iFIT PROSTHETICS

The Right Fit, Right Now

Transfemoral Instruction Guide

MODEL: TF 300

- **Aligned quickly:** Can be fit in under 1 hour
- **Lighter weight:** Making mobility easier
- **Eliminate visits:** The user can adjust their own setting
- **No socks:** Not required to accommodate limb changes
- **Reduced socket rotation:** More secure gait

Table of Contents

Our mission is to produce high quality, affordable prosthetic devices that enhance the lives of persons with amputations. iFIT Prosthetics is a proud, veteran-owned American business making products in Milwaukee, WI.

Unique features of the iFIT transfemoral device

BUCKLE SYSTEM EASILY ACCOMMODATES HIGHLY COMPRESSIBLE THIGH TISSUE

LIGHT WEIGHT, DURABLE INJECTION MOLDED SOCKET MATERIALS

WORKS WITH PIN SUSPENSION

SPECIALLY DESIGNED OFFSET TO FACILITATE ALIGNMENT

FLEXIBLE INNER LINER CUSTOMIZED TO EACH PATIENT

HOOKS PROVIDE A WIDE RANGE OF ADJUSTMENTS THAT CAN BE MADE BY THE USER

Section I • 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 prosthetic sockets 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.

Our design is revolutionary in the prosthetics industry. It is a lower profile ischial level socket that can be modified to subischial. By means of comfortable and firm soft tissue compression, the wearer is well supported. The socket grips the residual limb securely to provide a comfortable and highly functional gait for the user.

In addition, this low profile is quite comfortable for the person when sitting — there is no extended brim.

The prosthesis is designed to be 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. This prosthesis is also designed to be used with pin suspension, with pin release on the lower lateral side of the prosthesis cup. Please always use with a locking silicone or gel liner.

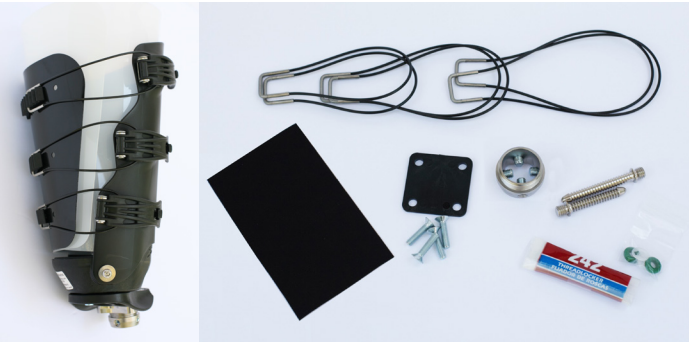
There are two sizes currently available which are based on the circumference measurements of the patent's limb. These sizes fit most persons with transfemoral limb loss. Please refer to the sizing chart in this manual.

Transfemoral Kit Includes:

- Adjustable socket with flexible inner liner
- Rotating offset with attached rotating pyramid receiver
- Non-slip grip material
- Five cables (45cm-25cm)
- Two locking pins
- 2 degree wedge with longer screws
- Loctite 424
- Loop velcro
- Utility cord

Transfemoral Kit DOES NOT Include:

- Prosthetic Knee
- Pylon
- Tube clamp
- Foot
- Locking liner



Tools Needed:

- Heavy duty scissors
- Deburring tool or sand paper
- 4 & 5mm Allen wrench
- Torque wrench
- Heat gun (optional)

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 300 pounds

Legal disclaimer

iFIT warranties 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 transfemoral 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.

