MATERIAL BEHAVIOR AT THE MICRO SCALE:
The Core of Medical Device Innovation

MTD MICROMOLDING

Material Science at the Core of Medical Device Innovation

As the medical device industry rapidly evolves, we're seeing many opportunities.

Pharmaceuticals or smart technology are being incorporated into more medical device designs. Parts are getting miniaturized to improve patient comfort, performance, efficiency, and convenience. Micro overmolding can present opportunities to mold a device as a single unit, improving cost efficiency and overall quality.

At the core of each of these innovations is material science—specifically micro-level polymer science.

Material behavior on the micro level is very different than at the macro level. As medical OEMs have experienced:

- The material that worked well for your original medical device design may not be well-suited for the miniaturized version with smaller, nominal wall stock and thin-wall features.
- PEEK worked well for machining parts for prototyping but will not be cost-effective now that you need to scale to produce annual volumes of 500,000.
- Unsure of material options but aware of the application needs? This helps narrow the options that may be suitable. For example, a load-bearing or force-distributing implant requires a strong but somewhat supple or flexible low-durometer bioabsorbable material that holds strength for nine months before resorption.

Material behavior on the micro level is very different than what traditional (macro-level) plastics engineering has taught us. It surprises us on a regular basis. This energizes us to find ways to control these characteristics and harness them for our benefit.

As Patrick Haney, MTD's Research and Development Engineer, says, "From my perspective, the factors that drive all growth in this field is an ever-growing understanding of how the viscoelastic and thermal behaviors of specialty polymers change when exposed to the micro-environment. A stronger understanding of the science that drives polymer behavior can allow us to become more inventing and daring in areas spanning from mold and part design, to optimizing processing techniques and manipulating material characteristics, to even finding new ways to utilize materials in ways never been done before."

Understanding Polymers

In various industries, plastics can be synonymous for "cheap" or "low-quality." This is a massive misconception because they are not only high-quality, complex materials but also provide unique functionality and performance that other materials simply cannot.

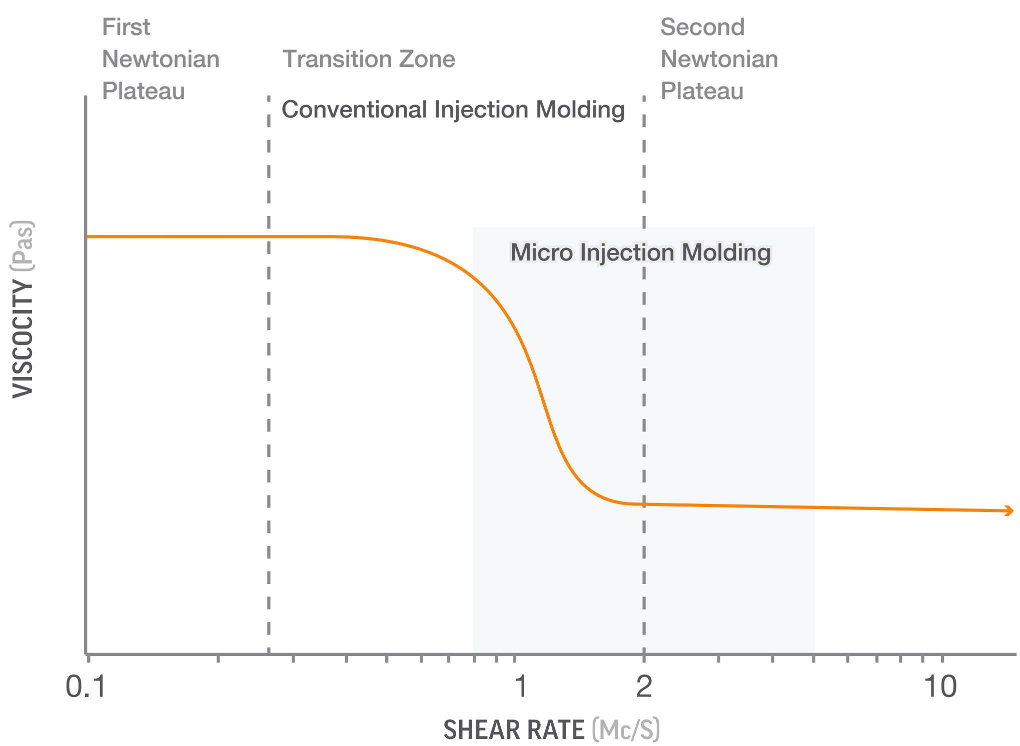
The implantable medical device industry demands the utmost level of performance and quality in the materials it uses. Medical device companies continue to demand smaller parts, thinner walls, and sharper features—without narrowing material choices. This requires molders to push the limits of polymers, achieving thinner walls than what is traditionally doable—all while meeting tight tolerances, holding up to extremely high shear rates, and maintaining the material's desired mechanical properties.

