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MICRO MOLDING WITH BIOABSORBABLES:

Not Your Average Thermoplastics

MTD MICROMOLDING

Background

BIOABSORBABLES VS. THERMOPLASTICS

For micro medical components, there is a wide variety of materials to choose from. Thermoplastics are commonly used for medical micro injection molding.

Thermoplastics are polymers that become pliable and moldable above a specific temperature, then return to a rigid state upon cooling. They have long been used in the micromolding world.

Many new micro medical applications rely on **bioabsorbable** materials (also called resorbable, bioresorbable, or biodegradable), a type of thermoplastic. They dissolve in or are absorbed by the body, eliminating the need for additional surgeries and minimizing concerns about adverse effects. Devices made from these materials metabolize over time so secondary invasive procedures are not needed to remove them.

Across the board with plastics, the processing rules are different when molding on the micro scale. Specifically, bioabsorbable materials require a much more extensive and specialized micromolding approach.

FIGURE 1: Material comparison from a processing perspective

MICROMOLDING THERMOPLASTICS	MICROMOLDING BIOABSORBABLES
Raw material and parts stored at room temperature	Raw material and molded product kept in refrigerated storage
Follows standard IQ/OQ/PQ plan for validation	Extensive validation process
Molecular weight loss is not as significant with processing	Molecular weight loss can be dramatic with processing
Materials generally less expensive—runner and sprue waste not as significant	Materials generally more expensive—optimized sprue and runner technology required for cost efficiency
General purpose screw with an aggressive 25% overall screw length melt transition zone	Custom screw with a longer than 25% overall screw length melt transition zone for a more gradual melt
Material conditioning is more forgiving	Material conditioning is *always* critical
Utilized for permanent implants/components	Implant applications, where the material is broken down over time and absorbed by the body

BIOABSORBABLE TACK

This design's sharp points must be less than 0.0002"R. Bioabsorbable materials degrade with shear generated in small flow paths. Economical micro processing of bioabsorbable materials requires minimum runner sizes to reduce waste. Manufacturing a solution that balances these conflicting needs is a challenge a molder must conquer.

SPECIALIZING IN BIOABSORBABLES

If you have a complex bioabsorbable medical device design, you need a specialist to be successful.

Think of it this way. Who would you go to to fix your complex medical issue, your general practitioner or a specialist?

The general practitioner can offer a broad spectrum of services, but cannot offer the same high-level expertise as a specialist. Because the specialist devotes all their effort on that one specialty, their level of expertise, specialized equipment, extensive knowledge, and experience allows them to diagnose and fix your problem in the quickest and best way possible, whereas even a great general practitioner may not have the knowledge and tools needed to solve your problem at all.

For example, say you're a runner and you have a recurring knee problem. Your general practitioner might tell you to take some pain medication and stop running. Since that's likely not the right solution for you, you'd likely find a doctor who specializes in sports medicine. Having worked with numerous athletes and being equipped with specialized diagnostics tools, the sports medicine specialist could offer in-depth insight on how to manage your knee injury—and hopefully help you avoid surgery.

The same premise holds true for bioabsorbable micro molding. A molder who does not focus solely on medical micromolding and bioabsorbables will not have the necessary tools or knowledge to effectively find the optimal solutions for your bioabsorbable needs. Like the general practitioner who says "stop running," a non-specialized molder may tell you that your bioabsorbable design is impossible and can't be done. By turning to a bioabsorbable specialist instead, you get access to the in-depth expertise and equipment to make your ideas possible.

BIOABSORBABLE ANCHOR

This device is made of PLG and weighs only 0.025g. The anchor is used in a fascia closure device that aims to minimize port site herniation following laparoscopic abdominal surgery. The reduced IV loss (less than 5%) is critical in ensuring optimal wound healing.

Key Markets & Applications for Bioabsorbable Micro Molding

With the steady growth and interest in bioabsorbables, applications are always evolving and expanding. *(See Figure 2 below.)*

Historically, the bioabsorbable marketplace for molded components has been in the static fixation market such as rigid screws, tacks, or staples—especially for orthopedic applications. Bioabsorbables have also become popular for products in the closure market and laparoscopic procedures.

With the advent of new materials and engineers pioneering new solutions, the products have expanded into dynamic devices. Materials now need to bend and flex like an elastomer but provide high mechanical strengths to achieve the desired result.

Many traditional molders would believe that it's impossible to put a drug into a material before molding without destroying it through the injection molding process. With specialized medical micro molding it is, in fact, very possible. Products like drug-eluting bioabsorbable implants are becoming more prevalent in the market. These products consist of an active drug that is compounded with a bioabsorbable material that gets molded and then implanted inside the body. The bioabsorbable carrier dissolves, delivering the drug over an extended period of time.