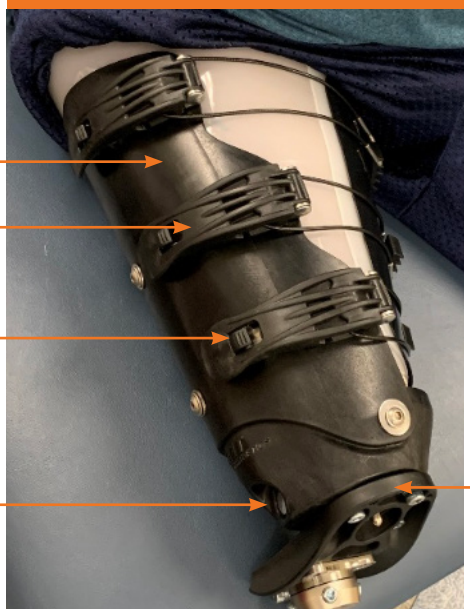
⚠ IMPORTANT WARNINGS

- Only the inner liner can be heated along the proximal brim. Do not heat any other area of the prosthesis.
- Only the inner flexible socket material and external 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 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 all three 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.
- The components sold with this device are only for use with the iFIT prosthesis.
- Do not modify the iFIT offset in any way, it is an integrated system designed to function exactly as described in this manual. Any additional connectors, spacers, component replacements, use of different screws/bolts, or extended offsets will void the warranty and could cause a serious malfunction
- **All prosthetists 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.**

Section II • Parts of the iFIT Transfemoral Socket

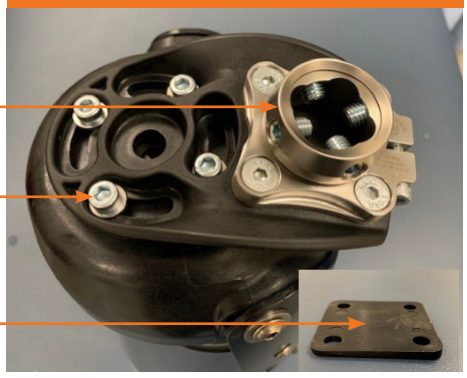
MODEL: TF 300

LATERAL VIEW



MEDIAL VIEW

iFIT 5 DEGREE ROTATING OFFSET



INSIDE VIEW

NOTE: The prosthesis comes with a black inner liner. The white is shown in the guide to delineate between the upright wall and the liner.

SIZING CHART

LIMB CIRCUMFERENCE		
Size	**Distal (cm)***	**Proximal (cm)***
Standard	30** - 44 cm	36 - 50 cm
Wide	43 - 60 cm	50 - 65 cm

*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.

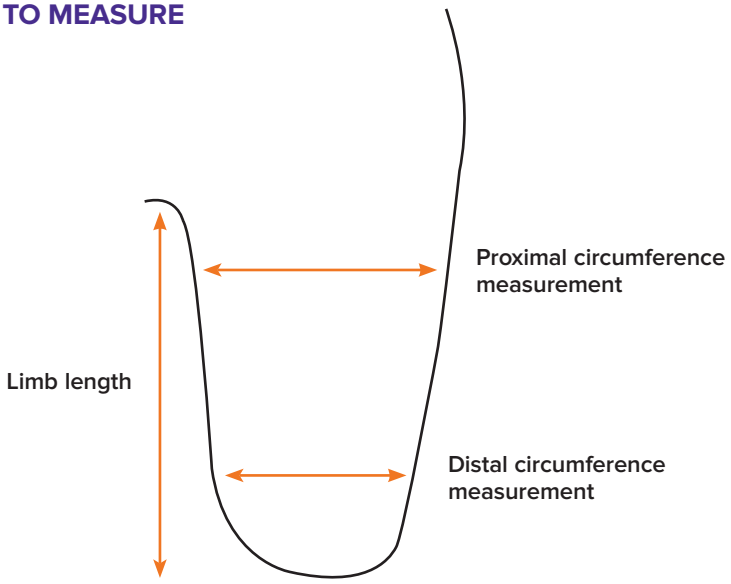
**If the patient measures closer to 30cm use a 6mm liner.

TRANSFEMORAL LIMB LENGTH CHART

The iFIT transfemoral prosthesis will fit limb lengths 15cm to 30+cm measured from pubic bone to end of residual limb.

