EN

CE 2025	**ETHOS™ LP – LP3** *Instructions for use* ***Read before use***	IFU-01-020 Rev. C 2025-07

Pass on § 10, 11, 12, 13, 14, 15, 17, 18, and 19 of these instructions to the patient.

1. INCLUDED ITEMS

Part description	Part number	Included / Sold separately
ETHOS LP Adult Foot with Sandal Toe	LP3-00-0xAxx-xx*	Included
ETHOS LP Pediatric Foot with Regular Toe	LP3-00-0xPxx-RU*	
ETHOS LP Adult Foot with EVAQ8	LP3-V3-0xAxx-xx*	
EVAQ8 Rebuild Kit	EV2RB	Sold separately
EVAQ8 Release Valve	EVRV	Sold separately
Black Spectra Sock	S0-NPS-200xx-00*	Included
Adult Heel Wedge	OTS-39-00057-00	Included with Adult Feet
Pediatric Heel Wedge	OTS-39-00072-00	Included with Pediatric Feet
Foot Shell Removal Tool	ACC-00-10300-00	Sold separately
Adult Foot Shell with Sandal Toe (no cap)	FTC-2K-1	Sold separately
Pediatric Foot Shell with Regular Toe (no cap)	FTC-2M-1	

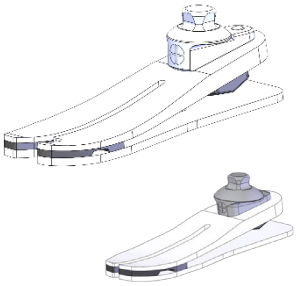
** See Catalog*

2. DESCRIPTION

ETHOS LP is an energy-storage-and-return prosthetic foot consisting of:

- A carbon and fiberglass keel
- A carbon and fiberglass half-rocker
- A male pyramid connection
- A rubber heel bumper
- A spectra sock

Available with right or left sandal toe for adult sizes and regular toe in pediatric sizes and delivered with a heel stiffening wedge.



3. PROPERTIES

Foot	**ETHOS LP for Adults**			**ETHOS LP for Pediatrics**
Side	Right or Left			
Size	22 to 25 cm	26 to 28 cm	29 to 30 cm	19 to 21 cm
Sandal toe option	Only	Only	Only	No
Weight*	425 g / 0.9 lbs	485 g / 1.1 lbs	656 g / 1.4 lbs	275 g / 0.6 lbs
Build height*	57 mm / 2.26''	58 mm / 2.3''	63 mm / 2.48''	42 mm / 1.66''
Heel height	10 mm / 3⁄8"			

**Based on sizes 20 cat 2P, 23, 26, 29, cat. 4, with foot shell, spectra sock and 10 mm heel height*

ETHOS LP for Adults was tested according to ISO 10328 for a maximum patient weight up to 166 kg for 2 million cycles.
ETHOS LP for Pediatrics was tested according to ISO 10328 for a maximum patient weight up to 60 kg for 2 million cycles.

Selection of foot category based on patient's weight and impact level for ETHOS LP for Adults											
Weight*)	**lbs**	100-115	116-130	131-150	151-170	171-195	196-220	221-255	256-285	286-325	326-365
	kg	44-52	53-59	60-68	69-77	78-88	89-100	101-116	117-130	131-147	148-166
Impact Level	**Low**	1	1	2	3	4	5	6	7	8	9
	Moderate	1	2	3	4	5	6	7	8	9	-
	High	2	3	4	5	6	7	8	9	-	-

**) Body mass limit not to be exceeded (ISO 10328)*

Selection of foot category based on patient's weight and impact level for ETHOS LP for Pediatrics					
Weight*)	**lbs**	<58	59-79	80-100	101-132
	kg	<26	26-36	36-45	46-60
Impact Level	**High**	1P	2P	3P	4P

**) Body mass limit not to be exceeded (ISO 10328)*

4. MECHANISM OF ACTION

At heel strike, the composite and heel bumper compress to absorb vertical shock forces and store energy to aid in progression to midstance. As the user progresses into terminal stance, the keel compresses with toe loading to store energy and return it at toe off.

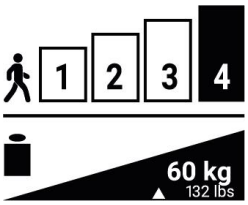
5. INTENDED USE/INDICATIONS

This medical device is supplied to healthcare professionals (prosthetists), who will train the patient in its use. The prescription is drawn up by a doctor who assess the patient's ability to use the device.

