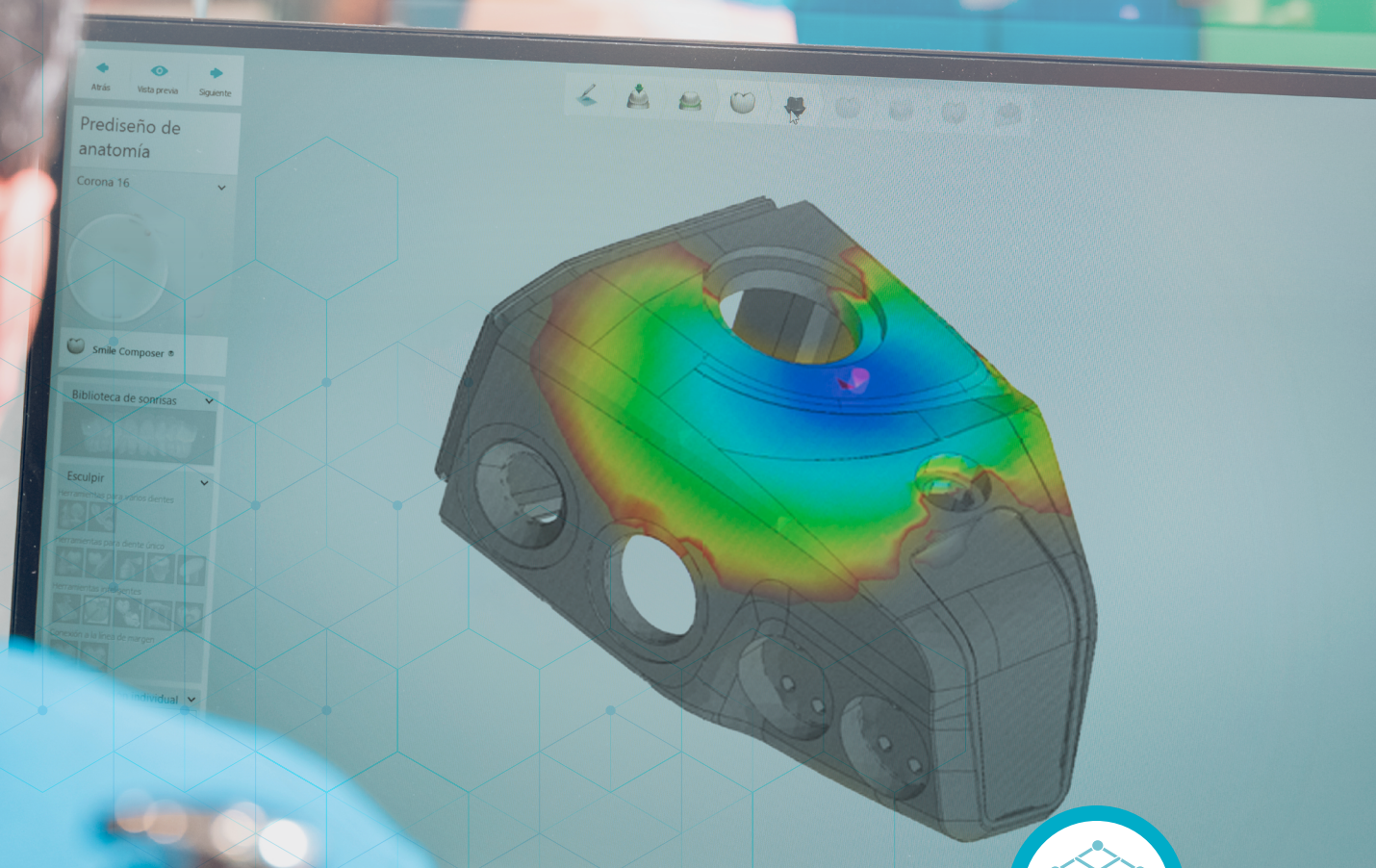


Medical Device Design for Plastic Injection Molding

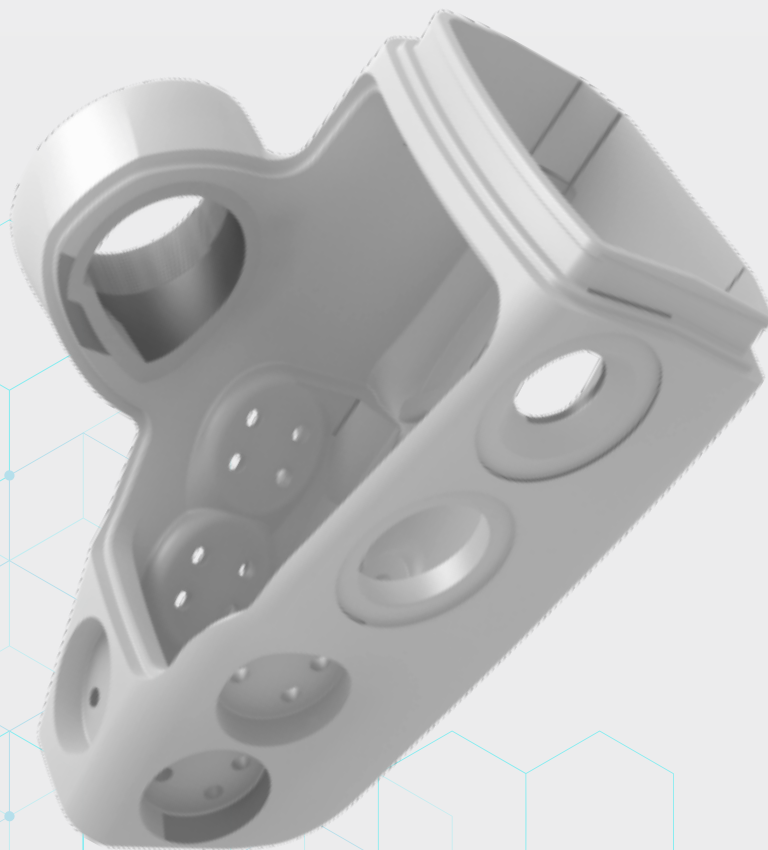


Introduction

Beginning medical device design for injection molding

Designing a new medical device is an exciting, albeit intimidating, venture with endless possibilities. Over the years, our team has collaborated with countless design engineers to turn their visions into reality. Using good Design for Manufacturing (DfM) practices early in the design process can decrease the chance of costly manufacturing issues and increase product quality and performance.

