ÖSSUR®
LIFE WITHOUT LIMITATIONS

CONNECT® TF
Clinical Manual

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INTRODUCTION

Connect® TF is an adjustable socket indicated for low active amputees. The open socket donning feature designed into the on/off tensioning handle, helps ease of donning and doffing while the user is in sitting position. Connect TF can be custom fitted by a certified prosthetist and adjusted throughout the socket lifetime in height, angle and circumference.

Key components:

- Iceross Transfemoral locking liner
- Connect TF socket

Key features:

- Easy to put on, take off, tension and clean
- Socket fitting and delivery in one session
- Initial setup is fast and effective
- Socket fit can be optimized with user on socket
- Allows objective adjustments
- Facilitates improved clinical records
- Provides ability to replicate socket fit

GENERAL SAFETY INSTRUCTIONS WARNINGS:

- Only use the device for a single patient. Do not use for multiple patients.
- Only use the device with the Iceross® Transfemoral Locking liner.
- Only use the device with Össur components and adapters.
- Instruct amputee to stop and seek advice from CPO if they feel the device is too tight.
- Warn the amputee against making self-adjustments and the associated harm that may result. More specifically, make sure to tell the user to not make any changes to the device. Tell the user any changes can cause damage. If damage is caused the user can be hurt.
- Instruct the user to contact their CPO in case of damage or impairment to the device. Specifically, tell the user to contact their CPO if the device is damaged. A damaged device is not safe to use and can result in injury.
- IFU instructs on not to expose the device to abrasive particles (for example sand)
- Amputee instructed in IFU regarding flammability and heating hazards. Specifically, do not use heat to dry device. Let device air dry. Heat from example from a hairdryer or radiator, can deform the device.

COMPONENTS

Description	Össur	Non-Össur	Part number
Iceross Transfemoral locking liner (standard)	✓		I-7032XX*
Iceross Transfemoral locking liner (conical)	✓		I-7132XX*
Connect TF socket	✓		CTF020YY*
Locking Knee Lanyard Kit	✓		CTF10008
Medium Distal End	✓		CTF12001
Large Distal End	✓		CTF12002
Distal Elevation Kit	✓		CTF12010
Connect TF Handle - left	✓		CTF12012
Connect TF Handle - right	✓		CTF12013
Attachment pin Clutch - standard 40mm, 12 notches	✓		L-292000
Attachment pin Clutch - short 22mm, 7 notches	✓		L-292003
Attachment pin Clutch - long 52mm, 17 notches	✓		L-292005
Spare Parts kit	✓		CTF12009
Torque wrench (up to 5Nm) (with 0.1 Nm increments)	✓		CTF10009
Torque wrench (up to 15Nm)		✓	
Tape measure		✓	
4mm hex key		✓	
6mm hex key		✓	
Phillips screwdriver		✓	

* See charts on the next page for full part number details

Part Number Information

Iceross Transfemoral

Part#	Profile	Suspension Method	Matrix	Sizes
I-7032XX	Standard 2mm	Locking	Full Length	25,26.5,28,30,32,34,36,38,40,45,50,55.
I-7132XX	Conical 3mm	Locking	Full Length	25,26.5,28,30,32,34,36,38.

Connect TF Socket

Part#	Description
CTF0202L	Medium Short, left side
CTF0203L	Medium Standard, left side
CTF0204L	Large Short, left side
CTF0205L	Large Standard, left side
CTF0202R	Medium Short, right side
CTF0203R	Medium Standard, right side
CTF0204R	Large Short, right side
CTF0205R	Large Standard, right side

