



Clinical Evaluation Summary

CES FRE F08

Freedom Catapult Foot

Warranty period - 12 Months

Weight Limit - 166kg Jogger
- 147kg Runner
- 116kg Sprinter

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

Building on their experience with the Nitro running blade, Freedom developed the Catapult, with the aim of providing the user with a running blade that could be tuned, so as to make it adaptable for different applications, or to keep up with improvements in the users' ability. Each foot is supplied with three secondary Power Springs, appropriate in strength to that of the main C spring, which is based on the patient's activity level and weight. Swapping the springs is not as simple as trying a different running shoe, but can be achieved by the user and does appear to increase the energy return and also to make the foot function adjustable. The Power Springs also increase medial/lateral stability, making it excellent when used on an even surface, but slight less so when running on very uneven terrain, such as trail running.

Indications

Patients who would benefit from a running foot that:

- Gives high energy return
- Can be adjusted suit different activities
- Can be adjusted to keep up with improved ability
- Provides good medial/lateral stability
- Goes to a high weight limit

Contraindication

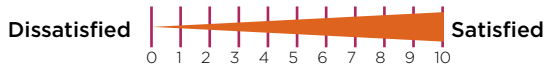
Low and moderate activity patients
Patients outside the weight limits of the foot
Users who want to run on uneven terrain
Patients with long residual limbs, due to build height of the foot

Evaluation Patients

Patient Details

Patient 1	Transtibial	75kg	49 year old male	Director	Sigam F	Freedom 5
Patient 2	Transtibial	85kg	50 year old male	Electronics Engineer	Sigam F	Freedom 4/5
Patient 3	Bilateral TT	62kg	25 year old female	BBC Journalist	Sigam F	Freedom 4
Patient 4	Transtibial	66kg	39 year old male	Phychologist	Sigam F	Freedom 5
Patient 5	Transtibial	59kg	31 year old female	Quality Surveyor	Sigam F	Freedom 3/4
Patient 6	Transtibial	86kg	55 year old male	Builder	Sigam F	Freedom 4

Evaluation Result



Current Prescription

Patient 1	Lam socket, Medi Protect 3C Cushion liner, Contex Gel sleeve and Freedom Renegade
Patient 2	Laminate socket, Alps Liberty liner and Ossur Flexrun foot
Patient 3	Laminate TSB socket, TEC vacuum system and Freedom Sierra feet
Patient 4	Laminate TSB socket, TEC vacuum system and Ossur Flexrun foot
Patient 5	Laminate TSB socket, with silicone pin liner and Ossur Elation foot (no running foot to date)
Patient 6	Laminate TSB socket, Iceross pin liner and CPI Truststep foot

Prosthetist's Comments

Patient 1 – The patient had started to increase the frequency and lengths of his runs and had started to take part in 10k events. He wanted to improve his performance and, although he felt that his current prosthesis was very good, scoring it 4, wanted to see if a dedicated running prosthesis would help him achieve more. Set up was easy and the only fault was with the sole tread, which wore rather quickly. A trainer sole was glued on instead and this proved more effective.

Patient 2 – A keen runner, entering events from 5k to marathons, he has found his Flexrun fine for longer distances, but too firm over short distances. Wanting to see if the Catapult would enable him to “tune” the foot to suit, he was given the opportunity of a three week trial. There were no problems with the set-up, though the sole tread did have to be glued back after a short period.

Patient 3 – Already running 100m in 17secs, she was advised by her coach that running blades would be needed to help her make further progress. The Catapults were chosen since the additional springs increase the medial/lateral stability, as well as allowing the feet to be adjusted to suit the running style. Freedom recommended cat 5 springs and the secondary spring was left unchanged at the fit/delivery stage. The prosthetist expressed some concern regarding achieving the alignment shown in the diagram provided with the feet, but felt that the feet were functioning correctly and “look the business”.

Patient 4 – Already running significant distance and, unusually for this type of foot, across fells and trails, he was given the opportunity to trial the Catapult, to see how it would compare with the Flexrun, especially as he has used both versions of that product. There were no problems with the set-up, though, due to the type of running he normally participates in and the fact that it was a trial foot, he had to limit the trial slightly.

Patient 5 – Having been keen on running prior to her injuries, regularly running 6 to 9 miles (10km to 15km), this young woman was keen to get going again. The prosthetist was interested in trying the Catapult and exploring its features, in an attempt to find the optimum set up for the patient. Though the patient was very light the prosthetist was impressed by the maximum weight limit available and also by the lower build height compared with other similar feet. Set-up and alignment proved to be easily achieved.

Patient 6 – Keen on keeping fit by attending a gym, cycling and running, this gentleman felt that he needed a foot more appropriate for running. His prosthetist chose the Catapult to allow the opportunity to customize its function to the patient's ability. No problems were encountered in set-up or alignment.

Patient's Comments

Patient 1 – He liked the appearance of the foot and apart from the sole tread issue, has had no problems with it. Whilst has not taken up any new sporting activities, he states that he now finds running easier, he runs more and has increased his activity level.

Patient 2 – The ability to swap the springs and “tune” the foot was found to be a very positive feature of the foot, but after some time using it he felt that the main spring, cat 6, was too stiff. His schedule didn't allow him to try a softer spring at this stage, but he wanted to take up that option when possible.

Patient 3 – The patient was delighted with the feet and was soon bouncing around on them and was confident enough to take them without any further training. Unfortunately her job took her out of the catchment area for the centre and therefore further feedback has not been possible.

Patient 4 – He stated, even after a fairly short trial period, that he felt that the Catapult feel somewhere between the 1st and 2nd generation versions of the Flexrun, though lighter than either of them. He felt that the addition of the secondary spring made the foot feel too stiff for his liking, causing the energy return to come too soon, creating a jarring sensation. He also felt that it prevented the primary blade from “loading” completely and also prevented inversion/eversion, making it harder on uneven ground or tight turns. Given the type of running he does this is an understandable issue, but a lower category primary spring may have been better, as for Patient 2.

Patient 5 – Though the patient gave no direct feedback, suffice to say that, though a private patient, she chose to purchase the foot following a trial period.

Patient 6 – The patient gave little initial feedback, other than to state that it was easy to walk on, good to run on and pleasing to look at. At the review he added very little, but added that he'd increased his sporting activities and that it had, thereby improved the quality of his life. It had needed no attention and he felt it was a reliable product.

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