We will guide you on good DfM practices by helping you understand which design considerations will affect manufacturability, how plastic material selection influences the molding process and how to avoid common defects.



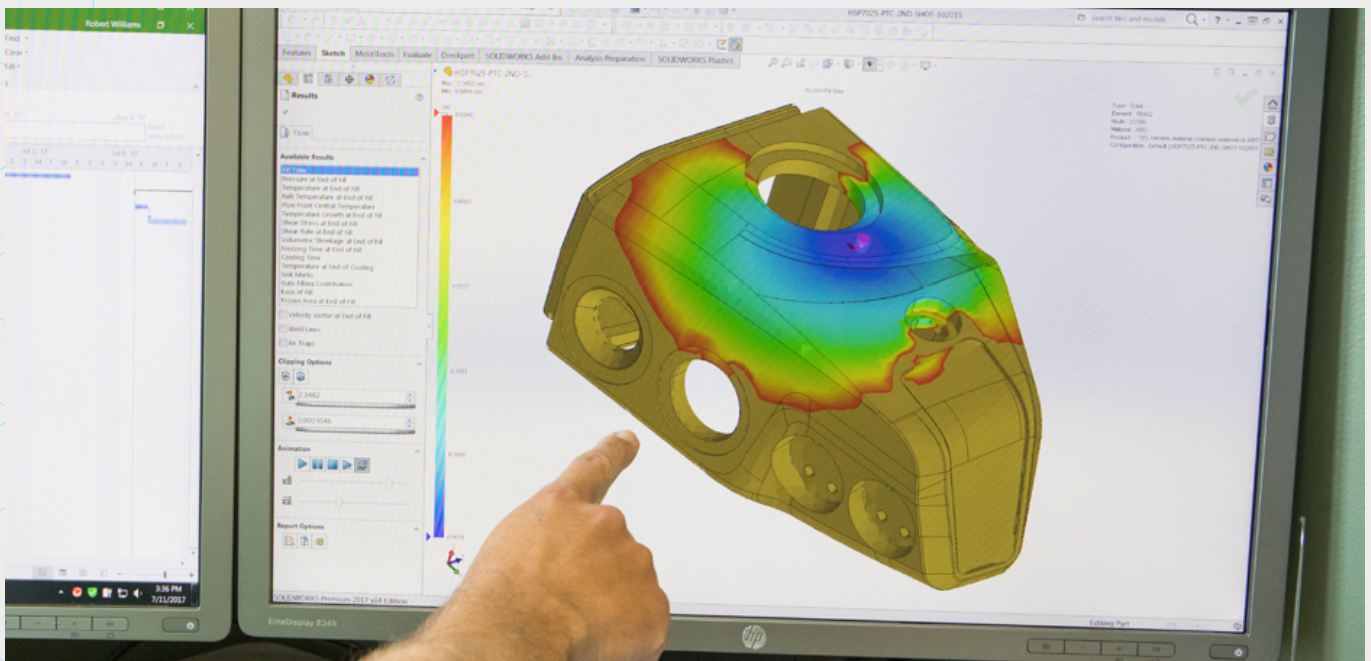
Design Considerations for Medical Device Injection Molding

Designing medical devices for injection molding requires extensive understanding, reasoning and planning. Careful consideration of certain aspects throughout the design process will yield favorable results.

There are different aspects to evaluate in order to make certain the actual design meets the desired criteria. Design engineers need to account for part size, impact, material selection, production volume and budgets during the early stages of design. These aspects are major components

that drive future decisions of mold designs, components, options and costs.

We have compiled major considerations that designers should examine when designing medical devices that rely on plastic injection molding. These considerations, if properly addressed, will reduce overall tool and part costs as well as benefit the manufacturing process by achieving the highest possible quality and reliability.



Considerations for medical device design

Draft

The most misunderstood consideration design engineers run into is incorporating proper draft into the part design. Draft is a slight tapering of the part that allows it to eject from the cavity. As the plastic part cools in the tool, it shrinks, which causes it to adhere more firmly to the core of a mold. A draft on the part of just a few degrees reduces this effect. Draft also reduces frictional damage during ejection. A draft of '0.5 to 3.0' degrees should be considered dependent on texture.

Shrink allowance

Each plastic material shrinks as it cools. Fortunately, plastics sometimes come with their own shrinkage data to be accounted for

during design, although it can still be difficult to estimate the shrink value of some materials. Shrink is incorporated into the mold design and thus designers must be aware of its impact, some materials may not have well-defined shrink characteristics.

