



Clinical Evaluation Summary

CES CLM A01

RevoLock

Warranty period - 6 Months (BOA reel only)

Weight Limit - N/A, Cable rated to 100kg tensile load

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

Though lanyards were the original method of retaining a liner in a socket, they are seldom used now, unless there is a need to draw the residual limb into the socket, due to its shape. This is due to a number of issues pulling the lanyard tight enough and locking it off, without leaving any play in the system.

The RevoLock system, however, is so positive and easy to use that there are no longer any issues of this type. Also, when fully home, the insert seals the socket; such that the addition of a valve and sealing sleeve, suspension can be easily provided over a larger area. It is also fully waterproof.

Indications

A patient with a residual limb -

- that is bulbous
- or has excess soft tissue
- or is too long to accommodate a pin lock

Limited dexterity such that a standard lanyard, or shuttle lock, cannot be operated.

Limb comes into contact with water, or is used in a wet environment.

Contraindications

A patient who -

- is not able to use a liner*
- likes to hear the ratchet lock clicking home
- only requires a simple suspension system
- who requires a very cosmetic finish

*See Best Practice Guidelines TT P SSS 01 and TT P GEL 01

Evaluation Patients

Patient Details

| | | | | | |
|-----------|--------------|------|--------------------|------------|-----------|
| Patient 1 | Transfemoral | 61kg | 88 year old female | Retired | Sigam C |
| Patient 2 | Transtibial | 96kg | 42 year old male | Unemployed | Sigam Dc |
| Patient 3 | Transfemoral | 84kg | 48 year old male | Unemployed | Sigam D/E |
| Patient 4 | Transfemoral | 92kg | 41 year old male | Farmer | Sigam F |
| Patient 5 | Transfemoral | 75kg | 60 year old male | Unemployed | Sigam D |
| Patient 6 | Transfemoral | 63kg | 77 year old female | Retired | Sigam E |

Evaluation Result

Current Prescription

Patient 1 - Quadrilateral socket with TES belt suspension, Ortho Europe Easi Knee and Endolite Multiflex foot

Patient 2 - PTB socket, with silicone liner, Össur clutchlock and Reflex Rotate foot

Patient 3 - Quadrilateral socket with suction liner, Endolite ESK and Multiflex foot

Patient 4 - Ischial Containment socket with lanyard, C-leg and Triton foot

Patient 5 - Laminate socket with flexible inner and APC lock, NOP4 and Tres foot

Prosthetist's Comments

Patient 1 - The RevoLock was chosen with the hope of improving the suspension and comfort for this elderly lady.

Patient 2 - This patient has a bulbous residual limb and struggles to manage the clutchlock, or the Össur lanyard system, due to weakness. It was decided to try the Click Medical RevoLock in an attempt to improve donning and increase the security of the socket fit. The only negative comment the prosthetist made was that it created air noises through the lanyard tube. Since this can only mean that the O rings on the distal connector had failed to seal into the housing, it was suggested that the socket may have been a little too tight. This is not easy to check.

Patient 3 - The patient had become unhappy with constant loss of suction. The prosthetist had no problems with the RevoLock Kit, even though the patient did manage to break off the dial. This was easily repaired as a day job. As with patient 2, they again had issues with air noise, probably for the same reason.

Patient 4 - Looking for a positive and reliable lanyard following issues with them snapping, leading to reinforcing with sailing lanyard. Found this system to be more reliable and did not need to replace the cord.

Patient 5 - The patient has had consistent difficulty engaging a pin. Due to having a short, heavily grafted residuum with redundant tissue, patient requires a liner with a positive suspension method and a liner for protection. Looking to increase wear time to allow for successful rehabilitation. Other than incidents with the patient donning incorrectly and causing knots in the lanyard, which was easily replaced, the RevoLock proved to be easier for the patient when donning.

Patient 6 - The RevoLock was chosen to ease issues with donning and doffing, caused by the patient having a fleshy distal residuum. Product found easy to fit and improved ease of donning over the Össur clutch lanyard. Required new cable to be fitted due to knotting, spare cable and re-threading kit included for easy maintenance.

Patient's Comments

Patient 1 - Despite some uncertainty at first, due to coming off of the TES belt and using a silicone liner for the first time, after two months of use she stated that she felt "more confident" and was not using her stick so often. It had made it possible for her to get out more often. Five months on again, she felt it had improved her quality of life and was still getting out and about, due to her increased confidence and was using her stick even less.

Patient 2 - He was pleased with the socket and lanyard system from the start and within the first month felt that it had improved his quality of life, by allowing him to be more active and in less pain. He felt confident enough to ride his bike and go to watch rugby. He felt it was better in every way.

Patient 3 - The patient only made a couple of comments, one being to do with the knee function and the other a simple "it broke", regarding the RevoLock. He is still using it after 3 months.

Patient 4 - When compared with previous lanyard systems used, patient found this to be more secure and significantly more reliable "The best lanyard to date!"

Patient 5 - Found a significant improvement compared with the previous pin lock within the first two weeks. Other than issues with the lanyard knotting, found the RevoLock more secure and allowed patient to walk further distances. Lanyard was easily replaced on the day by the Clinical Support Technician.

Patient 6 - Patient stated product being better than previous suspension method and improved the function of her limb. After initial problems with lanyard knotting and being replaced, there were no further issues.

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.