Spare Parts

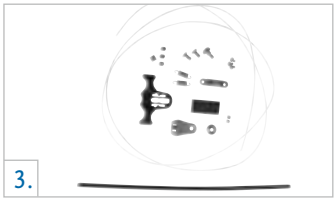
Pict.	Part#	Description
1.	CTF12001	Medium Distal End – distal end used for sizes Medium-Short and Medium-Standard
2.	CTF12002	Large Distal End – distal end used for sizes Large-Short and Large-Standard
3.	CTF10008	Connect TF Locking Knee Lanyard Kit – Contains all the parts needed to fix the locking knee release mechanism onto the Connect TF socket
4.	CTF12009	Spare parts kit
5.	CTF12010	Distal Elevation Kit
6.	CTF12012	Connect TF Handle – left
7.	CTF12013	Connect TF Handle – right

Tools

Pict.	Part#	Description
8.	CTF10009	Bobbin Screwdriver Kit


1.


2.


3.


4.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8.

CONNECT TF – STEP-BY-STEP

Patient Assessment

Examine the strength of the hip joint without the prosthesis.

1. Tell the patient to lie down on the bench.
2. Examine the strength in anterior, posterior, medial, and lateral direction. Use your hand to push down against the residual limb. Tell the patient to push the limb up against your hand.

   Examine the movement of the hip for a flexion contracture.

3. Tell the patient to pull the knee of the sound side up towards the head and extend the hip on the other side.

► These findings should be considered as a starting point for the sagittal socket position during the static prosthetic alignment.

Sizing Liner

1. Measure the circumference 4 cm above the distal end of the residual limb. Measure the circumference of the residual limb at the level of the perineum. Refer to the selection chart to find the correct liner profile, standard or conical.
   ► Select residual limb length to use the correct chart, refer Iceross size to the vertical axis, refer perineum measurement to the horizontal axis, select profile at intersection.

BEST PRACTICES

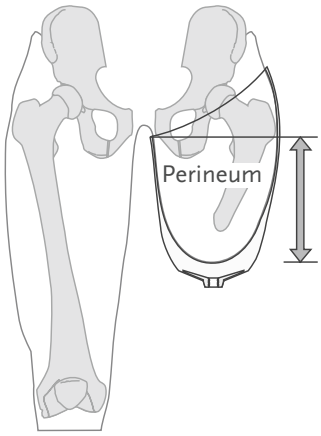
When on the edge of standard and conical profile, select the conical profile for a more compliant fit of the proximal edge, with less tension on the edge of the liner.

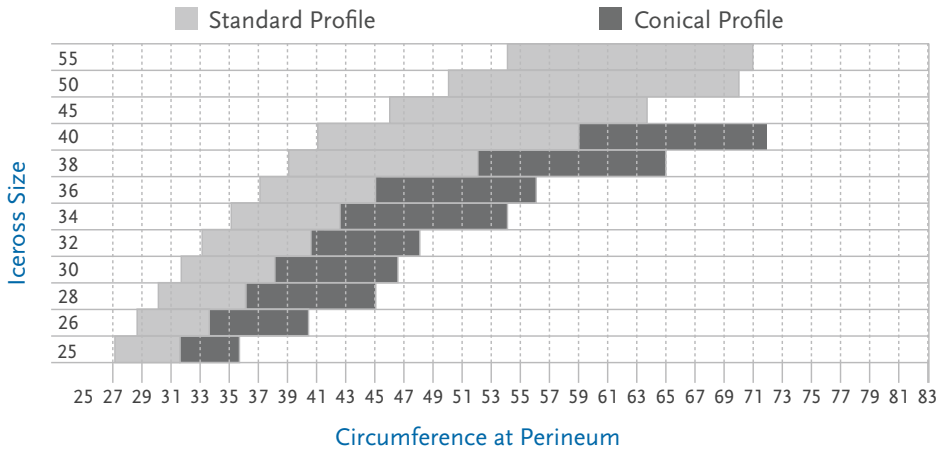
Choosing a (standard profile) liner above size 40 is not recommended for Connect TF, as the liner umbrella interferes with the socket.

Fitting Connect TF to users with a distal circumferential measurement above 40cm must be handled on a case-by-case basis.