FIGURE 2: Examples of bioabsorbable micromolded medical components

ORTHOPEDIC/ORTHOPAEDIC

- **Sports Medicine:** hard and soft bone anchors, soft tissue fixation, knotless suture anchors
- **Reconstructive Devices:** craniomaxillofacial, plastic surgery
- **Spinal Implants:** spinal degenerative disease therapies
- **Soft Tissue/Arthroscopy:** suture anchors, interference screws
- **Fixation:** screws, staples, tacks, plugs

OTHER APPLICATIONS

- **Cardiovascular:** structural heart disease therapies, suturing devices
- **Wound/Port Closure:** subcutaneous fasteners, anchors, staples, suture devices, fascia closure, femoral access closure
- **Neurological:** brain/neural implants
- **General Surgical:** surgical clip, minimally invasive surgery (MIS) therapies

ADVANCED DRUG DELIVERY

- **Drug Delivery:** drug delivery vehicles/carriers, drug delivery implants, drug-eluting implants

Bioabsorbable Materials

Designing a bioabsorbable medical device is expensive. First, these materials often cost significantly more than conventional polymers.

Adding to the expense is the fact that due to their sensitivity, bioabsorbable materials are much more difficult to mold and process than other polymers. It's important to understand the material capabilities—and limitations—to help avoid costly delays in the development process and material waste.

A medical micromolder possessing in-depth knowledge of both standard and custom-compounded bioabsorbable materials can help to produce a component design that affords better speed-to-market and quality control.

Typical challenges faced in using these novel materials include characterizing critical temperatures such as the glass transition temperature, crystallization temperature, and melt temperatures. Another challenge is ensuring the proper amount of crystallinity is present in the post-molded product, and maintaining a consistent and acceptable molecular weight loss (IV loss) over long-term larger production lots.

STANDARD BIOABSORBABLE MATERIALS

Commercially available bioabsorbable materials include PLA (polylactide), PLG (polylactide-co-glycolide), PLDL (Poly-L-lactide/DL-lactide copolymer), and PCL (polycaprolactone).

FIGURE 3: Commonly used bioabsorbable materials

- **PURASORB® PLG 8531** (85/15 L-lactide/glycolide copolymer)
- **PURASORB® PLG 8523** (85/15 L-lactide/glycolide copolymer)
- **PURASORB® PLG 8218** (82/18 L-lactide/glycolide copolymer)
- **PURASORB® PLG 1017** (10/90 L-lactide/glycolide copolymer)
- **PURASORB® PDLG 5010** (50/50 DL-lactide/glycolide copolymer)
- **PURASORB® PLDL 7024** (70/30 Poly-L-lactide-co-DL-lactide)
- **PURASORB® PL 38** (Poly-L-lactide)
- **RESOMER® L210S** (Poly-L-lactide)
- **RESOMER® LR 706** (70/30 Poly-L-lactide-co-DL-lactide)
- **RESOMER® LR 708** (70/30 Poly-L-lactide-co-DL-lactide)
- **RESOMER® LR 704** (70/30 Poly-L-lactide-co-DL-lactide)
- **RESOMER® RG 509 S** (50/50 Poly-L-lactide-co-glycolide)
- **RESOMER® X 206 S** (Polydiaxanone)
- **Glycoprene®**
- **Lactoprene®**
- **Strataprene®**
- **P4HB** (poly-4-hydroxybutrate)
- **PCL** (polycaprolactone)
- **PLGA** (poly lactide-co-glycolide)
- **PLLA** (Poly-L-lactide)
- **Other** (customer proprietary bioabsorbable materials)

ADDITIVES & FILLERS:

- Color concentrates
- Pharmaceuticals for drug elution
- TCP (Tricalcium phosphate)

As with any material, it's useful to obtain information about how to optimally process the specific resin. However, that's the challenge: Detailed documentation for micro injection molding with bioabsorbable materials does not exist from any material manufacturer. With limited processing data to start from, a micro molder needs to employ a rigorous characterization process for any new materials to assess and determine material behavior at the micro scale—before, during, and after molding.

For example, consider the striking differences between RESOMER X 206 S (polydioxanone) and PURASORB PLG 8218 (polylactide-co-glycolide). The latter poses less molding challenges, flows easier, and can achieve crisp features and narrow geometries. The former is unique in that it is not stiff at room temperature, which is below its glass transition point. It degrades in the body faster than other bioabsorbable polymers. Despite its inherent molding difficulty, it offers advantages to unique designs and applications.

