Digital Manufacturing for the Medical Industry

Volume 2: A deeper dive into digital manufacturing for prosthetics, dentistry, implants, medical devices and surgical instruments.

PROTOLABS
Manufacturing. Accelerated.

INTRODUCTION

Digital manufacturing is continuing to support the medical industry to quickly and easily develop designs and whip up new prototypes, proving invaluable to the innovation and R&D projects within the industry.

In our first volume of "**Digital Manufacturing for the Medical Industry**", we talked about how the technology has supported the industry and what the future looks like. Covering current and future medical applications, a toolkit for designing for the industry, how to move from prototype to production and real-life examples, this edition is your one-stop guide to learning about digital manufacturing in the medical industry.

In this volume, we explore in greater depth the evolution of digital manufacturing in specific sectors, covering prosthetics, dentistry, implants, medical devices and surgical instruments.

WHAT IS DIGITAL MANUFACTURING?

The term digital manufacturing refers to an integrated approach, combining computer software (for CAD upload, automated quoting and design feedback) and connected manufacturing systems, accelerating part creation and product development using 3D printing, CNC machining (for low volumes) and injection moulding (for higher volumes).

DIGITAL MANUFACTURING AND THE FUTURE OF DENTISTRY

Major dental work traditionally takes days of time and effort but as technology evolves even complex treatment is possible in just a few hours thanks to digital technology.

Advances in 3D imaging and modelling technologies such as cone beam computed tomography and intraoral scanning and the history of using CAD/CAM technologies in dentistry is opening up new possibilities.

While CAD/CAM is not new to the industry, the digital thread that it provides and the advances in both milling and 3D printing technologies is making a real difference.

Traditionally the results of such scans, or even wax impressions, would be taken away and if for example the patient needs a new crown then it would take days to process and mill it. The patient would have to make several visits to complete their treatment.

It is no wonder that many of us fear that regular check up with the dentist, yet alone the prospect of major treatment.

The good news is that milling technology has evolved to reduce this time to within a day with minimal post processing. But the real disruptive technology that reduces this time even further and promises to revolutionise dentistry is in [3D printing].

Dental 3D printing applications

Dentists are really beginning to wake up to all the possibilities that 3D printing offers them. It is suitable for creating practically any type of dental appliances and implants. Let's run through just a few examples.

Medical modelling

Anatomical modelling was one of the first medical applications of 3D printing. Dentists can scan the patients jaw and 3D print an accurate model for study before deciding on treatment and surgery. This is ideal for patients who have serious injuries or an unusual anatomy.

For other procedures, such as fixed and removeable prosthodontics a technician can take the scan and plan the whole treatment before designing the restorations in CAD. This means the treatment is planned in a virtual environment before it is even started.

Retainers, aligners and guards

By using transparent resins, you can use dental 3D printing to create virtually invisible retainers, aligners and guards. Thanks to the combination of accurate scanning and the ability of 3D printing to create virtually any geometric shape these can be customised for a close fit to minimise discomfort. The result is a pain free, aesthetic solution.

Surgery guides

Using high resolution 3D printers and materials, dentists can create accurate drilling guides that perfectly fit into a patient's mouth. This will make surgery faster and also reduce that chance of any errors.

Implants

Using digital imaging and data you can now manufacture an exact copy of a patient's missing tooth for a new implant. 3D printing allows you to create extremely complex geometries such as bone like morphologies that other manufacturing simply can't do. While milling still has its place in this area of dentistry since it can use harder wearing resins such as zirconium dioxide, expect to see some interesting material advances in 3D printing including antibacterial tooth implants.

Bond trays

Again, using the digital data from a patient's scan you can create bond trays to hold braces in place while they adhere to their teeth. This allows dentists to work faster with fewer errors so there is less time involved for the patient.

Dentures

Traditionally developing dentures for a patient will require several visits to mould, design and fit them. Even then some patients will find them uncomfortable to wear and use. Using digital manufacturing technology ensures that they are more accurate and comfortable to wear. The process of developing them is also far faster which saves both time and money.

Dental tools

Because 3D printing is ideal for low volume manufacturing you can develop surgical tools that are custom made to either your needs or perhaps for a particularly tricky operation.

