

Tips for Designing Custom Cable Assemblies Used in Medical Diagnostics Equipment

09.17.26



Agenda

- ▶ Capabilities
- ▶ Application Examples
- ▶ Medical Industry Standards and Certifications
- ▶ Overmolding - Custom and House Tooling
- ▶ Biocompatibility - Impacts and Requirements
- ▶ Customizing Your Cable for a New Project
- ▶ Q&A

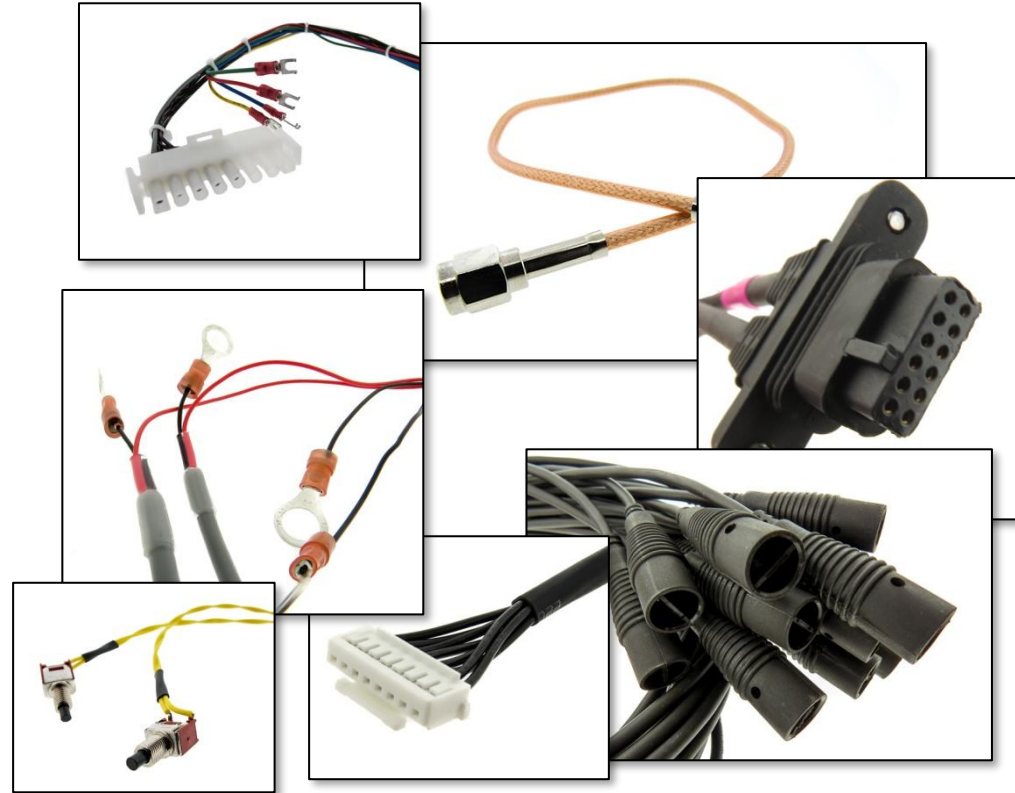


A photograph of a cable assembly machine, likely a crimping or soldering station, with a blue overlay. The machine has a digital display showing '9.80.0/0' and several control knobs and buttons. A blue flexible arm is attached to the top. The background shows other industrial equipment.

Cable Assembly Capabilities

Medical Device - Cable Assemblies & Wire Harnesses

- ▶ UL Hook-Up Wire
- ▶ Heavy Gauge Cables
- ▶ Custom Overmolded Cables
- ▶ RF Coaxial Cable
- ▶ Biocompatible Materials
- ▶ D-Sub (9, 15, 25, etc.)
- ▶ Circular & Metal Connectors
- ▶ Power and Ribbon Cables
- ▶ RJ45, CAT5E & 6, USB



