

Little Feet Product Manual

Distributeur
LOTH fabenim
ORTHOPAEDIC AND REHAB SUPPLIES





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Intended Use / Purpose

EN Little Feet are simple, pediatric sized feet for use in lower extremity prosthetics. They are a bolt on design but also come in Symes versions which can be laminated. They are similar to SACH feet, but they have unique energy dynamics because they are molded from true polyurethane rubber elastomers not elastomeric foam. They are designed to fit children with foot sizes up to 15 cm long. Little Feet come in six model lengths; 10cm, 11cm, 12cm, 13cm, 14cm, and 15cm in both wood core and Symes versions, both left and right and in three colors Tan, Medium Brown, and Dark Complexion. All models have realistic anatomical, flexible “toes” and are slim enough to accommodate most all types of footwear. They are designed with a “heel plug” that seals the bottom of the foot for “barefoot” ambulation. Models 10-11 are molded in solid, flexible, strong polyurethane. Models 12-15 are molded with similar materials but have keels added for stability. The feet are functional for crawling, toddling, walking, etc. for children up to 5-6 years of age. Little Feet can be used unilaterally or bilaterally.

These devices are intended for single user/patient use only.

1.1 Performance Characteristics

Little Feet are prosthetic components for infants and young children. They provide limited energy storage and release action because of their materials but they are not categorized as true “energy storing” feet. They are functional for, crawling, toddling, walking, and running around but they are not designed for any level of sports performance. They provide very good stability and good “cushion”. They are applicable for trans-tibial and trans-femoral absence. They are soft to the touch and have good anatomical realism and can be used without socks and shoes or other foot ware. They need no additional prosthetic foot covering. Little Feet have not been stress tested and are not required to meet any USA prosthetic feet codes, but they have performed very well with minimal problems for over fifteen years. Align these feet as any regular SACH foot would be installed and aligned to meet the individual user’s needs.

1 Intended Use / Purpose

1.2 Indications / Contraindications

These prosthetic feet are designed especially for infants and young children up to ages 5-6 years old with transtibial and transfemoral absence with a shoe-foot size up to 15 cm in length. They are useful and will perform in crawling, toddling, ambulation walking and lower level running activities. They are strong but they are not high performance, energy storing, sports type prosthetic feet. They provide good barefoot cosmesis and stability and fit into most all footwear. Models 12-15 cm use a keel for extra stability. They install easily in a manner similar to any SACH type foot. They are available in Symes models.

Contraindications:

Fillauer TRS Pediatric Feet are not recommended for applications with clearance less than .684" (1.67 cm).

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Storage and Handling

It is recommended that any Fillauer TRS Pediatric Feet are stored in a cool, clean, dry environment away from harsh chemicals (chlorine, acids, acetone, etc.).

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Warnings and Precautions



CAUTION: Abnormal or improper environmental conditions will lead to malfunction and damage of the prosthesis and is not covered under the warranty of the device. This prosthetic component must not be subjected to dust/debris, liquids other than fresh water, abrasives, vibration, or activities which would damage the biological limb. Do not allow debris or liquids to remain in the prosthesis and its components during use. Rinse the foot with fresh water and dry immediately after exposure.



CAUTION: They are washable and mostly waterproof, but wood core models should not be immersed for any significant periods of time, unless the wood core block has been sealed. They can stain and certain types of inks and colors will permanently penetrate their polyurethane materials. Such stains may not be removeable. If submerged, these should be rinsed with fresh water and **dried** immediately to remove salt, chlorine, or debris.

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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.

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Specifications and Preparations Before Use

Specifications	LITTLE10	LITTLE11	LITTLE12
Length	3.0 in. (10.0 cm.)	4.3 in. (11.0 cm)	4.7in. (12.0cm.)
Width	1.9 in. (4.7cm.)	2.1 in. (5.2 cm.)	2.2 in. (5.6 cm.)
Height	1.7 in. (4.2 cm.)	1.7 in. (4.2cm.)	2.0 in. (5.0 cm.)
Weight	3.4 oz. (96 gm.)	4.1 oz. (117gm.)	5.9 oz. (167 gm.)
Wood Core	1.25 in. (3.2 cm.)	1.5 in. (3.8 cm.)	1.5 in. (3.8 cm.)
Diameter Major	1.7 in. (4.4 cm.)	1.9 in. (4.9 cm.)	2.1 in. (5.3 cm.)
Diameter Minor	1.6 in. (4.0 cm.)	1.7 in. (4.3 cm.)	1.9 in. (4.8 cm.)