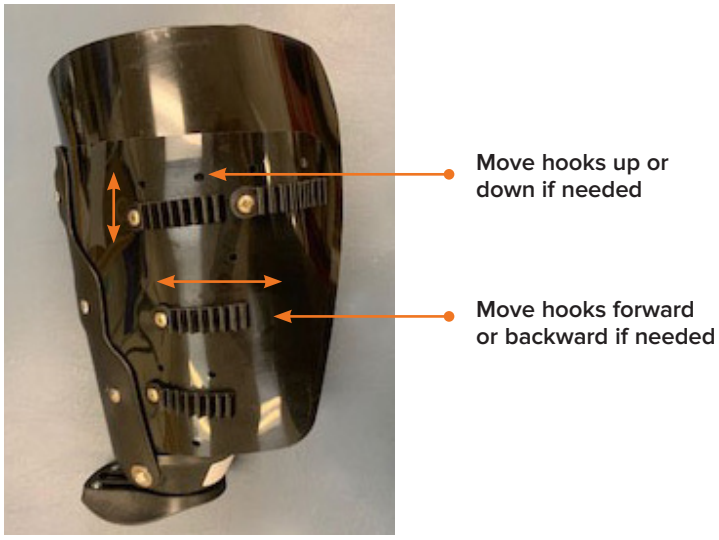
LIMB LENGTH	PROSTHESIS MODIFICATION
15cm-20cm	Spacer plus trimming of prosthesis inner liner.
20cm-25cm	Trimming of prosthesis inner liner.
25cm-30cm	May or may not need trimming, assess on patient.
30cm +	Use at prosthetist discretion. Patient must have adequate contralateral limb strength and stability.

HOW TO MEASURE



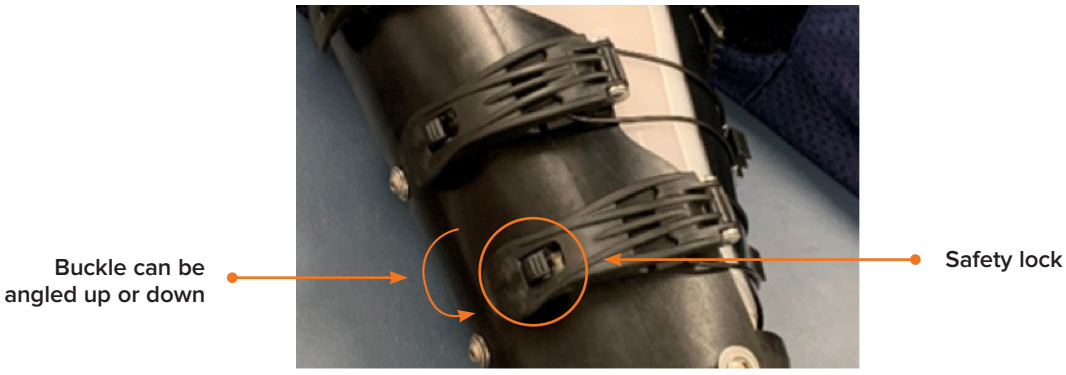
STEP 1 :

Start by inserting cables into the buckles. You can switch these to be smaller or larger as needed. The hooks are already attached to the external flap in the spots where we find most patients need them. They can be moved back if the patient is smaller, and forward for larger patients. You can also move the hooks up or down to change the direction of pull. Patients with longer limbs may feel more supported with the hooks moved into the upper holes.



