

Clinical Evaluation Summary

CES OSS K03

Össur - NKHP3/NOHP3 knee

Warranty period - 3 Years

Weight Limit - 100kg



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 design includes long side links which when combined with the high performance pneumatic cylinder results in a smooth and controlled swing phase. Stance phase stability is achieved by virtue of the geometry of the polycentric unit. The knee is available with both male pyramid and lamination adaptor distal attachments therefore making this knee suited for any level of transfemoral amputation, but especially those with long residual limbs, and knee disarticulation amputees. The knee is recommended for use with patients of mobility class 3. The results of the evaluations to date would suggest that the enhanced performance of the pneumatic cylinder combined with the geometry of the knee does indeed produce a smooth swing phase for the amputee.

Indications

Patients who would benefit from -
Stance phase control offered by the geometrical stability of the knee design.
Independent flexion and extension swing phase adjustment.
Fluid swing phase with increased ground clearance and enhanced pneumatic performance and adjustability.
Short build height with alignment (especially short with the K version)
Large knee flexion required (Max. 150°)

Contraindication

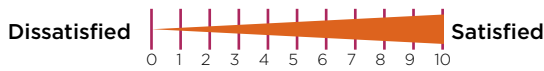
Patients who -
Are of low or very high activity
Exceed 100kg
Require very high levels of stance phase stability
Who are unable to toe load effectively at the end of stance in order to release the knee.

Evaluation Patients

Patient Details

| | | | | | |
|------------------|--------------|--------|-------------------|------------|---------|
| Patient 1 | Transfemoral | 80kg | 75 year old male | Retired | Sigam F |
| Patient 2 | Transfemoral | 102*kg | 35 year old male | Stonemason | Sigam F |
| Patient 3 | Transfemoral | 74kg | 37 year old male | Unemployed | Sigam F |
| Patient 4 | Transfemoral | 80kg | 55year old female | Unemployed | Sigam D |
| Patient 5 | Transfemoral | 74kg | 74year old male | Retired | Sigam D |
| Patient 6 | Transfemoral | 49kg | 65year old female | Retired | Sigam E |

Evaluation Result



Current Prescription

| | |
|------------------|---|
| Patient 1 | Laminate Quad socket Tran femoral Locking liner, KFM1 knee, Tribute Foot |
| Patient 2 | (First prosthesis) Laminate Quad socket, NOHP3 knee, Axia foot |
| Patient 3 | Medi AKOS liner on a polypropylene socket with Medi Imatik knee and CPI Truststep |
| Patient 4 | No previous/current prescription. |
| Patient 5 | No previous/current prescription |
| Patient 6 | No previous/current prescription |

Prosthetist's Comments

Patient 1 - Due to increased mobility the primary prescription was no longer appropriate. Upon supply of the changed prescription additional physiotherapy support was provided. He adjusted excellently to his knee reporting that it felt smooth. His gait improved dramatically and he achieved symmetry in swing phase. The pneumatic cylinder proved easy to adjust to achieve optimum swing, with small alterations resulting in greater changes than would normally be expected from a pneumatic cylinder.

Patient 2 - This gent became an amputee as a result of RTA prior to which he had been an active and healthy individual. This knee was prescribed because this gent appeared to fill all of the manufacturers recommended criteria. It was anticipated that this gent would be suited to the benefits of fine adjustment afforded by a hydraulic cylinder. This cylinder has proven to be adequate for this gent's gait. He walked at a varied cadence and the cylinder could be adjusted to accommodate this with small adjustments. Swing phase is very smooth in appearance.

Patient 3 - Previously prescribed Endolite IP+ and OrthoEurope Sensor knees the patient liked the speed change feature of the IP+, steps descent feature of the Sensor though neither knee achieved what he felt he needed. He'd previously benefited from the pre-launch version of the Imatik knee, so an NOHP3 loaner unit was fitted in its place. As the Imatik and the NOHP3 share the same chassis design the Prosthetist thought it would be a good opportunity to check which particular feature of the Imatik he'd benefited from most.

Patient 4 - This lady did not initially receive sufficient physiotherapy to achieve her full potential and so progress post amputation was hampered. The Prosthetist noted that the knee was easy to set up, silent in operation and that there was a good angle of knee flexion. Since fitting the knee no adjustments or maintenance have been required.

Patient 5 - This knee had been applied to a primary amputee requiring gait training. The patient had had difficulty in loading the forefoot in order to release the knee and found this difficult when away from the walking gym environment. He fell on a number of occasions and his prescription was reviewed. The knee was an inappropriate prescription for this gentleman even though the knee functioned well when used during gait training.

Patient 6 - This was the first prescription for this patient. No maintenance or further adjustment was required after initial provision. A possible need for a specific cosmesis that will "accommodate the change in dimension of the knee during swing without effecting function" was identified. This has continued to be a successful prescription for this patient who has progressed well with her rehabilitation.

Patient's Comments

Patient 1 - The patient reported that he found this knee a considerable improvement on his previous prescription. He reported that it took him a little while to adjust to. He felt that the knee action was smooth and that he had gained some freedom in mobility with this knee. He reported that the design of the knee allowed him to kneel more comfortably and he felt more stable.

Patient 2 - This patient reported that he found wearing a prosthesis easier than he expected and that the "knee felt good". He did however add that he was unable to be objective with his comments because he had no point of reference. (This was this gent's first prosthetic prescription). He also reported that the knee felt "smooth" and "easy to walk with".

Patient 3 - Though it took time for the patient to get used to the polycentric Imatik knee, he persevered with it, due to liking the "immediate and smooth change in function as he increased his speed". He found ascending hills easier, (probably due to the effective shortening at mid swing). The change to the NOHP3 was simple and though he noticed the fact that the pspc wasn't able to cover the full range of speeds he could achieve with the Imatik, it was still smooth in its action and just as effective in every other way.

Patient 4 - Being a Primary amputee this patient had no other prosthetic experience to compare the knees performance with - however the patient stated that she felt stable and secure and was generally pleased with her prosthesis as a whole.

Patient 5 - The patient noted that he had difficulty getting into his car because he was unable to unlock the knee.

Patient 6 - The patient recorded that she was happy with the function and performance of the knee. She continues to lead a full and active life.

For almost 100 years, we have broken boundaries in healthcare to create fundamental, positive turning points that enhance lives. Contact us today on customerservice@steepergroup.com to find out more about our products and services.