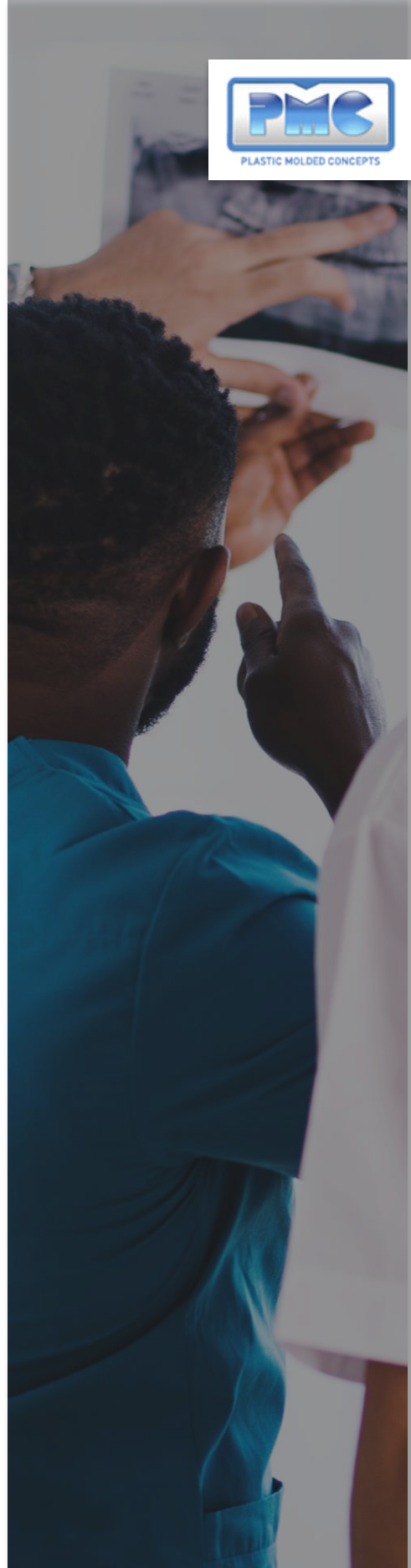


# How to Choose the Best Plastic Resin for Your Medical Device

## Medical Device Molding



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# Importance of Resin Selection

## Why Does Resin Selection Matter?

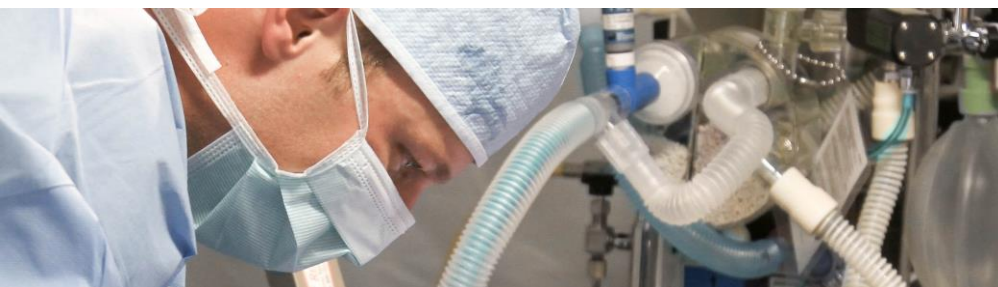
Whether you're introducing a new product into the market, or you're looking to improve the integrity of an existing medical device, resin selection is one of the most critical considerations of the entire process.

## When Should We Start the Resin Selection Process?

Because resin selection can affect every factor - from design considerations to final product, it's extremely important to start the process with resin selection *first*.

Selecting the right resin(s) can be overwhelming and confusing for many medical device engineers, but addressing a variety of device considerations will help eliminate the wrong resins and illuminate the right ones. Once the ideal resin candidates have been identified, testing can be performed to determine the best resin for the device.