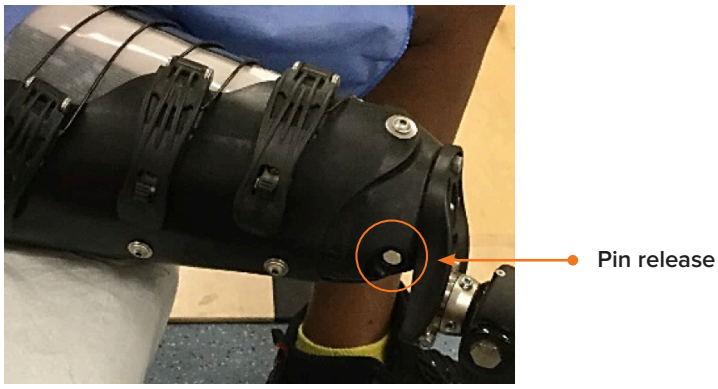
STEP 2 :

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 lock button needs to be pushed forward and released. The buckles can also be rotated slightly up or down as needed. **We suggest buckling the proximal or mid buckle first, and distal buckle last.**



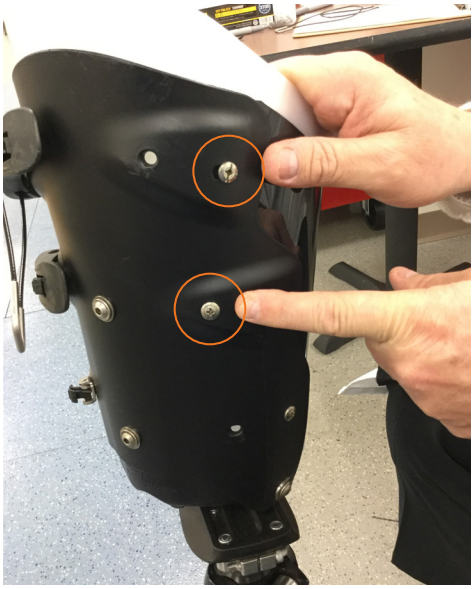
STEP 3 :

To disengage the prosthesis, there is a recessed button on the lateral side of the prosthesis. This must be held down while the prosthetic is slid off of the limb. Note: if the patient has problems disengaging the pin have them buckle the middle buckle only and try again. This ensures the pin is aligned and can be released.



STEP 4 :

The liner of the prosthesis is attached to the lateral wall by two screws. You can keep both together and fit the prosthetic on the patient's limb to identify where to trim, or you can take the liner out to make alterations and replace the screws afterwards.



STEP 5 :

The first step to fitting the socket is to trim the inner liner so that it will fit the patient's limb length. The goal is to have comfortable fit without the proximal brim impinging on the pubic bone ischial ramus or groin region. Have the patient lie (or sit) on an exam table wearing their silicone locking liner. We recommend putting the socket on the patient and buckling it (Figure 1). From here you can mark where to trim (Figure 2). This material can be trimmed along the anterior, posterior and medial side with heavy duty scissors. Heavy duty titanium scissors can be used to cut through this material (Figure 3). Alternatively, for short limbs you can wrap the inner liner around the limb and mark where to trim along the bottom edge (Figure 4). Smooth the edges before the patient tests the prosthesis. The edges can be smoothed with an edge smoothing device or a heat gun can dull the sharp edges that result from cutting the liner as well.

Figure 1

Figure 2

Figure 3

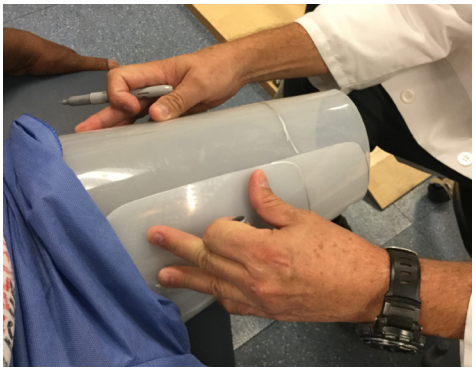
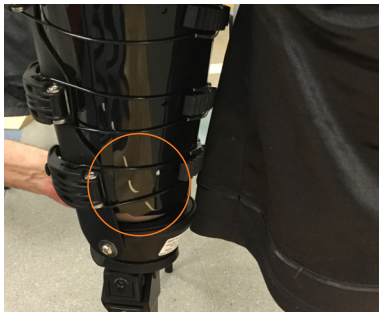


