




# Transtibial Advanced Closure Instruction Guide

MODEL: TRANSTIBIAL ADVANCED CLOSURE (TTAC-S & TTAC-N) for adult and pediatric patients

- **Aligned quickly:** Can be fit in under 2 hours
- **Lighter weight:** Making mobility easier
- **Eliminate visits:** The user can adjust their own setting
- **No socks:** Not required to accommodate limb changes
- **Low profile:** Sleek adjustability

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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 Advanced Closure System



PULL LOOPS ALLOW WEARER TO EASILY ADJUST THE SYSTEM

LIGHT WEIGHT, DURABLE SOCKET MATERIALS

WORKS WITH PIN SUSPENSION

WORKS WITH THE MAJORITY OF CONVENTIONAL PROSTHETIC FEET AND LINERS

INTERNAL PULLEY SYSTEM ALLOWS FOR A WIDE RANGE OF ADJUSTMENTS THAT CAN BE MADE BY THE USER

PADDED NEOPRENE LINER INSIDE SOCKET



## Section I • Introduction

This latest innovation from iFIT Prosthetics was developed to provide a low profile, adjustable device that is both lightweight and durable. Below you will find a series of instructions that are essential to follow in order to get the best results from the device. Please also review the modifications as these are generally required to tailor each device to the individual. The iFIT system works with a variety of silicone locking liners as well as many commercially available low-profile prosthetic feet.

This patented (8470050, 8491667, 8845755, 10398577, 10806608, 11382775, 11766343) prosthetic device has undergone extensive engineering design and testing to ensure a high strength, durable device that can be modified in a patient-centered way.

It has adapted ISO testing standard and was designed

for ease of fitting and patient use. The flexible socket is adjustable through high strength cords. The soft inner neoprene liner encompasses the limb and comes with additional padding that can be added to customize the fit. The prosthesis can be worn with or without the neoprene liner according to patient preference.

With sizes fitting both pediatric and adult patients, our sockets are lighter and lower in profile for greater comfort and better fit under clothing. Our patented adjustable cup provides flexibility to accommodate a wide range of limb circumferences.

Please refer to the sizing guide as these sockets are purchased in different lengths. Customizable sockets are also available. For patients with symes amputation a customizable socket is required.

### Advanced Closure Kit Includes:

- A. Socket with cup/shuttle lock/ pyramid
- B. Neoprene liner (inside socket)
- C. (2) Locking Pins 1.5" & Pin adjustment washers (.5mm and 1 mm)
- D. Loctite 242
- E. Pull tab w/ cord (attached to socket)
- F. Padding kit (2 crescents, 2 rectangles, 1 large posterior pad)
- G. Cosmetic cover
- H. Sock
- I. Extras: pull tab, 4 feet of cord, 2 cord loops, 1 cleat and screws
- J. Tube clamp
- K. Pylon
- L. Extender flap w/ screws



### Tools Needed:

- 4mm hex key- to adjust the pylon and tube clamp
- Torque wrench- for properly tightening screws on the bottom pyramid, tube clamp and pylon
- Heavy duty cutters – for cutting the inside flap to proper length or trimming the proximal brim
- Scissors- for cutting cord or shaping neoprene
- Sander or sandpaper- to smooth cut edges
- Heat gun and vice grips (optional)- for bending the proximal brim
- Phillips and flathead screwdrivers- to change cleats or cord loop if necessary
- Saw or pip cutter- for cutting the pylon to the proper length

## Legal disclaimer

iFIT warrants that the iFIT transtibial 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 and locks. Cords and inner liners are not included in the warranty. The socket is an injection molded part, the are not to be heat molded or altered other than what is described in this manual. Doing so will void the warranty. Any iFIT transtibial prosthesis which you or your patient alleges to be defective (and/or any sockets, 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 or locks, as applicable), and provided iFIT confirms that the prosthesis (or sockets, 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 or locks, as applicable). By purchasing the iFIT transtibial 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 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 transtibial 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 transtibial 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 transtibial 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 transtibial 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 transtibial 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 transtibial prosthesis, you waive, release and agree not to hold iFIT responsible for any and all losses, damages or liabilities in excess of that amount.

### **Return Policy:**

For safety and quality control purposes, we are unable to accept returns if any of the following conditions apply:

- 1.The device has been cut, heat-molded, or otherwise altered.
- 2.Loctite or similar adhesive has been applied to the device.
- 3.The device has been worn outside of the clinic.

However, we do offer exchanges for a different size if needed. To initiate an exchange, please contact your sales representative.

