

1425 Knee Rotator with Threads (Ti)

Instruction For Use



Application

The 1425 threaded top rotator is suitable for low to high functional levels (excluding K4 type activities). The 1425 Rotator is to be exclusively used for the prosthetic fitting of lower extremity amputations up to 100kg / 220lbs (must include carrying items, and impact from daily obstacles such as stepping off curbs or steps).

Product Description

The 1425 is intended to be mounted into a corresponding receiver socket adapter. A release button on the Rotator is used to allow for rotation below the socket.

Be familiar with this product by reading the instruction manual carefully, and instruct your patient on proper use to ensure safety.

Keep this instruction manual in a conveniently located place for easy access, and reference this IFU should you need instruction.

Indications For Use and Target Patient Population

The device is intended as a component of a prosthetic system that replaces lower limb loss, amputation, or deficiency for Knee Disarticulation up to Hip Disarticulation levels.

Suitability of the device for the prosthesis and the patient must be evaluated by a healthcare professional.

The device must be fitted and adjusted by a healthcare professional. Intended for single device use only, not to be reused on another device.

Contraindications For Use

- Wearers who may have difficulty with dexterity to operate the device properly and consistently.
- Those that may have issues comprehending and lacking ability to safely operate device properly and consistently.



GENERAL SAFETY INSTRUCTIONS

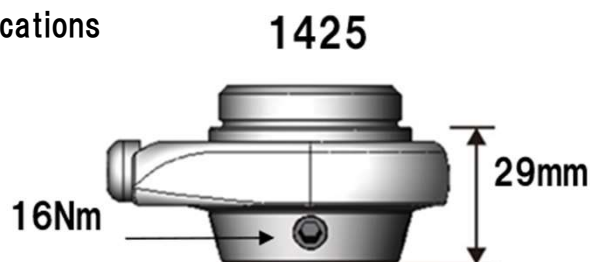
The healthcare professional should inform the patient about everything in this document that is required for safe use of this device.

Warning: If there is a change or loss in device functionality, or if the device shows signs of damage or wear hindering its normal functions, the patient should stop using the device and contact a healthcare professional.

⚠caution

Tighten according to the specified torque value. Incorrect torque can cause the rotator to become loose, damaged, or to malfunction, and will void warranty.

Product Specifications



product	1425
weight	160 g
material	Titanium
Proximal connection	36mm Thread
Distal connection	Female Receiver
Assembly height	29 mm
Convolution range	360 °

Daily Care and Maintenance

The Prosthetist should discuss the following inspection procedures and guidelines with the patient. Failure to follow these guidelines may void any warranty.

- The rotator is intended for daily activities and should not be used for any other purpose.

- Torque to the default value, as shown above. Not adhering to the specified torque value may damage the rotator and cause it to not work which will void the warranty, or the wearer may fall due to failure from this damage.
- Make sure that the rotator can be cycled into a locked and unlocked position.
- Do not load the prosthesis while it is unlocked. The prosthesis may rotate under load, and there is a fall risk.
- Make sure that the rotator does not come into direct contact with the knee joint frame or knee cylinder when the knee joint is flexed. Damage or malfunction of interfering parts may cause a fall.
- Teach the wearer how to operate the rotator.
- Should the lock malfunction in any way (e.g. accidentally disengage, fail to release, etc.), discontinue use of the lock immediately and contact your Prosthetist.
- Be sure to discuss maintenance so as to prevent the lock from malfunctioning, and may not release allowing for unintended socket rotation.
- Avoid bumping the button to prevent accidental unlocking. This risk increases if the prosthesis is fabricated without a button shield.
- Do not hit the release button with any metal object as it can cause damage to the bearing or lock mechanism.
- Keep the lock clean and free of debris for the best performance and proper lock engagement.
- Contact your Prosthetist should you have any questions or concerns.
- Not to be submerged, and not for swimming purposes. Bi-annual inspection should be carried out.
- A trained technician must perform fabrication of the prosthesis.
- Do not modify the housing or the locking mechanism in any way.
- Use a thread locker to secure all threaded fasteners.



Maintenance instructions

Depending on the amputee's activity, there is a service life of three to five years. We recommend carrying out bi-annual inspection / safety checks. Never reuse components on a different prosthesis.

Warranty Period is 2 Years.

Liability

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregard of this document, particularly due to improper use or unauthorized modification of the product, or if reusing on a different prosthesis than originally intended for. If used on a different prosthesis than originally fabricated for, liability will fall solely on the clinician. No warranty or liability will be transferrable.

CE Conformity

This product meets the requirements Council EU 2017/1745 (MDR) for medical products. This product has been classified as a class I product according to the classification criteria outlined in appendix IX of the guidelines. Please keep this manual in safe place for future use.

Useful Life

Service life of the product is covered by the warranty period.

Single use only, not to be used for any patient than initially delivered to. Cancels warranty and Liability of the manufacturer.

Disposal

The device and its packaging must be disposed of in accordance with respective national/local environmental regulations.

Disclaimer: Actual production version may vary from pre-production photo representation on IFU.

Specifications subject to change

