iFIT POST OP CONVERSION SYSTEM (POCS) PROTOCOL

The iFIT POST OP CONVERSION SYSTEM (POCS) is designed to protect the limb and prevent edema following transtibial amputation surgery. There are two components to this system. The first is a removeable rigid dressing that is designed to protect the wound while in bed, during transfers and other non-standing activities. It will provide gentle limb pressure to reduce edema and will protect the limb while it heals. It is held on with a waistbelt and "Y" strap and closed with Velcro straps.

The second component is a preparatory prosthesis that the patient can use when in physical therapy under the close supervision by the prosthetist, therapist, and physicians. Limited initially then progressive weight bearing and ambulation can occur early in the healing phase. The care team and attending physician must monitor the surgical wounds carefully as mobility is advanced to insure optimal wound care.

This system can facilitate more rapid rehabilitation, gait training and prosthetic use.

POCS Kit Contains:
- iFIT socket with Velcro strap
- 2 neoprene liners with distal pads
- Waist Belt
- Y strap
- 2 Socks
- IFIT Preparatory prosthesis

Patient Selection

- Most patients should benefit from the POCS.
- Patient should be coherent and able to understand instructions.
- Most patients will require the x-wide prosthesis due to swelling. For smaller limbs that measure 34cm or less at widest portion, a wide can be used.
- The iFIT cannot be used with symes amputations, or amputations longer than 21cm from base of patella to end of limb.

Post-Op Protocol

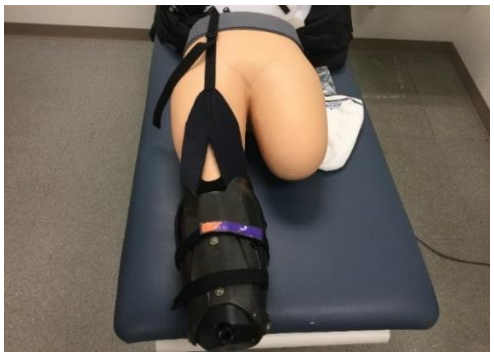
1. The iFIT POCS is only to be used under nurse or therapist supervision. Proper education of the care team is key to insuring success.
2. Make sure the POCS has the neoprene liner and distal pad velcroed together, and is placed together within the prosthesis.

3. The patient's wounds should be bandaged as per usual protocol.

4. <u>One sock should be placed over the bandaged limb in between the limb and the neoprene</u>. This sock should be checked for spotting and laundered or discarded if needed.
5. The iFIT POCS should be placed over the bandaged limb with sock. Mild compression should be applied using the Velcro strap. The strap should be snug but not tight- <u>do not overtighten</u>. If there are any pressure areas or the patient complains of discomfort, loosen the POCS socket.

6. Make sure there are no areas of increased pressure above the knee or below the knee- adjust the Velcro strap accordingly.
7. Once the POCS is in place, the protective sock should be placed over the POCS to protect the opposite limb.
8. The Y strap is then attached to the inside of the prosthesis, which will adhere to the Velcro in between the socket and neoprene liner. The Y strap attaches to the waist belt which should be snug but not overly tight. This will provide modest distal compression.

9. These straps should be adjusted depending whether the patient is sitting or lying down, to ensure only modest compression is applied to the limb.
10. If there is any pain or discomfort, remove the device and check the patient's skin.
11. The POCS should be removed at least twice per day- once in the morning and once in the evening to inspect the limb. Any excessive bleeding or skin changes should be reported to a physician immediately.
12. If the neoprene liner or distal end pad is soiled with wound seepage or blood, it must be replaced with the second liner and pad (included in POCS kit). Use a Clorox wipe or similar to wipe off the inside of the prosthesis after liner is removed.



POST OP CONVERSION (POC) with waist belt, y strap and compression straps applied

POST OP CONVERSION (POC) with protective sock covering

Weight Bearing Protocol:

1. The preparatory iFIT prosthesis can be kept in physical therapy and put on when the patient is in therapy. A prosthetist (certified by IFIT Prosthetics) should properly fit and align this prosthesis to insure proper function.
2. The Y strap can be used for suspension when the patient is ready to bear some weight on the limb and use toe touch ambulation and weight transfer. A pin suspension is also available but the amputee must have a silicone sleeve and pin to use it. This can be rolled on over surgical wounds and dressings.
3. Weight bearing should be mostly pain free. If patient experiences pain check the alignment or tightness of the device. It is suggested that the therapist start with limited weight bearing and progress as the patient tolerates, carefully monitoring skin and surgical wound integrity.
4. Any would seepage or blood should be noted. Replace any components such as the sock or neoprene liner with unsoiled parts.

Transition to Everyday Walking Prosthesis: Advancement from POCS to the iFIT complete system is based on judgement of attending physician. Seek out advice of the attending physician prior to advancing ambulation intensity and training.

1. The patient's sutures should be completely healed prior to switching over full time to the iFIT complete system.
2. The preparatory iFIT system contains buckles, cables, pin suspension lock and pyramid adapter. They will then have their pylon and foot attached to this prosthesis for ambulation.
3. If the patient has shrunk substantially, they may need a smaller sized socket, refer to prosthetist guide for prosthesis modifications.
4. Patients will need to be instructed on how to use the buckle system to adjust the circumference of the device when their limb changes in volume.
5. Please refer to the prosthetist instruction guide manual when fitting the complete system for further fitting instructions and modifications.

⚠ IMPORTANT WARNINGS:

- *Please do not heat the prosthesis in any areas other than what is explained in the prosthetist instruction manual.*
- *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 continue to use the preparatory prosthesis use in patients with skin breakdown.*
- *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.*
- *Use extra padding in pressure sensitive areas between the neoprene insert and the socket wall to accommodate limb differences in size and shape and to relieve areas of pressure sensitivity.*
- *The prosthetic socket must be securely buckled before standing. The buckles must be closed such that both buckles are locked. The therapist and person using the device 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) that is supervised by a physical therapist and the attending physician to get used to the device.*
- *This preparatory 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.***