## IMPORTANT WARNINGS

- Only the lateral brim and posterior portion of the socket can be heated. Do not heat any other area of the prosthesis.
- Only the posterior flaps can be trimmed. Do not cut, trim, bend or mold the injection molded cup.
- 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.
- Patients who lack protective sensation should not use this device. The mechanical pulley 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 secured prior standing. The user should check to ensure the cord is secured before standing
- The prosthesis should be put on and taken off from a sitting position. All 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 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 cup 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 ADVANCED CLOSURE PROSTHESIS

MODEL: TTAC-S & TTAC-N



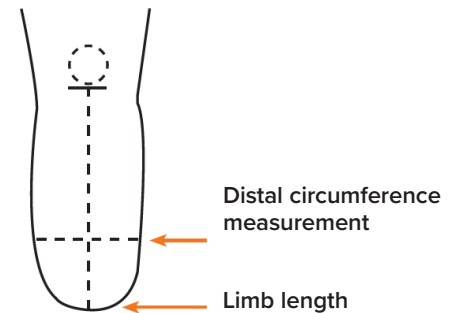
## Section III • Measurements & Patient Characteristics

### PATIENT CHARACTERISTICS

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

- Well healed residual limb
- Intact skin sensation
- Good hand function and visual acuity
- Ability to understand instructions
- Weight under 260 pounds
- K1-K3 Ambulation Level

### HOW TO MEASURE



### SIZING CHART

Distal Circumference	Wearer Weight	Limb Length (base of patella to end)	Socket Size Transtibial Advanced Closure
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**Narrow or Pediatric Socket** - Ideal for pediatric patients (children and teens) or adults with narrow limbs.

18 - 24 cm on the skin or 20 - 26 cm with liner	Must weigh less than 120 pounds (54kg)	12 cm - 15 cm	<b>TTAC - N - S</b> Narrow - Short
		16 cm - 19 cm	<b>TTAC - N - M</b> Narrow - Medium
		20 cm - 24 cm*	<b>TTAC - N - T</b> Narrow - Tall

**Standard Adult Socket**

25 - 32 cm on the skin or 27 - 34 cm with liner	Must weigh less than 260 pounds (125kg)	14 cm - 17 cm	<b>TTAC - S - S</b> Standard - Short
		18 cm - 22 cm	<b>TTAC - S - M</b> Standard - Medium
		23 cm - 26 cm*	<b>TTAC - S - T</b> Standard - Tall

**Wide Adult Socket**

32 - 38 cm on the skin or 34 - 40 cm with liner	Must weigh less than 260 pounds (125kg)	14 cm - 17 cm	<b>TTAC - W - S</b> Wide - Short
		18 cm - 22 cm	<b>TTAC - W - M</b> Wide - Medium
		23 cm - 26 cm*	<b>TTAC - W - T</b> Wide - Tall

\*For longer limb lengths please speak with sales representative regarding a custom device.

## Section IV • Fitting Instructions

### STEP 1:

The patient should be weighed and measured prior to fitting the prosthesis. Order the proper size of prosthetic socket from iFIT to insure the optimal fitting. Our representatives can assist you with this.

Once they have donned their silicone liner, check the prosthesis is the right length. These sockets are supracondylar, providing excellent stability and alignment.

- ✓ Part of the patella should lay on the anterior brim.
- ✓ The lateral walls should encapsulate the knee condyles.
- ✓ The patient should be able to easily bend their knee.

Liner should go above the lateral walls of prosthesis



Part of patella should be at the brim of the prosthesis

### STEP 2:

Find the optimal cup diameter by sliding the base to cover the distal end of the residual limb. Apply loctite 242 to the four screws on the base of the pyramid and torque to 10Nm once distance is set.



Cup can slide forward and backward

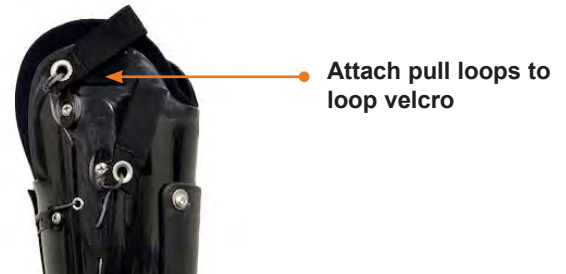


Apply loctite 242 and torque to 10Nm

### STEP 3 :

Have the patient place two fingers in the pull loops and pull until the prosthesis feels sufficiently tightened. The prosthesis should feel snug and can be re-adjusted after walking.

The patient will wrap the cord around the cleat and then attach the pull loop to the hook velcro on the socket. This cord can be cut and re-tied so that the cord is wrapped 3-4 times around the cleat.



### STEP 4 :

Cut the pylon to length according to foot selection. Attach foot and pylon to prosthesis using set screws which will be torqued after the alignment is finalized. Have the patient stand in the parallel bars to further assess the pylon length.



