



The Right Fit, Right Now



Prosthetist Instruction Guide

MODEL: TT200

www.ifitprosthetics.com

Fit and Aligned in a Single Session

Today's prosthetics from iFIT—*Immediate Fit, Innovative Technology*—gives prosthetists a new option for their patients. Our unique design affords one-session fittings, is adjustable, comfortable and affordable.



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WHAT FIRST-TIME WEARERS ARE SAYING:

“It feels like I’m walking on a pillow!”

“iFIT comes in handy when my stump goes through a hard day’s work and there’s some swelling, which causes pressure in a conventional solid socket. Since the iFIT is adjustable, it’s perfect for times like that—especially after hiking or running.”

“The inside padding prevents rubbing and irritation—you’re really onto something here!”



The Right Fit, Right Now

Section I • Introduction

We hope your patients enjoy the comfort and adjustability of the iFIT Transtibial Prosthesis. Years of research and development have gone into the design of this prosthesis so that we could provide the best possible product for transtibial amputees. Below you will find a series of instructions which are essential to follow in order to get the best results from the device. The iFIT system works with a variety of silicone locking liners as well as many commercially available low profile prosthetic feet.

The iFIT Prosthetic system is an advanced design intended to give patients the maximum adjustability and comfort. This patented (8470050, 8491667, 8845755, 10398577, 10806608) 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 met ISO testing standards and was designed for ease of fitting and patient use.

The flexible socket is adjustable by means of a buckle and cable system. The soft inner neoprene liner encompasses the limb within the socket and comes with additional padding that can be added to customize the fit. This system is designed to work with a pin suspension system; two pins that work with the shuttle lock are included. The kit also comes with spacers that can be inserted into the bottom of the prosthesis to accommodate limbs of varying lengths.

This device is designed to optimally fit amputees with the following residual limb measurements:

LENGTH (BASE OF PATELLA TO END): 14-20CM

Distal Circumference skin	Distal Circumference w/liner	Socket	Description
20 - 28cm*	25 - 30cm	Narrow	Hooks on the front, buckles all on right
25 - 34cm	27 - 36cm	Standard	Standard with small flap
33 - 39cm	35 - 40cm	Wide	Spacers and larger flap
38 - 46cm	41 - 50cm	X-wide	X-wide cup with largest flap
45 - 60cm	46 - 62cm	Ultra Wide	X-wide cup with 2 of largest flap, nite-ize adjustment, buckles on right. <i>Available on special request</i>

LENGTH (BASE OF PATELLA TO END): 20-26CM

Distal Circumference skin	Distal Circumference w/liner	Socket	Description
24 - 34cm	27 - 36cm	Tall	Tall cup (sizing follows Standard cup)

Legal disclaimer:

iFIT warranties 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, 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 provid-

ed 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 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, 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 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.



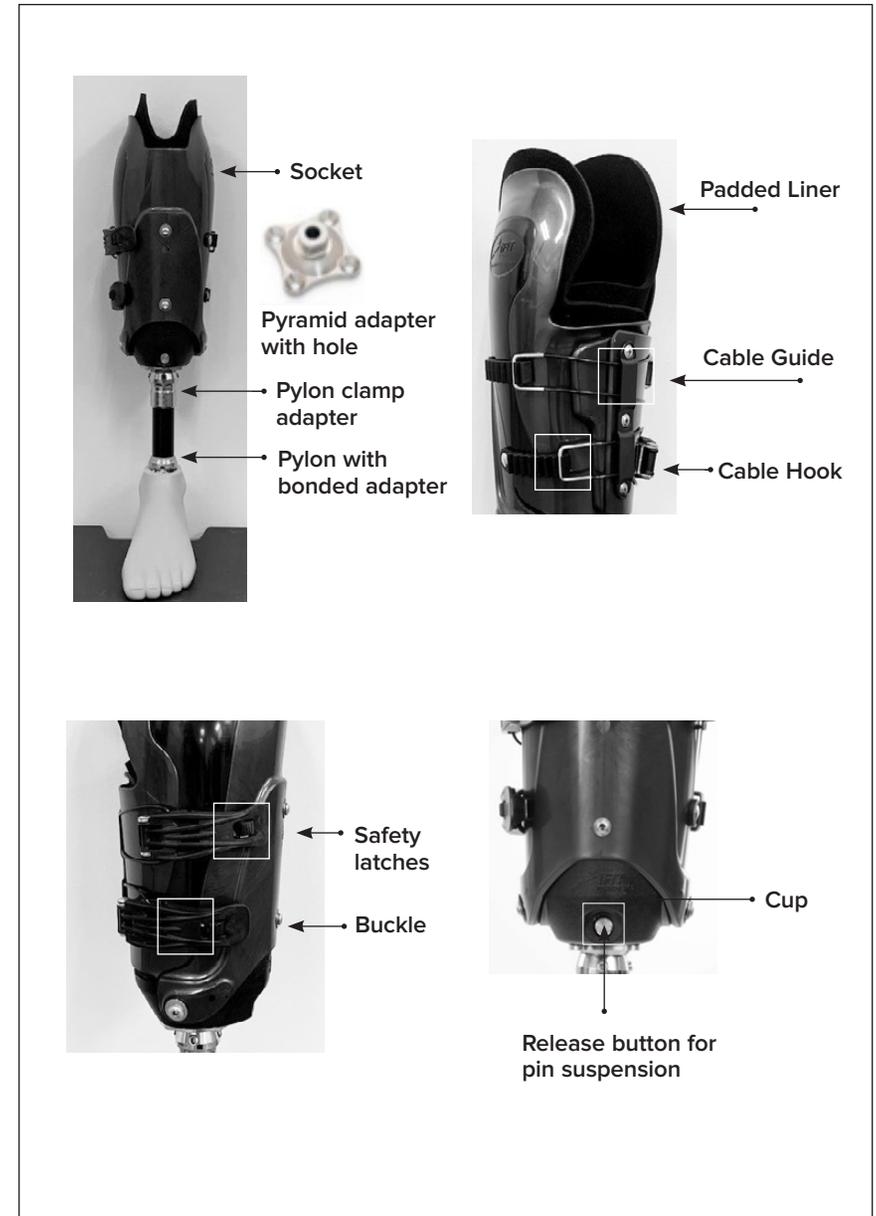
BEFORE GETTING STARTED PLEASE READ THE IMPORTANT WARNINGS ON THE FOLLOWING PAGES.

