



Sierra® – FS1
Instructions for use for prosthetists
Read before use

IFU-01-013
 Rev. B
 2024-03

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
Sierra Foot	FS1-00-0xAxx-xx*	Included
Sierra Foot with EVAQ8	FS1-V2-0xAxx-xx*	
EVAQ8 Rebuild Kit	EV2RB	Sold separately
EVAQ8 Release Valve	EVRV	Sold separately
Black Spectra sock	SO-NPS-200xx-00*	Suitable sock included
Stiffening bumpers	KIT-00-1135U-00	Included (not with EVAQ8)
Foot Shell Removal Tool	ACC-00-10300-00	Sold separately
Foot shell with regular toe (no cap)	FTC-3M-1	Sold separately (See Catalog)
Foot shell with sandal toe (no cap)	FTC-2M-1	

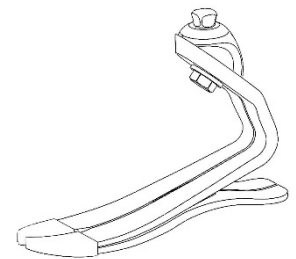
* See Catalog

2. DESCRIPTION

Sierra® is an energy-return prosthetic foot consisting of:

- A carbon keel
- A carbon sole plate
- A male pyramid connection
- 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	22 to 25 cm	26 to 28 cm	29 to 31 cm
Sandal toe option	Yes	Yes	No
Weight*	504 g / 1.1 lbs	597 g / 1.3 lbs	756 g / 1.7 lbs
Build height*	135 mm / 5.3"	158 mm / 6.2"	172 mm / 6.8"
Heel height	10 mm / 3/8"		

*Based on 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 166 kg for 2 million cycles.

Selection of foot category based on patient's weight and impact level

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)

4. MECHANISM OF ACTION

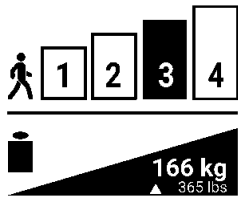
During the strike phase, the sole and heel store energy, which they return in the middle of the stance phase. This property creates the impetus enabling the forefoot to accumulate energy and return it upon the step completion.

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 activity level (K3) for walking and physical activity without excessive overload.

Maximum weight (load carrying included): 166 kg / 365 lbs (See table §3)

6. CLINICAL BENEFITS

- Walking comfort
- Reduction of joint impacts
- Stability on variable terrain
- Possible walking on uneven ground

7. ACCESSORIES AND COMPATIBILITY

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

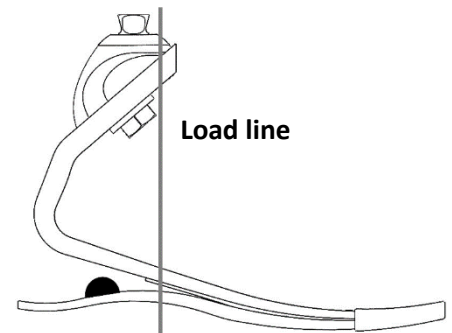
The foot includes a male pyramid connection designed to be compatible with standard female pyramid connectors (see our catalog).

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 to the anterior dome of the pyramid (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 Sierra 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 damage of the foot module.

⚠ 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

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)	
22-25 cm	29 mm / 1,14"	
26-28 cm	35 mm / 1,4"	
29-31 cm	48 mm / 1,9"	

11. TROUBLESHOOTING

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

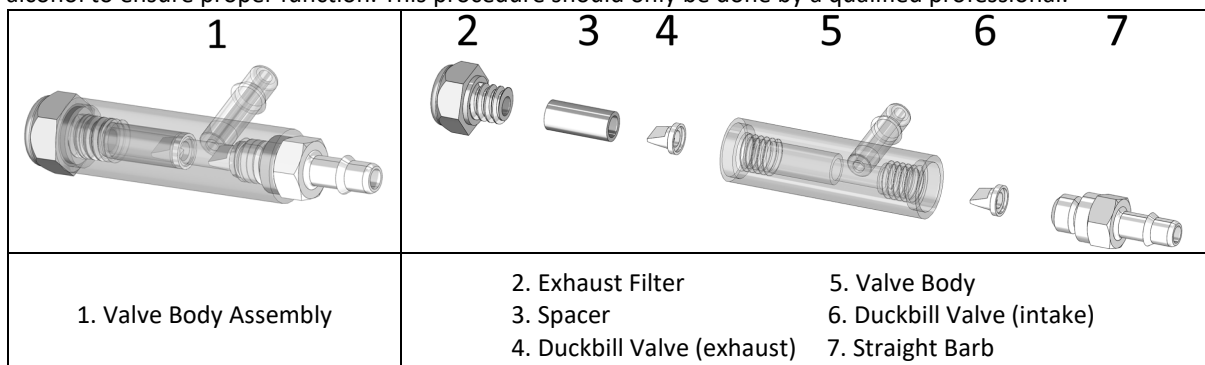
The Spectra sock and the foot shell must be replaced by the prosthetist at regular intervals, depending on the patient’s level of activity. If these parts are damaged, it can lead to premature foot wear.

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.

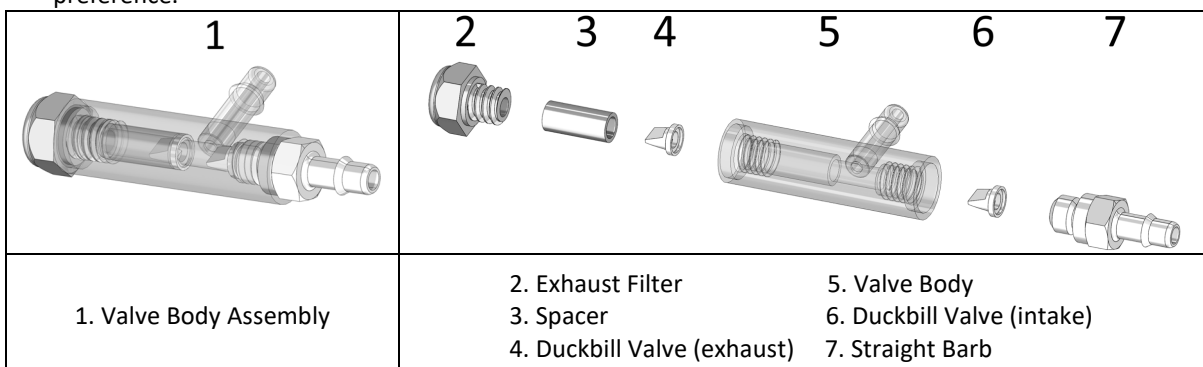
16. PERIODIC INSPECTION OF THE EVAQ8 SYSTEM

- 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.



- **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.



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.

18. ENVIRONMENTAL CONDITIONS

Temperature range for use and storage: -20 to 60°C






Relative air humidity: no restrictions

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

19. DISPOSAL

The foot is made of carbon fiber composite, epoxy, PU polymers, titanium, and stainless steel. 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 st 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	Update for compliance with Regulation (EU) 2017/745	2023-05-03	CO 22968	Léa LUAIRE
B	Addition of EVAQ8 details and instructions + change of "activity level" to "impact level"	2024-03-12	CO 27884	Léa LUAIRE