EN

CE 2021	**Freedom ShockWave™ by PROTEOR** *Prosthetist Instructions for use* ***Read before use***	IFU-01-097 Rev D 2022-01

Pass on § 3, 7, 8, and 9 of these instructions to the Patient.

1 INCLUDED ITEMS

Part Description	Part Number	Included/Sold Separately
ShockWave Foot	F20-S3-XXAYY-ZZ	Included
Foot Shell	FTC-3F-1XXX4-RX FTC-2F-1XXX4-SX	Sold Separately
Spectra™ Sock	SO-NPS-XXXXX-00	Included
Heel Bumper Kit (Sizes 23-25 cm)	KIT-00-11463-00	Appropriate Kit Included
Heel Bumper Kit (Sizes 26-28 cm)	KIT-00-11464-00	
Heel Bumper Kit (Sizes 29-30 cm)	KIT-00-11465-00	

2 DESCRIPTION AND PROPERTIES

A. Description

The ShockWave is an energy storing prosthetic foot with J-shaped keel, heel component, and a vertical loading pylon that provides controlled motion for shock absorption and axial rotation.

B. Properties

Weight		2.10 lbs / 978g
Build Height	23 – 25cm	6.9” / 176mm
	26 – 28cm	7.4” / 189mm
	29 – 30cm	7.8” / 200mm
Heel Rise		3⁄8”/ 10mm
Weight based on a size 26cm, Cat 4 Foot Module with Foot Shell and Spectra Sock. Build height based on 23cm, 26cm or 29cm, Cat 4 Foot Module with Foot Shell, Spectra Sock, and 10mm heel rise.		

This device has undergone a two-million-cycle test, in accordance with standard ISO 10328 (at a P7 load level for 147kg [325 lbs.]), which corresponds to a service life of 2 to 3 years, depending on the patient’s activity level.

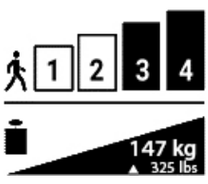
Category Selection Guide										
Weight	lb	110-115	116-130	131-150	151-170	171-195	196-220	221-255	256-285	286-325
	kg	44-52	53-59	60-68	69-77	78-88	89-100	101-116	117-130	131-147
Activity Level	Low	1	1	2	3	4	5	6	7	8
	Moderate	1	2	3	4	5	6	7	8	-
	High	2	3	4	5	6	7	8	-	-

3 INTENDED USE/INDICATIONS

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

⚠ This device is for **SINGLE PATIENT** use. It should not be reused on another patient.

This device is intended for use by prosthesis wearers who would benefit from the safety, stability, and improved gait dynamics of the ShockWave. Users should meet the requirements of a Medicare functional level of K3 or higher.



This device is indicated for use as a component in a prosthetic leg for individuals with unilateral or bilateral lower-limb amputations or limb deficiencies, including:

- Transtibial amputation
- Transfemoral amputation
- Knee disarticulation amputation
- Hip disarticulation amputation
- Congenital, lower-limb deficiencies

Maximum weight (load carrying included): See above table

4 CLINICAL BENEFITS

The device provides clinical benefits and performance including:

- Ability to ambulate on variable terrain
- Shock absorption
- Axial rotation
- Reduced socket forces and increased comfort

5 ACCESSORIES AND COMPATIBILITIES

The foot incorporates a male pyramid link that allows it to be used with female pyramid connectors (refer to our catalog).

6 ASSEMBLY AND PATIENT FITTING

A. Assembly

The ShockWave foot module is pre-assembled consisting of composite components (keel and sole plate), a Spectra sock, and a foot shell. Stiffening bumpers for increasing heel stiffness are provided. After dynamic alignment, torque pyramid adjustment screws to the manufacturer's specifications. Secure pyramid adjustment screws with thread locking adhesive (e.g., Loctite 242).

