Pylons

2T12, 2T13, 2T14, 2T15, 2T16, 2T17, 2S15, 2S16, 2S17,
2A12, 2A15, 2A16, 2A17, 2A18

Instructions for Use

Technical Specification

Part No.	Alloy	Tube Length	Product Weight	Max Patient Weight	Torque (M8x12mm)
2T12	Titanium	40 cm.	313 g	136 Kg. / 300 lbs.	15 Nm.
2T13	Titanium	40 cm.	334 g	205 Kg. / 450 lbs.	15 Nm.
2T14	Titanium	40 cm.	300 g	136 Kg. / 300 lbs.	N/A
2T15	Titanium	40 cm.	308 g	136 Kg. / 300 lbs.	15 Nm.
2T16	Titanium	25 cm.	218 g	136 Kg. / 300 lbs.	15 Nm.
2T17	Titanium	45 cm.	343 g	136 Kg. / 300 lbs.	15 Nm.
2S15	S. Steel	40 cm.	351 g	136 Kg. / 300 lbs.	15 Nm.
2S16	S. Steel	25 cm.	261 g	136 Kg. / 300 lbs.	15 Nm.
2S17	S. Steel	45 cm.	385 g	136 Kg. / 300 lbs.	15 Nm.
2A12	Aluminum	89 mm.	106 g	100 Kg. / 220 lbs.	15 Nm.
2A15	Aluminum	40 cm.	308 g	100 Kg. / 220 lbs.	15 Nm.
2A16	Aluminum	25 cm.	218 g	100 Kg. / 220 lbs.	15 Nm.
2A17	Aluminum	45 cm.	343 g	100 Kg. / 220 lbs.	15 Nm.
2A18	Aluminum	40 cm.	242 g	136 Kg. / 220 lbs.	N/A

Description and Purpose

These instructions are for use by the practitioner. This product is designed to be used for lower limb external prosthetic length, toe direction and alignment corrections. Intended for single user only. This product can be used for mobility classes 1-4. 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 maintenance information.

Construction

Use 4mm Allen wrench for all screws. Before fitting this product onto the patient, all parts must be joined properly and any set screws must be secured enough for the patient to walk. In order to make final adjustments, there should be no loose screws. After the final adjustments, apply single drop of removable Loctite® 242 to each of the set/cap screws and then torque the product.

Function

If the pylon needs to be cut for height adjustment, a tube cutter is strongly recommended. After the proper length is achieved, all edges of the tube need to be free of burrs. Avoid sanding the external side (outer edge) of this product. If a tube clamp adapter (2T20/2S20/2A20) is used, the tube has to be pushed into the tube clamp adapter until it sits on the inner rim.

Improper installation or uneven, insufficient or excessive torque may cause bolt or adapter failure. Always use quality metric tools for installation. When tightened securely using Loctite on the pyramid screws only and torque settings shown, the device offers a secure way to connect two parts of the limb.

Limitations on Use

Intended life:

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

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:

Thoroughly rinse with fresh water after use in abrasive environments such as those that may contain sand or grit, for example, to prevent wear or damage to moving parts. Thoroughly rinse with fresh water after use in salt or chlorinated water. Exclusively for use between -15˚C and 50˚C (5˚F to 122˚F).

Maintenance

Maintenance is to be carried out by competent personnel only. An annual visual inspection is recommended. During maintenance, it is appropriate to consider any weight or activity increase by the user. If the prosthesis is exposed to circumstances or impact for which it was not designed, inspection by a qualified practitioner is recommended.

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

The user should be advised to contact their practitioner if:

- Their condition changes.
- Performance of the device changes.
- Changes in performance may include:
  - Any unusual noises
  - Excessive play or loss of alignment

Warranty

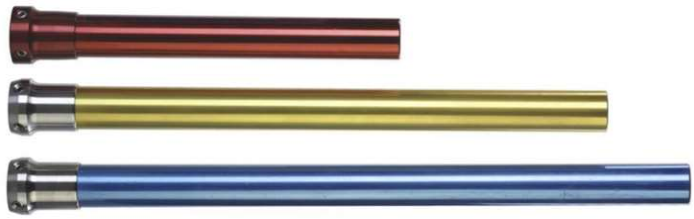
All MEDEX Modular Adapters are unconditionally guaranteed for 2 years. Cutting, drilling, modifying or using the component other than as described in this manual will void the warranty.

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.

CE Conformity

This product meets the requirements of 93/42/EEC guidelines for medical products. This product has been classified as a Class 1 Product according to the classification criteria outlined in Appendix IX of the guidelines.



MEDEX INTERNATIONAL, INC. – 2720 Duvall Road, Burtonsville, MD 20866 – Phone: 1 888-886-2420 – Fax: 301-657-2796 – Last Revised 26/5/16

CE