

Pediatric Adjustable Alignment Bracket



Instructions

These instructions should be read prior to fabricating and fitting and should be followed to ensure the proper integration of the bracket into the prosthetic system. **Carefully follow all listed torque specifications.**

The Adjustable Alignment Bracket is designed to assist in the fitting and alignment of posteriorly mounted feet. The bracket allows for dynamic adjustment of height, inversion/eversion, and medial/lateral translation. It is for in-clinic fitting only; the Adjustable Alignment Bracket is not a permanent mounting solution, but rather a fitting tool.

The adult Adjustable Alignment Bracket is compatible with the Formula and Posterior Mount AllPro feet, and the pediatric Adjustable Alignment Bracket is compatible with the Pediatric Formula. Please see the specific foot manual for alignment details.

Once correct alignment is determined, the foot can be mounted with the Fillauer Posterior Mounting Bracket Kit (**180-10-3000**) or directly laminated to the socket.

Product Specifications

Weight rating: 132 lbs. (60 kg)

Weight: 4.8 oz. (136 g)

Dimensions: 3.7 × 2.9 × 1.0 in. (95 × 73 × 25 mm)

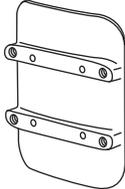
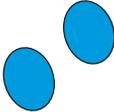
Socket offset distance: 0.16 in. (4 mm)

Compatible feet: Pediatric Formula

Warranty

6 months from date of receipt

Warranty is voided by alteration, misuse of product, or failure to comply with instructions.

	Product Name	Quantity	Product Number
	Socket Plate	1	180-30-5100
	Pylon Clamp	1	180-30-5150
	M6 Socket Head Screw	4	100-30-2381
	M6 Set Screw	4	100-30-2560
	Socket Plate Stickers	20	100-80-0180

Installation

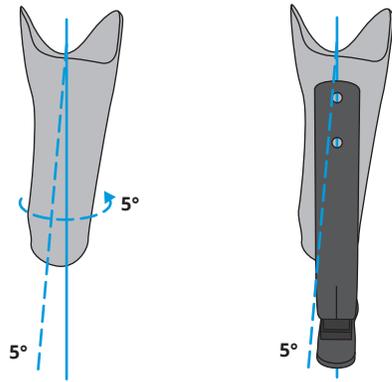
Attention: Deviating from the installation instructions or modifying the alignment bracket in any way will void any product warranty and could lead to product failure and injury to the patient.

Initial Alignment

Use the following method to approximate the location of the socket plate on the posterior of the socket. It is recommended to begin with an existing distal mount prosthesis in order to approximate the alignment of the posterior mount foot on the new socket.

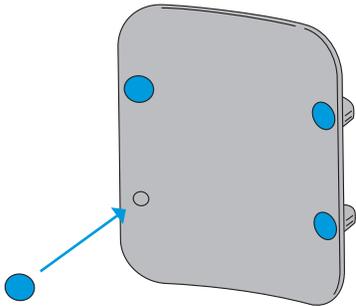
1. Trace the current prosthesis in the sagittal plane noting foot position and height of MPT to bottom of foot. If this is the patient's first prosthesis, it is recommended that a static alignment is done with an endoskeletal system and foot that can be replaced during dynamic alignment.
2. Place the new socket in the same position on the tracing.
3. Place the posterior mount foot in the same position as the current foot, noting that the posterior mount foot may have greater, approximately 5 – 7° deflection upon static loading (standing).
4. Trace position of new socket and posterior mount foot on paper using a different color.

- Observe the rotation of the foot, pylon M/L angle (lean) and pylon M/L position (inset) on the current prosthesis and approximate this position on the new socket by drawing a vertical line on the posterior of the new socket.



Socket Plate Installation without Flexion / Extension / Rotation Wedges

- Determine the location of the Socket Plate on the socket that leaves at least 1 in. (25 mm) of carbon pylon proximal to the Pylon Clamp for adjustments.
- Place four circular stickers on the back side of Socket Plate so that all threaded holes are completely covered. This will prevent adhesive from migrating into threaded holes during mounting.



