steeper
Creating life's turning points, together

Clinical Evaluation Summary

CES **OSS** K00

Össur - Monolock NOFM0 knee

Warranty period - 3 Years

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

It appears from these evaluations, that this lightweight monocentric knee is easily unlocked, even when there is some weight still on the prosthesis and, on standing, locks with a very positive and audible click. This makes it ideal and very safe for the application it was designed for. When flexed, despite its slightly posterior pivot point, it only "bird-mouths" a little and the design of the upper section still provides a knee profile that allows a good cosmetic shape to be achieved.

Indications

Low activity patients. Medi I.

Primary patients who only need a lightweight SAKL, with no likelihood of progressing to a free knee.

Where there is a particular need for easy operation of the lock mechanism, to provide safe transition from standing to sitting.

Contraindication

Reasonably active patients. Above Medi I.

Patients requiring greater swing phase control, or who do no need a lock option at all.

Where a very low build height is required above the knee.

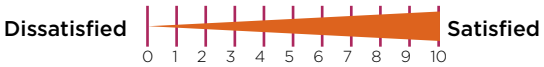
Patients above 125kg

Evaluation Patients

Patient Details

Patient 1	Transfemoral	56 kg	79 year old male	Retired	Sigam Cd
Patient 2	Transfemoral	67 kg	74 year old male	Retired	Sigam Cd
Patient 3	Transfemoral	53 kg	69 year old male	Retired	Sigam Cd
Patient 4	Transfemoral	81 kg	61 year old male	Retired	Sigam Dd
Patient 5	Transfemoral	86kg	81 year old male	Retired	Sigam Cd
Patient 6	Transfemoral	68 kg	79 year old male	Retired	Sigam Cd
Patient 7	Transfemoral	67 kg	62 year old male	Retired	Sigam Dd
Patient 8	Transfemoral	49 kg	62 year old male	Retired	Sigam Dd
Patient 9	Transfemoral	66 kg	85 year old male	Retired	Sigam Dd

Evaluation Result



Current Prescription

Patient 1	**Primary** – Quadrilateral socket, RPB suspension and SACH foot
Patient 2	**Primary** – Quadrilateral socket, TES belt suspension and CPI Trés foot
Patient 3	Ischial Containment Socket, TES belt suspension, Medi NOFM2 knee and CPI Trés foot
Patient 4	**Primary** – Quadrilateral socket, TES belt suspension and SACH foot
Patient 5	**Primary** – Quadrilateral socket, TES belt suspension and SACH foot
Patient 6	**Primary** – Quadrilateral socket, TES belt suspension and CPI Trés foot
Patient 7	**Primary** – Quadrilateral socket, TES belt suspension and CPI Trés foot
Patient 8	**Primary** – Quadrilateral socket, TES belt suspension and CPI Trés foot
Patient 9	**Primary** – Quadrilateral socket, Silesian belt suspension and OB 1G6 foot

Prosthetist's Comments

Since all the patients, except Patient 3, were being prescribed their first issue prosthesis, the Sigam Mobility Grades shown are all anticipated grades and, following examination by the Rehabilitation Consultant; assessment by the Physiotherapist and in consultation with the Prosthetist, the prescription was decided and agreed by the MDT.

Unfortunately Patient 3 did not achieve his originally anticipated level of activity and, due to his ill health and increasing frailty, was not coping with the weight of the NOFM2 knee originally prescribed. Consequently he was issued with the NOFM0 which he managed more easily.

The Medi NOFM0 knee was chosen because it is lightweight and appeared to be robust and easy to operate, though all, except Patient 9 (see Patient Comments), were set up with the Endolite thigh release lever, simply because levers are the preferred option at the centre where the patients were being rehabilitated.

With a three year warranty and a very reasonable price, the MDT agreed that it was a cost effective option.

Patient's Comments

The fact that, as primary amputees, all but one of the patients had no experience of any other prosthesis, meant that there was little they could comment on at this stage in their rehabilitation. It was therefore decided to simply canvass the opinions of the Physiotherapists, Prosthetists and Prosthetic Technicians, in an attempt to determine whether there were any significant positives or negatives with this knee, over those that had previously been issued to such patients.

The only exception to this was Patient 9 who, having been set up with the standard Medi thigh release and despite having no knowledge of the options available, asked if it could be changed for something "less bulky and easier to use". It was replaced with the Ortho Europe actuator.

The Physiotherapists were surprised at how many had been issued, but had nothing negative to report. They couldn't recall there being any issues with the knees at all, but had noted a marked change in the way they were able to teach the patients to transition from standing to sitting. They found this much easier, since there was not the need to get the patient to off load, or toe load the prosthesis in order to unlock the knee. They discourage the patients from keeping the knee loaded, but find that the knee unlocks easily, even if there is some load on it.

The Prosthetists have all found the knee easy to use, with no problems setting up the alignment. Setting up the thigh release can only be effectively done once the appropriate alignment has been achieved, but this has caused no problems.

The Technicians have had none of the knees come back with play in them, or any other problems and have found it simple to assemble and set up in the prosthesis. They have also found no problem when producing the cosmesis.