



Tube Clamp Adapter, 30mm

1212

Instructions For Use



1212A



1212T



1212S



1212MS



1212T-SH



1212T-B

1. Application & Description

- This is exclusively for lower extremity prosthetic fittings connecting a pyramid to a pylon.
- **Field of Application:** The pylon together with the corresponding Tube Clamp Adapters comprise structural components for modular lower limb prostheses. The adapter combinations allow for controlled angular and linear adjustments in the sagittal and frontal planes, and internal and external rotations in the transverse plane.
- For maximum structural strength the Tube Clamp Adapter must be placed proximally. The clamping slot must always be positioned anteriorly.
- **Compatibility:** 1211 Series Pylons, 1241T, 1209A, and 1210A fit all 1212 Tube Clamp Adapters.
- When 1212T-SH is used with 1205T, 1206T, or 1207T the weight rating is 375 lbs (170 kg).
- If 1212T-SH is used with any other pylon, including Series 1211, 1241T, 1209A, or 1210A, the weight rating reduces to 275 lbs (125 kg).
- The weight limit of the assembled prosthesis is determined by its lowest-rated component.
- The four set screws anchor the mating system and allow for angular alignment.

2. Technical Specifications

P/N	Material	Build Height	Weight	Weight Limit
1212A	Aluminum	18mm	83g	158kg/350lbs
1212T	Titanium	15mm	79g	170kg/375lbs
1212S	Stainless Steel	15mm	128g	136kg/300lbs
1212MS	Molded Stainless Steel	15mm	117g	136kg/300lbs
1212T-SH	Titanium	14mm	69g	170kg/375lbs*
1212T-B	Titanium	15mm	79g	170kg/375lbs

* 1212T-SH: 170 kg/375 lbs with 1205T, 1206T, or 1207T; 125 kg/275 lbs with any other pylon (see Section 1).

- **Recommended Torque:** Always cross tighten Alignment Set Screws
- **M8 Alignment Set Screw Torque:**
 - (Aluminum): 10Nm
 - (Titanium/Stainless Steel): 15Nm
- **M6 Cap Screw Torque:**
 - (Stainless): 7Nm
- **M5 Screw Torque:**
 - (Titanium/Stainless): 7Nm
 - (Aluminum): 5 Nm

Thread Locker: Apply Loctite 243 (blue) once alignment and connection are finalized

3. Handling

3.1 Connection to the Tube Clamp Adapter

- The pylon (1211T, 1241T, 1211A, 1211S) must be shortened according to the patient's measurements. To avoid deforming the pylon, care must be taken to carry out the steps accurately as described below. Given the low tolerances of the adapters, a deformed pylon will not fit easily into the Tube Clamp Adapter.
- **Note:** Do not clamp the pylon into a vise. This could cause damage or deformation.
- **The cut surface must be perpendicular to the longitudinal axis of the pylon (Fig. 1).** Use of a tube cutter or equivalent is recommended.
- **All inner and outer burrs must be removed from the cut edge (Fig. 2).** Use of a reamer or equivalent is recommended. For best results, it is recommended to sand and buff the inner and outer edges to ensure the smoothest transition, and to eliminate pipe cutter mushrooming.
- **Note:** To ensure structural solidity, the remaining pieces of the shortened pylon are not to be used as components in the prosthesis. The 1219T can be utilized should height adjustment be needed.



Fig. 1 Cutting the pylon



Fig. 2 Deburring the cut edge

- **Attention!** The interior surface of the Tube Clamp Adapter and the exterior surface of the pylon must be cleaned with a cleaning agent in the insertion area prior to final assembly (insertion of the pylon into the Tube Clamp Adapter).
- Loosen the Cap Screw of the Tube Clamp Adapter by two turns, and then insert the pylon 5 mm deep into the Tube Clamp Adapter while slightly rotating the pylon. Next, place the Tube Clamp Adapter with the pylon inserted vertically on the worktop and fully insert the pylon into the Tube Clamp Adapter until the pylon is in contact with the base rim inside the clamp.
- **Warning:** For final use, the Cap Screw must be torqued to 7 Nm (see Section 2) with a torque wrench. Failing to comply with this instruction may lead to permanent over-extension or breaking of the screw.

3.2 Maintenance Instructions

- As a basic principle, all modular adapters are subjected to tests in accordance with ISO 10328 involving three million load cycles. Depending on the amputee's activity this corresponds to a service life of three to five years.
- We recommend carrying out regular safety checks once a year.

4. Adjustment Set Screws

- Adjustments may be made through adjusting the four Adjustment Set Screws during fitting and at any time after the prosthesis has been completed. The optimal position of the components may be preserved when exchanging parts or when servicing the prosthesis by removing only the two most deeply set adjacent screws.
- Once positioning has been determined, replace any set screws that are too short (lacking strength).

- If alignment adjustment is necessary, always loosen the 2 adjacent screws to make angular adjustments. This will prevent galling of the pyramid.
- Do not overly tighten the Alignment set screws when adjusting alignment, as this will gall the pyramid and lead to noise issues.

4. Adjustment Set Screws (continued)

- Screws are available in the following sizes:

P/N	Size	Description	For Use With
812SS-AZ	M8x12	Set screw, AL Zinc	Titanium components
816SS-AZ	M8x16	Set screw, AL Zinc	Titanium components
812SS-Z	M8x12	Set screw, Zinc	Aluminum & stainless steel components
816SS-Z	M8x16	Set screw, Zinc	Aluminum & stainless steel components

- Use a torque wrench to tighten the screws.
- **Attention!** Tighten the set screws in two steps:
 - **For testing:** Using a torque wrench, screw in the set screws clockwise at 10 Nm (7.4 lbf·ft / 88.5 lbf·in).
 - **For finalizing (Titanium/Stainless Steel):** Secure the set screws with Loctite 243 (blue), tighten clockwise at 10 Nm (7.4 lbf·ft / 88.5 lbf·in) first, and then tighten completely at 15 Nm (11.1 lbf·ft / 133 lbf·in).
 - **For finalizing (Aluminum):** Secure the set screws with Loctite 243 (blue) and tighten clockwise at 10 Nm (7.4 lbf·ft / 88.5 lbf·in).

5. Safety & Environment

- **Temperature Range:** Between -20°C to 80°C (-4°F to 176°F). 
- Rinse with clean water if exposed to salty, chlorinated, or otherwise potentially corrosive liquids.
- **Storage:** Store at room temperature; avoid wet, very hot, or extremely cold environments.
- **Warranty:** 2 years, provided it is used as intended without modification, and only for the original intended user. The warranty applies from the date of purchase and covers defects that can be proven to be a direct result of flaws in the material, production, or construction.
- Do not reuse on another prosthesis. 
- **Conformity:** This product meets the requirements of Regulation (EU) 2017/745 on medical devices (MDR). It is classified as a Class I medical device according to Annex VIII of the MDR. The EU declaration of conformity has been drawn up by the manufacturer under its sole responsibility in accordance with Article 19 and Annex IV of the MDR.
- **Serious Incidents:** Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- Please read this document carefully and follow the safety instructions. Please keep this manual in a safe place for future reference.

6. Liability

- The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to these Instructions for Use.
- The device must only be operated with tested modular components approved by ST&G. The manufacturer is not liable for damage caused by component combinations that were not authorized by the manufacturer.
- This product must always be fitted under the supervision of a certified prosthetist.

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Specifications subject to change.