- Apply a liberal amount of Fabtech +PLUSeries® 60 Second Adhesive to the rear surface of the Socket Plate and press onto the socket at the determined mounting location. Hold in place until adhesive has cured.

Socket Plate Installation for Wedge Use Only (180-10-5010)

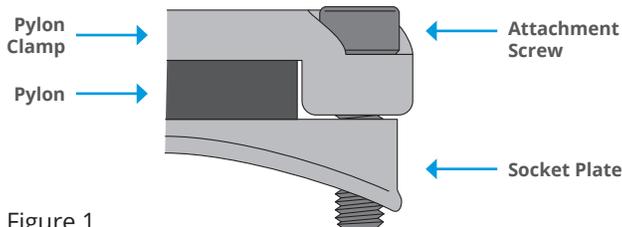
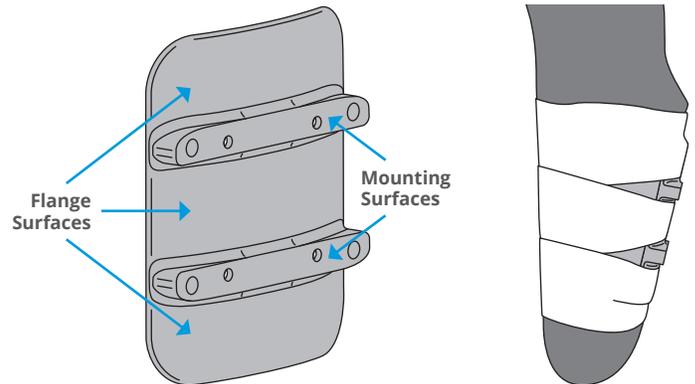


Figure 1

- Before attaching the socket plate to the posterior socket wall, ensure that the longest screw in the kit is installed and the foot is placed between the pylon clamp and socket plate as shown in Figure 1. The screw will, in most cases, protrude through the socket plate. Adding silicone spray to the screw end can simplify removal.

Wrap Fiberglass

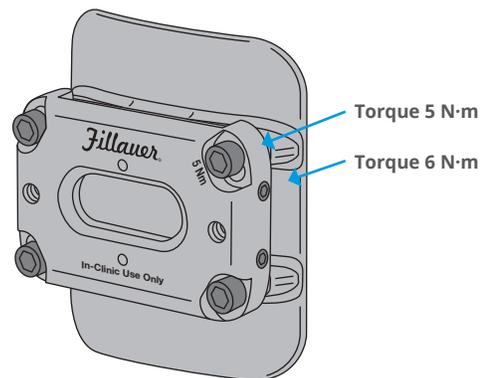
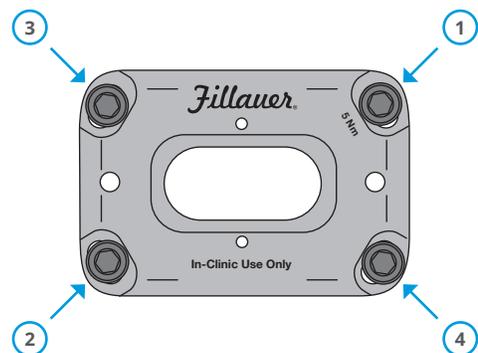
- Wrap fiberglass casting tape around the curved flange surfaces. Be sure that the casting tape does not stack up to be higher than the Socket Plate mounting surfaces. See finished product below.



Final Alignment

- Using the supplied hardware, clamp the prosthetic foot to the Socket Plate with the Pylon Clamp. Insert M6 Socket Head Screws through the Pylon Clamp slots and thread into the Socket Plate. Torque the Socket Head Screws to 5 N·m in alternating diagonal order shown below. Tighten the four M6 Set Screws on both sides of the Pylon Clamp until they contact the foot and torque to 6 N·m.

Warning: If incorrect length Socket Head Screws are used, the Socket Plate could be lifted off of the socket surface when screws are torqued. Only use the supplied hardware with this product.