Addressing the right considerations can help eliminate an entire group of plastics, making the resin selection process easier and less time-consuming.



# Things to Consider When Choosing a Resin



# Considerations

## 8 Factors to Consider When Selecting a Resin

### 1 Device Strength

When molding medical devices, the strength of the device is a key consideration. The device must be designed to successfully function for its intended:

- Purpose
- Environment
- Service Life

You'll want to work with an expert in engineering grade resins to ensure you select the best resin for the medical device without paying for strength properties the device does not necessitate.

### Device Environment

The environment in which a medical device will be exposed must be accounted for during the resin selection process. Some of the most common conditions a medical device may encounter include: temperature extremes, moisture, humidity, chemicals, bodily fluids and / or tissue, radiation, and others.

### Part Design

The more complex the geometry of a medical device, the more challenging it will be to mold. It's wise to share files, drawings and/or a 3D printed model of your design with the plastic molder early in the process as this will help the molder to modify the design as needed for optimal manufacturability, as well as key technical aspects such as resin flow, gate location, etc.

#### **4 Device Overmolding**

If a medical device will require overmolding, all resins must seamlessly mate and bond with each other to ensure medical device integrity. The same resin considerations that apply to plastic injection molding also apply to resin selection for overmolding.

#### **5 Metal Replacements**

Many medical device engineers are replacing outdated metal devices with contemporary plastic ones. With modern advances in engineered resins, nearly anything metal can be made plastic without losing any of its integrity! Plus, there are a lot more options for modifying characteristics in plastic than there are in metal. It's important to discuss metal device replacements with your plastic molder early in the process (along with other device considerations) to ensure the right plastic polymers are used to replicate (or enhance) the properties of the previous metal.

#### **6 Cost**

If cost parameters are in place, it's best to notify the plastic molder of this right away so they can help determine the best resin at the best value for the medical device's intended purpose and environment. Plastic molders should provide full disclosure if cost parameters will affect certain aspects or properties of the medical device as falsification, misrepresentation, or lack of due diligence or resin expertise can be both dangerous to patients and expensive for medical device manufacturers.

#### **7 One Time Use or Re-Use**

Medical devices that are designed for re-use typically require a resin with chemical-resistant properties. Medical devices that are designed for one time use (which are becoming increasingly popular in the orthopedic industry) may not require a resin with chemical-resistant characteristics, potentially saving on overall product development costs.

#### **8 Implantation or Direct Contact**

A major factor to consider during the resin selection process is whether the medical device will be implanted and/or have direct human contact. If the device will be implanted and/or encounter direct contact with humans, you must ensure that an FDA-compliant, biocompatible resin is used.

# Biocompatible Resins for Implantation or Direct Contact

## Additional Factors to Consider

Medical components that will be in contact with bodily fluids or tissues must be biocompatible. If the resins are not biocompatible, polymer degradation can occur when the device is exposed to the biochemical and mechanical factors that are present in the human body. Material degradation can result in side effects, such as:

- Irritation
- Inflammation
- Acute toxicity
- Sub-chronic toxicity
- Genotoxicity
- Chronical toxicity
- Reproduction toxicity

Some resin additives can also be the cause of side effects like those listed above.

Medical Device Contact	Commonly Accepted Resins
<b>Non-Contact</b> syringes, IV bags, blood storage bags, etc.	Polyamide (PA), Polyethylene (PE), Polystyrene (PS), Polyvinyl Chloride (PVC)
<b>Short-Term<sup>1</sup></b> catheters, feeding tubes, surgical instruments, etc.	Polyurethane (PUR or PU), Polyethylene (PE), Polypropylene (PP), Polyetheretherketone (PEEK), Polyphenylsulfone (PPSU or PPSF)
<b>Medium-Term<sup>2</sup></b> cultures, sutures, etc.	Polypropylene (PP), Nylon, Polyester
<b>Long-Term<sup>3</sup></b> implanted devices like pacemakers, heart pumps, etc.	Polyethylene (PE), Polyethylene Terephthalate (PET), Polyurethane (PUR or PU), Polymethyl Methacrylate (PMMA), Polysulfone (PSU)

