

Clinical Evaluation Summary

CES FRE F02

Freedom - Sierra (F1000) Foot

Warranty period - 3 Years (6 months Foot shell)

Weight Limit - 166kg



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 retrospective evaluation of the Freedom F1000 foot, whilst it demonstrates the effectiveness of the foot, also majors on one particular failing of the original design, namely the poor cosmetic shape that could be achieved, which was caused by the anterior positioning of the pyramid mount and the width of the spring at the posterior curve. Whilst the position of the pyramid made alignment easy, the resultant undesirable cosmetic shape did create such an adverse reaction that some modifications to the design were clearly necessary. Freedom have since redesigned the foot and the cosmetic appearance that can be achieved, has been significantly improved, without any noticeable reduction in the function. To help with this they have also produced a two-part foam, already cut out to accommodate the ankle and shin tube and only requiring to be ground out to take the socket, glued together and shaped to match the patient's sound side.

Indications

Most suited to the moderate and high activity categories, as defined by the Freedom activity levels.

Where a patient requires a foot which can be used for their routine activities, but which will also allow them to participate in sports.

For activities where smooth energy return between heel strike and foot flat, and from foot flat to toe off, would be beneficial.

Where a robust, low maintenance foot is required.

Contraindication

Patients of low activity or less, as defined by the Freedom activity levels.

Patients whose weight fluctuates frequently to any significant degree, or who are over the weight limit.

Where uneven ground and/or frequently undulating ground has to be negotiated regularly.

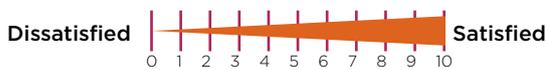
Patients requiring a high level of cosmetic appearance, especially if they are of slim build.

Evaluation Patients

Patient Details

Patient 1	Transtibial	96 kg	39 year old male	Engineer	Sigam E
Patient 2	Transtibial	74 kg	33 year old male	Unknown	Sigam F
Patient 3	Transtibial	90 kg	31 year old male	Unemployed	Sigam F
Patient 4	Transtibial	70 kg	26 year old male	Property Developer	Sigam F
Patient 5	Transtibial	60 kg	42 year old male	Sheetmetal Worker	Sigam F
Patient 6	Transtibial	111 kg	63 year old male	Hospital Porter	Sigam F

Evaluation Result



Current Prescription

Patient 1	Laminate Condylar Bearing Munster socket with Variflex foot replaced
Patient 2	Laminate socket, Iceross with Icelock 600 shuttlelock
Patient 3	Laminate Iceross socket
Patient 4	Laminate socket, Iceross with Icelock 600 shuttlelock
Patient 5	Laminate socket, Iceross with Icelock 100 shuttlelock with Variflex foot replaced
Patient 6	Laminate PTB Supracondylar socket with Variflex foot replaced

Since this is a retrospective evaluation summary, the build includes the Sierra (F1000) foot, but where applicable comparisons with any previous build are included in the comments.

Prosthetist's Comments

Patient 1 - No problems with the instructions 4. Easy to assemble and set up, but experienced some problems with noise from the split toe sections rubbing together. The cosmesis was very poor (old style foot), both the overall shape and the foot shell -5. Durability and function have been good however scoring 5 and 4 respectively.

Patient 2 - The patient was supplied with this foot because he had found previous feet had restricted his activity in the gym. He has not returned to the centre for over 18 months.

Patient 3 - This foot was chosen because of the high activity sport this patient is involved in. The foot needed to be replaced after 2 years, though the prosthetist had hoped for greater durability.

Patient 4 - This ex-soldier, was provided with an Elation foot on his first limb, but needed a foot on his second limb that would enable him to get back to playing football, cricket and running, amongst other things. The cosmetic shape, if important to the patient, would clearly be a problem (old style foot). Easy to set up from recommended bench alignment 4.

Patient 5 - This active guy was supplied with this foot because of the level of his activity.

Patient 6 - Despite his age, this fairly heavy patient is still a very active user, but was having problems with the Variflex foot that had previously been supplied.

Patient's Comments

Patient 1 - The patient has been wearing this foot for nearly 3 years and still finds the function good, but thinks the cosmetic shape poor, even though not "fussed too much" by it.

Patient 2 - On eventually attending the centre, over 18 months since delivery, he rated everything about the foot at 5. It was still in good condition despite his having used it for numerous gym activities including running.

Patient 3 - This young man gets involved in motocross and simply states that he is satisfied with the foot, rating it at 5.

Patient 4 - Attending for a fitting on a new socket for this limb, he says the socket has recently prevented him from using the limb, but until then had played numerous sports on it. He feels there is a slight dead spot at mid stance, but otherwise feels it is very springy. Alignment of the new socket may help reduce the dead spot feeling. It is still in good condition after over 2 years of use. He is not bothered about the cosmetic shape.

Patient 5 - This patient serves to demonstrate one of the contraindications for this foot. He found it walked well on level ground, but felt it gave little help on steep hills or uneven ground, scoring it at -1.

Patient 6 - The patient uses the foot to walk long distances and also to ride a motorcycle. He describes it as "brilliant" and "better than the Variflex", with a "smooth action". He does state that it took a bit of effort to fine tune it in order to get the best from it. He was not bothered at all by the cosmetic appearance.

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