- Evaluate the patient's dynamic alignment. The following alignment changes can be made:

- Height adjustment
- Inversion/eversion, 4° from neutral (Pylon Clamp rotation)
- Medial/ lateral translation (Pylon Clamp M6 Set Screw adjustment)

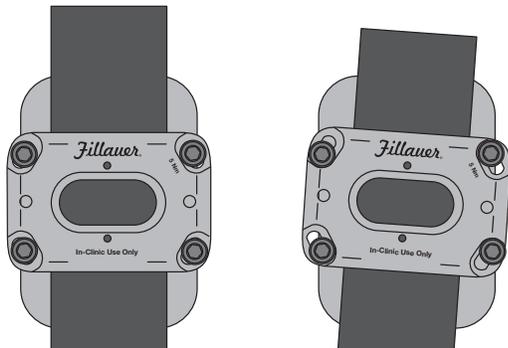
Follow the procedures below for each alignment change. **Warning: Do not use any foreign material to shim or angulate the foot inside the Adjustable Alignment Bracket. This could cause the foot to slip in the assembly and result in injury to the patient.**

Height Adjustment

To adjust the height of the prosthesis in the Adjustable Alignment Bracket, first mark the current position of the foot with a silver marker. Loosen both M6 Set Screws on one side of the Pylon Clamp. Leave the two Set Screws on the other side in their positions to maintain foot alignment. Loosen all M6 Socket Head Screws on the front face of the Pylon Clamp. Move foot to desired height. Tighten the two Set Screws against the foot and torque to 6 N·m. Torque all Socket Head Screws in alternating diagonal pattern to 5 N·m.

Abduction/Adduction

To adjust the abduction/adduction angle of the prosthesis, first mark the current position of the foot with a silver marker. Loosen all M6 Socket Head Screws on the front of the Pylon Clamp. Rotate the foot and Pylon Clamp subassembly to the desired angle, and torque all Socket Head Screws in alternating diagonal pattern to 5 N·m.



Medial/Lateral Translation

- To adjust the medial/lateral position of the foot in the Adjustable Alignment Bracket, first mark the current position of the foot with a silver marker. Loosen both M6 Set Screws on the side of the Pylon Clamp that the foot will be moved towards. Loosen all M6 Socket Head Screws. Translate the foot to desired position and ensure other height and angles have been maintained. Torque the Set Screws on the other side of the Pylon Clamp to 6 N·m. Torque the Socket Head Screws in alternating diagonal pattern to 5 N·m.



- Once final alignment is found, the foot can be mounted to the socket with the Fillauer Posterior Mounting Bracket Kit (**180-10-3000**) or directly laminated onto the socket.

Plantar/Dorsiflexion Internal/External Rotation

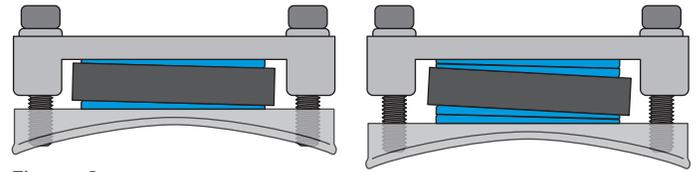


Figure 2

- When adding wedges, two wedges must be used at any time in the manner shown in Figure 2 where each wedge faces in the opposite direction to keep the bracket square. A maximum of four wedges (2 on each side) may be used at any time.
- Attach the pylon clamp with four socket head screws, be sure to use a screw that will go through the pylon clamp and engage the socket plate with at least 4 full thread rotations.

To Transfer from an Adjustable Alignment Bracket

- Before transferring be sure to torque the M6 side set screws.
- Attach the Transfer Fixture to your Hosmer VFJ (**52056**) by removing the fixture for the SACH foot adapter and replace it with the Transfer Fixture. This will allow adjustments on the VFJ and angle adjustment within the Transfer Fixture (Figure 3).

