Digital Manufacturing for Medical Applications

PROTOLABS
Manufacturing. Accelerated.

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Medical manufacturing is one of the fastest growing industries.

Medical manufacturing is critically important because every component has the potential to save lives. That's why ensuring the quick, reliable delivery of high-quality parts is a priority for us. With decades of experience, Protolabs is committed to bringing our expertise to every medical part we produce.

Attributes of a Quality Medical Manufacturer

It's likely that you have worked with both traditional and digital manufacturers. If you're in the medical vertical, the difference between the two can mean the difference between a rapid go-to-market strategy and one that leaves you on your heels waiting for your parts. The reasons for working with a digital manufacturer are considerable and directly relate to the medical sector's need for speed, quality, compliance, and the ability to work with high requirement parts, such as those needing expanded manufacturing capabilities.

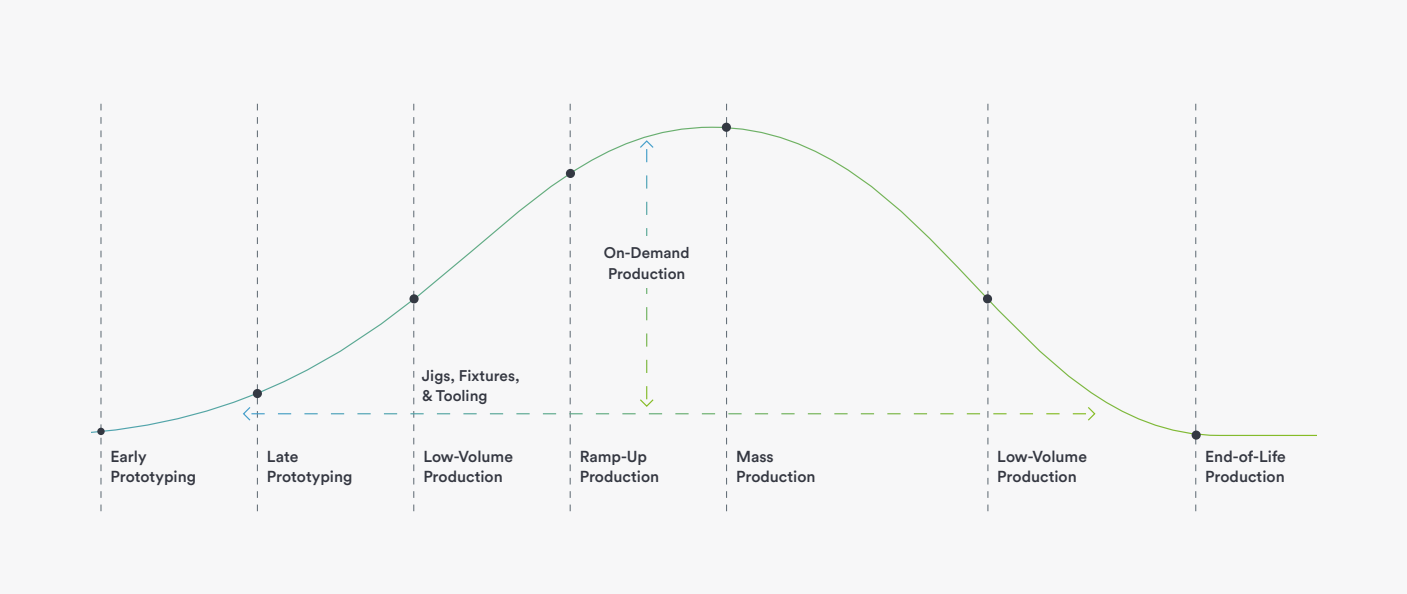
Comparing Traditional and Digital Production Methods

Traditional	Digital
Focuses on older manufacturing processes	Leverages AI, machine learning, IoT, and more to optimize workflow
Data input, process monitoring, and material handling all manual	Automation informs and improves efficiency, productivity, and quality
Linear workflow with minimal—if any—real-time adjustments	Integrated sensors provide metrics for data analysis while monitoring manufacturing in real-time, enhancing opportunities to adjust design to address issues
Tasks tend to be siloed, rather than informing part of a process	Protolabs' digital thread is a workflow that is purely digital. From CAD and quote to production and shipment, it's possible to do almost everything within the cloud, yielding higher consistency, reducing back-and-forth, and maximizing speed at all stages
Focus is on mass production, not iteration	From prototyping to production quantities, the digital manufacturing workflow is essentially the same
Ingrained internal processes make it difficult to react to technological trends and changes in customer demand	Nimble and responsive to customer and industry changes