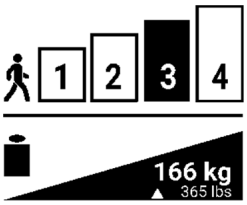
⚠ This device is for multiple use on a **SINGLE PATIENT**. It must not be used on another patient.

ETHOS LP is intended to be integrated in a custom-made external lower limb prosthesis to ensure the function of the foot in patients with unilateral or bilateral lower limb amputation and/or congenital limb deficiency. ETHOS LP is particularly suitable for patients with a long residual limb. The ETHOS LP for adults is indicated for adult patients with moderate activity level (K3) for walking and physical activities without excessive overload. The ETHOS LP for pediatrics is indicated for pediatric patients for walking and physical activities without excessive overload.

ETHOS LP Pediatric



ETHOS LP Adult



Maximum weight (load carrying included) for adults: 166 kg / 365 lbs

Maximum weight (load carrying included) for pediatrics: 60 kg / 132 lbs

(See table §3)

6. CLINICAL BENEFITS

- Walking comfort
- Walking on uneven ground
- Stability on variable terrain

7. ACCESSORIES AND COMPATIBILITY

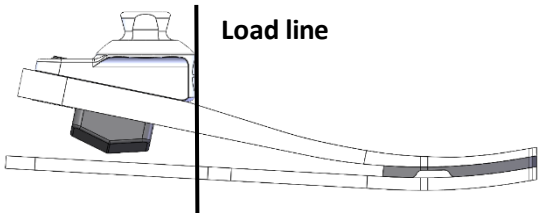
An appropriate foot shell must be mounted on the foot module (refer to our catalog).
The adult foot includes a 30mm male pyramid connection designed to be compatible with adult PROTEOR -female connectors. The pediatric foot includes a 22mm male pyramid connection designed to be used with pediatric PROTEOR -female connectors. See catalog for more information.

8. ALIGNMENTS

Bench Alignment

Before installing the prosthesis on the patient:

- Align the foot module in plantar/dorsal flexion, by inserting the foot (with foot shell) into the shoe to account for the heel height
- Align the socket in adduction/abduction, to ensure an appropriate angle in the frontal plane
- Align the socket in flexion/extension, to ensure an appropriate angle in the sagittal plane
- Adjust the position of the socket so that the load line falls to the anterior dome of the pyramid (see illustrations)



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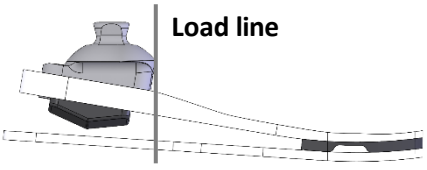


ETHOS LP Pediatric

Dynamic alignment

To optimize roll-over from heel to forefoot, adjust the following variables:

- Foot position in the anterior/posterior plane
- Plantar/dorsal flexion
- Heel flexibility

The dynamic alignment is performed in accordance with good professional practices.

9. ASSEMBLY

ETHOS LP is pre-assembled and consists of a foot module, a spectra sock, and a foot shell. After dynamic alignment, tighten the pyramid adjustment screws according to the specifications of the connector manufacturer. Secure pyramid adjustment screws with a thread locking adhesive (i.e., Loctite 242).

Spectra Sock

A spectra sock is included to protect the foot shell and minimize noise. It must be placed on the foot module before mounting the foot shell.

Foot Shell

To install and remove the foot shell, use the foot shell removal tool to prevent damaging the foot module. Foot shell may be modified for increased clearance as needed to accommodate various socket designs. Up to 30 mm may be removed.

⚠ Never remove the foot from the foot shell by pulling manually. This could damage the foot.

EVAQ8 models

The straight barb, exhaust filter, tubing, inline filter, socket right angle barb, and hose retainer are included with the foot and may require assembly prior to use.
The connection method to the socket is left to the discretion of the prosthetist. It is entirely dependent on the clinician's chosen socket design that will dictate how the EVAQ8 will be connected. There are many fabrication methods and materials that can be used. A socket should be fabricated using materials that will hold vacuum and provide a connection point for the EVAQ8 pump.

