Revision History				
Rev.	DCR No.	Date	Description	Originator
X1	00295	2022-8-25	Initial Release	C. Trinh
X2	00538	2023-03-27	Remove operations related to PRU Cable stripping and soldering to Bridgeboard; Add fixtures and equipment; Add inspection criteria and in-process inspection steps; Update photos; Break out operations; Clarifications	C. Trinh
X3	00671	2023-06-03	Add epoxy. Change solder material and bridgeboard insulation process. Clarify solder workmanship criteria	C. Trinh
X4	00774	2023-08-10	Change CON-1166 referenced to pot bridgeboard circuits with CON-0310. Clarify coaxial cable cutting tools.	C. Trinh
X5	00859	2023-11-20	Move catheter subassembly steps from MIN-0433 to assembly level	C. Trinh
A	01225	2024-04-05	Added clarifications on cutting he proximal end of inner lumen tubing and proximal end of spine wire subassembly on sections 7.10.1 and 7.10.2; Transfer to production.	C. Trinh
B	01341	2024-05-06	Add PRT-0305 Collar and associated manufacturing steps. Change Section 7.8 Inspection per QTI-0642 to Impedance Test per QTI-0781. Add QTI-0781 to Section 4.1. Clarifications in Section 5 per TRE-1370.	C. Trinh
C	01355	2024-05-28	Clarification and note to Step 7.7.5	C. Trinh

Table of Contents

1 Purpose

This document details the process for assembling the 0.018" SLT IVUS Support Crossing catheter.

2 Scope

This manufacturing instruction applies to assembling the 0.018" guidewire compatible SLT IVUS Support Crossing Catheter with 150cm functional length (PRT-0638).

3 Definitions

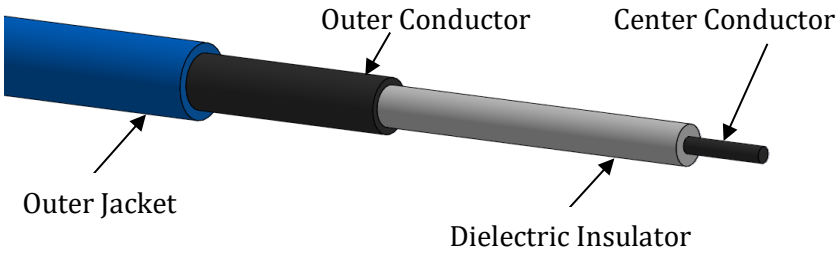
ESD – Electrostatic discharge. Electrostatic discharge can damage or destroy sensitive electronic components or set off explosions or fires in flammable environments.

PRU – Pulse Receiver Unit

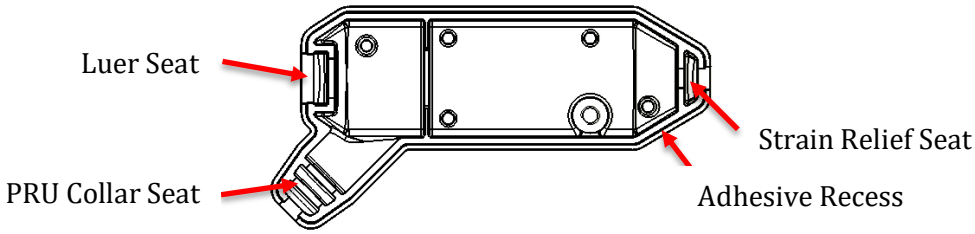
GND – Ground potential

RF Coaxial Cable Construction – An RF (radiofrequency) coaxial cable consists of the following elements to conduct electrical signal:

- **Outer Jacket –** The outermost insulating material which is typically plastic.
- **Outer Conductor –** The outer conductor acts as metallic shielding and is typically kept at ground potential. The construction of the outer conductor may consist of one or more layers of braided wire and/or foil.
- **Dielectric Insulator –** An insulating material between the inner and outer conductor that is a poor conductor of electricity.
- **Center Conductor –** Signal carrying voltage is typically applied to the center conductor, which can be made of solid or stranded metal copper or copper-plated steel wire.



