

How will your medical device come to life?

With a single vendor

that makes your entire device, from the sharp metal “business end” to the molded plastic handle and everything in between.

With a dedicated partner

offering unparalleled experience in manufacturing components and medical devices.

With end-to-end manufacturing solutions

encompassing DFMA, prototyping, product development and production all the way to packaging.

With stringent quality standards

built into every step.



Where medical devices come to life.®

END-TO-END SOLUTIONS FROM

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MANUFACTURING PARTNER

Prototyping and Product Development

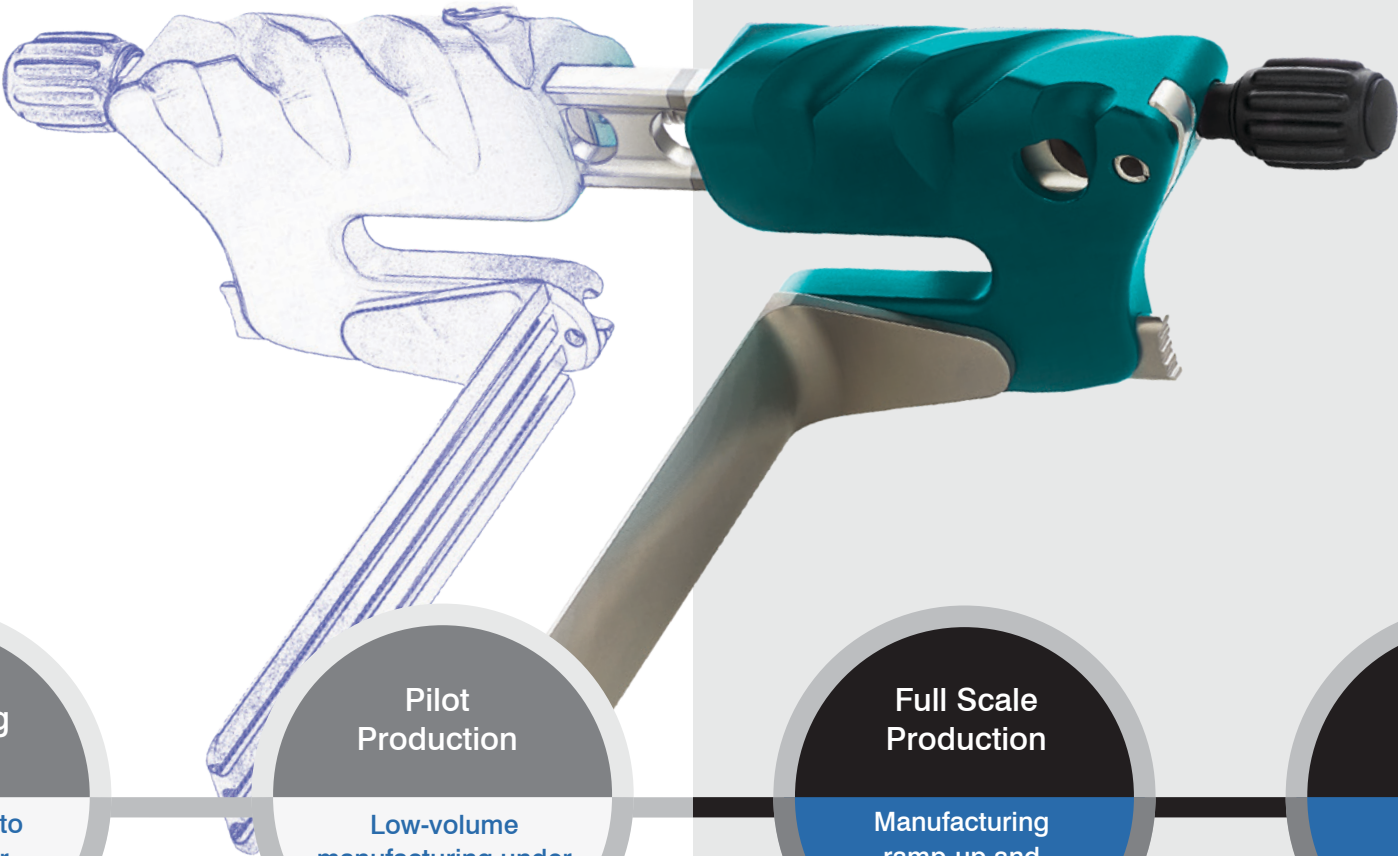
The first step in offering end-to-end manufacturing solutions is our GENESIS Tech Center® product development service.

Featuring dedicated resources including production-level machines and product development experts, our GENESIS Tech Center services are focused 100-percent on prototyping, development, and pilot production.

Manufacturing Capabilities

Manufacturing of complex components to finished devices, taking advantage of robotic automation and Class 7/Class 8 cleanrooms for production, assembly, and packaging.

Quality is infused at every step with ISO 13485 certification, FDA QSR compliance, FDA contract manufacturer registration, and a full quality staff to support process development and production.



Design for Manufacture and Assembly

Cost-effective, scalable refinement of product designs

- Review design, materials, processes
- Identify cost-drivers and potential risks
- Complete program management

Prototyping

Get products into clinical trials or production sooner

- Prototype on the same equipment used for lean production
- 3-D prototyping available
- Seamless scale-up to pilot or full production

Pilot Production

Low-volume manufacturing under tight deadlines

- Same range of capabilities and quality standards as full-scale production
- Seamless scale-up to full production

Full Scale Production

Manufacturing ramp-up and production

- Wide range of capabilities
- Full program and quality management
- Continuous improvement for year-over-year cost reductions

Assembly

Full device assembly

- Thermal and ultrasonic bonding
- Adhesive and UV bonding
- Validated cleaning, passivating, electropolishing
- Soldering and testing for electronic applications
- Shrink tube application
- Pad printing and electrochemical marking
- Robotic automation

Packaging and Sterilization

Complete packaging and sterilization management

- Class 7 and 8 cleanrooms (for molding, assembly, and packaging)
- Pouch and tray sealing, IFU, labeling and more
- Bulk and individual unit packaging
- Management of Gamma and ETO sterilization



Medical Specialties

Cardiac care
Diabetes
Neurology
Ophthalmology
Orthopaedics
Pain management
Radiology
Women's health
and other medical
specialties

Examples of Use

Our devices play a role in many interventional, minimally-invasive and other procedures including arthroscopy, endoscopy, joint reconstruction, biopsies, and drug delivery.

Product Examples

Cannulas
Catheters
Fixation systems
Implants
Mandrels
Needles
Probes
Stylets
Wires and many more

Technologies

With a wide range of manufacturing technologies we can make your complex components and complete, finished devices.

CNC grinding
CNC milling & turning
CNC Swiss machining
Gundrilling
Injection/insert molding
Laser processing
Metal forming
Nitinol shape setting
Stamping
Wire & Sinker EDM

Wire and Hypotube Shipped Overnight

We offer over two million feet of coated and uncoated stainless steel wire and tubing, plus Nitinol wire for same-day shipment. Custom cutting, grinding, and finishing is available in a few days.



QUALITY SOLUTIONS SPEED SERVICE

www.tegramedical.com or 508.541.4200



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