Digital Manufacturing for the Medical Industry

Volume 1 & Volume 2

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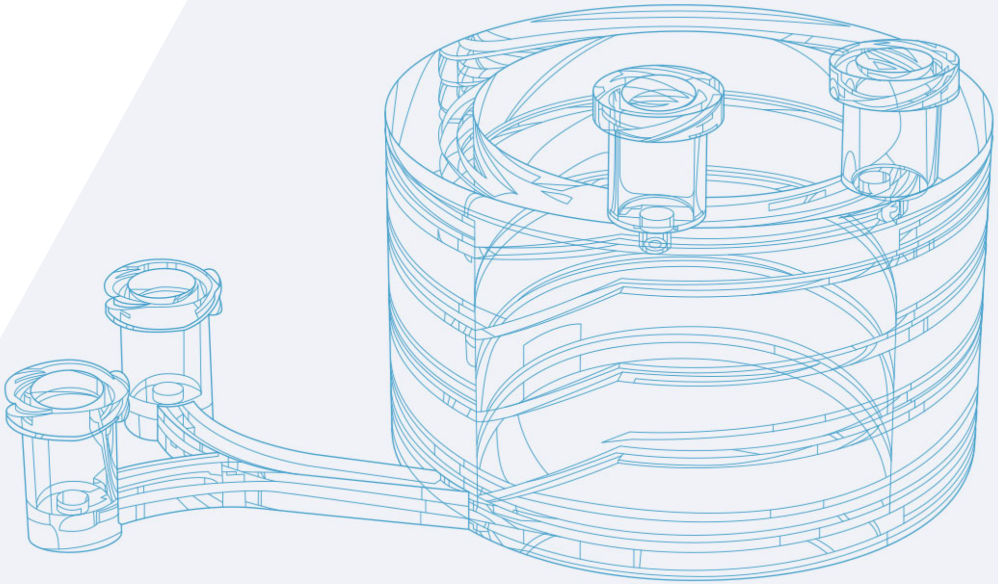

Digital Manufacturing for the Medical Industry

Volume 1: how digital manufacturing has supported the industry and what the future looks like.

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Medical Applications for Additive Manufacturing

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Introduction

Over the past few years, additive manufacturing - better known as 3D printing - has established itself as a driver of innovation in a wide variety of industries. In addition to its many industrial applications - for example for the production of prototypes and spare parts - there are many benefits to using 3D printing in the medical sector.

Since the beginning, 3D printed parts and their applications in the medical field have been as varied as the production possibilities and the materials themselves. For example, as an ideal technology for prototypes and one-off production parts, you can for example use 3D printing for implant production.

In this guide we will take a more detailed look at the benefits of additive manufacturing in the medical sector, the potential applications that are already commonplace and its significance for medicine in the future.

Additive Manufacturing - Production Processes, Benefits and Materials

To get an overview of additive manufacturing applications within the medical sector, it is necessary to understand how the 3D printing process works. Additive manufacturing differs from other manufacturing methods. The material is not cast, as it would be in the manufacture of injection moulded parts, or cut from a larger block, as is the case with CNC machining.

As the term "additive" suggests, the material is added layer-by-layer. Even if the individual additive methods differ in the precise process and materials, the process of layered production is still the same. This enables more freedom for part design and possible geometries compared to other processes.

Since its early days, 3D printing has seen a great deal of differentiation, with a number of manufacturing processes that vary greatly. The most important manufacturing processes used in the production of medical products today are direct metal laser sintering and stereolithography.

Direct Metal Laser Sintering (DMLS)

In principle, the procedure for printing DMLS parts differs only slightly from other methods of additive manufacturing. Support structures dissipate the heat generated during the process and ensure stability of the components. Without support structures there would be a risk of wiping away new material during the printing process.

DMLS uses a computer-controlled, high-power laser beam to melt and fuse layers of metallic powder together. This melting and fusing process is done layer-by-layer, to finally produce a solid, finished component.

Once completed, the component is released from its support structures and the excess metal powder is post-processed depending on its application. A large number of metals are suitable for production using DMLS including titanium alloys, which are important for medicine, for example in the production of bone implants.

Stereolithography

Stereolithography is comparable to other additive manufacturing methods. It prints polymers and plastics with complex geometries or very small structures that require a particular rigidity, impact resistance or durability.

As with DMLS, it uses a laser to do the actual printing. Unlike DMLS, however, the raw material is not in powder form, but rather a resin consisting of photopolymers and additives. An ultraviolet laser hardens this resin into a thermosetting plastic. The build platform is lowered at each stage, ensuring that a new layer of resin covers the component, which is then hardened into the required shape by the laser.

After the part is produced, the remaining resin is cleaned off in post-processing and the support structures are removed. Finally, the parts undergo a UV-curing cycle to fully solidify the outer surface of the part.

It's worth noting a new material called MicroFine™ Green. Using stereolithography it produces particularly fine, high-resolution structures e.g. miniaturised catheters or minimally invasive tools.

Medical Applications for Additive Manufacturing

The medical sector adopted 3D printing shortly after it appeared. Initially the benefit of being able to easily produce individual parts, such as medical device housings, proved ground-breaking. Shortly after this the industry recognised DMLS' potential and the first production of implants took place.

3D printed implants

Currently implants are the most extensively produced 3D printed parts in the medical industry. They offer a whole range of advantages, particularly when it comes to the replacement of bone material. These parts are printed using CAD files, often generated using medical imaging techniques.

Applications of 3D printed implants

Since implants are usually custom-made products for a well-defined purpose, additive manufacturing is ideal, due to its ability to produce unique items quickly and cost effectively. Until recently these types of implants would usually have been mass-produced and then adapted for the patient, often by the surgeon.

It can make simple parts such as femur implants or hip bones tailored to the individual patient, figure joints, zygomatic bones and jawbones, as well as complex implants such as orbital implants, cranial bones and thoracic implants. And implanting/attachment of artificial teeth is now a standard application for 3D printing.

Due to 3D printing's comparatively fast manufacturing times and the possibility of on-demand production (i.e. implants as and when they are needed), the medical sector is increasingly recognising the benefits of this technology and is using it for both standard implants, such as individual vertebrae in the spine as well as more customised options.

Advantages of 3D printed implants

The benefits of 3D printing in medicine are similar to those of more industrial sectors. First, there's the wide range of possibilities that 3D printing opens up when designing individual implants. Other manufacturing processes simply cannot create the geometries and shapes that are possible with 3D printing and are therefore less suitable for use. The flexibility additive manufacturing allows in the manufacturing process, also enables the integration of lattice and sponge structures that can drastically improve biocompatibility of implants, helping improve their ability to integrate with endogenous material.

For hospitals and health insurers, there is the advantage that individual specialised implants are more cost-effective than those produced using conventional methods. Other manufacturing processes require significant investment in special tools and equipment geared in each case to the individual implant. In 3D printing, these additional costs are eliminated due to the more flexible manufacturing process. Special implants produced using additive manufacturing do not have to be expensively reworked.

Materials and legal requirements for 3D-printed implants

By manufacturing parts using DMLS, implants can be printed directly from a material that is suitable for medicine. For implants such as hip bones or orbital implants, in most cases Ti6Al4V is used - an alloy that's main component is titanium. This alloy is characterised by its high-biocompatibility and enormous strength and stability, whilst being comparatively light. Another material used in medical 3D printing is stainless steel 316L.

In contrast, when producing standard implants by milling or casting, the materials used have poorer biocompatibility ratings, which means that in addition to production they need the addition of a titanium coating.

Implant production must observe legal regulations, especially in regard to the selection of materials. For Ti6Al4V, legal requirements include, ISO 5832-3, ASTM F1472 and ASTM B348, which classify the material and chemical components as suitable for use in medicine. Special implants require no CE certification. Ultimately, the responsibility and decision as to whether and how an implant is suitable for use on a patient, rests with the relevant doctor. Another advantage of 3D printing in this area is that many of the materials are familiar to the medical industry. The strict standards and regulations that these materials must meet are not affected by 3D printing. Thus, there is nothing to prevent them from the medical industry using them after the additive manufacturing process.

Medical Equipment and Custom-Made Products

Another important area where 3D printing is gaining ground in medicine, is for the production of individual medical devices and custom-made products. These devices are often for short-term use to perform specific tasks.

Special templates and individual parts

Surgical aids often need specifically designing for the individual patient and the respective operation e.g. templates help with drilling the cranial bone to millimetre precision. Due to the high-level of accuracy using processes such as DMLS (individual features of less than one millimetre can be achieved - depending on material biocompatibility and intended application), there are huge benefits to using 3D printing for this. Accurate CT scans of a drill section can create precise files that allow the production of parts quickly. The resulting needs-based drilling templates allow for more accurate work and help avoid dangerous errors during the operation.

Another additive manufacturing material used in the production of medical devices and custom-made products is the relatively new MicroFine™ Green. Using this bright green material to create microscopic structures, opens a whole range of possible applications, which were previously not feasible in medical 3D printing. Single parts for pacemakers, only a fraction of a millimetre in size, are just as conceivable as miniaturised catheters or liquid and gas injectors.

By using processes such as DMLS and stereolithography to print complex geometries, there are almost no limits to what additive manufacturing can produce for the medical industry.

Medical instruments

Besides providing templates for specific operations, which differ from patient to patient, the new manufacturing methods also allow innovations in medical instruments for the operating theatre. 3D printing makes it easier to produce instruments that were previously not economically viable or, in some cases, even impossible.

