

# DuraTwist

## Product Manual



## Intended Use

The DuraTwist component is intended for use in lower extremity prostheses for adult populations. The DuraTwist allows transverse plane motion that permits normal internal/external rotation while walking. This benefits the user by diminishing peak shear forces on the residual limb interface during walking and other activities of daily living.

### Indications

- Transtibial or transfemoral amputees.
- Unilateral or bilateral patients

### Contraindications

- Clearance: Less than 2.625 in. (6.6 cm)
- Patient's weight: Greater than 250 lbs. (113 kg)
- K4 Activities

The device is intended for single user/patient use only.

### Performance Characteristics

DuraTwist		
Product Number	DT002	DT001
Color	Blue	Black
Patient Weight	< 180 lbs. (82 kg)	< 250 lbs. (113 kg)
Activity Level	K2 – K3	K2 – K3
Build Height	2.625 in. (6.6 cm)	2.625 in. (6.6 cm)
Product Weight	8.8 oz. (250 g)	8.8 oz. (250 g)
Torque Setting	15 N·m	15 N·m
Range of Motion	20° Internal / External Rotation	
Materials	Titanium and Urethane Rubber	
Durable	Meets ISO-10328 Standard	
Waterproof	This device is rated for submersion to 1 meter for 30 minutes	

## Storage and Handling

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

## Warnings and Precautions



**CAUTION:** Repeated rotation of the DuraTwist unit beyond 20 degrees in either direction will result in premature failure of the product and a loss of rotational alignment. If the patient notices any changes in alignment, the clinician should be notified immediately. Malfunctioning units should be replaced as soon as possible.



**WARNING:** The DuraTwist is not intended for tensile forces (forces that pull the foot away from the socket). The patient should never suspend themselves distal to the DuraTwist unit. Not intended for sports where high tensile forces are likely (waterskiing, bungee jumping, some gymnastic exercises, etc.). Failure to follow these guidelines could result in serious injury or death.



**CAUTION:** The DuraTwist unit should not be disassembled or lubricated unless instructed by an authorized Fillauer representative.



**CAUTION:** For patient safety and device compatibility, only Fillauer or equal, ISO 10328 compliant, componentry should be used with this component.



**CAUTION:** The DuraTwist unit is waterproof to 1 meter for 30 minutes. However, if the unit is submerged, it should be rinsed with fresh water and dried immediately to remove salt, chlorine, or debris.



**CAUTION:** The alignment screws should be checked at least every 6 months if the DuraTwist is frequently in contact with water. If the DuraTwist is frequently exposed to wet environments, it is best to place the pyramid receiver toward the distal end.



**CAUTION:** The component should be inspected by the clinician every 6 months for signs of abnormal wear and to assure that every function is in working order.



**CAUTION:** 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.

## Qualified Provider

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

## Specifications and Preparations Before Use (Risk Management for Installation and Calibration)

### Orientation

The pylon may be installed with the pyramid receiver in the proximal or distal position (up or down) without effect on the functional performance. If the DuraTwist is frequently exposed to wet environments, it is best to place the pyramid receiver toward the distal end. Adjustments to alignment should be done below the DuraTwist to assure that the DuraTwist remains in line with the patient's weight at heel strike. Plantar flexing or dorsiflexing the unit will result in premature wear.

### Distal attachment

Attachment of the component may be achieved via the distal female pyramid receiver attachment component to any ISO 10328 compliant, Fillauer or equal, standard adult componentry.

Torque the four set screws to 15 N·m. Loctite™ 242 or equivalent threadlocker must be used for final delivery.

## Compatibility (Combination of Devices)

This prosthetic component is compatible with Fillauer's system of modular components. Functionality with components of other manufacturers that have compatible modular connectors has not been tested.

## Care and Maintenance

The DuraTwist pylon is designed to be maintenance free.

### Adjustment

The alignment screws should be checked and torqued to the specifications of 15 N·m at least once per year.

### Lubrication

The DuraTwist pylon is filled with a special permanent lubricant that will last the life of the unit. No lubricant should be used on or in the DuraTwist as it may cause failure and will void the warranty.

### Cap Screw

The cap screw in the top of the DuraTwist pylon is not to be removed. It is the factory lubrication port. Turning this screw does not adjust the function in any way. Tampering with or removing this screw will void the 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.

All metal components may be removed and recycled at the appropriate recycling facility

## Warranty

This product has a 12 month warranty for manufacturer defect from date of patient fitting.

# User Instructions

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

- Keep the DuraTwist clean and free of debris for the best performance.
- Avoid submerging the DuraTwist and always dry the components should they get wet.
- Should the DuraTwist malfunction in any way, discontinue immediately and contact your prosthetist.
- Contact your Prosthetist should you have any questions or concerns.

## Warnings and Precautions for the User



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## 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.

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