Specifications	LITTLE13	LITTLE14	LITTLE15
Length	5.1in. (13.0 cm.)	5.43 in. (14.0 cm.)	5.8 in. (15 cm.)
Width	2.3 in. (5.9 cm.)	2.44 in. (6.2 cm.)	2.5 in. (6.4 cm.)
Height	2.1 in. (5.2 cm.)	2.2 in. (5.6 cm.)	2.2 in. (5.6 cm.)
Weight	7.0 oz (199 gm.)	8.4 oz. (238 gm.)	9.3 oz . (264 gm.)
Wood Core	1.5 in. (3.8cm.)	1.5 in. (3.8cm.)	1.5 in. (3.8cm.)
Diameter Major	2.2 in. (5.6 cm.)	2.27 in. (5.8 cm.)	2.23 in. (5.7 cm.)
Diameter Minor	1.90 in. (4.8 cm.)	1.94 in. (4.9 cm.)	1.94 in. (4.9 cm.)

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Applications

Trans-tibial - trans-femoral

5 Specifications and Preparations Before Use

5.1 Installation

Little Feet are easily installed and aligned in a manner similar to any SACH type foot, using standard endo-skeletal or exo-skeletal components. A titanium pyramid adapter is pre-installed with hardware to manufacturer's specifications. Attachment, alignment, and delivery of these feet must be performed by or under the direct supervision of a qualified prosthetist. Any adjustments or modifications should be completed by the clinician.

Mounting Hole: 5/16 inch, (8 mm) diameter

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Mounting Hardware: 5/16 x 2 inch bolt. M8 bolt, steel washer and "T" nut (all models)
2- 3/4 in. bolt also included with 12-15 cm models

5.2 Preparation

Consider the following factors as you determine the most appropriate technology and prosthesis design for your client:

1. In what types of environments will the device(s) be used?
2. In what positions will the person use the device?
3. How will the user or caregiver switch terminal devices if needed?
4. Will the user/caregiver benefit from additional training in the use of the device?

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Compatibility

Wood Core models can use standard pediatric pyramid adapters. Symes models can use standard pediatric Symes Nuts.

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Care and Maintenance

The foot should be cleaned with detergent-soap and water regularly and thoroughly dried. If barefoot use is a factor remove any soiling or staining from the sole of the foot and toes as soon as possible. Inspect the foot for any damage including tearing in the toe areas. The foot is water resistant but if it is to be submerged the wood core must be sealed to prevent water penetration. Remove any debris, salt, chlorine, etc. by washing with mild detergent and fresh water and dry thoroughly.

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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.

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User Information

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

9.1 Preparation for User

Consider the following factors as you prepare for this device:

1. Are you or caregiver able to don and to doff the device independently?
2. Are you able to access services from a skilled therapist for additional training if needed?

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Warnings and Precautions for the User



CAUTION: 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 component must not be subjected to dust/debris, liquids other than fresh water, abrasives, vibration, or activities which would damage the biological limb. Do not allow debris or liquids to remain in the prosthesis and its components during use. Rinse the foot with fresh water and dry immediately after exposure.



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11 Serious Incidents

In the unlikely event of a failure resulting in a fall and/or injury, seek immediate medical help and contact your prosthetist at the earliest possible convenience.

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12 Warranty

This product has a 12-month warranty against manufacturer defects.

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Fillauer Europe

Kung Hans väg 2

192 68 Sollentuna, Zweden

Tel: +46 (0) 8 505 332 00

Email: support@fillauer.eu

www.fillauer.eu



Contact



Loth Fabenim B.V.

De Liesbosch 14-G

3439 LC Nieuwegein, THE NETHERLANDS

Tel: +31 30 27 32 506

Fax: +31 30 27 11 045

Email: sales@lothfabenim.nl

www.lothfabenim.nl

Please contact us if you find any page missing or disordered.