Bridgeboard Housing, Bottom Shell Features



4 References

4.1 Internal References

SOP-0012	Production and Process Control
SOP-0299	Procedure, Electrostatic Discharge (ESD) Precautions and Handling
PRT-0638	Assembly, Catheter, SLT, OTW, 0.018, 150cm
TVR-0638	Traveler, Assembly, Catheter, SLT, OTW, 0.018, 65cm
QTI-0781	Test Instruction, Impedance, Catheter Components, Subassemblies, and Assemblies
QTI-0642	Test Instruction, Pulse Echo, Tube SNR
QTI-0841	Inspection Instruction, Dimensional and Visual
FRM-1192	Form, Dymax UV Intensity Log

4.2 External References

NA

5 Precautions

Measures should be taken to prevent buildup of electrostatic discharge per SOP-0299 when handling transducers.

Handle transducer subassemblies with care. Do not excessively bend or flex subassembly.

Handle solder, flux, and adhesives with gloves in well-ventilated area.

Handle UV curing system with UV protective eyewear. Verify the intensity of UV light emitting from the UV curing system measures a minimum of 0.8 W/cm^2 per wand using a UV Intensity Meter (Asset#0209) at the beginning of each working day. Record measurements in UV intensity log (FRM-1192).

6 Materials & Equipment

PRT-0427-026 or equivalent	Mandrel, 304 Stainless Steel, Teflon Coated, 0.0195”
MFG-1035 or equivalent	Spatula, Dispensing, 0.010in Tip, Black
MFG-1201 or equivalent	Soldering System, Single Channel, Hakko FX-971
MFG-1202 or equivalent	Soldering Iron, Micro, Conversion Kit
MFG-1203 or equivalent	Tip, Soldering Iron, T50, Chisel, 0.2mm
CON-1218 or equivalent	Flux, Water-Soluble, 1 gallon
MFG-0355 or equivalent	Blade Breaker
CON-0356 or equivalent	Blade – Double Edge, Stainless Steel, Degreased
MFG-1314 or equivalent	Holder, Circuit Board, Modified Stickvise
PRT-0427-045 or equivalent	Mandrel, 304 Stainless Steel, Teflon Coated, 0.029”

MFG-1318 or equivalent	Tool, Transducer Alignment, 0.034in OD Octagon
PRT-0429-007 or equivalent	Tubing, Silicone, Platinum Cured, Clear, 0.040" x 0.065"
Asset#0374 or equivalent	UV curing system, Dymax 4x light Guide
Asset#0206 or equivalent	UV intensity meter
MFG-1306 or equivalent	Fixture, UV Curing, 4x Wand, Circumferential
MFG-0351 or equivalent	Screwdriver, Phillips, No.1, 6-3/4in Length
MFG-0352 or equivalent	Dispenser, Manual, Two-Part Adhesive
CON-0345 or equivalent	Nozzle, Two-Part Adhesive Mixer, Bayonet Connection, Taper Tip
CON-0407-002 or equivalent	Syringe, Polypropylene, Luer Lock Connection
CON-0346 or equivalent	Tray, Disposable, Polystyrene
MFG-0353 or equivalent	Clip, Binder, Stainless Steel

7 Procedure

7.1 Prep and Solder Proximal End of Micro-Coaxial Cables to Bridgeboard

7.1.1 Insert a 0.0195" Teflon coated stainless steel mandrel through the proximal end of the central lumen of the catheter for approximately 5cm length. Allow approximately 5 cm length exposed for later extraction in subsequent steps.

7.1.2 Strip the outer jacket of each colored coaxial cable approximately 4mm using blade breaker.

7.1.3 Separate the outer conductors from the dielectric insulator by pulling the insulator off the main line of the coaxial cable. Hold all the outer conductors with a tweezer and twist the conductors tightly together by rotating the outer jacket with the opposite hand.

7.1.4 Strip the dielectric insulator using blade breaker (or equivalent stripping tool) as illustrated in Figure 1, leaving approximately 1mm of dielectric insulation on the prepped wire.

7.1.5 Apply a thin layer of solder paste to the outer and center conductors using spatula. Tin the outer and center conductors using soldering system set to 350°C.

7.1.6 Cut the outer and center conductors to final length per Figure 1.

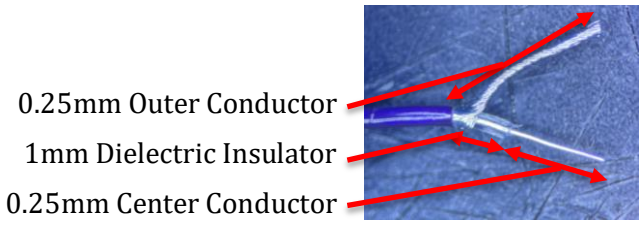


Figure 1: Example of micro-coaxial cable

7.1.7 Place the bridgeboard circuit from the Cable Subassembly in the circuit board holder.

7.1.8 Fix the inner lumen with pre-loaded mandrel and spine wire to the magnet to prevent heat damage from soldering tip.

