EN

CE 2023	**Kinterra® – RM3** *Instructions for use for prosthetists* ***Read before use***	IFU-02-005 Rev. D 2024-02

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
Kinterra Foot & Ankle system	RM3-00-0xAxx-Sx*	Included
Kinterra Foot & Ankle system with EVAQ8	RM3-V2-0xAxx-Sx*	Included
EVAQ8 Rebuild Kit	EV2RB	Sold separately
EVAQ8 Release Valve	EVRV	Sold separately
Black spectra sock	S0-NPS-200xx-00*	Suitable sock included
Stiffening Bumpers	KIT-00-1147U-00	Included (not with EVAQ8)
Foot Shell with sandal toe (no cap)	FTC-2K-1xxt4-Sx*	Sold separately (See Catalog)

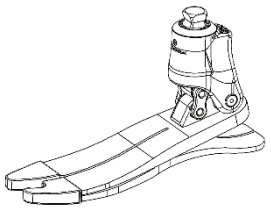
** x = See Catalog*

2. DESCRIPTION

Kinterra is a foot-ankle system consisting of:

- A hydraulic ankle with dorsi-assist spring
- An EnduraCore® foot module
- A male pyramid connection
- A black spectra sock

Available in right or left sandal toe and delivered with a set of elastomer stiffening bumpers.



3. PROPERTIES

Side		Right or Left Sandal Toe		
Sizes		22-25 cm	26-28 cm	29-30 cm
Weight*		764 g / 1.7 lb	833 g / 1.8 lb	956 g / 2.1 lb
Build Height*		118 mm / 4.65”	119 mm / 4.67”	122 mm / 4.81”
Heel Height		10 mm / 3/8”		
Range of Motion	**Plantarflexion**	15°		
	Dorsiflexion	2°		

**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 150 kg for 2 million cycles.

Selection of foot category based on patient’s weight and activity level										
Weight*)	**lb**	100-115	116-130	131-150	151-170	171-195	196-220	221-255	256-290	291-330
	kg	44-52	53-59	60-68	69-77	78-88	89-100	101-116	117-132	133-150
Impact Level	**Low**	1	1	2	3	4	5	6	7	8
	Moderate	1	2	3	4	5	6	7	8	-

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

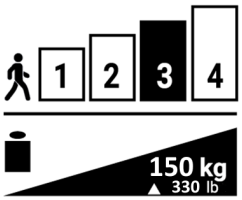
4. MECHANISM OF ACTION

At heel strike, the EnduraCore heel compresses to store energy, and the hydraulic ankle plantarflexes to reach foot flat depending on the angle of the terrain. Once foot flat is reached, the hydraulic ankle allows tibial progression to 2° of dorsiflexion and the heel compression energy is returned midstance. Once full hydraulic dorsiflexion is reached, EnduraCore foot module deflection begins to store energy. This energy is then returned 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 provided by a doctor who assesses 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 and ankle in patients with unilateral or bilateral lower limb amputation and/or deficiencies (transtibial/transfemoral amputation, knee/hip disarticulation, congenital limb deficiencies).

⚠ Caution should be used when fitting bilateral patients due to added movement of the ankle.

This device is indicated for patients with moderate activity level (K3) for walking and low to moderate impact activities.

Maximum weight (load carrying included): 150 kg / 330 lb (See table §3)

6. CLINICAL BENEFITS

- Increased step length and gait symmetry
- Increased swing phase toe clearance
- Improved sitting comfort
- Improved comfort and safety on uneven terrain
- Improved comfort and control descending ramps
- Improved knee stability

7. ACCESSORIES AND COMPATIBILITY

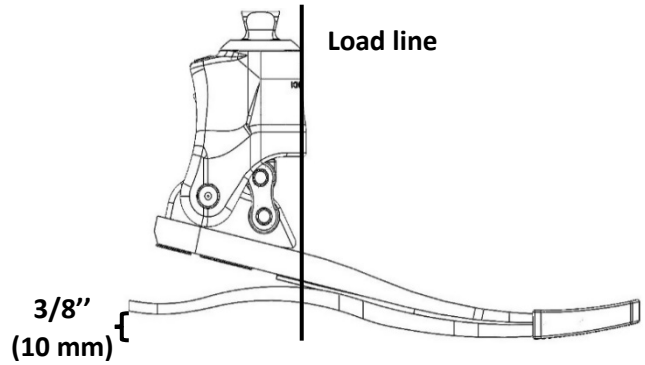
An appropriate foot shell must be installed on the foot module (refer to our catalog).

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

8. ALIGNMENTS

Bench Alignment

Before fitting the prosthesis on the patient, with the foot shell installed and a 3/8" (10 mm) lift under the heel, or preferably placed in the desired shoe, use a plumb line or laser level to confirm that the load line falls along the anterior edge of the pylon and pyramid (see illustration).



