

# ibex

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## PRODUCT MANUAL

eMOTIS





## THE IBEX

The IbeX is a leap forward in multi-axial foot design. 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 store more energy and full length heel plate that allows the IbeX to reach foot flat sooner. 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.



# FEATURES AND BENEFITS

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- Innovative Micro-slice pylon
- Energy optimized pylon/heel plate design
- Multi-axis heel/toe for terrain conformance
- Designed for patients up to 330 lbs. (150 kg)
- Weighs only 16.2 oz. (459 g)/Build height 6.75 in. (17 cm)
- Ibex XD designed for patients up to 440 lbs. (200 kg)
- Ibex XD weighs 21.2 oz. (602 g)/Build height 7.63 in. (19 cm)
- Durable; meets the ISO-22675 test standard
- 3 year warranty/30 day patient trial
- 6 month foot shell warranty

## INDICATIONS

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- 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 330 lbs. (150 kg)
- Ibex XD for patients weighing up to 440 lbs. (200 kg)

## CONTRAINDICATIONS

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- Build height below 6.75 in. (17 cm)
- Ibex XD: Build height below 7.63 in. (19 cm)
- Patients weighing over 330 lbs. (150 kg)
- Ibex XD for patients weighing over 440 lbs. (200 kg)

## PRODUCT SPECIFICATIONS

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- Weight rating: 330 lbs. (150 kg)/Ibex XD 440 lbs. (200 kg)
- Foot sizes: 22-30 cm/Ibex XD 25-30 cm
- Heel height: 3/8 in. (10 mm)
- Product height (in shell to base of pyramid): 6.75 in./Ibex XD 7.63 in.
- Product weight (27 cm): 16.2 oz. (459 g)/Ibex XD (30 cm): 21.2 oz. (602 g)
- Attachment: Modular Pyramid

## L-CODES

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- L5980\* – All Lower Extremity Prostheses, Flex Foot System
- L5986\* – All Lower Extremity Prostheses, Multi-Axial Rotation Unit (“MCP” or Equal)

*\*Suggested L-Codes are provided as a reference only. It is the responsibility of the practitioner to confirm this information.*

## PART NO. 120-10-XX-XX(XX\*\*) – IBEX FOOT SYSTEM

Foot, elastomer heel wedge, heel band, Spectra Sock and instruction manual. Foot selection is determined by foot size and patient weight.

\*\*Add “XD” for patients 330-440 lbs. as described in chart below.

		22 cm	23 cm	24 cm	25 cm	26 cm	27 cm	28 cm	29 cm	30 cm
100-119 lbs.	45-54 kg	22-A2	23-A2	24-A2	25-B4	26-B4	*	*	*	*
120-139 lbs.	54-63 kg	22-A2	23-A2	24-A2	25-B4	26-B4	27-C5	28-C5	*	*
140-159 lbs.	64-72 kg	22-B3	23-B3	24-B3	25-B5	26-B5	27-C5	28-C5	29-D6	30-D6
160-179 lbs.	73-81 kg	22-B3	23-B3	24-B3	25-B5	26-B5	27-C6	28-C6	29-D6	30-D6
180-199 lbs.	82-90 kg	22-B4	23-B4	24-B4	25-C6	26-C6	27-C6	28-C6	29-D7	30-D7
200-224 lbs.	91-102 kg	22-B4	23-B4	24-B4	25-C6	26-C6	27-D7	28-D7	29-D7	30-D7
225-249 lbs.	102-113 kg	NA	NA	NA	25-D7	26-D7	27-D7	28-D7	29-E8	30-E8
250-275 lbs.	113-125 kg	NA	NA	NA	25-D7	26-D7	27-E8	28-E8	29-E8	30-E8
276-300 lbs.	125-136 kg	NA	NA	NA	25-E8	26-E8	27-E8	28-E8	29-E9	30-E9
301-330 lbs.	137-150 kg	NA	NA	NA	25-E8	26-E8	27-E9	28-E9	29-E9	30-E9
330-440 lbs.	150-200 kg	NA	NA	NA	25-E8XD	26-E8XD	27-E9XD	28-E9XD	29-E9XD	30-E9XD

*\* Contact your distributor for recommendations.*

# MCV FOOT SHELL

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**XX XX 13 CC 3** Micro Coated Vinyl Foot Shell  
*Example: 45 24 13 13 3 = Left, Size 24, Color 13*

To order, select the side (left or right) and foot length (24–30 cm) from the chart below. Then, choose the color (CC 03, 09, or 13).