In-House Wire & Conductor Capabilities

▶ **UL-Approved Wire-Single**

- UL1007/1569, UL1015
- UL1061
- Many others

▶ **UL-Approved Wire-Multi**

- UL2464, UL2517
- UL2651 Flat Cable
- Many others

▶ **Materials**

- Extruded Thermoplastics
- Silicone Jacketed Cables

▶ **Conductor Size**

- 4 AWG to 40 AWG

▶ **Shielding**

- Braided Tinned Copper
- Foil Shield
- Shield + Drain Wire

▶ **Full Electrical Test**

- Network Analyzer
- Custom Test Stands
- Dedicated Cirris Electrical Tester



Automated Equipment



Automated Wire Stripping



Fully Automated Electric Testing



Automated Termination and Circuit Identification



**Automated Cut-To-Length, Wire Stripping,
and Simple Termination**

Electrical & Functional Testing

- ▶ 100% Electrical Test
 - Continuity Test
 - Hipot Testing ex. 1000V @ 60s
 - Insulation Resistance
- ▶ Customer Specific Functional Test
- ▶ AS9102 FAI
 - Bubble print drawing
 - CoC





Application Examples

Application Examples

- ▶ Basic Examination Tools
 - Blood pressure measurement
- ▶ Advanced Clinical Systems
 - Laser therapy device
- ▶ Medical Imaging Equipment
 - Ultrasound machines
 - CT and MRI scanners
- ▶ Laboratory Testing
 - Centrifuges
 - Microscopes



We cannot support Class III Medical Devices

Application Examples- Cable Assembly Options



Patient Contact Cable

Biocompatible Cable and Overmold

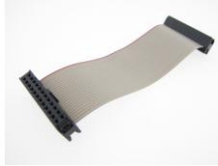


Coaxial Cables

RF cables, Microcoax, etc

Overmolded Strain Relief

Custom or House Tooling



Ribbon Cables

IDC Cables, UL-Rated



FFC

Flat Flexible Cable



Multiconductor Cables

Pin and Housing Connectors, UL-Rated

DSUB Cables

DB25, DB44, House Tools



Power Cables

Hospital Grade, SJOW/SOOW



Highly Custom - Medical Device Cable Assemblies

- ▶ Specialty locking connector
- ▶ Custom extruded multiconductor wire
- ▶ Evaluation of mating interface
- ▶ Hybrid cross section
 - Coaxial cable
 - Stranded cable
 - Braided shielding



Common Connector Types - Industry Standards

- ▶ Phillips IBP 12-pin
- ▶ GE Marquette 11-pin
- ▶ ECG Snaps
- ▶ DisplayPort
- ▶ HDMI
- ▶ USB-C