FIGURE 4: Comparison of materials

MATERIAL	MICRO MOLDING EASE (1=HARD, 5=EASY)	AVG. IV LOSS (%)	COST ($–$$$$)	NOTES
PURASORB® PLG 8218	4	4%	$$$	Easy to flow. Can fill very thin walls/details.
RESOMER® X 206 S	1	4%	$$$$	Extremely narrow melt temperature window. Degrades quickly.

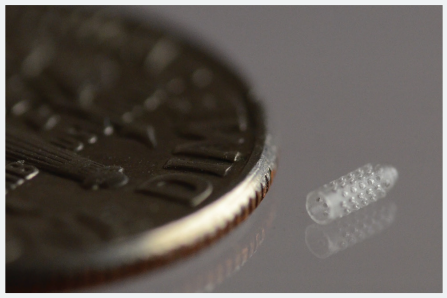
It's critical to know what the design requires from a material in terms of, for example, strength, inherent viscosity (IV), and physical properties. It's also important to select a material that will ensure premium quality and maximum cost-effectiveness.

BIOABSORBABLE TACK

The dead-sharp tip of this spring-shaped design is critical to its function. Unconventional tool construction methods were needed to allow the five (5) slides come together and shut off precisely, in order to make the tack's final geometry with no measurable vestige

CUSTOM BIOABSORBABLE MATERIALS

Boutique material suppliers are producing special-recipe materials to meet the exact needs of up-and-coming next-generation products. By adding pharmaceuticals, fillers, or lower molecular weight materials that dissolve quickly, the required material properties can be tailored to meet the specific needs of the application, both physically and chemically. For example, some medical applications require bioabsorbable materials with more flexibility, higher rigidity, or higher or lower rates of absorption. There are many possibilities and the various iterations of products that are available cover a wide spectrum.



Machined prototype made in a bioabsorbable resin

BIOABSORBABLE PROTOTYPES

OEMs working on micro medical designs need to iterate fast and innovate fast—and ultimately get their product to market faster. Prototypes often help in the product development process.

3D printing, the most common type of prototype, cannot use bioabsorbable materials.

But there are other prototyping services for a medical OEM to consider: micro machining and test tooling. These services allows the OEM to receive a prototype of their design in their actual material, so they can evaluate the physical properties of the part, especially as it may relate to other components on their device.

FIGURE 5: Prototyping services for bioabsorbable micro medical components

MICRO MACHINING

Better for quickly evaluating a design in one or multiple thermoplastic materials

Achievable Tolerances:
± 0.002"

Materials for Use:
Any *rigid* thermoplastic, including bioabsorbable materials

Lead Time:
1–2 weeks

Cost:
$$

TEST TOOLING

Better for receiving injection molded prototypes, specifically in softer durometer materials

Achievable Tolerances:
± 0.001"

Materials for Use:
Any thermoplastic (rigid or not), including bioabsorbable materials

Lead Time:
2–4 weeks

Cost:
$$$

6 Keys to Bioabsorbable Success

Because bioabsorbable polymers are so easily affected by slight processing variations, it is difficult to achieve repeatable results and consistency among different molding runs for a given part. It's therefore important to understand the potential impact that each manufacturing step may have on the end result.

To ensure lot-to-lot consistency, a micro molder must implement dedicated steps to maintain consistency in material handling and process consistency. Although these steps seem obvious, molders that do not specialize in bioabsorbable materials may not be as vigilant in enforcing process and handling consistency because these steps are typically not as critical when dealing with conventional materials.

1: Runner Optimization

Given that bioabsorbable materials are so expensive, runner optimization is extremely important. A micro molder should have tools to determine the minimum runner size required to fill the volume of the part, and size a runner system to adequately mold a product without sacrificing material.