	22 cm	23 cm	24 cm	25 cm	26 cm	27 cm	28 cm	29 cm	30 cm
Left	45 22	45 23	45 24	45 25	45 26	45 27	45 28	45 29	45 30
Right	46 22	46 23	46 24	46 25	46 26	46 27	46 28	46 29	46 30

Custom colors are available as a special order with three weeks lead time. Please contact Fillauer Customer Service for more details.





# DAILY CARE AND MAINTENANCE

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The Ibex is designed to be maintenance free. The foot is water resistant. However, if the foot is submerged in water, the foot and foot shell should be rinsed with fresh water and dried soon after getting out of the water. The Ibex should be inspected every six months to ensure no damage has occurred and that the attachment/alignment screws are secure.

## INSTRUCTIONS TO THE PRACTITIONER

- Please review the indications, contraindications, and F.A.Q. sections of the manual before use of the foot. These instructions for use should be read and followed to ensure the proper integration of the Ibex foot into the patient's prosthetic system.
- The foot model recommendations on the selection chart are based on average patients, engaged in normal activities. If your patient is much more active than average or is lifting heavy loads as part of their daily routine; going up one weight category is advised. If you are not sure

which foot to select, please consult with one of our technical service representatives.

## INSTRUCTIONS TO THE PATIENTS

- Patients should clean the prosthetic foot shell with a soft cloth and a soap and water solution weekly. The patient should also inspect the shell for the presence of sand or other debris weekly if the leg is not covered. The foot shell may also be cleaned with rubbing alcohol (70%). *The foot shell should not be cleaned with acetone as this will damage the coating on the shell.*
- If the foot performance changes or if it begins to make noise, the patient should contact his or her practitioner immediately to have the foot inspected and, if any problem, corrected.
- As with all prosthetic devices, the foot should be inspected every six months by a certified practitioner.

# INSTALLATION

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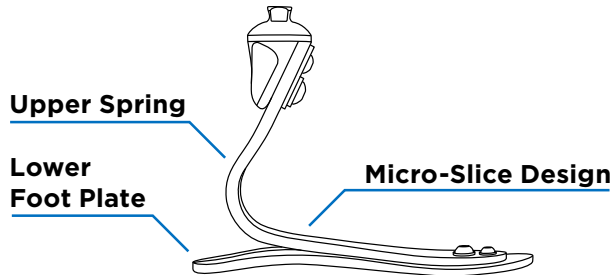
Deviating from the installation instructions or modifying the foot in any way will void any product warranty and could lead to product failure and injury to the patient.

## 1.0 - Product Description

The IbeX foot uses two carbon composite elements that conform to terrain while storing and releasing energy during gait. The IbeX foot is designed to be used with most pyramid receiver devices (Figure 1). The pyramid dome for the IbeX foot is permanently attached to the composite spring and should not be removed.

## 1.1 - Heel Wedge Installation

The heel stiffness and heel deflection of the IbeX foot are affected by alignment and the position of the heel wedge. To install it in the initial position, slide the wedge into the split in the lower foot plate so that the small side is under the heel and the larger plastic side is on top of the lower foot plate. Some rubbing alcohol or talc will help the wedge slide into



position. Slide it forward so the front edge of the wedge is in contact with the pylon and lower foot plate creating a bumper between the two. This is

the initial position for the wedge during set up and alignment as shown in Figure 2. Secure the wedge temporarily by securing the black band around the heel just behind the wedge.

## 2.0 Static (Bench) Alignment

Standard bench alignment techniques may be used for the IbeX foot. Before aligning, the initial heel height should be established. The IbeX is designed for a 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 alignment. A backward leaning pylon indicates that the heel height is too low and will make late stance rollover difficult.

### Transtibial Bench 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

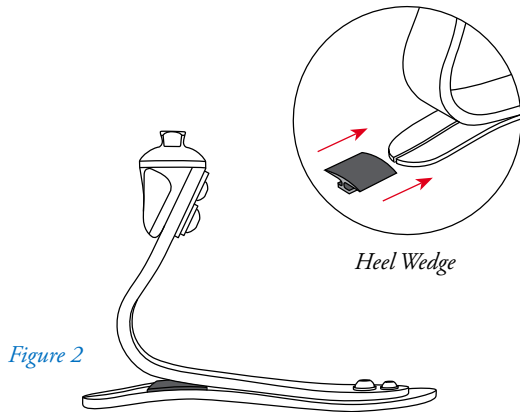


Figure 2

may tolerate a greater varus thrust at 10-12 mm. The longitudinal axis of the foot will be outset approximately  $5^{\circ}$  by aligning the medial border of the foot with the line of progression.

