



Where medical devices come to life.SM

Services and Capabilities

SERVICES OVERVIEW

Tegra Medical is an end-to-end contract manufacturer of finished medical devices and complex components. We offer a range of services from Design for Manufacture and Assembly (DFMA) and prototyping to full production, including final device assembly and packaging.

GENESIS TECH CENTER® PRODUCT DEVELOPMENT

- Dedicated equipment and personnel
- DFMA
- Prototyping
- Pilot production

ASSEMBLY PROCESSES

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

FINISHED DEVICES

- Class 7 and Class 8 cleanroom molding, assembly and packaging
- Sealed tray and pouch packaging
- Finished product labeling
- Sterilization logistics management

PROJECT MANAGEMENT

- Program managers assigned from development to production
- Process validation including Production Part Approval Process (PPAP)
- Supply chain management
- Kanban agreements
- Continuous improvement for year-over-year cost reductions

QUALITY MANAGEMENT SYSTEMS

- ISO 13485:2003 certified
- FDA QSR-compliant
- Registered with the FDA as a contract manufacturer
- Full quality staff to support process development and production operations



CAPABILITIES OVERVIEW

Tegra Medical offers a wide range of manufacturing capabilities with metal and plastic. We share these capabilities across our four locations to increase flexibility and mitigate risk. The table below highlights some of our key manufacturing technologies and associated capabilities.

| KEY TECHNOLOGIES | CAPABILITIES |
|-----------------------|---|
| CNC milling | 4- and 5-axis / instruments and implants |
| CNC lathes | Up to 4" diameter |
| Swiss machining | From .020" to 1" diameters |
| Wire EDM | .004" to .012" wire |
| Sinker EDM | Micro hole drilling included |
| Laser cutting | Tubular and flat components |
| Laser welding | All metals / miniature components |
| Laser marking | Marking and engraving |
| CNC grinding | Custom needle, biopsy and surgical cutting |
| Electrochemical | Burr-free cutting and grinding |
| Stamping | Progressive die stamping |
| Injection molding | Insert molding / Class 8 cleanroom |
| Metal forming | Swaging, bending, flaring, coining |
| Cleaning systems | Validated cleaning system in all facilities |
| Nitinol shape setting | Wire, tube, and sheet metal |

| MATERIALS | |
|-----------------|----------|
| Metals | Plastics |
| Stainless steel | PEEK |
| Nitinol | PTFE |
| Titanium | ABS |
| CoCr | Parylene |
| MP35N | Radel |
| Platinum | Pebax |

Tegra Medical® is an end-to-end contract manufacturer of medical devices. From the "business end" to the handle and everything in between, we manufacture the whole device, then finish, assemble and package. Tegra Medical - Where medical devices come to life.