Wall thickness

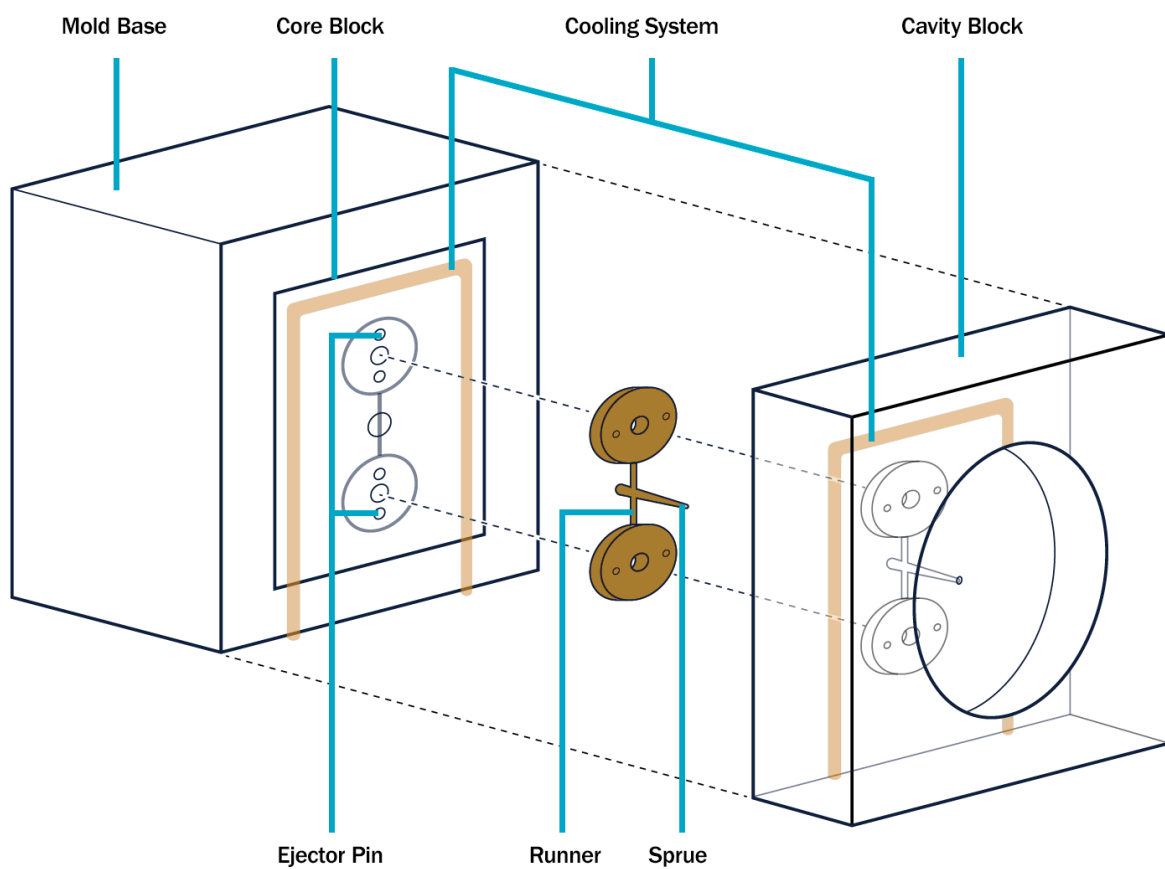
Injection molding does not work well with walls that are too thick or too thin. In particular, wall thickness can make gate placement challenging. It is difficult to gate on thin wall sections. Further, plastic material does not flow effectively from thin to thick sections of the cavity. Uniform wall thicknesses provide for the most flexibility when deciding on gate location and can reduce the potential for warping, sink and other defects.



Parts of the mold

Design engineers must consider all components in the mold when reviewing designs for best DfM practices. Understanding how the mold

components impact design and the overall injection molding process will improve the general quality of the final medical device.



Gates

Gates are the entry points for molten plastic to flow into the cavity of the mold. There are many types of gates – edge, ring, diaphragm, sub-gate, direct sprue, etc. – that are used based on the shape of the device. The sprue is the initial gate, where plastic is received from the injection molding machine. It can also run as a hot tip gate, which is used with hot runners. Hot tip gates eliminate the “runner” for the part, allowing for faster cycle times and reducing the amount of material used in molding the part. It should be noted that sprues can be removed (generally to save material costs) with the use of hot runner systems. It can also be known as a hot tip gate, which is used with hot runners.

Gate location is important to design so plastic resin flows efficiently and fills the mold. Consider locating gates at meaningful cross sections. This will minimize voids and sink while ensuring the cavity is filling properly. Further, place gates away from cores and pins in order to mitigate obstructions in the flow path. Gate locations should always improve efficiency without negatively impacting the functionality or aesthetic of the part. In fact, a mold flow analysis can help you determine optimal gate locations.

Runners

Runners are channels in the mold that carry plastic from the sprue to the gates. There are two types of runners: hot and cold runner systems. Hot runners are more expensive, but life cycle costs are considerably lower due to reduced plastic waste, shorter cycle times and design flexibility. When material costs are particularly expensive