Common Connector Types – Off-the-Shelf Circular

- ▶ Binder
- ▶ ODU
- ▶ Amphenol
- ▶ LEMO
- ▶ Fischer
- ▶ M8/M12 Metric

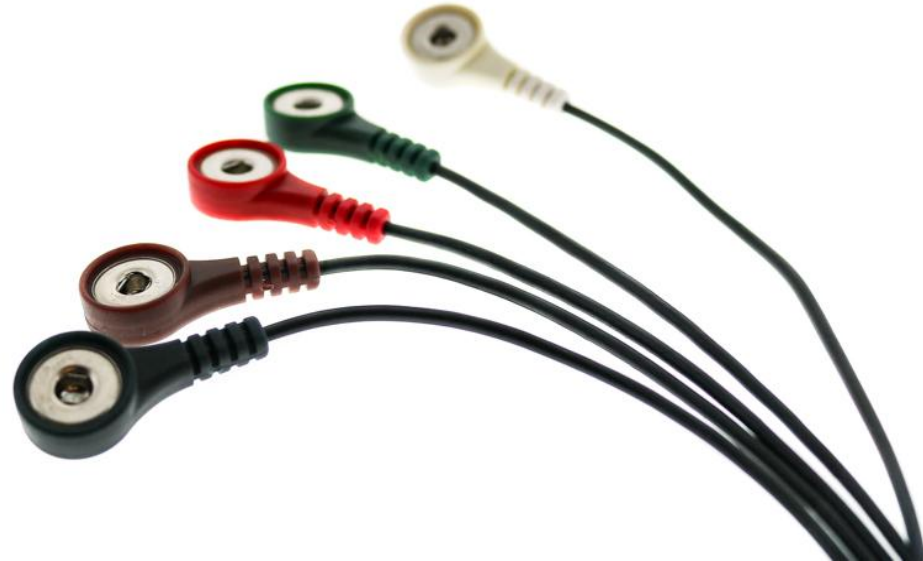


A close-up photograph of a person's hand wearing a blue nitrile glove, interacting with a medical device. The device has a white plastic housing and a color LCD screen at the top. The screen displays a green and white interface with some text and a small icon. The person's hand is positioned near a circular opening on the device, possibly a sample port or a control knob. The background is slightly blurred, showing more of the device and a white surface.

Medical Industry Standards and Certifications

Product Safety Considerations

- ▶ UL Wire & Overmolds
 - UL1015, UL2464
 - C12, C13, NEMA 5-15P
- ▶ Chemical & Environmental Compliance
 - REACH & RoHS
 - SVHC (Substance of Very High Concern)
- ▶ Biocompatibility
 - ISO 10993-1:2018
 - Cytotoxicity, sensitization, irritation
- ▶ EMI / EMC
 - General: IEC 60601-1
 - Application Specific: IEC 80601-2-26



Industry Certifications

- ▶ ISO 9001:2015
 - Quality management systems
- ▶ ISO 27001:2022
 - Information security, cybersecurity and privacy protection
- ▶ ISO 13485:2016
 - Medical devices - quality management systems



NRTL Certification - Cost and Timeline

- ▶ It depends...
 - The exact UL and CSA standards
 - Previous certifications
 - Listed components
 - Complexity of the build
 - Schedule availability
 - Samples
- ▶ Roughly 3-5 months and \$20K-\$200K
- ▶ Part marking will require site audit and additional fee



Recertification is very simple with minor listed component changes



Overmolding - Custom and House Tooling

Adding Overmolds to Medical Device Cables

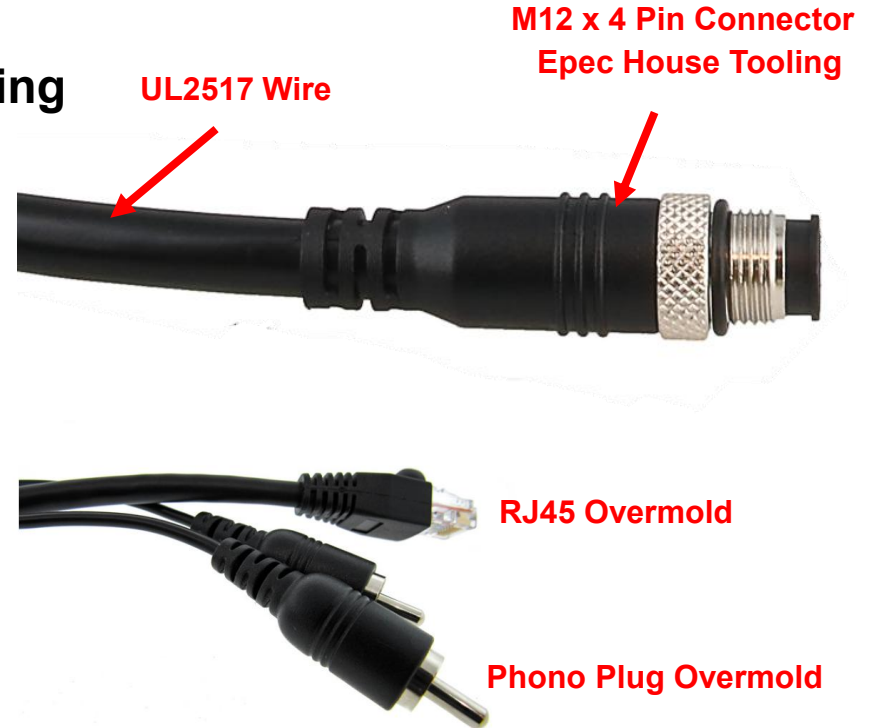
- ▶ **Overmold will not violate wire UL rating**