Nowadays you can 3D print virtually any material – whether resins, ceramic or metal, so the opportunities to improve dental practice for the patient and the dentist are huge.

When you add the development of new biocompatible materials and the improvements in scanning technology then the whole future of dentistry will be revolutionised. In the near future even some of the more complex treatments that currently take several appointments will be faster and, in some cases, even be completed in one visit.

Just like manufacturing, the dental industry is entering a new digital age that promises faster turnarounds and better solutions for both the dentist and the patient. When you bring together scanning, digital design and visualization, CAD and add in the advances in milling and 3D printing then it's an incredibly exciting time to be involved.

SMILEDGE

When a dentist from Liguria, wanted to create a device that could sanitise a child's dummy and dental equipment, he turned to Protolabs for support. The first 3D printed prototype was made possible in just a few days, and once compatibility tests had been passed, 2000 devices were manufactured using injection moulding, in two different colours, in two days.

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3D PRINTING AND CUSTOMISED MEDICAL IMPLANTS

3D printing is making major inroads into customising medical implants for individuals. It allows implant manufacturers and sometimes even hospitals to create complex geometries and patient specific solutions that saves the surgeon time and improves a patient's outcome.

Largely used for orthopedic surgery, [3D printing] is starting to break into other areas such as heart surgery and even replacement retinas in eyes. With research into bio printing there is even the chance that the future could bring a 3D printed heart. What was once science fiction is rapidly becoming science fact.

Just like industrial 3D printing, the process starts with digital data; in this case a computerised tomography (CT) scan. This is an imaging technique that uses x-ray measurements taken from many different angles to produce an image of the body. It is hailed as a way to see inside the body without surgery. The surgical team then use this information to plan and produce custom designed implants using 3D printing, often, but not exclusively, using titanium or stainless steel.

Better patient outcomes

At the moment most applications involve musclo skeletal injuries. The human body has 206 bones all of which support our body or protect vital organs, so when they are damaged this can severely affect a patient's health and quality of life.

Using traditional methods creating an implant for a patient requires multiple medical appointments. At a time when a damaged bone could be causing the patient pain, reduce their mobility and affect their lifestyle, this long wait for an implant can be incredibly uncomfortable.

It also means that the implant is not ideal as it's not tailored to their body. For the skull it could even mean that the patient is fitted with a mesh implant, which can be weak and lack precision.

This places the surgeon in a difficult position since they often need to not only operate on the patient but spend time adapting and reshaping the implant to make it fit better.

Fortunately, using digital imaging technology to produce customised 3D printed implants is making this process far faster for the surgeon and the result better and more comfortable for the patient. It also means that hospitals can reduce their inventory of expensive implants on site.

While additive manufacturing is still very much at the forefront of current medical technology and is not widely available, it is progressing rapidly.

Some applications:

Common examples of 3D printed implants include for the spine, shoulder joints, hip implants and for facial surgery and dental implants.

The skull and facial implants are good examples that require highly customised solutions. In the Netherlands for example, doctors have replaced the whole top of a 22-year-old woman's skull with a 3D printed implant instead of a traditional option. In studies doctors found that 3D-printed skull implants were cosmetically superior, and patients often had better brain functions as a result.

New applications and materials

While titanium and stainless steel are favourite materials for orthopedic implants there is also progress in using high performance plastics such as PEEK. PEEK expands opportunities for the technology to move off the shop floors of medical device manufacturers and into labs at hospitals and clinics worldwide.

This opens up the possibility that a patient could be scanned, an implant designed and discussed in a virtual 3D environment, produced on site and then surgically implanted; all in the space of a couple of days. And because its design is based on the patient's individual needs the surgery itself will take less time.

Meanwhile research is continuing to extend how far such customisation of implants can go.