### Transfemoral Bench Alignment

Standard TKA alignment can be utilized with the trochanter line bisecting the distal ankle. The knee is set 3-6 mm posterior to the TKA line. A plum line may also be used from the proximal sagittal socket bisection, falling 10 mm anterior to the knee axis (or through the knee axis for an SNS unit) and the 10-15 mm posterior to the mid-foot. The knee and foot should both be aligned with  $5^{\circ}$  of toe out and external rotation respectively. The socket should also be set in the proper adduction angle of  $7-12^{\circ}$  and the flexion angle should be  $5^{\circ}$  more than the hip flexion contracture if present.

#### 2.1 - Dynamic Alignment

The Ibex foot is flexible and conforms to uneven terrain. This characteristic may mask forefoot loading anomalies during static alignment that may then become more noticeable during dynamic alignment. Small alignment

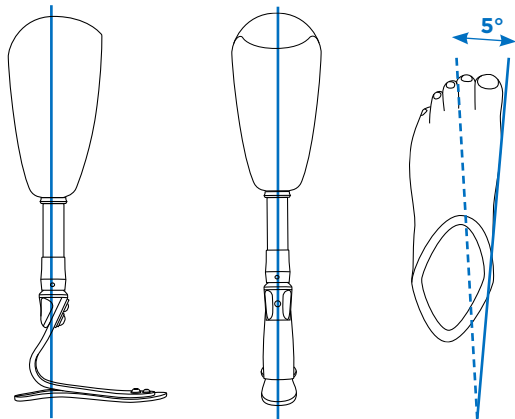


Figure 3

changes will smooth the transition from heel to toe, and optimize gait. Patient feedback during this process is essential. Adjustments of the plantarflexion and dorsiflexion angles will help the patient achieve a smooth transition from heel to toe. The pylon should remain vertical in the frontal plane throughout gait.

- Check for smoothness of gait and ground contact throughout the stance phase of gait.
- If the tibial progression is slowed from heel strike to midstance, or the heel compression is too great, dorsiflexion of foot may correct this problem. If this does not, see Section 2.2 on heel stiffness.
- If the socket progresses rapidly forward from heel strike to midstance or the heel seems too hard, plantarflexion of the foot may solve this problem. If not, see Section 2.2 on use of the heel stiffness.
- If the foot progresses too quickly from midstance to toe loading, increased plantarflexion may solve this issue.

- If the foot hesitates from midstance to toe loading, dorsiflexion may be indicated.
- Check to make sure pylon is vertical throughout gait. If there is a medial lean, tighten proximal medial screw; if there is a lateral lean tighten proximal lateral screw.

### Special Considerations

Due to the torsion compliance of the Ibex, it is very important to establish the proper external rotation of the foot in relationship to the socket. If the foot rotates too far internally or externally, it may feel less stable to the patient. Making an external rotation adjustment during the dynamic alignment should fine-tune the stability of the forefoot and improve the rollover characteristics of the foot.

### 2.2 - Changing the Heel Stiffness

If the heel is too soft or the foot is slow to transition to midstance, moving the heel wedge forward may increase the heel firmness and smooth the

transition from heel to midstance. This will speed up transition from heel to midstance. If the patient transitions too rapidly from midstance to forefoot, move the wedge posterior or plantar-flex the foot. If the heel is still too soft, then check the pylon angle and A/P position of the socket to ensure alignment has been established as described in section 2.0 above and correct if indicated. Generally, moving the socket more anterior will cause the heel to feel firmer and the toe to be softer.

### **2.3 - Securing the Wedge After Alignment**

Before the patient takes the delivery, the heel wedge should be glued into place. To do so, clean the elastomer and heel plate with 70% isopropyl alcohol and place two drops of Superglue® on the bottom surface of the heel wedge and reinstall the position determined as optimal in section 2.2.

