

Low Profile Foot Shell & Protective Sock

Instructions for Use

Fillauer®

Device Information

Intended Purpose

The Low Profile Foot Shell is intended as a mechanical interface between the prosthetic foot and the user's chosen shoe.

Use conditions

- Keep away from prolonged periods of direct sunlight.
- Keep away from temperatures outside the range of -10C to 60C.
- Salt water and strong bases will shorten the products lifespan.
- Activity level K2, K3, K4.
- The protective sock must always be used together with the foot shell

Storage conditions

- Storage shelf life 2 years.
- Store in a dry, dark, and cool place.

Material and disposal

- The foot shell is made from BIOVYN PVC and can be disposed of as plastic waste.

Variants, accessories, and combinations

The Low Profile Foot Shell is available in 9 sizes (22–30 cm) and four colors (tan, brown, dark brown, and jet black), in a left or right option. The included sock serves as a protective interface between the prosthetic foot and foot shell and is available in three size ranges (22–24 cm, 25–27 cm, and 28–30 cm) corresponding to the foot shell size.

The Low Profile Foot Shell is intended for use with AllPro, Traverse, and Formula Fit prosthetic feet sizes 22-30. Selection is made by matching the foot shell size with the prosthetic foot size.

Specifications

Size	Weight
22 cm	170 g
23 cm	175 g
24 cm	181 g
25 cm	220 g
26 cm	230 g
27 cm	260 g
28 cm	280 g
29 cm	309 g
30 cm	350 g

Weight differs ± 10 g

Ordering Information

Replace XX with foot length (22–30 cm). Foot shell includes black protective sock.

Color	Left	Right
03	45-XX-12-03-3LP	45-XX-12-03-3LP
09	45-XX-12-09-3LP	45-XX-12-09-3LP
13	45-XX-12-13-3LP	45-XX-12-13-3LP
99	45-XX-12-99-3LP	45-XX-12-99-3LP

Expected lifetime and warranty

Lifetime varies with the user's activity level, maintenance, and the degree to which the foot shell is protected from external factors. The product is a wear part, which means it is subject to normal wear and tear.

Fillauer provides a 9-month warranty from the date of first installation for the Low Profile Foot Shell and protective sock.

Instructions for Users

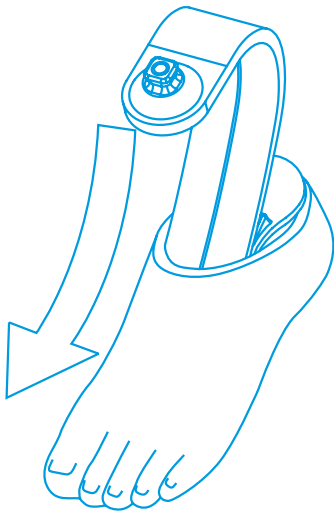
A qualified prosthetist or licensed healthcare professional shall select the appropriate product for the patient's prosthetic, verify correct fitting, and instruct the patient on the safe use and maintenance of the foot shell. This manual shall be provided to the patient for future reference.

Installation

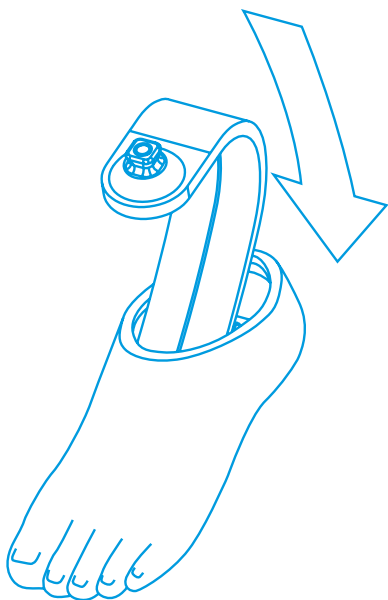
1. Inspect the foot shell and protective sock before each use.

2. Slide the protective sock onto the prosthetic foot from toe to heel with the size showing at the top of the heel. Pull any excess material toward the ankle so that the sock does not bunch under the heel or toe.

