



endolite

get busy living



aqualimbTF

Instructions for Use

1 Description and purpose

The AqualimbTF is a prosthetic knee designed for above knee users.

The knee is water resistant and is intended for use as a shower limb ONLY.

Application:

These instructions are for use by the Clinician/Practitioner

The product is to be used exclusively as part of a lower limb prosthesis

Intended for single user

Maximum user weight 100kg

Ensure that the user has understood all instructions for use, drawing particular attention to the section regarding safety and maintenance.

Features:

- Geometrically stable 4 bar knee
- Hand operated knee lock, HOKL
- Corrosion resistant

Activity level:

Although intended for Activity Level 2 this device will benefit Activity Level 3 and 4 users for the purpose of showering only.

Contra-indications:

This device may not be used for any activity above level 2.

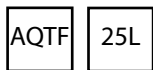
As the AqualimbTF is a free swinging device when the lock is not engaged , only users who can offer some control of the swing should be prescribed with the knee.

Not for use by transtibial users.

Checking the package contents:

1. Shin/Foot
2. Top Housing
3. Knee
4. Distal attachment nut, bolt and washer
5. Instructions for Use
6. User Guide

Order Example:



Size/Side

e.g. AQTF25L

Available from size 22 to size 27:

AQTF22L to AQTF27R

Safety Information



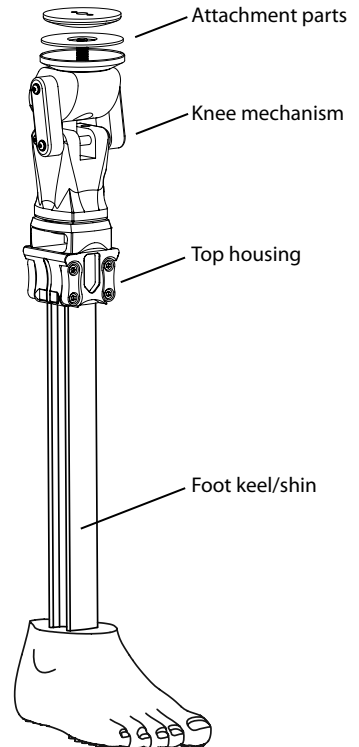
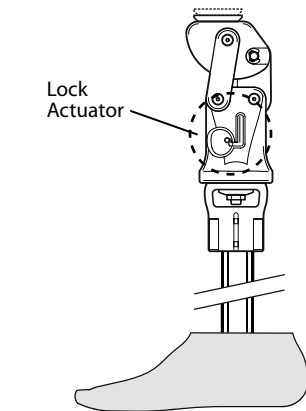
Be aware of a potential finger trap hazard at all times

1. Any changes in performance for example 'play', instability, lock not engaging, or changes in swing resistance should immediately be reported to your service provider.
2. Take all necessary safety precautions and due care on wet and slippery surfaces.
3. Avoid exposure to extreme heat and/or cold.
4. The product is not suitable for activities such as sports, running or cycling, ice and snow sports, slopes and steps. Any such activities are undertaken completely at the users' own risk.
5. The user must not adjust or tamper with the set-up of the product.
6. The user should be advised to contact their clinician if their condition changes.
7. The freedom of swing of the knee will vary slightly between when the knee is dry and when it is wet and /or contaminated with soap for example.

2 Construction

Principal parts:

- Knee mechanism
- (Acetal Homopolymer, Stainless Steel)
- Top housing
- (Glass fibre reinforced Nylon)
- Foot keel /shin
- (Glass fibre reinforced Nylon/PU)
- Attachment parts
- (Stainless Steel/ Aluminium Alloy)



3 Function

The knee has a polycentric design comprising pivots connecting a chassis to a main body via three link arms. A hand operated spring loaded pin operates within a latched slot in the body. The pin may be located to engage into the chassis and lock the knee in full extension. A housing is bolted to the distal aspect of the knee into which is clamped a foot/shin component. The shin may be shortened to suit the user. The sole of the foot features an anti-slip tread pattern.

Knee lock operation

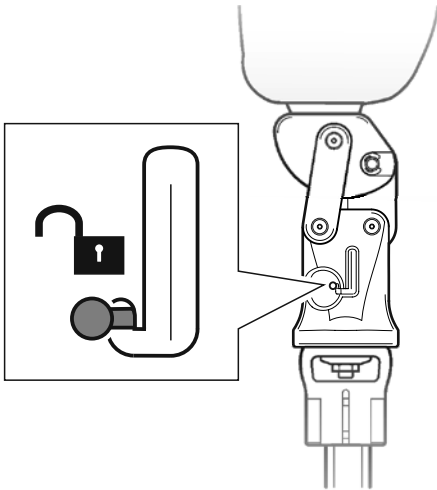


If lock mode is required ensure that the lock actuator is fully engaged before walking or showering.