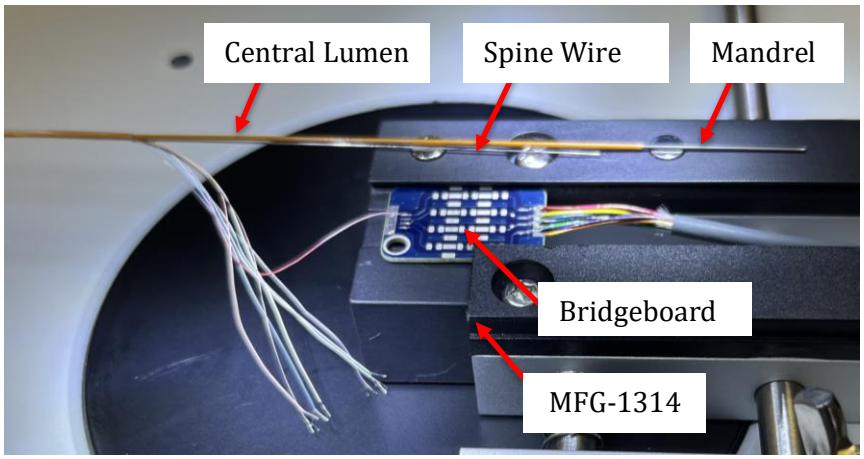


Figure 2: Placement of catheter subassembly and catheter cable onto circuit board holder

7.1.9 Pre-wet the circuit ground and signal for catheter joints using solder and Soldering Station on both the front and back sides of the bridgeboard circuit.

7.1.10 Using tweezers, hold the outer conductor wires against the pre-wetted circuit ground. Solder the conductor wires to the circuit using soldering station set to 350°C. Cut the excess conductor wires from the Bridgeboard circuit using blade breaker as necessary. As the following steps are performed, ensure that colors are electrically connected to the bridgeboard per specification.

7.1.11 Using tweezers, hold the insulator jacket adjacent to the pre-wetted circuit signal pad. The exposed center conductor wires should be between 25% to 75% of the full length of the pre-wetted circuit signal pad. Solder the conductor wires to the circuit using soldering station set to 350°C. Cut the excess conductor wires from the Bridgeboard circuit using blade breaker as necessary.

7.1.12 Clean circuit from excess solder as necessary using antistatic swab and 70% alcohol.

7.1.13 Repeat steps 7.1.11 thru 7.1.12 for the back face of the bridgeboard circuit.

7.1.14 **In-process inspection:** Perform visual inspection of the soldered conductors.

- Verify color order of coaxial cables are positioned as specified drawing.
- **Pass:** Both outer conductor and center conductor are tinned to their pads (ground and signal, respectively)
- **Pass:** Center conductor is on 25-75% length of signal pad and does not exceed boundaries of pad
- **Pass:** Dielectric insulator is adjacent (up to) or past the the signal pad
- **Pass:** Dielectric insulator is not melted or otherwise deformed by heat

7.2 Prep and Solder Distal End of Micro-Coaxial Cables to Transducer Circuit

7.2.1 Insert 0.0195" Teflon coated mandrel through the distal end of the central lumen.

7.2.2 Strip approximately 4mm of the proximal end of the micro-coaxial cable outer jacket using blade breaker.

7.2.3 Separate the outer conductors from the dielectric insulator by pulling the insulator off the main line of the coaxial cable. Cut approximately half the outer conductors approximately closest to the stripped edge of the outer jacket with wire cutters. Hold the remaining outer conductors with a tweezer and twist the conductors tightly together by rotating the outer jacket with the opposite hand.

7.2.4 Strip the dielectric insulator of each colored coaxial cable using blade braker so that approximately 1mm is available, measuring from the edge of the colored outer jacket.

7.2.5 Apply a thin layer of solder paste to the outer and center conductors using spatula. Tin the outer and center conductors using soldering system and chisel tip set to 350°C.