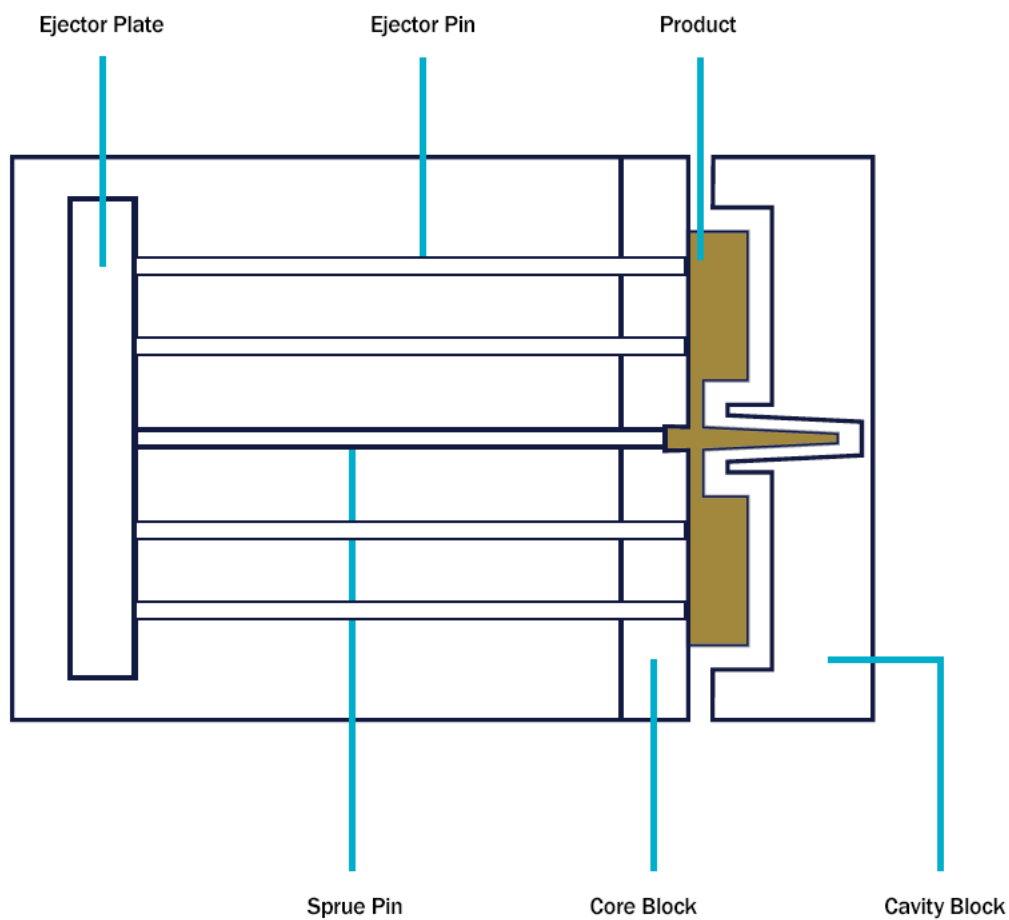
and part volume demands are high, hot runner systems are ideal. Cold runner systems use unheated channels. A mold with cold runners will need a large enough shot of molten plastic to fill the cavity and runners. Cold runner systems are ideal for lower product volumes and less expensive materials.



Ejector system

Every molded part requires a way to be ejected without causing damage to the part or the mold. Proper draft will facilitate the ejection process, but each mold still needs a system for ejection. There are many kinds of ejector systems, from pin and sleeve ejectors to blade and air ejectors.

Understanding ejection systems will influence design determinations to find a balance that promotes the integrity of the part and mold. In fact, ejector systems leave a “mark” on locations that need to be considered for high cosmetic parts.



Cavity and core plate

The cavity and core plate, or block as it is also called (see image), is the section of the mold to be filled with the plastic resin and accounts for the external shape of the device. The cavity and core combine to form the part geometry based on the parting line. When designing the cavity and core

plate, it is important to incorporate the draft and account for decorative and textured components. However, note that the decorative and textured components may be better accounted during the finishing stage of the manufacturing process.

Cooling circuit

Essentially, a mold is a complex heat exchanger. The mold must be hot enough to effectively enhance the molding cycle and be designed to cool as quickly as possible. The cooling circuit removes the heat by [running water through hollowed channels](#) in the mold.

This expedites cooling to help meet the cycle times necessary for production. Most companies reach out to Trelleborg after their designs are

completed and ask our engineers to adjust the designs for better DfM practices. We strongly recommend coming to Trelleborg when you begin designing your device.

Of course, no design is complete without an appropriate plastic material. However, most design engineers don't consider the various options that are available to them.



Plastic Material Selection for Molding

Plastic material selection is an involved process filled with complexities such as medical classifications, mechanical properties and cost. Streamlining the selection process by eliminating classes of plastics and individual plastics based on your specifications can help you pinpoint an appropriate material. Second opinions and new device designs can also provide new and / or cost-effective possibilities.

Note that identifying the type of plastic material should take precedence over identifying a specific brand. You should also consider resins based on their availability and performance capabilities.

There are two major families of plastics: thermoplastics and thermosets. Thermoplastics are moldable at specific temperatures and cool upon solidification. They are defined by their ability to be heated and reheated. Thermosets, on the other hand, remain in a permanently solid state once cooled, making them ideal for sealed products (e.g., rubber O-Rings). Products made with thermosets have high temperature resistance.



Thermoplastics

Thermoplastics are optimal for medical devices due to their moldability, compliance with FDA and medical classifications, and their ability to accommodate complex geometries. Their adaptability is paired with melt flow rates, vibration resistance, ergonomics and temperature resistance.

There are two classes of thermoplastics – amorphous and semi-crystalline thermoplastics – that are further classified into high-performance, engineering and commodity thermoplastics.

Thermoplastics*	Amorphous Thermoplastics	Semi-crystalline Thermoplastics
	Amorphous High-Performance Thermoplastics <i>Example: Polysulfone</i>	Semi-crystalline High-Performance Thermoplastics <i>Example: Polyetheretherketone</i>
	Amorphous Engineering Thermoplastics <i>Example: Polycarbonate</i>	Semi-crystalline Engineering Thermoplastics <i>Example: Nylon</i>
	Amorphous Commodity Thermoplastics <i>Example: Acrylic</i>	Semi-crystalline Commodity Thermoplastics <i>Example: Polypropylene</i>

*Cost, strength and temperature resistance are highest with high-performance thermoplastics and lowest with commodity thermoplastics. However, commodity thermoplastics have higher production volumes than high-performance thermoplastics.