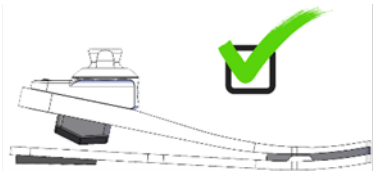
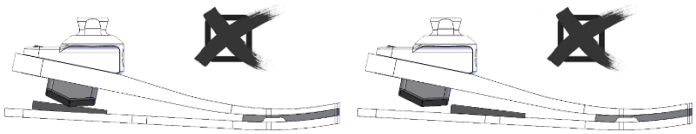
- This can be done using a specifically designed socket attachment plate for vacuum assisted suspension.
- A hole can be drilled and tapped into the distal end of the socket to accept a 90-degree barbed fitting. The barbed fitting provided with the kit is a 10-32 UNF thread.
- A hole can be drilled and tapped to accept an expulsion valve designed to be used with vacuum assisted systems.
- All 3 systems should be checked for leaks when completed.

To connect the vacuum system to the socket:

- Locate the vacuum hose coming out of the foot shell and sock. The hose should come connected to the inline filter, which is connected to a bent 90 degree tube, which is connected to the straight barb of the Valve Body Assembly.
- Route the vacuum hose to the medial side of the pylon or wrap the tubing around the pylon (to prevent damage to the tube or snagging while walking).
- Secure the tubing to the pylon using the included hose retainer or appropriate tape.
- Cut the tubing to desired length and connect to the barbed connection on the socket.

10. ADJUSTMENTS

If the patient still requests additional heel stiffness, use the heel wedges provided. The lower face of the sole plate should be degreased before using. Adult heel wedges use a double-sided sticker. Pediatric heel wedges need to be attached with cyanoacrylate (super glue). See figures below for correct wedge placement.

CORRECT HEEL WEDGE PLACEMENT	**INCORRECT HEEL WEDGE PLACEMENT**
	
Install Heel Wedge on plantar surface of the sole plate approximately 3.2 mm (1/8") anterior from posterior end.	Placement between components will adversely affect foot performance.

11. TROUBLESHOOTING

CONCERN	SYMPTOM	SOLUTION
Heel too soft	• Foot flat occurs too rapidly • Toe feels excessively stiff • Knee hyperextension	• Shift socket anteriorly in relation to the foot • Attach heel wedge. See section 10 above for installation details
Heel too hard	• Rapid knee flexion, instability • Heel to toe progression too fast • Lack of energy return sensation	• Shift socket posteriorly in relation to the foot • Verify appropriate foot module category
Foot module too stiff	• Flat spot in rollover motion at slow cadences	• Consider a lower category foot module
Foot module too soft	• Clicking noise at initial contact • Excessive toe deflection with high impact activity	• Consider a higher category foot module

12. WARNINGS

⚠ In case of damaged packaging, check the integrity of the device.

⚠ Never use the foot without a foot shell.

⚠ Never loosen the pyramid fastening screws.

⚠ The patient must inform their prosthetist if they gain or lose significant weight.

⚠ Always use the foot with a sock and shoe. Failure to adhere to this advice may cause product failure, as well as serious injury.

⚠ Make sure that the foot and inside of the foot shell are free of impurities (e.g., sand). The presence of impurities causes the graphite parts to wear out. Clean the foot according to the instructions (see §16).

⚠ After swimming, using in water or if splashed by a liquid, the foot must be cleaned (see §16).

⚠ If the patient notices any abnormal behavior or feel any changes in the characteristics of the device (noise, play, excessive wear…), or if the device has received a severe impact, they should stop using the device and consult their prosthetist.

⚠ Failure to follow the instructions for use is dangerous and will void the warranty.

13. CONTRAINDICATIONS

⚠ Do not use for a patient whose maximum weight (load carrying included) may exceed 166 kg / 365 lbs for adults, 60 kg / 132 lbs for pediatrics.

⚠ Do not use for activities associated with a risk of excessive overloading.

14. SIDE EFFECTS

There are no known side effects directly associated with the devices.
Any serious incident that has occurred in relation to the devices should be reported to the manufacturer and to the competent authority of the State in which the user is established.

15. MAINTENANCE AND CONTROL

The foot module must be inspected by the prosthetist at least every six months. Inspections at shorter intervals are required if the user is more active.
The spectra sock and the foot shell must be replaced by the prosthetist at regular intervals, depending on the patient's level of activity. If these parts are damaged, it can lead to premature foot wear.
The lifetime of the foot depends upon the patient's level of activity.