Figure 4

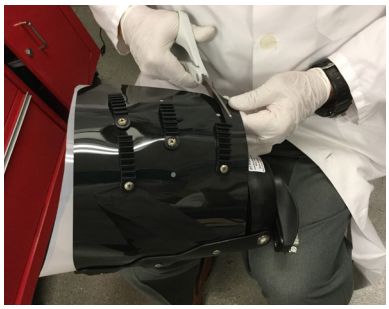
STEP 6 :

The black external 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 external flap with a heavy duty cutting tool, titanium scissors were used for this fitting (c). The proximal portion of the external 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.



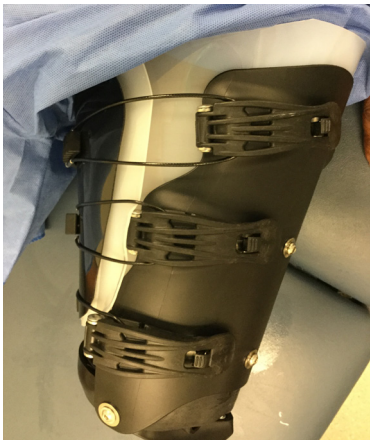
c) Trim the black nylon along the edge.

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

STEP 7 :

Replace the inner socket back into the cup, matching the Velcro adhesive strips. 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. An estimated 10-15cm of overlap may be optimal. Trim excess material (a) so that it slides more smoothly. The inner liner will also need to be trimmed if it is running into the lateral upright (b).

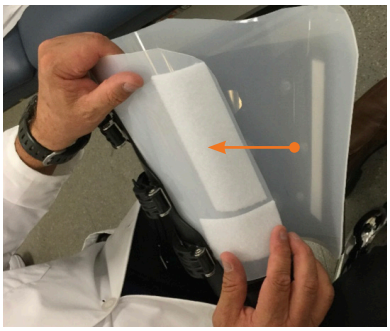
a) Trimming the inner flap



b) Running into lateral upright

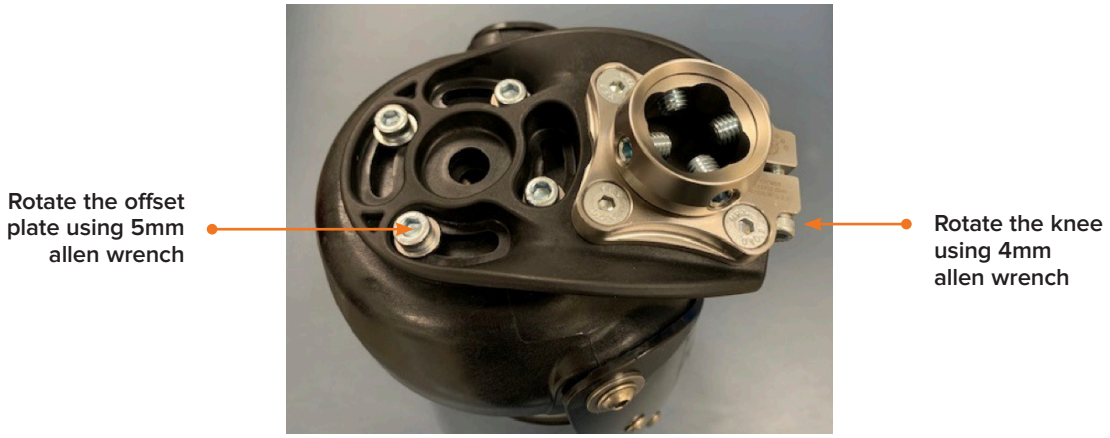
STEP 8 :

Optional: Once the inner material is trimmed to the correct width, you can apply loop velcro to the flaps if you find the material needs to slide better. The velcro tape can be placed either horizontally or vertically. We have found using two pieces on the inner flap horizontally with another vertical piece on the inner flap works well. You can also use the extra velcro to hold the liner in place.