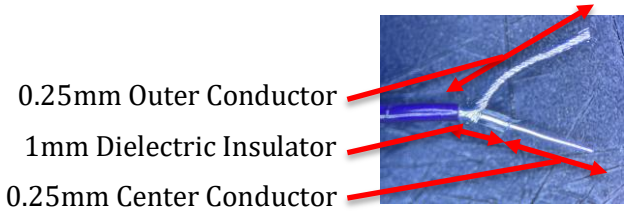


Figure 3: Example of micro-coaxial cable

7.2.6 Place the transducer subassembly array on aluminum base plate with double sided tape. Cut the lower section of the array with blade breaker and double edge blade (Figure 4).

Figure 4: Transducer array with lower section indicated in red box

7.2.7 Place the pre-tinned outer conductor wires over the ground pad. Solder the outer conductor wires to the ground pad using soldering system and chisel tip set to 150°C. Apply flux as necessary to achieve good solder wetting. Clean flux as necessary with isopropyl alcohol.

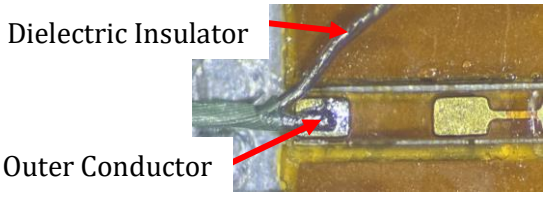


Figure 5: Soldered outer conductor to ground pad of transducer subassembly

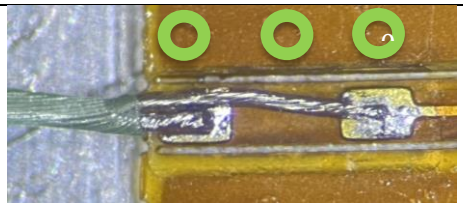
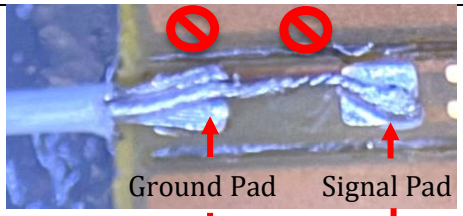
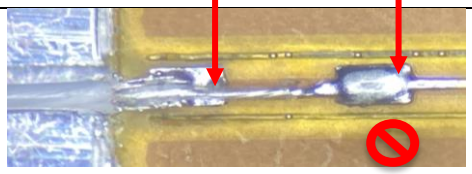
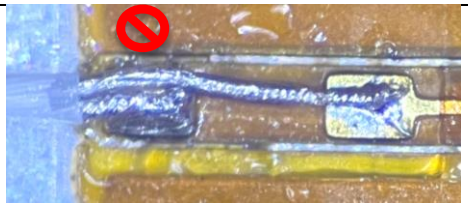
7.2.8 Bring down the exposed inner conductor wires over the signal pad. Take care not to join the inner conductor wires with the outer conductor wires with solder. Solder the inner conductor wires to the signal pad using soldering system set to 150°C. A low-profile attachment between micro-coaxial cable and transducer subassembly is preferred (see Table 2). Apply flux as necessary to achieve good solder wetting. Clean flux as necessary with isopropyl alcohol.

Note: Do not obstruct the outer conductors with the dielectric insulator.

7.2.9 Repeat steps 7.2.7 thru 7.2.8 for the remaining micro-coaxial cables (PTE-0200 thru PTE-0206). Care shall be taken not to entangle the micro-coaxial cables during this operation.

7.2.10 **In-process inspection:** Inspect each transducer subassembly for soldering workmanship per Table 1.

Table 1: Micro-Coaxial Cable soldering to transducer subassembly Workmanship Examples

	Photo	Comments
(A)		• **Pass:** Both outer conductor and center conductor are tinned within their bond pads (ground and signal, respectively) • **Pass:** Outer conductor is on 25-75% length of ground pad and does not exceed boundaries of pad • **Pass:** Center conductor is on 25-75% length of signal pad and does not exceed boundaries of pad • **Pass:** Dielectric insulator is adjacent (up to) or past signal pad • **Pass:** Dielectric insulator is not melted or otherwise deformed by heat
(B)		• **Fail:** Outer conductors exceed the boundaries of the ground pad • **Fail:** Dielectric insulator is not adjacent (up to) or past signal pad, allowing too much center conductor exposure for potential short
(C)		• **Fail:** Center conductors are poorly wetted to signal pad (not tinned well)
(D)		• **Fail:** Outer conductor length is greater than 25-75% length of ground pad

7.3 Impedance Test

Verify electrical continuity per QTI-0781.

