



Design for Manufacturing (DFM) is crucial in micro injection molding as it ensures that the part, tooling, and process design considers the manufacturing constraints and requirements specific to this process. Manufacturers can enhance production efficiency, reduce costs, and consistently produce high-quality micro-injection molded components and products by considering DFM principles, such as optimizing part geometry, material selection, and tooling design.

The top five considerations for design for manufacturing in micro injection molding are as follows:

### 1. PART DESIGN

We'll highlight three key factors in part design: wall thickness, draft, and undercuts.

**WALL THICKNESS** – It is important to maintain consistent wall thickness throughout the part to ensure proper flow of the molten material and prevent the following types of defects:

**Warping:** Non-uniform wall thickness can cause differential cooling rates, leading to warping and distortion of the part as it cools and solidifies.

**Sink Marks:** If certain areas of the part have thicker walls, they might take longer to cool and solidify, causing thinner sections to sink inward, creating sink marks.

**Flow Lines:** Uniform wall thickness promotes consistent material flow during injection, reducing the likelihood of flow-related defects like flow lines or air traps.

Additionally, uniform wall thickness allows for even cooling throughout the part, reducing the risk of uneven shrinkage, minimizing the potential for residual stresses, and the following other less commonly discussed benefits:

**Enhanced Structural Integrity:** Parts with uniform wall thickness are likelier to have consistent mechanical properties and structural integrity, which is crucial for functionality and load-bearing capacity.

**Reduced Cycle Time:** Parts with uniform wall thickness generally cool more evenly, leading to shorter cycle times and increased production efficiency.

**Tooling and Manufacturing Costs:** Mold design and fabrication are simpler and more cost-effective when the uniform wall thickness is maintained. Complex molds for varying wall thicknesses can be more expensive and challenging to produce.





**DRAFT** – It is important to incorporate draft angles in the design for several reasons, including the following:

**Easy Ejection:** Draft angles are included in the design of parts to allow for smooth and easy ejection from the mold. Without sufficient draft angles, the part might become stuck in the mold, causing production delays and potential damage to both the part and the mold.

**Minimized Friction:** Draft angles reduce friction between the part and the mold’s core and cavity surfaces during ejection. This helps prevent scuffing, scratching, or other surface defects from excessive friction.

**Reduced Tearing:** Adequate draft angles help prevent the part from tearing or deforming during ejection. This is especially important for parts with complex shapes or undercuts.

**Improved Surface Finish:** Draft angles contribute to a better surface finish on the part since they reduce the likelihood of the part dragging against the mold surfaces, which can result in blemishes or imperfections.

**Enhanced Mold Life:** Using draft angles properly can extend the life of the mold by minimizing wear and tear caused by repeated ejection cycles.

By utilizing appropriate draft angles, part designers have more flexibility to create intricate and complex part geometries while still enabling successful ejection. Incorporating draft angles into the design of injection-molded parts is a critical consideration that helps facilitate the smooth operation of the molding process and ensures high-quality finished products.

**UNDERCUTS** are features or indentations in a part’s design that prevent straightforward ejection from a mold due to their geometric complexity. While they might seem challenging, undercuts offer unique design possibilities and functionalities. Let’s start with some of the positive attributes of undercuts before reviewing the related challenges.

**Enhanced Aesthetics:** Undercuts allow for the creating of intricate and visually appealing designs that can’t be achieved with simple, flat surfaces. They can add complexity and uniqueness to the final part.

**Functional Features:** Undercuts can introduce functional elements to a part, such as snap-fit connections, interlocking mechanisms, or gripping surfaces. These features can improve the overall usability and functionality of the product.

**Reduced Assembly Steps:** Parts with integrated undercuts might eliminate the need for separate assembly steps, as these features can allow components to snap together, reducing labor and assembly costs.

**Space Optimization:** Undercuts can enable compact designs by allowing parts to fit together tightly or by incorporating additional functionalities within limited space.

**Improved Ergonomics:** Undercuts can provide ergonomic benefits by creating comfortable gripping surfaces or user-friendly interfaces.

However, undercuts also pose challenges in injection molding, primarily related to ejection and mold complexity. Special mechanisms, like side actions or collapsing cores, are often required to release parts with undercuts from the mold. These mechanisms increase the complexity of the mold design and may result in longer cycle times and higher production costs. Balancing the benefits and challenges of undercuts requires careful consideration during part design and mold engineering. When used effectively, undercuts can elevate the design and functionality of injection-molded parts, leading to innovative and compelling products.





## 2. MATERIAL SELECTION

Material selection in injection molding, particularly for medical applications, is paramount due to the critical nature of medical devices and the stringent requirements they must meet. Here are a few reasons why material selection matters:

**Biocompatibility:** Medical devices come into direct contact with the human body, so the chosen materials must be biocompatible, meaning they won't cause adverse reactions or harm to patients. Extensive testing and compliance with medical standards are crucial.

**Chemical Resistance:** Medical devices often encounter various chemicals, disinfectants, and pharmaceuticals. The chosen material must resist degradation, ensuring the device's performance and safety over its intended lifespan.

