

## **Transfemoral Instructions**

### **Introduction**

The iFIT transfemoral prosthesis was developed to provide an immediate fit, fully adjustable prosthetic system for persons with limb loss. It can be used as a preparatory device or permanent device. For persons that experience changes in limb volume or who have substantial soft tissues, the iFIT prosthesis is ideal. Our prostheses are rugged and waterproof—ideal for people who like the outdoors—as a recreational prosthesis or can be used in the swimming pool or shower if using a waterproof knee and foot. The prosthesis trim line can fit at the ischium or below it. The prosthesis is designed to be slightly lower in profile and length than a conventional socket. When properly closed it provides a high level of comfort as well as a firm attachment to the limb to provide optimal support for stable and safe ambulation.

There are two sizes currently available which are based on the circumference measurements of the patient's limb. These sizes fit most persons with transfemoral limb loss. Please refer to the sizing chart in this manual.

Transfemoral Kit Includes:

- Adjustable socket with flexible inner liner
- Rotating offset with attached rotating pyramid receiver

Transfemoral Kit Does Not Include:

- Prosthetic Knee
- Pylon
- Tube clamp
- Foot

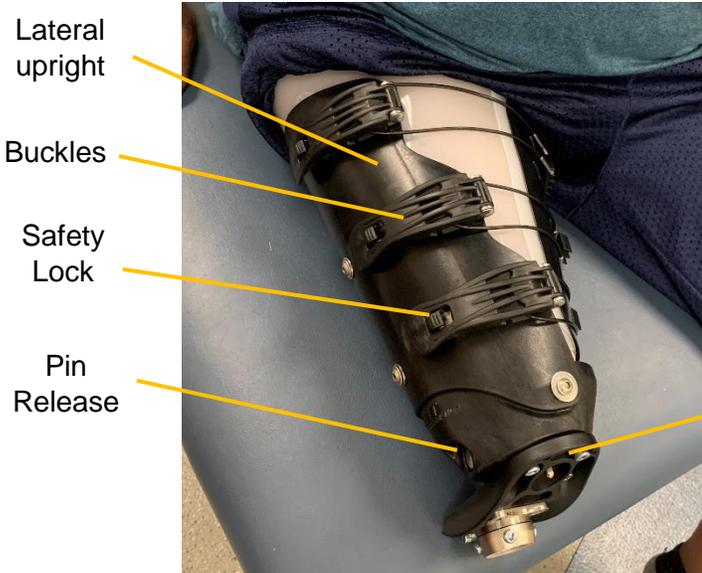
### **Patient Characteristics**

Patients must meet the following criteria to safely walk with this prosthesis:

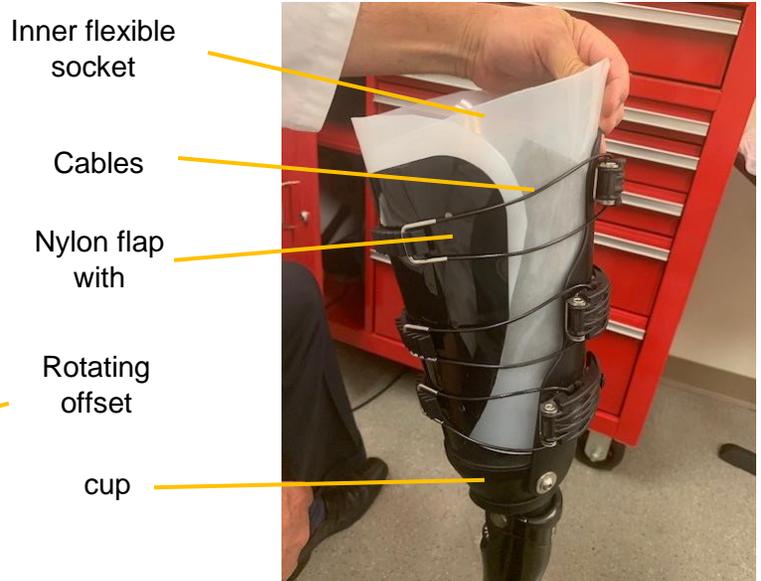
- well healed residual limb
- intact skin sensation
- ability to operate buckle system (good hand function and visual acuity)
- weight under 260 pounds