For example, DMLS can produce surgical devices that allow special drilling or incisions, which can crop up repeatedly in medicine. Additive manufacturing applications also include other specialised medical instruments to better suture surgical wounds or used as tools during the surgery itself. Instruments precisely adapted to an individual surgeon, such as handles for scalpels, are an example. Parts manufactured from special plastics using additive production can also be used, for example as highly specialised brackets or spacers.

Such extensive use of 3D printed parts in the medical industry is possible because the materials and methods combine a whole range of benefits including; mechanical strength, cleanliness and ease of cleaning and sterilisability. It is also cheaper to produce parts designed for a single task or purpose than by traditional production methods.

Prosthetics and Orthoses

For a long time, 3D printing has been a useful manufacturing process for specially adapted prostheses and orthoses. Compared with other manufacturing processes, 3D printing allows you to produce individual parts that are specially tailored to an individual patient, inexpensively, quickly and easily.

Parts have to be specially adapted in the production of both orthoses and prostheses. However, whilst in prosthetics missing limbs or body parts are replaced, in orthoses the goal is usually more the support or immobilisation of individual limbs or joints. In both cases, additive manufacturing helps enormously in bringing innovative ideas to market faster and more cost-effectively. This way, people who urgently need the assistance of these medical aids can get assistance more quickly.

An example of this is the faster product development of exoskeletons - i.e. orthoses, that allow users a better functioning musculoskeletal system.

Manufacturing processes such as injection moulding often take a long time, while the waiting period for 3D printed parts is far less. 3D printing has similar advantages in the production of innovative prostheses, which need to be specially adapted to the respective wearer, or in prototypes of and entire new generations of prostheses which, like exoskeletons, have yet to go through a product development cycle.

Models for Planning, Research and Training

Modern imaging techniques such as CT and MRI give doctors much better insights into the human body than was the case a few years ago. These methods have played an essential role for doctors helping them diagnose diseases in their everyday work. These diagnostic imaging techniques also have a significant impact in their preparation for complicated procedures and operations.

This is another area where additive manufacturing processes can help. Modern imaging techniques are so accurate they can be used to create 3D printed life like models of the relevant organ on which a surgeon can trial the operation before the actual procedure. These models are also suitable for determining optimal approaches or trying out riskier procedures without risk to the patient. Because flexible materials can also be printed using additive manufacturing, the models can also have characteristics that you would expect from the biological material.

Replicas for research and training

Replicas of organs and skeletal parts made of a variety of materials using additive manufacturing also provide universities and colleges with the opportunity to gain a deeper insight into the human body.

While conventional replicas of anatomical parts have often been expensive and of poor resolution and quality, today's 3D printed replicas present a viable alternative to conventional modelling. Models made for surgical preparation can be used for training medical students, illustrating malfunctions of the human body and displaying disease in realistic examples.

The replicability of examples like these, is a major advantage of 3D printing. Particularly in cases involving a specific body part or organ, you can generate any number of models for medical faculties worldwide.

Looking to the Future - Applications of 3D Printing in the Medical Industry

Few new technologies have changed medical research as much in recent years and decades as additive manufacturing. At the moment, the development of additive processes and the possibilities created is still in its infancy. Work is currently in progress on a variety of new, modern applications that could change the medical world and our understanding of healing and care over the coming decades.

Current Research into Organic Materials

So far, the metals and plastics used for medicine are well-suited to 3D printing. These materials can help with patient care, but quickly reach their limits when it comes to living material. There are, for example, already the first 3D printed prototypes replicating entire organs, such as the heart; but since the material is not organic, not designed to remain permanently in the body and is not designed for the high stresses of everyday life, these are currently only being used for individual prototypes. Developers and researchers are now focusing on innovating/ improving processes for printing organic materials for the future.

Current experiments mainly focus on applying additional tissue from cellulose and organic materials to existing structures, which are then suitable for implantation, leading to functional tissue. The benefits of such a technology, once fully developed and usable, will be enormous. Machines could produce vessels, organs or muscle tissue to be implanted into the human body. Research projects, such as an artificial heart produced via 3D printing, have proven that replicas of entire organs work and can potentially save lives. By extending and improving such systems, the lifespan of the implants could be extended from a few hours to medically useful time intervals.

In addition to this research, other experiments are taking place which may improve medical care in the future. For example, work is currently being carried out to produce human skin in so-called bioprinting processes, to produce biological prostheses such as ears and to print organic material directly onto the patient. 3D printed tissue is also well-suited for trials and testing of new drugs and medical applications. In future, the best-case scenario would be that animal and human trials testing new, active substances would become redundant.

The innovative power of 3D printing in the medical field is almost unlimited. This is because of its flexibility, for example in the production of complex geometries. This is a major benefit, especially when considering the complexity of some medical applications, which typically involve working in difficult to access areas that allow little margin for error.

Optimisation of Existing Processes

In the near term, applications of 3D printing in medicine will be towards processes that are already possible and how well everyday clinical practice can incorporate them.

Currently no other area produces as much innovation as additive manufacturing. This is due to the fact that constant development of processes and improvements to existing processes always generates new applications for 3D printing.

Techniques such as stereolithography, direct metal laser sintering and polyJet have gradually emerged and have been constantly evolving to print a wider variety of materials. In future there will be additional 3D printing processes to expand and optimise the range of possible applications. As new processes develop, the choice of materials will continue to expand and provide additional solutions. Subsequent advances in organic materials, new additive methods and results from future research, promise far-reaching innovations.

How will 3D Printing work with Medical Facilities?

When it comes to additive manufacturing and medical applications, people have suggested that hospitals and research institutions might need their own machines and be able to use them, problem free. This is currently not the case, specialist companies are the primary manufacturers of implants, orthoses, prostheses etc. which are then sent to hospitals or end-users. Having 3D printers in hospital basements is unlikely to be common anytime soon.

One big reason for this is that the machines used for the production of bone implants made of titanium, for example, are very expensive to buy and use, and the additional post-processing of printed implants incurs additional expense. In addition, the use of additive manufacturing processes and machines requires a considerable amount of specialist knowledge and training. The fact that these procedures will be even more differentiated and that specialist companies have more extensive production options is another argument against its direct use in hospitals.

Instead the cooperation between hospitals and medical professionals and companies specialising in modern manufacturing processes for prototype production and additive manufacturing, will expand and become more interconnected. Since a wide variety of new applications are already emerging, the importance of additive manufacturing within medicine will continue to increase. Doctors in generations to come will wonder how medicine ever managed without 3D printing.

3D Printing in Medicine - A Technology of Today and Tomorrow

Whilst 3D printing has been with us for almost 40 years and has continued to evolve, the application of this manufacturing technology in medicine is still relatively new. Yet, the benefits of 3D printing have been quickly recognised by the medical community, and its applications are already very diverse.

With implants of any kind, specific designs for operations, medical instruments and the use of 3D printed parts for preparation, research and training - other technologies are increasingly fading out. And with the quality management system for medical devices – ISO 13485 – now recognised within the 3D printing supply chain, additive manufacturing is able to meet strict legislative requirements across the world.

In the future, new materials and processes will increase 3D printing's importance to medicine, and it will be hard to imagine the everyday life of patients and doctors without it. Science and applied research have long been working on applications that will surpass the wildest expectations of many doctors. In fact, to speak of a boom in medicine thanks to additive manufacturing is, if anything, an understatement.

For the sick and injured, 3D printing promises improved chances of recovery, the alleviation of pain and a better quality of life, which is surely the most important goal of all.

Manufacturing Tool Kit for the Medical Industry

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Introduction

Prototypes help design teams make more informed decisions by obtaining invaluable data from the performance of, and the reaction to, those prototypes. The more data gathered at the design stage of the product development cycle, the better the chances of preventing product or manufacturing issues down the road.

Indeed accelerated prototyping has always been important in medical development, and especially now during the COVID-19 crisis as designers and engineers create critical medical products to fight the pandemic.

At Protolabs, we produce prototypes for a range of medical devices and other medtech products and assemblies. A well thought out manufacturing strategy greatly increases the chances that a product will pass strict regulatory and compliance standards, launch to the market on time, be accepted, perform reliably, and be profitable. Our services and quality processes ensure you get there faster by leveraging our decades of experience in medical device product development combined with the ability to quickly iterate on designs with our accelerated manufacturing processes.

Here are eight ways we can help improve your parts during medical device product development.

1. Use Design for Manufacturability Analysis

A common manufacturing method for end-use medical parts and components is low-volume injection moulding, although functional medtech prototypes are also 3D printed and machined. At Protolabs, our moulding process starts with an online quote. Each quote comes with a free, automated, interactive design for manufacturability (DFM) analysis. Beyond the online interactive analysis, we have dedicated design review teams for free design consultation for all three of our manufacturing services: moulding, machining, and industrial-grade 3D printing (additive manufacturing). Everything starts with your uploaded CAD model.

Additionally, regarding moulding in the medtech world, sometimes you may find that a part that was originally designed to be 3D printed or CNC machined may need to be redesigned for injection moulding. Our applications engineers are available for consultation on these types of redesigns. For customers who may need more support in the design process, Protolabs offers Consultative Design for Manufacturability, a consultative deep-dive into your product design with recommendations and insight on how to improve geometries to maximise function.

Our goal is to help save time and money—even if you need to make modifications you didn't plan for—to avoid designs that are not manufacturable.

The next section dives deeper into molding for medical device and medtech parts and products.

2. Leverage Injection Moulding for Medical Applications

In the highly regulated world of medicine and medical products, our medical moulding service moves part and component design rapidly from prototype to production. This is especially important in this industry, where products need to pass rigorous testing from the development phase through commercialisation. Our high-quality aluminium tooling, combined with automated DFM analysis, can quickly cut product development time, taking just days to cut a tool vs. steel tooling.