<sup>1</sup> Less than 1 day | <sup>2</sup> 1-30 days | <sup>3</sup> 30 days or more



# Sterilization Treatments

## Autoclaving

If the medical device will be receiving autoclaving (or steam sterilization treatments), it may jeopardize the part's dimensional stability or lead to warpage at high temperatures (249F – 285F). Resins that do well with the high heat and moisture content of autoclaving, include Polyphenylsulfone (PPSU or PPSF) and Polyetheretherketone (PEEK), which can typically undergo thousands of autoclaving cycles without compromising integrity.

## Chemical Treatment

If the medical device is designed for re-use, it will typically receive multiple chemical sterilization treatments before being discarded, so it's important to choose resins with exceptional toughness and the ability to resist discoloration. Resins that stand up well to multiple chemical sterilization treatments include, Polyphenylsulfone (PPSU or PPSF), Polyetheretherketone (PEEK), Polyetherimide (PEI, and Polycarbonate (PC).

## Radiation

Since radiation exposures are cumulative and compounding, certain resins may lose important characteristics, such as tensile strength and impact strength. Resins that stand up well to multiple radiation treatments include, Acrylonitrile Butadiene Styrene (ABS), Polyethersulfone (PES), Polysulfone (PSU), Polyphenylsulfone (PPSU or PPSF), Polyetheretherketone (PEEK), Polyetherimide (PEI) and Thermoplastic Polyurethane (TPU).



# Mechanical Property Considerations

## Which Mechanical Properties Matter in Resin Selection?

There are various mechanical properties to consider during the resin selection process, including:

- Toughness (Impact Resistance)
- Tensile & Compressive Strength (Load or Stress Bearing)
- Flexural Strength (Bending Stiffness)
- Dielectric Strength (Electrical Insulation)

## Resins by Highest Tensile Strength

Resin	PSI
Ultem	15,200
PEEK	14,000
Cast Nylon 6	10,000 – 13,500
Polyphenylene Sulfide (PPS)	12,500
Nylon 6/6	12,400
Polyethylene Terephthalate (PET)	11,500
Polysulfone (PSU)	10,200
Acrylic	10,000
Homopolymer Acetal	10,000
Copolymer Acetal	9,800

*Table data obtained from curbellplastics.com*

## Resins by Highest Flexural Strength

Resin	PSI
30% Glass Filled Nylon	1,300,000
20% Glass Filled Polycarbonate	800,000
Polyphenylene Sulfide (PPS)	600,000
Polyetherketone (PEEK)	590,000
Polyvinyl Chloride (PVC)	481,000
Ultem	480,000
Acrylic	480,000
Cast Nylon 6	420,000 – 500,000
Homopolymer Acetal	420,000
Nylon 6/6	410,000

## Resins by Highest Impact Strength

Resin	Ft. - Lb./in
Low Density Polyethylene (LDPE)	No Break
Ultra High Molecular Weight (UHMW)	18.0
Polycarbonate	18.0
Copolymer Polypropylene	12.5
Acrylonitrile Butadiene Styrene (ABS)	7.7
Polytetrafluoroethylene (PTFE)	3.5
Kynar® Polyvinylidene Fluoride (PVDF)	3.0
High Impact Polystyrene (HIPS)	2.0
Polyethylene Terephthalate – Polyester with Glycol Additive (PETG)	1.7
Polybutylene Terephthalate (PBT)	1.5