**Parts of the Transfemoral Socket**

Lateral View



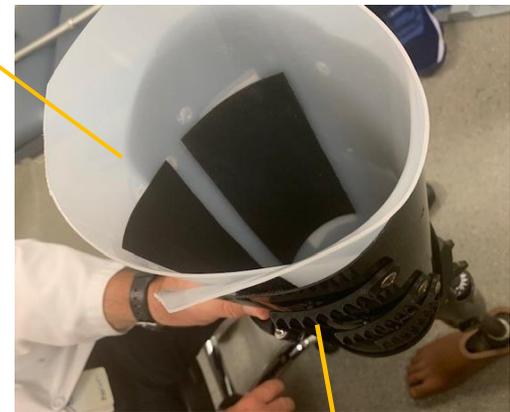
Medial View



iFIT Rotating Offset



Inside View



Anti-rotation pads

Rotating pyramid

Attachment bolts for offset rotation

5 Degree wedge

Above view of nylon coated nuts and screws that attach the rotating pyramid receiver to offset plate

Hooks attached at variable sites on the nylon flap

**Disclaimer:** Legal disclaimer: iFIT warrants that the iFIT transfemoral prosthesis sold to you will be free from manufacturing defects for a period of one (1) year from your purchase of the prosthesis provided you and your patient have fully complied with all use and care instructions in this guide and the user's guide. Parts covered under the warranty include the sockets, buckles and locks. Cables and inner liners are not included in the warranty. Any iFIT transtibial prosthesis which you or your patient alleges to be defective (and/or any sockets, buckles or locks your or your customer alleges to be defective), despite you and your customer's full compliance with all use and care instructions contained in this guide and the user's guide, may be returned by you to iFIT within one (1) year of your purchase of the prosthesis (for any unit not sold to a patient) or by your patient to you and by you to iFIT within one (1) year of your patient's purchase of the prosthesis (for any unit sold to a patient). Upon timely return of such prosthesis (or sockets, buckles or locks, as applicable), and provided iFIT confirms that the prosthesis (or sockets, buckles or locks, as applicable) included a manufacturing defect (and that any defect was not due to your patient's failure to comply with all use and care instructions), iFIT shall repair or replace the prosthesis (or sockets, buckles or locks, as applicable). By purchasing the iFIT transfemoral prosthesis, you agree that the foregoing repair or replacement obligation is the only obligation iFIT has to you and your customer relating to any defective prosthesis (including sockets, buckles or locks), and that this limited warranty and obligation is in lieu of all other warranties or obligations, express or implied, oral or written, including the implied warranties of merchantability and fitness for a particular purpose, all of which are hereby waived. By purchasing and re-selling the iFIT transfemoral prosthesis you also agree that other than iFIT's repair or replacement obligation set forth herein, in no event shall iFIT be responsible for any direct, indirect, consequential, incidental or special losses, damages or liabilities, including without limitation medical expenses, lost wages and lost profits, arising out of any such manufacturing defect, and you waive, release and agree not to hold iFIT responsible for any and all such losses, damages or liabilities. If, notwithstanding the foregoing, iFIT is determined by any court of law with jurisdiction to be liable for any such losses, damages or liabilities, regardless of whether such liability arises in contract, tort (including, without limitation, negligence or strict liability) or otherwise, by purchasing and re-selling the iFIT transfemoral prosthesis you further agree that the amount of the losses, damages or liabilities shall in no event exceed the amount paid by you for the prosthesis. By purchasing and re-selling the iFIT transfemoral prosthesis, you waive, release and agree not to hold iFIT responsible for any and all losses, damages or liabilities in excess of that amount.

