LINDHE XTEND

xtend your life

Instructions for Use

Xtend® Foot Fri H100

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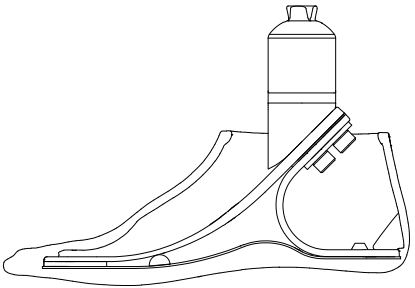
XTEND FOOT FRI H100

A flexible and waterproof prosthetic foot with shock/torsion functionality.



The foot and its different components

A complete foot consists of three main parts:

1) Fiber composite foot:
   - A) Forefoot laminate
   - B) Heel laminate
   - C) Base laminate
   - D) Pyramid
2) Footshell
3) Protective sock

Size and weight guide

It is important to match the correct foot prosthesis to the patient. The table must be followed when choosing a foot prosthesis. Before connecting the foot, double check the article number in the table to the right with the number marked on the foot's attachment socket. Always check that the patient's weight category is correct.

	Foot size [CM]						
Category	23	24	25	26	27	28	29
P3 Max. 60 kg	H100-323-STW	H100-324-STW					
P4 Max. 80 kg	H100-423-STY	H100-424-STY	H100-425-STY	H100-426-STY	H100-427-STY	H100-428-STY	H100-429-STY
P5 Max. 100 kg	H100-523-STG	H100-524-STG	H100-525-STG	H100-526-STG	H100-527-STG	H100-528-STG	H100-529-STG
P6 Max. 125 kg			H100-625-STR	H100-626-STR	H100-627-STR	H100-628-STR	H100-629-STR
P7 Max. 150 kg				H100-726-STB	H100-727-STB	H100-728-STB	H100-729-STB

INTENDED USE:

Xtend Foot Fri is a prosthetic foot intended to be used by below-knee or above-knee amputees and replaces a human foot. The prosthetic foot is designed to be fitted to the remaining prosthetic leg with a pyramid connection.

PATIENT INDICATIONS:

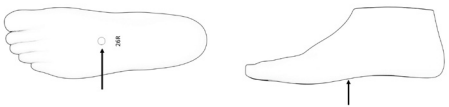
The prosthetic user is physically disabled, and the disability can vary from unilateral amputation of a lower leg or foot to bilateral hip amputation.

LIMITATIONS OF USE AND CONTRAINDICATIONS:

- The product is not intended for running or other repetitive high impact activities.
- Not intended for patients with a body weight over 150 kg (330 lbs). The permitted maximum weight, including body weight and any external load, 150 kg (330 lbs). Therefore, be mindful of lifting heavy weights.

GENERAL INSTRUCTIONS:

- Review the care and patient instructions with the patient at the time of fitting the product.
- Use Lindhe Xtend's size and weight guide to find the right product for the patient.
- Only authorized prosthetists may install the product on patients.
- If the footshell or sock should become worn, have it replaced immediately by a prosthetist.
- We recommend having the foot inspected by a prosthetist every six months. With very active use, shorter service intervals may be necessary.
- In extremely dirty or sandy environments, we recommend using a protective cover (such as Pro Armour).
- The foot is waterproof. If the foot has been exposed to water, or has been immersed in water, both the foot and footshell must be rinsed and dried. Make sure, however, that the prosthetic user does not detach the footshell from the fiber composite foot. This must be done by an authorized prosthetist.
- The foot prosthesis is designed for use in temperatures ranging from -30°C to +80°C.
- We recommend that the foot is used with socks and shoes as it prolongs the service life of the foot.
- All adverse events that occur and are related to this product should be reported to the manufacturer and the local authority in the country of occurred event.
- At the end of its lifecycle, the product should be disposed of through metal recycling.
- If the prosthetic foot is frequently used in water, a draining hole can be drilled in the footshell according to directions in the drawings below.



