

A white line drawing of a dental curing light is centered on a dark teal background. The device features a circular base at the top, a long, curved handle, and a rectangular curing head at the bottom with a textured, ribbed surface.

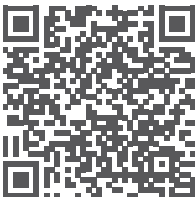
# Obsidian DM

Product Manual

*Fillauer*®

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# Intended Use

The Obsidian DM prosthetic foot is intended for use in lower extremity prostheses. The adult direct mount option offers a pyramid slide for a variety of alignment locations and easy adjustments. It has a split blade design that improves cornering performance and trail running. The Obsidian Running Blades are also available in a posterior mount option for kids and adults that have height restrictions and/or run at faster paces and shorter distances.

## Indications

- Moderate to highly active transtibial or transfemoral amputees as defined by functional K3–K4 activity levels.
- Unilateral or bilateral patients
- The distal mounted product is ideal for slower paces and longer distances but is effective in all running activities.
- Patients weighing up to 330 lbs. (150 kg)

## Contraindications

- Clearance below 10.75 in. (27.3 cm)
- Patients weighing over 330 lbs. (150 kg).

The device is intended for single patient use only.

## Performance Characteristics

- Patient weight: Up to 330 lbs. (150 kg)
- Foot weight with sole: 19.4 oz. (550 g)
- Sole weight: 5.3 oz. (150 g)
- Build height: 10.75 in. (27.3 cm)
- Foot size: One size fits 22 – 30 cm
- Functional level: K3–K4
- Durable; meets ISO-22675 standard.
- Primary Materials: Carbon composite, stainless steel, titanium, and aluminum
- Waterproof: The foot unit is waterproof to 1 meter. See additional information below.

## Storage and Handling

It is recommended that prosthetic feet be stored in a cool, clean, dry environment away from harsh chemicals (chlorine, acids, acetone, etc.).

# Warnings and Precautions



**CAUTION:** The Obsidian is designed to be maintenance free. Attachment, alignment, and delivery of the foot must be performed by or under the direct supervision of a qualified prosthetist. Any adjustment or modifications should be made by the clinician and not by the user.



**CAUTION:** For patient safety and device compatibility, only Fillauer or equal, ISO 10328 compliant, pyramid receivers should be used with this foot.



**CAUTION:** Abnormal or improper environmental conditions will lead to malfunctioning and damage of the prosthesis and is not covered under the warranty of the device. This prosthetic/orthotic component must not be subjected to dust/debris, liquids other than fresh water, abrasives, vibration, activities which would damage the biological limb, or prolonged, extreme temperatures ( $< -5\text{ }^{\circ}\text{C}$  or  $> 50\text{ }^{\circ}\text{C}$ ). Do not allow debris or liquids to remain in the prosthesis and its components during use. Rinse the foot with fresh water and dry immediately after exposure.



**CAUTION:** The foot unit is waterproof to 1 meter. However, if the foot is submerged, the foot should be rinsed with fresh water and dried immediately to remove salt, chlorine, or debris.



**NOTICE:** The foot should be inspected by the clinician every six months for signs of abnormal wear and to assure that the attachment/alignment screws are secure.



**NOTICE:** The foot stiffness is based on weight and activity level. Please provide accurate patient information so that the appropriate foot may be selected.



**NOTICE:** Attachment, alignment, and delivery of the foot must be performed by or under the direct supervision of a qualified prosthetist. Any adjustments or modifications should be made by the clinician and not by the user.



**NOTICE:** If any serious incidents occur in relation to the usage of the device, contact your Fillauer Representative and the appropriate authority in your country.

# Specifications & Preparations

## Before Use: Alignment

### Proximal Attachment

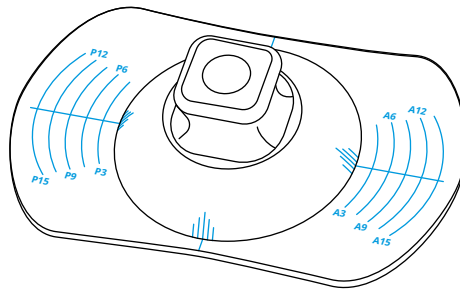
Attachment of the foot may be achieved via the proximal pyramid to any ISO 10328 compliant, Fillauer or equal, standard adult pyramid receiver. Torque all set screws to the setting specified by the manufacturer of the pyramid receiver. For Fillauer components, this is 15 N·m. Proper threadlocker must be used for final delivery per the component manufacturer's specifications.