- ▶ **Primary overmolding concerns**

- Biocompatibility
- Material compatibility
- Flammability

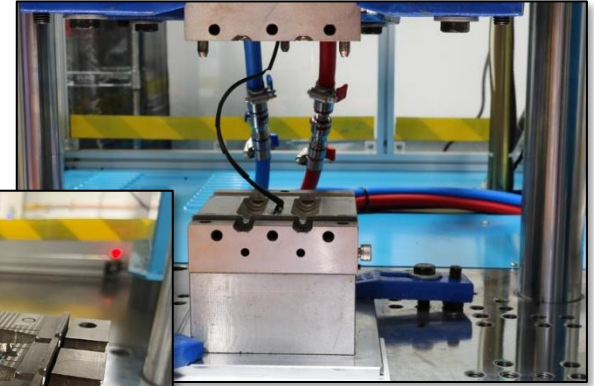
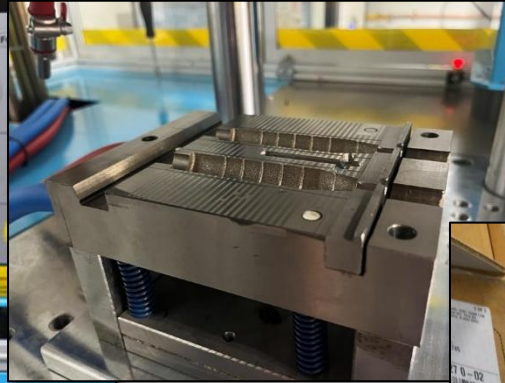
- ▶ **Additional levels of customization**