*Table data obtained from [curbellplastics.com](http://curbellplastics.com)*

## Resins by Highest Dielectric Strength

<b>Resin</b>	<b>v/mil</b>
<b>Ultem</b>	<b>830</b>
<b>Cast Nylon 6</b>	<b>500 – 600</b>
<b>Polyvinyl Chloride (PVC)</b>	<b>544</b>
<b>Acetal Homopolymer &amp; Acetal Copolymer</b>	<b>500</b>
<b>Polytetrafluoroethylene (PTFE)</b>	<b>400 – 500</b>
<b>Polyetheretherketone (PEEK)</b>	<b>480</b>
<b>Polyphenylene Sulfide (PPS)</b>	<b>450</b>
<b>Acrylic</b>	<b>430</b>
<b>Polysulfone (PSU)</b>	<b>425</b>
<b>Polyethylene Terephthalate – Polyester with Glycol Additive (PETG)</b>	<b>410</b>

*Table data obtained from [curbellplastics.com](http://curbellplastics.com)*

# Medical Device Aesthetics & Functionality

## Resin Color-ability

Medical device engineers will often have colors molded into medical devices for improved aesthetics and to eliminate post-molding coloring costs. Glow-in-the dark color technologies are also being utilized more in medical applications where it makes sense.

Some coloring methods can adversely affect part properties. A lot of the colorant is done in the base resin, which can be blended to a specific ratio. There are other color chemicals that are not blended with the resin, which can be added directly to the molding machine – this method can also adversely affect part properties. It's important to note that some resins have better color-ability than others.

## Resin Radiopacity

Today, many medical devices can achieve radiopacity through certain polymer additives, which are added prior to the molding process. Radiopacity allows medical devices within the body to be visible via medical imaging such as X-Rays or Fluoroscopy.



## **Device Grip**

A soft and/or textured grip may be a key component in a medical device. Adding these friendly grips is often done through overmolding (a post injection molding process that binds one part onto another). To reiterate, it's critical to ensure the resins you choose for all components of your medical device are compatible and bond seamlessly.

## **Drug Delivery**

In some cases, permanently anti-static compounds must be accounted for in the drug delivery device design process.

Aerosol and dry powder drug delivery devices can cause static build-up on the surface of the medical device, which can actually attract the drug and lead to incorrect dosages.

There are a variety of compounds that can be used to eliminate static build-up and its dangers, including compounds that are based on Acrylic, Polypropylene (PP), clear Acrylonitrile Butadiene Styrene (clear ABS), Acrylonitrile Butadiene Styrene + Polycarbonate (ABS+PC), etc.

## **Medical Devices with Moving Parts**

In many cases, medical devices will have moving parts, such as gears, sliding covers, etc. These moving parts need to have high wear-resistance properties to ensure smooth operation over an extended period of time.

Polymer additives like Polytetrafluoroethylene (PTFE) are often used to improve wear resistance of the moving part(s).

# Comparing Properties of Popular Medical Resins



# Properties of Popular Medical Resins

Resin	Advantages	Limitations	Service Temp Range
<b>ABS</b>	<ul style="list-style-type: none"> <li>○ Widely used</li> <li>○ Versatile</li> <li>○ Strong</li> <li>○ Excellent surface appearance</li> <li>○ Chemical resistant</li> <li>○ Moderate heat resistance</li> <li>○ Moderate impact resistance</li> <li>○ Moderate moisture resistance</li> <li>○ Low creep</li> <li>○ Easy to process</li> </ul>	<ul style="list-style-type: none"> <li>• Poor weathering resistance</li> <li>• Flammable with high smoke generation</li> </ul>	86°C – 89°C
<b>Acetal Copolymer</b>	<ul style="list-style-type: none"> <li>○ High strength</li> <li>○ High rigidity</li> <li>○ High dimensional stability</li> <li>○ Good chemical resistance</li> <li>○ Good wear properties</li> <li>○ Good friction properties</li> <li>○ Easy to machine</li> <li>○ Better resistance to organic and inorganic solvents and acids compared to Acetal Homopolymer</li> </ul>	<ul style="list-style-type: none"> <li>• Longer Molding Cycles</li> <li>• Sinks</li> <li>• Relatively High Cost</li> </ul>	80°C – 105°C
<b>Acetal Homopolymer</b>	<ul style="list-style-type: none"> <li>○ High Strength &amp; Rigidity</li> <li>○ Ability to Resist Scale Build-Up</li> <li>○ Good Machinability</li> <li>○ Good Creep Resistance</li> <li>○ Good Dimensional Stability</li> <li>○ Good Lubricity</li> <li>○ Good Impact Resistance</li> <li>○ Low Friction</li> <li>○ Low Moisture Absorption</li> <li>○ High Wear Resistance</li> <li>○ Wide Operating Temperature Range</li> <li>○ Good Color-ability</li> <li>○ Good Mating with Metal &amp; Other Polymers</li> </ul>	<ul style="list-style-type: none"> <li>• Longer Molding Cycle Times</li> <li>• Sinks</li> <li>• Less Chemical Resistance than Acetal Copolymer</li> <li>• Relatively High Cost</li> </ul>	Varies