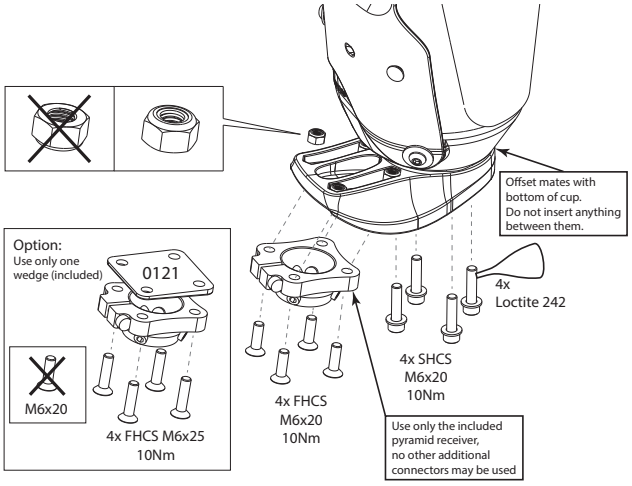
STEP 9 :

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. Re-tighten once set. Attach the knee, pylon and foot system as usual. Note: this offset can be changed out to another offset if you prefer. Only use the approved iFIT wedge under the pyramid rotator if you want 2 degrees of greater angle. Do not add any other components to the offset/wedge or cup. You can only use one wedge- do not stack them. If you use the single iFIT wedge, use the included longer screws and tighten them to 10 N-m. Be sure the self-locking nuts are facing the proper direction.



STEP 10 :

If the patient requires a larger or smaller angle of their pylon, an optional 2 degree 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 with the longer screws included in the bag. The nuts are nylon coated and do not need Loctite.



STEP 11 :

We recommend starting with the offset set at a posterior-lateral position with the lower bolt on the lateral upright facing upwards. You can then make fine adjustments from here. **We also recommend instructing the patient to put the prosthetic on so that their foot is always flat on the floor with bolt on lateral upright facing upward. This way they can insure that the correct alignment of the socket on the residual limb is achieved.**

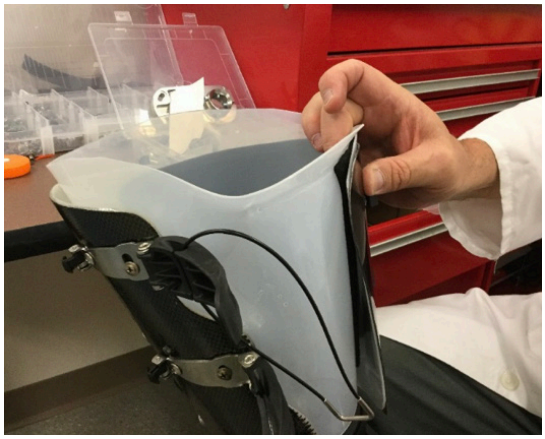
STEP 12 :

Once the patient stands you can continue to make adjustments to the socket by trimming areas that remain too high. We have also found that cables may need to be switched out once the patient begins to ambulate and they begin loosing volume.

SOCKET MODIFICATIONS:

STEP 13 :

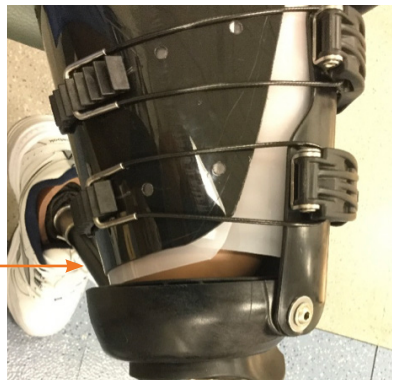
The anterior portion of the white inner liner can be heated and flared out to accommodate hip flexion. Using a clamp, heat this area and slightly bend out. Cool off prior to placing back on the patient.

