



endolite

get busy living



aqualimbTF

User Guide

1 Description and purpose

The aqualimbTF is prosthetic knee designed for above knee users.

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

Application:

- The product is to be used exclusively as part of a lower limb prosthesis
- Intended for single user
- Maximum user weight 100kg

Please keep these instructions.

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.

Safety Information



Be aware of a potential finger trap hazard at all times

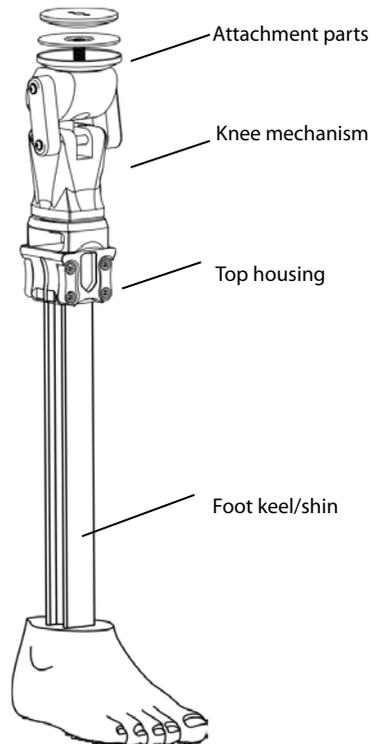
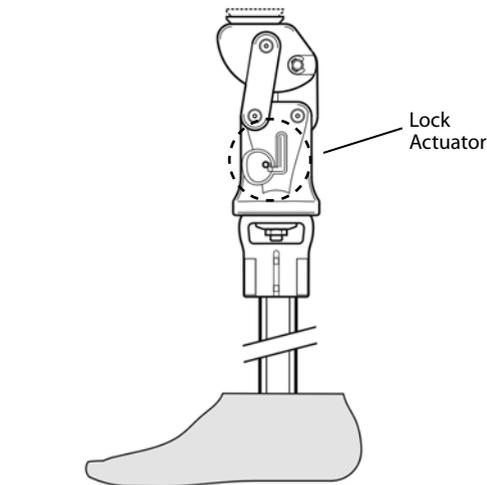
1. Any changes in performance for example 'play', instability, lock not engaging, or changes in swing resistance should immediately be reported to your service provider.
2. Take all necessary safety precautions and due care on wet and slippery surfaces.
3. Avoid exposure to extreme heat and/or cold.

4. The product is not suitable for extreme sports, running or cycling, ice and snow sports, extreme slopes and steps. Any such activities undertaken are done so completely at the users' own risk.
5. Do not adjust or tamper with the setup of the product
6. Contact your clinician if your 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

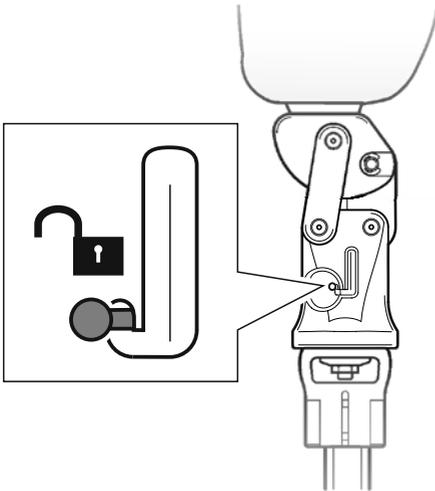


If lock mode is required ensure that the lock actuator is fully engaged before walking or showering.

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

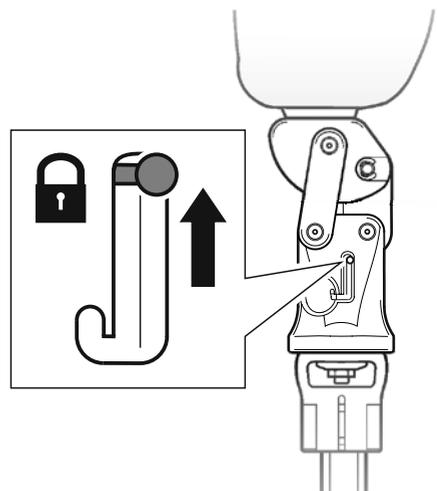


Knee shown in free mode.

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.

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

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 Technical Data

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

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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