Heart surgery

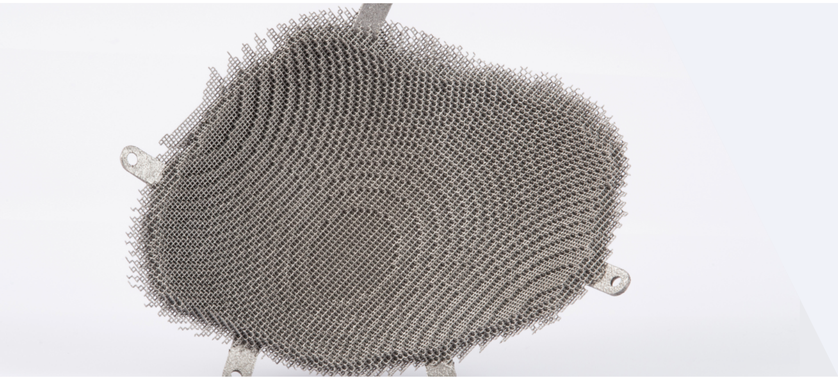
Recently, we have seen examples of implants for parts originally made from organic tissue. A good example is a heart valve prosthesis made from silicone AM. Created by a team of researchers from ETH Zurich, these artificial 3D printed heart valves make it possible to replace valves in an aging population. Early results are promising, although such a solution is probably still a decade away.

Beyond this 3D printing technology offers new ways of working with other implant materials. This includes research in Australia for 3D printing stents using nitinol. This is a metal alloy of nickel and titanium that will resume its intended shape after deformation. While surgeons are already using this material for arterial stents, 3D printing will enable more sizes and configurations to better suit patients' needs.

Revolutionising medicine

Clearly the idea of tailoring implants to a patient using 3D printing opens up numerous opportunities for more personalised healthcare. While many of these advances could be a few years off yet, the possibilities are almost limitless. Other examples of research include the production of artificial retinas for eye surgery and the potential of printing skin grafts or even a new heart.

While the latter two examples may not be available in the near future, it does open up a glimpse of what is possible using this amazing technology. Even more than other industries, it appears that the only limitations of 3D printing in medicine is our imagination.



NOVAX DMA

When challenged to develop and manufacture a perfectyly-fitting implant for the cranial area that is able to accomodate permeability to liquids and heat dissipation, Novax DMA and Protolabs experts pulled together to find the solution. The result? a perfectly cut implant tailored to the specific requirements of the patient's condition.

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SURGICAL INSTRUMENTS, AIDS AND MODELS AND THE ROLE OF DIGITAL MANUFACTURING

Digital manufacturing is revolutionising surgery. It provides both surgeons and instrument manufacturers with the information and equipment that they need to achieve better results faster and more cost effectively.

In this blog we take a look at how it is transforming three critical areas:

> its use in pre operation modelling for planning;
> the development of bespoke instruments;
> the development of new disposable surgical equipment.

Anatomical models and templates

The development of anatomical models and patient specific templates to aid surgery starts with digital information, in this case from a scan.

Such models of a patient help medical professionals with preoperative planning, intraoperative visualisation, and the sizing of medical equipment for procedures. They are also used to train medical students and to discuss the operation with patients beforehand. Research has shown that using such models has increased patient consent because it aids their understanding.

3D printing significantly reduces the cost of producing these models which makes it an increasingly viable option.

Using the data from CAT scans to create a CAD, 3D printing can also produce specific surgical guides for a patient to help make surgery faster and reduce errors.

Customising surgical instruments

Creating such single-use, procedure-specific, surgeon-matched tools requires a fast response between surgeon feedback and product development. This is where 3D printing can make a real difference using both digital data from scans and feedback from surgeons to reduce development and production times. It is helping drive forwards a new era of customised patient and surgeon centric medicine at a cost-effective price. Ultimately as technology progresses, we will see surgeons freed up from traditional trays that are typically only updated every few years.

These customised 3D-printed surgical instruments such as scalpel handles, forceps or clamps help surgeons perform better and reduce operating time leading to better outcomes for patients.

Reducing development time for disposable surgical equipment

Another area of huge demand is for single use instruments. Prepackaged, individually wrapped and pre-sterilized, single-use devices offer a convenient, off-the-shelf option.

An obvious benefit for hospitals is that they do not require sterile processing, which can be costly and time-consuming.

The challenge for instrument manufacturers is how to develop new instruments that will meet the rigorous requirements of the medical industry quickly and cost effectively.

The first step is to ensure that the design is manufacturable using your chosen production process. The secret to managing the process quickly and efficiently starts with your CAD.