By purchasing and re-selling the iFIT transfemoral prosthesis you also agree that in no event shall iFIT be responsible for any direct, indirect, consequential, incidental or special losses, damages or liabilities, including without limitation medical expenses, lost wages or lost profits, arising out of any such risks, and you waive, release and agree not to hold iFIT responsible for any and all such losses, damages or liabilities. If, notwithstanding the foregoing, iFIT is determined by any court of law with jurisdiction to be liable for any such losses, damages or liabilities, regardless of whether such liability arises in contract, tort (including, without limitation, negligence or strict liability) or otherwise, by purchasing and re-selling the iFIT transfemoral prosthesis you further agree that the amount of the losses, damages or liabilities shall in no event exceed the amount paid by you for the prosthesis. By purchasing and re-selling the iFIT transfemoral prosthesis, you waive, release and agree not to hold iFIT responsible for any and all losses, damages or liabilities in excess of that amount.

## **Sizing Chart**

Limb Circumference:

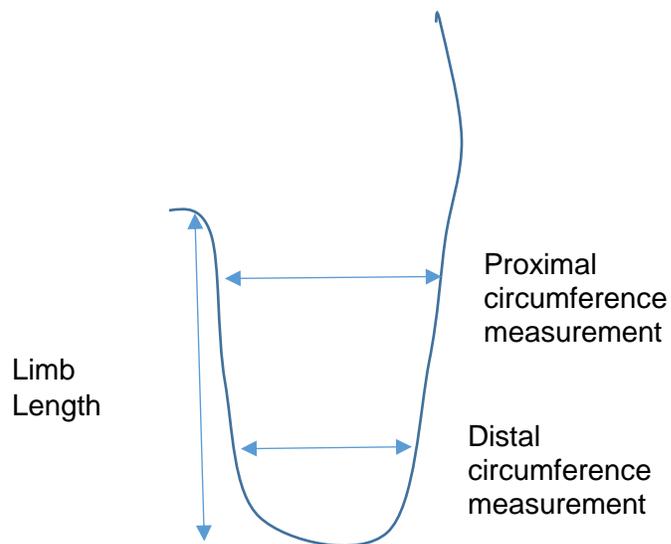
<b>Size</b>	<b>Distal (cm)*</b>	<b>Proximal (cm)*</b>
Standard	30 – 40 cm	36 – 50 cm
Wide	39 – 60 cm	50 – 65cm

\*These measurements are taken while the patient is wearing a 3mm liner. There may be some overlap due to compressibility of the residual limb soft tissues. Also take into account some patients may have a bulbous or conical shaped limb.

Limb Length:

The measurement from adductor tubercle to end of residual limb should be at least 25cm for optimal fit. Measurements 20-25cm will still fit but require trimming the socket insert. We have found the current length of socket also works well for longer limbs.

### **How to Measure:**



### Fitting Instructions:

1. Start by inserting a 30,35, and 40cm cable into the buckles. You can switch these to be smaller or larger as needed. The hooks are already attached to the nylon flap in the spots where we find most patients need them. The can be moved back if the patient is smaller, and forward for larger patients.



Hooks can be moved forward or back

2. The first step to fitting the socket is to trim the inner white liner so that it will fit the patient's limb length. Have the patient lie on an exam table wearing their silicone locking liner. Place the inner white socket liner around the residual limb. You can then mark where the socket trim line needs to be reduced. This material can be trimmed along the anterior, posterior and medial side with heavy duty scissors. Smooth the edges before the patient tests the prosthesis. The edges can be smoothed with a heat gun as well.



Trim inner white flap

Longer limbs may not require any trimming. We have found that the current length of this prosthesis gives enough purchase to be used on longer limbs as well (person below measured 28cm in length, no trimming was required).



3. The black nylon flap may also be trimmed. If this flap is too close to the lower buckle (a), it can be trimmed down so that there is space when buckled. Mark off how much to trim after the prosthesis is firmly buckled on the limb (b). Trim the lower part of the nylon flap with a heavy duty cutting tool, titanium scissors were used for this fitting (c). The proximal portion of the black nylon flap can also be trimmed if it is impinging on the groin area (d).



a) The nylon flap is too close to the lower buckle.



b) Mark off where to trim.



c) Trim the black nylon along the edge.



d) The proximal part of the black nylon can also be trimmed.