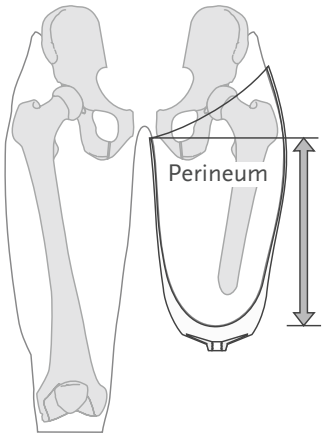
Sizing Liner

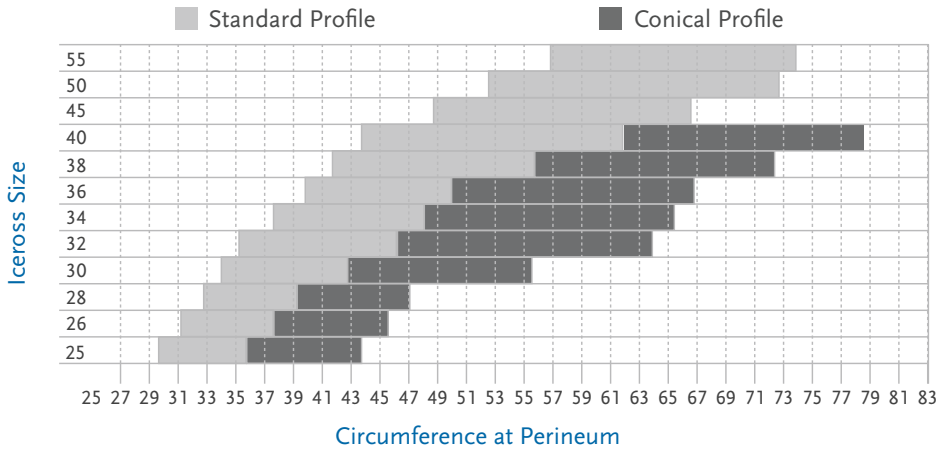
Short Residual Limb - Amputation in Proximal Third of Thigh



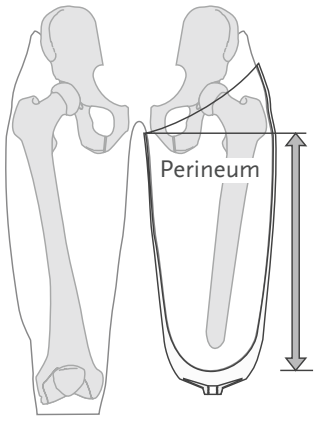


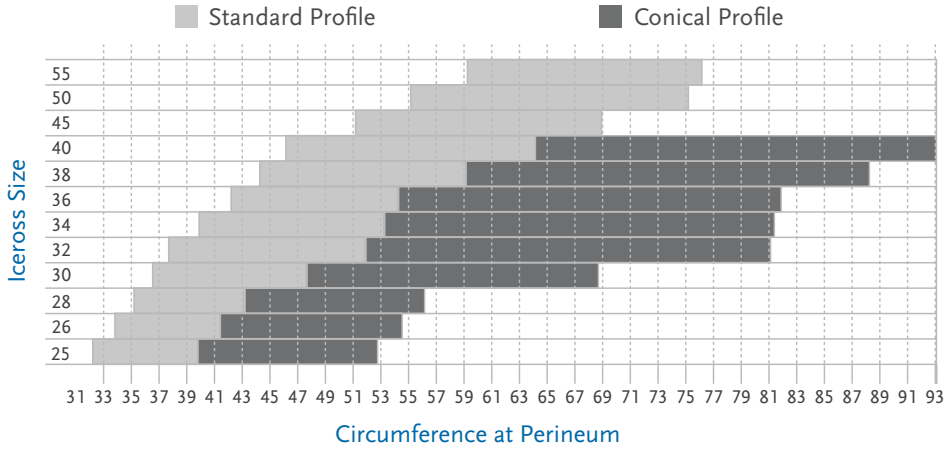
Medium Residual Limb - Amputation in Middle Third of Thigh





Long Residual Limb - Amputation in Distal Third of Thigh





Sizing Liner

2. Roll on the liner.

3. Perform a distal distraction test to examine soft tissue stabilization. This can help to assess the proper liner size and profile.