⚠ IMPORTANT WARNINGS:

- Please do not heat the prosthesis in any areas other than what is explained in this guide.
- Do not cut or modify the prosthesis socket, except for the back flap as explained in this guide. This can result in the rigid side material detaching from the softer socket material and causing a sharp edge to form.
- 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 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 amputee choosing this device. These include; falls, pain in the limb, or skin breakdown.
- After using in the water make sure all water is emptied out of the device. Rinse the prosthesis with freshwater after using in saltwater.

Section II • iFIT Prosthesis Component Guide

iFIT TT200



Section III • iFIT Transtibial Prosthesis Kit & Tools Needed

TT 200 KIT

- iFIT transtibial prosthetic socket (includes shuttle lock, pins and pyramid adapter)
- Neoprene inner liner
- Extra padding kit (pre-cut neoprene shapes)
- Cables
- Pylon with bonded adapter
- Pylon adapter
- Spacers
- 2.5" Ratchet Pin



ITEMS YOU WILL NEED TO PURCHASE FOR PATIENT

- Prosthetic foot
- Silicone Locking Liner



TOOLS YOU WILL NEED

- Means of cutting an aluminum pylon such as a pipe cutter or carbide radial arm saw
- Locktite®Blue
- Allen wrench (4mm)
- Torque wrench (4mm Hex attachment)
- File



May need/optional:

- Heat gun
- Utility knife
- Pliers
- Scissors
- Cutter
- Velcro
- Screwdriver

Section IV • Step by Step Instructions

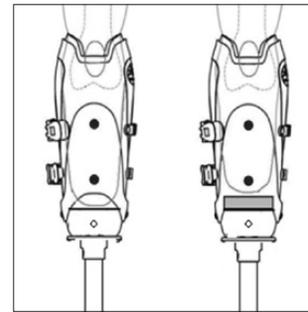
STEP 1: PATIENT ASSESSMENT

1) Please use the Patient Checklist and iFIT Prosthesis Information sheet in Appendix B for new patients. ***Patients must all meet the following criteria prior to being fit with the iFIT transtibial prosthesis:***

- Healed residual limb
- No open wounds, infections, or skin irritation
- Intact skin sensation
- K level 1: Ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence household ambulatory
- Good hand dexterity for opening and closing buckles
- Weight under 260 pounds for the wide and 350 pounds for the extrawide.
- Demonstrate cognitive ability to safely use and adjust the device.



2) The patient's limb measurements should be known before fitting to order the silicone liner and guide prosthesis assembly. A 1cm or 2cm spacers can be placed on the bottom to accommodate shorter limbs. This spacer is placed directly in the bottom of the prosthesis, and adhered with the enclosed 3M tape after testing the patient with it in. The patella should be near the front of the prosthesis and the medial and lateral walls should be above the femoral condyles.



The shorter limb on the right uses a spacer so that the patella's midline sits at the prosthesis brim.



1 and 2cm spacers shown

SOCKET SIZING AND SPACER CHART

Limb Measurement (distal patella to end)	Socket	Spacer
14 - 16cm	Narrow, Std, Wide, X-wide	1 or 2cm*
16 - 18cm	Std, Wide or X-wide	1cm
18 - 20cm	Std, Wide or X-wide	None
20 - 22cm	Tall Cup	1 or 2cm
22 - 24cm	Tall Cup	1cm
24 - 26cm	Tall Cup	None

*If an amputee needs more stability use either a 1cm or none to get them further into the socket. This may require heating and bending outward the back flap if it compresses the popliteal fossa or puts pressure on the posterior knee area when sitting.

CIRCUMFERENCE CABLE CHART

Circumference (skin)	Circumference (w/silicone liner)	Socket	Top Cable	Bottom Cable
20 - 28cm	25 - 30cm	Narrow	45 - 50	30 - 40
25 - 30cm	27 - 32cm	Std or Tall	40 - 45	30 - 35
30 - 34cm	32 - 36cm	Std or Tall	45 - 50	35 - 40
33 - 36cm	34 - 38cm	Wide	50 - 55	40 - 45
36 - 38cm	38 - 40cm	Wide	55 - 60	40 - 50
39 - 48cm	41 - 50cm	X-Wide	60 - 65	45 - 55

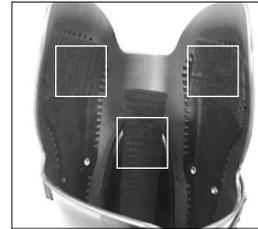
This is a general guideline which may be adjusted depending on the amount of padding used and thickness of the silicone liner. The circumference measurements for estimating socket size is taken while the patient is wearing their silicone liner around the mid-point or distal end of the limb (use wider measurement). The shape of the limb (bulbous, cylindrical, or conical) will dictate the lengths of cables used and the liner padding. This table is a guideline for general consideration.

3) During the initial residual limb inspection, note any bony prominences which may require extra padding. Limbs that are sensitive at the bottom benefit from a gel pad or gel cup placed inside the liner. We generally recommend a 3mm thick silicone locking liner since the neoprene padding protects the sides of the limb.

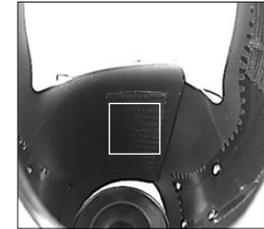


STEP 2: PROSTHESIS ASSEMBLY

1) The neoprene prosthesis liner should be placed in the prosthesis so that there are no wrinkles or bunches in the fabric. Each prosthesis has Velcro on the inside as shown below. The neoprene liner should be secured in the prosthesis prior to wearing.



