

Case Example (#MIN-0434)

MIN-0434 (before)

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 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 shown 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. Then solder 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.

Modified Draft:

7. Procedures

7.1 Preparation and Soldering of Proximal End of Micro-Coaxial Cables to Bridgeboard

1. Insert Mandrel:

- In accordance with **SOP-0012 Production and Process Control**, insert a 0.0195" Teflon-coated stainless steel mandrel (PRT-0427-026) through the proximal end of the central lumen of the catheter, leaving approximately 5cm exposed for later extraction.

2. Strip Outer Jacket:

- Following the stripping procedure outlined in **SOP-0299 Electrostatic Discharge (ESD) Precautions and Handling**, strip approximately 4mm of the outer jacket from each colored coaxial cable using a blade breaker (MFG-0355).

3. Separate Outer Conductor:

- As specified in **SOP-0299**, separate the outer conductors from the dielectric insulator by pulling the insulator off the coaxial cable. Use tweezers to twist the conductors tightly together while rotating the

- outer jacket with the opposite hand.
4. **Strip Dielectric Insulator:**
 - Strip the dielectric insulator using a blade breaker (MFG-0355), ensuring approximately 1mm of dielectric insulation remains on the prepped wire, as required by **PRT-0638 Assembly, Catheter, SLT, OTW, 0.018, 150cm**.
 5. **Apply Solder Paste and Tin Conductors:**
 - Apply a thin layer of solder paste to the outer and center conductors using a spatula (MFG-1035), then tin the conductors using the soldering system set to 350°C (MFG-1201), in accordance with **QTI-0781 Test Instruction, Impedance, Catheter Components, Sub-assemblies, and Assemblies**.
 6. **Cut Conductors to Final Length:**
 - Trim the outer and center conductors to the final length as specified in **PRT-0638 Assembly, Catheter, SLT, OTW, 0.018, 150cm**.
 7. **Position Bridgeboard:**
 - Secure the bridgeboard circuit (PRT-0427-026) in the circuit board holder (MFG-1314) per **SOP-0012**.
 8. **Pre-Wet Circuit Pads:**
 - Pre-wet the circuit ground and signal pads on both the front and back sides of the bridgeboard circuit using solder and a soldering station (MFG-1201) in compliance with **QTI-0781**.
 9. **Solder Outer Conductor Wires:**
 - Following **SOP-0012**, use tweezers to hold the outer conductor wires against the pre-wetted circuit ground pad. Solder the wires to the circuit using the soldering station set to 350°C, and trim excess wires as necessary.
 10. **Solder Center Conductor Wires:**
 - Position the insulator jacket adjacent to the pre-wetted circuit signal pad, ensuring the exposed center conductor wires cover 25-75% of the pad length as specified in **QTI-0781**. Solder the wires to the circuit and trim excess conductor wires as necessary.
 11. **Clean Circuit:**
 - Clean the circuit of excess solder using an antistatic swab and 70% alcohol, in line with **SOP-0299**.
 12. **Repeat Soldering for Back Face:**
 - Repeat the soldering process for the back face of the bridgeboard circuit as outlined in **PRT-0638**.
 13. **In-Process Inspection:**
 - Perform a visual inspection of the soldered conductors, verifying the following criteria specified in **QTI-0841 Inspection Instruction, Dimensional and Visual**:
 - Correct color order of coaxial cables.
 - Both outer and center conductors are properly tinned to their respective pads.
 - The center conductor is positioned correctly within the bound-

- aries of the signal pad.
- The dielectric insulator is not deformed and is positioned correctly.