What's important to understand is that micro injection molding is different than conventional (macro) injection molding. The rheology chart below (Figure 1) shows that most of the macro injection molding industry exists in the transition zone. In this zone, polymers move in laminar flow and filling behavior is predictable.

But micro injection molding lives in the gray-shaded area. There's a point where the predictable behavior stops, and simulation and conventional viscosity equations no longer represent what happens when working at the micro scale.

The reality is that materials do not behave on a micro scale the same way they do on a macro scale. Temperatures, mechanical properties, macro molecular behavior—all are different on the micro scale. Developing molding process windows for materials on this scale, therefore, is not the same. The methodology and strategy to optimize the micromolding process are different because of how little material is used per cycle.

FIGURE 1: Rheology



Polymer Mechanics

The word “polymer” derives from Greek, where *poly* means many and *mer* means unit. A polymer, or plastic, is made up of many units or molecules that chain together to form long molecules with large aspect ratios.

When in the molten state, the heat energy causes the polymer chains to entangle and lay together like cooked spaghetti. If you had a plate of cooked spaghetti and started pushing the noodles around, the spaghetti might get tangled or knotted up—much like polymer chains. The more polymer entanglement there is, the more resistance to flow there is. That resistance to flow is called viscosity.

There are typically two different types of fluids:

- **high-viscosity**: flow is thick, much like honey
- **low-viscosity**: flow is easier, more like oil

When it comes to polymer entanglement, the viscosity that the molten state produces will vary depending on the environment. Typically, the harder you push plastic, the easier it will flow—to a point. In micromolding, you can reach a shear thinning threshold (see Figure 2) where that behavior stops and the material becomes less controllable. Note that this is where the Second Newtonian Plateau begins.

Two major driving factors in micro molding are injection pressure and shear rate.

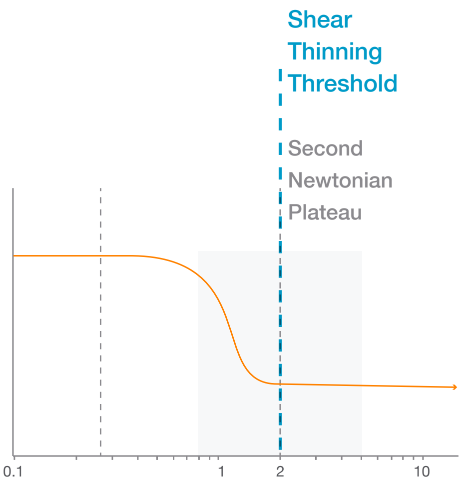


FIGURE 2: Looking at the rheology graph again, we see the Shear Thinning Threshold is reached at the Second Newtonian Plateau.

SHEAR RATE

Imagine if a group of us went out in a long, thin hallway and we were also holding two-by-fours (boards of framing lumber). Now imagine we were told to run down to the end of the hallway as fast as we could, all at the same time. And we did that with no organization whatsoever and we were closely packed together. Our two-by-fours would run into each other, and it would take longer to get down the hallway than we might expect.

