

Fabrication Guidelines - Lower Limb

General Manufacturing Standards, Common Terminology, & Socket Designs

Alignment

Össur Custom Solutions (ÖCS) will align distal adapters with respect to the weight line of the socket for a given alignment value.

FOR TRANSTIBIAL SOCKETS, if a specific alignment isn't provided, Össur Custom Solution's standard alignment is 0° flexion and 0° adduction.

FOR TRANSFEMORAL SOCKETS if a specific alignment isn't provided, ÖCS's standard alignment is 3° flexion and 3° adduction if using expulsion/elevated vacuum suspension or 0° flexion and 0° adduction if using locking suspension.

Locks/lanyards with an integrated distal 4-hole pattern must remain at 0° flexion and 0° adduction alignment. Alternative alignments can be achieved with certain locks/lanyards with use of a distal attachment plate/pronged adapter. In many cases, this increases the build height significantly to ensure clearance for the locking pin proximal to the distal adapter.

TERM	DEFINITION	EXAMPLE
Transfer	Socket adapter will be in the same location as check socket.	Locks with a 4-hole pattern are centered at the distal end of the limb and will be transferred from check socket to definitive in a neutral alignment regardless of angles achieved through set screw changes during the check socket fitting.
Transfer & Zero Out	Socket adapter location will reflect the alignment achieved by attached components. This allows new/reused components to be placed in a neutral state.	Alignment of the check socket was achieved during fitting using an offset plate and changes to pyramid set screws. The alignment of the definitive will be the same as the check socket without using the offset plate, and the set screws will be set to neutral by having the distal attachment set accordingly.
Use Lines	Socket adapter is located according to the lines on cast or socket.	Cast/socket is sent with alignment lines.
Use Angles	Socket adapter is located according to the angles entered on order form/Portal.	Scan and measurements submitted for transtibial expulsion suspension check socket requests socket to be flexed 5° and adducted 3°.
Other	Please provide explanation.	Align using lines, but then outset 1/4".

Materials

Materials are only available in ÖCS fabricated sockets.

Check Socket Plastics		
Type	Thickness	Size
Polyethylene terephthalate glycol (PETG)	12mm (1/2") 6mm (1/4") 3mm (1/8")	16" x 16" & 24" x 24" sheet 16" x 16" & 24" x 24" sheet 16" x 16" & 24" x 24" sheet
Rigid Polyethylene terephthalate glycol (Rigid PETG)	15mm 10mm	20" disc 18" bell & 25" bell
High Impact Polystyrene (Orfitrans Stiff, Thermolyn)	15mm (5/8") 12mm (1/2")	16" x 16" sheet 24" x 24" sheet

Össur technicians will determine the size used to obtain optimal quality considering the model's size. If the practitioner has a preference, please indicate that with a note on the order.

Inner Socket Plastics		
Type	Thickness	Size
Flexible EVA with Silicone (Proflex with Silicone)	15mm (5/8") 12mm (1/2") 10mm (3/8") 5mm (3/16")	16" x 16" & 24" x 24" sheet 16" x 16" & 24" x 24" sheet 16" x 16" & 24" x 24" sheet 16" x 16" sheet
Flexible EVA without Silicone (Proflex without Silicone)	15mm (5/8") 12mm (1/2") 10mm (3/8") 5mm (3/16")	16" x 16" & 24" x 24" sheet 16" x 16" & 24" x 24" sheet 16" x 16" & 24" x 24" sheet 16" x 16" sheet
Flexible EVA – Black (Optek Flex Comfort - Black)	12mm (1/2") 10mm (3/8") 5mm (3/16")	16" x 16" & 24" x 24" sheet 16" x 16" & 24" x 24" sheet 16" x 16" sheet
Flexible EVA – Optek Flex Comfort White + Black (BiLam)	12mm (1/2")	16" x 16" & 24" x 24" sheet
Modified Polythylene (MPE)	12mm (1/2") 10mm (3/8") 6mm (1/4")	16" x 16" & 24" x 24" sheet 16" x 16" sheet 16" x 16" sheet
EVA (ÖssurFlex)	15mm (5/8") 12mm (1/2") 10mm (3/8")	16" x 16" sheet 16" x 16" sheet 16" x 16" sheet 16" x 16" sheet

Össur technicians will determine the size used to obtain optimal quality considering the model's size. If the practitioner has a preference, please indicate that with a note on the order.