The **EVAQ8 models'** components (tubing, inline filter, one-way valves housed inside the Valve Body Assembly, etc) may need periodic cleaning or replacement during the life cycle of the system and are not replaceable under the warranty as it is considered normal wear.

16. PERIODIC INSPECTION OF THE EVAQ8 SYSTEM

- Visually inspect the tubing for kinks, cracks, or wear that may leak air into the system. Replace tubing if any of these conditions exist.
- Remove the inline filter from tubing and look through it. If light can be seen, the filter is clean. If light is blocked, push air from a syringe through the inline filter from distal to proximal end (reverse of normal flow) to attempt to clear the blockage. If blockage persists, the filter needs to be replaced.
- The one-way valves contained in the vacuum heel may need to be cleaned and flushed with distilled water or isopropyl alcohol to ensure proper function. This procedure should only be done by a qualified professional.

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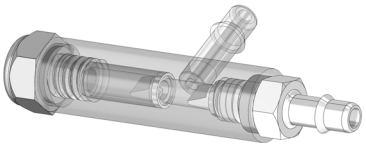
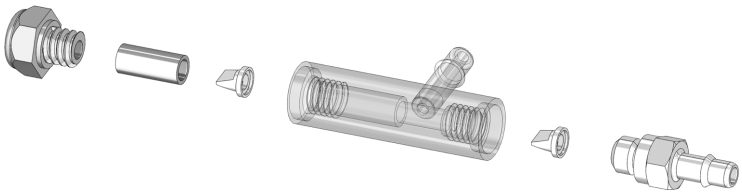
<tr><td>1
  </td><td>2 3 4 5 6 7
  </td></tr>
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3. Spacer
4. Duckbill Valve (exhaust)
5. Valve Body
6. Duckbill Valve (intake)
7. Straight Barb</td></tr>
</table>

- **To flush the one-way valves and vacuum pump:**
  - Disconnect the vacuum hose from the socket barb and remove the EVAQ8 foot from the user's socket.
  - Place the socket end of the vacuum hose into isopropyl alcohol or distilled water and slowly cycle the vacuum pump by compressing the heel of the foot with a T-bar or similar until the liquid can be seen coming out of (2) Exhaust Filter.
  - After a few cycles of fluid flowing through the system, remove the hose from the isopropyl alcohol or distilled water and cycle the pump slowly until no more fluid is exiting through the exhaust filter.
  - Reconnect the pump and vacuum hose.
- **To service and clean, or replace the components:**
  - Remove the vacuum hose from the user's socket keeping it attached to the EVAQ8 foot.
  - Remove the EVAQ8 foot from the user's socket.
  - Remove the vacuum hose from the EVAQ8 foot.
  - Remove (1) Valve Body Assembly from the rubber pump by pulling on it, while rocking side to side.
  - Using a $^{5}/_{16}$" socket, remove the (2) Exhaust Filter from (1) Valve Body Assembly.
  - Carefully tap the end of (1) Valve Body Assembly against your hand or on a table to allow (3) Spacer and (4) Duckbill Valve (exhaust) to slide out and allow removal from (1) Valve Body Assembly.
    NOTE: (4) Duckbill Valve (exhaust) will likely be pressed into the bottom of (3) Spacer.
  - Using a $^{1}/_{4}$" deep socket, remove (7) Straight Barb from the other side of (1) Valve Body Assembly.
  - Inside (1) Valve Body Assembly beneath where the (7) Straight Barb was located is another (6) Duckbill Valve (intake). Remove (6) Duckbill Valve (intake) by tapping (1) Valve Body Assembly against your hand or on a table, or by straightening out a paperclip and inserting it into the other side of (5) Valve Body to push out (6) Duckbill Valve (intake).
  - Clean the female threads in both sides of (5) Valve Body with a cotton swab and isopropyl alcohol or distilled water.
  - If you are reusing (2) Exhaust Filter, (7) Straight Barb, in-line filter, and (4) and (6) Duckbill Valves, clean them with isopropyl alcohol or distilled water. Take extra care and make sure (4) and (6) Duckbill Valves are clean and free from debris (a magnifier is helpful for inspection). Flush the in-line filter from both directions to ensure it is clean. **Allow valves to air-dry. DO NOT use a towel or cloth.**
  - Once the parts are dry, or if you are using new parts from a rebuild kit, set all the parts out on a clean surface.
  - Insert (4) Duckbill Valve (exhaust) into the end of (3) Spacer so that (4) Duckbill Valve (exhaust) rim is flush against the opening of (3) Spacer and the tip of (4) Duckbill Valve (exhaust) is inside (3) Spacer.
  - Slide (3) Spacer into the longer side of (5) Valve Body with (4) Duckbill Valve (exhaust) toward the inside. Thread (2) Exhaust Filter into (5) Valve Body **BY HAND** until snug. Torque to 15 in-lbs. Do not over torque. Over torquing will snap the threads and will not be covered under warranty.
    NOTE: If you do not have a torque wrench, thread (2) Exhaust Filter until you feel a hard stop and then turn $^{1}/_{16}$ of a revolution more.
  - Insert (6) Duckbill Valve (intake) into the short side of (5) Valve Body so the tip of (6) Duckbill Valve (intake) points into (5) Valve Body. Using a small screwdriver or a straightened-out paperclip, make sure (6) Duckbill Valve