### **3.0 - Foot Shell Installation and Removal**

The Ibex foot features a unique cosmetic foot shell that is flexible and durable. Use care in the installation and removal of the foot shell to

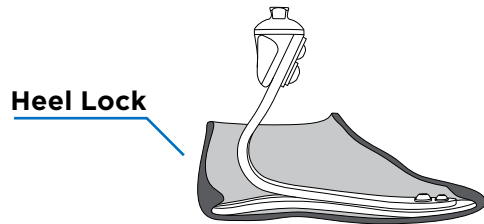
maintain its appearance and durability. NOTE: Never use a sharp edged tool such as a screwdriver to install or remove the foot shell.

#### **Installation**

- 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.
- 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.
- Rotate the foot side to side to allow the foot shell to slide onto the heel
- Push foot shell up onto heel, or if necessary insert shoehorn into foot shell, and allow heel to slide down shoehorn into the heel lock.
- IMPORTANT: The heel of the Lower Foot Plate must slide into the heel lock in the foot shell for proper alignment and to secure the foot in the foot shell (Figure 4).

## Removal

- Place the foot on the bench so that the heel is hanging over the edge of the bench.
- 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.
- If foot shell is too tight, a smooth edged shoe horn may be used to disengage the heel lock.



*Figure 4*

# FREQUENTLY ASKED QUESTIONS

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## *What is the weight rating of the Ibex?*

The Ibex foot is rated for patients weighing up to 330 lbs. (150 kg) and the Ibex XD foot is rated for patients weighing up to 440 lbs. (200 kg). The products were tested in accordance with the new ISO-22675 standard. Ibex feet are selected for a specific patient weight range. It is important to use the properly rated foot in order to ensure safety, durability, and maximum performance. The individual components of the Ibex foot: pyramid, upper spring element, and lower foot plate are combined based on a patient's weight and foot size.

## *Should the practitioner “go up one category” to accommodate more active patients or heavy lifting load?*

The Ibex foot is designed for an average patient that would be engaged in average activities. Higher activity levels and moderately high loads are

accommodated within the foot design. However, if your patient is much more active than average or is lifting heavy loads as part of their daily routine, going up one category is advised.

## *What can the practitioner do if the heel or toe is too soft or too firm?*

The deflection load and rollover of the heel may be increased or decreased by sliding the heel wedge anterior or posterior as discussed in section 2.2. In addition, the heel and toe rollover resistance may also be fine tuned during the dynamic alignment (section 2.1) by plantarflexing or dorsiflexing the forefoot.

## *What is the ISO-22675 Standard?*

The ISO-22675:2006 Test Standard is the newest and most comprehensive standard for testing feet and ankle-feet devices. This standard simulates



the dynamic loading conditions of stance phase of walking from heel strike to toe-off during two million (2,000,000) cycles. The standard also requires the foot to pass a static ultimate strength test in which the heel and forefoot are loaded to 1,400 lbs. (635 kg). As required, these tests were performed on two different Ibex feet. In passing this high standard, the Ibex has established its strength and durability, ensuring outstanding performance and a long service life.

*Can the pyramid assembly be removed or altered?*

No, the pyramid assembly should not be removed or altered in any way. Removing or altering the pyramid assembly will void the warranty and could put the patient at risk of injury. Any repairs or modifications, if required, should be made by Fillauer LLC.

*How long should the foot shell last?*

The foot shell is designed to provide realistic appearance and maximum performance of the Ibex foot. While the warranty of the foot shell is six months, the life of the shell will depend on the actual level of activity and

degree to which it is protected from wear and damage with socks and shoes.

*The foot is making noise. How can this be corrected?*

The most commonly reported noise is snapping or popping as the foot rolls to midstance. This may be corrected by removing the foot from the shell and adjusting the position of the heel wedge then reattaching it as instructed in section 2.3. The foot should be cleaned with compressed air or a soft cloth and inspected for visible damage to the foot or debris in the foot shell. Also, ensure that the spectra sock is free of holes, then reinstall in foot shell per instructions in section 2.2.

## WARRANTY

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- 3 years from the date of shipment to the practitioner

*The Ibex has been designed and manufactured for specific patient weights. Failure to follow the weight guidelines and/or overload conditions caused by the patient, such as heavy lifting, high impact sports, or abusive activities, that would otherwise damage the natural limb may void the warranty.*

- Foot Shell - 6 months from date of shipment to the practitioner

## SATISFACTION GUARANTEE

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- 30 days from the date of shipment to the practitioner





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### **Fillauer LLC**

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