Inner Socket Foams		
Type	Thickness	Size
Lightweight Polythylene – Firm 25 Shore A (PeLite)	12mm (1/2") beige & white	Sheet
	5mm (3/16") beige	Sheet
	3mm (1/8") beige	Sheet
Lightweight Polyethylene – Medium 15 Shore A (Plastizote)	12mm (1/2") beige & white	Sheet
	6mm (1/4") pink	Sheet
	5mm (3/16") pink	Sheet
Firm Ethylene Vinyl Acetate 55 Shore A (Puff*)	12mm (1/2") black	Sheet
	10mm (3/8") black	Sheet
	6mm (1/4") black	Sheet
Lightweight Ethylene Vinyl Acetate (Keasy)	6.5mm profile 10mm distal	Cone

*Puff is used for padding on RevoFit panels.

- ÖCS uses Prosthetic Research Specialists (PRS) pigments numbers 1-18 in our laminations. PRS 3 is used for beige and PRS 13 is used for brown to match Össur foot shells.
- For decorative laminations, such as t-shirts, ÖCS does a white lamination before the decorative lamination to help maintain the image colors. The finished color of fabric used for decorative lamination will be same as if it was wet. Fabric used must be water permeable for the resin to saturate. Some images on fabric do not laminate well due to them not being water permeable. Material with people/pet faces is not recommended as socket curves often distort face shapes. *Caution: Customer supplied fabrics may be ruined due to unexpected factors. Example: Air bubbles in the lamination.*

Technical Standards

- Össur will fabricate with all Össur suspensions as well as select non-Össur suspensions listed in the Össur Custom Solutions Lower Limb Price List.
- When ordering components with an Össur Solution, the patient's body weight is used to determine correct weight-rated components. For patient's weighing over 100kg (220 lbs), Össur's heavy duty aluminum pylon with bonded titanium female pyramid (165kg/365lbs wt. limit) will be used instead of the standard aluminum pylon with aluminum bonded female pyramid (100kg/220lbs wt. limit). Only Össur components will be assembled with Össur feet as an assembled Össur Solution.
- On an assembled Össur Solution or socket using Össur components, the components will be assembled, torqued, and thread-locked according to the Instructions For Use (IFU).
- Foam, epoxy adhesive, and/or automotive body filler are not used to shape the transition from a distal adapter to the socket unless requested differently on an Össur Legs order form or Össur Portal.
- For definitive socket manufacturing, ÖCS' lamination layup is based on the patient's weight and impact level. ÖCS will not compromise the layup to fabricate a "lightweight" socket. We are regulated to maintain our tested socket strength. Basalt replaces carbon fiber in any layup when requested on an Össur Legs order form or Össur Portal.
- When possible, definitive socket will be laminated with a thin PETG layer inside the socket. Some suspensions/distal adapters don't allow this technique.
- Cosmetic foam covers are shaped as closely to the measurements provided as the socket and components will allow. For transfemoral covers, a one-piece cover is standard unless requested differently on an Össur Legs order form or Össur Portal.
- Knee locking/release cable guides will be laminated into the socket if provided unless requested differently on an order form/Portal.

Technical Standards (con't)

- Socket wall valves will be in the distal anterior medial quadrant of the socket for transtibial and transfemoral socket unless requested differently on an Össur Legs order form or Össur Portal.
- Lock release buttons will be medial and trimmed to the minimal length unless requested differently on an Össur Legs order form or Össur Portal.
- 850 Hybrid lanyards will be put on the lateral socket wall unless requested differently on an Össur Legs order form or Össur Portal.
- KISS lanyards will be oriented with opening anterior unless requested differently on an Össur Legs order form or Össur Portal.
- ÖCS' standard reveal for sockets that have a flexible inner socket is 6mm (1/4") for transtibial sockets and 10mm (3/8") for transfemoral sockets unless requested differently on an order form/Portal.

Check Socket Reinforcement

All check sockets manufactured at ÖCS are shipped with 2" or 3" of fiberglass wrap for reinforcing the socket prior to weight-bearing and/or ambulation. Check sockets are sent without the fiberglass on the socket to enable visual fit assessment by the practitioner prior to reinforcing. ÖCS recommends the practitioner reinforces the distal end of the socket prior to the patient ambulating either within or outside parallel bars.

Shape and Measurement Submission

ÖCS accepts 3D scans from the Össur Design Studio Scanning app, utilizing Occipital's Structure Scanner, and/or .aop, .stl, or .obj files from other 3D scanners. Length and circumference measurements are required, and pictures of the limb are highly recommended for all 3D scan submissions if ÖCS is designing or modifying the socket design. ÖCS digitizes all plaster/fiberglass casts and socket shapes after receiving. ÖCS will align the model according to the specifications given on the order form/Portal.

Please follow these guidelines for the fastest turnaround time when submitting your own socket designs. Not following these guidelines may cause a potentially longer delivery time.