Amorphous thermoplastics

Amorphous thermoplastics are fairly easy to injection mold because their randomly ordered molecular structure allows them to soften gradually. Furthermore, their translucent nature makes them easy to color and decorate. Additional attributes include:

- Ability to bond with other materials
- Cost-effectiveness
- Dimensional stability
- Impact resistance

Note that amorphous thermoplastics generally have poor fatigue resistance and final products

are prone to stress cracking if they aren't designed properly. However, they are ideal for secondary operations and can be used to manufacture handheld devices for medical operations.

High-performance amorphous thermoplastics (e.g., polysulfone and polyetherimide) exhibit high chemical, temperature and strength resistance. Although commodity amorphous thermoplastics (e.g., acrylic and polystyrene) cost less, they exhibit lower strength and temperature resistance.

Semi-crystalline thermoplastics

Semi-crystalline thermoplastics are characterized by their overall strength and sharp melting points due to their ordered molecular structure. Key attributes include good:

- Chemical resistance
- Electrical properties
- Fatigue resistance

Semi-crystalline thermoplastics are not usually biocompatible, which is why popular materials, such as glass-filled nylon, are used for the inside of handles where they won't be exposed to patients. In fact, their crystallinity and lubricity make them strong contenders for the internal components

of medical devices. Other applications include breakaway features for medical devices that will be used once, such as ratcheting gears, spring arms and structural loads.

High-performance semi-crystalline thermoplastics, (e.g., PEEK and PPS) exhibit good wear, temperature and chemical resistance, and high stiffness. They can also withstand sterilization and be autoclaved multiple times, such as for dental applications. Semicrystalline engineering thermoplastics (e.g., nylon) are not as strong or temperature-resistant but work well for the internal moving parts of a medical device.





Comparing amorphous and semi-crystalline thermoplastics

Thermoplastics are generally provided to injection molders in pellet form. The pellets are then heated into a liquid state and injected from a heated barrel into a cooled mold to harden and set. Thermoplastics can be reheated into a liquid state to be processed again. Thermosets, on the other hand, only turn into a liquid state when heated one time; they cannot be heated and processed again once set.

Injection molding amorphous thermoplastics require special attention to material shrinkage in the mold and moisture absorption. Although the

material usually needs to be injected with high pressure, overpacking is a significant concern. Furthermore, their ability to chemically bond with similar materials makes them ideal for [overmolding](#) applications.

Injection molding semi-crystalline thermoplastics requires precise temperature settings because they have sharp melting points and subsequent cooling times. Incomplete crystallization can result in warp, while underpacking can cause sinks and voids.



Suggested process

Although there is no perfect selection method due to the amount of available materials, the following steps can help narrow your search:

1

Determine if your plastic material options comply with regulations for:

- Biocompatibility (USP Class VI and ISO 10993)
- Bioabsorption
- Electric properties (UL)
- Food contact (FDA)

2

Look at how materials stand up to sterilization (e.g., autoclaving, gas and radiation) since their properties and color can change depending on the method and / or number of exposures.

3

Establish part design as a constraint since some materials are not conducive to certain applications.

4

Consider chemical resistance with regard to color, aesthetics, internal exposure and external exposure.



5

Research mechanical properties, such as:

- Dielectric properties
- Heat deflection temperature
- Impact strength and hardness
- Maximum operating temperature
- Physical properties
- Tensile and flexural strength
- Ultraviolet filtering
- Ultraviolet resistance and visible light transmission

6

Research the availability of plastic materials based on order volume. For example, within amorphous plastics, polysulfone is more expensive per pound than HIPS.

7

Establish your budget; anything from the amount of material to additives can increase cost.

Carefully consider shrink rates because once a mold with a specific shrink is designed, you are locked into that mold. Since the selection process can get complicated, we recommend that you consult a material supplier.