## Installation

**Attention:** Deviating from the installation instructions or modifying the foot in any way will void the product warranty and could lead to product failure and injury to the patient.

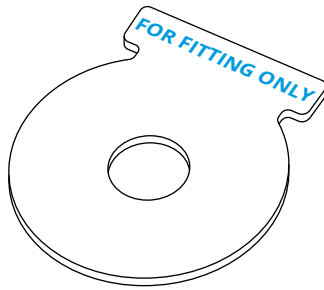
### Pyramid Slide

The Obsidian DM features an integrated slide adapter which allows for posterior / anterior pyramid adjustment and internal / external rotation. The pyramid plate has anterior (A3–A15) and posterior (P3–P15) markings in 3 mm increments as well as angle markings in 2.5° increments. By default, the pyramid is set at “A6,” the most commonly preferred position.



### Fitting Washer

The Obsidian DM comes with a Fitting Washer installed beneath the pyramid to prevent blemishes to the pyramid plate during fitting. Once the pyramid position and alignment are finalized, the Fitting Washer must be removed.



First, make note of the pyramid position in the slide, then unthread the pyramid bolt. Remove the Fitting Washer, then reassemble the pyramid, bushing, and bolt in the determined alignment

### Final Bonding

Apply blue threadlocker (included) to the pyramid bolt threads, and torque bolt to 40 N·m. If the pyramid position is changed, threadlocker will need to be reapplied to the bolt threads, and the bolt torqued again to 40 N·m.

### Static and Bench Alignment

Standard bench alignment techniques may be used for the Obsidian DM (Figure 2). Begin with a neutral socket alignment and the pyramid located at the A6 pyramid position. For more aggressive runners, socket extension and posterior translation of the pyramid will quicken the response for faster pace.

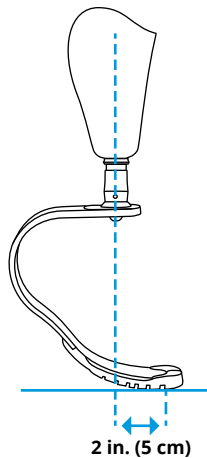


Figure 2

## Transtibial Frontal Plane Alignment

Most runners prefer a wider base of support with the foot slightly lateral to the distal bisection of the socket, 7–13 mm. The longitudinal axis of the foot should be tuned to the runner's preference. Ideally, the foot will be in the line of progression at running speed which will require accommodation of natural, internal rotation at the hip during running by externally rotating the foot 2–3°. Slower runners or those with instability may elect to have some additional external rotation in the foot at the cost of efficiency.

## Transfemoral Static Bench Alignment

Begin with a standard TKA alignment and a neutral attachment to the pyramid located at the A6 pyramid position. The line will fall approximately 2 inches (5 cm) posterior to the contact point on the sole of the blade.

## Dynamic Alignment

It is important to align the prosthesis so that the C-spring is loaded sufficiently to provide dynamic response late in stance but not so much deflection that there is no terminal stance support. Compression of the C-spring is desirable for optimal performance and foot deflection may be more noticeable during dynamic alignment. Approximately 0.5–2 inches (12–51 mm) additional height accommodates for spring deflection during high activity.

Patient feedback during this process is essential. Adjustments of the plantar/dorsiflexion angles will help the patient achieve balanced compression of the spring.

# Compatibility

Fillauer feet are appropriate for use with Fillauer or equal, ISO 10328 compliant, endoskeletal components.

# Disposal / Waste Handling

The product must be disposed of in accordance with applicable local laws and regulations. If the product has been exposed to bacteria or other infectious agents, it must be disposed of in accordance with applicable laws and regulations for the handling of contaminated material.

All metal components may be removed and recycled at the proper recycling facility.

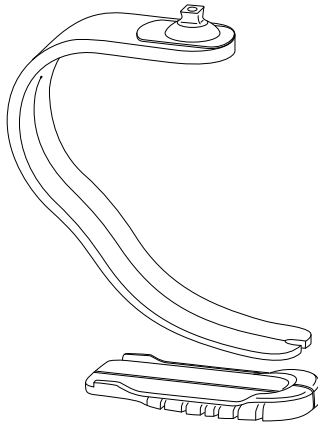
# Resoling Instructions

The following procedure applies to the Obsidian DM, PM, and Pediatric feet. These instructions should be read prior to any alterations and followed to ensure proper assembly.