Velcro on the inner front portion



Velcro on the inner back flap



Liner inside the prosthesis

2) The outer flap with cable guide **MUST GO ON THE OUTSIDE** of the prosthesis socket. The inner flap will have Velcro which secures it to the neoprene liner.



3) Cables for the top and the bottom buckle are included; these are dependent upon limb circumference and layers of padding used. Press the cable into the buckle opening and thread through the outer buckle guides.

STEP 3: FITTING THE PROSTHESIS

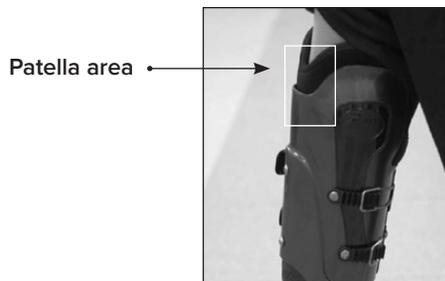
1) The patient should have a silicone locking liner and prosthetic foot ordered for them prior to the fitting. Most low profile commercially available feet will fit with this device (build height 10cm and under).



2) There are two pins supplied with the TT200 that work with the Bulldog Genesis located in the cup of the prosthesis. The pyramid adapter has a hole the pin can go through if the patient does not need a spacer. The pyramid can be unscrewed and an offset can be placed on the bottom. You may need to pop out the bottom plate of the socket to access the nuts that are in the bulldog shuttle lock.



3) Refer to the sizing chart on page 12 to select a spacer and cables. Have the patient put on the socket with the spacer to check that it fits properly on the limb. This means (a) the medial and lateral wall of the prosthesis should extend over the femoral condyles and (b) the patella sits either right above or slightly below the anterior brim of the socket.



4) Have the patient lay on exam table with the prosthesis on. Align the base of a prosthetic foot attached to a pylon up to the patient's sound limb to estimate where to cut. Cut a little longer since the patient may sink down into the prosthesis when standing. **Alternate method:** Measure sound leg from top of patella to end. Then measure top of patella to base of pyramid with socket on the amputated side. Subtract this difference and that is the height with foot and pylon.



5) Attach the pylon to the prosthesis to double check the length once cut. You can then put the patient's shoes on and begin aligning the prosthesis.



6) Begin with a slightly valgus alignment and slight externally rotated foot position. This can be changed depending on where the amputee feels pressure on their limb.



STEP 4: PUTTING ON THE IFIT AND ADJUSTMENT

1) Slide the prosthesis onto the patient's residual limb after they have put on their silicone liner. Make sure the prosthesis overlaps smoothly in the back.

⚠️ Ensure the pin engages and the prosthesis cannot be pulled off. The TT200 shuttle lock will have a clicking noise. You should instruct the patient on how to test that the pin is engaged by having them try to push it off.



2) When buckling, determine a hook that will be tight enough to secure the prosthesis but not so tight as to cause discomfort. **TIP:** When the patient is buckling the prosthesis on their own, advise them to start with an outer notch and move the cable toward the desired notch to achieve the desired tightness.

⚠️ Advise the patient that buckling too tight may restrict blood flow to limb. If there is any pain when buckled at a particular setting, they should reduce the tension by moving another hook back.



Cable can be moved gradually forward to desired tightness

3) Make sure the inner flap is under the outer flap which has the cable guide when pulling the buckles closed. Pulling while the inner flap is on the outside may cause breakage. If this happens frequently, a wide device with a flap may be needed.

Also, make sure the inner neoprene liner stays in place and doesn't wrinkle or fold into the prosthesis when putting it on, this may cause discomfort.



Correct



X Incorrect

4) Make sure the cable is not hooked over the buckle as shown in picture **A**. This can cause excess wear on the cable. To prevent the cable from catching, the buckle can be shifted up or down as shown in picture **B**.



A.



B.

5) Make sure the back flap is not hitting or not running into buckle based or buckle hooks. If so, the flap should be removed for the standard device, or unscrewed and have new holes drilled along the recessed areas for the wide and x-wide (refer to page 25). The old holes can then be trimmed off before screwing back onto the prosthesis. Please alert amputee users that they should report this, as they may shrink and need this flap cut down in the future.



6) Once buckled, show the patient how to test that the safety locks are engaged. You should not be able to pull the buckle open without first pressing the safety lever.

Patients should also close the prosthesis with an open palm as shown below.



STEP 5: FINE TUNING THE ALIGNMENT

1) Once the prosthesis is securely on, have the patient stand. Once standing you can further assess the length of the pylon and alignment adjustments.



2) The next step is for the patient to walk in parallel bars. Encourage the patient to take small steps. They can then indicate any areas receiving high pressure or causing discomfort.



3) Make one adjustment at a time to the socket and the foot until the amputee feels their gait is optimized. Refer to the Alignment Strategies in Section 5 for more details.

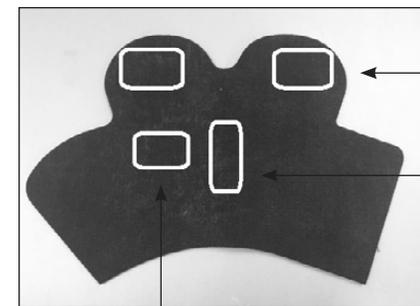


STEP 6: PADDING THE LINER

1) Padding the liner allows for customization of the iFIT prosthesis. Limbs with bony prominences might require heavier padding than those without. The kit comes with a variety of neoprene patches and foam square which can be placed onto the neoprene liner.



2) The padding can be placed on a variety of ways depending on the patient's needs. Pads can be stacked if needed.



Use the crescents to provide greater stability to the knee.

The longer neoprene or foam can be used on the anterior portion to alleviate pressure on the tibia.