DISTRACTION TEST

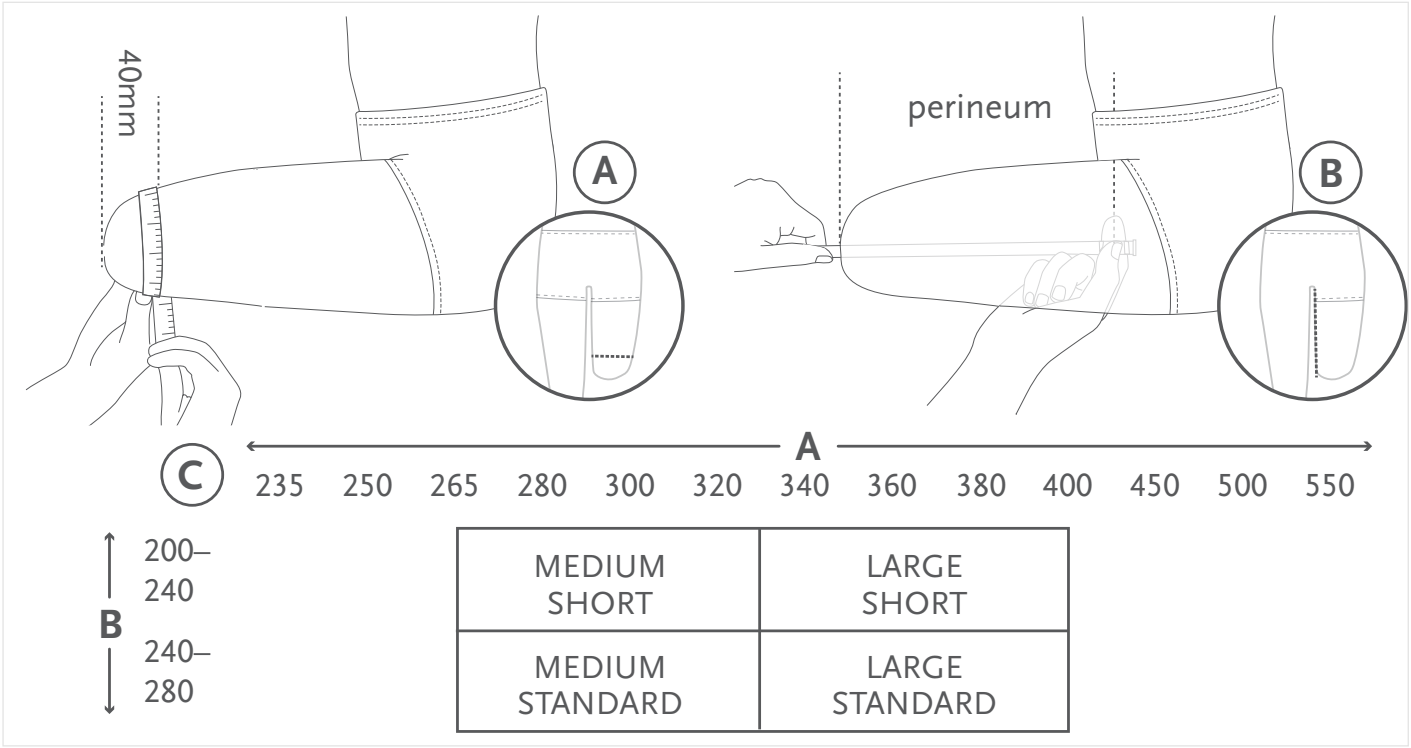
- Hold tape measure over anterior aspect of limb and take note of length at umbrella.
- Screw lanyard into pin receiver and pull on liner
- Record amount of distraction.
- Repeat with other liner (assess size below and above, assess standard and conical profile).
- Liner with less distraction has less tissue distortion.
- Excessive movement may suggest liner too big, concave profile and elongation may suggest liner too small. Select liner that stabilizes soft tissue best.