**Sterilization Compatibility:** Medical devices must be sterilized to prevent infection. Materials need to withstand various sterilization methods, such as steam autoclaving, gamma irradiation, ethylene oxide, and more, without compromising their properties.

**Durability:** Medical devices must endure rigorous usage and mechanical stresses. Material selection is critical to ensure the device remains reliable and functional throughout its lifespan.

**Dimensional Stability:** Precision and accuracy are crucial in medical applications. To maintain the device's accuracy, materials must exhibit minimal dimensional changes over time and under varying conditions.

**Transparency and Clarity:** In cases where visualization is important, such as in ophthalmic or imaging applications, high transparency and clarity materials are essential for accurate monitoring and diagnosis.

**Mechanical Properties:** Different medical applications require specific mechanical properties, such as stiffness, flexibility, impact resistance, and fatigue resistance. Choosing the right material ensures that the device can withstand its intended usage.

**Regulatory Compliance:** The medical industry is highly regulated to ensure patient safety. Materials used in medical devices must comply with strict regulatory standards, such as REACH and RoHS.

**Longevity:** Medical devices often have long lifespans, and their materials must be chosen to resist degradation and wear over extended periods.

**Cost-Effectiveness:** While the primary concern is patient safety and device performance, material selection must also balance costs to ensure that medical devices remain affordable without compromising quality.

Choosing the right material for injection molding in medical applications requires collaboration between materials experts, engineers, and medical professionals. It involves understanding the device's intended use, regulatory requirements, and the unique challenges medical environments pose. The goal is to create safe, reliable, and effective devices to improve patient care.

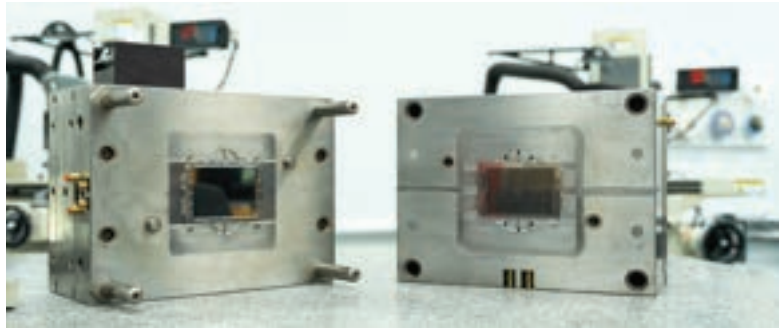
MATERIAL PROPERTY	UOM	PEEK*	PEBA**	PSU***
MODULUS OF ELASTICITY	MPa	4200	4140	4000
TENSILE STRENGTH	MPa	50.3-265	54	95
YIELD STRESS	MPa	65-120	23	65
ELONGATION AT BREAK	%	25	>50	35
MELTING TEMPERATURE		340	172	340
MELT TEMPERATURE – INJECTION MOLDING		400	230-290	260-410
MOLD TEMPERATURE – INJECTION MOLDING		175-205	25-60	65.6-210
SHRINKAGE RATES	%	1.3	1.2-1.5	0.1-0.7
MELT FLOW INDEX	g/10 min	20.0-60.0	13.4	5.0-9.0

Resin Grades:  
 \*PEEK LT3  
 \*\*PEBAX 7033 SA01 MED  
 \*\*\*EV-500



### 3. TOOLING DESIGN

Tooling design for injection molding, especially for medical applications, requires careful attention to ensure precision, consistency, and compliance with strict standards. Here are vital considerations for tooling design in micro injection molding:



**Part Geometry and Complexity:** Analyze the part's geometry, including undercuts, thin walls, and complex features. Design the mold's core and cavity to accurately replicate the part's shape, considering draft angles and parting lines for smooth ejection.

**Material Selection:** Choose tooling materials that match the requirements of the chosen injection molding material and can withstand the stresses and temperatures of the injection process. For medical applications, materials with high corrosion resistance and biocompatibility are crucial.

**Tolerances and Precision:** Medical devices demand high precision and tight tolerances. Design the mold with precision in mind to ensure consistent part dimensions and accuracy.

**Ejection Mechanisms:** Incorporate appropriate ejection mechanisms, such as ejector pins, lifters, or slides, to facilitate the easy and damage-free removal of parts from the mold.

**Venting:** Proper venting is critical to allow air and gases to escape during injection. In medical applications, trapped air can lead to defects or impurities compromising device quality.

**Cooling System:** Efficient cooling is essential for cycle time optimization and consistent part quality. Design a cooling system that ensures uniform cooling and minimizes warping or distortion.

**Gate Design:** Select an appropriate gate location and design to ensure optimal material flow into the mold cavity. The gate should leave minimal evidence on the final part and should be positioned for easy removal.

**Surface Finish:** Achieve the desired surface finish by considering mold texture and polishing requirements. Smooth surfaces are important for medical devices to prevent bacteria buildup and ensure easy cleaning.