Pads can cut and placed on the medial and lateral sides right above places of discomfort to release pressure.

3) One effective method for padding areas, is to wrap the liner around the patient's limb first. Then place the pads over bony areas to ensure they are placed in the correct spot. **Most amputees will benefit from a pad placed over the lower tibia area.**



4) An alternative is to pad around sensitive areas creating a donut effect to take pressure off this area. Here is a liner that is padded around the tibia area.



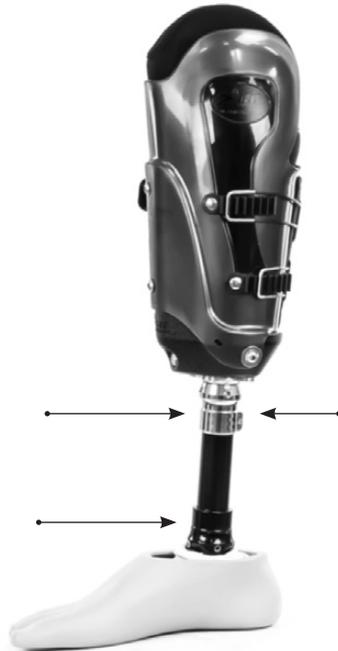
STEP 7: FINALIZING THE PROSTHESIS

1) A torque wrench with a 4mm attachment is needed to tighten the pylon adapter near the foot and pylon clamp

Apply **Loctite Blue** prior to tightening

Tighten screws on the receivers to **13-14 Nm**

Tighten side clamp on adapter to **10 Nm**



2) After all the padding has been added, decide which hook is the most comfortable for the patient.

Use a white or metallic marker to mark the ideal hook. Instruct the amputee they can adjust either one hook above or one below, unless they experience drastic changes in volume.



3) Finished! The amputee can now leave with their new iFIT Prosthesis. Schedule the patient for a 1-week follow up appointment and refer to our guide in Section VII for items to check. You should be available for during the first 48 hours in case the patient has questions about their new iFIT device.

4) Please refer to the wear schedule in Appendix A and review with the amputee- it is also located in the User Guide. It is important that although the iFIT device is very comfortable, they should gradually acclimate to it by adhering to the wearing schedule.

The Clinical Exam and Device information in Appendix B is helpful in tracking patients and the items used on each prosthesis. If you would like, an amputee questionnaire is included in Appendix C for you to gain patient feedback.

NOTE: This prosthesis can be used in the water. Make sure it is rinsed with freshwater after using in saltwater. Empty all of the water out of the prosthetic after water use. The patient may need a second neoprene liner to use while the original dries.

Section V • Other Prosthesis Modifications

Accessing the Shuttle Lock

If you need to access the shuttle lock, the top plate can be easily removed with a flat head screwdriver. For instance to change the pyramid to an offset pyramid. There is a recessed area on the back of the plate where a screwdriver can leverage it off. The double sided tape on the back of the top plate should remain adhesive, and can remain in place.



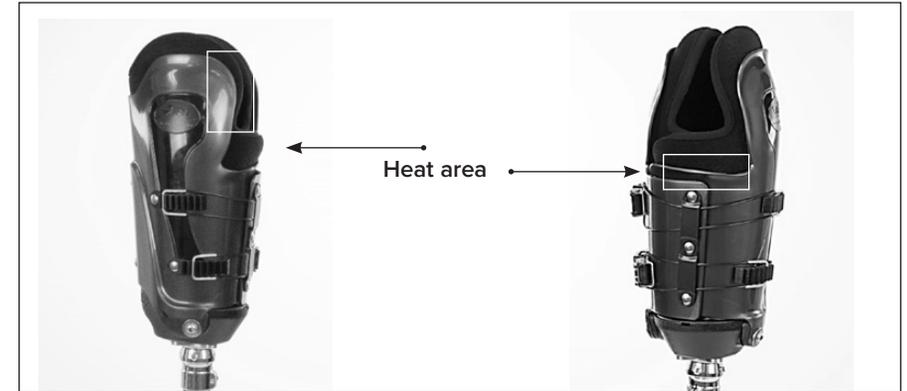
Adding an Offset Pyramid Adapter

The pyramid adapter on the iFIT can be replaced with an offset pyramid. For patients that experience distal tibia pain, use an offset toward the front, to move the foot more anteriorly. For patients that need a medial or lateral offset, you can either replace with an offset pyramid or an offset plate or offset adapter. A shorter pin may be required to avoid hitting the pylon adapter.



Heating Molding the Prosthesis

NOTE: DO NOT HEAT ANY AREAS OTHER THAN INDICATED BELOW! Heating other areas is not advised and may cause structural weakening. Only the upper portion of the prosthesis near the back, and the back flap without the cable guide may be heated.

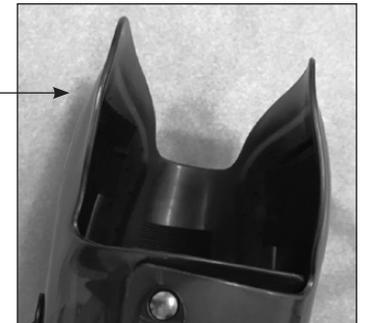


Upper Portion of Prosthesis: Some patients with large thigh circumferences may need the upper posterior edge of the prosthesis flared slightly out.

Heat the posterior edges of the prosthesis and bend slightly outward by placing a pylon in between while the prosthesis cools. You can also place a vise or clamp with a flat piece of metal against this edge for similar results. The prosthesis must be fully cooled before removing.



The result will be a slightly straighter edge. The prosthesis below was heated on only the left side for comparison.



Back Flap: Patients with short limb lengths may want the back flap modified to accommodate them better when sitting. This will involve cutting and heating the back portion of the prosthesis. Make sure after cutting there are no sharp edges.

First, cut only the outer flap with cable guide. Be sure not to cut into the guide itself.