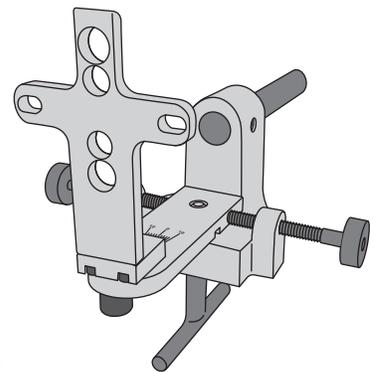


Figure 3

- Attach the Adjustable Alignment Bracket to the Transfer Fixture by placing two M6 socket head screws through the slots in the Transfer fixture into the threaded holes 5 & 6 (Figure 4) in the Adjustable Alignment Bracket and tighten to prevent movement.

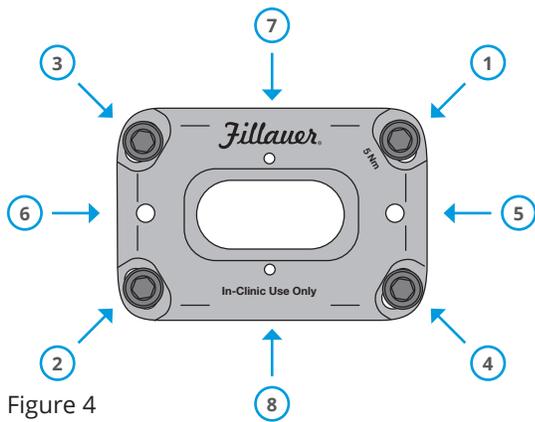


Figure 4

To Transfer from a Two-hole, Posterior Mounting Bracket

1. Remove the foot from the two-hole Posterior Mounting Bracket, but be sure to leave any wedges in place.
2. Attach the Transfer Fixture to your Hosmer VFJ (52056) by removing the fixture for the SACH foot adapter and replace it with the Transfer Fixture (Figure 1). This will allow adjustments on the VFJ and angle adjustment within the Transfer Fixture.
3. Attach the two-hole, Posterior Mounting Bracket with wedges in place to the Transfer Fixture through either pair of the two larger holes.
4. Pour the socket as usual being sure to mark the VFJ with the expectation of moving the foot closer to the socket when transferring (a small shift of $\frac{1}{8}$ – $\frac{1}{2}$ in. will improve the foot performance and typically does not require changes to the shape of the soling build up).
5. After the plaster is set, remove the socket and bracket from the VFJ.

To transfer to a two-hole, Posterior Mounting Bracket (180-10-3000)

1. Place the two-hole bracket back in the Transfer Fixture without any wedges.
2. Place the new socket back into the VFJ. The socket may now need to slide in the anterior-posterior direction toward the bracket to attach, be sure to properly mark the VFJ before sliding the socket.
3. Bond the bracket in place and follow lamination and drilling instructions located in the bracket manual.

To transfer to a direct lamination

1. Rough 3 in. of the surface of the foot and clean a bonding surface on the socket.
2. Place the Pylon Clamp from the Adjustable Alignment Bracket on the foot with holes 7 & 8 (Figure 2) centered on the holes in the foot. Tighten the M6 set screws.
3. Attach the Pylon Clamp to the Transfer Fixture using holes 5 & 6 (Figure 2).
4. Place the socket back into the VFJ. The socket may now need to slide in the anterior-posterior direction toward the bracket to attach, be sure to properly mark the VFJ before sliding the socket.
5. When attaching, be sure to fill the holes in the foot with Fabtech PluSeries™ adhesive.
6. Follow lamination instructions available in the Formula manual or in video form from Fillauer.

4. Pour the socket as usual being sure to mark the VFJ with the expectation of moving the foot closer to the socket when transferring (a small shift of $\frac{1}{8}$ – $\frac{1}{2}$ in. will improve the foot performance and typically does not require changes to the shape of the soling).
5. After the plaster is set, remove the socket from the foot by removing only socket head screws 1 – 4 in Figure 2. This will leave the surface of the foot exposed for direct bonding to the socket or transfer to a two-hole Posterior Mounting Bracket (180-10-3000) and will allow you to remove the bracket from the socket to clean that surface.