(intake) is seated all the way into the recess.

- **BY HAND**, thread (7) Straight Barb into the short side of (5) Valve Body.
- Once the (7) Straight Barb is threaded in snugly **BY HAND**, torque it to 15 in-lbf. This is a very low torque value, and over torquing will snap the threads on the (7) Straight Barb and will not be covered under warranty.
  NOTE: If you do not have a torque wrench, thread (7) Straight Barb until you feel a hard stop and then turn $^{1}/_{16}$ of a revolution more.
- Insert (1) Valve Body Assembly into the rubber module with (7) Straight Barb pointed to the medial side of the foot. This allows the hose to be routed on the medial side of the pylon (to prevent damage to the tube or snagging while walking).
- Reattach the bent 90 degree tubing with the hose and inline filter. Reconnect the tubing to (7) Straight Barb.
- Put the Spectra Sock and foot shell over the EVAQ8 foot.
- Reattach the EVAQ8 foot to the user's pylon and socket.
- Reattach the other end of the vacuum hose to the user's socket. The vacuum hose may be routed to the prosthetist's preference.

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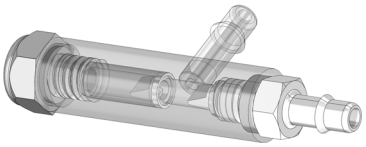
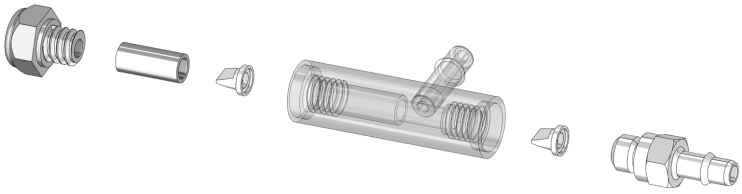
  </td><td>2 3 4 5 6 7
  </td></tr>
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17. CLEANING

Remove the foot shell and spectra sock, clean the foot with clear water and neutral soap and dry carefully. The foot shell can be cleaned with a damp cloth or sponge.

18. ENVIRONMENTAL CONDITIONS

Temperature range for use and storage: -28°C to +60°C/ -20°F to 140°F
Relative air humidity: no restrictions
Waterproof: the device is resistant to fresh, sea, and chlorinated water.

19. DISPOSAL

The feet are made of carbon and glass composite, epoxy, PU polymers, titanium, and stainless steel. The devices and their packaging must be disposed of in accordance with local or national environmental regulations.

20. DESCRIPTION OF THE SYMBOLS

	Manufacturer		**Identified risk**	CE 2025	**CE marking and year of 1st declaration**
EU REP	**Authorized representative in the European Union**	1	**Single patient, multiple use**		

21. REGULATORY INFORMATION

These products are CE-marked medical devices and are certified as conforming with Regulation (EU) 2017/745.

REVISION HISTORY			
Version	Date	Change Order	Description
A	28JAN2025	CO-30812	Initial Release
B	16MAY2025	CO-30812	Added foot shell modification for increased clearance + updated EC REP symbol to EU REP
C	09JUL2025	CO-32057	Added EVAQ8 details