Sizing Socket

1. Tell the user to sit down.
2. Measure the circumference of the residual limb at 4 cm from the distal end (same measurement as taken for the liner size). Figure A.
   NOTE: It is important to take this measurement with the user sitting.
3. Measure the length of the residual limb from the distal end to the perineum. Figure B.
4. Select the correct device size from the chart. Figure C.

BEST PRACTICES

Move the patient to the edge of the chair to take the measurement.



- ▶ Select device by referring measurement A to the horizontal axis, and measurement B to the vertical axis. Select device at intersection.
- ▶ Circumference range between 26,5 and 40,0cm, length range between 20,0 - 28,0cm.

CONNECT TF – STEP-BY-STEP

Pre-Fitting

1. Screw pin into liner.
2. Use Phillips screwdriver to remove medial and lateral cover.
3. Use 4mm hex key to loosen medial and lateral telescoping screws.
4. Use 4mm hex key to loosen tension bobbins.
   - ▶ Push bobbin IN and turn counterclockwise while pulling on corresponding cord closest to tension bobbin.
   - ▶ Repeat with all 4 bobbins.
5. Use 6mm hex key to loosen medial and lateral distal end screws.

Socket Fitting

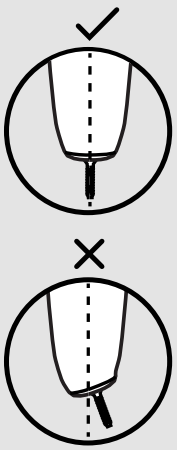
Donning

Don the device with the user in a seated position. It is safest and easiest if the user sits on a hard and smooth surface, such as a chair. Don as follows:

1. Fully invert the liner and roll it on the residual limb.
   NOTE: Make sure to align the pin correctly.

BEST PRACTICES

For smooth engagement of the pin in the lock, pay attention to the alignment of the pin.



Socket Fitting

Before donning Connect TF, verify that the lock release button (knob) on the distal end is facing anterior, and the handle is on the lateral aspect of the patient and in open position (towards the user).

2. Put the socket onto the liner.

3. Push the pin on the liner into the hole. The knob will turn until the pin is fully in the lock.

BEST PRACTICES

Take advantage of visibility of the pin while donning, to make sure it engages with the lock mechanism.

If the pin doesn't engage smoothly in lock mechanism, remove socket and liner, reapply liner making sure that pin is oriented correctly.

Ensure that the residual limb is inside the socket as far as possible prior to manually turning the knob of the clutch lock.

Socket Fitting

4. If needed, rotate the knob to pull the pin fully into the lock.

To fit or adjust Connect TF, a fixed sequence should be followed, consisting of 3 steps.
The steps will be explained on the next pages in more detail, in sequence of application.

Adjusting the Height

The height of the shells can be adjusted to fit the length of the residual limb. Change the height as follows:

1. Adjust the height of the medial proximal shell.

BEST PRACTICES

Adjust strut to ~2cm from perineum.

NOTE:

SHORT version of Connect TF uses 0-40 mm marking on the medial telescoping strut. 0 mm corresponds to a residual limb length of 200 mm when the strut is vertical.

STANDARD version of Connect TF uses the 40-80 mm marking on the medial telescoping strut. 40 mm corresponds to a residual limb length of 240 mm when the strut is vertical.

2. Adjust the height of the lateral proximal shell. We recommend that the lateral proximal shell is a very small distance above the medial proximal shell.

BEST PRACTICES

Notice clearance of socket in relationship to perineum and consider if adjustments are needed after completing initial fitting.