Second, **heat** the back flap that does not have a guide. Pull slightly out with pliers to create a slight curve.

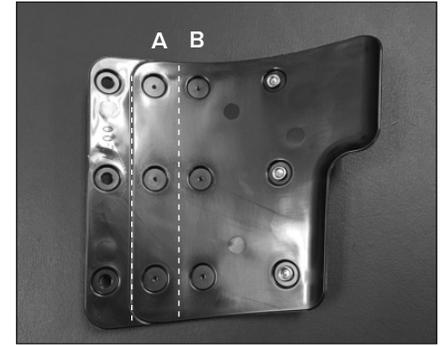


The resulting shorter flared back flap will allow for the knee to bend more easily when sitting.



Modifying the Wide and X-Wide Prosthesis

The back flap can be removed and cut to shorten the length. Drill new screw holes in the recessed areas. The X-wide flap shown below can use either set **A** or **B**, while the wide has only set **A** available. Cut along the dotted line next to the new set of holes and screw back onto the prosthesis.



The side spacers on the WIDE device can also be removed for amputee, one or both, that are wide on top, but narrow down near the bottom. Be sure to re-apply Loctite to the side bolts when screwing back in.

Removable side spacer

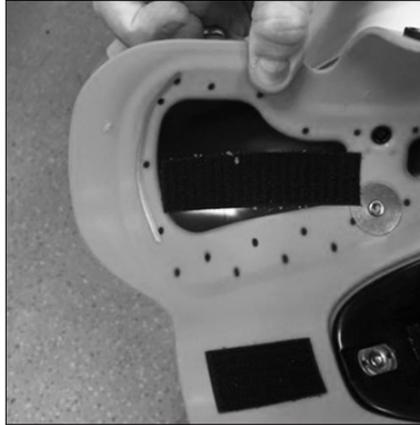


Trimming down the prosthesis

For patients with shorter limbs 15-17cm, the top of the prosthesis can be trimmed instead of using a spacer. We recommend trimming no more than 3cm from the top or above the black dots on the inside. Be sure to smooth the edges prior to giving to the patient.



Measure up to 3cm down



Ensure the black dots are not cut into



Mark where to trim, then cut



Finished product

Trimming the back flap when using a spacer

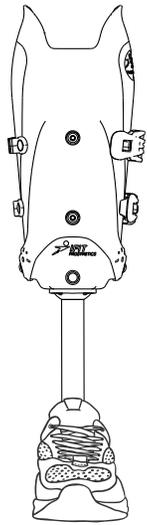
If using a spacer, you can trim the back flaps so that the prosthetic better squeezes the limb. Use a heavy cutting tool to trim 1-2cm depending on spacer used.



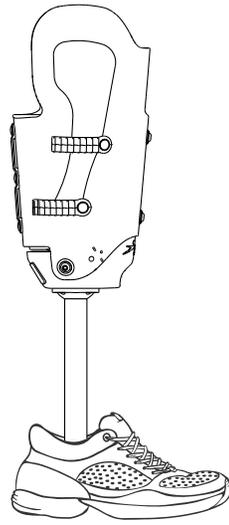
Both flaps can be trimmed up to the cable guide

Section VI • Alignment Strategies for iFIT Prosthesis System

Optimal Alignment



Anterior View



Lateral View

Starting Alignment:

- Begin with a slightly valgus alignment and outward rotation of the foot.
- The socket should be initially aligned so that there is a slight amount of flexion in the socket.

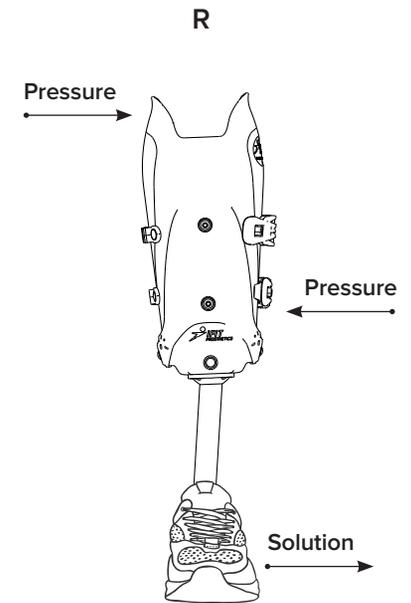
PROBLEM:

In frontal plane, **foot too far out** or increased pressure on distal medial and proximal lateral socket.

SOLUTION:

Move foot in toward patient midline

- Adjust socket at pylon clamp so that foot moves toward the mid line of the amputee.
- An offset pyramid adapter or plate placed toward the midline of the prosthesis may also be used.



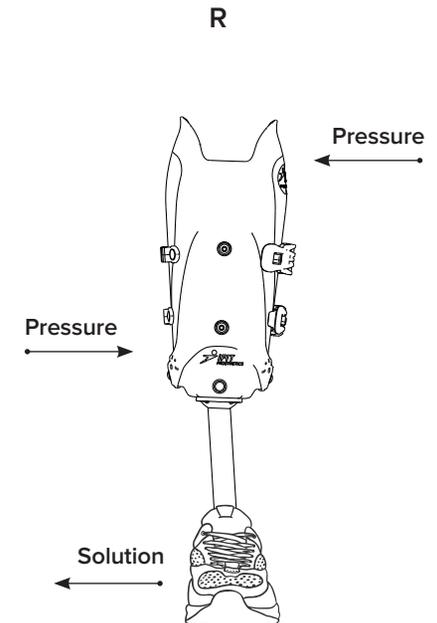
PROBLEM:

In frontal plane, **foot too far in** or increased pressure on distal lateral and proximal medial.

SOLUTION:

Move foot out laterally

- Adjust socket at pylon clamp so that the foot moves away from the midline of the amputee.
- An offset pyramid adapter or plate placed toward the lateral portion of the prosthesis may be used.



