RESOLUTION MEDICAL

Comprehensive Manufacturing for Complex Medical Devices

We offer sub-assembly through full finished goods manufacturing supporting commercial launch through full scale production.

At Resolution Medical, we have a 36,000 square foot facility dedicated to manufacturing, FDA registration, and **decades of experience.** Our team is well-prepared to accommodate a wide range of manufacturing needs **from low to high volume,** and our collaborative process emphasizes transparency and open communication to ensure the success.

We have multiple ISO Class 7 Cleanrooms providing a controlled environment for precise finished goods assembly, sterile barrier packaging, product labeling, inspections, and cleaning. We also offer a UL certified electrostatic discharge area, non-clean room manufacturing, and a distribution center designed for efficient logistics, all aimed at assisting you in the most effective way possible.

Our Specialties:

- Class I, II, & III Medical Devices
- Complex Device Assembly & Testing
  Active Implantables, Catheter Delivery Systems, Diagnostic Systems, Sub-Assemblies & Components
- Sterile Kitting, Packaging, and Labeling
- Sterilization Management & Product Release
  Distribution, Supply Chain Management, Continuous Improvement & Lean Manufacturing, Quality, Regulatory, & Clinical Support, and More

New Product Introduction (NPI) Process Development: Structured Product Transfer

We offer three proven transfer methods, all of which are backed by program managers, NPI/ manufacturing and quality engineers together with our supply chain experts.

Direct Transfer
Achieve consistency with the existing setup by transferring all components, suppliers, and documentation without a hitch, ensuring minimal disruption.

Transfer with Process Improvements
Refinements and supplier enhancements optimize cost and quality, leading to a larger return on investment. Focus on process development without impacting design.

Transfer with Design Improvements
Delve into process and design improvements for manufacturability resulting in the most comprehensive transformation with the potential for significant returns.

Quality is a personal pledge at Resolution Medical:

When it comes to medical device manufacturing quality is paramount. Our quality management system (QMS) ensures every step of our process is precise, repeatable, and documented per ISO 13485:2016 and FDA guidelines. Regardless of your organization's quality system maturity, we stand ready to support you at every stage.

Your device built with on-site engineering support.

In-House Manufacturing Capabilities, Matched by Engineering Expertise

Implantables
- Hermetic glovebox welding
- Resistance Welding
- Soldering
- Baking & Cleaning
- Hermetic Leak Testing
- Electrical Testing

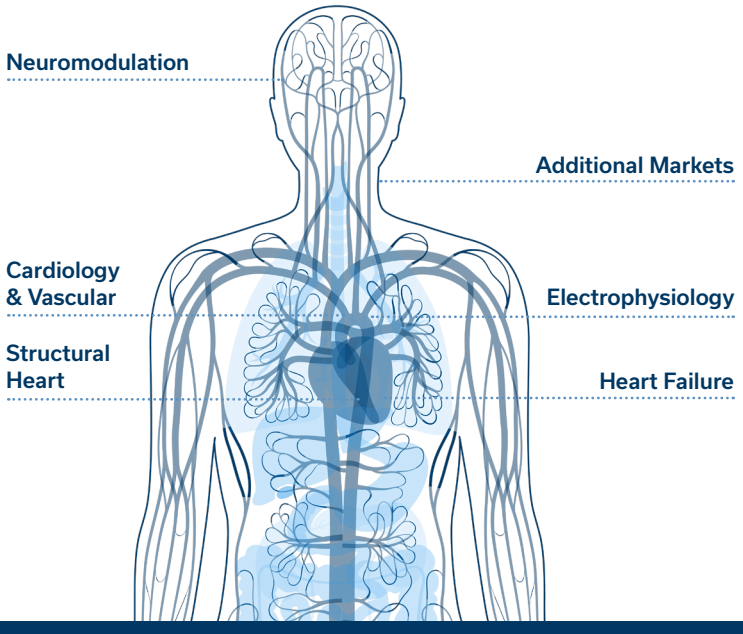
Laser Cutting & Welding
- Metals (Nitinol, Titanium, Stainless, Platinum)
- Plastics (Peek, Nylons, etc.)
- Sub-assemblies
- Testing and analysis
- Production Glovebox for hermetic welds

Catheters
- Braiding & Coiling
- Reflow
- Bonding & Tip forming
- Resistance and Laser welding
- Handle Assembly
- Testing

Additive Manufacturing
- Multiple Carbon M2 printers
- Formlabs and Stratasys printers
- Biocompatible and sterilizable materials
- Low to mid-volume production efficiencies
- Optimizes component complexity through quick-turn iterations
- Compliments Injection Molding

Molding
- Vertical and horizontal presses
- Insert Molding (hubs, tips, handles)
- TPE, TPU, PEEK, Nylons, Pebax, HDPE, Polycarbonate, etc.
- Exclusive quick change tooling platform designed to lower tooling costs and reduce lead-times on smaller part geometries
- Complements Additive Manufacturing

And More.



We Serve a Wide Range of Markets

Our expertise spans a wide range of markets. From intricate cardiac interventions to cutting-edge neurological therapies, our team has the in-house experience, technology, and anatomical understanding to accelerate manufacturing production.

EARLY PROTOTYPING | DESIGN & DEVELOPMENT | TECHNOLOGY TRANSFER | COMMERCIAL MANUFACTURING

RESOLUTION MEDICAL

Get a Quote on Your Project Today: resolutionmedical.com