### STEP 5 :

Once the pylon height is correct, begin the alignment process. Once the alignment is optimized, refer to the modifications section for further modification to enhance patient comfort. Modifications include padding the prosthesis, heat molding the upper lateral portion of the prosthesis, trimming and heating the posterior flaps and adjusting the cord loop locations.

### STEP 6 :

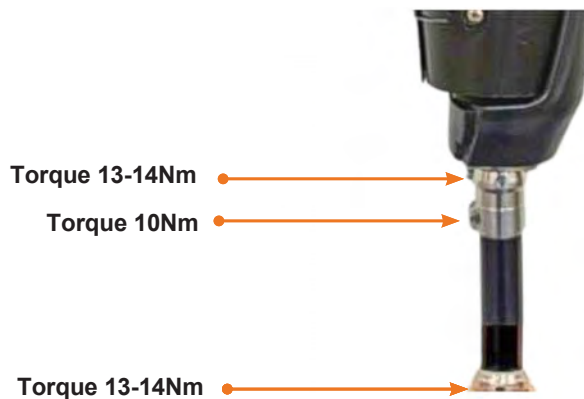
Review how to loosen the prosthesis by pulling the cord from the posterior side (similar to loosening a shoe lace). Pull back flaps slightly apart.



### STEP 7 :

The prosthesis needs to have Loctite 242 applied to screws and torqued. Use the checklist below to finish the prosthesis:

- ✓ Apply Loctite to all screws on the pylon and tube clamp
- ✓ Torque receiver screws on tube camp (4 total) to 13-14Nm
- ✓ Torque clamp screw (1 on tube clamp) to 10Nm
- ✓ Torque receiver screws on pylon (4 total) to 13-14 Nm
- ✓ If you have not already done so, apply Loctite and torque the screws to the pyramid receiver, which is described in step 3.



### STEP 8 (optional) :

To add a basic cosmetic cover to the prosthesis, cut the foam to the length of the pylon. You can use zip ties (pictured) or wrap electrical tape around the foam. A sock can be added over the cover.



## Re-Lacing Guide:

Should the prosthesis need to be re-laced please use these images as a guide

Side View



Posterior- Tall



Posterior- Medium



Posterior- Short



## How to Tie Knot on Cord Loop or Pull Loop :

Step 1: Thread cord through pull loop



Step 2: Make a loop



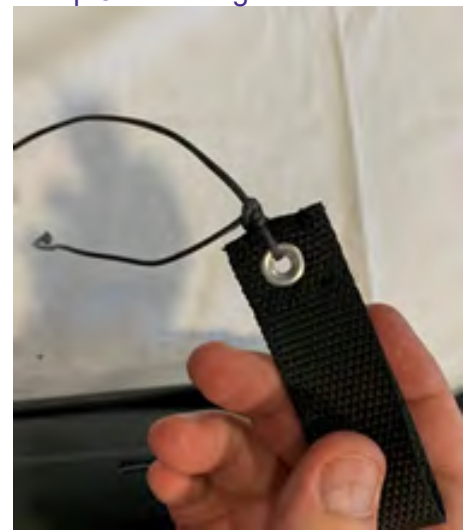
Step 3: Loop cord around 2-3 times



Step 4: Thread end through loop



Step 5: Pull to tighten



**Modifications:**

**FOR THIN LIMBS – Decreasing the circumference**

Check that the cord loops are not running into each other and that the prosthesis can adequately tighten.

The posterior flaps can be trimmed down for thinner limbs. In this picture, the outer posterior flap was trimmed on the left side to prevent the edge from hitting the opposing cord loop. You can also trim the inner flap as well.

Should the subject need an even tighter fit, the cord loops can be removed and new holes drilled further out.

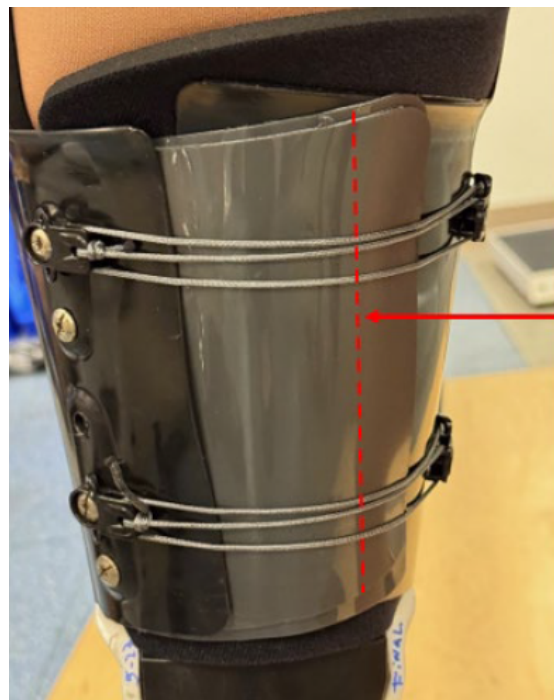


Trim the flap if needed

Cord loops can be removed. Drill a new hole further out and replace

**FOR LIMBS OVER 31cm CIRCUMFERENCE - All Wide devices come with extender flap**

This flap comes loctited onto the socket. You can trim it down or remove it if needed. Make sure the edge of the flap is not running into the cord loops on the opposite side.