The lock is hand operated. To lock the knee release the acuator from the down position, fully extend the knee and push the actuator up to the top position and ensure the actuator is fully engaged as shown.

Knee unlocked:

Actuator in down position

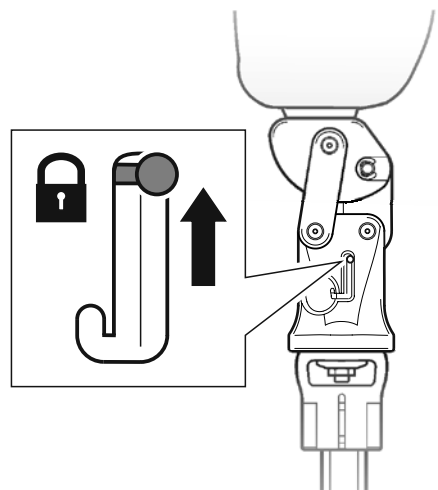


Knee shown in free mode.

The lock will not engage at full knee extension.

Knee locked:

Actuator fully engaged in top position



Knee shown with lock in place.

4 Maintenance

Maintenance must be carried out by competent personnel.

It is recommended that the following maintenance is carried out annually:

- Check the security of the proximal attachment nut and distal alignment bolt.
- Check for satisfactory function of knee lock and freedom of swing.
- Visually check for wear. Some surface damage may occur after a period of use; this does not affect the function or strength of the device.

The wearer should be advised:

Any changes in performance of this device must be reported to the practitioner.

Changes in performance may include:

- 'Play' in moving parts
- Lock not engaging
- Instability

Check condition of knee bumper and replace if necessary.

Cleaning:

Use a damp cloth and mild soap to clean outside surfaces, DO NOT use aggressive cleansers, wipe dry.

5 Limitations on use:

Intended life:

Service life of the product is covered by the warranty period - 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:

Avoid excessive contact with abrasive environments such as those containing sand for example, and rinse thoroughly after any such exposure.

Exclusively for use between -15°C and 50°C.

It is recommended that only Endolite products be used in conjunction with the product.

6 Assembly Instructions

1



Manufacture the socket using the appropriate Endolite single bolt former. Cut a 27mm diameter hole in distal end of socket. Place socket plate inside socket. Assemble alignment parts supplied. Minimum socket thickness 6mm

2



Apply Loctite 243 and torque the proximal alignment bolt to 35Nm.

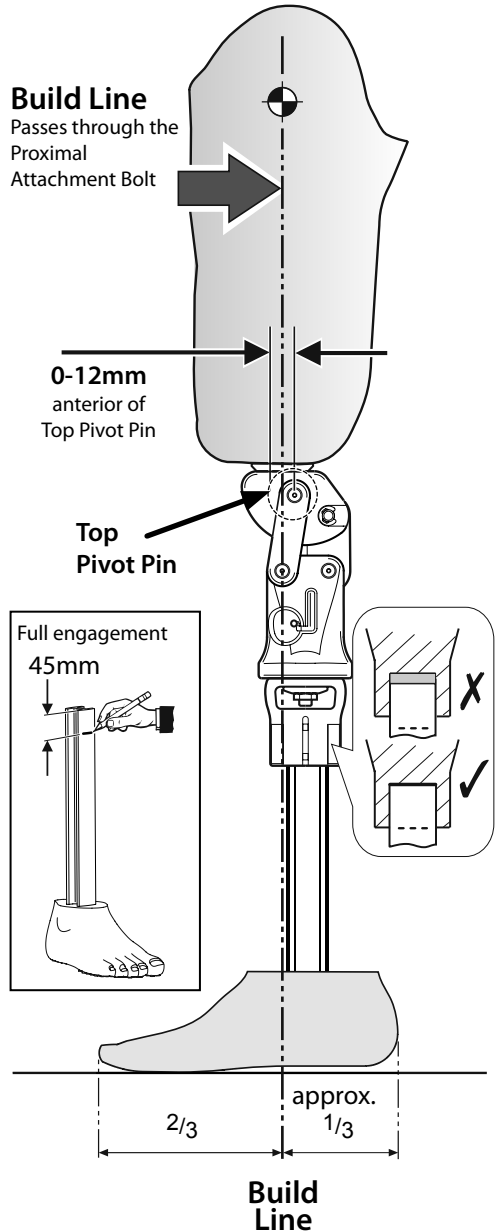
3



Apply Loctite 243 to bolt threads. Assemble the distal top housing using the nut and washer as shown and torque tighten to 35Nm after alignment.