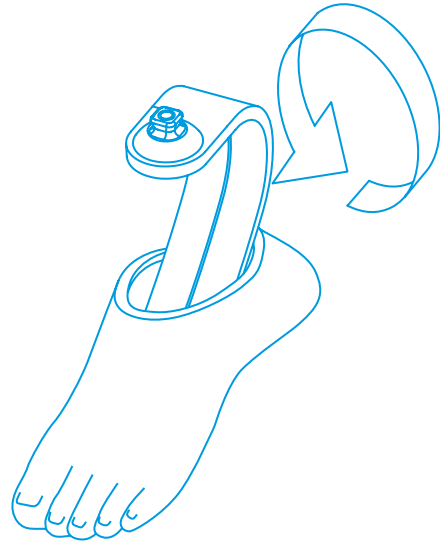
3. Insert foot into shell until toe is fully seated.



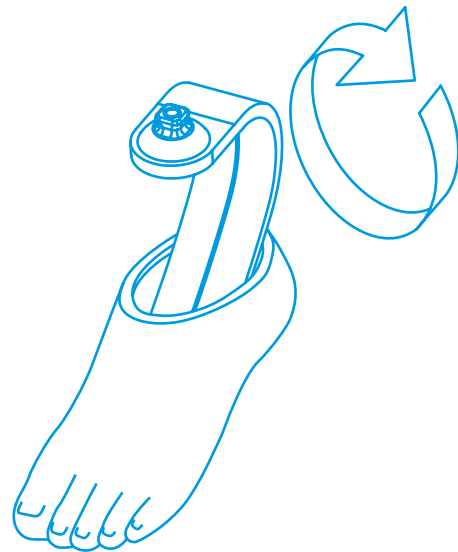
4. Press heel into shell as far as you can.



5. Rotate foot shell heel portion until one side of heel lock pops over foot heel.



6. Rotate foot shell heel opposite direction to pop the heel fully into the heel lock



7. Inspect the foot shell and protective sock daily before use for any defects, damage, or contamination.

Verification of correct installation

1. Confirm that the heel is securely locked in the heel lock (image ref.) position by feeling with your fingers that the heel is beneath the heel lock. Twist the foot multiaxially and pull the heel cap with moderate force to make sure it does not pop off the foot.
2. Confirm performance by test walking and looking for any deviations in performance, e.g., gait deviation or noise.
3. Do not use if the above confirmations cannot be made. Consult your healthcare professional if you are ever unsure of the performance of the foot shell.

Removal

1. Place the foot on the bench so that the heel hangs over the edge.
2. Remove the foot shell by hand, or with a smooth-edged shoehorn if the foot shell is too tight, by applying downward force to the top of the foot shell at the heel. The heel plate should disengage from the heel lock.

Maintenance

Cleaning

The foot shell and protective sock should be cleaned by the user at least once a month and whenever exposed to salt water, chlorinated water, sand, or other abrasive substances.

1. Hand wash the foot shell and protective sock with a soft cloth, a mild pH-neutral soap, and clear fresh water. Do not machine wash. The foot shell may also be cleaned with rubbing alcohol (70%). Do not use acetone or other solvents, as they may damage the shell material.
2. Rinse thoroughly with clear, fresh water, dry excess water with a soft cloth, and allow to fully air-dry to remove residual moisture before using or storing. Do not tumble dry.

Inspection

The protective sock should be inspected and replaced every 3–6 months by a prosthetist, if needed. The plantar surface of the foot should be inspected at this time. If the protective sock shows excessive wear, it should be replaced.

Replace the foot shell if any of the following occur:

1. The foot shell is cracked, torn, or shows signs of degradation.
2. The heel no longer locks securely in place.
3. Debris present inside the foot shell that cannot be removed by rinsing.

4. The protective sock is worn, has holes, or no longer fits properly.
5. You have any concerns about the condition or safety of the device.

Residual Risks

Warning

- Risk of injury from fall.
- Do not use the foot shell without appropriate shoes on wet or slippery surfaces.

Precaution

- Risk of injury from worn shell.
- Do not use product if inspection shows any degradation as this may lead to loss of function.

Contraindications

- Do not use without the included protective sock.
- Do not attempt to paint, grind, or structurally modify the shell.
- Do not use with other prosthetic feet and sizes than approved in this document.

Reporting of Serious Incidents

Any serious incident that has occurred in relation to this device shall be reported to the healthcare provider, manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

To report an incident, contact Fillauer Europe AB at:
support@fillauer.com.

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