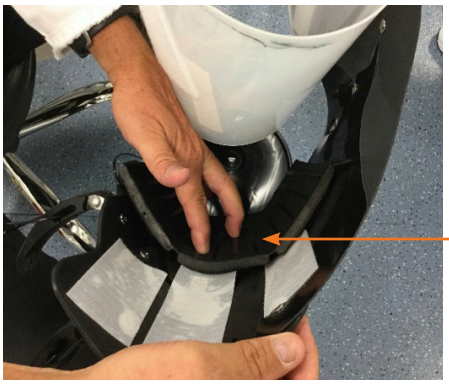


STEP 14 :

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. This can also be done for patients wearing the standard sized socket that have a smaller or conical shaped limb.

Note the large amount of tapering





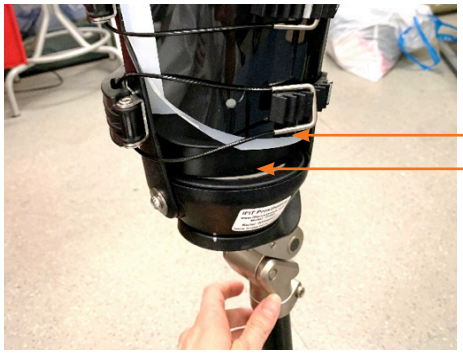
Padding added on the inside of lateral upright

STEP 15 :

If a limb measures 20cm or less we recommend placing a spacer in the bottom of the prosthesis. Use the longer pin provided when using a spacer. Take the inner liner out of the prosthesis, then adhere the spacer into the prosthetic. It should be placed flush with the lateral upright walls so that the openings for the pin line up. Use the enclosed 3M tape to adhere.

Replace the inner liner above the spacer. Note, the inner liner will still need to be trimmed down. You will also need to trim the external flap to above the spacer (a). This allows the socket materials to better grasp the limb (b). Alternatively, you can trim a space in the liner to accommodate the spacer. This is especially helpful for bulbous limbs (c and d).

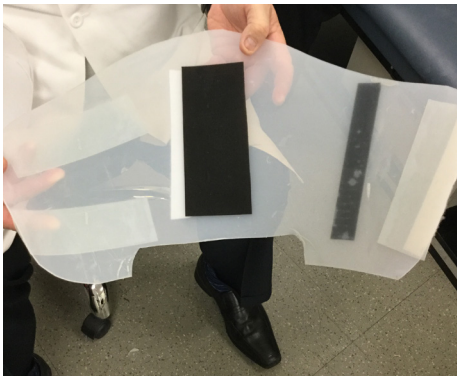
a)



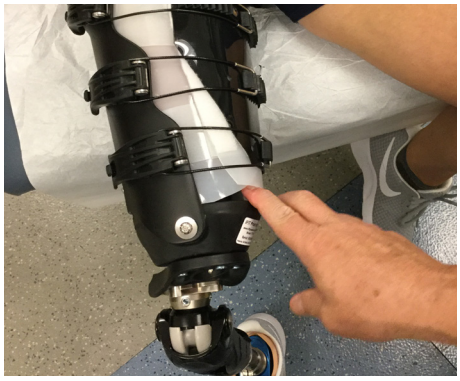
Trimmed flap and liner

Spacer

b)



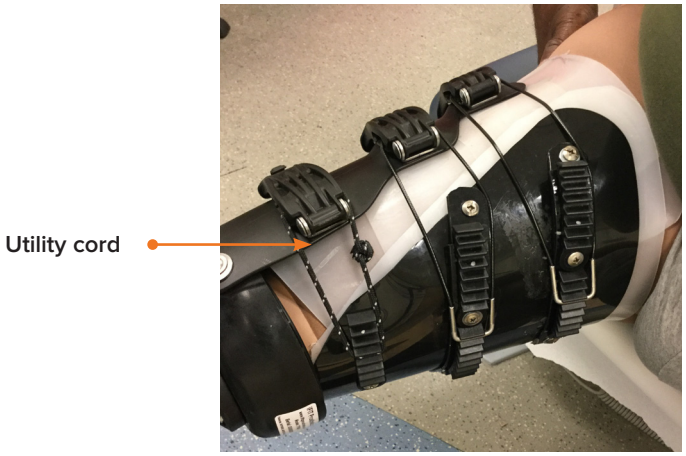
c)



d)

STEP 16 :

If the cables provided are not short enough, we have provided utility cord that can be tied into a loop.



