

# Torsion Adapter

Product Manual

*Fillauer*®

# Contents

Intended Use/Purpose.....	<b>3</b>
Indications.....	<b>3</b>
Contraindications.....	<b>3</b>
Features/Clinical Benefits.....	<b>3</b>
Performance Characteristics.....	<b>4</b>
Storage and Handling.....	<b>5</b>
Warnings and Precautions for the User.....	<b>5</b>
Specifications and Preparations Before Use.....	<b>6</b>
Compatibility (Combination of Devices).....	<b>6</b>
Disposal/Waste Handling.....	<b>6</b>
User Information.....	<b>7</b>
Consultation of Health Care Professional.....	<b>7</b>
Care and Maintenance.....	<b>7</b>
Serious Incidents.....	<b>7</b>
Liability.....	<b>8</b>
Warranty.....	<b>8</b>

## Intended Use/Purpose

The Fillauer Torsion adapter is a modular component for use in lower extremity prosthetics. Torsion Adapter offers a smooth +/-45° rotation with increased resistance, greatly reducing force to the residual limb. The torsion adapter is for low activity use.

The device is intended for single patient use only.

U.S. Patents 6,468,315 & 6,682,569

## Indications

- Reduces rotational forces to residual limb
- Patients weighing up to 125 kg
- +/-45° rotation with increased resistance

## Contraindications

- Patients weighing over 125 kg
- Patients wanting to run or jog regularly on the device

## Features/Clinical Benefits

The Fillauer Torsion Adapter has rotational functions that reduce rotary forces on the residual limb.

The adapter can be installed with the pyramid receiver in the proximal or distal position without effecting the performance.

## Performance Characteristics

- Three stiffness options
- Titanium core
- Maintenance free
- Tube diameter: 30 mm
- System height: 58 mm
- Weight: 310 g
- Rotational stop: +/- 45°



**731 000 081 Fillauer Torsion Adapter, hard (black)**

**731 000 082 Fillauer Torsion Adapter, medium (blue)**

**731 000 083 Fillauer Torsion Adapter, soft (red)**

## Storage and Handling

It is recommended that Torsion Adapters be stored in a cool, clean, dry environment away from harsh chemicals (chlorine, acids, acetone, etc.).

Clean device with a soft damp (water) fabric cloth if it is exposed to sand or similar substances to avoid increased wear or noise. Dry after cleaning without using heat.

The device can tolerate light splashing (e.g. rain). Dry thoroughly if device is submerged in water. Avoid contact with salt or chlorinated water.

## Warnings and Precautions for the User



**WARNING:** This device has been designed and tested for activities of daily living and not for abnormal activities such as extreme sports. To avoid risk of injury, handle your prosthesis and its components with care. If your prosthetic components are subjected to abnormal stress (such as a fall) contact your prosthetist/orthotist to have the components inspected for any damage.



**NOTICE:** Attachment, adjustment, alignment, and delivery of this device must be performed by or under the direct supervision of a qualified prosthetist/orthotist. Unless stated in this manual, any such activities should not be attempted by the user and will potentially void the device warranty.



**NOTICE:** Compatibility of components and the overall prosthesis must be evaluated by a medical professional.



**NOTICE:** Abnormal or improper environmental conditions will lead to malfunctioning and damage of the prosthesis and is not covered under the warranty of the device. This prosthetic/orthotic component must not be subjected to dust/debris, harsh chemicals, abrasives, vibration, activities which would damage the biological limb, or extreme temperatures (<-15C or >50C). Do not allow debris or liquids to remain in the prosthesis and its components during use.

## Specifications and Preparations Before Use

Connect the appropriate receiver/adaptor to the Torsion Adapter. Apply Loctite 243 or equivalent on the alignment screws on the receiver and tighten the screws to 10 Nm.

The Fillauer Torsion Adapter is designed to be maintenance free. The torsion adapter is filled with a permanent lubricant that will last the life of the unit. No additional lubricant should be used as this may cause failure and will void the warranty. The alignment screws should be checked and torqued to the specifications of 10 Nm once per year.

## Compatibility (Combination of Devices)

Fillauer has tested (ISO 10328) and recommends the use of standard, adult, endoskeletal components from Fillauer to be used in combination with Torsion Adapters. Components from other manufacturers may or may not be compatible. Failure due to use of other manufacturers' products is not covered under warranty.

## Disposal/Waste Handling

The product must be disposed of in accordance with applicable local laws and regulations. If the product has been exposed to bacteria or other infectious agents, it must be disposed of in accordance with applicable laws and regulations for the handling of contaminated material.

# User Information

The providing health care professional must review the following information directly with the user:

## Consultation of Health Care Professional

The user should monitor their prosthesis daily and contact their health care professional if they experience changes in performance of the device or noise.

## Care and Maintenance

The device can tolerate light splashing (e.g. rain). Dry thoroughly if device is submerged in water. Avoid contact with salt or chlorinated water.

Clean device with a soft damp (water) fabric cloth if it is exposed to sand or similar substances to avoid increased wear or noise. Dry after cleaning without using heat.

## Serious Incidents

In the unlikely event a serious incident occurs in relation to the use of the device, users should seek immediate medical help and contact their prosthetist at the earliest possible convenience. Clinicians should contact their local Fillauer representative immediately in the event of any device failure.

## 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. The device must only be operated with tested modular components. The manufacturer is not liable for damage caused by component combinations that were not authorised by the manufacturer.

## Warranty

This product has a 12 month warranty against manufacturer defects





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