The Five Stages of Manufacturing in Protolabs' Digital Thread

All four of our manufacturing services—injection molding, CNC machining, 3D printing, and sheet metal fabrication—benefit from our digital thread. To that end, the fastest and most streamlined way to partner with Protolabs is straight through from the early stages of design iteration, through prototyping and production, followed by end-of-life production.

Working with us through the following product development stages ensures seamless transitions through the lifecycle of your part.



Iterative Design

- Instant quoting with design for manufacturability analysis
- Hundreds of metal and plastic materials
- Enhanced finishing and post-processing options

Iterate with confidence. Our digital quoting platform delivers near-instant DFM feedback so every revision moves closer to a production-ready design. With a wide range of materials, finishes, and optional inspection documentation, you can validate decisions at each step and progress from prototype to production without losing momentum.

Rapid Prototyping

- Parts in hand within days
- Form, fit, and function testing for agile development
- Move with ease from 3D printing and machining to molding

Medical parts often come with high requirements that must be addressed from the prototyping stage. With rapid manufacturing across all of our manufacturing services, you can move from design to parts in hand in just days—exactly the speed needed to meet urgent demand. Every part we produce is measured against your most critical specifications to ensure it performs as designed.

Start with speed, finish with scale. Rapidly iterate in 3D printing or CNC machining, then shift your validated design into injection molding with confidence. Our applications engineers align DFM across processes to make the handoff seamless. With our free Consultative Design Service (CDS), you'll streamline tooling decisions, avoid rework, and reach molded parts faster at lower cost.

Early Production

- Cost-efficient bridge tooling before production
- Pilot runs and market testing to validate design
- No minimum order quantities (MOQs)

If you're not ready to commit to mass production, early production provides a controlled, flexible path forward for medical programs. Build production parts in small batches so you can evaluate form, fit, function, and user experience while keeping timelines moving.

To support your quality plan, we offer optional inspection reports, certifications, and documentation aligned to medical expectations. When you're ready to scale, we streamline the transition by helping you move from rapid prototyping to production smoothly, on your schedule.

Full Production

- Dedicated account manager with production expertise
- Large orders up to 1 million+ parts are possible
- ISO 9001:2015 | ISO 13485:2016 | AS9100D | ITAR

Scaling to full production carries risk—especially at high volumes. We help you manage that risk through clear communication and dedicated support. You'll work with an account manager who understands your design goals and procurement requirements. While we're a digital manufacturer with a robust e-commerce platform, every production order is treated as unique. Our experienced account team partners with you offline to align on specifications, timelines, and documentation.

Ultimately, you can move forward confident that your parts are produced using validated manufacturing processes with documentation aligned to medical industry regulations and standards.

End-of-Life Production

- Reduced cost with parts on demand and as needed
- Resourcing for maintenance, repair, and operations (MRO)
- Transition into new product introduction (NPI) for extensions

Earlier, we mentioned we have no MOQs. That helps you at multiple stages in your product life cycle, but for many companies it's especially crucial when your product is approaching end-of-life. With Protolabs, you can get the parts you need on-demand whenever you need them, keeping a tight rein on costs.

Also helpful is that we can manage all production aspects of a given product's ramp-down to ensure that you can still order the quantities you need and avoid maintaining an inventory of unneeded parts. Simply put, we are there for you to help transition to a revised part design for your existing product or for new product introductions.

It's important to note that when you work with us through these five stages, you know the parts made at production quantities will be of the same quality as your approved prototype. Our digital thread collects manufacturing data continuously, and it allows us to adapt learnings from each stage to improve quality while accelerating our processes, gaining consistency along the way. All of these are critical qualities for medical manufacturing.

