she'd been initially supplied with, to the Kinterra, was always going to provide her with a significant improvement in her gait, she was thrilled by just how much it achieved for her and very soon wanted to know if she'd "be able to run on it and would it be ok to play football with it?". The benefit to her when descending slopes was very obvious. Though no problems were reported regarding the foot, she has since progressed so much that an alternative foot has now been issued, in order to better accommodate the activities she now wants to get involved in.

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