Along these lines, our quality control and tooling items include:

- Process validation, which may be achievable by a standardised qualification package, industry-accepted protocol, or customer-defined

Additionally, on the topic of tooling, our software program for mould flow analysis can help improve a medical part's overall design through a number of ways, such as: aiding in the positioning of the gate or gates on your part; showing the position of knit lines, which allows you to improve your part's cosmetic and physical properties; locating trouble spots that are hard to fill within your part; and identifying the proper material for your design.

At Protolabs, companies have turned to us for recent medical-related projects such as:

- Lower volume or difficult-to-forecast products
- Early-in-development parts and products
- Components requiring complicated supply chains
- Projects in which design flexibility is needed all the way through development
- Parts in which early process lessons can benefit in a transfer to production
- Design verification testing, clinical trial submissions, and regulatory-body submissions.

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3. Iterative Prototypes Rapidly with Multi-Cavity Tooling

Developing parts and devices for the medical industry is challenging because things move so quickly. Accordingly, you can take advantage of our family and multi-cavity tooling in injection moulding so you can mould, in final, end-use material, multiple versions of the same prototype, then test those multiple versions, and move forward with the prototype version that succeeds.

In addition to the benefit of rapid iterations, using multi-cavity moulds can also be an efficient way to boost production volume and reduce part cost. We have a design tip on multi-cavity moulds that goes into more detail.

4. Consider 3D Printing in Metal for Complex Medical Parts

Direct metal laser sintering (DMLS) is a frequently used metal additive manufacturing technology with applications for the medical industry. There are several benefits to DMLS—including printing high-resolution parts to support metal instrumentation design, for example. Materials include stainless steel (17-4 PH & 316L), aluminium (AlSi10Mg), cobalt chrome (CoCr), Inconel (IN718), copper (CuNi2SiCr), and titanium (Ti-6Al-4V).

Consider surgical tools with ultrafine features and medical components with organic shapes. These devices may be designed for metal injection moluding or casting, both of which have relatively high tooling costs and lead times that can span weeks. With DMLS, you can print a prototype surgical hand tool at the exact weight and strength of the final product and have it in a surgeon's hands within days.

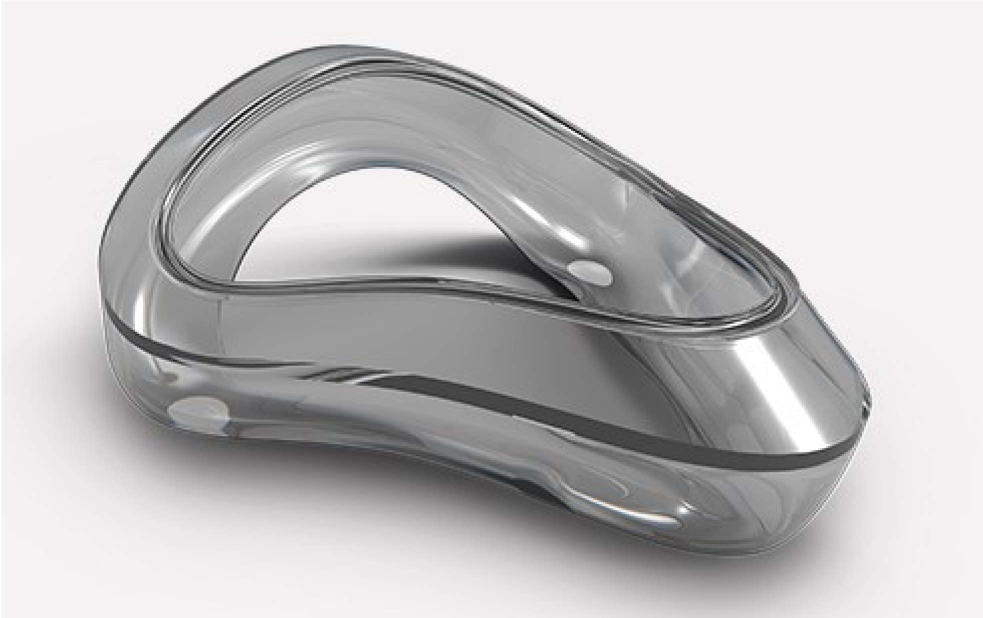
For DMLS projects, check out our design guidelines.

5. Choose Finishing Options for Moulded Medical Parts

Medtech companies often leverage post-processing options for their moulded medical parts. We offer a wide selection of finishing options for moulding that strengthen parts, improve cosmetic appearance, and provide customization, among other benefits.
These finishing processes include:

- Mould texturing
- Threaded inserts
- Pad printing
- Heat Staking
- Laser Engraving
- Basic Assembly

Medical device company Hemosonics, for example, recently turned to Protolabs for finishing options in addition to using our injection moulding, 3D printing, and machining services. The company used heat staking and pad printing for its Quantra System blood analysis machine.



6. Use the Right Material for Medtech Parts

We have suitable, medical-grade material for most injection moulding or 3D printing projects. Choosing the best material for your project means that your prototypes will match final parts as closely as possible.

Customers with proprietary materials for final production, common in the medical industry, often want to select a material as similar as possible to their in-house material by providing a close match in elasticity, hardness, strength, and other critical characteristics.

For help deciding which material or colour will work best for your job, you can also consult with one of our applications engineers.

Common Materials for Medical Applications

High-temp Plastics

PEEK and PEI (Ultem) offer high-temperature resistance, creep resistance, and are suited for applications that require sterilization. For example, parts for a medical device may have to tolerate the extreme high heat of an autoclave or harsh chemical sterilization between uses.

Silicone Rubber

Elastosil 3003, for example, has excellent thermal, resistance and biocompatibility traits for injection moulding.

True Silicone

True Silicone is biocompatabile, shows high resistance to harsh environmental conditions and printed parts are water repellent, insulating and have a high gas permeability. It is typically used in healthcare applications like prosthetics, ear plugs or wearables.

Micro-Resolution ABS-Like

MicroFine™ (green and grey) is an exclusive Protolabs material. Print complex 3D-printed parts, like precision instrumentation and diagnostic components, with micro-sized features as small as 0.7mm. MicroFine™ mimics a typical ABS plastic and enables great design freedom.

Transparent ABS-Like and PC-Like

3D printing materials like ABS-Like Translucent/Clear (WaterShed XC 11122) can be finished to show functional clarity in microfluidic parts and transparent components like lenses and housings, which are used in a variety of medical applications.

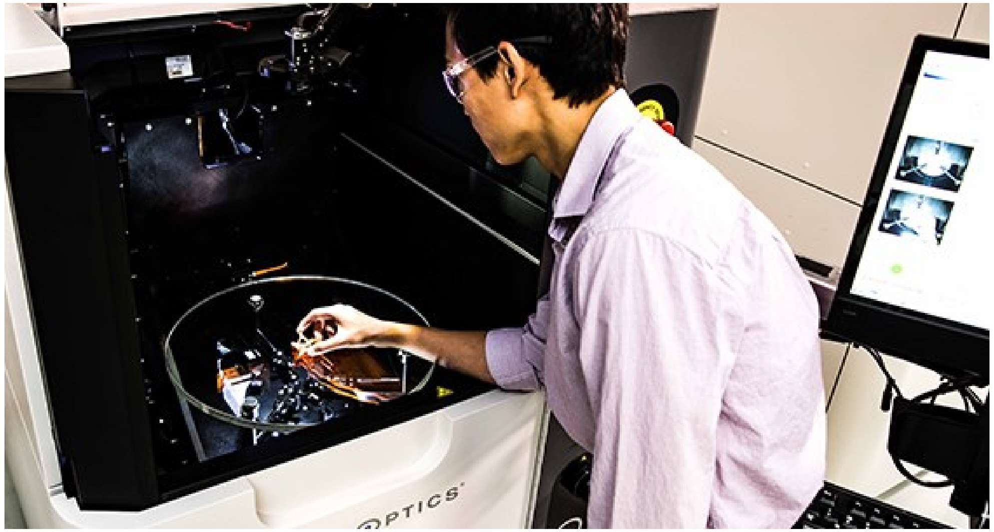
Medical Alloys

Among machined and 3D-printed, there are more than 20 metal material options for medical components, instrumentation, and other applications. Metals like titanium and Inconel have attributes such as temperature resistance, while various stainless-steel materials have corrosion resistance and strength.

This material comparison guide can help you make the best choice.

7. Ensure your Manufacturer has a Proven Quality System

Medical manufacturers navigate many challenging quality checks and regulatory approvals before a product hits the market. Our quality systems for molding and 3D printing continue throughout our entire manufacturing process. While they share similarities, each service has unique quality measures.



For injection moulding, several quality-assurance steps span the moulding process:

- Tight part-number and material controls ensure material requirements are met
- Thermoplastic moulding resins are dried to specifications in calibrated drying equipment
- Dimensional quality inspections are conducted at the start of orders and during manufacturing, are documented electronically, and become part of the manufacturing record
- In-process visual inspections can be conducted on an hourly basis to ensure parts match initial samples and workmanship standards
- Press settings are documented for future production runs
- Pressure and temperature controls are maintained for each shot in the moulding process

Quality systems for industrial-grade 3D printing drive part consistency and repeatability:

- Additive manufacturing instructions are sent to software-enabled 3D printers
- Before the build begins, process engineers verify and prep the material using an extensive checklist covering loading, unloading, and cleaning, which safeguards against mistakes.
- Temperatures during the build are monitored and adjusted accordingly
- Final parts are digitally tracked and have any required finishing or post-processing options performed before moving to inspection stations
- Overall, Protolabs is ISO 9001-certified as a quality system for all 3D printing services.