**Mold Maintenance and Accessibility:** Design the mold for easy maintenance, repair, and cleaning. Accessibility to all mold components helps extend the mold's lifespan and ensures consistent performance.

**Documented Procedures:** Maintain comprehensive documentation of the tooling design, including drawings, specifications, and procedures. This documentation is crucial for quality control and future reference.

In addition to the above design considerations, collaboration between tooling designers, part designers, and the entire engineering team is vital to ensure the mold design aligns with the intended medical device's purpose and performance requirements. In medical applications, tooling design plays a significant role in producing devices that meet stringent quality, safety, and functionality standards. It requires a holistic approach that considers both the technical aspects of molding and the application's specific needs.





## 4. PROCESS OPTIMIZATION

Optimizing micro injection molding process parameters applications is crucial to ensure consistent, high-quality, and safe products. Here are key considerations to keep in mind:

**Injection Speed and Pressure:** Adjust injection speed and pressure to ensure complete material filling without causing flow-related defects like flow lines, air traps, or voids.

**Injection Temperature:** Set appropriate melt and mold temperatures to ensure proper material flow, optimal cooling, and consistent part dimensions. Temperature control is crucial for minimizing defects and ensuring material properties.

**Cooling Time:** Optimize cooling time to achieve proper solidification and dimensional stability. Cooling time affects cycle time and part quality.

**Packing Pressure and Time:** Adjust packing pressure and time to ensure complete material packing and eliminate voids or sinks in the final part.

**Hold Time:** Set an appropriate hold time to prevent premature ejection and ensure the part maintains its shape while cooling.

**Cycle Time:** Balance cycle time with part quality. Longer cycle times may be necessary for intricate medical parts, but efficient cycle times are important for cost-effective production.

**Screw Speed and Back Pressure:** Adjust screw speed and back pressure to achieve consistent melt quality and uniform material feeding.

In addition to the optimization of specific process parameters, the following best practices are recommended to ensure consistent and reliable performance in manufacturing:

**Process Monitoring and Control:** Implement real-time process monitoring systems to detect variations or deviations in process parameters. This allows for prompt adjustments and maintains consistent quality.

**Documentation:** Maintain detailed records of the process parameters used for each production run. This documentation aids in troubleshooting, process optimization, and regulatory compliance.

**Validation:** Validate the optimized process parameters through rigorous testing and validation to ensure the final product meets medical standards and specifications consistently.

**Continuous Improvement:** Implement a culture of constant improvement, regularly reviewing and analyzing process data to identify areas for enhancement and optimization.

In micro injection molding, process optimization is crucial for ensuring product quality and adhering to strict regulatory requirements. Collaboration among engineers, quality control experts, and medical professionals is essential for consistent and safe medical device production.







## 5. MEASUREMENT & INSPECTION

Measurement and inspection are critical aspects of micro injection molding, particularly in medical applications where precision, quality, and safety are paramount. Here are key considerations for effective measurement and inspection in micro injection molding:

**Metrology Equipment:** Invest in high-quality metrology equipment, such as coordinate measuring machines, optical measurement systems, and non-contact measurement tools, to accurately measure part dimensions and features. Utilize surface profilometers or optical systems to measure surface roughness and ensure it meets required standards, especially for medical devices that require smooth and clean surfaces.

**Initial Part Approval:** Perform initial part approval processes to ensure that the injection molding process can consistently produce parts that meet specifications. This involves detailed measurement and inspection of sample parts. Require first article inspection (FAI) for new molds or significant process changes. This involves measuring and inspecting parts from the first production run to verify their conformity to specifications.

**In-Process Monitoring:** Implement real-time process monitoring systems to track key process parameters during production. Deviations from set parameters can trigger alerts for immediate corrective action. Use SPC techniques to monitor and control the injection molding process by analyzing process data over time. This helps maintain process stability and identify trends or variations.

**Tolerance Management and Sampling Plans:** Define appropriate tolerances for critical dimensions and features, considering the intended medical device's function and regulatory requirements. Develop effective sampling plans that ensure a representative sample of parts is inspected while minimizing waste and production disruptions. Combine visual inspection with measurement techniques to identify surface defects, cosmetic issues, and anomalies that measurements might not capture.

**Gauge Calibration:** Regularly calibrate measuring equipment to ensure accuracy and traceability. Calibration records should be maintained for regulatory compliance. Validate measurement methods to ensure they are capable of accurately assessing part quality. Verify measurement equipment against traceable standards.

In addition to the above processes, documentation and training should be considered in implementing and maintaining these areas. Specifically, maintain detailed records of measurement results and inspection outcomes. These records are crucial for quality assurance, traceability, and regulatory compliance. Lastly, require and invest in thorough training for personnel involved in measurement and inspection to ensure consistency and accuracy in the evaluation of parts.

Effective measurement and inspection processes ensure that micro injection-molded parts meet the highest quality and safety standards required for medical applications. Collaboration between engineers, quality assurance experts, and regulatory specialists is essential to establish reliable measurement and inspection procedures.

