

CATHETER ASSEMBLY



QUICK OVERVIEW

Electronic catheter designs start with electrical conductors/wires. The number of conductors needed can range from a handful to dozens for a large volume electrophysiology mapping catheter for example. In order to provide the optimum electrical signal quality, usually conductors need to be arranged in twisted pairs, and then built into large arrangements of wire pairs. In many cases, no custom conductors are available from suppliers.

CATHETER MANUFACTURING CAPABILITIES

Avicenna, a brand of Paragon Medical has created custom cable manufacturing production lines in order to supply to customers' specific requirements. We can start with wires as small as 46 AWG (0.0016"). Our wire twister machines produce twisted pair conductors which can be fed directly into cable machines that bundle twisted pairs in volume to the quantity required for the specific application.

This cable building process can continue autonomously and may be over to a mile in length for bulk production. As the cable bundle is finishing, a thin strengthening polymer is regularly braided over the outside of the cable.

At Paragon Medical we work closely with our customer engineering design teams to build a unique extrusion for each application. We also partner with vendors to manage the manufacturing and delivery of the custom catheter extrusions. With a catheter body in hand, our staff inserts the cable bundle that has been cut to the required length. Then the ends of the wires are laser ablated to remove insulation for further assembly.

Many times customers require electrical sub-assemblies that they can bring in-house for final catheter assembly. When this sub-assembly includes electrode conductors, we refer to this as a **spline assembly**.

CATHETER ASSEMBLY



Paragon Medical excels at automated wire ablation of electrodes as well as welding the conductor inside the electrode in high volumes. Nitinol frames can be laser-cut as per requirements, and utilized in an assembly for final spline shaping. Laser ablation is utilized to drill small holes in the polymer tube sleeve material for the placement of the wires.

Paragon Medical also uses a unique swedging process to bring the electrode OD down to the spline diameter to facilitate smooth ODs on the catheter spline. Utilizing excimer, solid state and Nd:YAG laser allow for choosing the best laser processing for the application including all these processes.



The ends of the wires are usually attached to further solid conductors. From a commercial standpoint, we will attach a flex circuit with as many conductors as wires via soldering. We can solder these conductors with a minimal gap of 0.0020" between solder pads. Sometimes active components on the distal end of the catheter require soldering a sensor connector further into the catheter. On the proximal end of the catheter we can leave the wire hanging if the customer

requires a sub-assembly or we can connect the wires to connector components like PCBs for card edge technology connector designs. Paragon Medical will design specialized connectors for customer applications if the customer prefers custom offerings for better fit, form and function capabilities. We will also manage the molding vendors to fully complete connector assembly.



Once the catheter is assembled, joints are encapsulated with epoxy or adhesives. Sometimes heat shrinks are added over the joint if required.



FUNCTIONAL TESTING

Electrical testing

We perform a wide range of electrical testing. Typically, requirements call for simple electrical conductivity checks from the distal electrode to the connector conductor location. Dielectric strength testing and active functional component testing are often required.

Mechanical testing

Mechanical testing might include deflection testing or strength testing. Dimensional inspection is also performed for all applicable requirements.



Mechanical catheter shafts are utilized for delivery catheters. Various metal components are purchased and inspected for conformity. Sometimes flexible laser cut tubes are required for deflection and strength while torquing to deliver implants. Some sections of the assembly might be simple metal tubing but other sections for long distance flexibility might be manufactured torque cables. Laser welding is the joining method of choice for most of these assemblies. Once all the pieces are brought together, cleaning of the assembly and passivation are requirements within our facility.

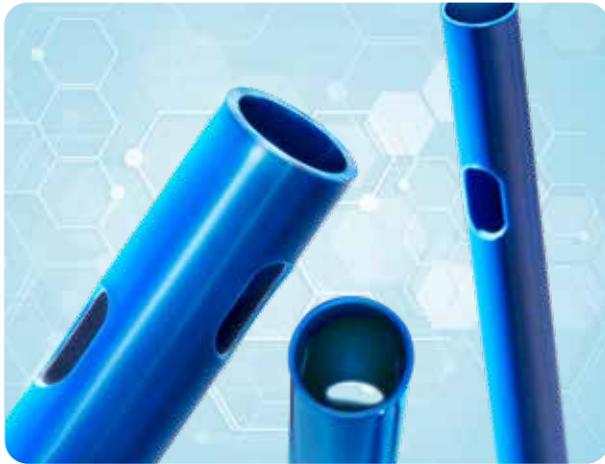


Securely packing the catheter assembly for sterilization and delivery is critical. Paragon Medical designs innovative custom packaging and tooling for package solutions. If the sub-assembly requires, we use custom spools and automated spooling for catheter sub-assemblies.

Paragon Medical supports complete process validations including catheter manufacturing lines as well as supplier managed vendors. Writing protocols, performing the measurements and inspections, and documenting the results are all part of the capabilities.



OVERVIEW MANUFACTURING CAPABILITIES



Cable harness manufacturing

- Twisted pairs
- Bundling groups into cable
- Over braiding for strength
- Wire capability down to 46AWG (0.0016")

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Wire soldering

- Vary fine pitch to 0.002"
- Solder to flex circuits
- Solder to PCBs
- Solder to active electrical components

Vendor management

- Extrusion inspections
- Molding tool design
- Mold inspections
- Validation oversight

Spline assembly

- Polymer tube cutting to length
- Ablation hole drilling into polymer tubing
- Fine wire insulation ablation
- Laser welding of fine wire to (Platinum Iridium) electrodes
- Stringing
- Swedging (electrode rings over poly tubing)
- Nitinol frame design & laser cutting
- Lasers utilized: Excimer, Solid State & Nd:YAG

Electrical connector

- Design
 - Overall
 - Mold
 - PCB
- Soldering
- Mechanical assembly

CATHETER ASSEMBLY



Catheter assembly

- Wire management
- Wire routing
- Mechanical assembly
- Adhesive and epoxy bonding
- Waterproof encapsulation of joints, active electrical components, and PCBs
- Shrink wrapping
- Multiple coating
- Sensor assembly
- Connector assembly

Ridged or flexible delivery catheter assembly

- Vendor management
- Flexible shaft laser cutting
- Laser welding
- LaserSwiss component manufacturing
- Pull strength testing
- Cleaning and passivation

Packaging

- Design
 - Fixture
 - Tray
 - Spool
- Loading automated or manual

Testing

- Electrical conductivity all elements
- Hipot (dielectric strength)
- Capacitance
- Functional components
- Overall catheter
- Stresses
- Leak check
- Deflection
- Force

CATHETER ASSEMBLY



OUR MANUFACTURING CAPABILITIES IN SUMMARY



Key capabilities

- Small wire cable design & manufacturing
- Small wire handling (placing & soldering)
- Polymer ablation
- Automated electrode ring welding
- Laser welding
- Laser cutting
- Electrical connector design
- Medical interconnects

Manufacturing volume capabilities

- 10s per week in development
- Months to year for development
- 100s per week after validation
- 5k or more per week in production

Key manufacturing locations

- Montevideo, MN, UNITED STATES
- Jackson, MN, UNITED STATES
- Reynosa, TA, MEXICO
- Waukegan, IL, UNITED STATES



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