Static Alignment

- Set the hydraulic valves to highest resistance.
- Ask the patient to stand between parallel bars with weight evenly distributed. The patient should be able to stand comfortably without feeling as if the knee is flexing or hyperextending. The weight line should fall along the anterior edge of the pylon and pyramid.
    - If the knee is flexing, shift the foot anteriorly.
    - If the knee is hyperextending, shift the foot posteriorly.

⚠ Angular adjustment of the pyramid will impact the ratio of the 17 degrees range of motion. Plantarflexing at the pyramid will decrease the dorsiflexion range of motion and dorsiflexing at the pyramid will increase the plantarflexion range of motion. Ensure that the range of dorsiflexion and plantarflexion motion is maintained when flexion is properly accommodated. The ankle is intended to have 2° dorsiflexion and 15° plantarflexion.

- After at least a 10 minute acclimation period, proceed to valve resistance adjustments.

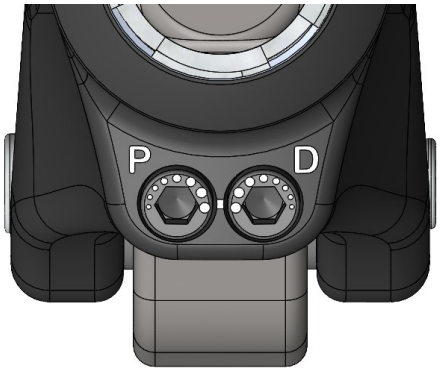
Dynamic Alignment

Adjust the hydraulic valves carefully to balance the comfort provided by the hydraulic ankle and energy return provided by the foot module. Higher resistance will allow the carbon fiber to be loaded more and provide more energy return. Lower resistance will allow more ankle motion and comfort while sitting and ambulating on slopes and uneven terrain.

Changes to the plantarflexion and dorsiflexion resistance settings will be most noticeable to the patient when they are walking on slopes. Adjustments of the resistances are best done on a gradual slope as a final step in dynamic alignment.

- Observe the patient walking between parallel bars.

- Adjust **plantarflexion resistance** (P) using a 4 mm Allen wrench (see illustration below):
  - If there is foot slap or heel strike is too abrupt, increase plantarflexion resistance.
  - If the heel is too firm or the knee is buckling at heel strike, decrease plantarflexion resistance.
- In the same way, adjust **dorsiflexion resistance** (D) using a 4 mm Allen wrench:
  - If the patient feels they are walking downhill, increase dorsiflexion resistance.
  - If the effort to advance over the foot (tibial progression) is challenging for the patient, decrease dorsiflexion resistance.



Smaller Dot = Lower Resistance **Larger Dot = Higher Resistance**

9. ASSEMBLY

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 EnduraCore foot module before mounting the foot shell.

Foot shell

To install and remove the foot shell, use a foot shell removal tool to prevent damage of 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.

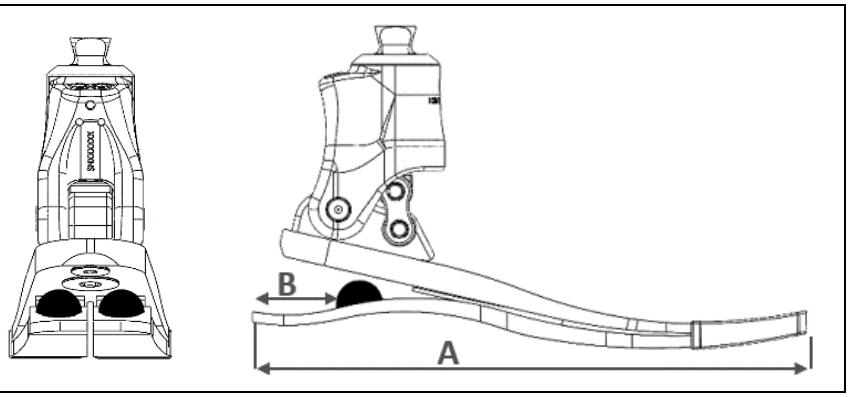
To connect the vacuum system to the socket:

- 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 heel strike 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 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	22 mm / 0.9''
26-28 cm	30 mm / 1.2''
29-30 cm	38 mm / 1.5''



11. TROUBLESHOOTING

CONCERN	SYMPTOM	SOLUTION
Heel too soft	• Sinking at heel strike, 'crushing' the heel. • Difficult to progress the step from heel strike to mid stance.	• Check anteroposterior alignment, ensure foot is not positioned too far anterior. • Increase plantarflexion resistance. • Attach heel stiffening bumpers. See section 10 above for installation details
Heel too hard	• Rapid knee flexion moment, instability at heel strike. • Lack of energy return sensation at heel strike.	• Check anteroposterior alignment, ensure foot is not positioned too far posterior. • Reduce plantarflexion resistance.
Foot module too stiff	• Flat spot in rollover motion. • Difficult to progress over toe.	• Assess true impact level (low or moderate). • Consider a lower category foot module.
Foot module too soft	• Clicking noise at initial contact. • Excessive toe deflection.	• Assess true impact level (low or moderate). • Consider a higher category foot module.