At Protolabs we have automated this step so that when you upload your CAD into our quoting platform you will get a free analysis alongside a quote within a few hours. If after uploading your CAD you need additional assistance then you can take advantage of our consultative design service where one of our engineers will help you optimise your design for injection moulding.

CONSULTATIVE DESIGN SERVICE

Protolabs' consultative design service helps you update your CAD model to address the manufacturability feedback you received with your quote. One of our experienced engineers will work with you on your part design to improve manufacturability and ensure your part is mouldable.

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The next step is prototyping and feasibility testing to check functionality. This may require several iterations in your design. In the early stages you may use rapid prototyping technologies such as 3D printing. But a word of warning; you need to keep sight of what your final production method will be and keep any future iterations manufacturable using this technology.

You will also need to get regulatory approval and this may involve ramping up the number of products you require. For injection moulding it is possible to keep the part cost down during this process and still achieve what you need rapidly – by which we mean getting your parts within 10 -12 days. How is this possible? The answer is by using aluminium moulds instead of steel.

The chances are that you may need to use different technologies for different phases of prototyping and product development; read our whitepaper "Rapid Prototyping Processes" to find out more.

When you are finally ready for production the volume you need will determine the production process. If it is a few hundred then 3D printing or CNC machining could be the answer. When you get up to a few thousand then consider rapid injection moulding such as our on-demand service.

For mass production, where you need hundreds of thousands of parts then you will probably need steel tooling for injection moulding. But even here you could use our on-demand service to bridge the production gap while you wait for the final production tools. This will help you get your product to market faster and earn revenue more quickly.

Digital manufacturing is connecting everyone in the supply chain for surgical instruments and aids. It means that manufacturing is more responsive to the needs of surgeons and patients to deliver products geared to specific needs faster than ever before. This in turn improves patient outcomes and this trend is set to continue as the technology develops, which has got to be good news for all of us.

OPUS KSD

Wanting to develop an innovative surgical tool to help close incisions, which would combine the ease of a hadnheld surgical stapler with proprietary, bio-absorbable subcutaneous fasteners, Opus KSD used Protolabs' CNC machining and injection moulding services to test form, fit, function, and overall performance before moving in to production.

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SPEEDING UP PRODUCT DEVELOPMENT FOR MEDICAL DEVICES

Getting a new medical device from concept through approval and to manufacture to the deadlines that you and your team expect is a real challenge. Yet something that the recent pandemic has taught us is that it is possible to innovate and achieve production quickly when it is really needed.

There are several steps to getting it right and how you shrink the development time between each can make a real difference to your deadlines. Often the innovators of new devices understand the clinical needs, but that does not mean that they have all of the skills needed to see it through the development cycle quickly.

While the concept may be sound and the clinical need very real, you need to translate that idea into a CAD design that you can manufacture using your chosen production technology. Then you need to test it for function and finally you may need to produce low volumes for clinical trials before you move onto mass manufacture.

Traditionally we all assumed that this process could take months if not years but since Covid, our expectations for faster turnarounds have grown. And using the full power of digital manufacturing it is possible to get through the prototyping stages to final production faster than many thought was possible.

Let's go through the development cycle one step at a time to see how you save time and ensure a successful outcome.

From concept to design

If you have your CAD the first thing to check is whether that design can actually be manufactured using your final production process – whether it's injection moulding, CNC machining or 3D printing.

At Protolabs we have automated this design for manufacturability analysis stage. When you submit your design, you will get an analysis back alongside your quote in just a few hours. If needed it will highlight areas where you have to change your design to meet the realities of production plus also areas where it would be advisable to do so.