Trim the flap if needed

### **Bottoming Out/ Distal Pressure Adjustment**

Instruct the patient to engage the pin just 1-2 clicks and then tighten versus putting their limb all the way to the bottom. This method “suspends” the limb off of the bottom.

The pin will continue to click into the prosthesis as they stand. This method however still helps keep the limb suspended.

The wearer may need to repeat this process if their limb loses volume during the day.



Some wearers can keep the prosthesis laced and continue to don/doff without having to re-tighten and cleat the prosthesis. This can be tested in the clinic prior to having the patient leave. Others may need to loosen the prosthesis to open it up in order to don and doff.



### Pinching or Tight Proximal Brim Near Knee- Heat Molding

The brim can be heated and pushed out slightly.

Heat the sides of the prosthesis for several seconds while pulling the brim outward. Wait until cool to test on the patient. You can also use a crescent pad at the top of the prosthesis.



Heat the lateral walls and gently bend out

### Posterior portion of the prosthesis pinches or is too high at posterior knee- Trimming and Heat Molding

The posterior flap can be heat-flared to alleviate pressure behind the knee. We recommend drilling holes the posterior flap about 1cm down, and then cutting slits to make three panels which can be heated and pushed back. Please refer to the instructional videos for this method.

Drilled holes in posterior flap with slits



Heating the posterior flap

## Padding Tips for Suspending Prosthesis

Padding the medial aspect of the limb can be helpful in further securing the limb in the prosthesis. Alternatively, a more dense foam such as pelite can be used inside the socket to further support this area.



Padding medial tibia area

## Padding Sensitive Areas

A padding kit is included in each kit. You can add extra padding for sensitive areas on the limb. Care should be taken not to over-pad the limb as this can result in a poorer fit. Many pediatric patients prefer the socket without the neoprene liner, and this may be the case with some adults. In this instance, you would remove the hook velcro from the internal socket along with the neoprene liner. The hook velcro can degrade the silicone suspension liners if left in tact.

Here are some areas that may require padding:

Crescent pad for added knee stability



Pad around the tibia

Rectangles or crescents around bony fibular head



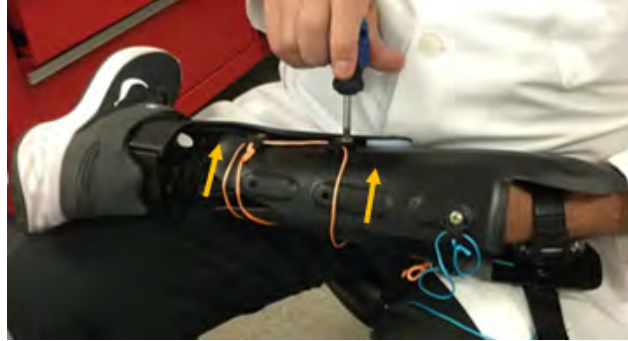
One or two pads can be added at base of tibia

## CORD LOOP RELOCATION

If the flap lap is running into cord loops for a thin limb or limb with highly compressible tissue, the cord loops can be removed and placed further out. This requires new holes to be drilled in the prosthesis.

You can also alter the lacing pattern of the prosthesis if desired. Some persons may need the cord moved higher or lower. There are pre-drilled holes to accommodate these changes.

Always remember to re-loctite the screws prior to replacing the cord loops



## PATIENT CHECK OUT LIST- Use this checklist to clear patients to leave with the prosthesis

- ✓ Patient can walk an extended period of time without pain
- ✓ Patient can don and doff the prosthesis
- ✓ Patient has good understanding of how device works
- ✓ The posterior flaps are overlapped correctly
- ✓ When tightened, the flap of the prosthesis is not running into the opposite cord loop

## Transtibial Advanced Closure Instructional Videos

*Please click on the image or title for the video link*

Transtibial Advanced Closure Fitting Tutorial



Adding the Extender Flap



Adjusting the Transtibial Advanced Closure Sliding Cup



How to Loosen the Advanced Closure



Fitting a Customized Socket for Symes/Longer Limbs



Cutting and Bending the Posterior Prosthesis



**For questions or more information:**

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