- Please ensure your model is centered vertically and rotated so that patella is centered in coronal plane. Please also ensure there is no flexion or extension in the model. Össur Custom Solutions uses the CAD center axis (vertical) to establish zero-degree alignment.
- Please ensure your design includes no ADduction or ABduction.
- Smooth your modifications during your design. The Designers at ÖCS will not modify your socket design unless requested differently on an Össur Legs order form or Össur Portal.
- Include your desired trim lines in your design by either trimming the model within Össur Design Studio or creating a ridge of at least 6mm along the trim line. Often, shaded regions and/or colors are not visible to the Designers at ÖCS.
- Do not add locking suspensions to your socket designs in CAD. The Designers at ÖCS will add them according to the specifications on the Össur Legs order form or Össur Portal.

For additional information regarding Össur Design Studio, visit the Help Desk at ossurdesignstudio.com

Socket Designs and Templates

The information below applies if ÖCS is designing the socket.

TRANSTIBIAL

- Circumference and length measurements are required regardless of shape submission method.
- Length measurements should be taken from the MPT to distal end without compression.
- Circumference measurements should be taken at MPT and every 5 cm above and below MPT, as appropriate for the socket design.
- M/L measurement should be taken at the widest point of the femoral condyles.
- PML measurement should be taken proximal to medial condyle.
- For Icepro specific information, please see the Össur Portal.

Socket Designs and Templates (con't)

The modifications below are ÖCS standards and can be changed depending on personal preferences or patient presentation:

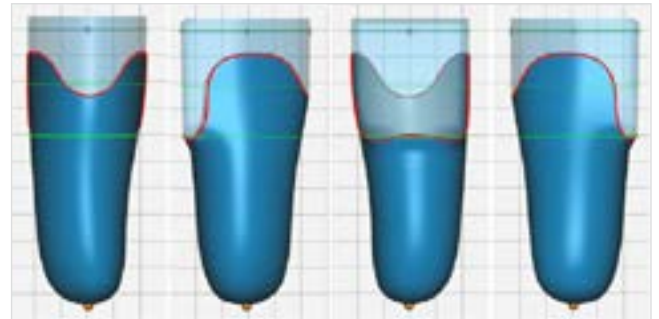
TRIM LINES

- Standard
 - Anterior = 4cm (1.5") above MPT
 - Medial & Lateral = 7.5cm (3") above MPT
 - Posterior shelf is a small "w" shape at MPT level
- Supracondylar (SC)
 - Anterior = 4cm (1.5") above MPT
 - Medial & Lateral = 10cm (4") above MPT
 - Posterior shelf is a small "w" shape at MPT level
- Supracondylar Suprapatellar (SCSP)
 - Anterior = above patella
 - Medial & Lateral = 10cm (4") above MPT
 - Posterior shelf is a small "w" shape at MPT level

TOTAL SURFACE BEARING (TSB)

Modifications

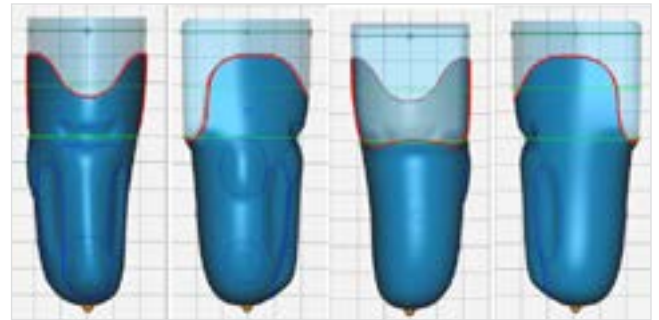
- 3% global reduction (if using Icross liners) OR 4% for any other liner ***The percent reduction needed for correct socket fit is highly dependent on practitioner's measurement technique as well as patient's tissue density. It's not uncommon to require a different percent reduction.**
- 6mm distal end reduction (with cushion liner) OR
- 6mm distal end extension (with locking liner)



PATELLAR TENDON BEARING (PTB)

Modifications

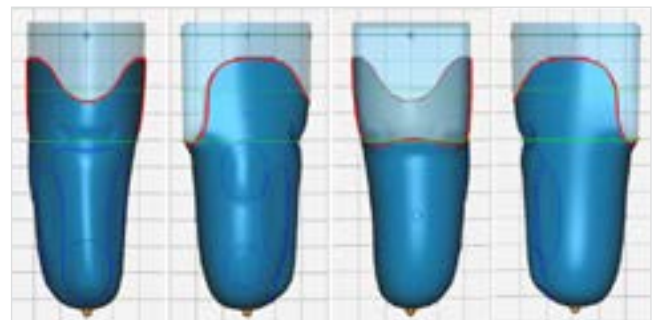
- No global reduction
- 5mm patellar tendon bar curve
- 5mm tibial crest & fibular head relief
- 5mm anterior tibialis curve
- 6mm distal end extension



MODIFIED PATELLAR TENDON BEARING (MODIFIED PTB)