8. Fast-Track Quality Inspections

Inspections are all about part conformity. Our injection moulding inspection reports are customised according to what service and inspection level are needed. Inspections are completed by quality control personnel and a calibration program is in place for all measurement equipment.

We conduct additional inspection reporting to support critical dimension verification and quality documentation requirements. An enhanced digital inspection option, which helps verify features such as ID/OD (inside and outside diameters) plane-to-plane, and hole locations, can be administered in our metrology lab. A high-speed 3D scanner provides a colour map with a direct CAD-scan comparison for additional quality reporting.

If an even more in-depth report is required, our metrology lab can generate a conventional inspection report using a Coordinate Measurement Machine (CMM) to support first article inspection (FAI) or Production Part Aproval Process (PPAP) requirements. The reports verify all part dimensions, including non-critical dimensions, plus additional supporting documentation as required. This works for all geometric dimensioning and tolerancing (GD&T) measurement types.

For 3D Printing we offer a wide range of secondary services; tensile testing, porosity analysis and hardness testing.

For additional help, feel free to contact an applications engineer at +44 (0) 1952 683047 or customerservice@protolabs.co.uk. To get your design project started today, simply upload a 3D CAD model and receive an interactive quote within hours.

From Prototype to Production

Introduction

In the drive to accelerate new product development and time to market, the pressure to validate a design can be intense. With a prototype of a product or component, designers' finally move designs from the screen to physical objects that can be handled. Does it fit? Will it function as intended? Can a 3D printed part be manufactured by injection moulding? And—in the case of prototype products, rather than parts—what might potential customers think of it?

But the pressure to prototype features or design elements, focus on the resulting end product can be lost. Aim for a prototype, and that's what you'll get—a prototype, and perhaps one of several as the design is refined.

Increasingly, smart manufacturers—and their design teams—are looking ahead, past the prototyping phase of the product design process, and are thinking in terms of the end product and its required performance characteristics.

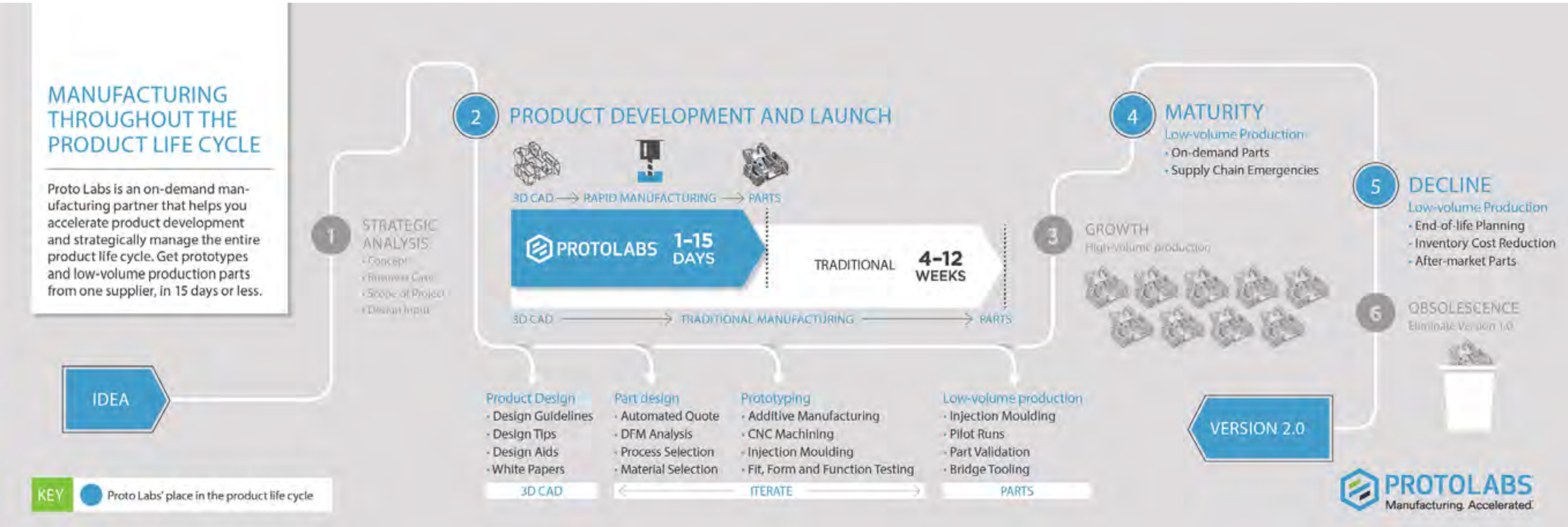
The objective: prototypes that are more than just physical representations of a design, but which instead smooth the way into final production, as well as providing valuable information on product performance and conformance.

In product development, parts or products generally move through three phases of evolution: first, prototyping; second, low-volume production; then third—and final—serial production.

Prototyping is about crystallising a proven, working design. A prototype can be one of several (or many) such iterations, or just a final one-off physical validation of an on-screen design before design sign-off. On the other hand, low-volume production is less about the product itself, and more about its market or production process: a phase of low-volume production can help to refine a manufacturing process, or alternatively get test products or launch products to market in order to gain and validate customer perceptions. Finally, the precise volumes that are associated with serial production will depend on the product itself, and its market, and will typically range from thousands each year, to millions each year.

In each case, the goal at each stage is to move smoothly from each phase of development to the next, refining the product and its manufacturability. Overall, the objective is to minimise the total time and cost of the overall process, bringing a product from initial concept to serial production smoothly and efficiently, and as quickly and cost-effectively as possible.

In some industries bringing a product to market involves extensive compliance testing, often involving third-party certification. Aerospace and defence product development, for instance, calls for such compliance, and no manufacturer will want to finalise a product design and get ready for serial production, only to discover that the product in question does not meet its design requirements in terms of durability, usage cycles, or some other testable attribute. Making use of the prototyping stage to carry out such testing—a process known as pre-compliance testing—is therefore prudent. In such circumstances, it makes excellent sense for a designer to seek guidance from the prototyping provider in order to use a prototyping material that will yield meaningful information on attributes such as strength, flexibility and durability.



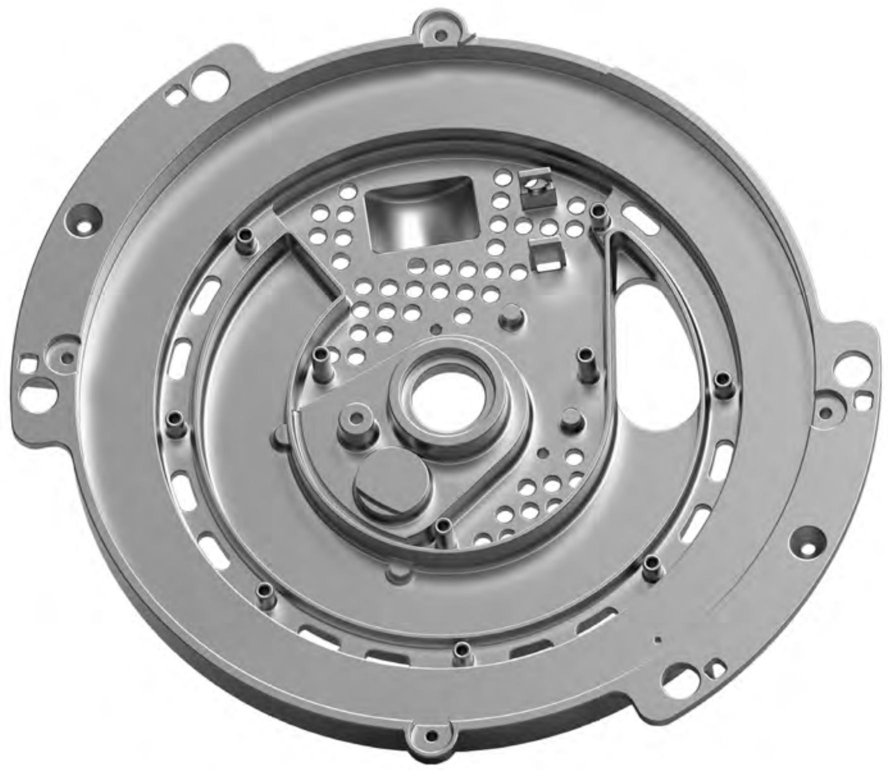
Finally, as well as these development and testing stages of bring a product to market, a manufacturer may wish the prototyping and development process of a product to take into account a number of broader business considerations.

Decisions about packaging, for instance, can impact packaging cost, vulnerability to damage during shipment, and the cubic utilisation of both primary and secondary packaging. Ultimately, of course, cubic utilisation will affect vehicle and container requirements, as well as shipping cost. It can be prudent to, wherever possible, use product prototypes in order to inform packaging decisions as early as is practicable.

Similarly, a business may have sustainability and branding objectives in addition to those impacted by packaging and shipping utilisation. A decision to use a particular means of packaging, for instance, may again impact damage statistics, or product aesthetics during a long shelf-life. An objective of using high levels of reclaimed plastic may not prove practical when injection moulding a specific part. And sourcing both prototypes and production parts over long distances will impact a business's carbon footprint, as well as drive costs higher.