Now imagine that instead of running haphazardly, we got organized. We hoisted the two-by-fours over our shoulders, parallel to the wall. Staying in alignment, we ran straight ahead—and much faster this time.

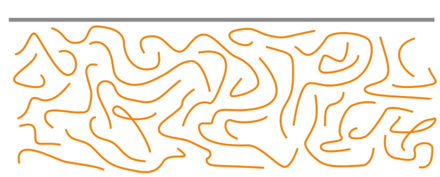


FIGURE 3: Polymer chains in the molten state are entangled and show no orientation.

FIGURE 4: Polymer chains become aligned during the injection molding process.

This analogy helps us understand orientation and flow of polymer chains in micro molding, which brings us back to shear rate.

To understand shear rate, it is first helpful to understand laminar flow. Laminar flow describes the characteristics of a material that flows in layers. A non-Newtonian fluid like plastic typically flows in this manner.

Looking at the velocity profile (Figure 5), we assume zero velocity at the mold walls. The longer arrows represent the polymer chains flowing at a faster rate than the shorter arrows.

When the polymer comes into contact with the steel mold, the steel can act as a rapid heat sink, as seen in the shear profile (Figure 6). The outer laminates, or polymer chains that are closest to the mold wall, tend to get dragged back because they meet resistance when rubbing up against the stationary wall—much like a car riding the guard rail on a highway. The outer laminates tend to have lower speeds because they experience more frictional drag, yet they experience higher orientation. The frictional drag decreases the amount of entanglement, thus increasing the amount of orientation.

FIGURE 5: Velocity profile of Non-Newtonian fluids, in which the vectors represent the flow speed.

FIGURE 6: Shear profile of Non-Newtonian fluids, in which the vectors represent the shear rate per layer.

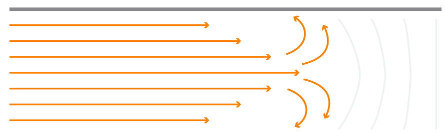


FIGURE 7: Fountain flow is a concept that describes the flow front.

The inner laminates experience the lowest amounts of shear and orientation, as well as the highest speeds. They flow faster because they experience less frictional drag.

Because the mold temperature is colder than the melt temperature, it causes the plastic to solidify or freeze. This phenomenon, called the frozen layer or skin layer, happens throughout the filling process. The skin layer is why we assume velocity is zero at the mold wall. While this skin layer happens in macro parts, it's more important in micro parts simply because of scale: the skin layer accounts for a much larger percentage of the part.

Combining the velocity profile and shear profile, we can then understand the phenomenon called fountain flow. (See Figure 7.) This is when polymer chains reach the flow front sooner and roll to the sides.

Temperature also facilitates orientation. As things heat up, they expand. With this expansion, pockets of space often called "free volume" form in-between the polymer chains. (See Figure 8.) That space allows those polymer chains to flow past each other more easily.

