



Clinical Evaluation Summary

CES OSS K02

Össur - NOFM2 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

This monocentric knee, allows prosthetists the opportunity to prescribe it as a free knee, with sensitive weight activated stance stability, but with the option of adding a semi automatic (SAKL) or manual, hand operated lock (MKL/HOKL), if the progress of the patient's rehabilitation should require it.

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.

Free knee users whose condition has deteriorated, requiring greater stability and maybe needing a HOKL or SAKL in due course. *

Where a very short build length is required. **

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 geometric stability.

* 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.

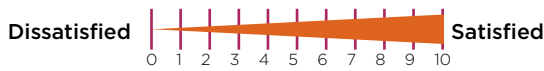
** The total height is 115mm including the pyramid. Please see the catalogue for all the other dimensions.

Evaluation Patients

Patient Details

Patient 1	Transfemoral	74 kg	60 year old male	Unemployed	Sigam Da
Patient 2	Transfemoral	71 kg	63 year old male	Retired	Primary
Patient 3	Transfemoral	76 kg	60 year old male	Unemployed	Sigam F
Patient 4	Transfemoral	62 kg	59 year old female	Retired teacher	Sigam D
Patient 5	Transfemoral	77 kg	70 year old male	Retired	Sigam C
Patient 6	Transfemoral	72 kg	71 year old male	Retired	Primary

Evaluation Result



Current Prescription

Patient 1	Laminate socket, Icelock 600, Alphamax liner. ESK, PSPC with MKL and Multiflex foot
Patient 2	Primary prescription
Patient 3	Flexible inner socket with valve, Seal-In liner, Total knee and Seattle Lightfoot
Patient 4	Laminate socket with Seal-In liner, Otto Bock 3R49 and Variflex foot
Patient 5	Primary prescription
Patient 6	Primary prescription

Prosthetist's Comments

Patient 1 - For safety, this patient now requires an increased level of stability in stance, but still wants to try and use a free knee, although he likes to use the HOKL when standing still and may need to use it more frequently as time goes by. The very positive lock and the internal spring assist were the two features of this knee that were noted by the prosthetist. The thigh release* and rather hard terminal impact bumper were the only negative issues mentioned.

Patient 2 - Chosen as the primary prescription in order to provide good stability when used as a free knee, but with the benefits of a lock option, the prosthetist found its assembly, alignment and adjustment very easy. Good stability and smoothness of action were both noted. Though not worn for very long, the knee gave no problem.

Patient 3 - Looking for a locked knee option, with increased stability even when used as a free knee, this unit was chosen. The prosthetist found its assembly, alignment and adjustment "OK" 4. The large socket required greatly hindered the function of the lock mechanism -2, though the knee appeared to be very stable in stance and smooth in the swing phase.

Patient 4 - This patient's contralateral leg was also badly damaged in the incident which resulted in the amputation; this limits her gait and general mobility. Nonetheless she doesn't like too much stance control and doesn't require much swing phase control. The prosthetist managed to achieve the necessary balance between these two factors, providing her with the security she needed and the swing control she likes, though it took a couple of attempts to get the adjustments just right.

Patient 5 - When the knee was prescribed, this patient was a primary amputee with a predicted Sigam C mobility grade, but with uncertainty as to whether this would be achievable most safely with a fixed or a free knee. The unit has required no maintenance or adjustment, other than to convert it from a HOKL to a free knee with the lock option completely removed.

Patient 6 - This gentleman, when he presented as a primary, appeared capable of managing with a free knee and was keen to try to do so, but his contralateral limb was showing some signs of being at risk. Therefore, the NOFM2 was chosen to accommodate the possibility that it may deteriorate sufficiently for him to require a lock option.

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

Patient's Comments

Patient 1 - Whilst the patient found the knee better and he felt safer on it 3, he felt the failure of the thigh release to always function as it should was problematic. The socket was also giving him problems, as was residual limb volume fluctuation. It should be noted that the prosthetist was concerned that the patient sometimes forgot to lock the knee when he really needed to and felt it would be better if he could be persuaded to have it converted to a SAKL, this being possible using the same knee unit.

Patient 2 - Though the patient found no problem with the knee unit, scoring it 4, in fairness he had nothing against which to compare it and unrelated health problems caused him to abandon his prosthetic rehabilitation a month after the delivery.

Patient 3 - Having struggled with the "lock" effect of the Total Knee, he rated it at 2. Despite the thigh release problems of the NOFM2 (see above), he scored it 4, finding the action of the knee to be smooth and stable when used as a free knee. Even the lock was declared "good" once the thigh release issues had been sorted out.

Patient 4 - The patient preferred the NOFM2 to the 3R49, once the correct set up had been achieved. Though she scored both 4, she found the NOFM2 less bulky and more reliable. It was initially too sensitive in the stance control and she found this very difficult, but once it was set up correctly, she found no functional difference between the two units.

Patient 5 - After an initial period of training the lock option was removed and the patient now uses the prosthesis with a free knee, finding the brake to be so effective that he has confidence in it, even when walking outdoors 4.

Patient 6 - Unfortunately the early expectations for this patient were not realized, due to the deterioration of his contralateral limb. Though surgery has improved the situation, he has only now begun any significant prosthetic rehabilitation and is using the knee as a SAKL at the moment. Whether he ever achieves sufficient confidence or ability to attempt to use the unit as a free knee remains to be seen.

Note! Most of the units evaluated were the original 100kg weight limit versions, but all new units are now rated at 125kg, following the introduction of an updated version.

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