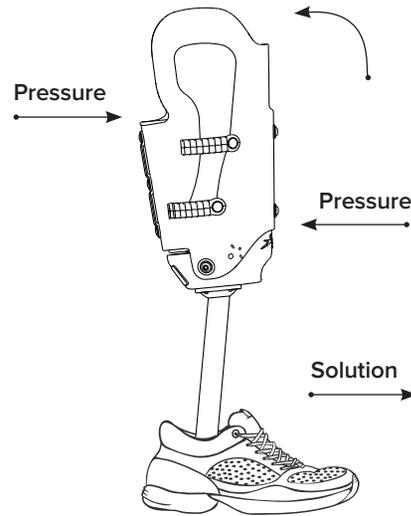
PROBLEM:

In sagittal plane, **foot is too far back** or increased pressure on anterior distal or posterior proximal (popliteal fossa) portion of socket.

SOLUTION:

Move foot forward

- Adjust socket at pylon



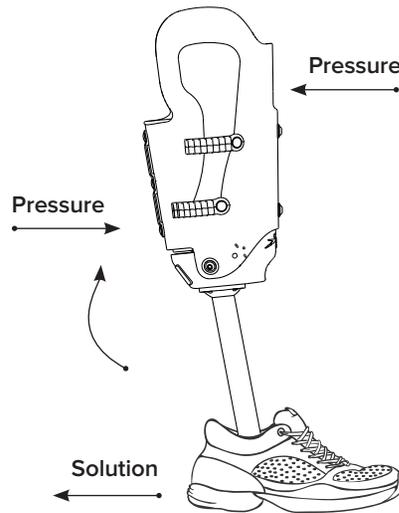
PROBLEM:

In sagittal plane, **foot too far forward** or increased pressure on anterior proximal and posterior distal portion of socket.

SOLUTION:

Move foot back

- Tighten both screws on posterior side of prosthesis 2 turns
- Loosen front screw 1 turns
- Repeat as necessary to achieve



Section VII • Patient Check Out

- Before the patient leaves, it is critical they demonstrate the ability to safely use the iFIT prosthesis. This includes:
 - Donning and doffing
 - Good understanding of the cable/buckle system
 - Uses good judgement
 - Can traverse stairs
- For patient with balance difficulties, instruct them to walk with feet slightly apart. They should turn around by making a few steps instead of a pivot on the one leg. Go up stairs with the intact leg, down with the prosthetic leg.
- Schedule one week follow up

Section VIII • Issues to Check During One Week Follow Up

Check screw tightness: Ensure all the screws in the pylon are tight and the alignment has not changed since the initial fitting.

Alignment changes: Make adjustments to the alignment if patient has any sensitive areas or discomfort. If alignment has shifted, re-align to the patient's preference.

Cable check: Make sure all the cables are smooth and do not have excessive fraying.

Pain: If the patient indicates pain, additional padding can be added to the liner.

Skin check: Inspect the residual limb for any skin irritation, breakdown or sensitive areas. If skin breakdown occurs, have the patient refrain from using the prosthesis until healed and have returned for re-alignment/ added padding.

Liner check: Check padded neoprene liner for signs of excess wear or areas of wrinkling. It should be smooth soft. Liners may need to be replaced after several months of use.

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, 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 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, 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 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.

Appendix A • Amputee Suggested Wear Schedule

DAY 1	Wear 2 hours	Check limb. Keep off for 5 minutes.	If no issues...	Wear 2 additional hours
DAY 2	Wear 3 hours	Check limb. Keep off for 5 minutes.	If no issues...	Wear 3 additional hours
DAY 3	Wear 4 hours	Check limb. Keep off for 5 minutes.	If no issues...	Wear 4 additional hours
DAY 4	Wear 5 hours	Check limb. Keep off for 5 minutes.	If no issues...	Wear 5 additional hours
DAY 5+	Wear as tolerated. Check every few hours to assess residual limb or if you have any discomfort. Check limb if any discomfort occurs.			

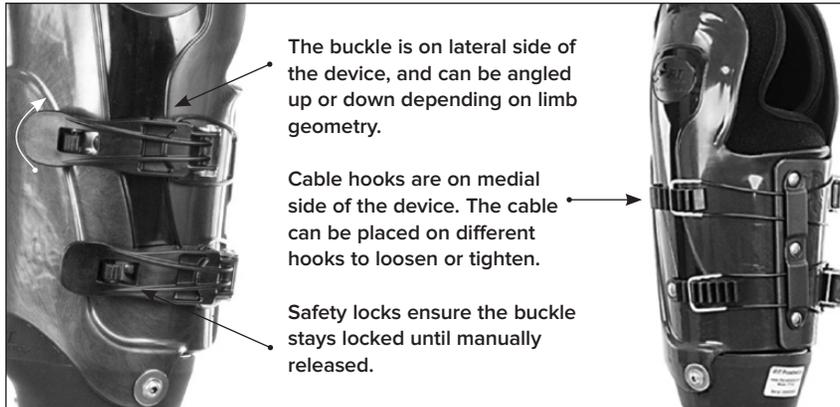
 **If pain develops loosen the prosthesis one notch. If pain does not decrease contact your prosthetist.**

Report any injury or skin problem immediately to prosthetist.

iFIT Prosthesis Key Features

Adjustable Buckle System

The diameter of the device is adjusted through the cable and buckle system. Several sizes of cable are available depending on limb circumference.



Standard and Wide Device

For limbs that measure 14-20cm in length from base of patella to end there are the following choices: standard, wide and x-wide. The wide version (pictured below) can be modified to become smaller if the amputee shrinks down.



X-Wide and Tall Socket

The X-wide socket fits limbs that measure up to 46cm in circumference. Good as a preparatory prosthesis for when the limb needs to shrink.



X-wide size

The tall socket is for longer limbs that measure 20-26cm from base of patella to end.



Tall size

Customizable Neoprene Liner and Padding Kit

Each device comes with a 5mm thick neoprene liner. The liner has silicone on the distal and tibia portion to provide extra comfort to these areas.