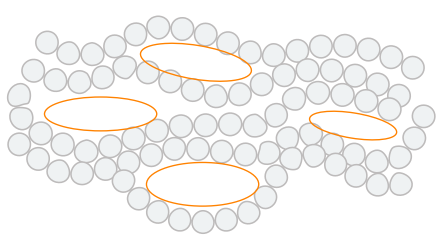


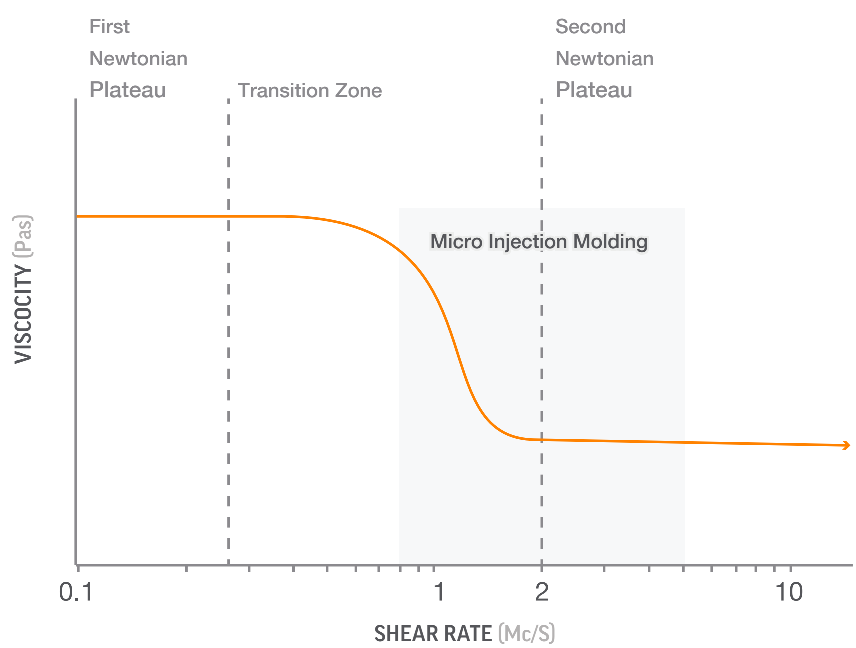
FIGURE 8: Free volume in-between polymer chains.

Understudied Material Phenomena

When we experience ultra-high orientation and make flow channels ultra-small, the shear rate tends to skyrocket.

The rheology graph (Figure 9) below depicts how the viscosity of plastic melt behaves under increasing shear rates.

FIGURE 9: Rheology



In the First Newtonian Plateau, plastics have low shear rates and low velocities. There is no significant influence from orientation or free volume, and the polymer entanglement is very high. We do not see a significant drop in resistance to flow at lower shear rates because we are not pushing it very hard.

In the Transition Zone, where most conventional injection molding occurs, non-Newtonian materials start to shear thin. This is the region that demonstrates conventional fountain flow.

In the Second Newtonian Plateau, polymers plateau and behave more like a Newtonian fluid, where all the laminar velocities are similar and the benefits from shear rate have reached a threshold because all the polymers have reached maximum orientation.

The Second Newtonian Plateau remains a greatly understudied area. Viscometers used in the plastics industry cannot replicate velocities at that speed, channels that small, and shear rates that high. Even simulation software often cannot account for this behavior. The theoretical equations widely used in polymer science also do not work in understanding the behavior at this scale. This is why micro molders need to be creative in finding alternative ways to determine how to optimize processing parameters and successfully create more complex designs for medical OEMs.

SHEAR LIMITS

What's important to understand is that when you reach the shear limit—when shear rates are high—the viscosity stops decreasing with increasing pressure. Once that happens, many tricks and tools of the trade a processor uses to fill thin walls or troubleshoot don't apply anymore.

> **"After you reach the sheer thinning threshold, you are really working with a non-Newtonian fluid that acts *like* a Newtonian fluid. There is a whole new set of rules you need to play by when it comes to plastic fluid flow."**
>
> **– Patrick Haney, R&D Engineer**

The microstructures that form in the Second Newtonian Plateau are entirely different than what would form if exposed to "regular" shear rates and pressures. Understanding the repercussions of the changes is just as important when you consider the part application and how it needs to perform, as well as what material characteristics are important. Depending on the material you are working with, this could affect anything from part rigidity and chemical resistance to things like shrinkage.

Like many OEMs, you may be wondering: If shear rates are so high, why do materials not degrade?

The reason is that degradation due to shear rate is a function of rate and time, and in micro injection molding, the exposure time is very fast. It's not unlike how you can quickly run your hand over a candle's flame without getting burned.

