



Clinical Evaluation Summary

CES OSS K09

Össur - NO/NKPASO 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 is the final outcome of a project started by Medi and evaluated by Steeper over several years. Its polycentric chassis, though improved and strengthened for the Paso, was already well proven. The pneumatic cylinder is a unique design that allows a wide range of gait speeds to be achieved, from below the suggested 2km/h to well above the advertised 7km/h, provided the user is capable of safely doing so.

Our evidence shows that there is no perceived delay as speed is increased or decreased and that the extension required to ensure stance stability is consistently achieved. The anterior/posterior shift increases or decreases the stance stability and the use of one of the two optional wedges that change the ICR, makes for a more dynamic transition into swing phase. There are no means of adjusting the pneumatic cylinder, since it self-adjusts to suit the activity of the user. Users whose current knee has no significant swing resistance, may find this a little difficult to get used to, but only two patients have rejected it on that basis.

Indications

K3 to K4 activity patients who would benefit from a knee that:

- Has a smooth self-adjusting swing phase
- Accommodates a wide range of gait speeds
- Has ICR adjustment wedges to fine tune the stability and transition into swing phase
- Has a low above knee build height**
- Has a large flexion angle
- Is robust and durable
- Is cost effective
- Is lightweight (compared with hydraulic options)

Contraindications

- Patients below activity level K3, or above the weight limit of the knee.
- Patients who currently make use of, need, or prefer a yielding hydraulic or weight activated stance control knee.*
- Patients requiring a very slim cosmesis or a very short total build height.

*Please also refer to the Steeper Prescription Guideline HW P KNE 02.

** Especially the NK Paso version.

Evaluation Patients

Patient Details

Patient 1	Transfemoral	85kg	53 year old male	Bookings Office	Sigam E
Patient 2	Transfemoral	95kg	36 year old female	Self Employed	Sigam F
Patient 3	Knee Dis	78kg	44 year old male	Unemployed	Sigam F
Patient 4	Transfemoral	67kg	16 year old female	Student	Sigam E
Patient 5	Transfemoral	110kg	43 year old male	Self Employed Carpenter	Sigam F
Patient 6	Transfemoral	95kg	51 year old male	Self Employed Photographer	Sigam E

Evaluation Result



Current Prescription

Patient 1	Quadrilateral socket, 4Seal liner, Medi NKFM1 knee and CPI Venture foot
Patient 2	Self-suspending end bearing socket, Medi NOH5 knee and Freedom Senator foot
Patient 3	Revision from transtibial on PTB Supracondylar socket with CPI Trés foot
Patient 4	Laminate socket, Össur Seal In liner, Medi NOFM1 knee and CPI Trés foot
Patient 5	Ischial Containment socket with silicone pin liner, Endolite KX06 (Total Knee), Proflex XC foot
Patient 6	Ischial Containment socket with Seal In liner, Össur Total knee and CPI Venture foot

Prosthetist's Comments

Patient 1 - Having started the patient on a NKFM1 knee, he has progressed beyond that prescription, limiting his gait and walking speed. As a result, the Paso was chosen in the hope of providing a smoother swing phase, with the ability to walk at variable speeds.

Patient 2 - Having been a long time user of a Total Knee, he was swapped to a Medi NOH5 over three years ago. Since that knee was now showing some significant wear, it was decided to trial an alternative unit in an attempt to upgrade the swing phase action and improve durability. The prosthetist had no problem setting up and aligning the knee and a year after delivery it had required no attention.

Patient 3 - Having been a fairly active transtibial amputee, it was expected that this patient would achieve K3 activity level and Sigam F following revision to knee disarticulation. To that end he was supplied with the Paso, its 4 bar construction allowing a low build height. It was easy to fit and align, but did need to be returned for repair soon after delivery, due to a hissing noise (maybe due to it being an open pneumatic cylinder).

Patient 4 - This young patient's activity level had increased significantly, such that the swing phase of the NOFM1 no longer provided adequate control. The Paso was chosen with the intention of improving the gait over a wider range of speeds, reducing gait deviations and lowering energy expenditure. Due to the age and petite build of the patient, this was an admitted risk, but one that the prosthetist felt it was worth taking. They had no problem with the set up, but commented that the knee was rather bulky for this patient, with limited adaptability to changes in speed.

Patient 5 - The prosthetist chose to trial the Paso in an effort to improve the patient's gait. The main features that influenced this choice were the fact that the Paso is lighter than the KX06 and has an auto adjustable speed range that, being pneumatic would require less effort from the patient. An A wedge had been fitted at the first review, the patient having become used to its function, to the point where he wanted it to release into swing phase more dynamically. The only negative was the fact that the knee cover had broken and it wasn't possible to obtain a replacement.

Patient 6 - Due to the fact that the patient walks quickly, with an aggressive swing phase, adjusting the knee settings himself, dependant on what activity he was about to engage in, the prosthetist thought he'd be safer on the Paso. Having fitted it, which was found to be very simple to do, the prosthetist commented that, apart from the stumble recovery feature, the Paso was as effective as an MPK.

Patients' Comments

Patient 1 - The patient felt that there was a need to over-emphasise loading the toe to achieve swing, or to sit down and to extend the knee fully for stability at heel strike.

Patient 2 - The patient found it slightly difficult when descending a slope, or stairs. A year after delivery he stated that its stability and durability had allowed him to do more manual work.

Patient 3 - At delivery the patient found some issues negotiating slopes and getting it to transition into swing, or to unlock for sitting. An A wedge was fitted and this improved the situation. The patient loves walking his dogs and found that he could still manage to do so on the Paso and stated that "I can do everything I want to do", scoring it with an "I love it" comment and a 10.

Patient 4 - At the delivery the patient felt that the knee did not unlock easily and was stiff to bend due to the cosmesis, though four months later her comments were more positive, even though she still felt some limitations to mobility (it would have been good to have been able to review the situation a year or so on).

Patient 5 - The patient's main issues with the KX06 were that it felt heavy and slow and that he'd had several falls as a result of it not "being there for me". Rating the Paso at 9, he was very positive about it in every way, stating that it had improved his quality of life.

Patient 6 - Although he had used the Total knee for about ten years, rating it at 6, he stated that he found it difficult going down slopes. He had been able to run on it. The response of the patient to the Paso caused him to score it 10. He was impressed with its stability even when he walked it backwards, though more difficult on slopes (the prosthetist fitted a wedge at the review and the patient didn't mention the issue again). He says that it has allowed him to access more machines in the gym and to go further for longer on the treadmill.

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