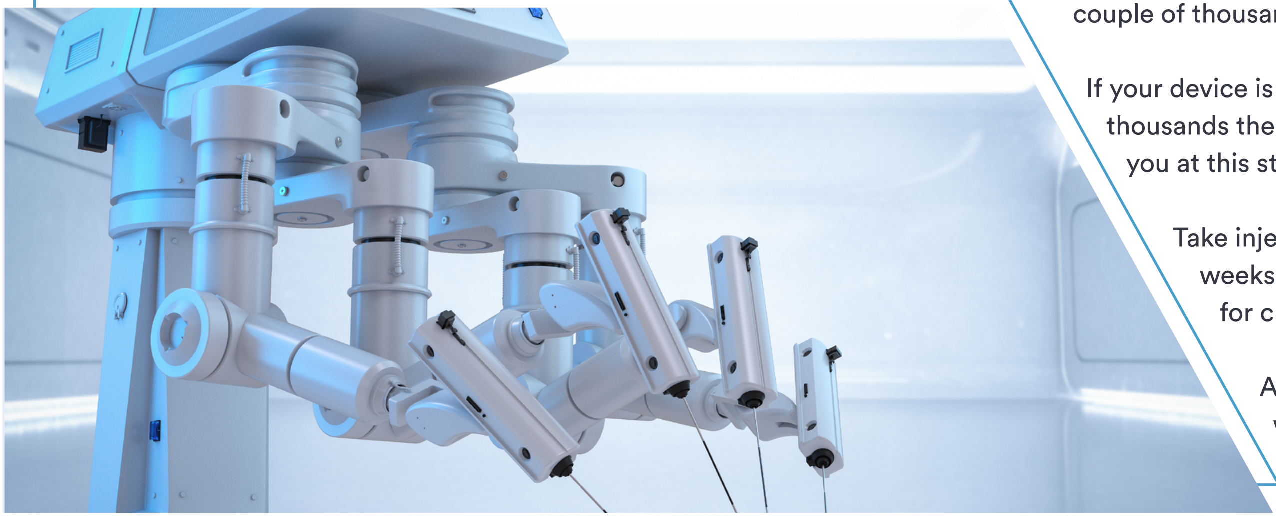
It's a useful sense check to see if your design will work in practice. If you need some help after this first stage, and many do to move the development through, then you can contact us to take advantage of our consultative design service for injection moulding – there is no charge for those who have already uploaded their CAD.

Prototyping

When you know that your design will work in theory, the next step is to test the part for form, function and fit. In practice you may need to go through a few prototype iterations before you are happy to commit a design to manufacture. You may also start off with prototypes produced using a different technology from your final production process.

A common example is to use 3D printing to produce plastic or resin parts for testing even though you will be using injection moulding as the final production process. This is because this process can produce parts in typically a few days, or even a day if it's really urgent.

At this stage it's important to use a supplier who understands both technologies so that the prototype that you design and use in testing from 3D printing can actually be manufactured using injection moulding. That link between design, prototyping and production is vital.



If your supplier offers both the prototyping technology and the final production capability then their engineers will have that knowledge and not lose sight of the final goal.

Read our whitepaper on which technologies to use for different stages of prototyping here.

Low volume production for clinical testing

When you are happy with the product there comes a time when you need to commit and get it clinically tested to ensure compliance with regulations and standards. At this stage you need to produce the final version that ideally uses the same production technology that it will be manufactured in.

For low volume production of specialist items, you may actually use 3D printing throughout the entire process and even plan to produce the product using this technology. The same is true if CNC machining is your chosen technology. This may be ideal if your production volumes are likely to number in the hundreds or a couple of thousand spread over time.

If your device is set for mass manufacture or production numbering in the thousands then there could still be rapid low volume manufacturing options for you at this stage that will save you both money and time.

Take injection moulding. Traditionally you can expect to wait 10 to 12 weeks for your steel moulds before you can produce a small number for clinical trials.

A better option to shorten that timeline is to find a manufacturer who produces moulds using aluminium which helps to shorten that time frame to about 10 days or even as fast as a day.

From clinical trials to production

Having got your concept through clinical trials you will be keen to get your product onto the market as soon as possible. Again, there are options to speed up this process. For low volumes you can probably use 3D printing or CNC machining.

If you need higher volumes numbering in the thousands or even hundreds of thousands then you will be exploring different production technologies.

Even here there are answers that will speed up the process. Remember we spoke about using aluminium moulds for faster turnaround in injection moulding, well you might be able to use these for production. For volumes of up to say 50,000 parts this might be your final solution.

Even if you are planning mass production beyond these numbers you could still use aluminium moulds to bridge the production gap until your final steel tooling is ready and save yourself waiting 2 or 3 months. Take a look at our on demand manufacturing service for example.