- Ruggedization
- Adding artwork or logos



House Tooling Is Readily Available With \$0 NRE Expense

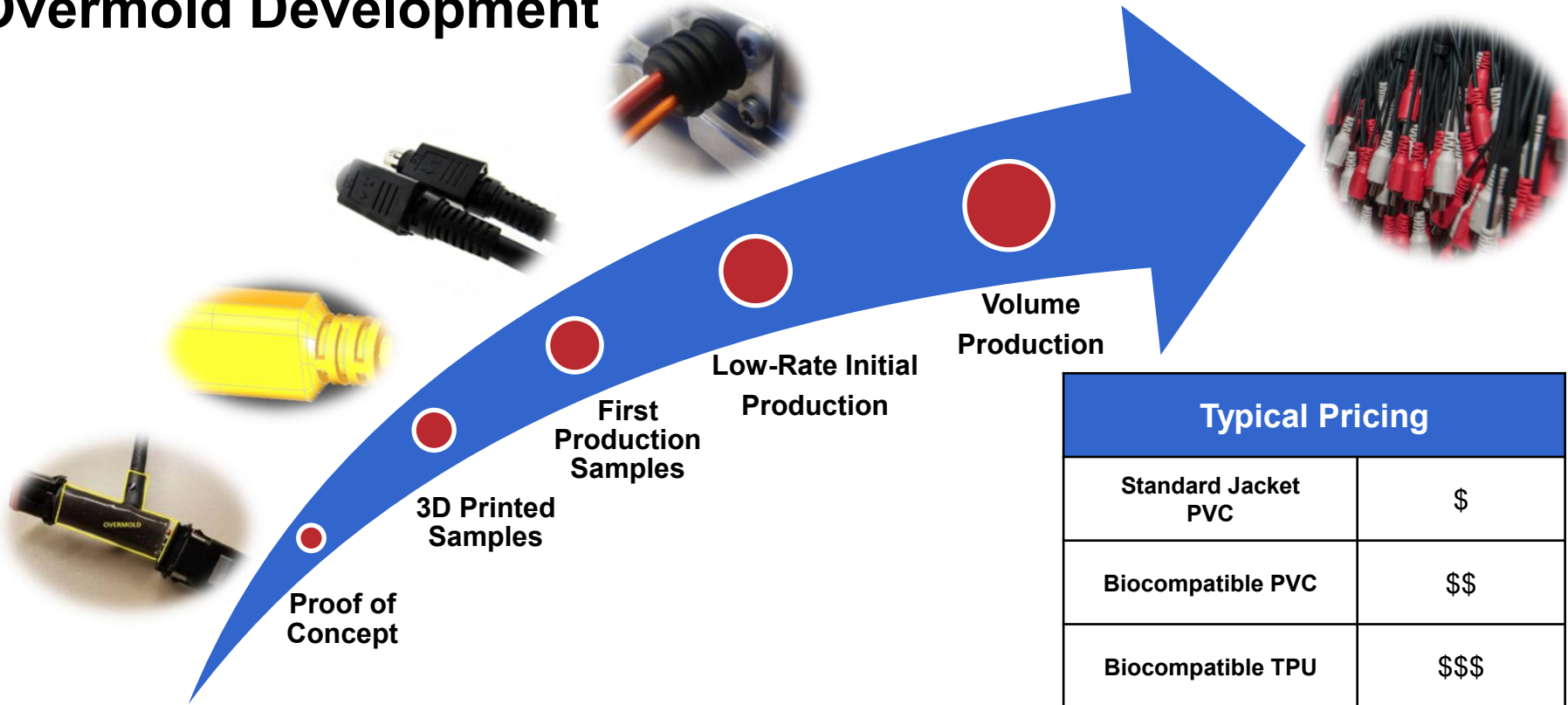
Overmold Process & Equipment



Overmolds - Custom and House Tooling



Overmold Development



Typical Pricing	
Standard Jacket PVC	\$
Biocompatible PVC	\$\$
Biocompatible TPU	\$\$\$

Overmolding materials can change without impacting the tooling

Overmold - Design Steps to Reduce Risk

▶ Incompatible Materials

▶ Risk Analysis

- Will the overmold bond to the wire jacket?
- Do you require a standard material?
- Biocompatibility?

▶ Dimensional Issues

- Failures during leak testing
- Fit checks

▶ Material Issues

- Degradation or breakdown
- Incompatibility





Biocompatibility - Impacts and Requirements



Biocompatible Cable Harnesses

▶ Medical Device Classifications

- Class I- Lowest Risk
 - Minimal potential for harm
- Class II- Moderate Risk
 - Sustained patient contact
- Class III- Highest Risk
 - Implantables
 - Life-sustaining/supporting

▶ What is involved with Biocompatible Cables?

- Required for prolonged direct skin contact
- Prevents skin irritation, sensitization
- Comply with testing limits



Most common for Class II and Class III devices

Medical Grade Overmolds & Wire Jackets

▶ Medical Grade vs. Standard Materials

- Biocompatibility
- Sterilization
- Controlled formulations

▶ ISO 10993-1:2018

- Biological evaluation of medical devices

▶ Processing Impacts

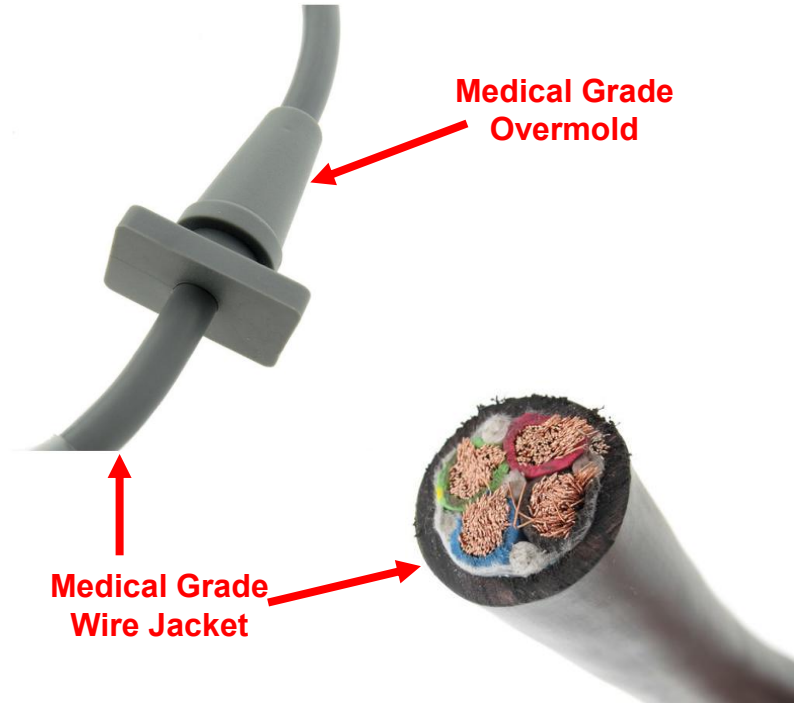
- Higher costs
- Isolated production environment
- Potential minimum order impacts