To transfer to a two-hole, Posterior Mounting Bracket (180-10-3000)

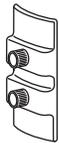
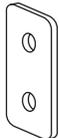
1. When transferring to a two-hole bracket, use the pilot holes 7 & 8 (Figure 2) in the Adjustable Alignment Bracket to mark the foot for the $\frac{1}{2}$ in. holes.
2. Now remove the Adjustable Alignment Bracket from the from the Transfer Fixture. This will expose the two sets of larger holes. The largest holes will hold the adult two-hole bracket and the smaller holes will hold the pediatric bracket.
3. Place the appropriate two-hole bracket in the Transfer Fixture. Place the socket back into the VFJ. The socket may now need to slide in the anterior-posterior direction toward the bracket to attach, be sure to properly mark the VFJ before sliding the socket.
4. Bond the bracket in place and follow lamination and drilling instructions located in the Posterior Mounting Bracket section of the manual.

To transfer to a direct lamination

1. Rough 3 in. of the surface of the foot and clean a bonding surface on the socket.
2. Place the socket back into the VFJ. The socket may now need to slide in the anterior-posterior direction toward the bracket to attach, be sure to properly mark the VFJ before sliding the socket.
3. Follow lamination instructions available in the Formula foot manual or in video form from Fillauer.

Pediatric Posterior Mounting Bracket



	Product Name	Quantity	Product Number
	Lamination Bracket	180-10-3100	1
	Lamination Dummy Cover	180-30-3150	1
	Pressure Plate	180-30-3260	1
	Sanding Screen	180-30-3250	1
	M8-1.25 x 18 mm HHCS	100-30-2378	2
	M8 Washer	100-30-2405	2
	Threadlocker TL42		1

Instructions

The Pediatric Posterior Mounting Bracket is designed for use with posteriorly mounted feet. It is the recommended attachment system for use with the Pediatric Formula and Pediatric Running Blade.

These instructions should be read prior to fabricating and fitting and should be followed to ensure the proper integration of the plate into the prosthetic system.

Product Specifications

Plate Thickness: 0.3 in. (8.5 mm)
Rated for patients up to 125 lbs. (57 kg)
Weight: 3.4 oz. (95 g)
Moderate to high activity levels

Warranty

12 months from date of patient fitting

The Posterior Mounting Plate System has been designed and manufactured for specific patient weights. Failure to follow the weight guidelines and/or overload conditions caused by the patient, such as heavy lifting, high impact sports, or abusive activities that would otherwise damage the natural limb, may void the warranty.

Installation

Attention: Deviating from the installation instructions or modifying the foot in any way will void any product warranty and could lead to product failure and injury to the patient.

Alignment

Using the following method to approximate the location of the pylon mount on the posterior of the socket.

1. Trace the current prosthesis in the sagittal plane noting foot position and height of MPT to bottom of foot. (If this is the patient's first prosthesis, it is recommended that a static alignment is done with an endoskeletal system and foot that can be replaced during dynamic alignment.)
2. Place the new DurrPlex (PETG) or laminated socket in the same position on the tracing.
3. Place the posterior mount foot in the same position as the current foot, noting that the posterior mount foot may have greater deflection upon static loading (standing).
4. Trace position of new socket and posterior mount foot on paper using a different color.
5. Observe the rotation of the foot, pylon M/L angle (lean) and pylon M/L position (inset) on the current prosthesis and approximate this position on the new socket by drawing a vertical line on the posterior of the new socket (Figure 1).
6. Remove the bolts from the mounting plate and use the bolt holes as "sights" to line up the mounting bracket. When choosing height for the mounting plate, place it as proximal as possible that does not eliminate room for growth, but be sure to leave enough room below the posterior socket brim to allow a suspension sleeve to seal if using vacuum or suction suspension plus ½ in. (1.3 cm) to accommodate height adjustment if needed (Figure 1).
7. Temporarily attach the mounting bracket by wrapping around socket with vinyl stretch tape and trace the edges onto the socket.
8. If you are using a pylon without a slot, use the drilling template to select the location to drill 7/16 in. holes in the pylon of the posterior mount foot. Holes must be drilled with the hole center no closer than 1 in. (2.5 cm) from the proximal edge of the cut pylon or the distal split in the pylon. Holes must be centered on the pylon.