MICRO STRAWS AND CANNULAS

The shear limit is especially critical when molding a high-aspect ratio, like the long thin-walled Polypropylene drug delivery straw (top), which features a .005" long-distance thin wall. The cannula (bottom) features walls as thin as .0025".

Material Selection

While an OEM doesn't need a thorough scientific understanding of how plastics behave, it's important to understand how material selection has a direct impact on the manufacturability of micro medical products. The correct material drives:

- tolerance
- dimension
- mechanical properties
- application functionality
- design
- speed-to-market
- critical features
- cost
- and more

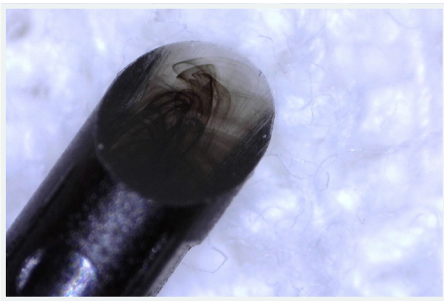
When determining the optimal material for your micro medical device, there are many factors to consider. First and foremost, the polymer's mechanical, thermal, and degradation mechanisms must all meet the requirements of the intended application.

In addition to the standard "form, fit, and function" considerations, properties such as crystallinity, shear sensitivity, compressibility, and other rheological aspects become exponentially more important when scaling down to a micro-sized component. This helps ensure the manufacturability of a reliable product.

Intrinsic viscocity testing is one of many ways that MTD tests and characterizes materials.

Lindsay Mann, MTD's Director of Sales & Marketing, looks at the array of materials in storage.

Material Advancements



As an example of how material additives flow differently on the micro scale, this progress sample shows the clear plastic filling a thin wall feature easier than the dark colorant.

Most polymerization and synthesizing of materials cater to a macro world. There are no polymers that are specifically micro-only materials.

Where we do see interesting advancements is with material additives. For example, there are common additives that can strengthen or soften the polymer. Bioabsorbable additives can help tailor degradation rates. Visual additives can produce specific product colors, create radio-opacity, or even allow parts to glow in the dark. Conductive additives integrated into a micro device enables it to sync with smart technology. In the future, we see potential for the advancement of inherently conductive polymers.

The most significant material advancements are in the materials knowledge itself—in understanding how materials will work on the micro scale. By rigorously studying various phenomena that we uncover and weighing these results with existing material engineering knowledge, we can continually push the boundaries of what's possible in micro medical molding.

New Manufacturing Technology

Patrick Haney runs material characterization studies in MTD's metrology lab.

When molding parts on such a small scale, it is imperative to use molding equipment with precision capability that exceeds typical injection molding machines. For example, if a part weight is measured in hundredths of a gram, the machine's shot-to-shot consistency must be perfected to prevent significant part-to-part variation.

Especially with the increasing functionality of micro molding technology, optimizing second-order process parameters is becoming increasingly important. Encompassing more than the typical factors like velocity, time, and pressure, these second-order parameters consider factors like cooling rates and pressure ramps. This allows manufacturers to optimize not only the final product but the kinetic process that the product sees during molding and cooling.

For MTD, one of our new technology focuses has revolved around issues like flow path temperature control. Using cyclic, spot, and flow path heating, we can keep the flow path hotter for longer, thus allowing the plastic to flow easier for a longer distance. Our localized mold temperature control technologies allow us to fill thin walls that would otherwise be impossible to fill.

With MTD's constant effort to learn how to optimize products on a micro level, we have launched a series of characterization projects to analyze the morphology of our molded components. Equipped with this knowledge, we are developing custom and original technology to incorporate into our injection molds so we can continue to manufacture breakthrough micro medical components for our customers.

