	<b>ShockWave™ – F20</b> <i>Instructions for use for prosthetists</i> <b>Read before use</b>	IFU-01-097 Rev. G 2024-03
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**Pass on § 12, 13, 14, 15, 17, 18 and 19 of these instructions to the patient.**

## 1. INCLUDED ITEMS

Part description	Part number	Included / Sold separately
ShockWave Foot	F20-S3-xxAxx-xx*	Included
ShockWave Foot with EVAQ8	F20-V2-xxAxx-xx*	
EVAQ8 Rebuild Kit	EV2RB	Sold separately
EVAQ8 Release Valve	EV RV	Sold separately
Foot Shell	FTC-3F-xxxxx-Rx* FTC-2F-xxxxx-Sx*	Sold separately
Black spectra sock	SO-NPS-200xx-00*	Suitable sock included
Stiffening bumpers	KIT-00-1146U-00	Included (not with EVAQ8)

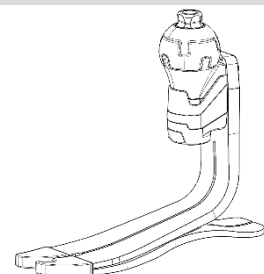
\* See Catalog

## 2. DESCRIPTION

ShockWave™ is an energy-return prosthetic foot consisting of:

- A J-shaped carbon keel
- A carbon sole plate
- A vertical loading pylon that provides controlled motion for shock absorption and axial rotation
- A spectra sock

Available with regular toe or right or left sandal toe and delivered with a set of elastomer stiffening bumpers (not with EVAQ8).



## 3. PROPERTIES

Side	Right or Left		
Size	23 to 25 cm	26 to 28 cm	29 to 30 cm
Sandal toe option	Yes	Yes	No
Weight*	897 g / 1.98 lb	978 g / 2.16 lbs	1131 g / 2.49 lbs
Build height*	176 mm / 6.9"	189 mm / 7.4"	200 mm / 7.9"
Heel height	10 mm / 3/8"		

\*Based on a sizes 23, 26, 29, cat. 4, with Foot Shell, Spectra Sock and 10 mm heel height

This device has been tested according to ISO 10328 for a maximum patient weight up to 147 kg for 2 million cycles.

Selection of foot category based on patient's weight and impact level										
Weight*)	lb	110-115	116-130	131-150	151-170	171-195	196-220	221-255	256-285	286-325
	kg	44-52	53-59	60-68	69-77	78-88	89-100	101-116	117-130	131-147
Impact level	Low	1	1	2	3	4	5	6	7	8
	Moderate	1	2	3	4	5	6	7	8	-
	High	2	3	4	5	6	7	8	-	-

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

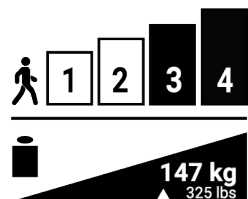
## 4. MECHANISM OF ACTION

From Initial Contact and into Loading Response, the sole and heel store energy, which is released as the user rolls into midstance. As the user surpasses midstance the forefoot is loaded, storing energy that is released at terminal stance for propulsion forward. The shock unit cushions shock and dampens rotational forces throughout the gait cycle and then returns the foot to a neutral position.

## 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.



This device 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 deficiencies.

This device is indicated for patients with moderate to high activity level (K3 to K4) for walking and physical activity without excessive overload.

Maximum weight (load carrying included): 147 kg / 325 lb (See table §3)

## 6. CLINICAL BENEFITS

- Walking comfort
- Possible walking on uneven ground
- Reduction of socket forces

## 7. ACCESSORIES AND COMPATIBILITY

An appropriate foot shell must be mounted on the foot module (refer to our catalog).

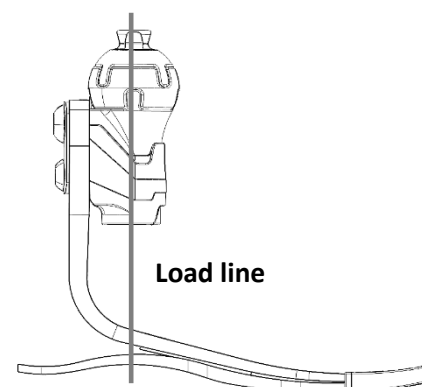
The foot includes a male pyramid connection designed to be compatible with standard female pyramid connectors (refer to our catalog).