Quality, reliability, and business resilience are other important considerations. These are generally trade-offs: the cheapest prototyping provider will not usually be the fastest, or produce the highest-quality prototypes, for instance. Maintaining a close business relationship with a prototyping provider is becoming a strategic consideration for many businesses; value is placed on sourcing a recommended manufacturer as an outsource partner with the ability to satisfy prototype needs, plus low- and medium-volume product requirements. These suppliers provide the support that fully understands the need for DFM (design for manufacture) and are key to smoothing the way.

In short, successfully bringing a new product to market can call for a multi-faceted approach to design and development, embracing a wide range of issues, priorities, and trade-offs. In this paper we look at how an intelligent approach to prototyping strategy at each phase of the development process can help with this. The objective: an approach to prototyping that shortens overall development time, and brings to market a better product with a better performance, and at a lower overall development cost.



Prototyping Considerations for a Design's Early Stages

The early stages of the project development process include concept development, initial design and product validation, and some product testing in terms of aesthetic appeal or functionality.

During these initial stages, the design function aims to combine the Voice of the Customer (VOC) requirements; the Voice of the Process (VOP), which specifies current manufacturing and sourcing capabilities, together with any known investment requirements; and the Voice of the Business (VOB), which details the business's demands and hurdles in terms of return on investment, sales, marketing and operations

Prototypes are a significant investment for R&D teams, and where possible, manufacturers are increasingly turning to rapid prototyping techniques to shorten development times and reduce risk, using technologies such as:

- 3D printing
  - MultiJet Fusion (MJF)
  - Selective Laser Sintering (SLS)
  - Stereolithography (SL)
  - Direct Metal Laser Sintering (DMLS)
  - PolyJet & 3D Printed Silicone
- CNC machining
- Injection moulding

Prototype quantities can range from as few as one per prototype iteration, to as many as hundreds or even thousands, depending on the product and the project's requirements. That said, the usual range is between one and five for initial concept prototyping using CNC machining or 3D printing, to hundreds when using rapid injection moulding. However, we should be mindful not to restrict or categorise these technologies to prototyping only. Indeed, where only a few production parts or components are required, 3D printing, CNC machining or injection moulding are commonly used to manufacture production-ready parts.

Each manufacturing technology produces compromises. Speed, cost and the level of useful information that a prototype can provide, are all considered at the initiate stage of the project. Prototypes are often manufactured using different materials and processes than would be used during actual production (3D printed plastics for example), with parts produced largely in order to provide information about fit, function, and aesthetics. For some projects, particularly in later prototyping iterations, manufacturers require pre-production prototypes that are representative of parts used in the final product, made from the same material and manufacturing process.

Prototyping Considerations for the Move to Low-Volume Production

Once prototypes have been validated in terms of fit, form, function, and aesthetics, development can move to low-volume production , developing on-demand supply chains or before moving on to serial production. This stage of manufacturing consists of batches of parts that range from 50 to several hundred of several thousands, scheduled to match production needs, providing parts that are delivered to meet fluctuating demand. Furthermore, for certain projects, low-volume production can be the actual, and final, method of production.

The project development strategy will dictate how quickly the manufacturer will move to low-volume production, and how long this stage of production is likely to last. Such a strategy will also include an understanding of the scale of such production—in tooling and production terms, batches of 50 are one thing, batches of several thousand quite another.

The principal implication at this stage is to have parts produced that provide useful insights in terms of fit, form, and function, but which are also optimised for manufacturability. Again, it is one thing to have a physical prototype that confirms that a part or product will perform the intended task, and quite another to have a physical prototype where the means of producing it have been optimised for manufacturability.

For low-volume production, a primary aim of optimised manufacturability is to tweak prototype designs so that moulding tooling can be manufactured more quickly, or more cheaply—or both, in conjunction. In addition to these tooling considerations, a manufacturer will usually want to achieve optimised mouldability, as well. Potentially, for instance, a small change to a mould's draft angle can deliver significant improvements in part ejection and therefore both surface finish and strike rate.

How to achieve this optimisation? In an ideal world, a manufacturer's choice of prototyping and low-volume production provider will have taken this requirement into account, and selected a provider that can offer both insights delivered through human-based application engineering skills, as well as automated tools that can cost-effectively provide an initial rough-cut optimisation analysis automatically, without human intervention.

Indeed, in many cases, it can prove possible for automated design optimisation tools to completely deliver a degree of optimisation that is perfectly adequate for low-volume production. Usefully, when such tools are delivered through high-powered compute clusters, this optimisation can be achieved at minimal delay to the part production process—which is usually important, as achieving a rapid time to market remains a primary objective.

At Protolabs, for instance, when designers upload a 3D CAD model to the website, a quote is returned within a few hours which highlights detailed sections of the model that are in need of draft angles, and which even offers suggested changes to improve the draft on those sections.

Rapid injection moulding works by injecting thermoplastic resins into a mould, just as in production injection moulding. What makes the process "rapid" is the technology used to produce the mould, which is often made from aluminium instead of the traditional steel used in production moulds.

Moulded parts are strong and can have excellent finishes. It is also the industry standard production process for plastic parts, so there are inherent advantages to prototyping in the same process if the situation allows. Almost any engineering-grade resin can be used, so the designer is not constrained by the material limitations of the prototyping process.

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Typically, an intelligent prototyping strategy will reflect on both the rate at which the project is expected to ramp up to low-volume production phase, andthe time—or rather, total output—that this phase of production is envisaged to take to complete.

Often, the production rate takes on greater significance during low-volume production, and as aluminium tooling does not retain heat to the same extent as steel tooling, mould tools are both quicker to reach temperature, and allow faster cooling prior to ejection or release, potentially leading to a higher output rate.

And given that well made low-volume or 'bridge' aluminium tooling can last for thousands of cycles—with some tools capable of producing over 200,000 parts—it definitely makes sense for manufacturers to view such tooling as a viable alternative to more expensive steel tooling.

Steel tooling may be required eventually, but there is little point in discarding perfectly serviceable aluminium tooling, if aluminium can do the job well indefinitely.

Prototyping Considerations for the Move to Serial Production

The move to serial production raises fresh issues for an intelligent prototyping strategy to consider. One key consideration, for instance, revolves around how quickly a given part or product will transition to serial production—in the case of parts or products that are in effect simply a new iteration of an existing proven design or product, the time spent in the low-volume phase of product evolution could be minimal or a way to adopt on-demand production allowing continual product development throughout the product lifecycle.

In such circumstances, it is important for prototyping to quickly prove serial production practicality, as the product or part will spend less time going through the low-volume validation process than it did during its first production run. So while early-stage prototypes may make use of rapid prototyping techniques such as MJF, DMLS, SL or SLS, it will make sense for later-stage prototypes to be manufactured using CNC machining or injection moulding that is consistent with the intended serial production technology.

And as with low-volume production, it makes sense to use a prototyping provider with strong capabilities—both automated and human—in application engineering. With serial production, the focus moves from simply producing a part or product to actively searching for design optimisation that can yield returns over a long production run. With such optimisation, manufacturers can achieve significant improvements in yield, material use, strike rate, and surface finish, fine-tuning a design that may have worked perfectly satisfactorily in low-volume production, but which still offered the possibility of longer-term improvements.

Light-weighting initiatives, for instance, not only reduce weight—a valuable attribute in many applications—but can also reduce material input and therefore cost: a general rule of thumb for wall thickness in the case of thermoplastic parts and products is somewhere between 1 to 3.5 mm (for ABS), applied consistently across the entire part. In other words, thinner walls do not simply reduce cost though reduced material input, but they also reduce cost through improved manufacturability.

Recommended wall thickness by resin.
For example, very thick cross sections increase both the likelihood of cosmetic defects such as sink, and the probability of yield losses through warp and sink during cooling. Paying careful attention to tooling radii, especially in the case of aluminium tooling, is also a useful way of improving yield over a long run of production.

Resin	MM
ABS	1.1 - 3.5
Acetal	0.8 - 3
Acrylic	0.6 - 3.8
Liquid crystal polymer	0.8 - 3
Long-fibre reinforced plastics	1.9 - 25.4
Nylon	0.8 - 2.9
Polycarbonate	1 - 3.1
Polyester	0.6 - 3.1
Polyethylene	0.8 - 5
Polyphenylene sulfide	0.5 - 4.5
Polypropylene	0.6 - 3.8
Polystyrene	0.9 - 3.8
Polyurethane	2 - 19

In serial production, too, there may be opportunities to take advantage of multi-cavity or family moulds in order to mould multiple parts in a single injection cycle. Multi cavity moulds involve more than one cavity cut into the mould to allow for multiple, identical parts to be formed in a single shot; family moulds involve more than one cavity cut into the mould to allow for multiple, different parts to be formed in one shot. If this looks to be a viable option, then engineering experts at Protolabs generally recommend first proving the design on a single cavity mould, before committing to the additional expense and complexity of a multi cavity or family mould.

Putting it all together: the big picture

The pressure to bring new products to market, as quickly as possible, can be intense. Naturally, then, the pressure to produce prototypes can be just as insistent.

But taking a step back, and thinking first about the end product—and its production and testing requirements—can pay dividends both in terms of the overall timescale, as well as the overall cost. Usually, too, there are benefits in terms of yield, product cost, and product performance.

Broaden that focus a little more, and include a consideration of such things as packaging, and the benefit stream is even more compelling.

To be sure, an intelligent prototyping strategy may add a little time in the early stages of the development process. But this is an investment, not a cost. An investment, in short, that leads to a better product, with a better performance, and one which has been derived at a lower cost, in a shorter overall timescale.