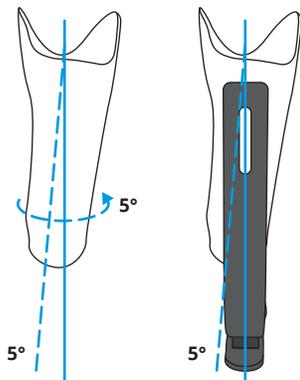


Figure 1

As many holes as desired may be drilled between those two points to allow for growth.

9. Drill the holes with a new drill bit and supporting material placed on the exit side of the intended holes. Carbon is an abrasive material and therefore carbide drills are recommended. Do not force the drill bit through the carbon, doing so can generate heat in excess of 250 °F leading to possible damage of the foot.
10. Temporarily mount the foot to the posterior mount bracket.
11. Visually compare the new prosthesis to the current prosthesis and make adjustments to the mounting bracket position as required and note any angulation that will be needed when mounting the foot. Lines may be drawn around the border of the bracket to help note the proper position.
12. Abrade the socket and anterior side of the mounting plate to allow good adhesion.
13. Clamp the foot to a level workbench to make visualization of socket angles simpler.
14. Add Fabtech PlusSeries epoxy to the bracket (with foot attached and masked to protect from dripping adhesive)
15. Place the socket on the bracket, aligned to match the angles noted above.
16. To perform a test fitting, wrap rigid, fiberglass casting tape through the grooves of the mounting plate being sure not to cover the two mounting surfaces (Figure 2).
17. When finished with alignment, transfer it to the vertical fabrication jig for test sockets or prepare for finish lamination by filling all gaps between the socket and bracket with your choice of structural filler.

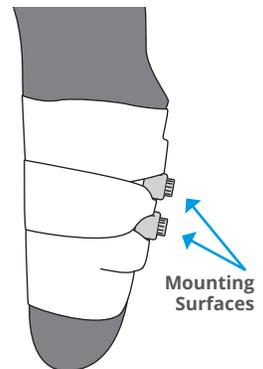


Figure 2

Lamination

1. Begin with an initial lamination comprised of 1 layer of 6K braid, 2 layers Nyglass, and possible felt reinforcement around the knee.

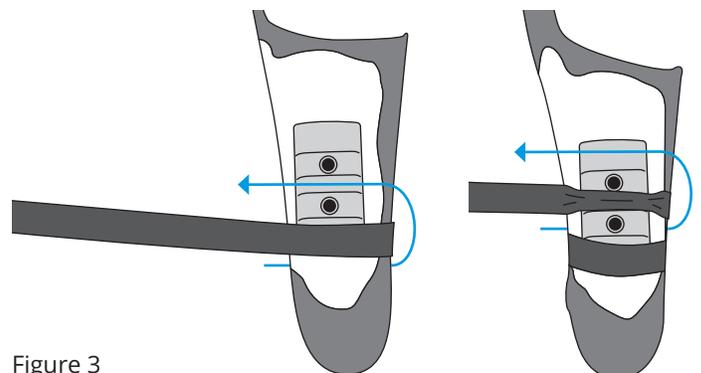


Figure 3

2. Sand and prepare for second lamination and bracket attachment.
3. Transfer bracket or follow the steps above to align the bracket on the first lamination.

4. To permanently attach the bracket:

Start by wrapping one strip of 1 in. (2.5 cm) carbon tape in a spiral fashion to capture all three grooves in the plate (Figure 3).

5. Wrap a second spiraling in the opposite direction.

6. Cover with three strips of 1 in. (2.5 cm) carbon tape wrapped circumferentially in such a manner that the strips cover the grooves and the spirals (Figure 4).