## 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 through the center of the pylon (see illustration)



### 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

The ShockWave 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 over 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 damage to the foot module.

⚠ Never remove the foot from the foot shell by pulling manually. Never use a screwdriver or any other inappropriate instrument to remove it. 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.

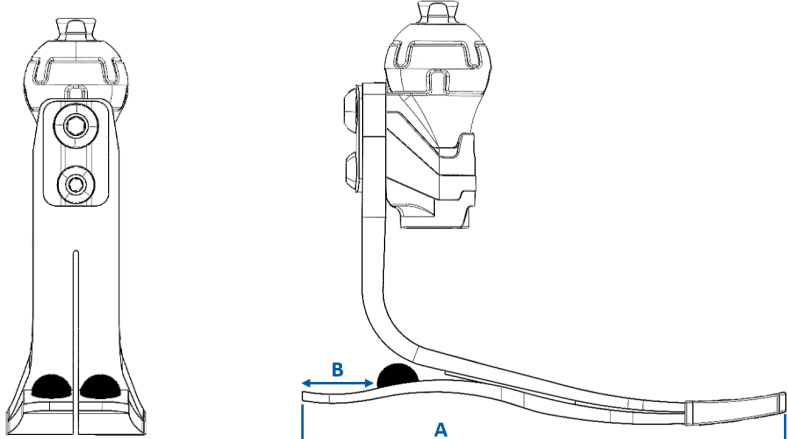
- This can be done using a specifically designed socket attachment plate for vacuum assisted suspension.
- A hole can be drilled and tapped into the distal end of the socket to accept a 90-degree barbed fitting. The barbed fitting provided with the kit is a 10-32 UNF thread.
- A hole can be drilled and 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

The heel stiffness at foot loading can be adjusted using the stiffening bumpers. The bumpers may be temporarily attached using the pre-applied adhesive in the location indicated in the table below. The recommended location will stiffen the heel of about 1 category. If necessary, move the bumpers anteriorly (stiffer) or posteriorly (softer) to get the desired stiffness. For permanent placement, clean off the pre-applied adhesive with acetone and adhere bumpers using cyanoacrylate glue. (Does not apply to EVAQ8 model)

Foot size (A)	Distance from the rear end of the sole (B)		
23-25 cm	29 mm / 1.1"		
26-28 cm	35 mm / 1.4"		
29-30 cm	48 mm / 1.9"		

## 11. TROUBLESHOOTING

CONCERN	SYMPTOM	SOLUTION
Heel too soft	<ul style="list-style-type: none"> <li>• Foot flat occurs too rapidly</li> <li>• Toe feels excessively stiff</li> <li>• Knee hyperextension</li> </ul>	<ul style="list-style-type: none"> <li>• Shift socket anteriorly in relation to the foot</li> <li>• Attach stiffening bumpers. See section 10 above for installation details</li> </ul>
Heel too hard	<ul style="list-style-type: none"> <li>• Rapid knee flexion, instability</li> <li>• Heel to toe progression too fast</li> <li>• Lack of energy return sensation</li> </ul>	<ul style="list-style-type: none"> <li>• Shift socket posteriorly in relation to the foot</li> <li>• Verify appropriate foot module category</li> </ul>
Foot module too stiff	<ul style="list-style-type: none"> <li>• Flat spot in rollover motion at slow cadences</li> </ul>	<ul style="list-style-type: none"> <li>• Consider a lower category foot module</li> </ul>
Foot module too soft	<ul style="list-style-type: none"> <li>• Clicking noise at initial contact</li> <li>• Excessive toe deflection with high impact activity</li> </ul>	<ul style="list-style-type: none"> <li>• Consider a higher category foot module</li> </ul>

## 12. WARNINGS

- ⚠ In case of damaged packaging, check the integrity of the device.
- ⚠ Never use the foot without a foot shell and a Spectra sock.
- ⚠ 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 147 kg / 325 lbs.
- ⚠ Do not use for activities associated with a risk of excessive overloading.
- ⚠ Do not use for a patient who do not meet the requirements of a Medicare functional level of K3 or higher.

