Electrophysiology Market Discovery Brief

ONE MINUTE PITCH:

Molex has extensive experience collaborating with market-leading manufacturers of electronic catheters used for diagnostic, therapeutic and monitoring applications. Molex is applying its product and engineering expertise to the MedTech industry. We draw from our broad portfolio of interconnect solutions as well as our contract design, development and outsourcing capabilities, focusing on next-generation electrophysiology (EP) devices.

From proximal- to distal-end applications, Molex has the technology and know-how to enable your success and overcome the challenges of EP applications. This breadth of converging capabilities is what has established Molex as a market leader in medical device products, solutions and services.

Explore the Molex MedTech portfolio by visiting **www.molex.com/molex/industry/medical.** And check out our medical industry and Electrophysiology interactive guides.

BASIC SYSTEM ELEMENTS

Diagnostic Catheter

Therapeutic Catheter

Signal Generator

Accessories

ABOUT ELECTROPHYSIOLOGY (EP)

- EP is a test/study that records the electrical activity and the electrical pathways of the heart to find an abnormal heartbeat (arrhythmia).
- EP is a specialized application that utilizes a minimally invasive (keyhole surgery) approach to insert an electronic catheter in the body to access a major artery.
    - There are several types of catheters. However the focus in EP is on electronic catheters.
- The EP probe is navigated through the artery into the heart chamber where it can aid diagnosis and/or apply a therapy.
- The procedure is conducted in a specialized room called an “EP Lab,” which is configured to efficiently apply the procedures.
- Functionally, there are 2 major modes the electronic catheter operates in:
    - Diagnostic, which measures the electrical performance from within the heart.
        - Ultrasound imaging is another tool that uses Doppler imaging of blood flow and velocity and myocardial wall motion to assess function.
    - Therapeutic, which stops the abnormal function (arrythmia) of the heart through the tip of the catheter. A typical therapy is radio frequency (RF) ablation.

Additional Resources: https://www.webmd.com/heart-disease/electrophysiology-test#1

WHERE WE PLAY

The EP system consists of:

1. The signal generator: the box that the respective cable assemblies are plugged into.
    a. Within the box there are in-the-box connectors and wiring assemblies.
    b. Connector receptacles also attach to the box for cables to interface.
2. EP cable assemblies plug into the signal generator receptacles.
    a. The system requires a suite of cable assemblies that interface to the signal generator box. The surgeon selects and configures the cables based on the specific procedure.
3. The interface between the cable assembly and distal side of the catheter is an electromechanical junction that houses the connections toward the distal end.
    a. This junction is referred to as the handle assembly, which the surgeon articulates to position the tip for diagnosis and/or therapy.
4. The distal-end probe assembly is application- and customer-specific requiring a “statement of work” document, as it is very likely to include IP considerations.
    a. Due to the unique nature, distal applications will be handled on a case-by-case basis.

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HOW WE WIN

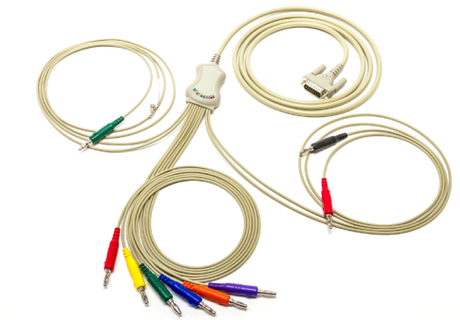
There are several areas in which Molex has differentiated advantages, starting from within the box to the distal end. Molex wins when we solve a “pinch point” for the customer. We can enter the business at any of the four sections of the playbook. However, the goal is an end-to-end solution leveraging the key Molex & Phillips-Medisize capabilities.

Signal Generator

- Wire harness assemblies
- Copper Flex and Premo-Flex Circuits
- Power and signal
- Board-to-board (B-to-B), wire-to-board (W-to-B), wire-to-wire (W-to-W) connectors
- Power connectors
- I/O connectors
- Integrated products

I/O Cable Assembly

- ISO13485 certified
- FDA-registered medical device manufacturer
- Japanese Ministry of Health accreditation
- CE marking under medical device directive
- Silicone molding
- AHA and IEC compliant
- High-cycle-life contact systems
- DIN 42802-2 safety contacts for connection to the interface panel and customer-specified catheter
- Design and manufacture adapter cables and cables



Handle Assembly

- Design for manufacturing (DFM)
- Design for assembly (DFA)
- ISO3485 QMS for medical devices
- ISO14001 environmental management
- FDA 21 CFR 820 QSR medical device
- FDA 21 CFR 210/211 good manufacturing practice
- Medical device directive 93/42/EEC
- Medical devices regulation (regulation [EU] 2017/745)
- Japan QMS MHLW ordinance No. 169
- China CFDA YY/T 0287 medical devices
- Canadian medical devices regulations
- (SOR/98-282)
- Regulated software and APP development
- Lean and Six Sigma methodologies

Distal Probe

Polymicro
- Medical-certified silica optical fiber
- Capillary tubing
- Packaged, labeled and sterilized devices
- ISO13485, ISO14001, ISO9001
- Biocompatible certifications
- Class-8 clean room
- UV-laser finishing

Temp-Flex Coated Wire
- Implantable biocompatible grade
- Fluoropolymer micro-extrusion
- Micro ribbon
- Micro cable bundles

www.molex.com/molex/industry/medical/electrophysiology

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