If Biocompatibility is required, this must be clearly communicated early

Medical Grade - Formulation Takeaways

- ▶ **Wire Jacket + Overmold**
 - Choose the same material to help bond
 - Medical-grade PVC and TPU
- ▶ **Medical-Grade Materials - Low Cost!**
 - More expensive vs. traditional materials
- ▶ **Non-DEHP, Non-Phthalate Formulations**
 - Permits direct patient contact
 - Omits additives, flame retardants
 - **Does not carry a UL rating**



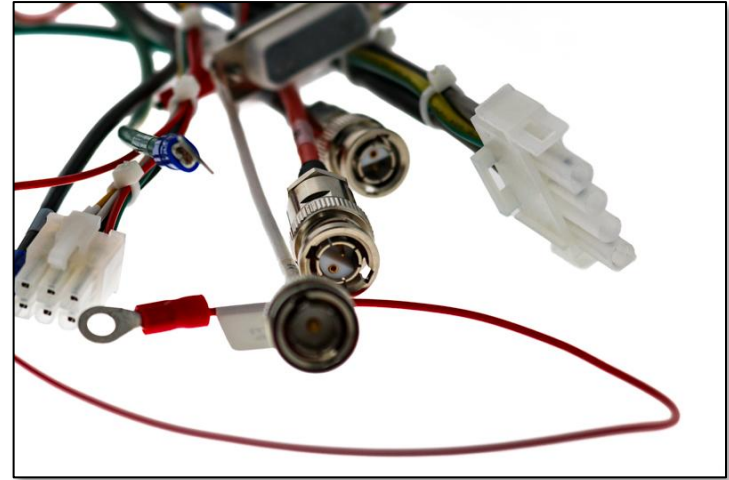
Medical grade materials are NON-UL



Customizing Your Cable for a New Project

Cable Manufacturing - Taking the Design First Steps

- ▶ What are you trying to accomplish?
- ▶ Industry specifications?
- ▶ Direct patient contact?
- ▶ How many pcs do you need and when?
- ▶ Must have
 - BOM
 - Wire Specs
 - Dimensions



To quote we must have: BOM, Wire Specs, and Dimensions

Cable Initial Design Requirements

Epec needs one of the following:

1. Detailed Drawing

- Preferred documentation
- Must review any critical requirements

2. Preliminary Sketch

- Need basic information
- Very common for first-time builds

3. Text Description

- Need overall size and length
- Wire specs and requirements
- BOM with manufacturers part numbers



- ▶ Are there existing drawings available?
- ▶ We always make our own
- ▶ Document critical dimensions and features
- ▶ Includes materials, stack-up, and power



Epec Inquiry Form

- ▶ When starting a project with Epec, we ask if you could please fill out our Inquiry Form
- ▶ This allows us to capture all the information of your design upfront, eliminating guess work
- ▶ Also allows us to provide you with an accurate quote

The image displays three overlapping Epec Cable Assembly Inquiry Forms. The forms are titled "epec Cable Assembly Inquiry Form" and contain the following sections:

- Project Questionnaire**: Includes a section for "Why is Epec Being Offered this opportunity?" and a section for "Terms we need to be aware of?" with checkboxes for Yes/No.
- Customer Profile**: Includes fields for Contact Name, Email Address, Company, Job Title, Phone Number, Fax Number, Address, City, Country, State/Province, and Zip Code.
- Application**: Includes fields for Project Name, Application, Project Timeline, First Articles, Regulatory Samples, Production Start, Start Date, Target Price, Est. Annual Usage, Year 1, Year 2, and Year 3.

