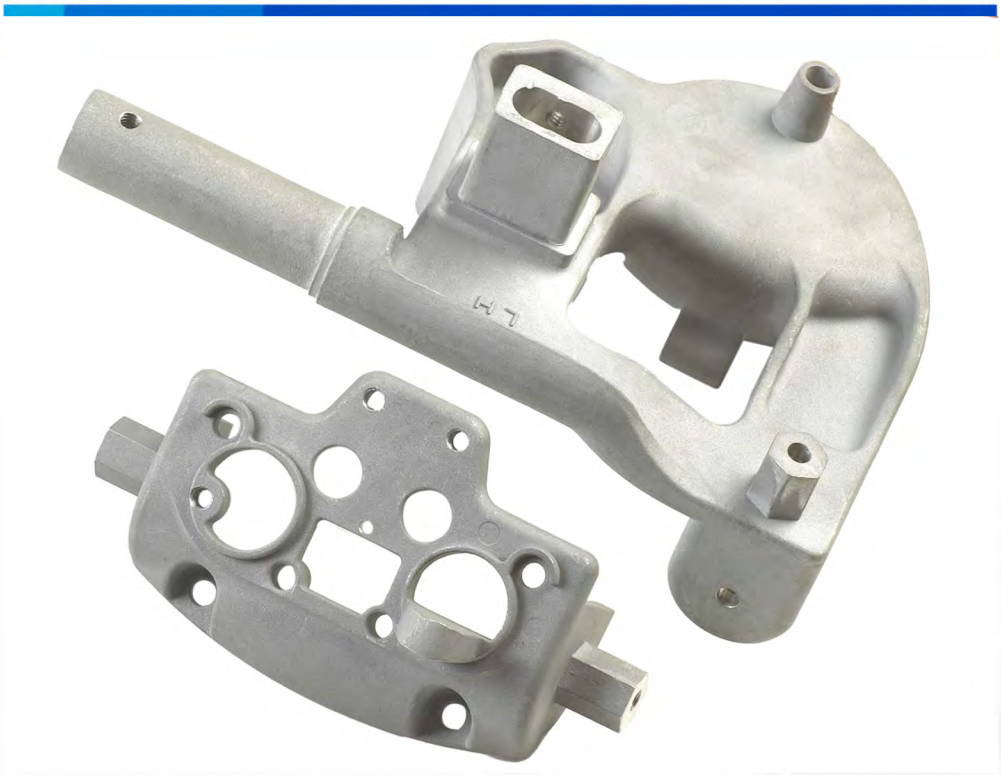


Manufacturing Medical Device Components

with Investment Casting and Precision Machining

Impro

Components used in medical devices are produced to tight tolerances from hard-to-machine metals. Smooth surface finishes are frequently a key requirement and quantities range from one-offs to thousands.



Parts like these are often hard to make, unless the manufacturer has the right processes, equipment and expertise. The casting and machining experts at Impro are very familiar with manufacturing challenges like these, and Impro has the resources to produce consistently high-quality components.

This eBook details the processes we use to manufacture parts for medical devices.

Sections address:

- What Count as Medical Devices?
- Alloys for Medical Device Components
- Challenges in Manufacturing Medical Device
- Components
- Casting: Why Investment Casting is Preferred
- The Precision Machining Challenge
  Medical Device Components Made by Investment Casting and Precision Machining

What Count as Medical Devices?

To those outside the medical profession a medical device is something like a hip joint or a replacement knee. While these are medical devices they come under the heading of “implantable medical devices.”



The reality is that the term “medical device” encompasses far more. The FDA defines three “classes” of medical devices while industry experts typically identify six categories. These are:

- Implants — replacement hip and knee joints, but also replacements for tibia, shoulder joints, elbows and ankles as well as screws, plates and maxillofacial implants (FDA Class 3)
- Prosthetics — this includes heart valves and eyeglasses as well as replacement joints or limbs (FDA Class 3)
- Diagnostic equipment — CT, x-ray and ultrasound machinery, plus equipment like whole blood oximeters and hemodynamic monitoring systems (FDA Class 2)
- Biosystem equipment — this covers equipment used in medical diagnostic and analytical procedures. It can refer to DNA sequencing machines, sample labeling systems, and everything in between. (Generally, FDA Class 2 but may vary depending on specific application.)