**Attention:** Deviating from the resoling instructions or modifying the foot in any way will void the product warranty and could lead to product failure and injury to the patient.

## Sole Removal

To remove the worn sole from the Obsidian blade:



1. Apply heat to the proximal end of the rubber sole for two minutes using a heat gun. Keep the heat gun nozzle 2 inches (5 cm) away from the foot to prevent charring of the composite.
2. Separate the proximal end of the rubber sole from the Obsidian blade using a putty knife. Continue until the separated end of the sole can be grasped in hand.
3. Grasp the separated end of the rubber sole and peel it away from the foot. If the sole is not easily removed, apply heat for another minute before trying again.

## Bonding Preparation

The bonding surfaces of the Obsidian blade and the replacement Rubber Sole must be prepped before assembly.

1. Remove remnant adhesive from the Obsidian blade with a rotary wire wheel or similar mild abrasive. Take care not to deeply abrade the composite surface.



2. Lightly abrade the bonding surface of Rubber Sole with 220 grit sandpaper or similar.
3. Clean the bonding surfaces of the Obsidian blade and rubber sole with an acetone damped rag. Let dry.

## Sole Installation

To install the replacement sole:

1. Apply a thin film of cyanoacrylate super glue to the bonding surface of the rubber sole. Adhesive should be  $\frac{1}{4}$  inch (6 mm) away from the edge of the toe recesses, see Figure 2.

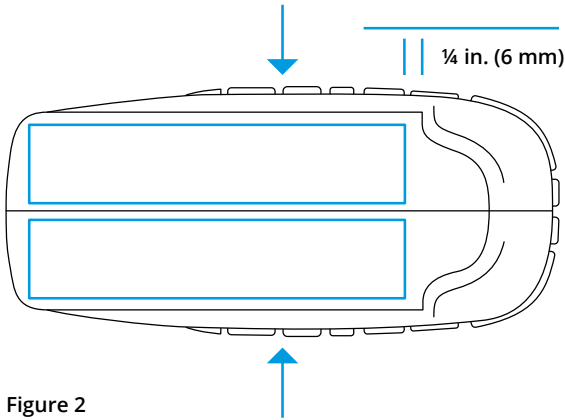


Figure 2

2. Quickly insert toes of the Obsidian blade into the rubber sole toe recesses as shown in Figure 3. No adhesive should have contacted the Obsidian blade at this point.

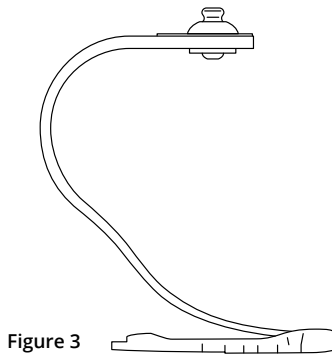


Figure 3

3. Squeeze the two halves of the rubber sole together in the direction shown by the arrows in Figure 2.
4. While holding the Rubber Sole halves together, roll the Obsidian blade completely back onto the Rubber Sole.
5. Firmly press Rubber Sole and Obsidian blade together for 60 seconds.

## Warranty

- 12 months from date of patient fitting.

## User Instructions

The providing health care professional must review the following information directly with the user.

### Care and Maintenance



**WARNING:** If the foot performance changes or it begins to make noise, the patient should immediately contact his or her practitioner. **These things may be as sign of a failure of the foot or other part of the prosthesis that could result in a fall or other serious injury.**



**CAUTION:** Attachment, alignment, and delivery of the foot must be performed by or under the direct supervision of a qualified prosthetist. Any adjustment or modifications should be made by the clinician and not by the user.



**CAUTION:** The foot should be inspected by the clinician every six months for signs of abnormal wear and to assure that the attachment/alignment screws are secure.



**CAUTION:** The foot is waterproof to 1 meter. However, if the foot is submerged, the foot should be rinsed with fresh water and dried immediately to remove salt, chlorine, or debris.

# Serious Incidents

In the unlikely event of a failure resulting in a fall and/or injury, seek immediate medical help and contact your prosthetist at the earliest possible convenience.

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