12. WARNINGS

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

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

⚠ Advise users to practice driving, sitting, and standing with the Kinterra in a safe place to ensure they adjust to the plantar and dorsiflexion movement provided by the ankle.

⚠ Never use the foot module without a foot shell and a spectra sock. Failure to comply may cause premature wear, loss of function, and/or product failure.

⚠ Always use the foot module with a shoe. Failure to comply may cause premature wear, loss of function, and/or product failure.

⚠ 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 and the foot shell to wear out. Clean the foot according to the instructions (see §16).

⚠ Never attempt to loosen the bolts affixing the ankle to foot.

⚠ If the patient notices any abnormal behavior or feels 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.

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

13. CONTRAINDICATIONS

⚠ Use for a patient whose maximum weight (load carrying included) may exceed 150 kg / 330 lb.

⚠ Use for K4 patient or activities associated with a risk of significant impact or 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 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.

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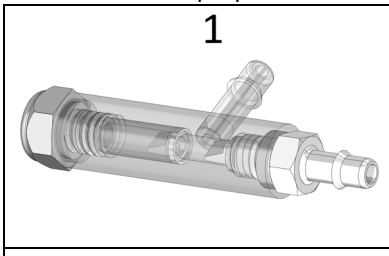
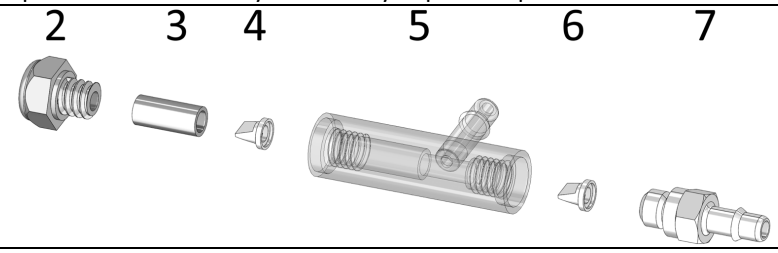
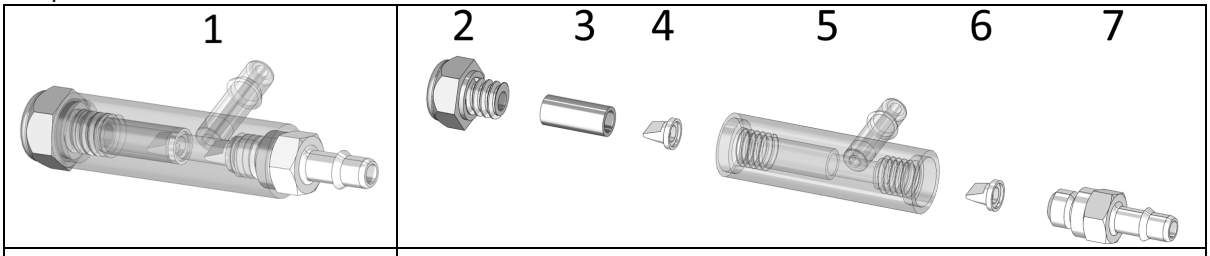
<tr><td>  </td><td>  </td></tr>
<tr><td>1. Valve Body Assembly</td><td>2. Exhaust Filter
3. Spacer
4. Duckbill Valve (exhaust)
5. Valve Body
6. Duckbill Valve (intake)
7. Straight Barb</td></tr>
</table>

- **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.



1. Valve Body Assembly	2. Exhaust Filter 3. Spacer 4. Duckbill Valve (exhaust) 5. Valve Body 6. Duckbill Valve (intake) 7. Straight Barb

17. CLEANING

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

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

18. ENVIRONMENTAL CONDITIONS

Temperature range for use and storage: -29°C to +49°C [-20°F to 120°F]
Relative air humidity: no restrictions
Water-resistance: Occasional submersion in water for maximum 30 minutes in 1 m of water.

⚠ Avoid prolonged use in water. Extended exposure to moisture may have a negative impact on the life of the product. After use in water, completely dry the foot, including its foot shell.

⚠ Avoid prolonged use in salt or chlorinated water. Extended exposure to these environments may have a negative impact on the life of the product. After use in these environments, the foot including its foot shell must be cleaned and dried (see §16).

19. DISPOSAL

The device is made of carbon fiber and other composite fibers, aluminum, titanium, stainless steel, hydraulic fluid, rubber, and epoxy. The foot shell is made of thermosetting polymer material. 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 1st 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.

REVISION HISTORY				
Rev	**Change Description**	**Date**	**Change Order**	**Editor**
A	Creation of document	2023-05-09	CO 24800	L. Luaire
B	Modification of section 17. Replace fresh water to water. Remove “Not recommended for a shower prosthesis.” Move 2 warnings from section 12. To section 17.	2023-09-28	CO 26508	V. Barbour
C	Correction of stiffening bumper location indications	2023-10-31	CO 26840	L. Luaire
D	Addition of EVAQ8 details and instructions	2024-02-08	CO 27664	L. Luaire