- Surgical instruments — clamps and scissors, power tools, saws, knives and rasps (FDA Class 1)
- Patient handling equipment — hospital operating tables plus beds, trolleys, wheelchairs and anything else used to help move patients through a medical facility (FDA Class 1)





Alloys for Medical Device Components

Something common to almost all medical devices and components is that they will go through rigorous cleaning. For some this will extend to sterilization after every use while others receive less frequent but still thorough sanitizing.

Such cleaning, extending to sterilization with hydrogen peroxide or peracetic acid, will quickly strip away paints or other coatings. Consequently, components used in medical devices are often made from corrosion-resistant alloys so they can be left uncoated.

In most applications it's expected that materials will be very hard-wearing and fatigue-resistant. Many are expected to bear high loads. Those that will be implanted into the human body must also be biocompatible, meaning they should not produce any kind of immune response.

The list of metal alloys meeting these requirements is short.

For implants the following are preferred:

- Stainless steel in 316 and 17-4 precipitation hardened grades
- Titanium, in grades 6AL4V and 6AL4V (containing 6% Aluminum and 4% Vanadium)
- Cobalt chrome alloys (CoCr)
- Tantalum
- Nitinol (nickel-titanium alloy)

In applications that don't need biocompatibility stainless steel is far and away the most widely used alloy due to its hardness and corrosion-resistance. Aluminum is used in select applications but will be anodized to ensure the surface is hard and non-reactive.

Challenges in Manufacturing Medical Device Components

The alloys preferred for medical devices all pose challenges in manufacturing. These are addressed under the headings of:

- Machinability
- Formability
- Tolerances
- Surface Finish

Machinability

Except for aluminum, the alloys used for medical device components are difficult to machine. This is down to their inherent toughness, combined with high hardness and a tendency to work-harden.

Titanium poses particular challenges. Titanium chips don't break easily and form ribbons with a gummy quality that has them sticking to the cutting tool. In addition, a low Young's modulus promotes springback and chatter, making it difficult to achieve consistent surface finishes.

Cobalt chrome alloys are particularly hard and wear cutting tools quickly, which again makes it difficult to maintain a consistent surface finish.

Like titanium, stainless steel tends to be tough and gummy and can seize and cause galling of cutting tool inserts.

Tantalum is not as hard as the other alloys but still has the work-hardening and "gummy" characteristics that make machining difficult.
Nitinol combines all the most challenging machinability characteristics of the alloys discussed above. In particular, high hardness causes rapid tool wear, making it very difficult to maintain an acceptable surface finish.

Formability

Forging is an option for some medical device components although the alloys used don't forge easily. The process yields high strength parts that still need finish machining. Forging dies for medical device components are expensive and tend to suffer high wear. Furthermore, the forging process is relatively slow and therefore expensive.

Tolerances

Dimensional tolerances on medical device components are often tighter than found in other industries. High stiffness machine tools are a necessity to minimize deflection during machining.

Cutting these very hard alloys generates a lot of heat. If this is transferred into the piece being machined the resulting expansion will make it difficult to maintain tight tolerances. Good practice is to take light cuts and ensure the heat stays with the chip.

Surface Finish

As discussed above, while medical device components frequently have exacting surface finish requirements, the alloys used make this difficult to achieve. Very close attention must be paid to machining conditions with cutting tools being replaced before they become excessively worn. High stiffness machine tools minimize deflection and chatter.