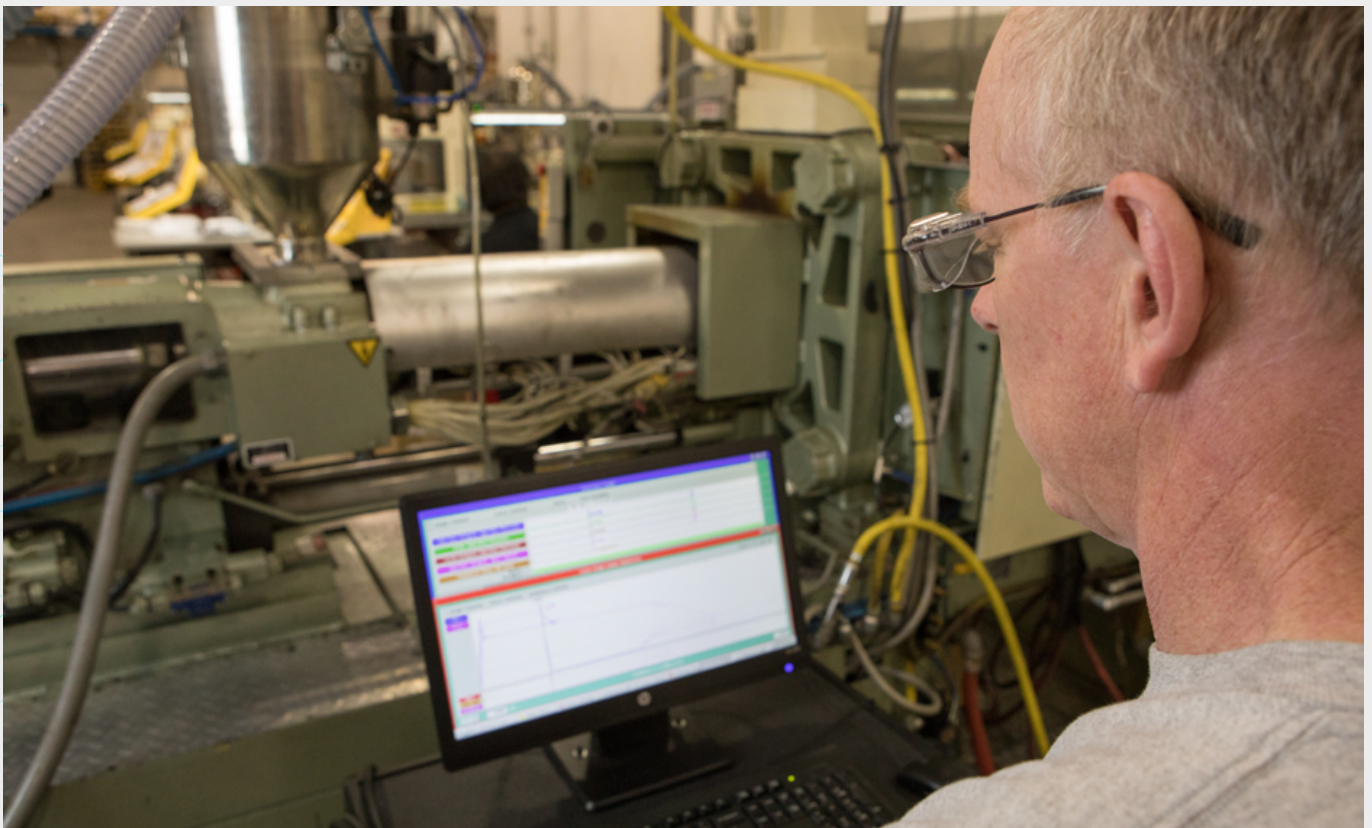
Overcoming Common Molding Challenges

Your medical device has been designed, and your preferred plastic has been selected. The final step is to mold your part, which should be simple. However, even the most seasoned injection molders, including medical device manufacturers, face challenges.

Although these challenges are common in every industry, defects associated with medical devices require special attention to plastic

material selection and part design along with the associated mold design and process parameters.

Medical devices are subject to stringent regulations, specifically FDA and ISO. Defects can seriously compromise the integrity of your final product and its subsequent approval. Fortunately, these challenges can be remedied and even prevented.



Causes of injection molding defects

Attention to detail, as well as adhering to best practices, can minimize and even prevent molding defects. The root cause of most molding defects can be narrowed to

issues associated with the machine, mold, plastic material and /or the operator. To minimize issues, be sure to consider:

- **Mold design**

- Mold flow
- Venting
- Gating

- **Plastic material**

- Viscosity
- Hydroscopy
- Material handling
- Melting temperature
- Cooling temperature

- **The optimal temperature settings for the selected plastic material**

- Mold temperature
- Melt temperature

- **Pressure at different stages of the medical molding process**

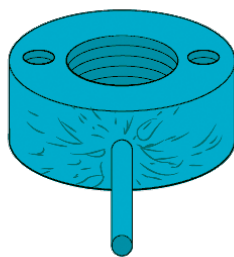
- Injection pressure
- Holding pressure
- Ejection pressure



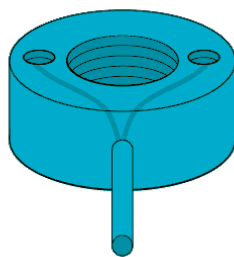
Common molding challenges

Defects can range in seriousness from simple cosmetic blemishes to concerns with the part's integrity. We have provided a list of 11 medical molding challenges along with their causes

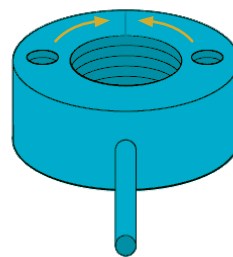
and remedies (see below). Although each defect varies in severity, we have categorized them based on whether they are cosmetic or structural.



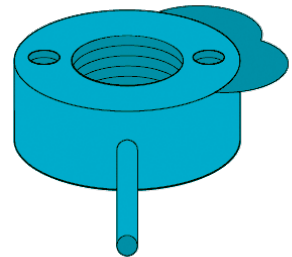
Splay



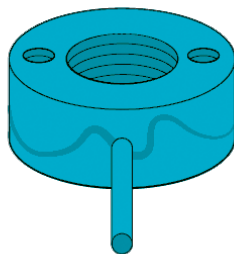
Flow Lines



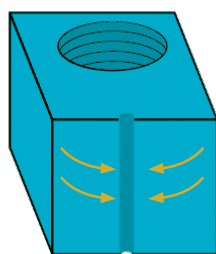
**Weld Lines
(Knit Lines)**



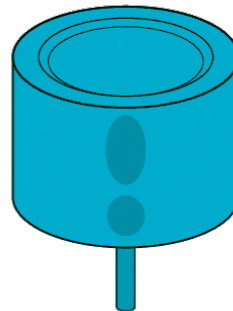
Flash



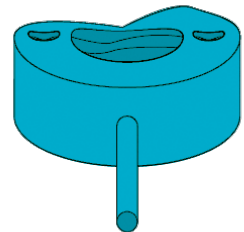
Jetting



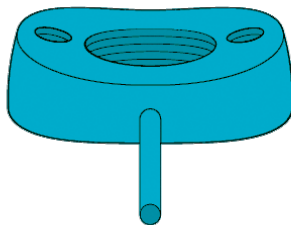
Sink Marks



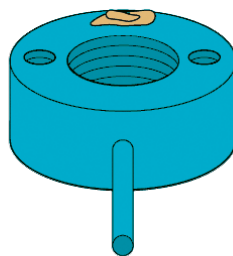
Vacuum Voids



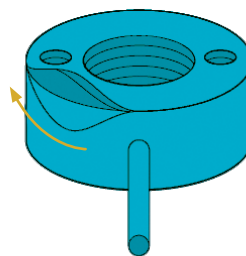
Short Shots



Warping



Burn Marks

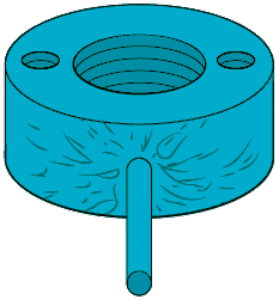


**Surface
Delamination**



Cosmetic challenges

Cosmetic challenges generally do not affect the structural integrity of a part. However, they do affect the part's aesthetics.