PATIENT INSTRUCTIONS:

- If the foot emits any noise, contact a prosthetist as soon as possible to inspect the foot. This also applies if the foot does not work properly.
- Note any change in or loss of function. This includes diminished shock absorptions, lateral flexibility, loss of forward elasticity or loss of torsion. Contact your prosthetist if this occurs, and do not use the product until its function has been examined.
- Remember that it can take up to 14 days to get used to a new foot prosthesis. Because the foot stimulates a natural pattern of movement, you may occasionally experience some muscle soreness in the amputated leg when you begin using it.
- If you dramatically gain or lose weight, contact your prosthetist to ensure that the foot prosthesis fits you.
- You should avoid heavy lifting, e.g. heavy rucksacks, as this affects the total load on the foot. If you often carry heavy loads, it is better to use a foot in a higher weight class. In this case, consult your prosthetist.

CLEANING INSTRUCTIONS:

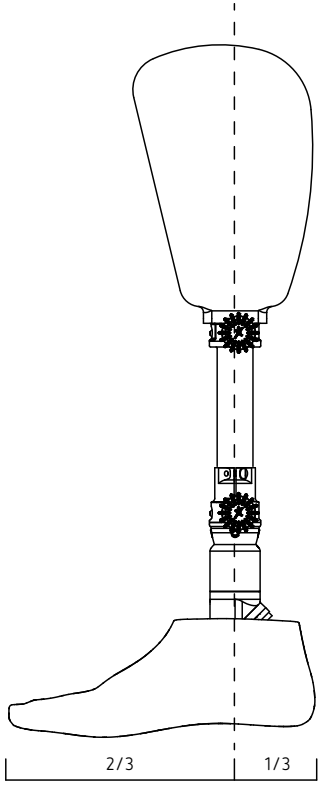
- The prosthetic user should clean the outside of the footshell at least once a week. We recommend using warm water and a gentle cleaning agent.
- If the foot has been exposed to sand or dirt on the inside of the footshell contact your prosthetist as soon as possible for cleaning and inspection.

INSTALLATION

Xtend Foot Fri has three different laminates that interact during use to reproduce sufficient energy while the foot compensates for uneven surfaces. The shock/torsion function inside the pyramid adds softness and movement in the transverse plane. Use only components according to industry standard when connecting to the foot pyramid. Thread locker e.g. Loctite 275 is needed for the installation

WARNINGS:

- Only trained personnel such as a prosthetist may install, carry out maintenance on and fit the product on prosthetic users.
- Do not remove the pyramid or modify the foot's construction. Any modifications made to the product will invalidate the product guarantee.



ADJUSTMENT

The foot must be adjusted and adapted to the patient for the greatest comfort possible. Observe the following fitting instructions to ensure proper fit.

Bench Alignment Instructions

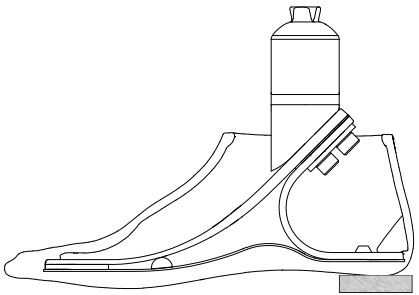
1. Position the foot so that the alignment reference line falls at the back 1/3 portion of the foot as seen from the side.
2. Use the applicable adapters to connect either the socket or the knee to the foot and establish the correct height.
3. If using a prosthetic knee: Position knee according to knee alignment instructions.
4. On the lateral side of the socket, make a first mark (alignment reference point) at the midpoint of the socket at either patellar tendon level or the ischial tuberosity level.
5. Position the socket so the alignment reference line goes through the alignment reference point.
6. Set the correct socket angles for flexion/extension and abduction/adduction.

Static adjustment

The foot prosthesis is designed for a 10 mm high heel. The foot prosthesis must be fitted in the footshell when tested on the patient. The unit must be either fitted in a shoe or alternatively a heel wedge can be used to adjust the height correctly when fitting. Centre the pyramid straight ahead and tighten the screws.

SETTINGS AND FINAL FITTING

The four adjustment screws for the tubular socket adapter must be tightened evenly using the torque value recommended by the manufacturer of the meeting component. Secure the adjustment screws when the right position is achieved using e.g. Loctite 275.



