

CLINICAL EVALUATION SUMMARY - CES FRE F 04

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.

FREEDOM RENEGADE FOOT

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

EVALUATION SUMMARY



Whilst it is clear that this is a foot intended for use by more active individuals, it is surprising how it manages to be so readily usable in lower activity situations. This is born out by the fact that at least two of the patients in the evaluation use it as their only prosthetic foot.

It is also very compliant for this type of foot, and though other feet may be more appropriate where compliance is the major issue, their energy return is inevitably less effective than the Renegade. * It has been reported that, when running over rough ground, soft sand, or severely undulating ground, the foot accommodates the unevenness without compromising the energy return.

Available in standard and low profile versions, neither have a very low build height, but selecting the lower profile has little effect on the function, except at higher activity levels.

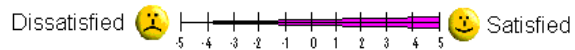
INDICATIONS	CONTRAINDICATION
Suited to patients in the low to very high activity categories, as defined by the Freedom activity levels	Patients whose activity categories fall below those outlined in the Freedom activity levels
Where a foot is required which can be used for routine activities, but which will also enable participation in sport to a reasonably high level	Patients who are over the weight limit, or whose weight fluctuates to such a degree that the foot function, or safety is compromised
For activities where very smooth energy return between heel strike and foot flat, and from foot flat to toe off, would be beneficial	Where walking over very uneven or severely undulating ground make foot compliance the most important function of the foot *
Where a robust, high activity, low maintenance foot is required	Patients requiring a high level of cosmetic appearance, especially if they are of slim build

EVALUATION PATIENTS

PATIENT DETAILS

Patient 1	Transtibial	70 kg	45 year old male	Importer	Sigam F
Patient 2	Transtibial	85 kg	26 year old male	Transport Planner	Sigam F
Patient 3	Transtibial	96 kg	54 year old male	Senior Manager	Sigam F
Patient 4	Transtibial	79 kg	58 year old female	Artist	Sigam F
Patient 5	Transfemoral	80kg	35 year old male	Unemployed	Sigam F
Patient 6	Transtibial	68 kg	19 year old male	Student	Sigam F

EVALUATION RESULTS



CURRENT PRESCRIPTION

Patient 1	Laminate socket with valve and TEC liner, with Reflex VSP foot
Patient 2	PTBSC socket and Variflex foot – replaced first with F1000 and then Renegade
Patient 3	Laminate socket with TEC profile liner and valve, Flex Modular 3
Patient 4	Laminate socket with Iceross Dermo locking liner and Endolite Dynamic Response 2 foot
Patient 5	Seal-In liner suction socket with an Ossur Total knee and Venture foot
Patient 6	Laminate socket with Ossur 600 shuttlelock. Medipro liner and Otto Bock 1D10 foot

PROSTHETIST'S COMMENTS

Patient 1 – This very active Triathlete, who trains for 3 hours every day, had destroyed every type of foot he'd been given. The Renegade was issued, more in desperation than expectation. Though it has proven to be effective and durable, some initial problems were experienced and he currently uses a foot rated 2 categories above that which his weight and activity level would indicate. This is now very effective, having lasted over 18mths with minimal attention, apart from worn foot shells and a broken titanium adaptor.

Patient 2 – This active individual was prescribed this foot because his current foot did not meet his needs. Easily assembled, it proved initially difficult to align dynamically, though reference to the documentation provided solved the problem **4**. Like the above patient he chose not to bother with a cosmetic cover.

Patient 3 – A lacrosse player who, despite his amputation, played for Great Britain, this patient's Flex Modular 3 had eventually cracked and since he was no longer playing, a more appropriate foot was required for use in the gym and as a back up for his other prostheses. The foot was easy to set up and align **4**. He has required minimal maintenance apart from two foot shells in as many years.

Patient 4 – The patient had been having problems with the DR2 foot making noises and was also looking for a more responsive foot. Whilst the prosthetist had no problem setting up the foot, and found it had a satisfactory cosmetic appearance, he concluded at the end of the evaluation that it was more appropriate to the high activity patients. He was also uncertain of the compliance of the foot over uneven ground.

On reflection he suggested that, whilst he had chosen the foot module based on the table provided, the weight and activity level were both borderline and the patient may have benefited from using a "softer" unit.

Patient 5 – This young and very active patient with a transfemoral amputation, whilst already making good use of a CPI Venture foot, needed a second prosthesis and it was felt that this would be a good opportunity to evaluate the Renegade foot. The prosthetist found the foot easy to fit and align. He also thought it had reasonable inversion and eversion, as well as vertical compliance. No attempt has yet been made to fit a cosmesis.

Patient 6 – Whilst this patient was a fairly recent amputee, he had made very good progress and it was felt that a more responsive foot was clinically appropriate. The Low Profile version of the Renegade was chosen since, though very active, he wasn't involved in activities that involved running.

PATIENT'S COMMENTS

Patient 1 – The patient rated the function of his VSP at **5**, but from day one rated the Renegade at **5+++**. The durability he's experienced has only added to that. He declares it "brilliant" and "the best high activity foot I have experienced". This patient participated in the gruelling "Beyond Boundaries" program, taking a spare foot with him just in case, but despite the extreme conditions, he didn't need to make use of it.

Patient 2 – He had found his previous foot rather "flat" when he jogged on it, but despite the time it took to set it up, he initially scored the Renegade at **4**, increasing it to **5** when he'd had the opportunity to try running on it, stating "the more I put in the more I get out". He also found it easier for balancing on a ladder!

Patient 3 – Having used the Flex Modular 3 for several years of competitive lacrosse, his only negative comment was to say that it caused problems on uneven ground and required effort on his part before it gave back the performance he needed. No longer playing, but still wanting to keep fit, a more compliant energy storing foot was required, one that could possibly also be used on a day to day basis. He was delighted with it at the fitting stage, immediately running on it, even in the confines of the fitting room. He is still impressed by it, using it every day as his preferred prosthesis, as well as at the gym or jogging round the countryside with his dog. "If only I'd had this when I was seventeen, who knows what I could have achieved", was probably his most telling comment.

Patient 4 – Rating her current limb with the DR2 foot at **between 2 & 3**, her initial criticisms of the Renegade were that "roll over" was more difficult. She also felt the limb was shorter, even though it was set up at the same length. She disliked the rather "thick" ankle and would have preferred a split toe option. She wasn't happy with the finished shape and after a months use, requested her Endolite DR2 be refitted, feeling that her activity level had been significantly reduced, her score of **1** reflecting this.

Patient 5 – Scoring the Venture foot at a fair **2 to 3** despite commenting that it felt like an "entry level starter leg", he scored the Renegade **4**, since it "flexed more, giving a more natural step". He immediately felt that he may be able to run on it and has since started playing badminton and jogging again. His every day activities have not been affected detrimentally and no wear noted over the short time he's had the foot.

Patient 6 – Scoring his current prosthesis at **1**, he acknowledged that, as a first issue prosthesis, it was OK. The compliance and responsiveness of the Renegade noted by the prosthetist, was expressed by the patient as "it rolls better". At the review he stated that he was "able to walk more briskly and jog, if required", though perhaps his most telling comment was, "I don't have to think about using the leg as the foot responds as I want it to" **3**.