

# Ibex XD

Product Manual

*Fillauer*®



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# Intended Use

The Ibex XD prosthetic foot is intended for heavy duty (up to 440 lbs. / 200 kg) use in lower extremity prostheses. The innovative micro-slices in the Ibex pylon and the split heel plate provide controlled inversion/eversion for uneven terrain. The multi-axial design is energy optimized with a long carbon pylon and full-length heel plate that allows the Ibex to reach foot flat sooner and store more energy. The unique components of the Ibex work together from heel strike to toe off to provide stability without sacrificing energy return. The Ibex foot's balanced performance gives amputees the confidence they need to meet life's challenges head on.

**Only Ibex XD componentry may be used with the Ibex XD foot pyramid. These are the only components that are fully compatible and warranted to ensure customer safety and overall product functionality.**

## Indications

- Moderate to active BK or AK Amputees as defined by functional K3 and K4 levels
- Unilateral or bilateral patients
- Patients that would benefit from greater energy return and multi-axial function
- Patients weighing up to 440 lbs. (200 kg)

## Contraindications

- Build height below 7.63 in. (19 cm)
- Patients weighing over 440 lbs. (200 kg)
- Patients wanting to run or jog regularly on the device

### Performance Characteristics

Patient weight	Up to 440 lbs. (200 kg)
Foot weight	21.2 oz. (602 g)
Build height	7.63 in. (19.4 cm)
Functional level	K3 – K4
Durable; meets ISO-22675 standard	
Primary materials	Carbon composite

The device is intended for single user/patient use only.

## Storage and Handling

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

# Warnings and Precautions



**CAUTION:** The IbeX XD is designed to be maintenance free and should not be disassembled. The pyramid dome on the foot is permanently attached to the pylon (main and top) spring and should not be removed.



**CAUTION:** For patient safety and device compatibility, only Fillauer XD 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 and foot shell should be rinsed with fresh water and dried immediately to remove salt, chlorine, or debris. The foot shell and sock will experience significant deterioration if not allowed to fully dry before return to normal use and are not covered under warranty for this failure.



**NOTICE:** The foot should be inspected by the clinician every 6 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 adjustment or modifications should be done 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 competent authority in your country.

# Qualified Provider

Attachment, adjustment, alignment, and delivery of this device must be performed by or under the direct supervision of a qualified prosthetist. Unless stated in this manual, any such activities should not be attempted by the user and will potentially void the device warranty.

## Specifications and Preparations Before Use (Risk Management for Installation and Calibration)

### Proximal Attachment

Attachment of the foot should be achieved via the proximal pyramid to Fillauer XD Heavy Duty componentry. Torque all set screws to the setting specified by the manufacturer of the pyramid receiver. For Fillauer components, this is 15 N·m. Proper thread locker must be used for final delivery per the component manufacturers specifications.

### Parts and Accessories

Description	Part Number
XD Heavy Duty 4-Prong Receiver	126122
XD Heavy Duty 4-Prong Pyramid	126120
XD Heavy Duty 34 mm Pylon Tube	126133
XD Heavy Duty Tube Clamp Adapter for 34 mm	126100

### Static Alignment—Sagittal Plane

Standard bench alignment techniques may be used for the Ibx XD (Figure 2). Before aligning, the initial heel height should be established. The Ibx XD is designed for a  $\frac{3}{8}$  in. or 1 cm heel height. The initial heel height can be established with a simple spacer under the heel. The top of the pyramid should be parallel with the work surface before proceeding with

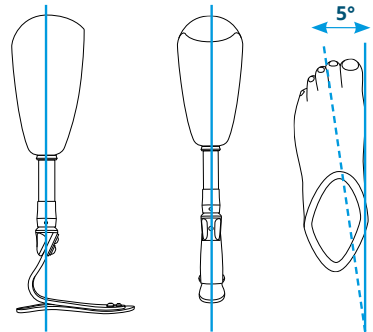


Figure 2

alignment. A backward leaning pylon indicates that the heel height is too low and will make late-stance rollover difficult.

### Transtibial Frontal Plane Alignment

The socket should be set in the proper amount of inset found in the evaluation. When using an integrated shuttle lock/distal attachment component, the plum line from the bisection of the socket at the proximal brim in the frontal and sagittal plane should bisect the ankle pyramid. When using separate suspension and attachment components, the foot may be slightly inset 1 – 12 mm depending on the limb length. Short limb lengths are set with very little inset of 2 – 3 mm and longer limb lengths may tolerate a greater varus thrust at 10 – 12 mm. The longitudinal axis of the foot will be outset approximately 5° by aligning the medial border of the foot with the line of progression.

### Transfemoral Bench Alignment

Alignment at the transfemoral level should be consistent with the instructions provided by the manufacturer of the prosthetic knee in use.

### Dynamic Alignment

The Ibex XD is flexible and conforms well to the ground. This characteristic may make the foot appear to be properly aligned after the static alignment. Small adjustments in the alignment however will smooth the transition from heel to toe, optimize gait and efficiency. Patient feedback during this process is essential. In the dynamic alignment of the foot, the socket flexion angle and heel stiffness are altered to achieve optimal alignment and patient gait.