## 14. SIDE EFFECTS

There are no known side effects directly associated with the device.

**Any serious incident that has occurred in relation to the device should be reported to the manufacturer and to the competent authority of the Member State in which the user is established.**

## 15. MAINTENANCE AND CONTROL

No maintenance operation such as lubrication, work on the screws or other parts is required.

It is recommended that the foot be inspected by the prosthetist at least every six months to check for damage to any components that may compromise the performance. Inspections at shorter intervals are recommended if the user is more active.

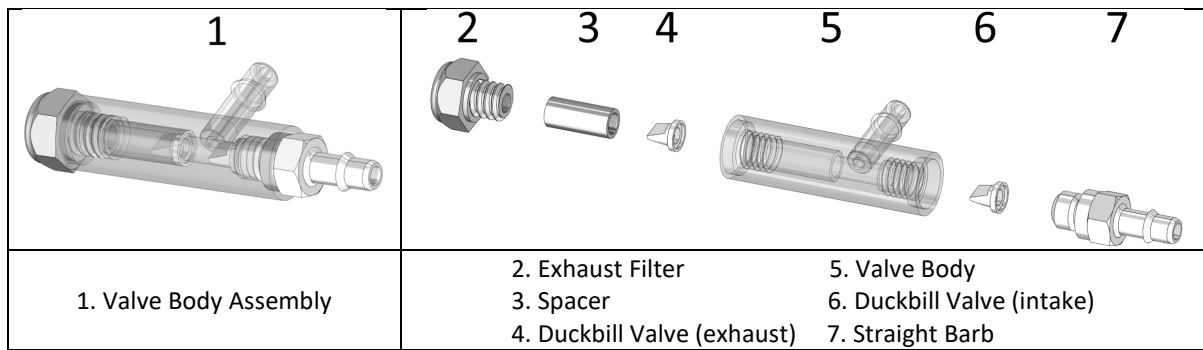
The Spectra sock and the foot shell should also be evaluated by the prosthetist at regular intervals, depending on the patient's level of activity. If these parts are damaged, it can lead to premature foot wear.

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.



• **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  $\frac{5}{16}$ " 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  $\frac{1}{4}$ " 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  $\frac{1}{16}$  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  $\frac{1}{16}$  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.

## 17. CLEANING

Remove the foot shell and the 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.


 The device is not resistant to solvents. Exposure to solvents may cause damage.

## 18. ENVIRONMENTAL CONDITIONS

Temperature range for use and storage: -29 to 49°C [-20 to 120° F]

Relative air humidity: no restrictions






**Water-resistant: the device is resistant to occasional immersion and splashes.**

 The foot shell is not resistant to ultraviolet light (UV). Do not store it under direct sunlight.

## 19. DISPOSAL

The foot is made of carbon fiber composite, epoxy, titanium, stainless steel, and rubber. The device and its packaging must be disposed of in accordance with local or national environmental regulations.

## 20. DESCRIPTION OF THE SYMBOLS

	Manufacturer		Identified risk		CE marking and year of 1 <sup>st</sup> declaration
	Authorized representative in the European Union		Single patient, multiple use		

## 21. REGULATORY INFORMATION

This product is a CE-marked medical device and is certified as conforming with Regulation (EU) 2017/745.

## INSTRUCTIONS FOR USE

REVISION HISTORY				
Rev	Change Description	Date	Change Order	Editor
A	Creation	2021-03-12	CO 6412	Stephanie PORTER
B	Update for compliance with Regulation (EU) 2017/745	2021-07-02	CO 7829	Valéry BARBOUR
C	Update of part numbers + deletion of the address of the manufacturer and authorized representative in each language and addition on the last page	2021-10-12	CO 9092	Valéry BARBOUR
D	Update of device properties (weight, build height) + modification of language code position	2022-02-10	CO 10424	Valéry BARBOUR
E	Addition of CERAH testing data in the French version	2022-11-11	CO 19901	Léa LUAIRE
F	Addition of stiffening bumpers installation details + new template	2023-10-11	CO 26636	Léa LUAIRE
G	Addition of EVAQ8 details and instructions + change of “activity level” to “impact level”	2024-03-12	CO 27888	Léa LUAIRE