The neoprene liner provides comfort to the residual limb. It comes secured within the prosthesis with Velcro.



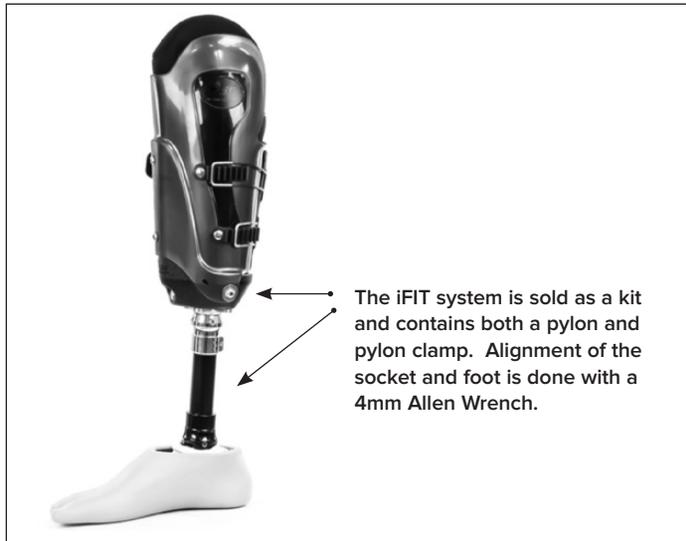
A padding kit comes with each device to customize the fit. There are a variety of shapes that adhere to the liner with Velcro and can be cut or trimmed down.



The neoprene liner can be built up in certain areas to relieve pressure on sensitive areas. Highly sensitive areas can be padded such as the tibia (pictured).

Alignment System

Both the socket and foot are aligned by the iFIT healthcare provider.



Shuttle Lock System

Each device has a Bulldog Genesis Shuttle Lock already secured in the cup. The lock is attached to a conventional pyramid adapter with hole. Two pins are provided with each prosthesis.



Front release button for shuttle lock system

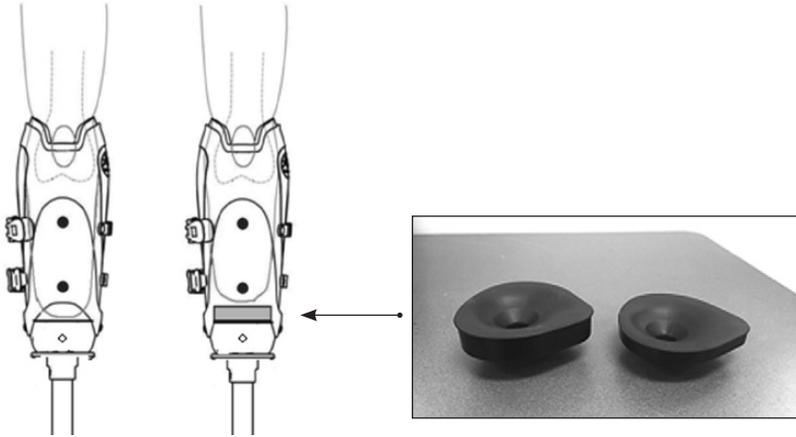
Supracondylar Support—Highly Durable Socket

The sides of the device are designed to go over the medial and lateral femoral condyles to give the knee more stability. Advanced polycarbonate materials comprise the socket to make it strong yet flexible and lightweight.



Spacers for Different Limb Lengths

Two sizes of spacers come with each prosthesis to allow for proper placement of the limb in the prosthesis. The patella should lie along the brim of the prosthesis to ensure supracondylar support. The device is recommended for limb lengths 14-20cm measured from base of patella to end.



Frequently Asked Questions

1) What materials are incorporated into the iFIT prosthesis for strength and durability?

The device is made of ultra-high strength injection molded polymers with unique material properties that combine to form a strong, durable, and flexible socket that can be easily adjusted. The iFIT prosthetic system has surpassed ISO testing standards.

2) Can I use with your device with vacuum system for suspending?

No, the device must be used with a pin suspension system. The TT200 uses a shuttle lock and includes pin.

3) Does the iFIT transtibial prosthesis kit come with everything I need to fit it to a patient straight from the box?

Yes, there is no need for casting or molding. The socket is highly adjustable and can be modified for each patient. It is highly adjustable. Purchase of an iFIT system includes the following (pictured below): socket, inner neoprene liner, several different sizes of cable, padding kit, spacers with adhesive tape, pylon, pylon clamp and pins.



4) What else do I need to purchase to fit a patient?

You will need to order a [silicone locking liner](#) and appropriate [low profile foot](#) appropriate for the amputee. We recommend a lighter and thinner silicone sleeve such as the Ossur Iceross liner as you do not need excess padding over the limb. The adjustable neoprene liner provides ample custom padding between the adjustable socket and the limb.

5) Is the prosthesis distal end weight bearing or patellar tendon bearing?

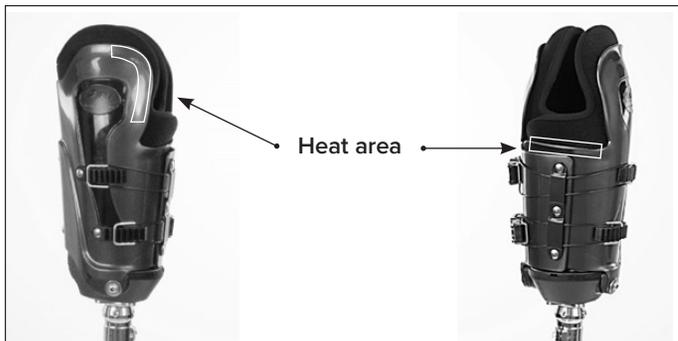
The iFIT prosthesis is designed to give total contact within the socket, so that pressure is distributed evenly around the limb. The force is spread out over a larger area, as opposed to one concentrated area below the patella seen in patellar tendon bearing hard sockets. If an amputee feels too much pressure on their distal end, this can be addressed by one or more strategies; i) either adjusting the alignment and putting more flexion into the socket, ii) using the custom fit foam liner that precisely fits the limb geometry and insures total contact, or iii) adding foam under the medial tibial flare and adjusting the lower buckle to make it slightly tighter to hold the limb off of the distal end. You can also try engaging the pin half-way, then buckle the socket so that the bottom of the limb is not touching the bottom of the socket. The pin can be partially attached, then buckle the prosthesis with the limb slightly elevated within the socket.