FOOTSHELL

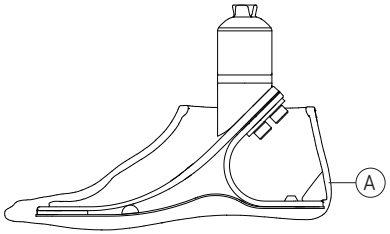
The foot is delivered assembled with the protective sock and the footshell. To secure the perfect fit, all sizes comes with a pre-mounted heel cap and the sizes 24, 25, 26 and 27 comes with a pre-mounted toe cap. The heel or toe cap should not be removed.
Please note: Only a Lindhe Xtend footshell may be used with the Xtend Foot Fri

REMOVING THE FOOTSHELL:

- Place the foot on a bench so the heel sticks out over the edge of the bench.
- Press down with your hand on the footshell heel's upper, so it snaps out of the heel retainer. If needed, carefully use a shoehorn to press down on the heel lock on the inside.

FITTING THE FOOTSHELL

When the footshell is fitted again, make sure that the heel and toe cap is on the foot for relevant sizes. Never use sharp tools such as screwdrivers to fit or remove the footshell. Use a shoehorn tooling to fit the composite foot under the heel lock in the footshell (See figure A).



WARNINGS:

- The product is not suitable for repetitive high impact activities.
- If heavy loads are carried or lifted, a foot in a higher weight class should be selected so that the max weight is not exceeded.
- Do not use the foot without a footshell. This can lead to unacceptable risk.
- Avoid using very acidic and alkaline cleaning agents when cleaning the foot prosthesis components.
- Do not reuse other persons prosthetic components due to unspecified history and use. It's a single user, multiple use device.
- Lindhe Xtend's foot prostheses are designed with a common pyramid interface. It is the prosthetist's responsibility to correctly adapt this interface to other prosthesis components.
- The prosthetic foot is NOT to be altered or modified outside the specifications of the product by the user or prosthetist.
- It is not allowed to use a prosthetic foot intended for a lower weight class, this can lead to unacceptable risks.
- Parts of the device can become hot when exposed to high temperatures.
- Be aware of pinch risk if holding fingers at the pyramids moving parts during load.

GUARANTEE:
36-month guarantee from the delivery date applies for the foot structure and 9-month guarantee applies for the footshell. Failure to follow the user instructions will invalidate the guarantee. Failure to follow the weight recommendations or exposing the component to unreasonable loads such as heavy lifting or similar activities which may otherwise have injured a human body part, will invalidate the terms of the guarantee.

The orange material is an active material in fiber-composite, designed to allow full lateral flexibility. This can cause superficial cracks in the laminate, which is completely normal, and the foot will maintain its function. Please contact Lindhe Xtend if you have any questions.

CUSTOMER SATISFACTION GUARANTEE
We offer a 30-day money-back guarantee from the consignment date. If you are not satisfied, you are entitled to return the item for a full refund.

FREQUENTLY ASKED USER QUESTIONS
What is the maximum weight for Xtend Foot Fri? The maximum weight for using the Xtend Foot Fri is 150 kg / 330 lbs (Category P7).

There is a maximum weight for each category of the foot, ensuring that the foot is safe, functional and durable. See the Size and weight guide on page 2.

Which other components, e.g. knee joints, fit with Xtend Foot Fri?
The interface between Xtend Foot Fri and other systems is a commonly used pyramid which can be adapted to those systems which are compatible with the pyramid.

The foot is making a noise. How can I correct it?
The cause of the noise has to be analysed. Contact your prosthetist. The prosthetist can remove the footshell and clean both the fiber composite foot and the footshell using compressed air or a soft cloth. Inspect the foot for visible damage or dirt. Also make sure the protective sock is intact and not damaged. Then mount the footshell as described above, and re-fit it on the patient. If the noise remains, contact Lindhe Xtend.

Can I run with the Xtend Foot Fri?
This foot is not developed for running or other sports activities, so for safety and durability of the foot we don't recommend running with Xtend Foot Fri.

Xtend Foot Fri H100 is covered by the following patents:

- USA US 10 383 746
- Japan JP 6 333 945
- European patent EP 2976049 in GB, FR, SE, DE
- European patent EP 3203933 in FR, GB, SE
- Germany DE 602014026164.7, 602015081091.0
- Sweden SE 538402
- New Patent Pending Application

Explanation of symbols

REF Product Reference Number
MD Medical Device
UDI Unique Device Information
SN Serial Number
Consult Instruction For Use
Warning
Manufacturer
Maximum weight

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If you don't find the information you need in this IFU - please contact customer service as per below.

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