

IFU-04-007 Rev. A 2023-07





# Instructions for Use Read before use

ACC-00-13500-00 4-Hole Male Rotating **Pyramid** 



PROTEOR SAS

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**REP** 

EC

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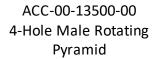


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### INTENDED USE/INDICATIONS

The ACC-00-13500-00, 4-Hole Male Rotating Pyramid is supplied to healthcare professionals (certified prosthetists/orthotists) to be used exclusively for the fitting of prosthetic lower limbs.



This device is for multiple use on a single patient.

# COMPATIBILITIES

The ACC-00-13500-00, 4-Hole Male Rotating Pyramid is to be used with any standard 30mm pylon systems in conjunction with standard prosthetic componentry.

### **ASSEMBLY**

Flathead screws must be used in two of the four mounting holes. These should be loosened to facilitate adjusting rotation. Loctite 242 thread locker must be used on all screw threads during final assembly, and screws torqued appropriately.

Weight Limit	136 kg	(300 lb)
Mounting Screw Torque	10 Nm	(88 in-lb)
Rotation Clamp Screw Torque	10 Nm	(88 in-lb)

 $\stackrel{\textstyle ext{$ \stackrel{\wedge}{ ext{$ .} } }}{ ext{$ .}}}$  WARNINGS: The clamp must be installed on the pyramid connector with the bolt in the posterior position. Failure to do so will potentially result in failures and injuries.

Any serious incident that occurs which relates to the device must be reported to the manufacturer and to the competent authority of the member state in which the incident occurred.

# WARRANTY

Proteor's warranty of 24 months applies only if the product is used according to the specified condition and intended purpose, following all manufacturer's recommendations. The products are tested according to ISO 10328.

# REGULATORY INFORMATION

This product is a CE-marked medical device and is compliant with Regulation (EU) 2017/745.

## DESCRIPTION OF SYMBOLS

<u></u>	Manufacturer	$\triangle$	Identified risk	(€	CE marking
EC REP	Authorized representative in the European Union		Single patient, Multiple use		

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