Protolabs' Automated Tools Speed Up Iterative Development for Vital Medical Cooling Unit

Introduction

Sweden's BrainCool is an innovative medical technology company that develops products for medical cooling in the event of stroke, sudden cardiac arrest, oral mucositis, migraine and traumatic brain injury. In 2018, the company PolarCool was spun off from BrainCool, to specialize in medical cooling in areas of sports and athletics.

BrainCool's products are used by trained healthcare professionals. PolarCool's PolarCap® System, on the other hand, has been developed with the aim of quickly lowering the brain temperature in a controlled manner following head trauma, directly at the sports facility where the injury occured.

Concussions Common in Sports

Unfortunately, every year a large number of athletes suffer from head trauma, not least in physical team sports such as football, rugby, martial arts and ice hockey.

Athletes often have elevated body and brain temperature when they exercise and if they injure their head, the higher temperature risks exacerbating any brain damage. The best thing in such a situation is to be able to quickly lower the temperature of the brain, so-called hypothermia, in the same way as you put ice on a muscle injury. The difference is that lowering the temperature of the brain must take place under controlled conditions because an excessively fast lowering, for example through ice bath, risks making any damage worse.

The PolarCap System consists of a helmet and a portable cooling unit, which means that it can easily be used directly at the sports facility, or at the place where the injury occured, even by those who are not medically trained. The advantage of the PolarCap System is also that it can be used for preventive purposes even when concussions are only suspected, until the athlete has been able to visit a doctor for a check-up, even if it later turns out that no injury has occurred.

Faster Recovery

Cooling as a treatment method for concussions has been shown to generate positive effects in most studies, both experimental and clinical. The PolarCap System has been evaluated in a large clinical study in ice hockey where the results show that the recovery time for treated players is significantly shortened. Notable, and perhaps even more important, was that the results showed a significant reduction (over 70 per cent) in long absences among players who received cold treatment. The product is used today by the Swedish Hockey League, among others, and since the 2018/2019 season, there are two PolarCap Systems at every match.

Erik Andersson is the CEO of PolarCool. He is a former elite hockey player who, due to repeated concussions, was forced to hang his skates up. He sees a great need for this type of solution in many sports. PolarCool already has a numbers of users in Europe, including the German champion club Adler Mannheim, the Swiss Zurich SC and HC Davos. In addition, an agreement has recently been entered into with Swedish elite football club Hammarby Football, which will include the use of the PolarCap System in its routines for concussions.

“We see great potential for the PolarCap System, in a number of sports around the world. Unfortunately, it is common for players and practitioners to get hit in the head and the research results speak for themselves” said Erik Andersson, CEO of PolarCool. “For elite athletes, as I was, it is extremely important to reduce the effects of repeated concussions. In addition, it is positive for both the individual and the club if the player can return to play earlier, both from a health and financial perspective. The results show that the PolarCap System improves the chances.”

Iterative Digital Design Process

The design product agency OIM Sweden, was commissioned to design and develop the PolarCap System and they have worked closely with Protolabs to find the optimal design for the injection moulded housing for the PolarCap System's cooling unit. Today, it is important for design engineers to quickly and easily arrive at the best design solutions and bring products to market. Protolabs' own automated quotation solution means that the customer uploads their CAD design via their website, and receives direct feedback regarding productivity and cost, and have prototypes delivered in as little as one day.

"Thanks to Protolabs' automated tool, we discovered at an early stage that the first design, with the cover cast as a single part, would not be possible to manufacture, because it was too large for the injection moulding machines," said Arash Golshenas, co-founder and CTO at OIM. "This is something you really want to find out early in development, rather than right at the end, just before the product is to go into production."

OIM used Protolabs' automated tools throughout the iterative innovation process, to find optimal solutions. At the end of the process, there were also opportunities to discuss in detail with the company's experienced technical experts, which also facilitated the project.

Arash explained: "With the online tool, we could always follow the cost implications, depending on our design. Improvements in one area of the design sometimes cause problems somewhere else. By being able to see the consequences of the changes, it was possible to create an optimal design. It was also a clear advantage to have Protolabs' technical experts to discuss with in detail, towards the end of the project."

> "We chose Protolabs because they are fast and efficient and can deliver prototypes really quickly. There is no one who beats them when it comes to injection moulding."

"We chose Protolabs because they are fast and efficient and can deliver prototypes really quickly. There is no one who beats them when it comes to injection moulding. The development of the product took place in the middle of the pandemic in the spring of 2020, so it was also important not to have a development partner too far away. When the world is worried, it is safer to have solutions close to home." Arash said.

PolarCool's CEO Erik Andersson concluded: "The development work has been crucial in creating a good product that can be used at arenas and by non-healthcare professionals, and is also cost-effective to manufacture. We are very pleased with how the collaboration with Protolabs has worked and they have met all our requirements."

Parker Hannifin Brings Robotic Exoskeleton to Life with Digital Manufacturing

PROTOLABS
Manufacturing. Accelerated.

Introduction

It all started seven years ago when then Parker Hannifin CEO, Don Washkewicz, challenged his team with the question, “What’s the future of our company?”

This triggered a flurry of activity to chart out new territory and opportunities that would secure the company’s growth well into the future. The initiative eventually led the company to investigate how it could adapt its core competencies in motion and control technologies to develop wearable robotic devices in the prosthetics and orthotics space.

As it explored the opportunity further, Parker Hannifin connected with researchers at Vanderbilt University working to adapt robotics technology to help patients with lower limb paralysis increase mobility and regain the ability to walk. This led to the development of a wearable exoskeleton that consists of a brace worn on the hips and legs, and is powered by motors, batteries, and other electronics.

In 2012, Parker Hannifin and Vanderbilt reached an agreement to license the technology and soon after the company began working to commercialize a robotic exoskeleton called Indego. Dr. Ryan Farris was a coinventor in the development of the technology as part of his doctoral work at Vanderbilt, and Parker Hannifin brought him on as the technical lead for the business unit tasked with bringing Indego to market.

Searching for a Flexible Material and Manufactuirng Solution

Early on during the project, Farris and his team at Parker Hannifin quickly found the time spent waiting for production quotes and final parts through the company's traditional manufacturing suppliers too long to meet their aggressive development deadlines.

Farris knew that in a highly competitive marketplace, where every day of product development can make or break success, time is of a premium. This pursuit—to shorten design cycles and manufacture parts faster—led him to Protolabs for prototyping and end-use parts.

"We primarily use Protolabs to test new ideas," Farris explained. "For instance, as we consider a potential design improvement, we want the ability to create parts and see how they perform as quickly as possible."

One particular design challenge that required quick-turn parts was related to a component that serves as a light pipe for the device. This part transmits light from a small LED on an embedded circuit board out to the exterior so the user can see the device's current status.

"This little indicator is particularly important because this is how the user—the paraplegic, the stroke patient, or whoever is using the system—knows what state they're in, what mode they're in, and what's about to happen with the device," said Farris.

The initial light pipe design was manufactured with a moulded transparent thermoplastic. After several testing cycles, it became apparent the material was too brittle to hold up to the rigors of daily use, since the system was designed to flex with the user's movement. Farris also explained the light pipe was a part of a larger assembly, and the relative motion of the assembly did not cooperate well with the rigid plastic-like component.

The pursuit to shorten design cycles and manufacture parts faster led him to Protolabs for prototyping and end-use parts.

Rapid Silicone Rubber Tooling Bridges Production Gap

Farris and his team reevaluated the material used for the light pipe component and decided to manufacture the part with liquid silicone rubber(LSR). A moulded LSR part would be able to naturally flex with the user's motion and have the durability to last indefinitely. But the challenge was more than identifying the proper material. They also needed a cost-efficient moulding option that was optimized for this stage of product development since design was not yet finalised.

The robotic exoskeleton was still in the prototyping phase and FDA approvals were still pending, so a costly investment in traditional tooling was not ideal. Farris turned to Protolabs' LSR moulding process to quickly manufacture several light pipe components so that he could test the new design and have the flexibility to iterate if necessary.

He notes that the key to accelerating the moulding process was Protolabs' automated, interactive quoting system. He and his team will often upload parts for quotes in a few hours, then go through several iterations until it is within their targeted cost. This enabled a highly iterative design process while reducing development costs since it could all be digitally achieved through software and did not require manufacturing final parts.

Automated Quoting Saves Weeks of Development Time

After receiving the moulded LSR parts, they put the new design through testing and found it had the flexibility and durability to withstand the daily use of the Indego system. "We have been very happy with the switch to a liquid silicone rubber part," Farris said. "The light transmission is excellent, the visibility of the indicator to the user is excellent, and we have not had any durability issues since the change."

Farris estimates that Protolabs' moulding service saved his team between one and two months of time by manufacturing the LSR parts within days. With tooling optimised for low-volume production, they could bridge the gap between early prototypes and final production.

"Internally, had we tried to make these parts ourselves, it would probably take a month due to bandwidth limitations," said Farris.

But this redesign was much more than a product improvement developed in an R&D lab. Farris shared that this one example of the company's larger, strategic effort to focus on customer service by listening to user feedback and implementing product improvements quickly.

"Our aim is to be as fast as possible. When we have new developments, part of our competitive advantage is speed. When we have issues in the field, one of the things that we believe shows concern for our customers in a big way is our speed of response," he explained.

In addition to the moulded LSR part, the Indego engineers and designers relied heavily on Protolabs' CNC machining and 3D printing capabilities throughout the development of the robotic exoskeleton. For example, Farris notes that he had fixtures machined in order to secure components in place for ultrasonic welding. He also used 3D printing to build nylon prototypes through selective laser sintering before transitioning to injection moulding.