7.4 Assemble Sonar Array to Octagon and Apply Backing Layer

7.4.1 Cut individual transducer subassemblies from array with blade breaker along laser cut dotted lines furthest from the transducer.

7.4.2 Load the octagon over a 0.029" Teflon coated mandrel (PRT-0427-045). Insert the mandrel with loaded octagon through the proximal end of the spoke tool until the octagon is positioned beside and proximal to the spoke tool.

7.4.3 While holding the silicone tubing in place over the spoke, pull the proximal end of each micro-coax cable as necessary to align the transducer subassemblies approximately in the same axial position on the spoke. Slide all 8 transducer subassemblies over the octagon by pulling the silicone tubing towards the octagon and away from the spoke. Adjust the transducer subassemblies as needed once all 8 are loaded on the octagon so that the transducer subassemblies are fully supported by the octagon underneath and that the transducers are aligned in the same axial position (see Figure 6). Use MFG-1318 as necessary to aid in alignment.

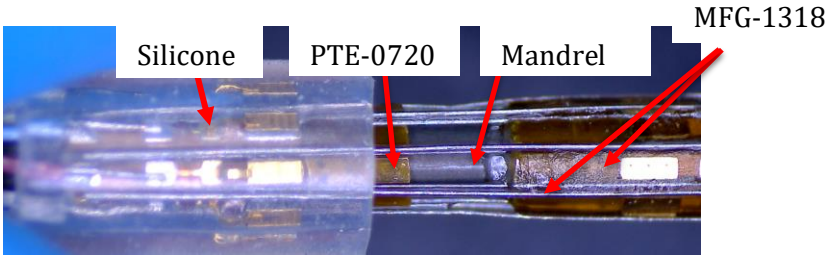


Figure 6: Loading transducer subassemblies onto octagon

7.4.4 At the distal end of the silicone tube, wick Loctite 3961 adhesive onto the sonar assemblies underneath the silicone tube. Remove excess adhesive as necessary. Ensure full length of transducer subassembly is potted with adhesive, taking extra consideration for the solder joints. No air bubbles should be formed over the transducers along indicated length in Figure 8. Allow wicked adhesive to travel proximal from the transducer subassembly for approximately 1mm (Figure 7).

7.4.5 Cure the adhesive with UV Curing System and wand holding fixture for 20 seconds.

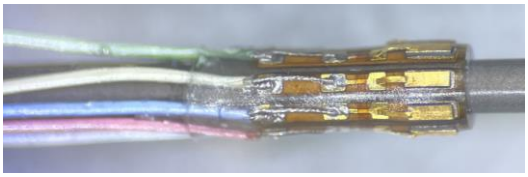


Figure 7: UV cured transducer array

7.4.6 Remove the mandrel from the UV cured transducer array.

7.4.7 Cut the excess adhesive from the distal end of the UV cured transducer array to maintain a flush mating surface with the molded distal tip in a later process step (Section 7.8).

7.4.8 Insert the distal end of the central lumen through the ID of the proximal end of the octagon array (side with soldered micro-coaxial cables) to position the transducers concentrically around the inner lumen.

7.4.9 Pull the proximal end of the micro-coaxial cables as necessary to remove the slack on the distal end.

7.5 Mold Distal Tip

7.5.1 Load marker band and mold distal tip onto inner lumen per MIN-0431.

7.5.2 **In-process inspection:** Visually inspect molded distal tip subassembly for flash and debris. Dimensionally inspect molded distal tip subassembly per specification.

7.6 Bond Distal Tip to Octagon Subassembly

7.6.1 Insert a 0.0195" mandrel (PRT-0427-025) through the distal tip.

7.6.2 Wick Loctite 4310 adhesive between the marker band and molded tip.

7.6.3 Cure the adhesive with UV Curing System and wand holding fixture for 20 seconds.

7.6.4 Apply Loctite 4310 adhesive generously over the marker band and approximately 1mm of the central lumen proximal to the marker band. Load the octagon over the pre-wetted marker band. Wick Loctite 4310 adhesive as necessary to prevent the formation of air bubbles between the marker band and octagon.

7.6.5 Cure the adhesive with the UV Curing System and wand holding fixture for 20 seconds, directing the UV light perpendicular to the subassembly.

7.7 Final Matching Layer over Sonar Array

7.7.1 Keeping all components exiting proximal from the outer lumen in place, carefully advance the outer lumen and bonded sleeve towards the distal tip until the outer lumen is approximately 5mm from the solder joints of the transducer subassemblies.