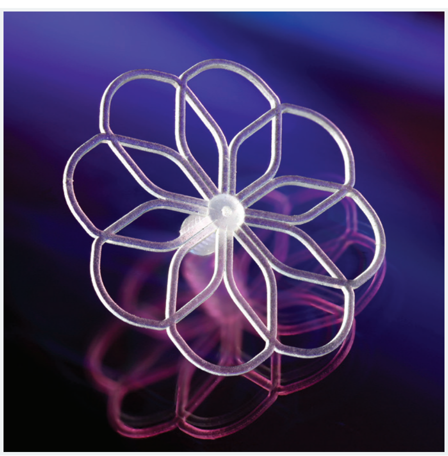
Manufacturing Challenges

The micromolding process continues to become more challenging and the engineering more complicated. We have more conversations about lot-to-lot variation than a macro molder would because minuscule changes can significantly affect our results. As part features get increasingly smaller, successful manufacturing relies on experience and strategy in building the tool and optimizing molding parameters.

For example, it can be very challenging to maintain part functionality and material identity on a micro scale with features like extremely thin walls. Consider:

Material	Thinnest wall possible*
Liquid Crystal Polymer (LCP)	.002"
Polypropylene (PP)	.002"
Polyester	.004"
Nylon	.004"
PEEK	.005"
Polyurethane	.005"
Polycarbonate (PC)	.007"
Elastomers	.010"

**Achievable thinnest wall value is highly dependent on geometry and aspect ratio.*



CATHETER TIP ABLATION HEAD

Made of an experimental shape-memory thermoplastic material, this device features a 0.009" (0.23 mm) wide webbing. The challenging design features long, looping channels that create multiple intersecting flow paths. Preventing one or more of these channels from prematurely solidifying and causing a "short-shot" is only possible with the right material and micromolding equipment.

Even when you have the option to use the best materials for molding ultra-thin walls, keep in mind that the thinnest wall highly depends on your part's geometry and aspect ratios. Ultimately, a polymer's ability to flow depends on its degree of entanglement. It's influenced by:

- morphology
- heat transfer rate
- molecular ratio
- filler content

Maintaining a material's expected mechanical properties for parts that have a mechanical application is a challenge. The micro geometry forces the material to be weaker than it would normally be at the micro scale, and techniques are employed to achieve acceptable mechanical properties and work with the design.

Depending on how demanding the details of a given part geometry is, micro parts can begin to push the limits of how an engineer might expect a typical non-Newtonian fluid to behave. Once you have surpassed the threshold of extreme shear and cooling rates, the resulting product—unless expertly manipulated—will rarely demonstrate the properties that are forecasted for the given material and mechanical functions. Due to these phenomena, successful micro molders must find creative and alternative ways to optimize their processing parameters to ensure that the resulting process is grounded in as much scientific data as possible.

Material Choice Example

As an example, let's say you're working on a micro medical device. Like many OEMs, you decided to start with PEEK. It is a popular choice because of its accompanying regulatory approval. It's also one of the easiest materials to machine, which was convenient for your prototyping phase. Given your design intent, PEEK seemed like a good choice because it offers:

- High strength
- High gloss
- Good resistance to wear over time
- Pre-approval for many medical applications

Now your project team has been tasked with increasing yearly quantities to 500,000 units per year. That presents a problem because these quantities are too high for cost-effective machining. It's time to transition to micro injection molding.

Is PEEK still the best choice? Let's look at some pros and cons of three materials.

PEEK (Polyether ether ketone)	ABS (Acrylonitrile butadiene styrene)	Acetal (Polyoxymethylene)
✓ High Gloss	✓ High Gloss	✓ High Gloss
✓ High Strength	✗ Rigidity Too Low	✓ High Strength – *very crystalline*
✗ Very High Processing Temp – *tooling problems*	✓ Lower Processing Temp	✓ Lower Processing Temp
✗ Rapid Cooling Rate – *difficult to keep flow front hot, causing short shots*	✓ Lower Cooling Rate	✓ Lower Cooling Rate
	✗ Not Self Lubricating	✓ Self Lubricating – *used in many low friction applications*

QUESTIONS WHEN CONSIDERING MATERIALS

When considering materials, don't make your choice based on what's popular. Remember, what works for prototyping may not work as well when you ramp up production.