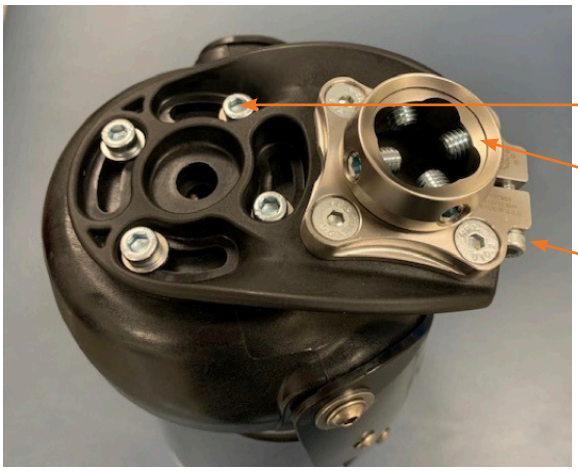
FINISHING THE PROSTHESIS:

STEP 17 :

Once the correct alignment and knee adjustments are completed, be sure to fully instruct the patient regarding the use of the socket and its adjustable buckle system as well as how to don and remove the prosthesis.

STEP 18 :

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 fully engage their pin before buckling or standing. This prosthesis must be worn with a silicone locking liner.

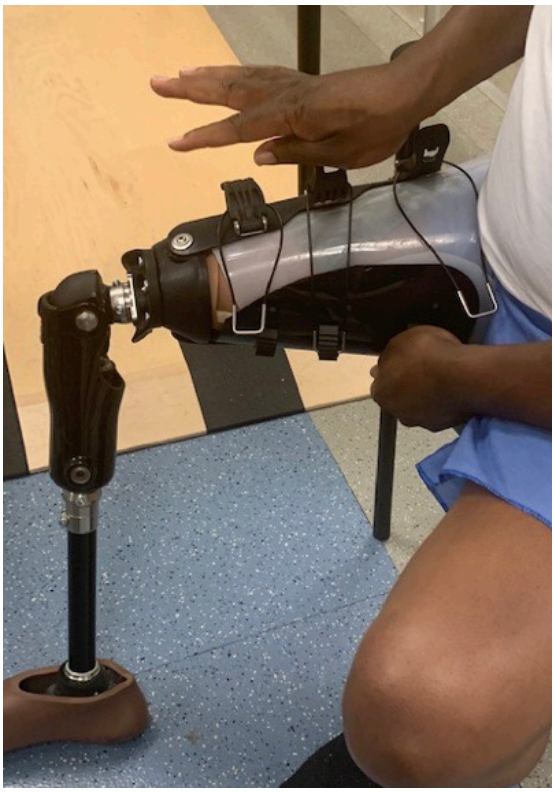
2) Make sure the patient is aware that the flap with hooks is on the outside. The flaps must be overlapped correctly in order to buckle the prosthesis.

3) We suggest buckling the middle or proximal buckle first and the distal buckle last. As one buckle is closed it will often loosen another that then must be adjusted.

4) Make sure the patient puts the prosthesis on with the lateral upright extending up the outside of their leg. We instruct patients to place on their limb so that the side bolt is facing upward with their foot flat on the floor. 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 feels more comfortable .

5. If the patient has large volume changes they may need to re-buckle several times after first standing and walking

6. Any painful areas should be pointed out to the prosthetist.



For questions or more information:

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