The pandemic has taught us that product development for medical devices can be far shorter than we excepted as the norm before. At Protolabs we have experience of helping medical manufacturers shorten their development cycles – read about how we helped develop a CPAP device for emergency ventilation for example.

We can help you achieve your deadlines faster. Put us to the test.

POLARCOOL

When start-up company PolarCool were developing a device that can quickly lower the temperature of the brain in a controlled manner following a sporting head trauma, alongside product design agency OIM, they turned to Protolabs' expertise and injection moulding service to accelerate product development.

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HOW DIGITAL MANUFACTURING IS MAKING PROSTHETICS MORE PERSONAL

Digital manufacturing is shaping the future of prosthetics and orthotics by producing more personalised and comfortable solutions faster and at a lower cost. It is also accelerating the development of new ideas through rapid prototyping to test new solutions.

Traditionally clinicians make prostheses and orthoses using manual processes because fit and comfort for the patient is the main aim. While the industry is highly scalable, solutions are one offs since every patient has different needs and anatomy.

Solutions typically have functional parts such as joints, which are industrially fabricated, and areas that connect to the patient's body. Clinicians need to produce a solution that is both suitable for the patient's size and strength and also has a comfortable connection with their body that can transfer and absorb force without discomfort.

Prosthetic limbs

For a prosthetic limb the fitting process often relies on casting to capture the patient's anatomy and then using this to build a mould by hand using composite resin. You then place fixtures and padding to complete the device. The whole process takes time and involves several visits by the patient to get it right.

For manufacturers, producing well-fitting prosthetics is expensive and needs highly skilled staff. While some products are standard, most are still customised and are expensive to produce. Faced with a demand for more complex products, but with less funding, healthcare providers need to make production more efficient.

This is where digital manufacturing can step in to reduce the number of processes needed and bridge the gap between the patient and the product. It starts with a scan to capture measurements and the features required. Using this information, the clinician and technician can customise and build high quality digital models that are ready for production.

Using this digital thread, the prosthetic is then manufactured, generally using CNC machining and/or 3D printing. Both have their advantages with the former offering high precision parts that need no finishing and the latter able to create complex geometries that are simply not possible using other production technologies.

The result for the patient is a faster process with a more comfortable customised fit, while the healthcare provider would expect to save time and therefore money. By automising much of the process, the health professional can also spend more valuable time with the patient to fit and optimise the device.

Digitilisation also opens up the development of new construction geometries and adapting these to meet a patient's personal wishes for function and aesthetics.

Once approved, the design can be manufactured at the push of a button and if necessary reiterated and adapted quickly. Using the more traditional casting method, the professional would often need to start again from scratch if there were any changes.

Faster prosthetic component development

A second area where digital manufacturing is helping the industry evolve is in the development of new ideas. One of the primary concerns of many manufacturers in the medical industry is the time to develop new products for the market.

Digital manufacturing speeds up this process from initial CAD right through to final production. Whether you are seeking to improve the functionality of a part, such as a joint for example, or are developing a new concept, designs often need to go through several phases before they are ready for final production.

Typically, this involves checking:
> that your design is manufacturable
> the form and fit are right
> that it provides the functionality you want
> that it meets regulatory approval

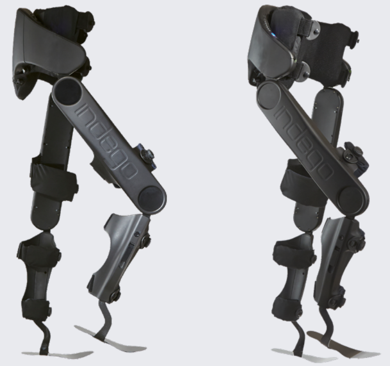
This all starts with your CAD and it pays to pick design issues up at this stage to save yourself time and money later in the development process. Protolabs automates this quoting and design for manufacturability analysis so that you can get a rapid sense check; if you need more help we also offer a consultative design service for injection moulding.

After this you will need rapid prototyping. Depending on where you are with the development you may mix and match your production technologies. You may, for example, start with 3D printing or CNC machining for speed even though you know that you will manufacture the final parts using injection moulding.

It is best to find a supplier that can offer all of these technologies under one roof, because although you may start prototyping using 3D printing, you still need to design the prototypes with the final production process in mind.