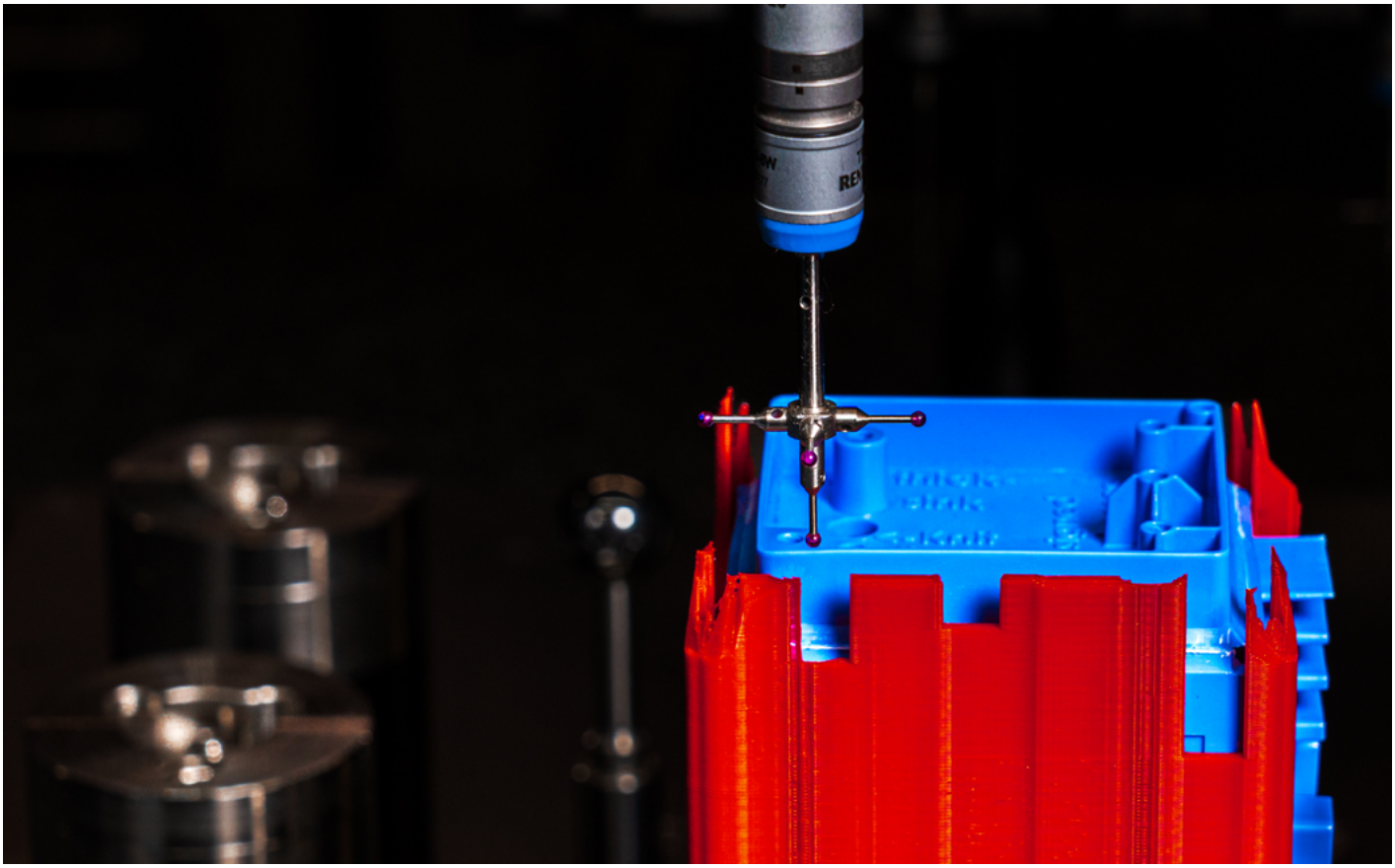
Working with Protolabs for Medical Parts

The process starts in our digital quoting systems, where you can submit your CAD file along with any specific needs for your part(s), such as finishing. Sometimes, parts require more detailed information than you can easily put into a CAD, so to maintain the clarity of what you need us to manufacture, you can include drawings/prints that provide those details.

Speaking of production quantities, Protolabs offers decades of manufacturing knowledge, and an optimized workflow through our digital thread. We have massive capacity and scalability thanks to the combination of multiple factories and our network of manufacturing partners.

