



Clinical Evaluation Summary

CES FRE F07

Freedom Dynadapt Foot

Warranty period - 3 Years

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

The Dynadapt has clearly been produced to compete against the current Ossur Variflex foot. The evaluations show that it is indeed possible to use it as a direct swap out for that product, since its build height and alignment are the same and the function is very similar, though the usual design features of the Freedom products do seem to provide greater energy return, a slightly smoother roll over and improved compliance.

To limit it to that role though would be to overlook both the effectiveness of the design and the benefits of the subtle improvements that Freedom has made to it. Whilst the build height is greater than that of the Sierra, for example, the longer spring gives even better energy return and makes it easier to produce a good ankle cosmesis for those patients where the build height can be accommodated.

Indications

Patients that would benefit from a foot:

- Lightweight for its activity level
- Smooth in its roll over action
- Reasonably compliant with good energy return
- Slender at the ankle to allow a good cosmesis
- Has a sandal toe option

Contraindication

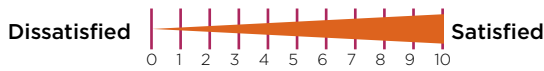
Patients outside the weight limit of the foot
Low activity patients (below Freedom's low).
Long residual limb, due to build height
Where high levels of compliance are required.

Evaluation Patients

Patient Details

Patient 1	Transtibial	116kg	60 year old male	Engineering Inspection	Sigam F	Freedom 4
Patient 2	Transfemoral	75kg	34 year old male	Unemployed	Sigam F	Freedom 3
Patient 3	Transtibial	100kg	69 year old male	Retired	Sigam E	Freedom 3
Patient 4	Transfemoral	85kg	25 year old male	Personal Trainer	Sigam F	Freedom 4
Patient 5	Transtibial	79kg	56 year old male	Office Worker	Sigam E	Freedom 4
Patient 6	Transtibial	115kg	41 year old male	Unemployed	Sigam E	Freedom 3

Evaluation Result



Current Prescription

Patient 1	Laminate TSB socket, silicone pin liner and Ossur Variflex foot
Patient 2	Laminate socket, silicone pin liner, Freedom Plié knee and Highlander foot
Patient 3	Laminate socket, silicone pin liner and Freedom Senator foot
Patient 4	Ischial containment socket with pin liner, Endolite KXO6 knee and Ossur Variflex foot
Patient 5	Laminate TSB socket, Medi Soft C liner, Ossur 600 lock and CPI Très foot
Patient 6	PTB supracondylar socket, with Juzo sleeve and CPI Très foot

Prosthetist's Comments

Patient 1 - Since this gentleman was already a good user of a Variflex which now needed to be replaced, opportunity was taken to trial the Dynadapt. The prosthetist found no problems swapping out the feet and setting up the alignment, and there were no issues in producing the cosmesis.

Patient 2 - This young man was supplied with the Dynadapt in an attempt to measure its effectiveness against the Highlander, especially in a transfemoral application, where Freedom has always promoted that product. He has found the Highlander to be an effective foot, though his prosthetist had always felt that it seemed a little too stiff for him, possibly contributing to the lateral rotation he experiences at heel strike.

Patient 3 - The Dynadapt foot was provided for this active gentleman, since he found the Senator foot a little too stiff, especially when walking down a slope. The prosthetist had no problem setting it up, finding that very little adjustment was required from the bench alignment. At a later review the prosthetist commented that the foot seemed to have a "lovely smooth roll over", with no problems or noises, declaring it to be "a great foot".

Patient 4 - Since the patient was finding the Variflex a bit too stiff, the prosthetist decided to replace it with a Dynadapt. The hope was that it would be a little softer, but would still give energy return. It proved easy to set up with the comment at the final review, that "it is a really nice foot, compliant, smooth roll over, with no dead spot" and that "the patient seems to like it better than the Variflex".

Patient 5 - Three years into his rehabilitation, this active gentleman was struggling to achieve the level of activity he wanted, so was trialled on the Medi Panthera CF1 and the Dynadapt. The prosthetist had no problem setting up either foot, but understandably felt the Dynadapt provided the higher level of dynamic response, which the patient seemed to want. It still seemed "flexible and responsive" though "more dynamic than compliant".

Patient 6 - The prosthetists was looking for a more compliant foot, with a smoother roll over that would help reduce the socket forces. It needed to be able to tolerate a wet environment, have a full length toe lever and energy return, with good support in standing stance. The prosthetists found no problem in setting up and aligning the prosthesis.

Patient's Comments

Patient 1 - The patient immediately commented on the increased "springiness" of the foot and nearly three months later stated that this seemed to have made walking a "little easier". He wasn't so sure that it provided a level of compliance that was greater than the Variflex, but did remark that the "foot feels flatter to the ground".

Patient 2 - At delivery, he immediately noticed the increased benefit of the longer spring in the Dynadapt, both in terms of its energy return and its compliance and has continued with it since then, though the rotation at heel strike has only reduced very slightly.

Patient 3 - The patient's initial comment was simply that it "seems much better than the old one" and even after 3 months his only comment was that it had made some activities "a little easier". At a later review the prosthetist noted that "the patient is very happy".

Patient 4 - At the delivery stage the patient declared the foot to be easy to walk on, with "more movement than the old foot". At the review stage, whilst it had not enabled him to take up any new activities, he did feel that there was more movement in the foot which made some things easier.

Patient 5 - The response of the patient to the change of foot was very positive. Rating his previous set up 3, he increased it to 4 with the Dynadapt. Though not involved in any sporting activities, he was now doing more walking, finding the foot significantly better going up and down hills.

Patient 6 - Wanting to get back to doing some sporting activities, the patient was pleased to report that he'd been able to make progress in that direction since getting the Dynadapt. He'd also found it easier when walking his children to school and when walking uphill. He'd lost some weight on account of his increased activity level and was looking forward to getting back to the gym and the pool.

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