Ensure the proximal edge of the medial and lateral shells are aligned for patient comfort.

3. After dynamic alignment of the socket torque to 5 Nm.
4. Note the final heights of medial and lateral struts in your clinical notes.

Socket Fitting

Adjusting the Tension

The shells can be adjusted to fit the shape of the residual limb. Laces are used to tighten or loosen a shell. Four bobbins above the handle adjust the tension of the laces.
Adjust the shell tension as follows (still in seated position):

1. Ensure that all laces are very loose and that the shells are significantly larger in volume than the user's stump.
2. Close the handle.
3. Push and turn each bobbin to remove excess lace length first (remove slack).

NOTE:
When you push the bobbin this releases it from its locking teeth, allowing it to rotate.

BEST PRACTICES

Be sure to press in the bobbin prior to rotating.

Only remove slack, be careful not to apply any tension on cords.

Make sure to remove slack from all 4 bobbins before tensioning.

4. Use a torque screwdriver set to 1 Nm and tighten the bobbins in increments doing multiple rounds across all 4 bobbins. (Do not tighten 1 bobbin straight to 1 Nm when the other 3 are still slack)

NOTE:
When you tension the bobbins, the angle of the struts will rotate in and align to the shape of the residual limb.

5. When 1 Nm is achieved on all 4 bobbins, open and close the handle. Reapply 1 Nm torque again.
6. 1 Nm is an initial guideline only. Clinical experience will determined final torque.
7. Note the final torque value of all 4 bobbins in your clinical notes.

BEST PRACTICES

Adjust tension in following sequence: distal posterior, distal anterior, proximal anterior, proximal posterior.

Adjusting the Distal End

The distal end can be adjusted to let the strut angles align with the residual limb. Align the distal end as follows:

1. Move the distal end to the medial or lateral side until it is perpendicular to the axis of the residual limb.

NOTE:

This will make it easier to put the pin through the lock.

2. Torque the two distal end screws to 20 Nm.
3. Note the final angle of medial and lateral struts in your clinical notes.

BEST PRACTICES

Sitting too far in the seat can cause posterior thigh soft tissue to push out, causing lateral socket gapping.

Have patient move to edge of chair if possible for socket fitting.

Alignment

1. Attach the device to the prosthetic system (the knee, pylon, and foot).
2. If the device is used with a locking knee, then it must be used together with the Locking Knee Lanyard Kit (see Chapter 2 Components).
3. Align full prosthesis according to knee and foot alignment instructions as mentioned in the corresponding Instruction for Use documents.

Adjustments

As mentioned in the chapter "Socket Fitting", a 1-2-3 sequence is used to fit Connect TF. Step 1 relates to height adjustment, step 2 to tension, and 3 to the distal end. When adjusting the socket after initial fitting, using small iterative adjustments, please respect this sequence and adjust as follows:

Readjusting the distal end:

- ▶ Loosen distal end screws, adjust angle, tighten distal end screws.

Readjusting the tension:

- ▶ Loosen distal end screws, adjust tension, open and close handle, reapply tension, repeat until patient comfortable, tighten distal end screws.

Readjusting the height:

- ▶ Loosen distal end screws, loosen tension bobbins, adjust height, reset tension, open and close handle, reapply tension, tighten distal end screws.

BEST PRACTICES

Offset adapters or alignment plates are common with target patient population.

Have the patient doff and redon the socket, stand up and ambulate in parallel bars.

Verify pin is not impacting the knee: 3 pin lengths are available to choose from.

In case of proximal lateral gapping, consider manually positioning the lateral strut and resetting the tension.

Secure fastening

When dynamic alignment is completed, do as follows:

1. Torque telescoping screws to 5 Nm
2. Torque distal end screws to 20 Nm.

No threadlocker is required.

Attaching Cosmetic Covers

1. Carefully tighten the lateral proximal and distal cover screws until the lateral cover is securely in place.
2. Carefully tighten the medial proximal and distal cover screws until the medial cover is securely in place.