6) Can the device be heat molded?

You may heat and remold **only** two places on the socket, the; i) upper posterior portion of the prosthesis, where it grasps the thigh, and ii) the posterior proximal inner flap to reduce pressure in the popliteal fossa area. These two areas can be heated and pushed slightly out to relieve pressure in these areas. **Do not heat any other areas of the prosthesis** as this can result in structural failures.

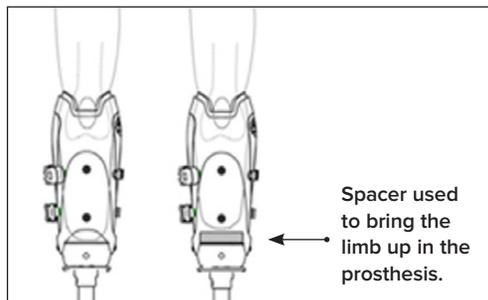
In order to relieve these two pressure areas by heat molding, first use a standard heat gun to heat the material until it is very warm, do not melt it. Then put in the position you would like using a gripping device or device to push the socket outward. Let the socket cool slowly and naturally while held in the position you wish.

Refer to the instruction manual (Section V. Other Modifications) for guidance on heating.



7) What is the shortest and longest limb length the device can fit?

The standard device will fit patients with limbs ranging from 14-20cm, while the tall will fit patients 21-26cm as measured from the base of the patella to distal end of limb. Spacers are provided to achieve proper limb position in the prosthesis.



The patella should fall at approximately the proximal anterior socket or a little more inside the socket. This ensures that persons with shorter limbs have a firm purchase of the socket above the femoral condyles. The image on the right features a shorter limb, boosted up by a spacer to reach the correct height.

8) What residual limb circumferences will the device fit?

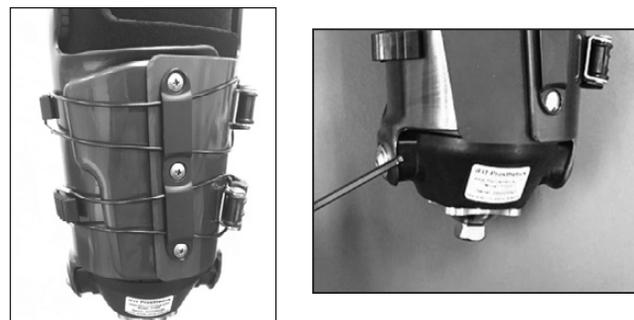
Please see our ordering guide for sizes to order. The iFIT will fit circumferences ranging from 23-48cm depending on silicone liner thickness. We have a standard, wide and extra wide device to choose from.

9) Are there different sizes of sockets?

Together these fit about 80% of amputees. Spacers can be used for shorter limbs, while the cable and buckle system can adjust to a variety of circumferences.

10) Can the wide socket be modified if the patient shrinks?

Yes, there are several adjustments you can make to decrease the size of the wide socket. The first is shortening the back flap extender. You may also take out one or both of the lower side spacers to reduce the bottom circumference of the wide device (pictured below). Lastly, you can add padding and switch to smaller cables.



11) What is the maximum weight the device can support?

The maximum weight is 350 pounds with extra wide device.

12) What is the weight of the device?

The TT200 is 2.7 pounds for the standard when weighed with neoprene liner.

13) When can the amputee take their device home?

An amputee can take their device home immediately after being fit. This is provided they can demonstrate safe use of the device; i) negotiating stairs safely, ii) putting it on and taking it off properly, and iii) demonstrating the hand function, vision, and judgement to safely use the iFIT prosthesis.

14) Can amputees wear the device under jeans?

The device is best worn with loose fitting pants. Amputees have found they can wear the device with somewhat narrower fitting pants that had some stretch.

15) Can I use an offset pyramid?

Yes, the TT200 model features the ability to change the pyramid adapter. You may switch to an offset pyramid or an offset plate for persons requiring such alignment with offsets to accommodate their alignment needs for a stable prosthetic gait. You can remove the screws on the bottom holding on the standard pyramid and replace the standard pyramid with the offset plate or pyramid. Be sure to re-Loctite the screws when replacing the pyramid with an offset pyramid.

Be sure to match the pin length to the spacer and the offset, particularly if the offset does not have a pin hole. You don't want a patient with the pin and cup holding them up like a golf tee.



16) What tools do I need?

You will need a saw of some kind to cut the pylon to the proper length, a file or deburring tool for once the pylon is cut, a 4 mm Allen wrench, torque wrench and Loctite. Scissors, a utility knife, cutting tools, screwdriver, extra Velcro and a heat gun are also helpful to have on hand if needed to adjust the inner liner and padding or the outer socket where heat molding is allowed.



17) Is it waterproof?

Our device can be used in the water. You may want to give the patient a second liner to use inside the prosthesis while the first one dries.

18) Can the device be used as an immediate post-operative prosthesis or a removal rigid dressing?

The prosthesis is designed as a preparatory prosthesis to be used when the medical and surgical teams feel the patient is sufficiently healed to begin ambulation and some weight bearing. It is designed so that when a patient is cleared for initial ambulation in a therapy setting, the iFIT socket can fit to the leg and accommodate the shape and volume changes as the residual limb matures and the patient learns to walk with a prosthesis.



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.



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N27 W23655 Paul Road • Pewaukee WI 53072

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The Right Fit, Right Now