Casting: Why Investment Casting is Preferred

The challenges of machining these alloys make metal removal a slow and expensive process. Manufacturers like Impro address this by using near-net shape processes which minimize the amount of machining required. Sand casting and investment casting are both cost-effective but the latter requires smaller machining allowances and yields higher quality surfaces. For those unfamiliar with investment casting or how it can yield close-to-net-shape parts, here's an overview.

Creating the Casting Cavity in Investment Casting

All casting processes entail filling a cavity the size and shape of the part required with molten metal. In the case of investment casting, that cavity is formed by a wax or polymer pattern.

Patterns are typically injection molded, although can also be 3D printed. A number of such patterns are assembled into a "tree". This is then coated with a ceramic slurry that dries to form a hard shell.

The coating is composed of a number of layers, built up either by dipping or spraying. The number of layers affects the rate at which the molten metal cools and solidifies.

The pattern is then melted out of the ceramic shell, leaving a void for the metal to fill. Metal is poured in and left to freeze, after which the shell is broken away to reveal the cast part.

Advantages of Investment Casting for Medical Device Components

Almost any metal can be investment cast, including the high-hardness alloys typically used for medical device components. The major limitation is fluidity or viscosity: alloys that don't flow as well limit the minimum section thickness and may not faithfully replicate intricate features.

In general though, one of the biggest advantages of investment casting is its ability to reproduce fine detail and fill thin sections. While there is some shrinkage it's consistent and predictable so dimensional accuracy and repeatability are very good. Together these aspects minimize the amount of machining needed to finish the part.



Furthermore, investment casting yields surfaces finishes as good as those on the pattern. Thus, by taking care to finish the pattern to the standard needed it's often possible to avoid grinding and polishing processes.

Investment casting is used for both high and low volume production. The principal consideration here is the pattern production method and quantity needed. Large quantities will often use patterns molded on large machines in multi-cavity dies while smaller volumes may need only a single cavity die running on a smaller molding machine.

The Precision Machining Challenge

Investment casting yields parts that are near net shape but some final machining is often needed. Reasons for this include:

- Providing surfaces that are smooth, flat and square for mounting onto other parts
- Creating mounting holes for screws, which may or may not need threading
- Enabling installation of precision components like bearings
- Meeting roundness and cylindricity specifications

As noted under “Machinability” the alloys used for medical device components are mostly very hard and quickly wear the cutting tool inserts. High hardness can cause deflection in the toolholder and other components of the machine tool, which lead to form and dimensional inconsistencies and chatter. It also generates heat which, if allowed to move into the part being machined, can affect size and even microstructure.

Chip control is a particular challenge when machining these “medical” alloys. Not only do “gummy” materials accelerate insert wear but the resulting ribbons are difficult to handle and dispose of without causing injury. In addition, as an insert wears cutting forces will go up which leads to deteriorating dimensional control and surface finish.



Avoiding problems in machining requires three things:

- High quality machine tools
- Effective machine tool maintenance
- Appropriate cutting tool selection, mounting and usage

Impro machines parts for medical devices on powerful CNC turning and milling centers, with some drilling and grinding being performed as needed. These machines provide exceptional strength and rigidity and their CNC controls deliver the flexibility to handle both large and small quantity orders.



Impro has extensive experience of manufacturing components for medical devices of various types. Those made by investment casting include:

- Mount Housings
- Flange Pivots
- Caster Mounts
- Guides
- Support Blocks
- Brackets
- Hinge Blocks
- Radial Supports

End use applications for these include diagnostic equipment, surgical instruments, biosystem equipment, prosthetics, patient handling equipment and implants.

Impro: Making Parts for Medical Devices

The metal parts used in many medical devices present manufacturing challenges not seen in other industries. To an extent that's down to highly variable volumes but the biggest issue is the materials used. Meeting the expectations of patients and medical professionals means these are made mostly from alloys that are very hard and difficult to machine.



Impro has extensive casting and machining experience and brings this to bear on a wide range of medical device components. To find out how that knowledge can be applied to your medical device components, contact us today.

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