With low-volume manufacturing at its disposal, Parker Hannifin has been able to reduce development time, bring innovative products to market faster, and effectively respond to customer feedback. Overall, including moulded production parts, Farris estimates Parker Hannifin's Human Motion and Control business unit has manufactured thousands of components with Protolabs and will continue leveraging its digital manufacturing services in future generations of the Indego.

3D Printed Cranial Implant Gives Better Quality of Life

Introduction

Cranial implants are highly intricate and must be manufactured to the highest standards. Once such patient in Argentina, who needed a particularly large implant after cerebrovascular surgery, required an implant to be the best fit possible, with good tolerance of the implant by the body and integration with biological functions. Novax DMA, based in Buenos Aires, was assigned the challenge to develop and manufacture a perfectly-fitting implant for the cranial area - able to accommodate permeability to liquids and heat dissipation.

Challenge

The body is very tolerant of titanium but, as it is a metal, there is a danger to patients exposing themselves to the sun and too much heat being transmitted into the body. In addition, a titanium structure would not be permeable for tissue fluid from the brain. For this patient, the procedure required special secondary process added to the specification. By including a secondary treatment after manufacturing - in this case 'cleaning' - made it possible to use a 3D printed part for this challenge. The importance of cleaning is vital because adherent particles are released from the body by the slightest movement, which can lead to infection or rejection. So a completely germ-free environment is a key criterion for the successful acceptance of an implant by the body.

It is important for an implant in the cranium-brain area to support - or at least not hinder - the recovery process. The first requirement is as perfect as fit as possible. This is one of the major
benefits of additive manufacturing: the layer-by-layer manufacturing by a laser - in this case with titanium - hardened on a piece-by-piece basis; lends itself to maximum customisation of shape and size.

As well as the need for a perfect fit, there were more challenges along the way for Novax DMA, who partnered by Protolabs, during the challenge to create the perfect part. Due to the size of the patient's hole in the cranial bone, the solution included integrating the biological function of the implant while minimising heat transfer into the brain tissue.

Solution

After Novax DMA and Protolabs experts pulled together and evaluated all aspects of the challenge, they came to the conclusion that only a porous structure would exhibit the required properties. The result involved a grill-shaped implant with integrated fixing lugs for the cranial bone. This will allow liquids to permeate it and enables growth of the bone. In addition, this design has an insulating effect, so the conduction of heat into the interior of the cranium is minimised. The dimensions: The pinholes themselves are approx. 1mm wide, the grill width being around 0.2mm. After the basic structure was confirmed, the medical technology specialists took over.

Daniel Fiz, Chief Executive Officer of Novax DMA, remembers: "Time was of the essence for this work. Patients need to receive their implant as quickly as possible. After we received the final information about dimensions, we started work on the construction and manufacture of the implant with Protolabs."

"We've completed many projects successfully with our manufacturing process", said Christoph Erhardt, Head of 3D printing and Quality Management at Protolabs. "We're particularly proud of this implant - and not just because of the precise forming of the shape. The chief concern was keeping things perfectly clean. Porous structures, with inherent small hollow spaces, are particularly difficult to keep clean. The precise nature of the process is confidential but, basically, Protolabs has a multi-step process of abrasive and mechanical cleaning, rinsing and ultrasound to reach the level of cleanliness needed for medical applications. It took a full 6 months to develop the process."

Outcome

The result: a perfectly cut implant tailored to the specific requirements of the patient's condition. Porosity reaches 95% so that liquids can flow with as little resistance as possible, so the bone tissue is able to penetrate the outer edges of the implant, again with as little resistance as possible, and grow with it. The material is also stable enough to enable the patient to lead a normal life; the standard grill structure allows for the required heat transfer properties - so the patient can enjoy time in the sunshine without problems.

Amongst all the possibilities for perfecting the process, one factor in particular was critical. Time-to-market is key in an industrial environment and plays to the strengths of additive manufacturing, particularly in the medical sector: the implant was in the operating theatre within just three weeks. The biggest log jam in the system was transport, which took around a week. Preparing the data and manufacturing were done in about 2 1/2 days, and the rest of the time was taken up with various procedures to do with logistics and coordination.

The two companies could verify the degree of cleanliness through a range of tests. Christoph Erhardt's team were able to carry out particle and cytotoxicity tests amongst other things. There was also analysis using gas chromatography. "All the investigations confirmed that the additively manufactured implant fulfilled the necessary requirements for the long-term stability and protection of the patient's skullcap.

The 90-minute-long operation was completed without incident in 2014. The patient was able to leave the clinic after 2 days, and the wound healed after 3 weeks. To date, the patient has experienced no complications after the operation.

Thanks to processes and projects such as this, 3D printing can significantly assist contribute towards patients with cranial injuries lead a full life.

Helping a Life Saving Idea Become Real

Introduction

The Evo System, from Norwegian start-up Moon Labs, is an unobtrusive, wireless and affordable solution that provides ongoing vital health information.

Like so many of the best ideas in life, the Evo System was conceived by a small team of people in response to a real need that was not being met. Having already prototyped it using its own 3D printing technology, the company needed to manufacture higher volumes for pilot testing and clinical trials in Norwegian hospitals.

The monitoring system consists of three elements: The Evo Sensor is a small wireless disposable biosensor that sits comfortably behind the patient's ear. It measures heart and respiration rate and oxygen saturation continuously for up to five days. The Evo Gateway transmits this data to the cloud using the communication system Fast Healthcare Interoperability Resources, or FHIR, so that it integrates directly with the patient's electronic journal. The final part, Evo Central, is software for doctors and nurses to track multiple patients' vital signs over time. It calculates early warning scores to highlight if their health is deteriorating and requires intervention.

Having prototyped the design to prove the concept, the next step for Moon Labs was to move towards manufacturing the system for pilot testing and clinical trials in hospitals.

While injection moulding significantly reduces the unit cost for larger production runs, it does have certain design requirements. Product lead and co-founder of Moon Labs Tord Åsnes used Protolabs Design for Manufacturability (DFM) analysis software to develop the design and make it suitable for future mass manufacture.

Talking about the process, Åsnes said: "I found the DFM analysis software excellent. After uploading my design, it highlighted areas where there could be manufacturing issues and then suggested alternative solutions. I put a number of design iterations through the system and, with the help of an Application Engineer at Protolabs, came up with a design that met our needs and could be injection moulded.

"Protolabs have really helped us take the Evo System onto the next stage of development and closer to a real-life solution that will save lives and cut hospital budgets. It is meant to be a cost-effective solution, so we had to find a way of mass manufacturing it to lower the unit costs."

Explaining the importance of the Evo System, Nils Kristian Skjærvold, medical director at Moon Labs and senior consultant at the Department of Cardiothoracic Anesthesia and Intensive Care at St. Olav's hospital in Norway said: "While patients in intensive care are monitored regularly, we must not forget that those people in general care in the hospital are still very ill people. There is always a chance that they can deteriorate and have a cardiac or respiratory arrest.

"When we get called out in an emergency, we sometimes have no idea how long a person has been in arrest. This is a life-threatening situation that could mean that they end up in intensive care where treatment is expensive, or worse they could lose their life.

"The Evo System is a cost-effective way of monitoring patients in general wards or rooms so that medical staff can see any deterioration in advance and take corrective action immediately."

After an initial production run of 500 Evo Sensors and 100 Evo Gateways, the system will be trialed in three hospitals in Norway. Moon Labs then hopes to gain CE marking and be able to manufacture the system by early 2021.

Digital Manufacturing Helps Medtech Firm's Goal to Improve Patient Outcomes

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Introduction

As often happens in the medical industry, innovative ideas hatched in university research settings, spawn innovative companies, who create innovative products. A case in point: HemoSonics.

The Charlottesville, Virginia-based medical device company was started in 2005 by two professors and a post-doctoral research student at the University of Virginia School of Medicine's Bio-Medical Engineering program; Bill Walker, Mike Lawrence, and Francesco Viola. The trio identified a method for measuring the stiffness of blood clots by using ultra-sound imaging technology, and created a system built around that technology aimed to improve patient outcomes and reduce costs.

A number of years of extensive research and development followed, which included securing key patents, conducting numerous hospital studies, and consulting with physicians and other clinicians.

More recently, HemoSonics has been prepping to bring its Quantra System diagnostic products to market, with prototyping and end-use manufacturing help from Protolabs. In fact, Protolabs has worked with HemoSonics since 2011, from those early R&D days to more recent, end-use production work on the Quantra System.

HemoSonics successfully launched its products commercially last year in Europe, and hopes to enter the U.S. market soon. HemoSonics has expanded its offices into Durham, North Carolina, and has grown to 50-plus employees.

A Need for Speed and Flexibility, Solved by an Agile Supplier

In HemoSonics' early research and development days, engineers were "iterating through multiple designs under tight deadlines," said Andy Homyk, senior engineer, who joined the company more than six years ago when it had just five employees. "We were on a tight timeline so we needed a supplier who could machine parts for us quickly, within a couple of days."

A number of suppliers contacted could not meet those challenging deadlines. Protolabs could, Homyk remembered. "The difference in lead times was dramatic."

That was in 2012. Since that time, Protolabs has produced hundreds of prototypes and thousands of components for HemoSonics, using 3D Printing, CNC Machining, and Injection Moulding—for a variety of projects and parts: robotic fixturing, thermal control units, pneumatic manifolds, and more.