7.7.2 Apply Loctite 3961 through the gap between the transducer subassembly and distal tip, ensuring no bubbles form. Apply a thin layer of Loctite 3961 adhesive over the pre-potted transducer array along the indicated length in Figure 8.

7.7.3 Cure the adhesive with UV curing system for 20 seconds in wand holding fixture.

7.7.4 Apply another thin layer of Loctite 3961 adhesive over the pre-potted transducer array along the indicated length in Figure 8.

7.7.5 Keeping all components exiting proximal from the outer lumen in place, carefully advance the sleeve over applied adhesive until the end of the sleeve overlaps the distal tip for approximately 1mm. Ensure there are no air bubbles in the indicated section in Figure 10. Wipe excess adhesive with lint-free wipe as necessary. **Note:** As necessary, adjust length of individual micro-coax cables to be equal length with one another on the distal end to reduce risk of kinking or folding distal micro-coax cables as the outer lumen is advanced..

7.7.6 Cure the adhesive with UV curing system for 20 seconds in wand holding fixture.

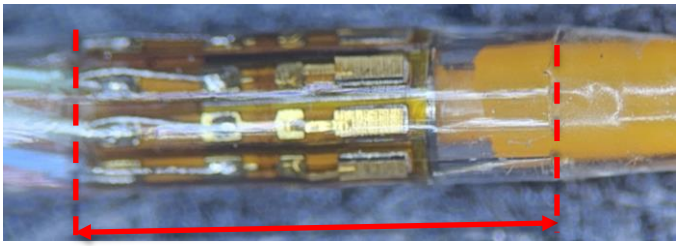


Figure 8: Example of distal section of completed catheter subassembly with no air bubbles over adhesive region indicated by double arrows

7.7.7 Adjust the spine wire subassembly through the proximal end of the outer lumen tubing as required until it is 10mm±1mm from the transducers per specification.

7.8 Impedance Test

Verify electrical continuity per QTI-0781.

7.9 Secure Bridgeboard Circuit to Housing, Bottom Shell

7.9.1 Load the collar (PRT-0305) over PRU cable subassembly (PTE-0965).

7.9.2 Place the front side of the bridgeboard circuit face up with screw hole aligned with the screw boss of the bridgeboard housing bottom shell (PRT-0306).

7.9.3 Secure the Bridgeboard circuit to the Bridgeboard Housing, Bottom Shell using screwdriver and Phillips screw (PRT-0308).

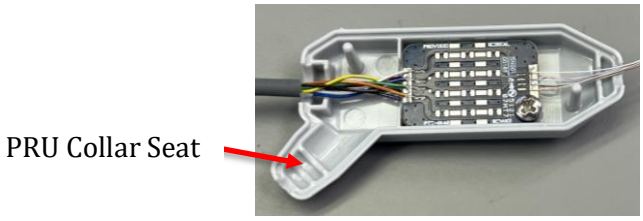
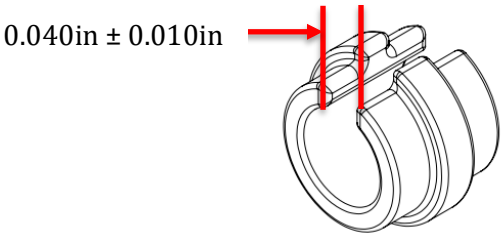


Figure 9: Orientation of bridgeboard circuit within bridgeboard housing bottom shell

7.9.4 Cut a slot through the collar (PRT-0305) with razor blade to allow clearance of PRU cables.



7.9.5 Position the collar and PRU cable together over the designated seat within the bridgeboard housing bottom shell.

7.9.6 Align the collar to the designated seating within the bottom shell of the bridgeboard housing bottom shell. Apply Loctite 401 adhesive between the internal diameter of the collar and the outer surface of the cable subassembly. Create an adhesive fillet at the interface between the collar and the cable on both ends of the collar.

7.9.7 Apply Loctite 401 adhesive between the outer diameter of the collar and its seat within the bridgeboard housing bottom shell. Fix the collar in the allocated seat within the bridgeboard housing bottom shell.

7.10 Central Lumen Assembly and Fixation of Internal Housing Components

7.10.1 Cut the proximal end of inner lumen tubing and proximal end of spine wire subassembly 30mm±3mm measuring from the proximal edge of the clear catheter shaft. Take care not to cut any of the micro-coaxial cables that connect the Catheter connector to the transducer circuit.