- Check for smoothness of gait and ground contact during stance phase.
- If the heel is too soft, there may be delayed heel rollover from heel strike to midstance. Dorsiflexing the foot may solve this issue or use a firmer heel bumper as described below.
- If the heel is too firm, heel rollover may be too rapid from heel strike to mid stance. Also, patient may complain of anterior distal pressure. Plantarflexing the foot may solve this issue or use a softer heel bumper as described below.
- If the anterior keel rollover progresses too quickly from midstance to toe loading, the patient may say that they are “walking up a hill.” Plantarflex the foot to provide more anterior support.
- If the anterior keel rollover hesitates from midstance to toe loading, the patient may say that they are “walking down a hill.” Dorsiflex the foot to increase the rate of rollover

## Bumper Replacement

If the heel bumper needs to be moved or replaced, it can be removed by application of heat and solvent being sure not to allow any solvent to contact the Poron® pad that is between the pylon and foot plate. The pylon should then be lightly sanded with 120 grit sandpaper to provide a good bonding surface. The bumper is then adhered to the carbon using cyanoacrylate instant adhesive (commonly referred to as "Super Glue"). Contact Fillauer for the proper bumper for the foot size.

## Changing the toe stiffness

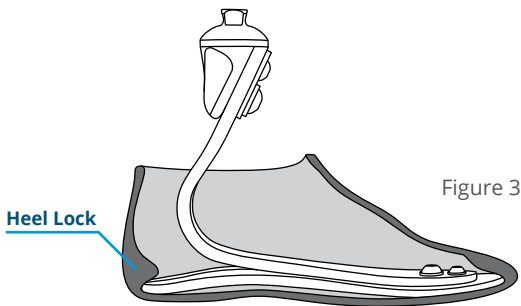
The toe stiffness is pre-determined by the load category of the anterior spring members. This stiffness can be dynamically adjusted by changing the amount of plantar/dorsi-flexion of the foot. This adjustment increases or decreases the amount of anterior support during gait.

If a smooth stance phase of gait cannot be achieved, contact Fillauer for additional assistance.

## Foot Shell Installation and Removal

The Ibx XD foot features a unique cosmetic foot shell that is flexible and durable. Use care in the installation and removal of the foot shell to maintain its appearance and durability.

**NOTE: Never use a sharp edged tool such as a screwdriver to install or remove the foot shell.**



## Installation

1. Pull the Spectra Sock provided onto the foot from toe to heel, pulling excess material to the ankle so that it does not bunch under the heel or toe of the foot.
2. Insert the forefoot into the foot shell as far as possible. Set the heel on a supportive surface with the toe up and push the shell onto the foot until the toe is in position.
3. Rotate the foot side to side to allow the foot shell to slide onto the heel.



4. Push the foot shell up onto the heel or, if necessary, insert a shoehorn into the foot shell and allow the heel to slide down a shoehorn into the heel lock. The heel must lock (Figure 3) in place for proper function and safety.
5. The Spectra Sock should be inspected and replaced if needed every 3-6 months by the prosthetist. The plantar surface of the foot should be inspected at this time and if there is excessive wear of the protective soling, it should be replaced.
6. The foot shell should be inspected daily by the user and replaced by the clinician when tears or breaks are evident in the surface of the shell.

## Removal

1. Place the foot on the bench so that the heel is hanging over the edge of the bench.
2. Apply downward force to the top portion of the foot shell at the heel and the heel plate should pop out of the heel lock, allowing removal of the foot shell by hand.
3. If the foot shell is too tight, a smooth-edged shoehorn may be used to disengage the heel lock.

## Compatibility

Fillauer feet are appropriate for use with Fillauer or equal, ISO 10328 compliant, endoskeletal components. A Fillauer spectra sock and foot shell should be used with this device, the fit of other manufacturers shells cannot be guaranteed.

## 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 appropriate recycling facility.

## Warranty

36 months from date of patient fitting

Foot Shell (sold separately) - 6 months from date of patient fitting

# User Instructions

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

## Warnings and Precautions for the User



**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 done 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 and foot shell should be rinsed with fresh water and dried immediately to remove salt, chlorine, or debris.



**CAUTION:** The foot shell is designed to provide realistic appearance and maximum performance of the Ibx XD. The life of the foot shell will depend on level of activity and degree to which it is protected from wear and damage with socks and shoes. Socks and shoes should be worn at all times and should be allowed to dry fully after exposure to water to prevent damage to the shell.



**CAUTION:** Patients should inspect the shell daily for signs of cracks or holes and for the presence of sand or other debris. If the foot shell shows signs of failure, it should be replaced as soon as possible to prevent damage to the carbon fiber and soling materials. If debris is present, the foot and shell should be rinsed and allowed too fully dry.



**CAUTION:** The foot shell may also be cleaned with a soft cloth and a soap and water solution or with rubbing alcohol (70%). Do not use acetone. It will damage the foot shell.

# Serious Incidents

In the unlikely event a serious incident occurs in relation to the use of the device, users should seek immediate medical help and contact their prosthetist, local competent authority, and Fillauer at the earliest possible convenience. Clinicians should at any time contact their local Fillauer representative and local competent authority immediately in the event of any device failure.

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