SPLAY

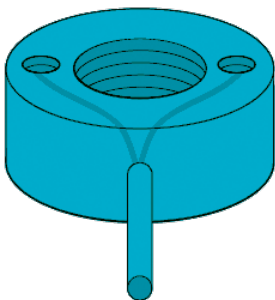
Splay is a common cosmetic defect that comes in the form of silver / white streaks on a part's surface.

Causes

Splay generally occurs when a hydroscopic material has not been dried properly before the medical molding process.

Remedy

Conduct a moisture analysis to verify that your dryer is functioning properly (note that moisture can compromise a material's properties). We strongly recommend conducting a moisture analysis at the start of every production run and whenever splay occurs.



FLOW LINES

Flow lines are streaks, patterns, circular ripples and lines that occur on the surface of a part.

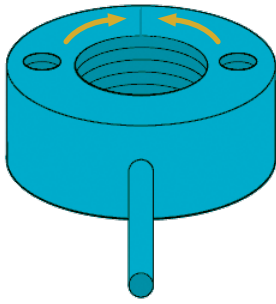
Causes

Flow lines are caused by the varying speeds at which molten plastic flows around a part's geometry. The disruption in the flow causes the plastic to solidify inconsistently. The cooler the material, the longer the flow lines.

Remedy

You may need to increase the temperature of the mold and / or press to increase flow. Other remedies include increasing the injection speed and pressure.





WELD LINES (KNIT LINES)

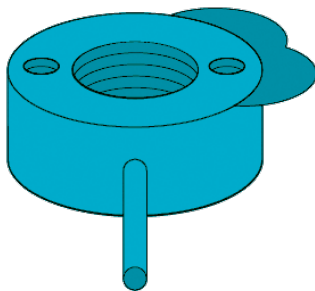
Weld lines form on the surface of a part where two flow fronts meet. They tend to be the weakest point on a part since the two fronts were unable to “knit” back together properly.

Causes

Weld lines occur when an obstruction forces the plastic flow front to split and reknit. If the plastic material doesn’t quickly reknit, the weld line will be more apparent.

Remedy

Be mindful of viscous plastics since their low melting points make them prone to weld lines. Increasing the injection speed in 10% increments and increasing the temperature of the mold and /or press also helps. In addition, consider addressing the gate positions.



FLASH

Flash forms thin plastic layers that harden outside of where the mold’s two halves (Part A and Part B) meet. You should fix flash immediately because it will damage your tool if it occurs over several cycles.

Causes

Flash is caused by plastic escaping from the mold cavity through a mold’s parting line, insert line or pin holes. This can be due to excess injection pressure or low clamp pressure (which keep both the A and B sides of the mold together).

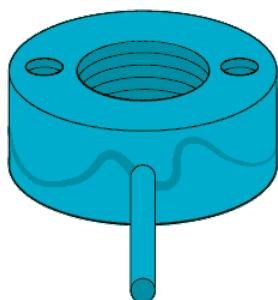
Remedy

Avoid overpacking the mold cavity, and make sure the clamp pressure is strong. Also try to reduce your injection pressure and stay within the process window. Reducing the cycle time and barrel temperature can help lower the plastic’s viscosity.



Structural molding challenges

Unlike cosmetic challenges, structural challenges can seriously compromise the integrity of a part and render it unusable.



JETTING

Jetting creates a buckled, “snakelike” stream. It can lead to part weakness and internal defects.

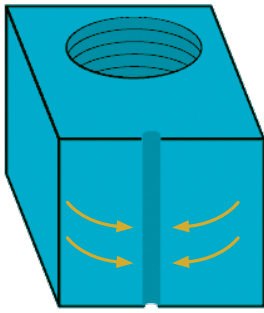
Causes

Jetting is a result of the plastic being pushed at a high velocity through tight areas in the mold without making contact with the walls. This can be due to excessive injection speeds, low mold temperature and improper gating.

Remedy

Optimize the plastic’s speed and gating for a consistent flow. Consult with a material supplier for the mold temperature that will facilitate proper flow.





SINK MARKS

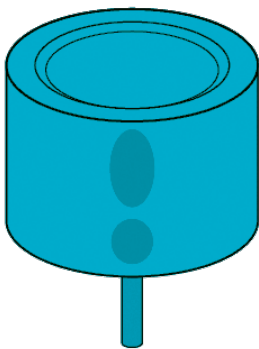
Sink marks result from shrinkage in the thicker sections of a mold and appear as depressions on the part.

Causes

Sink marks are caused by differential cooling in the thicker wall sections, inadequate pressure in the mold, or improper wall sections for part protrusions.

Remedy

Sink marks can generally be avoided with a part design that accounts for wall thickness (thicker walls require longer cooling times). We recommend having a proper wall section to rib section ratio since protrusions in the mold tend to leave sink marks. Also consider increasing the holding time and lowering the mold temperature so the part can cool properly.



VACUUM VOIDS

Vacuum voids are bubbles within a part that can weaken its integrity. They result from trapped air or differential shrinking.