Resin	Advantages	Limitations	Service Temp Range
<b>Acrylic PMMA</b>	<ul style="list-style-type: none"> <li>○ High Refractive Index</li> <li>○ Outstanding Light Transmissibility</li> <li>○ White Light Transmittance as High as 95%</li> <li>○ Excellent Surface Hardness</li> <li>○ Excellent Clarity</li> <li>○ Excellent Surface Finish</li> <li>○ Excellent Weatherability</li> <li>○ Scratch Resistant</li> <li>○ High Impact Strength</li> <li>○ Low Water Absorption</li> <li>○ Cost-Effective Alternative to Polycarbonate (<i>when extreme strength is not required</i>)</li> </ul>	<ul style="list-style-type: none"> <li>• Some Notch Sensitivity</li> </ul>	70°C – 90°C
<b>Acrylic PVC</b>	<ul style="list-style-type: none"> <li>○ Excellent Impact Strength</li> <li>○ Excellent Chemical Resistance</li> <li>○ Excellent Extensibility</li> <li>○ Low Water Absorption</li> </ul>	<ul style="list-style-type: none"> <li>• Low Tensile Strength</li> <li>• Poor High Temperature Performance</li> <li>• Poor UV Resistance</li> <li>• High Cost</li> </ul>	50°C – 80°C
<b>EVA</b>	<ul style="list-style-type: none"> <li>○ Flexible</li> <li>○ UV Resistant</li> <li>○ Water Resistant</li> <li>○ Stress-Crack Resistant</li> <li>○ Chemical Resistant</li> <li>○ Excellent Processability</li> <li>○ Excellent Transparency</li> </ul>	<ul style="list-style-type: none"> <li>• Difficult to Bond</li> <li>• Flammable</li> <li>• Low Strength/Stiffness</li> <li>• High Thermal Expansion</li> </ul>	45°C – 70°C
<b>LCP</b>	<ul style="list-style-type: none"> <li>○ Very Strong</li> <li>○ Ideal for High Stressed Parts</li> <li>○ Flame Retardant</li> <li>○ Excellent Dimensional Stability</li> <li>○ Excellent Chemical Resistance</li> <li>○ Good Weatherability</li> <li>○ High Dielectric Strength</li> <li>○ Low Coefficient Thermal Expansion</li> <li>○ Outstanding Mechanical Properties at High Temperatures</li> </ul>	<ul style="list-style-type: none"> <li>• Forms Weak Weld Lines</li> <li>• Highly Anisotropic Properties</li> <li>• Drying Required Prior to Processing</li> <li>• High Cost</li> </ul>	200°C – 240°C