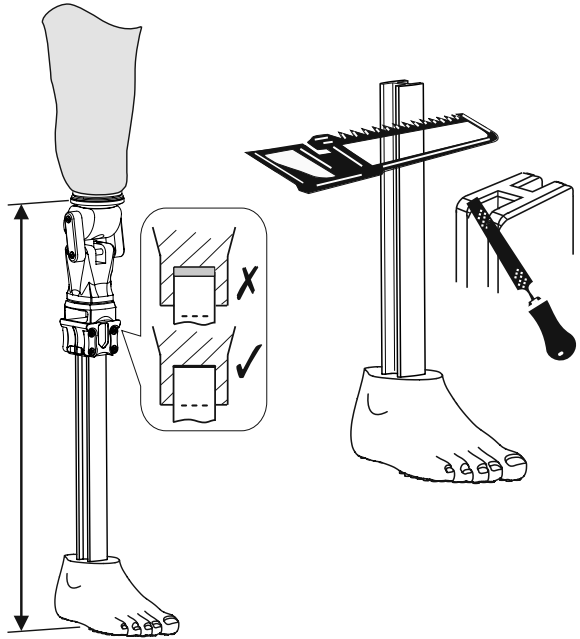
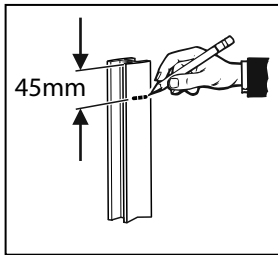
It may be easier to fit the shin before assembling the top housing. Ensure full engagement of shin, see diagram Section 7.

7 Alignment



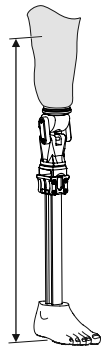
8 Fitting Instructions

- 1** Fit shin to housing ensuring full engagement. Measure length to determine amount to be cut from shin. Determine final cut length required. Remove shin from housing, cut to length and reassemble then check measurement.



Tighten clamp screws evenly, applying a torque of 5Nm at least twice to each screw. Example order of tightening shown to evenly spread load.

- 3** Check length and alignment. Finalise the screw settings during dynamic alignment.



9 Dynamic Alignment

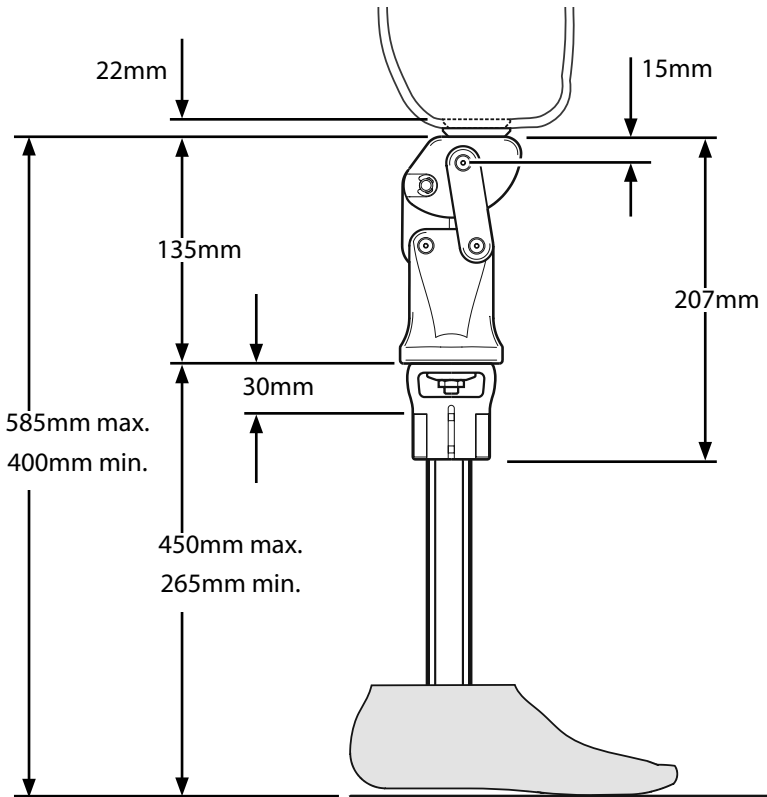
Set-up as shown in Bench Alignment if the user requires adjustment length, shift, rotation and angular adjustments are available by loosening, adjusting and re-tightening of distal and proximal alignment fixings.

Ensure after any adjustments are made, that the load line is not posterior to the top pivot pin.

10 Technical Data

Operating and Storage Temperature Range:	-15°C to 50°C 5°F to 122°F
Total Component Weight [size 24]:	2.0kg (4.4lbs)
Recommended Activity Level:	2
Maximum User Weight:	100kg
Proximal Alignment attachment:	Endolite single bolt alignment
Build Height:	400 - 585mm
[See diagram below]	

Fitting Length



11 Replacement Parts

Part	Part No.
Knee Bumper	622310
Screw Proximal M10 55 ST STL	910420

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. The manufacturer is not liable for damage caused by the component combinations that were not authorized by the manufacturer.

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. The Declaration of Conformity was therefore created by Blatchford Products Limited with sole responsibility according to Appendix VII of the guidelines.

Warranty

The aqualimbTF is warranted for 24 months from original date of purchase unless otherwise stated.

See Endolite catalogue for details.

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