At Protolabs we have worked with a number of prosthetic manufacturers to develop their solutions. A good example is our work with Parker Hannifin where we helped save their R&D team several months of development to bring its Robotic exoskeleton to market on time.

Digital manufacturing is changing the world of personalised medical care and nowhere is this seen more clearly than in the development of prosthetics and orthotics. Whether this is for customising artificial limbs for a faster and more comfortable fit or for developing new ideas or parts, find out how we can help [accelerate a solution for your medical manufacturing team](#).



PARKER HANNIFIN

Needing a rapid manufacturing solution to accelerate devleopment speed and reduce design risk of their robotic exoskeleton, a combination of digital manufacturing technologies and Protolabs' automated quoting system enabled a highly iterative design process without sacrificing time to market.

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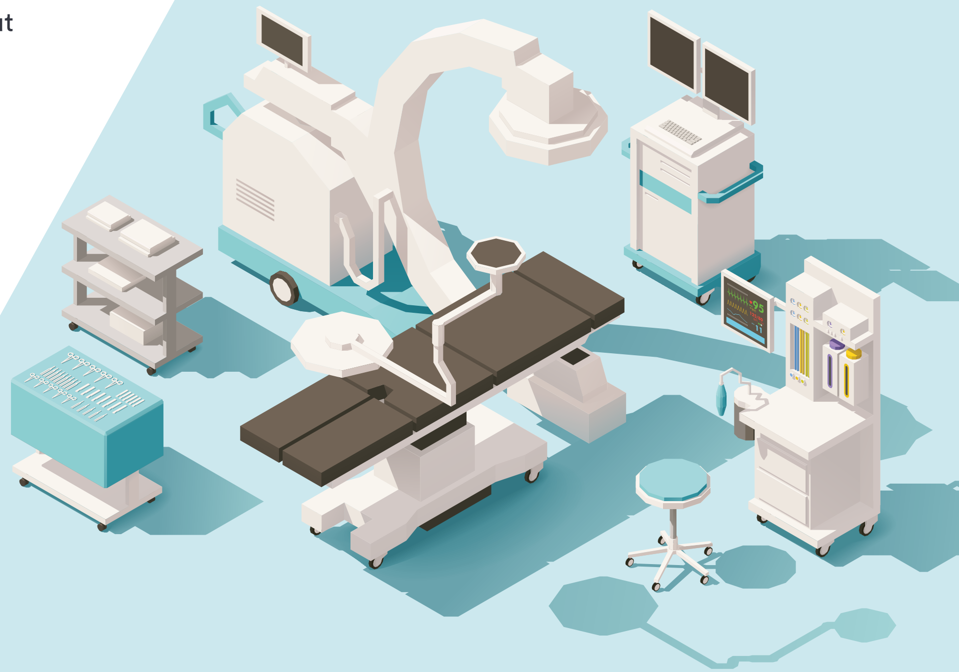
CONCLUSION

The opportunities that digital manufacturing presents to the medical industry are considerable and will continue to grow. 3D printing, CNC machining and injection moulding are helping the industry:

- Accelerate development and market introduction
- Faster turnarounds and better solutions for medical professionals and patients
- Customisable and personalised healthcare
- Improve patient outcomes
- Achieve better results faster and more cost effectively

Exactly which of these digital manufacturing technologies you use will vary depending on your project. If you need your parts quickly however then digital manufacturing will play a crucial role. To find out more about Protolabs' capabilities visit protolabs.co.uk, or feel free to contact us at +44 (0) 1952 683 047 or customerervice@protolabs.co.uk.