Resin	Advantages	Limitations	Service Temp Range
<b>LDPE</b>	<ul style="list-style-type: none"> <li>○ Flexible</li> <li>○ Retains Toughness and Pliability Over a Wide Temperature Range</li> <li>○ Highly Recyclable</li> </ul>	<ul style="list-style-type: none"> <li>• Density Drops off Dramatically Above Room Temperature</li> <li>• Exposure to Light &amp; Oxygen Results in Loss of Strength and Loss of Tear Resistance</li> </ul>	90°C – 110°C
<b>PEEK</b>	<ul style="list-style-type: none"> <li>○ Very Strong</li> <li>○ Good Thermal Properties</li> <li>○ Continuous Service at High Temperatures</li> <li>○ Low Moisture Absorption</li> <li>○ Excellent Resistance to Fatigue Hydrolysis and Chemicals</li> </ul>	<ul style="list-style-type: none"> <li>• Very High Processing Temperatures Required</li> <li>• Incompatible with Strong Bases and Halogenated Solvents</li> <li>• Notch-Sensitive</li> <li>• Anisotropic Shrinkage</li> <li>• High Cost</li> </ul>	154°C – 260°C
<b>PEI</b>	<ul style="list-style-type: none"> <li>○ Very Strong</li> <li>○ High Temperature Stability</li> <li>○ Excellent Electrical Insulation Properties</li> <li>○ Heat Resistant</li> <li>○ Flame Retardant</li> <li>○ Low Coefficient of Thermal Expansion</li> <li>○ Cost-Effective Alternative to PEEK</li> </ul>	<ul style="list-style-type: none"> <li>• High Processing Temperatures Required</li> <li>• Attacked by Strong Bases and Partially Halogenated Solvents</li> <li>• Notch-Sensitive</li> <li>• Limited Color-ability</li> <li>• Lower Impact Strength than PEEK</li> </ul>	170°C – 170°C
<b>PES</b>	<ul style="list-style-type: none"> <li>○ Very Strong</li> <li>○ High Temperature Metal Replacement</li> <li>○ Very High Surface Temperature Limits</li> <li>○ Exceptional Stability at High Temperatures</li> <li>○ Good Electrical Characteristics</li> <li>○ Low Moisture Absorption</li> <li>○ Low Creep</li> <li>○ Chemical Resistant</li> <li>○ Good Transparency</li> <li>○ Self-Extinguishing Ability</li> <li>○ Resistant to Common Greases &amp; Many Solvents</li> </ul>	<ul style="list-style-type: none"> <li>• Attacked by Some Solvents</li> <li>• Poor Weatherability</li> <li>• Subject to Stress Cracking</li> <li>• Difficult to Process</li> <li>• High Cost</li> </ul>	175°C – 180°C

Resin	Advantages	Limitations	Service Temp Range
<b>PET</b>	<ul style="list-style-type: none"> <li>○ Very Strong</li> <li>○ High Stiffness</li> <li>○ Lightweight</li> <li>○ Good Heat Aging Performance</li> </ul>	<ul style="list-style-type: none"> <li>• Not Suitable for Hot Water Service</li> <li>• Post-Mold Warp and Stress Cracking is Possible</li> <li>• Slow Cycle Times</li> </ul>	100°C – 140°C
<b>PPS</b>	<ul style="list-style-type: none"> <li>○ Tough/Stiff</li> <li>○ High Impact Strength</li> <li>○ Good Dimensional Stability</li> <li>○ Excellent Processing</li> <li>○ Good Surface Finish</li> <li>○ Low Creep</li> <li>○ Chemical Resistant to Acids, Alkalis and Bleaches</li> </ul>	<ul style="list-style-type: none"> <li>• High Processing Temperatures</li> <li>• Comparatively High Cost</li> <li>• Fiber-Filled Grades may show Mold Warp</li> </ul>	200°C – 220°C
<b>PSU</b>	<ul style="list-style-type: none"> <li>○ High Strength</li> <li>○ Very High Surface Temperature Limits</li> <li>○ Good Electrical Characteristics</li> <li>○ Low Creep</li> <li>○ Low Moisture Absorption</li> <li>○ Resistant to Common Greases</li> <li>○ Resistant to Many Solvents</li> <li>○ Heat Resistant</li> <li>○ Self-Extinguishing Ability</li> <li>○ High Temperature Metal Replacement</li> </ul>	<ul style="list-style-type: none"> <li>• Attacked by Some Solvents</li> <li>• Poor Weatherability</li> <li>• Subject to Stress Cracking</li> <li>• Difficult to Process</li> </ul>	150°C – 180°C

