PROTEOR

IFU-04-006
Rev. A
2023-07

CE

Instructions for Use
Read before use

ACC-00-13200-00
4-Hole Female Pyramid

EC REP

PROTEOR SAS
6 rue de la Redoute
21850 Saint-Apollinaire – France
+33 3 80 78 42 42
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INTENDED USE/INDICATIONS

The ACC-00-13200-00, 4-Hole Female 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-00-13200-00, 4-Hole Female Pyramid is to be used with any standard 30mm or 34mm pylon systems in conjunction with standard prosthetic componentry.

ASSEMBLY

Do not scratch the surface finish or otherwise alter the connector as these alterations may damage or weaken the device. Loctite 242 thread locker must be used on all screw threads during final assembly, and screws torqued appropriately.

Weight Limit	136 kg (300 lb)
Alignment Set Screw Torque	15 Nm (133 in-lb)
Attachment Screw Torque	10 Nm (88 in-lb)

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

	Manufacturer		Identified risk		CE marking
EC REP	Authorized representative in the European Union		Single patient, Multiple use		

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