7.10.2 Insert 0.019in Teflon coated mandrel through the proximal end of the inner lumen.

7.10.3 Loop the micro-coaxial cables attached to the distal end of the bridgeboard circuit around the distal bridgeboard housing pin (Figure 10). Apply tape over the cables and bridgeboard to hold the cables in place.

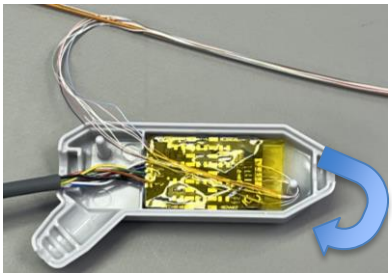


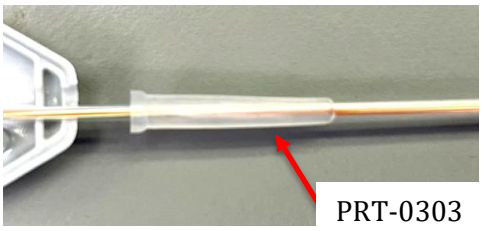
Figure 10: Micro-Coax loop around Bridgeboard housing pins

7.10.4 Insert distal end of the luer (PRT-0304) over the Teflon coated stainless steel mandrel until the central lumen of the catheter is fully inside the distal end of a luer.

7.10.5 Apply Loctite 401 adhesive between the central lumen and luer. Create an adhesive fillet at the interface between the luer and the central lumen tubing.

7.10.6 Insert the strain relief (PRT-0303) over the catheter outer lumen in the orientation illustrated in Figure 11.

Proximal



Distal

Figure 11: Placement orientation of strain relief on catheter outer lumen shaft

7.10.7 Continue the loop around proximal bridgeboard housing pin (Figure 12). Tape the remaining section of micro-coaxial cable to the bridgeboard circuit.

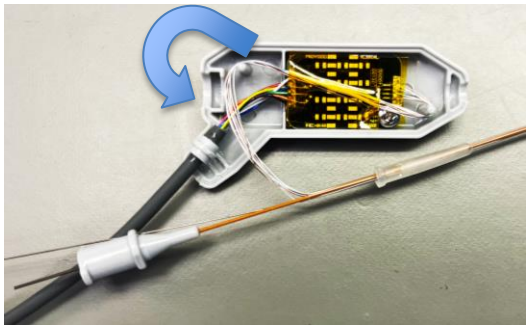


Figure 12: Micro-coaxial loop

7.10.8 Bend the spine wire away from the micro-coaxial cables. Tape the proximal end of the spine wire to the bridgeboard circuit. Cut the material as needed to stay within the boundaries of the bridgeboard circuit.

7.10.9 Apply Loctite 401 adhesive generously within the luer seat of the bridgeboard housing shell. Place the luer in the final position within the bridgeboard housing bottom shell.

7.10.10 Align the strain relief to the designated seating within the bottom shell of the bridgeboard housing bottom shell. Apply Loctite 401 adhesive between the outer lumen and strain relief to close off a potential leak path as indicated in Figure 13. Create an adhesive fillet at the interface between the strain relief and the lumen tubing.

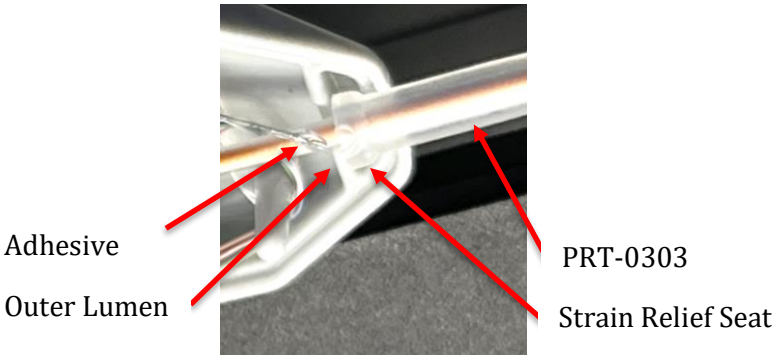


Figure 13: Adhesive application between outer lumen and strain relief

7.10.11 Apply Loctite 401 adhesive between the strain relief and bridgeboard housing bottom shell to hold the strain relief in place to fix the strain relief without the housing.