Doffing

1. Fully pull the handle up. This will open the socket.

2. Pull up and hold up the knob. Pull the residual limb out of the socket.

CONNECT TF – STEP-BY-STEP

Changing to the opposite side

A left Connect TF can be made into a right Connect TF (and vice versa). To do this the handle needs to be replaced and the distal end needs to be rotated 180 degrees.

Replace the handle as follows:

1. Ensure the laces are loose with lots of slack.
2. Remove the handle cover from the handle.
3. Remove the handle screw.
4. Replace with the handle for left- or right-side use.
5. Replace the handle screw.
6. Torque the handle screw to 3 Nm.
7. Replace the handle cover.

Rotate the distal end as follows:

8. Remove the distal end screws.
9. Rotate the distal end. The knob must face towards the anterior.
10. Turn the distal end screws back into.

Attaching the Lanyard Kit

Refer to page 5 "Spare Parts" for ordering as an additional item

Attaching the Lever and Guides:

1. Remove the lateral cover screws.
2. Put the locking knee lanyard washer over the proximal hole on the lateral strut.
3. Attach the lanyard lever, lanyard washer and lanyard screw to the strut.
4. Attach the proximal guide to the strut, below the lanyard lever.
5. Attach the distal guide to the posterior side of the strut.

Attaching the Lanyard Cord to the Proximal End:

6. Attach the spring, nylon lanyard, lanyard collar and heat-shrink tubing to the lever.
7. Attach the assembled end of the lanyard cord to the spring.
8. Heat the heat-shrink.
9. Put the tube with the nylon lanyard through the two guides.

Attaching the Lanyard Cord at the Distal End:

10. At the distal end, loop the end of the nylon lanyard through the lanyard collar.
11. Examine the function of the locking function to find the correct length of the nylon lanyard at the distal end.
12. Fasten the lanyard collar around the nylon lanyard.
13. Attach loop to the knee lock.
14. Cut off excess nylon lanyard.

Attaching the Distal Elevation Kit

Changing the funnel from 0cm to 2cm

1. Unscrew the 2 funnel screws.
2. Remove funnel 0 cm.
3. Put in place funnel 2 cm, the guide pin will help locate the correct position.
4. Screw in the 2 funnel screws to 5 Nm.

Note: It is likely a longer locking pin is required.

END USER DONNING AND DOFFING

Donning

1. Make sure to be in a seated position, preferably on a hard and smooth chair.
2. Open the socket by pulling the handle up, away from the knee.

3. Slide the socket over the residual limb, pull socket towards you and push residual limb into socket.

4. Push the pin into the hole. The knob on the outside will turn if the pin engages the lock. Try to turn the knob to pull the pin into the lock completely.

5. Close the socket by pushing the handle completely down, towards the knee.

Doffing

1. Make sure to be in a seated position, preferably on a hard and smooth chair.
2. Open the socket by pulling the handle up, away from the knee.

3. Pull up and hold up the knob. Slide the socket away from the residual limb.

EXTENDED BEST PRACTICES

The key to a good Connect TF fitting is to spend time on iterative adjustments to fine-tune the socket fit after the initial fit. As Connect TF adjustments are fast and easy it is possible to make real-time rapid changes and observe and discuss with amputee as to their effectiveness. In this way improvements are “dialed in”.

- Do not be afraid to adjust, it is easy to ‘undo’ the socket and start over.
- When fine-tuning the tension, work in 0,2 Nm increments.
- To ease donning, pay attention to the chair the user is sitting on.
- To ease donning, pay attention to the users sitting position. Lifting up the residual limb or moving to the edge of the seat and leaning backwards could help with donning.

FINAL THOUGHTS

Follow IFU / Videos / Clinical Manual to ensure success in socket fit. Do not hesitate if needed to undo and start over instead of comprising patient care.

Contact your Össur Clinical Specialist when help is required.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