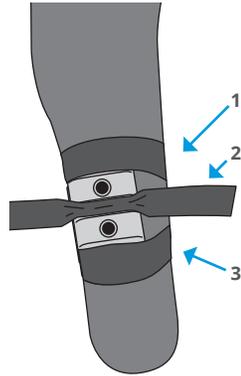


Figure 4

7. Add 2 layer of wicking material (Nyglass, Dacron felt, etc.) leaving the two flat mounting surfaces clear of material.

8. Add layers of 6K braid as needed for strength.

9. Expose the T-nuts through the carbon braid.

10. Add a thin layer of the stick wax to the exterior of the T-nuts. This step reduces the amount of resin build-up on the exterior of the T-nuts (Figure 5).

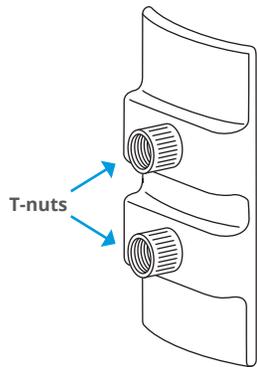


Figure 5

11. Apply the plastic dummy as described below.

Dummy Installation

1. Apply silicone putty or equal to the center hole of the dummy making sure that it does not protrude from either side (Figure 6).
2. Press the dummy over the two exposed T-nuts.
3. Apply stick wax to the threads of the bolts provided and tighten into the T-nuts to hold the plate in place.
4. Laminate socket while preventing air bubble buildup under the lamination dummy and keeping the least laminate possible on the surface of the dummy.

Removal of the Dummy

1. Using a knife, score the laminate around the edges of the dummy and expose the center hole filled with putty (Figure 6).
2. Remove both bolts going through the dummy.
3. Remove enough putty to start a bolt in the center tapped hole.
4. Screw one of the provided bolts into the center hole until the dummy breaks free. The remaining putty in the hole protects the lamination from the jacking screw (Figure 7).
5. Grind away excess lamination for a clean and level mounting surface.
6. Remove any lamination from the outside of the exposed T-nuts.

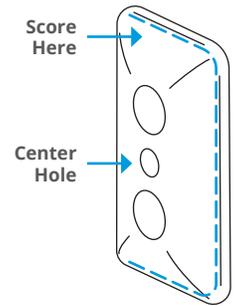


Figure 6

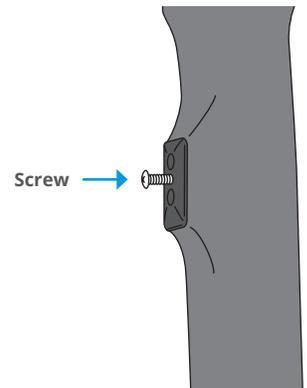


Figure 7

Foot Installation

1. Use the provided bolts and pressure plate to attach the foot to the bracket. Tighten the bolts to 18 – 20 N·m. Thread-locker (one capsule provided) should be applied to both bolts connecting the foot to the plate (Figure 8). Be sure to check the torque of the bolts regularly throughout the life of the foot (a minimum of 3 – 6 months).
2. Include the provided piece of sand screen between the foot and socket.

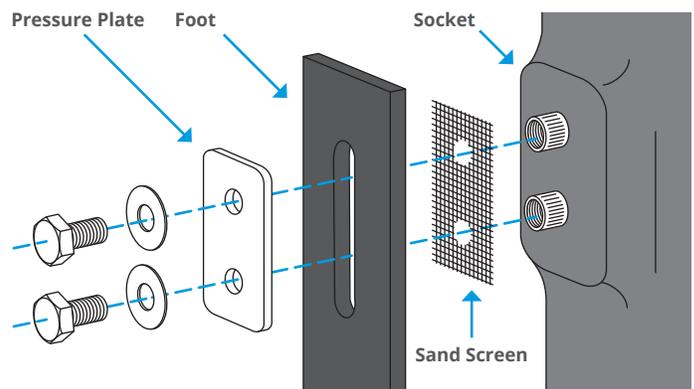


Figure 8

Fillauer[®]

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