Based on your design, prioritize your requirements and present them to your molding partner or material supplier. You may find that other materials may offer better and more cost-effective choices.

The types of questions you may want to ask as you're considering materials are:

- What are the parameters of my application?
- What's the application temperature? Range?
- Is the device load bearing?
- Is it an optical device?
- Does my device contain pharmaceuticals or chemicals?
- Is patient comfort a concern?

As Patrick Haney, our R&D Engineer, will tell you:

The answer is always in the chemistry.

Glossary

Amorphous A polymer that typically contains a matrix that is less than 35% crystalline. Some semi-crystalline polymers can be quenched or cooled very quickly so that crystals do not have time to form.

Aspect Ratio The ratio between the width and height of a polymer. Typically, in plastics, an aspect ratio refers to the length of polymer chains and is closely related to molecular weight.

Chain Scission The degradation of a polymer usually without the influence of a chemical agent. Often refers specifically to polymer chains breaking.

Crystallization The acts of polymer chains "folding upon themselves" to form dense, highly structured crystallites. This is done through intramolecular attraction.

Delamination A mode of failure for composite materials. In laminated materials, repeated cyclic stresses, impact, and so on can cause layers to separate, forming a mica-like structure of separate layers, with significant loss of mechanical toughness.

Excite When molecules excite, they experience an increased movement and a decrease in bond strength due to the addition of external energy.

Flow Length In processing, a flow length describes the distance that a polymer must flow to reach the end of the cavity, achieving a full part.

Free Radicals An uncharged molecule (typically highly reactive and short-lived) having an unpaired valence electron.

Gate Seal The time during the cooling process in an injection molding process when the plastic at the gate area solidifies. Gate seal is significant because once this event occurs, the pressure inside the cavity can no longer be controlled.

Glass Transition Temperature (Tg) A material property, the point at which a polymer will soften. In amorphous polymers, the Tg represents the gradual start of the melting process. In S/C polymers, crystallites are still intact, but the matrix has softened.

Heat Sink An area that absorbs excessive or unwanted heat.

Laminates Individual polymer layers of molten non-Newtonian flow.

Molecular Weight (MW) The ratio of the average mass of one molecule of an element or compound to one-twelfth of the mass of an atom of carbon-12. In plastics, MW is usually very high due to the nature of the repeating units found in a polymer. MW is also very important because a loss in this value generally means a drop in material properties.

Morphology Refers to the way a polymer forms or is ordered.

Orientation Typically refers to the direction in which most polymer chains are aligned.

Plastification The process that occurs in the injection unit, before entering the mold. This includes feed material, melting and mixing, as well as injection.

Purge The plastic product yielded from injecting out of the injection unit into the atmosphere as opposed to inside a mold.

Semi-Crystalline A polymer that typically contains a matrix that is 35% or more crystalline.

Sprue Break A molding parameter that causes the injection unit to retract away from the mold after injection.

Thermal History In plastics, the thermal history of a polymer refers to how many times that polymer has been processed or melted.

Viscoelastic The property of materials that exhibit both viscous and elastic characteristics when undergoing deformation.

Viscosity The resistance to flow.

ABOUT THE COMPANY

Founded in 1972, **MTD Micro Molding**, custom crafts ultra-precision molded components that meet the exact requirements of companies in the medical device industry. We offer in-house tooling, unparalleled bioabsorbable expertise, ISO 13485 certified systems, FDA registration, and state of the art equipment — all under one roof.

Our dedicated focus on bioabsorbable and drug delivery micro injection molding ensures successful delivery of complex custom products that nobody else can produce.

To learn more visit **mtdmicromolding.com**, or come tour our facility in Charlton, Mass.

Questions? Contact Lindsay Mann: lmann@mtdmicromolding.com