4. Replace the inner socket back into the cup, matching up the Velcro. Put the prosthesis onto the patient's limb, while they are wearing their silicone locking liner. Be sure to fully engage the pin lock system. The prosthesis can then be buckled to where it is snug. If there is a slight wrinkle in the white material (a) it should straighten once the patient stands. You can also trim the excess material from the white inner liner so that it overlaps more smoothly (b).



a) Wrinkling of white inner material



b) Trimming the inner flap

4. The buckles all have a safety mechanism. When closing the buckle, make sure this safety mechanism latches and the buckle cannot open by catching on clothing. To open the buckle, the safety needs to be pushed forward and released. The buckles can also be rotated slightly up or down as needed.



5. The distal offset plate features an attached pyramid receiver. The offset plate can be rotated using a 5mm Allen wrench to adjust the four screws on the base. Rotation of the knee unit can be done using a 4mm Allen wrench to adjust the set screw on the rotating pyramid receiver. Retighten once set. Attach the knee, pylon and foot system as usual. Note: this offset can be changed out to another offset if you prefer.



6. If the patient requires a larger or smaller angle of their pylon, an optional wedge is included. This can be used to increase the current 5-degree angle to 7 degrees, or decrease the angle to 3 degrees. You must first remove the pyramid receiver and then replace. The nuts are nylon coated and do not need Loctite



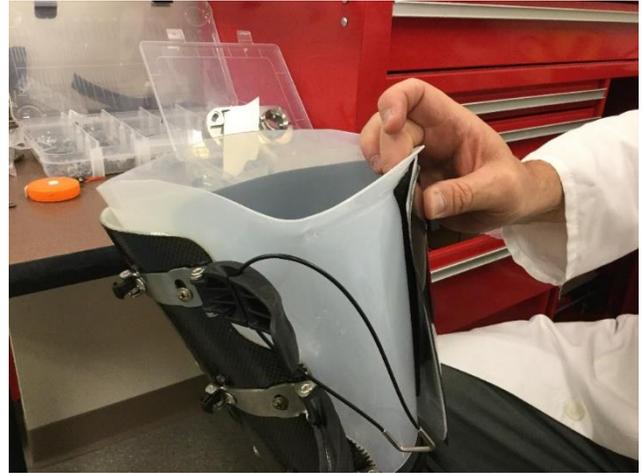
7. We recommend starting with the offset set at a posterior lateral position. You can then make fine adjustments from here.



8. Once the patient stands you can make further adjustments to the socket inner liner or alignment.

## Socket Modifications

9. The anterior portion of the white inner liner can be heated and flared out to accommodate hip flexion. Using a clamp, heat this area and slightly bend out. Cool off prior to placing back on the patient.



10. The proximal portion of the lateral upright can also be heated and moved slightly outward to expand the socket. This is generally not needed but can be done in cases where the patient notes this area is rubbing or tight against their thigh.



If there is pinching or pressure on this area, the lateral upright can be heated and bent slightly out. Check to ensure the buckle still latches correctly before fitting.

11. Some patients measurements are on the cusp of the standard and wide. For patients that measure 38cm-44cm on their distal end and are wearing a wide device, we suggest adding padding between the lateral upright and the white inner liner. A neoprene pad comes with kit, and additional padding can be added by the prosthetist if needed. This can also be done for thin patients wearing the standard.

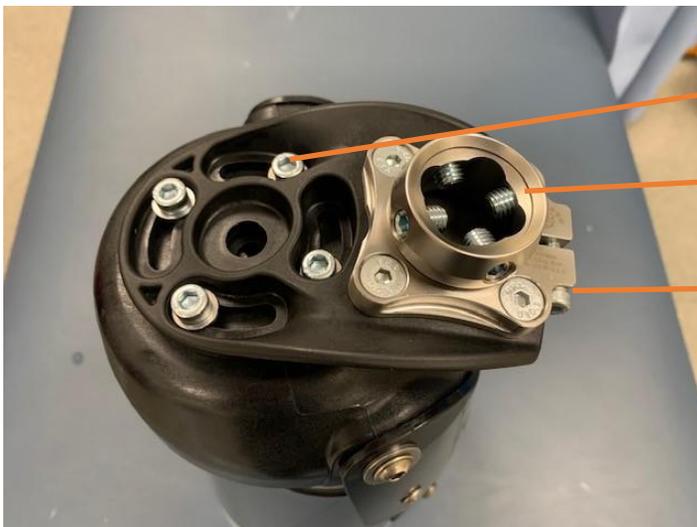


Padding added on the inside of lateral upright

### Finishing the Prosthesis

12. Once the correct alignment and knee adjustments are completed, ensure the patient can operate the buckle system and put on/take off the prosthetic on their own.