7.11 Pot Bridgeboard Circuit and Seal Housing Assembly

7.11.1 Insert a 0.013" Teflon coated mandrel (PRT-0878) through the proximal end of the outer lumen, beside the spine wire assembly, approximately 15mm.

7.11.2 Prepare Loctite epoxy adhesive (CON-0310). Insert the cartridge of epoxy into the manual adhesive dispenser. Remove the cap of the epoxy cartridge and replace with a disposable dispensing tip.

7.11.3 Dispense epoxy into a 10cc syringe. Remove excess air within the syringe. Attach a dispensing needle tip to the end of the syringe.

7.11.4 Slowly dispense epoxy into the bottom shell of the bridgeboard housing, underneath the bridgeboard circuit, using the epoxy filled syringe.

7.11.5 Slowly dispense epoxy directly on top of the bridgeboard circuit and taped components, ensuring the entire bridgeboard and exposed solder joints are fully encase in the epoxy.

7.11.6 Remove the pre-inserted Teflon coated mandrel from the assembly.

7.11.7 Apply epoxy adhesive with applicator or equivalent EFD dispensing equipment along the inner perimeter of the Bridgeboard Housing Bottom Shell and between the top and bottom surfaces of the bridgeboard housing mating components (i.e., Collar, Luer, Strain Relief). Refer to Figure 9 for full adhesive application layout.

Note: Leave the section of the Bridgeboard Housing Bottom Shell that is not outlined in red in Figure 14 free of any adhesive.

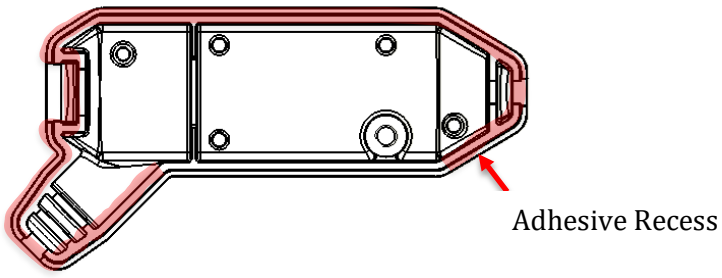


Figure 14: Epoxy adhesive application layout for Housing, Bridgeboard, Bottom Shell

7.11.8 Apply epoxy adhesive with applicator or equivalent EFD dispensing equipment within the indicated locations of the Bridgeboard Housing Top Shell in Figure 15.

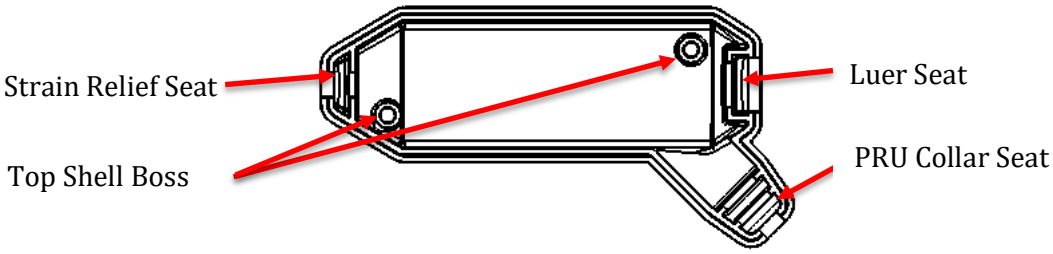


Figure 15: Epoxy adhesive application layout for Housing, Bridgeboard, Top Shell

7.11.9 Carefully align the Housing, Bridgeboard, Top Shell over the Housing, Bridgeboard, Bottom Shell and press the two parts together.

7.11.10 Wipe the outer surface of the bridgeboard housing assembly with pre-wetted IPA wipes to clean the part of excess epoxy adhesive.

7.11.11 Hold the two pieces together using binder clips. **Note:** The epoxy requires a minimum of 24 hours to fully cure.

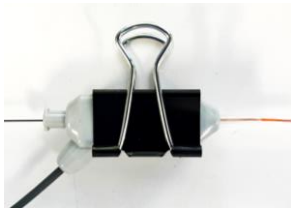


Figure 16: Binder clip loaded on assembled bridgeboard housing unit

7.11.12 After 24 hours, remove spring clips from the bridgeboard housing units.

7.11.13 Carefully remove the 0.0195" Teflon coated stainless steel mandrel from the proximal end of the luer.

7.12 Pulse Echo Test

Verify sonar performance per QTI-0642.

7.13 Material Inspection

Accept material if all criteria are met per QTI-0841.