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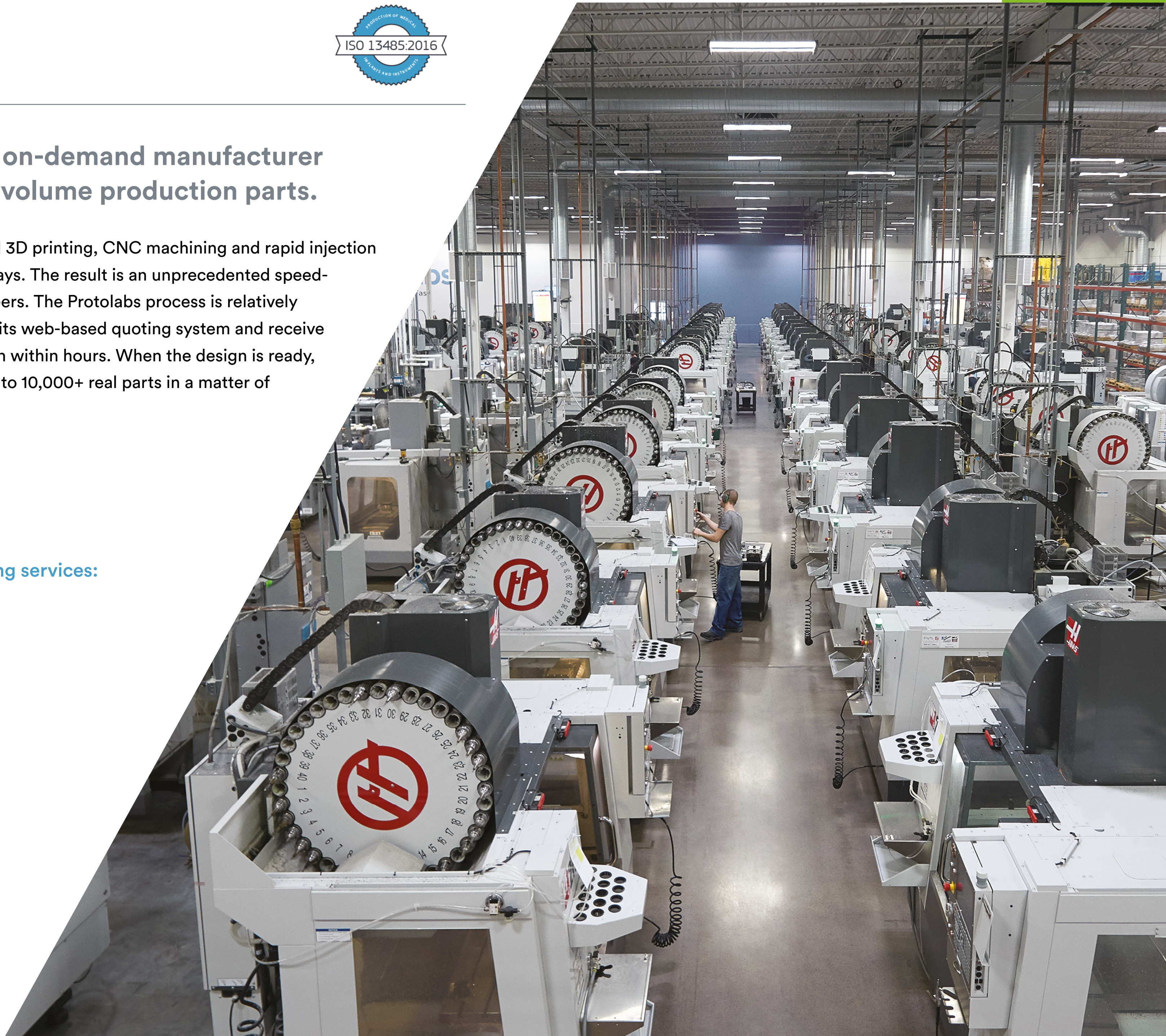

Protolabs is the world's fastest on-demand manufacturer of custom prototypes and low-volume production parts.

The technology-enabled company uses advanced 3D printing, CNC machining and rapid injection moulding technologies to produce parts within days. The result is an unprecedented speed-to-market value for product designers and engineers. The Protolabs process is relatively simple. Designers upload their 3D CAD model to its web-based quoting system and receive manufacturability analysis and pricing information within hours. When the design is ready, its manufacturing services can produce from one to 10,000+ real parts in a matter of days.

Protolabs offers three flagship manufacturing services:

3D Printing

- Stereolithography
- Selective laser sintering
- Direct metal laser sintering
- Multi jet fusion
- PolyJet & 3D printed silicone

CNC Machining

- Three-axis milling
- Five-axis milling
- Turning with live tooling

Injection Moulding

- Plastic injection moulding
- Liquid silicone rubber
- Overmoulding and insert moulding