Modifications

- 3% global reduction (if using Icross liners) OR 4% for any other liner ***The percent reduction needed for socket fit is highly dependent on practitioner's measurement technique as well as patient's tissue density. It's not uncommon to require a different percent reduction.**
- 3mm patellar tendon bar curve
- 3mm tibial crest & fibular head relief
- 3mm anterior tibialis curve
- 6mm distal end reduction (with cushion liner) OR
- 6mm distal end extension (with locking liner)



Socket Designs and Templates (con't)

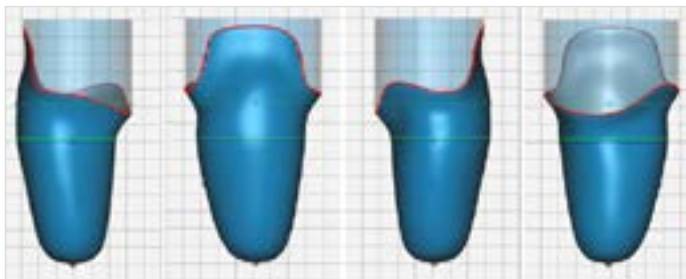
TRANSFEMORAL

- Circumference and length measurements are required regardless of shape submission method. Sockets can be manufactured without a cast using only these measurements.
- Length measurements should be taken from the ischium to distal end without compression with a length gauge.
- Tight and Loose circumference measurements should be taken starting 5cm below the ischium and every 5 cm below to the distal end. The length and the average of these measurements is used for the socket design. **Socket fit and reductions is highly dependent on practitioner's measurement technique as well as patient's tissue density. It's not uncommon to require additional percent reductions in addition to the average.**

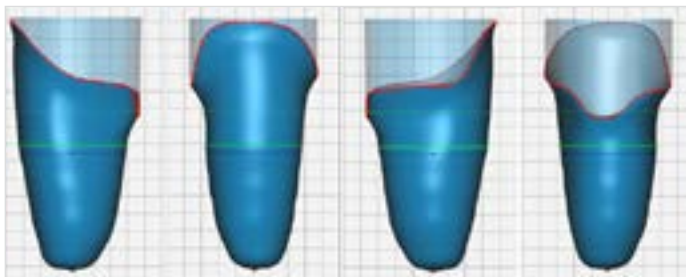
Individual practitioner brim templates can be added to the ÖCS Library if requested along with a model of the brim desired to be templated. It is recommended to send a fitted check socket with the exact brim that you would like added to the library with marks indicating the ischium, greater trochanter, and distal femur. If submitting via Design Studio, create a bump marker at these spots. Finally, provide the limb length of the patient on which the example socket was fitted to ensure better transition to each socket design.

For Icepro specific information, please see the Össur Portal.

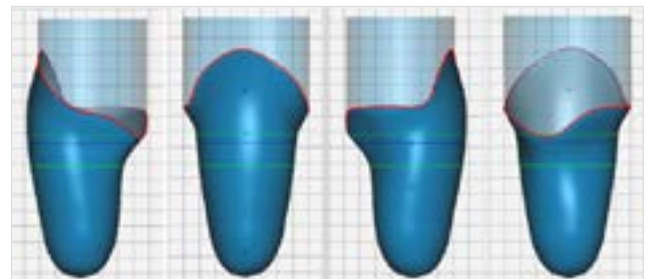
SOFT ISCHIAL CONTAINMENT (SOFT IC) – ÖCS default if no other brim selected



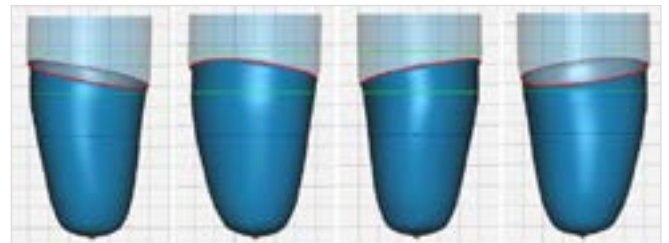
QUADRILATERAL (QUAD)



ISCHIAL CONTAINMENT (IC)



SUB-ISCHIAL



Modifications

ÖCS recommends new scan/cast and/or measurements for reductions or increases greater than 7-ply when moving from a check socket to a definitive socket. It is also recommended to provide numeric values for build-up areas and/or compression areas. For example, “please provide 3mm distal tibia relief” rather than “provide some distal tibia relief”.

6 of 6

FOLLOW ÖSSUR ON



ÖSSUR CUSTOM SOLUTIONS
9545 S JOHN YOUNG PARKWAY, STE #100 | ORLANDO, FL 32819
TEL (888) 839-6213, FAX (407) 367-3695
CS@OSSUR.COM | OSSUR.COM