7.2 Preparation and Soldering of Distal End of Micro-Coaxial Cables to Transducer Circuit

1. **Insert Mandrel:**
 - In line with **SOP-0012**, insert a 0.0195" Teflon-coated mandrel (PRT-0427-026) through the distal end of the central lumen.
2. **Strip Outer Jacket:**
 - Following **SOP-0299**, strip approximately 4mm of the proximal end of the micro-coaxial cable outer jacket using a blade breaker (MFG-0355).
3. **Separate Outer Conductor:**
 - In compliance with **PRT-0638**, separate the outer conductors from the dielectric insulator, and cut approximately half of the outer conductors closest to the stripped edge of the outer jacket using wire cutters. Twist the remaining outer conductors tightly together.
4. **Strip Dielectric Insulator:**
 - Strip the dielectric insulator from the colored coaxial cable using a blade breaker (MFG-0355), leaving approximately 1mm as specified in **PRT-0638**.
5. **Apply Solder Paste and Tin Conductors:**
 - Apply a thin layer of solder paste to the outer and center conductors using a spatula (MFG-1035). Tin the conductors using the soldering system and chisel tip set to 350°C (MFG-1201), following the guidelines in **QTI-0781**.
6. **Solder to Ground Pad:**
 - Solder the outer conductor wires to the ground pad using the soldering system set to 150°C. Apply flux as necessary for good solder wetting, in accordance with **SOP-0012**. Clean flux residue as needed with isopropyl alcohol.
7. **Solder to Signal Pad:**
 - Position the center conductor wires over the signal pad, ensuring they do not contact the outer conductor wires. Solder the center conductor wires to the signal pad using the soldering system set to 150°C, as specified in **QTI-0781**.
8. **In-Process Inspection:**
 - Inspect the soldered connections, ensuring they meet the workmanship standards outlined in **QTI-0841**:
 - Correct pad coverage.
 - No heat-induced damage to the dielectric insulator.
 - Proper alignment and attachment of conductors.

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Steps Taken to Achieve the Final Revision

Input: SOP Draft: Provided by the user.

Output: MDSAP-Compliant SOP: The revised and redrafted Procedure section of the SOP document, ensuring compliance with MDSAP guidelines and internal SOP references.

RAG (OpenAIEmbed + FAISS vector) -MDSAP Templates -FDA Guidelines -Referenced SOP

LangGraph Nodes/Agents:

1. Verification of SOP Draft Content:

- Verify that the SOP Draft (uploaded as a PDF file) pertains to the procedure for the assembly of medical devices. If the content does not qualify, the response will be: "Not a qualified SOP Draft. Please refer to SOP Draft example."

2. Review of SOP Structure for Internal References:

- Review the structure of the SOP Draft to identify the Internal Reference section. If no such section exists, the response will be: "Not a qualified SOP Draft. Please refer to SOP Draft example."

3. Review of SOP Structure for the Procedure Section:

- Review the structure of the SOP Draft to identify the Procedure section. If no such section exists, the response will be: "Not a qualified SOP Draft. Please refer to SOP Draft example."

4. Focus on Specific Sections of the Procedure:

- Redraft specific sections of the Procedure, ensuring that the content aligns with internal standard operating procedures. This involves integrating references to relevant SOPs, assembly instructions, and inspection criteria.

5. Incorporation of Internal References:

- Incorporate internal references into the Procedure section. This ensures that the redrafted content is compliant with the MDSAP template and consistent with existing internal processes and guidelines.

6. Review and Refinement:

- Review and refine the redrafted content to ensure clarity, accuracy, and completeness. This step involves cross-referencing the internal SOPs to verify that all procedural details are correctly captured and aligned with the MDSAP template.

7. Final Version Marking:

- Once the Procedure section is satisfactorily redrafted and refined, mark this version as the final result. This step also includes providing a summary of the entire process, including the purpose, inputs, and outputs.

8. Final Review and Confirmation:

- Conduct a final review to confirm that all elements are in place, ensuring that the document meets both MDSAP guidelines and internal SOP standards. This includes checking for consistency, formatting, and compliance with the template.

9. Completion and Documentation:

- Generate the final document in PDF format, marking the completion of the task.

These steps outline the complete process taken to achieve the final redraft of the Procedure section, ensuring it meets both internal and MDSAP standards.