

HYDRO₁₁₂₉



PDAC L-Code: L5972

Note: When placing an order, please use the below formula.

1129-size L or R Example, 1129-25R

Product #	1129
Sizes:	23-28
Weight of Foot Size 27	781g
Build Height of Foot Size 27	97mm
Heel Height:	0mm
Maximum Patient Weight	125kg / 275lb
Warranty	1 year

Features and Benefits

- Low profile
- High Tech composite for optimized movement
- Compliant heel helps with increased walking stability
- Textured sole for improved anti-slip characteristics
- Integrated pyramid
- Split toe design

PRODUCT DESCRIPTION

This prosthetic foot device is constructed with an integrated pyramid, high tech keel, and improved traction soling. The Hydro has split toe design which can accommodate sandals. The foot is not serviceable.

INTENDED USE

The walking friendly design, and particularly good anti-slip sole provides stability, and smooth roll over during walking at the beach or around the pool. It is only recommended that the user walk to the area with sandals or shoes, then remove them after arriving to the water activity area, and then reapplying the footwear prior to leaving the water activity area. The Hydro is not intended for walking extended distances bare foot, as this will accelerate the wear and tear on the soling, and will void the warranty.

INDICATIONS:

- The 1129 Hydro is intended exclusively for exoprosthetic fittings of the lower extremity.
- For activities in or around high exposure to water in conjunction with a secondary, not primary, prosthesis

CON

TRAININDICATIONS:

- Not intended for users with compromising balance or strength that should not be conducting activities in conditions that may expose them to serious harm or injury.
- Not intended for use in water depths greater than 1 meter, or to mid-torso depths of the wearer or rough water (I.E. heavy surf, fast moving deep rivers)

The 1129 Hydro is designed for use in modular prosthesis and includes an integrated Titanium pyramid. It may only be used in combination with ST&G components rated to be waterproof, inclusive of all ST&G Titanium modular components.

CAUTION:

The 1129 Hydro foot is intended exclusively for prosthesis alignment using an exoskeletal design. The foot may not be combined with a modular foot adapter. Water activities should only be taken with the highest degree of caution. Be sure others are around to ensure a safe environment.

TECHNICAL SPECIFICATIONS

The 1129 Hydro is approved for a body weight up to 125Kg / 275lbs

FOOT SIZE	BUILD HEIGHT (Average)	FOOT WEIGHT (Average)*
27 cm	3.8in / 97mm	781 g

*27cm Complete foot with pyramid

Safety

Explanation of the ANSI symbols

CAUTION - Warnings regarding possible risks of accident or injury.

Warning - Warnings regarding possible technical damage.

INFORMATION - Additional information on the fitting / use.

General safety instructions

CAUTION

Non-observance of safety instructions

Non-observance of the following safety instructions can lead to malfunction of the 1WR95 Aqua Foot, resulting in a risk of injury to the patient and in destruction of the product.

Safety instructions for patients / users

Please make your patients aware of the following safety instructions:

CAUTION

Risk of falls due to incorrect use

The waterproof walking device is not intended to replace the initial prosthesis and should only be used in wet areas. It may not be used for extreme activities such as extreme sports (water skiing, kite surfing, etc.).

CAUTION

Risk of falls due to incorrect use

Walking speed must be adjusted accordingly in wet areas and in areas where a higher risk of falls can be expected.

CAUTION

Risk of burns in cases of heat exposure

The components for waterproof walking devices are not suitable for use in saunas or for activities during which the prosthesis is constantly exposed to high heat above 50 °C.

Risk of loss of function due to incorrect storage/transport

The waterproof walking device may only be stored or transported at temperatures between -10 °C and +50 °C.

Risk of loss of function due to incorrect care

The waterproof walking device must be cleaned with clean fresh water every time after contact with saltwater or water containing chlorine/soap or contact with abrasive substances (e.g. sand). To clean the prosthesis, it should be placed in a sink (tub) with clean freshwater and moved around to rinse the corners, edges, and the tube.

The prosthesis must also be dried immediately after every use.

Contact with abrasive substance (e.g. sand) can lead to premature wear.

Preparation for use

1129 Hydro bench alignment of the waterproof walking device on a 0 mm heel height should be assembled with 1211T-W waterproof Tube Clamp Receiver, and 1212T-W waterproof Tube Clamp for a Trans-Tibial construction, or for the shin section of a Trans-Femoral.

Bench alignment

- 1) Move the mid-foot forward 30 mm relative to the alignment reference line (the rear 1/3 of the foot).
- 2) Set the effective heel height (0'') of the foot flat on the floor and add 2-5 mm safety factor.
- 3) Set the outward rotation of the foot.

