



Where medical devices come to life.SM

Prototyping and Development

Prototyping and development services that get your medical devices to market sooner — and smarter

Launching a new product is a huge commitment. Tegra Medical partners with you by providing dedicated GENESIS Tech Center[®] resources that are focused 100-percent on prototyping, development and pilot production. These product-launching services are the first step in the end-to-end manufacturing solutions we offer, working in concert with full production, assembly and packaging. From the “business end” of your device to the handle and everything in between, we’ll tackle your project from start to finish.

Our headquarters in Franklin, MA is the original home of our GENESIS Tech Center expertise, with a dedicated 18,000-sq.ft. space. We’ve now extended the product-launching concepts to all our locations.

QUICK TURNAROUND PROTOTYPING FOR RAPID RESULTS

When you’ve got a design for your medical device in hand, you don’t want to be delayed by a contract manufacturer’s inability to iterate prototypes quickly. Tegra Medical’s prototyping and development services are all about speed — manufacturing your prototypes to spec so you can get them into the lab or clinical trials and ultimately to market sooner.

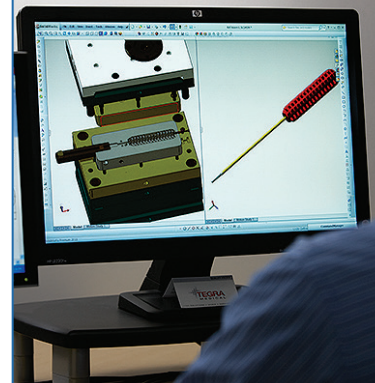
We use the same type of manufacturing equipment as our lean production environment. So once your design is frozen and the manufacturing process has been established, the scale-up for your commercial launch is seamless.

REDUCE COSTS AND INCREASE QUALITY WITH DESIGN FOR MANUFACTURE AND ASSEMBLY (DFMA)

You’re feeling good about your medical device design, but you’ve got questions. Is it manufacturable? Can you achieve the target cost your sales and marketing team is demanding? We’ll help you find the answers.

The best time to take cost out of a product is during the design stages. We can help you quickly assess different approaches and settle on the best solution to meet your project needs. And when the design is frozen and ready for production, we’ll handle all the qualifications and validations. We use products including SolidWorks[®], AutoCAD[®], MiniTab[®] and Microsoft[®] Project to support your programs, and have a machine shop with a skilled staff of process development engineers and highly-experienced technicians.

DFMA reduces cost, increases quality and shortens the development cycle of your medical device. Together, we can explore alternatives in processes and materials, and immediately see the cost impact.



COMPLETE PROJECT MANAGEMENT

Our experienced project managers provide a single point of contact for your team to move through design iterations smoothly and efficiently. And as your design advances, we can support your quality system requirements with process failure mode and effects analysis (PFMEA), Design of Experiments (DOE) and process control plans.

ACCELERATE TIME-TO-MARKET WITH PILOT PRODUCTION

Our services include a broad range of manufacturing capabilities for metals and plastics under one roof and a dedicated staff of machinists, technicians and operators. Our pilot production uses the same machining capabilities as our regular production facilities, including:

- Laser cutting, welding, drilling, engraving
- Wire and sinker EDM
- Precision grinding
- CNC milling and turning
- 3D printing
- Polymer and metal manufacturing
- Forming, swaging, bending, flaring, coining
- Nitinol shape setting
- Cleaning, finishing, passivation and electropolishing
- Cleanroom and white room assembly and testing

Pilot production can help you meet tough deadlines for product or process evaluations, one-off product builds and prototypes.

We can pilot-produce single-level components or finished assemblies, and offer complete documentation and traceability as required, but also have the flexibility to adapt to your product and schedule requirements.

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.

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