



Clinical Evaluation Summary

CES OSS K01

Össur - NOFM1/NKFM1 knee

Warranty period - 3 Years

Weight Limit - 136kg

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 polycentric knee, allows prosthetists the opportunity to prescribe it as a free knee, with inherent geometric stance stability, but with the option of adding a semi automatic or manual lock, if the progress of the patient's rehabilitation should require it. It is particularly useful where a low above knee build height is also required.

Indications

Low to medium activity patients. Medi I and II.
Primary patients who, in the opinion of the M.D.T needs a SAKL in order to start rehabilitation, but who may progress to a free knee, providing good stability is available. The option of a manual knee lock can be retained if required.
Users of SAKL knees who need a low AK build height, (to improve the cosmesis or accommodate additional hardware) or who wish to progress to a free knee, whilst still retaining good stability with a lock option. *
Free knee users whose condition has deteriorated, requiring greater stability and maybe needing a SAKL in due course. *
Short build length required.
Very low AK build height required (NKFM1).

Contraindication

Reasonably active patients. Above Medi II.

Patients requiring greater swing phase control, or who do not need a lock option at all.

Patients who only need a lightweight SAKL, with no likelihood of progressing to a free knee

Where the patient has become dependant on some other form of stance control, such as weight activated.

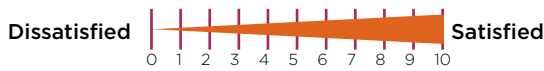
* It is imperative that the M.D.T assess very carefully the current limb use, not just the gait, but every aspect of the patient's activity before choosing to change any components.

Evaluation Patients

Patient Details

Patient 1	Transfemoral	63.5 kg	74 year old male	Retired	Sigam E
Patient 2	Transfemoral	60 kg	82 year old female	Retired	Sigam D
Patient 3	Transfemoral	64 kg	61 year old male	Retired	Sigam D
Patient 4	Transfemoral	70 kg	61 year old male	Retired	Sigam D
Patient 5	Transfemoral	50kg	15 year old male	Schoolboy	Sigam Dc
Patient 6	Transfemoral	70 kg	44 year old male	Unemployed	Sigam C

Evaluation Result



Current Prescription

Patient 1	Endolite Uniaxial Knee with SAKL and Multiflex foot.
Patient 2	Iceross socket. Otto Bock 3R33 with HOKL and Multiflex foot
Patient 3	Primary
Patient 4	Quadrilateral socket with TES belt, Endolite UK SAKL and Multiflex foot
Patient 5	Iceross socket. OrthoEurope Easy Knee SAKL and Multiflex foot
Patient 6	Endolite SK with PSPC, RPB suspension and Multiflex foot, but he has been unable to wear it for some time due to various health problems.

Prosthetist's Comments

Patient 1 - NOFM1 Ease of alignment scored 4 and other adjustments 3. Due to its short build height cosmesis scored 4, with durability at 3. The thigh release was problematic -2.

Patient 2 - NKFMI Easy to align and adjust 4. It was chosen because of the short build and manual knee lock option, with the possibility of progressing to a free knee. The thigh release proved problematic.

Patient 3 - NOFM1 Assembly, alignment and adjustment were simple enough 4, but the thigh release proved a problem -2. The patient quickly started to use the knee unlocked, finding it stable and smooth, despite only having a friction control swing phase 4.

Patient 4 - NOFM1 Patient was chosen because he has the potential to use a free knee, but should benefit from the stability of the 4 bar geometry and the MKL option. It was easy to assemble, but needed a better thigh release. Ease of alignment 4. The unit enabled the patient to walk well 5.

Patient 5 - NOFM1 chosen for this boy because he was showing the potential to progress to a free knee, despite being a Hip Disarticulation amputee on the contralateral side. No problems with general assembly 4. The thigh release had to be replaced with an alternative.

Patient 6 - NOFM1 Chosen because the current prosthesis is now unsafe for him, this knee was set up for use as a SAKL, but with the option to progress to a stable free knee.

Patient's Comments

Patient 1 - Initial comparison with the current prosthesis scored 3 and the patient was satisfied with the cosmesis and with the function of the knee when walking. The knee was completely let down by the thigh release, until an alternative was fitted. **

Patient 2 - Liked the knee from day one, but progressively improved and now has had the lock removed completely since she feels the knee is stable enough without.

Patient 3 - Since the patient was a primary he had nothing to compare the knee with, but walked it as a free knee very quickly, only using the lock when additional security was required 4. Unfortunately the patient was not recalled for 3 months and the socket was too tight to use for the last month. Once the new socket had been produced he immediately walked with a free knee again. No signs of wear at the review 4.

Patient 4 - The only comment the patient made on the questionnaire was, "Very effective, good." 5.

Patient 5 - The patient is a teenage boy and a relatively recent traumatic bilateral amputee, (Transfemoral with NOFM1 & hip disarticulation with NHM3 & NOM8) and therefore his comments on the function of the knee have been limited. His progress on them speaks for itself however. He is walking with crutches and has now progressed to walking with a free knee on both sides.

Patient 6 - Since the patient had used a free knee in the past and was now unsafe on it, he had very little positive to say about the new item. He wanted to be free of the SAKL as soon as possible. Thigh release was a real problem, both because of its bulk and because it didn't function very well either. At a later date we effectively removed the lock to see if he could cope without it. Due to the knee being very stable in stance phase he did well and scored it 4.

** The original thigh release was a problem every prosthetist and patient commented on. An alternative has since been developed by Medi in response to these Clinical Evaluations and the Clinical Support Group have also produced instructions for the use of a lever type actuator, if preferred.

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