13. Torque the device. Apply Loctite 242 (included in bag) to all screws indicated below. Insert screws using a torque wrench and tighten the screws to the torques listed. Loctite 242 takes several hours to cure. Check the torque of the fasteners periodically – a loose fastener could cause failure. Apply Loctite to any loose fastener and re-torque.



#### Offset

M6 Flat head screws that attach offset to bulldog lock: 10Nm

M8 Rotating pyramid receiver set screws (attaches to knee unit): 13-14Nm

M5 Cap screw on rotating pyramid receiver: 10Nm

#### Knee

Torque to the manufacturer's specifications.

#### Pylon

Torque to the manufacturer's specifications.

### Instructing the patient:

1. Instruct the patient to full engage their pin before buckling or standing. This prosthesis must be worn with a silicone locking liner.
2. Make sure the patient is aware that the black nylon flap with hooks is on the outside. The flaps must be overlapped correctly in order to buckle the prosthesis.
3. It is best to begin with the upper or middle buckle first. Buckle the lowest cable last, since the can come undone once the others are tightened.
4. Make sure the patient puts the prosthesis on with the lateral upright going up the side of their leg. We instruct patients to place on their limb so that the side bolt is facing upward. Many times patients will put the prosthesis on with the lateral upright facing back. If this occurs naturally, and the patient doesn't feel there are any issues it is fine to keep it this way. Align the knee to where the prosthesis lies naturally.
5. If the patient has large volume changes they may need to re-buckle several times after first standing and walking
6. Any pain or parts that become loose on the prosthesis must be reported to the prosthetics immediately.



### IMPORTANT WARNINGS:

- *The upright piece of the prosthesis and the inner liner can be heat molded using a standard heat gun. Do not heat and attempt to mold any other pieces.*
- *Only the inner flexible socket material and nylon flap can be trimmed. Do not trim the injection molded lateral upright.*
- *Do not use in patients with skin breakdown.*
- *Do not use in patients whose residual limb skin is not fully healed.*
- *Do not use as an immediate prosthesis system after amputation surgery, it is not designed for this purpose- unless you purchase the IPOP add on kit.*
- *Patients who lack protective sensation should not use this device. The buckle system could potentially squeeze the limb too tightly and reduce circulation in people who cannot feel the discomfort that would normally prevent them from tightening it too tightly.*
- *The prosthetic socket must be securely buckled before standing. The buckles must be closed such that both buckles are locked. The user should check each buckle to ensure the buckle is fully locked before standing.*
- *The prosthesis should be put on and taken off from a sitting position. All buckle adjustments should be made from a sitting position.*

- *The prosthesis should be comfortable to wear. If any pain is experienced with wearing the device, you must address the alignment, padding or other fitting issues before letting the patient take the prosthesis home.*
- *Although this prosthesis is very comfortable, the patient should use a gradually increasing walking schedule (provided at the end of this instruction manual) to get used to the device.*
- *This prosthesis is designed for normal walking and daily activities. It is not designed for running or other aggressive sports activities. Using this device for such activities may result in device malfunction, loss of prosthesis suspension, falls, or skin breakdown.*
- ***All prosthetics fitting the iFIT Prosthesis must be certified as an iFIT Prosthetics, LLC certified provider. Please go to our website <http://www.ifitprosthetics.com/prosthetists-registration.html> for more information regarding how to become an iFIT Provider.***
- ***As with any prosthetic device there are inherent risks to the patient that must be clearly articulated to the patient choosing this device. These include; falls, pain in the limb, or skin breakdown.***