Follow the instructions in the respective knee joint's instructions for use for the remainder of the bench alignment.

Static alignment

Be sure the patient can stand in a relaxed posture with very good balance and control of the prosthesis.

TT prostheses

The following alignment is used to achieve the highest possible degree of physiological knee stability for TT prostheses.

Positioning the load line in the sagittal plane:

The foot must be positioned so that the load line runs at the posterior 1/3 of the Hydro foot.

TF Modular prostheses

Follow the knee manufacturers knee alignment recommendation, and position the Hydro foot as described with the TT Positioning load line in the sagittal plane.

Dynamic alignment should be optimized during trial walking for TT and TF applications.

Maintenance / repair

INFORMATION

The fundamental design of all ST&G foot components allows for a possible usage duration of 2 to 3 years, depending on the patient's activity level, and usage conditions (I.E. always on concrete, or very abrasive surfaces versus on less aggressive surfaces).

We recommend always performing regular yearly safety inspections by a Certified Prosthetist.

DYNAMIC ALIGNMENT

For a firmer toe response, plantarflex the foot, or move load line posterior

For a softer toe response, dorsiflex the foot, or move load line anterior

For a firmer heel response, dorsiflex the foot, or move load line anterior

For a softer heel response, plantarflex the foot, or move load line posterior

WARNING

- Do not expose this product to pH extremes or corrosive materials (water, salt water or other liquids)
- Failure to follow these technical instructions or use of this product outside the scope of the Warranty may result in injury to the patient or damage to the product, and will void the warranty
- Any modification of components will void the warranty.

WARRANTY INSPECTION / MAINTENANCE INFORMATION

It is recommended that you schedule your patients for annual.

High patient weight and/or impact level may require more frequent inspections – Bi-Annually.

- Never allow aggregates such as sand to remain in the sandal. Upon exposure to aggregates, immediately thoroughly rinse out aggregate with water. The abrasive properties of aggregates will quickly wear the foot.

- Never attempt to loosen the bolt affixing the pyramid connector.
- Discontinue use and consult your prosthetist if any part of the prosthesis starts to make noise, or has reduced performance. This may be a sign of abnormal wear, or possible failure.
- Inform your prosthetist if you lose or gain a significant amount of weight.
- ST&G Foot products are manufactured and tested for a particular weight and activity impact level. Use by another user for whom it was not originally manufactured may cause injury and shall void any written or implied warranty.

Foot should not be exposed to extreme and continuous UV exposure, as it will prematurely fade and break down the material. The life of the foot could be extended from UV exposure by the use of a covering such as a water shoe, and be sure to routinely clean off the foot and inner aspect of the shoe so as to keep the enclosed environment clean and debris free.

STORAGE / ENVIRONMENT

Operating & Storage Temperature Range: -10°C to 50°C (14°F to 122°F)

Allowable storage relative humidity 0 % to 90 %, non-condensing

Store away from UV exposure

Not to be used in depths greater than 1 Meter



LIABILITY

The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the instructions for use. The manufacturer is not liable for damage caused by component combinations that were not authorized by the manufacturer.

Always apply Blue Loctite to all alignment screws and assembly fasteners with appropriate torque. This is the responsibility of the Certified Prosthetist to ensure device integrity. Do not over torque the alignment screws, as this will damage the foot mounting pyramid faces.



CE Conformity

This product meets the requirements Council EU 2017/745 (MDR) for medical products. This product has been classified as a class I product according to the classification criteria outlined in appendix IX of the guidelines. Please keep this manual in safe place for future use.

Warranty covers defects in workmanship for the given warranty period. Signs of abuse, lack of biannual inspection, improper installation are examples of areas not covered by warranty.

Useful Life

Service life of the product is covered by the warranty period. Not to be used on another wearer other than original intended wearer.

Disposal

The device and its packaging must be disposed of in accordance with respective national/local environmental regulations.

Do not expose Carbon feet to sand, talcum powder, or wet environments

Warranty can be void due to: Unusual usage or abuse (ex. excessive dusty/sand environmental, overly high impact (jumping), non-typical usage), Tampering with any fasteners, Modification to the module such as sanding or damaging the finish, patient weight too close to weight limit of foot module (we require a 20-25 lb. buffer).

Warranty Period is 2 years for the Keel and 6 months for the foot shell.

* Alignment screw galling or the pyramid may void foot returns. Utilize the pyramid protector during initial alignment! Acceptable returns require the item be returned in "saleable" condition.

*** Never use Red Loctite, ONLY Blue Loctite on any prosthetic adjustment screws or fasteners!**