

PDE with RevoFit Closure Instructions.

The RevoFit™ system from Click Medical™ as utilized on the proximal cuff offers the latest advancement in user controlled brace interface.

While its application isn't very involved, getting started will require attention to details.

For the fabrication process utilizing the Fabtech/RevoFit™ uppercuff design, first we will layout and setup the boa system on the model. Once the system is setup we will remove the complete assembly from the model. The complete assembly will be then be applied as a step in the lamination layup process.

The Revofit closure kit includes:

- High tension BOA® technology dial
- Dial base with silicone dummy
- 48" Teflon guide tube
- 2 Spectra filaments
- Wire feeder
- T6 tool from Boa technology

Additional Items:

Needed for fabrication process:
Pluseries Adhesive Item #: C1L,
a marker,
1" masking tape and modeling clay.

Setup and layout

1. Establish all device trim lines on the plastic covered model. Be sure to be as accurate as possible in the intended final placement.
2. Use a marker to draw guide tube lines, and base location. A few points to remember:
 - Base location is best on the posterior section just proximal of the PDE spring.
 - Make the largest arcs possible in all cable routing.
 - Leave room from the trim lines to allow for any changes needed in fitting.
 - Note the location of the red dot on the silicone dummy. The red dot on the housing indicates the position of the dial removal pilot hole to be drilled in step #4 of the finishing instructions. Make sure to remember its location. For the most accurate location, we recommend taking a picture for reference.
3. Bond the base directly to model with using minimal adhesive.
4. Plug the end of the Teflon tube with clay.
5. Insert the plugged tube end into the base. Be sure it is inserted into the silicone at least 3/8" or approx. the base center.
6. Using 1" masking tape every 2-3" attach the guide tube along the guide tube lines drawn on the model. Once you have come all the way around and back to the base cut the tube to length.
7. Plug the end of the Teflon tube with clay.
8. Insert the plugged tube end into the base. Be sure it is inserted into the silicone at least 3/8" or approx. the base center.
9. Using Pluseries Adhesive (Item# C1L) bond all exposed areas of tube to the model be sure and use a liberal amount on each side of the tubing.
10. Once all adhesive has firmed up remove all the masking tape.

11. Using Pluseries Adhesive (Item# C1L) bond all un-bonded areas of tube to the model be sure and use a liberal amount on each side of the tubing.
12. Once all adhesive has firmed up slowly peel the entire cable system and base off of the model. Be careful and go slowly. The tubing will hold its shape because of the Pluseries. This shaped assembly will be kept off to the side until placement within the lamination of the cuff. See step #10 of "Fabrication Instructions".

Finishing

1. Evenly grind all laminate of the face of silicone dummy.
2. Carefully extract silicone from base.
3. Trim the guide tube ends that had been inserted into the silicone flush with the inner surfaces of the base. This is to prevent tube from interfering with spool.
4. Using a 3/16" drill, Drill through the lamination to access the pilot hole & release tab.
5. Test the pilot hole before installing the Boa® dial into the laminated base.
6. Tie a double overhand knot (Fig.1) into one end of the spectra filament.
7. Thread the other end of the filament through the head of the wire feeder, leaving a 2" tail of filament.
8. Thread wire feeder & filament through one of the two holes in the bottom of the spool which will exit a green hole on the side of the spool.
9. Pull knot into the recess hole in bottom of spool and trim the end so it doesn't impede the spools movement.
10. Starting on one side of the base opening, thread the wire feed through the entire cuff and back out of the base.
11. Thread wire feeder & filament through the green hole on the spool which exits out the bottom of spool.
12. Pull the ends of the filament until the anterior panel is snugly in place

(Continued Next Page)

13. The amount of slack before you tie the knot dictates how much expansion for donning the system will have. Typically we want enough slack to allow 10" between the dial and the base.

Do not exceed 10" (250mm) of filament, as this may result in jamming of the dial and housing.

14. Tie a double overhand knot (**Fig.1**) into the end of the spectra filament.
15. Pull 2nd knot into its recess and trim the end so it doesn't impede the spools movement.
16. Carefully install spool/dial into the base and cycle a few times to ensure proper function. To install dial insert 4 base tabs into the laminated base and Turn counter clockwise ¼ turn and lock dial into base.

(TO REMOVE THE BOA DIAL INSERT BOA T6 TOOL INTO PILOT HOLE AND PUSH IN ON THE BASE TAB AND TWIST KNOB BEZEL ¼ TURN CLOCKWISE,PULL TO REMOVE)

17. Save the wire feeder and T6 tool in the extra filament bag that is provided for any needed additional servicing.
16. Laminate the entire job using epoxy resin. (Item# RES1)
17. Trim the finished laminate to the intended trim lines.
18. Grind the plastic lamination tooling and remove from the job.
19. Remove the set screws.
20. Using 242 Loctite, bolt the PDE spring to the brace using the supplied hardware and finish washers.

DOUBLE OVERHAND STOPPER KNOT

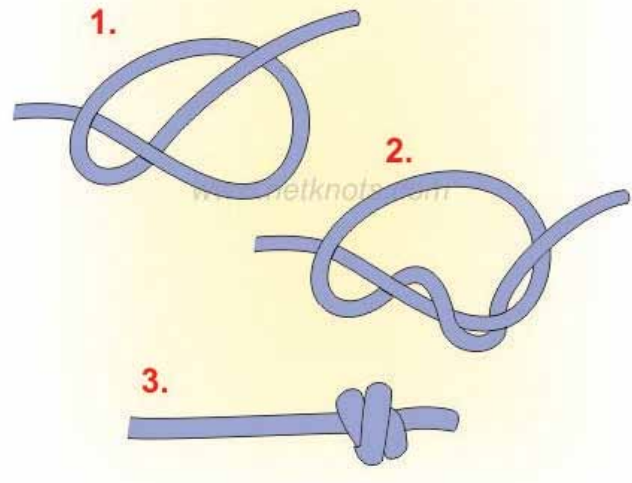


Figure 1



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