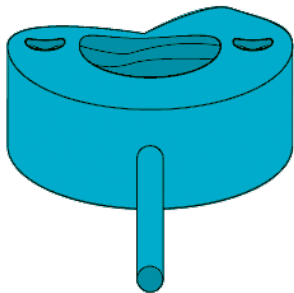
Causes

Vacuum voids can be traced back to the wall sections. A mold's steel is cooler than the molten plastic material, which creates a void because the outside cools faster than the inside.

Remedy

Increase the holding pressure and time to enable the molten plastic to align with the mold's walls.





SHORT SHOTS

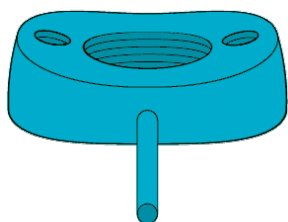
Short shots occur fairly often during a first run. As their name suggests, they are areas of the part where the amount of plastic material is insufficient, resulting in missing elements in the final part. They can also be an extension of flow lines and knit lines.

Causes

Molten plastic will naturally flow along the path of least resistance. However, it will stop at thinner sections if the holding pressure is too low. Low process parameters can also result in shorting.

Remedy

Have your plastic material undergo a validation process to ensure proper flow. Increasing the mold and / or press temperature, accounting for gas generation, and increasing the material feed can also prevent short shots. Thin-walled sections require a material with increased flowability. Conversely, thick-walled sections work better with a stiffer material.



WARPING

Warping is a dimensional deformation that results from uneven plastic shrinkage. Semi-crystallines are more likely to warp since they have specific cooling times. Glass-filled materials have a tendency to warp more than unfilled materials.

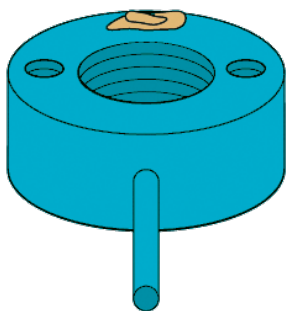
Causes

Warping can be caused by inadequate injection pressure, a low nozzle temperature, inadequate gating, and issues with material flow. Warping generally occurs during cooling.

Remedy

Try increasing the cooling time to reduce residual stresses on the part, and be sure the plastic flows in one direction so its molecules align. Proper gate positioning will also help with alignment. In addition, installing a nominal wall throughout your part will help the plastic cool consistently.





BURN MARKS

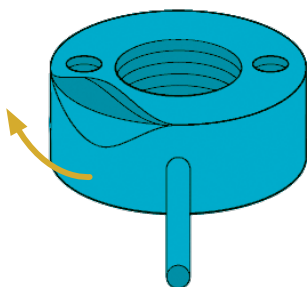
Burn marks occur on the surface of a part. They generally appear in blind pockets or at the end of the flow path.

Causes

Fast injection speeds and excessive heating without proper venting trap gases in the molding, causing the plastic to overheat and burn.

Remedy

Reduce the temperature of the mold and the injection speed. Add additional venting, and clean your vents regularly to prevent blockage.



SURFACE DELAMINATION

Surface delaminations are flake-like layers on a part's surface that can reduce its strength.

Causes

Surface delaminations can occur if the molten material has cooled too fast while moving through the mold, hence forcing the plastic layers to solidify before they can fuse together. Material handling issues can also cause surface delaminations by allowing foreign material to enter the mold. The foreign material's inability to properly bond to the plastic material can result in delaminations.

Remedy

Recheck the mold's gating, and reduce sharp turns in the part design. Sharp turns can disrupt the mold flow and cause shearing. Confirm that the drying times and mold temperatures have been optimized for the plastic being used. You can also try increasing the injection speed in 2% increments. Lastly, check for contaminants in the plastic supply.



Medical Molding Considerations

Staying within the range of your process parameters during the molding process will help prevent most defects. To this end, a [process validation](#) can help you establish a high and low range for critical process parameters. We recommend having a print of your part with its dimensions and related tolerances to help you determine when a parameter is out of range. In addition, a verification can be conducted after

the molding process to ensure that the final part meets all specifications.

We also recommend conducting a mold flow analysis to identify potential failure points before the injection molding process. The analysis will pinpoint potential issues with the flow rate, pressure, cooling, and temperature so you can adjust each accordingly.

Next Steps

Implement DfM early in the design process to optimize your design, product development, and manufacturing processes. Consider how certain design elements can yield reliable parts, how plastic material selection affects the molding process, and how to avoid common defects.

Consider collaborating with our team on your medical device design to ensure it follows good DfM practices from the initial design to final packaging. Our years of experience in medical device injection molding can influence the design to improve efficiency, ensure part success and target the lowest overall cost.



Additional Resources

We recommend using the following resources to help guide your plastic material search:

- [UL Prospector](#) to identify materials.
- [Matweb](#) to learn more about different materials.
- Material data sheets (provided by suppliers) to determine mechanical properties.

These additional resources can give you a general overview of various plastic materials and their properties:

- [Plastic selection guide](#)
- [IAPD's Thermoplastic Rectangle](#)

Selecting an appropriate plastic material that won't deter the manufacturing process will decrease lead times and the chances of defects occurring on the final part. However, defects are also caused by designs that don't follow DfM practices, which is why it's important to understand how common ones occur and how to remedy them.



Trelleborg is a world leader in engineered polymer solutions that protect essential applications in demanding environments. Its innovative solutions accelerate performance for customers in a sustainable way.

Trelleborg Medical Solutions partners with the world's leading medical device and biopharmaceutical companies, collaborating from concept to commercialization to bring to market impactful solutions that improve patient quality of life. It leverages decades of design and manufacturing experience, in-depth knowledge of polymer materials to deliver pioneering, engineered solutions for transformative health technologies.

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