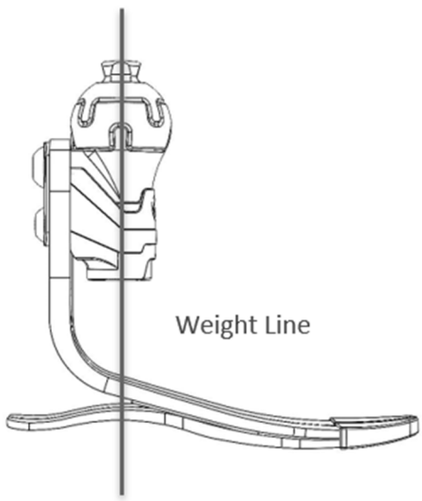
B. Spectra Socks

A Spectra sock is provided to minimize noise and protect the foot shell/ composite components. The Spectra sock should be placed over the keel and the sole plate before donning the foot shell. Spectra socks must be replaced at intervals appropriate to the user's activity level. Failure to inspect and replace the Spectra socks may prematurely wear the foot module and will void the warranty.

C. Foot Shell

When removing or installing the foot shell, use the Foot Shell Removal Tool (ACC-00-10200-00) to prevent damage to the foot module. Do not attempt to remove the foot from its shell by pulling out by hand. This may damage the foot, voiding the warranty.

D. Bench Alignment



Prior to the user donning the prosthesis:

- Plantarflex/Dorsiflex the foot to match the shoe heel height
- Adduct/Abduct the socket to provide appropriate frontal plane angle
- Flex/Extend the socket to provide appropriate sagittal plane angle
- Move the socket linearly to ensure the weight line falls through the center of the pylon (see illustration)

E. Dynamic Alignment

During loading response, the heel lever stores energy and releases it during midstance. This action provides momentum for the keel to store energy and release it during terminal stance. To optimize the heel to toe rollover motion, adjust the following variables:

- Anterior/posterior foot placement
- Dorsiflexion/plantarflexion
- Heel stiffness

F. 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 stiffening bumpers. See Stiffening Bumper Kit label for installation details.
Heel too hard	• Rapid knee flexion, instability • Heel to toe progression to rapid • 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

7 DETECTION OF MALFUNCTIONS

⚠ If you notice any abnormal behavior or feel any changes in the characteristics of the device, or if the device has received a severe impact, consult your prosthetist.

8 WARNINGS, CONTRAINDICATIONS, AND SIDE EFFECTS

A. Warnings

⚠ Inappropriate use of the device, in relation to the recommendations of your prosthetist, can cause the degradation of parts of the foot (carrying heavy loads for example, excessive stress, exceeding the service life, etc.).

⚠ Never use the foot module without a foot shell.

⚠ Never attempt to loosen the bolts affixing the pyramid connector.

Water resistant: The device will withstand occasional submersion and is splash resistant.

B. Contraindications

⚠ The device is inappropriate for users who do not meet the requirements of a Medicare functional level of K3 or higher.
This device is not intended for activities where there is a risk of severe impact or excessive overload.

C. Side effects

There are no known negative side effects.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority.

9 MAINTENANCE, STORAGE, DISPOSAL, AND DURABILITY

A. Maintenance / Cleaning

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

⚠ Inspect the foot module every six months. If the user is more active, more frequent inspection may be necessary. Service as necessary. Replace sock and/or foot shell if worn to prevent damage to the composite components.

The foot module may be cleaned and/or disinfected with soap and warm water.

⚠ Do not allow aggregates such as sand to remain in the foot shell. Upon exposure to aggregates, immediately disassemble foot module and rinse with water. The abrasive properties of aggregates will wear the composite components of the foot module.

⚠ After use in water:

- Remove the foot shell and take off the sock
- Rinse the foot with clean water
- Dry well

B. Storage

Storage and operating temperature range: -29 to 49° C [-20 to 120° F]
Storage and operating relative humidity range: No restrictions.

C. Disposal

The different items of the foot are special wastes and must be handled according to local laws.

D. Durability

Purchase of the Freedom ShockWave includes a 36-month warranty covering all manufacturer defects effective only if the product is used according to manufacturer recommendations. The foot shell is covered for 6 months. Failure to adhere to the guidelines of the Instructions for Use will void the warranty.

10 DESCRIPTION OF SYMBOLS

	**Manufacturer**		**Warning**	CE 2021	**CE marking and year of 1st declaration**

11 REGULATORY INFORMATION

CE This product is a tested and certified to comply with MDR 2017/745, ISO 10328, and carries the CE mark.