> "Speed and flexibility—being able to deploy different manufacturing options—and a commitment to customer service, are the main reasons we use Protolabs"

More recently, HemoSonics looked to Protolabs for help with the "skins" or casings that fit around the Quantra System, Homyk explained. HemoSonics engineers needed design prototypes about the size of a computer monitor—first using 3D printing and then injection moulding—to demonstrate form, fit, and function of the Quantra System to physicians at various hospitals.

The Quantra System is designed as a rapid, easy-to-use diagnostic platform that uses disposable cartridges to conduct a panel of tests. The Quantra Hemostasis Analyser is designed for use in critical care settings that require results to be generated quickly from an instrument that is easy to operate at the point of care.

A challenge emerged when the project switched from additive manufacturing to injection moulding. "These are pretty big parts, so one of the moulding challenges, in prototyping, was colour matching," Homyk said.

Moulding Materials and Finishing Touches

HemoSonics wanted these casings Pantone colour-matched to its marketing department's specifications. One of the ways Protolabs normally does that, in the injection moulding process, is to take the plastic resin in the natural colour of the specific material chosen, apply around a 3 percent salt-and-pepper mix of coloured resins, and final parts are typically very close to the preferred colour. But, because of the nature of HemoSonics parts, some swirling and flow marks were showing up on them. "The first batch of parts did not look good cosmetically," Homyk remembered.

Undaunted, Protolabs went to one of its plastic resin suppliers and the supplier collaborated with Protolabs and HemoSonics to pre-compound the colours. "They mixed the plastic with the dye before moulding to get pellets with a nice uniform colour," Homyk said. This custom, pre-coloured resin produced flawless parts. "This again speaks to Protolabs' customer service going the extra mile, and to how agile the company can be."

Material selection was also carefully considered, Homyk said, given that a requirement of almost any kind of medical device is that it needs to meet certain flammability standards. For the casings, HemoSonics opted for an ABS plastic that met those standards and also offered durability.

Beyond machining, 3D printing, and injection moulding, HemoSonics engineers also used some additional finishing options on the injection-moulded parts, such as heat staking and pad printing. Heat staking is a process that uses a heated stake to melt metal threaded inserts into plastic parts. This makes it so that screws can be used to attach the Quantra casing parts to a frame, for example.

Pad printing is a process that uses a stamp called a cliche to apply coloured logos or decals to parts. HemoSonics used pad printing to put company logos on the Quantra System case parts. Protolabs plans to make these and other finishing options such as mould texturing and part assembly more widely available in the future.

The Outcome? Quantra System Launched in Europe, and is Progressing toward the U.S.

Those long years of research and development, multiple design iterations and prototypes, numerous hospital studies, scores of visits to physicians and other clinicians, the securing of key patents, and the landing of important certifications in Europe—including the CE Mark, is finally paying off, Homyk said. Last year, the Quantra System launched in Europe, and company leaders hope to launch the Quantra System in the U.S.

Going forward, Homyk expects Protolabs to continue to play a key supplier role to support the company's work. "We pick you guys (Protolabs) because of familiarity, speed of production, flexibility, and exceptional customer service."

Digital Manufacturing for the Medical Industry

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

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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.

READ MORE

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

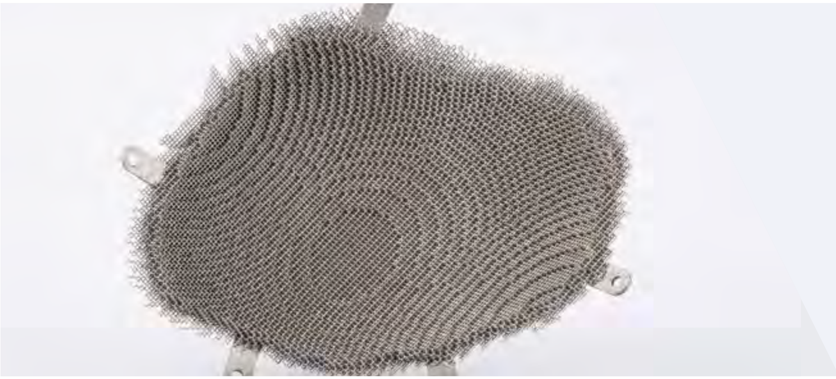
Recently, we have seen examples of implants for parts originally made from organic tissue. A good example is a heart valve prosthesis made from silicone AM. Created by a team of researchers from ETH Zurich, these artificial 3D printed heart valves make it possible to replace valves in an aging population.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

READ MORE

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.

LEARN MORE

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.

READ MORE

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.

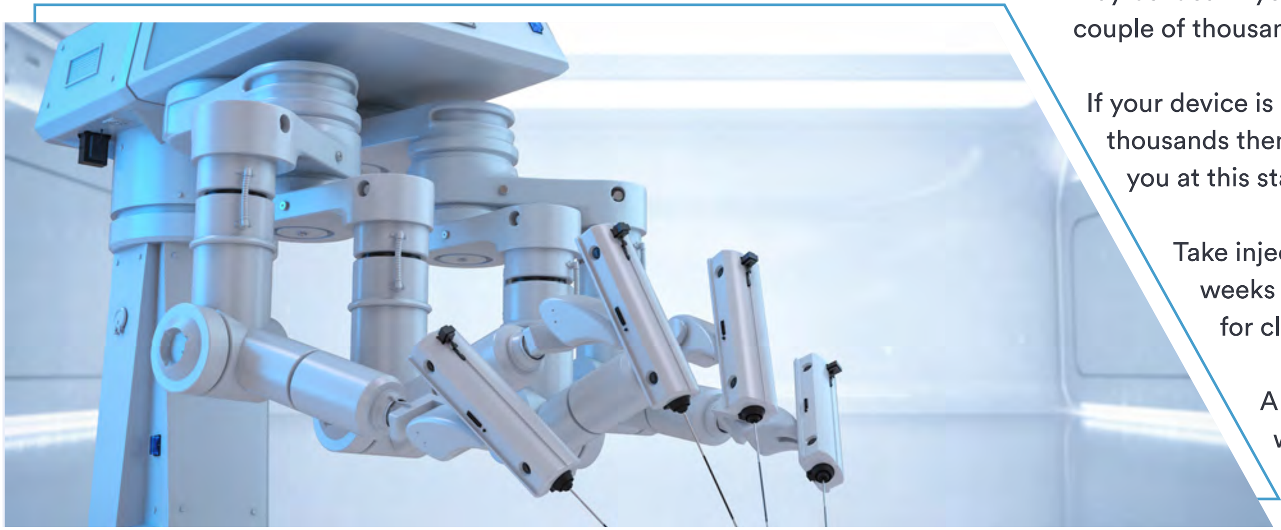
It's a useful sense check to see if your design will work in practice. If you need some help after this first stage, and many do to move the development through, then you can contact us to take advantage of our consultative design service for injection moulding – there is no charge for those who have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

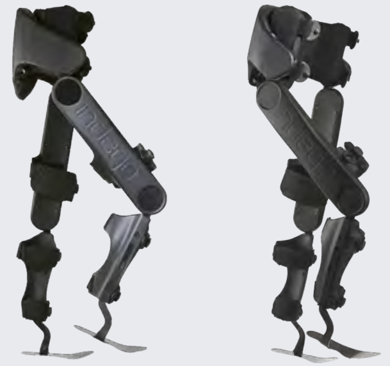
This all starts with your CAD and it pays to pick design issues up at this stage to save yourself time and money later in the development process. Protolabs automates this quoting and design for manufacturability analysis so that you can get a rapid sense check; if you need more help we also offer a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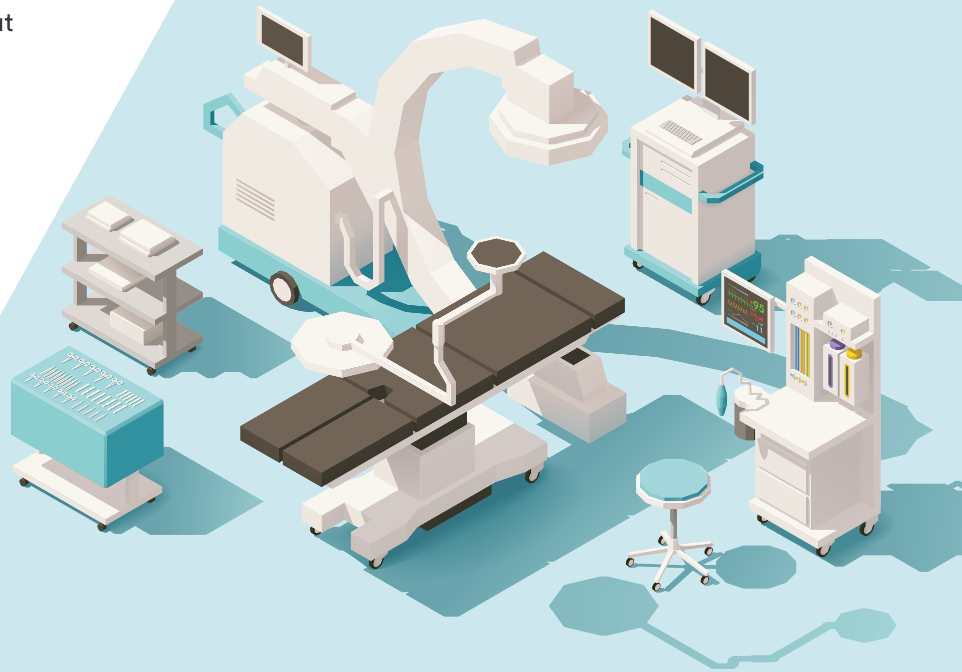
CONCLUSION

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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Manufacturing. Accelerated.

ISO 13485:2016

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