The forms are labeled "FQ224-E" and "Released: 11/26/2018". A "Print Form" button is visible on the bottom right of the forms.

A clear medical incubator, likely for newborns, is shown in a clinical setting. The incubator has a transparent front with circular viewing ports. A blue semi-transparent overlay covers the lower half of the image, featuring the word "Summary" in white text. The background is slightly blurred, showing other medical equipment and a person in a red shirt.

Summary

Summary

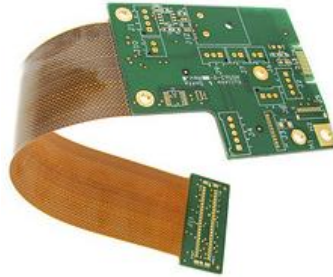
- ▶ Various cable technologies and material types are used in medical devices
- ▶ Numerous existing house tools can be used for \$0
- ▶ Understanding direct patient contact is the most critical design requirement
- ▶ If Biocompatibility is required, it must be a NON-UL wire
- ▶ Focus on PVC and TPU for wire jackets and overmolds
- ▶ Choose connectors in active production to mitigate cost and leadtime risk

Our Products

Battery Packs



Flex & Rigid-Flex PCBs



Cable Assemblies



Printed Circuit Boards



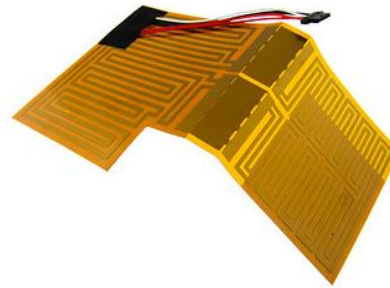
CNC Machining



User Interfaces



Flexible Heaters



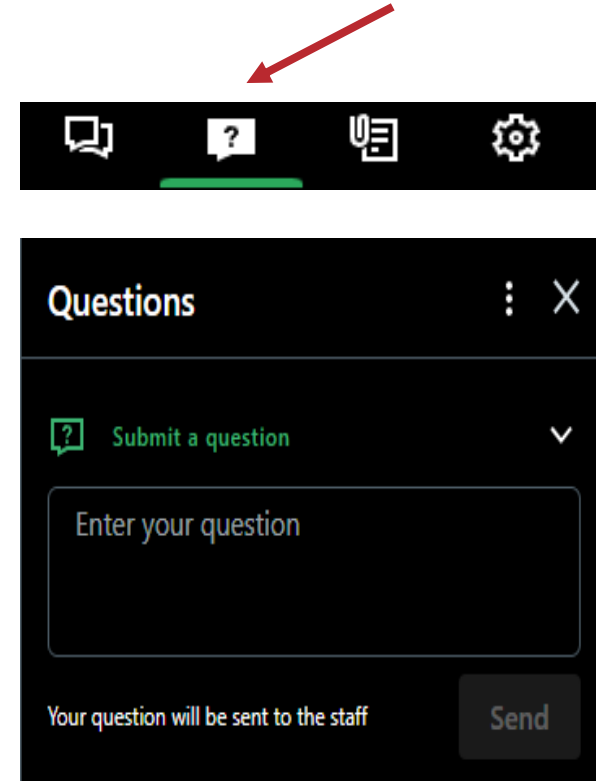
EC Fans & Motors



Q&A

► Questions?

1. Select the “?” in the top right control panel.
 2. Enter any questions you may have
- If we don't have time to get to it, we will reply via email



Thank You

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