# Finding a Plastic Molding Company to Meet Your Needs



# What to Look for in a Plastic Molding Company

## Five Key Features

### 1 Resin Expertise

When it comes to the medical industry, you need to be certain you're working with a plastic molder who specializes in engineered resins (*not commodity resins*).

A plastic molder with true resin expertise will be able to analyze and advise on which engineered resin(s) will be best based on factors like product performance, cost, environment of use, manufacturability and post-molding operations.

### 2 Scientific Molding Expertise

Very few plastic molding companies in the world have certified Master Molders, so if you can find a molding company that has these in-house Master Molders, you've probably hit a gold mine!

**Master Molders** are experts in providing molding solutions that are optimized for performance, cost and efficiency. They use scientific molding methodologies, strategies, techniques and best practices to achieve improved mold quality, production and device profitability. Master Molders also have the adept knowledge and skills to resolve the toughest molding challenges.

### Manufacturability Optimization

Scientific plastic molders know how to modify, when needed, a design to optimize it for manufacturability. Modifying sharp angles or curves, changing **gate locations**, identifying the right resin at the right value, etc. are all part of optimizing a medical device for maximum manufacturability.

## 4 Comprehensive Molding Services

Since medical devices usually involve multiple processes, you should choose a plastic molding company that provides comprehensive, value-add services like:

- [Mold Design Assistance](#)
- [Injection Molding](#)
- [Overmolding](#)
- [Insert Molding](#)
- [Plastic Welding](#)
- [Pad Printing](#)
- [CNC Machining](#)
- [In-Mold Decorating](#)
- [Hot Stamping](#)
- [Consulting](#)

**Partnering with a plastic molding company that can do it all in-house will save you lots of time, stress and money!**

## 5 Medical Industry Experience

Choosing a plastic molder who has experience in the [medical industry](#) is a big plus. Familiarity with medical molding issues, resins, requirements and regulations all help make the molding process go more smoothly.

Look for plastic molding companies who specifically call out the medical industry on their website, in their print materials, etc.

## Conclusion

Selecting the right resin(s) for your medical device is essential for achieving optimal design, function, manufacturability, and profitability. It can also be critical to patient safety.

Partner with an experienced molding company at the beginning of your project to ensure the right resin(s) are selected for the device's intended purpose, environment and service life.

If possible, choose a molding company that specializes in engineered resins, has in-house Master Molders, offers all-inclusive molding services and has experience in the medical industry.



# Plastic Molded Concepts (PMC)

**Plastic Molded Concepts (PMC)** is one of the very few plastic injection molding companies in the world who uniquely specialize in engineered resins.

**We provide mold design assistance, as well as all-inclusive molding and post-molding operations.**

**Our in-house Master Molders are specialized in scientific plastic molding, including design, troubleshooting, issue resolution and manufacturability.**

**Our quality control process centers on stringent systematic checks throughout every process, as well as at critical checkpoints. Our quality assurance system also enables complete traceability from raw materials to final product delivery.**

**Specializing in complex molding projects, PMC has been a premier molder for some of the top medical manufacturers in the world.**



# Disclaimer

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**The methods described within this eBook are not intended to be a definitive set of instructions for this project or application. You may discover there are other methods to accomplish the same end result.**

**For the most up-to-date information on engineered resins, please visit <https://plastics.ulprospector.com>.**

**To avoid improper resin selection, contact PMC for additional help in determining a specific group of materials needed for your application.**