endolite

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Female Shifting Pyramid Adapter Part No. **189128**

Instructions for Use

1 **Description and purpose**

These instructions are for use by the Clinician/ Practitioner.

Application:

The Female Shifting Pyramid Adaptor is for use exclusively as part of a lower limb prosthesis. The device connects an open ended Endolite slotted chassis or top housing to a male pyramid receiver. This allows for shifting and angular & rotational adjustment between the two limb parts.

- Intended for single user only
- There are no known contra-indications if used in accordance with these instructions

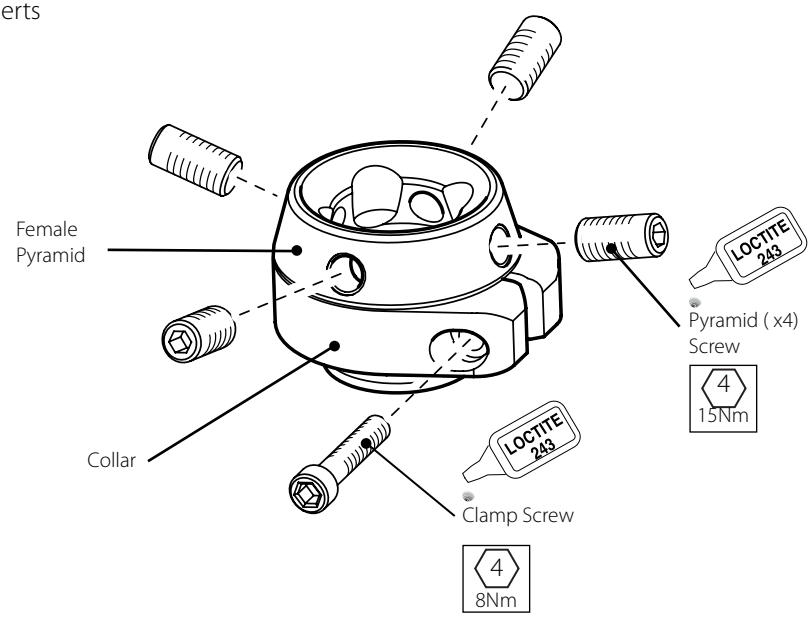
Ensure that the user has understood any Instructions for use, drawing particular attention to the safety information.

Part No. 189128

2 **Construction**

Principal Parts:

Female Pyramid	Titanium
Collar	Aluminium Alloy
Pyramid Screws	Stainless Steel
Clamp Screw and inserts	Stainless Steel



3 **Function**

The Female Shifting Pyramid Adapter comprises two main components.
The movement between these two components prior to tightening the pyramid screws and clamp screw allows for alignment of the limb to suit the individual user.
When tightened securely using Loctite and torque settings shown, the device offers a secure way to connect two parts of the limb.

4 **Maintenance**

Maintenance is to be carried out by competent personnel only.

An annual visual inspection is recommended

- Ensure all screws are secure. If not remove and clean screws, reapply Loctite and tighten all screws to the correct torque settings.
- Check for visual defects that may affect proper function.

The wearer should be advised:

The user should be advised to contact their Clinician/Practitioner if their condition changes.
Any changes in performance of the device must be reported to the Clinician/Practitioner.
Changes in performance may include:

- Any unusual noises
- Excessive play or loss of alignment

5 **Limitations on use**

Intended Life:

The service life of the product is covered by the warranty period.

A local risk assessment should be carried out based upon activity and usage.

This product is recommended for use with other Endolite products.

Lifting Loads:

User weight and activity is governed by the stated limits.

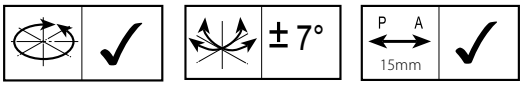
Load carrying by the user should be based on a local risk assessment.

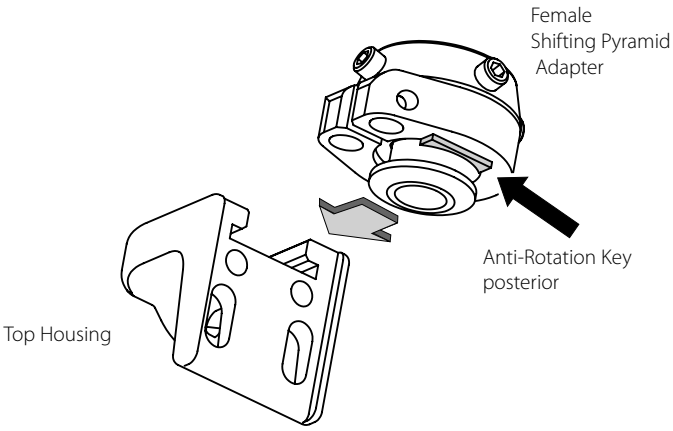
Environment:

Avoid exposing the product to corrosive elements such as water, acids and other liquids. Avoid abrasive environments such as those containing sand for example as these may promote premature wear.

Exclusively for use between temperatures of -10 and 50˚C

6 **Assembly and alignment**





Adjustment:

1. To adjust loosen clamp screw
2. Hold collar to slide/rotate as required
3. Tighten clamp screw to 8Nm torque.

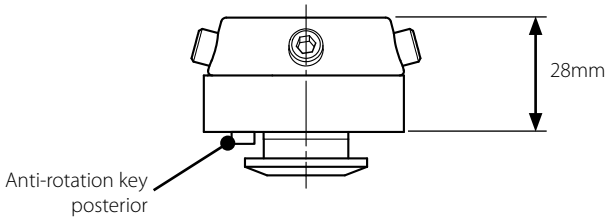
7 **Technical Specification:**

Part No.	189128
Operating and Storage Temperature Range:	-10˚C to 50˚C 14˚F to 122˚F
Product Weight:	114g
Maximum User Weight:	150kg
Recommended Activity:	up to K4
Range of adjustment:	360 degrees rotation 7 degrees angular
AP Shift (dependent upon mating housing/chassis)	typically 15mm
Build Height:	28mm
Connections:	Distal Endolite Slotted Chassis or top housing Proximal Female Pyramid

Materials:

Titanium, Aluminium Alloy and Stainless Steel

Key Dimensions:



8 **Warranty and Service:**

Warranted for 3 years.

The user should be aware that changes or modifications not expressly approved could void the warranty.

9 **Liability**

The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the instructions for use supplied with the device. The manufacturer is not liable for damage caused by the component combinations that were not authorized by the manufacturer.

CE Conformity

This product meets the requirements of 93/42/EEC guidelines 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. The declaration of conformity was therefore created by Blatchford Products Limited with sole responsibility according to appendix VII of the guidelines.

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