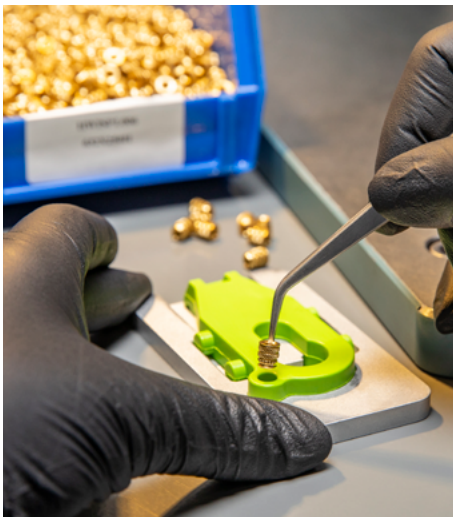
Also, we offer a variety of reporting options, such as:

- Critical to Quality (CTQ) with Partial First Article Inspection (FAI)
- CTQ with Capability Study
- Digital Inspection Reports with Full FAI
- Production Part Approval Process (PPAP)
- Customized reporting available upon request



Secondary Operations Post-Processing Services

When designing parts, you may need to apply various finishing options after your parts are manufactured to improve mechanical properties, enhance surface finish, facilitate the assembly process, or further customize parts. Another benefit? You can streamline your supply chain— prototyping to production—through a single, digital manufacturing parts supplier. Here's a look at what is available across molding, machining, 3D printing, and sheet metal fabrication.



Injection Molding

- Mold Texturing
- Threaded Inserts
- Pad Printing
- Laser Engraving
- Basic Assembly
- Part Cleaning
- UV Part Printing

CNC Machining & Sheet Metal Fabrication

- Powder Coating
- Wet Paint
- Bead Blasting (Machining Only)
- Part Marking
- Press Fit Hardware Installation
- Part Assembly Welding and/or Hardware (Sheet Metal Fabrication Only)

3D Printing

- Clear Coating
- Plating
- Dyeing
- Decaling
- Texturing
- Polishing
- Heat Treating
- Secondary Machining

Why This Matters: Factors Driving the Growth of Medical Manufacturing

Aging Population

Increasingly, senior citizens are working to improve and extend their lives with devices to help maintain mental acumen and physical capabilities. Traditional assistive devices such as wheelchairs and walkers will always be in demand, but more technical products are driving rapid innovations in the sector. For example, hearing aids—which are now an over-the-counter product—are a growth area, as are devices to assist with chronic conditions such as heart disease, arthritis, and diabetes. To address these needs, medical equipment companies are designing technologically advanced monitors to evaluate blood glucose levels, your heart, and other measurable physical metrics.

Healthcare Spending

A Kaiser Family Foundation study forecasts a 50% increase in healthcare spending through 2032. While people are spending more each year on medical care of all sorts, inflation, rising insurance premiums, and more expensive cutting-edge testing technology all play a part in the rapid increase.

Emerging Markets

One factor that is crucial to consider is the growth of wealth in countries outside the West, and their citizens' needs/desires for improved healthcare systems, for people at all economic levels. For example, according to India's National Health Accounts Estimates, the Global Health Expenditure as a percentage of GDP increased 39% between 2013 and 2022. Other countries experienced similar rises. More spending globally and in the U.S. brings more money into the healthcare manufacturing sector.

Technological Advancements

While medical innovations certainly improve outcomes for people requiring prosthetics, hip/knee replacements, 24/7 monitoring of vital signs, and more, companies designing medical devices pay for that innovation, which repays for itself over time.

The process of rapidly iterating critical parts (prototyping) before moving to production quantities is not inexpensive, but it is fundamental to a product's success in the marketplace. Digital manufacturing provides a go-to-market pathway moving from rapid innovation to consumer product in half the time of a traditional manufacturing route.

The Protolabs Advantage
We don't believe in standing still, and we have a reputation to uphold as the fastest and highest quality manufacturer in the world. We're always adding and improving the capabilities we offer you.

This guide provided an overview of our offer but to get a granular perspective, contact a member of the applications engineering team at customerservice@protolabs.com or 877-479-3680. We look forward to working with you.

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