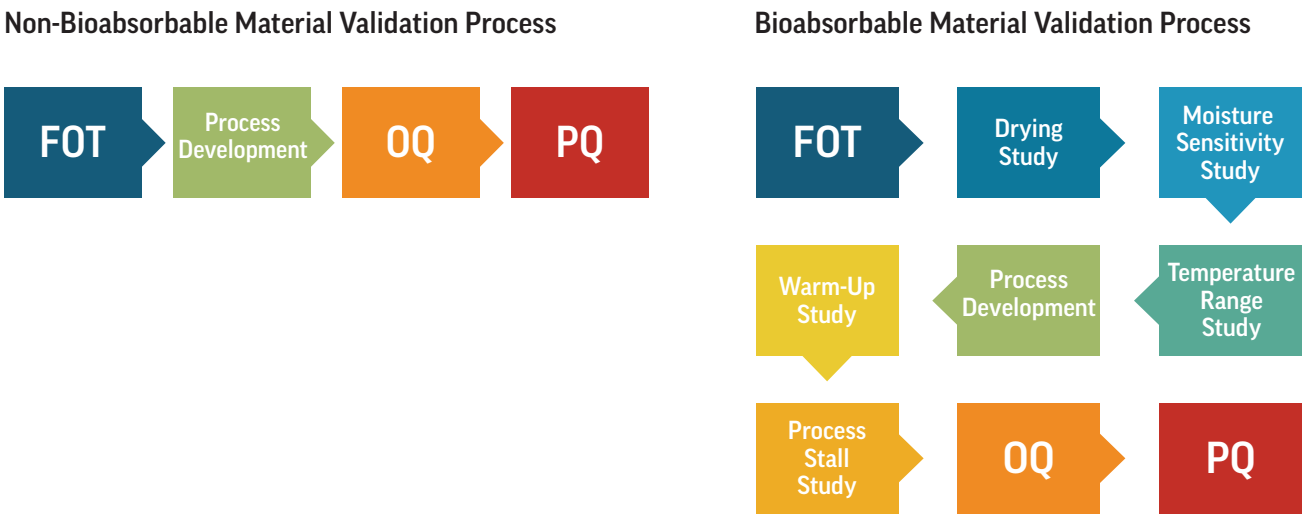
FIGURE 6: Typical runner (left) and MTD's optimized runner (right)

Looking at the runner systems photographed side-by-side, you can clearly see the size difference. The competitor's larger runner is more than 10 times bigger than MTD's optimized version. With bioabsorbable resins costing around $5 per gram and assuming an annual volume of 100,000 parts, this equates to an annual savings in material waste of over $100,000.

2: Robust Validation

Validating a bioabsorbable part requires more steps than a non-bioabsorbable part *(see Figure 7)*, but with good planning and exact execution, the timeline to get to production is far from daunting. With a collaborative approach, a micro molder should fully document and customize their validation processes for each client and project. Each micromolded part's quality score and all the process data should be stored, thus providing a high level of traceability.

FIGURE 7: The difference in MTD's validation process.

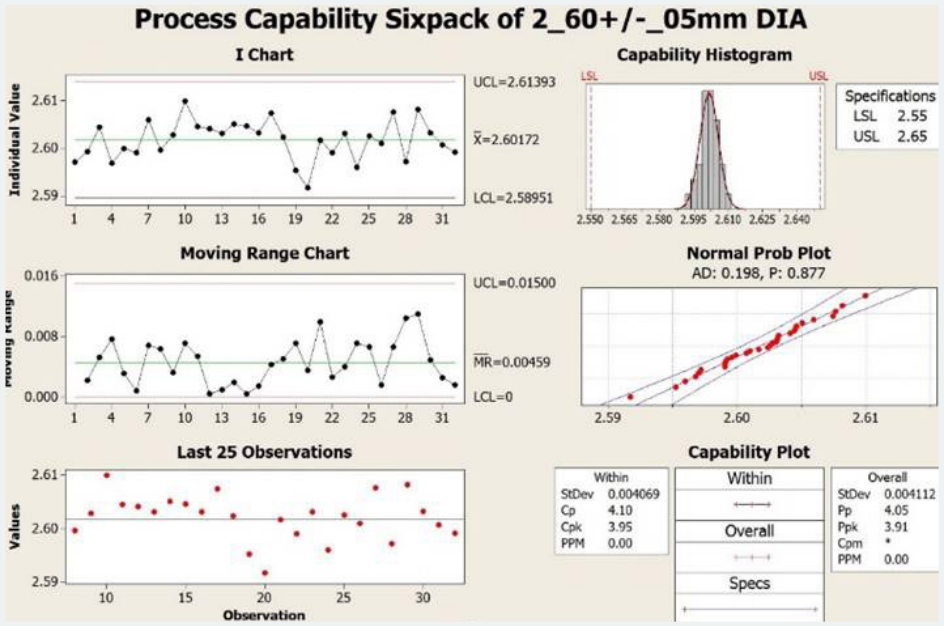


3: In-House Testing

Testing is particularly important when processing bioabsorbable materials because some manufacturing steps can cause IV loss during processing. Many micro molders outsource their testing for inherent viscosity, gas chromatography, and differential scanning calorimetry. Outsourcing can add weeks or months to the project time frame.

More importantly, without in-house testing and its immediate, real-time data, it is nearly impossible to efficiently evaluate the impact of the injection molding process and create an optimized process for a given part. In-house analytical equipment allows the micromolder to monitor, optimize, and report things like IV loss throughout the development and validation processes of a product, as well as verify post-molded outputs, like IV and critical dimensions, in order to successfully release production lots to the customer.

In this process capability analysis example, the minimum acceptable requirements were defined with a capability index of 1.33. The data indicates that the process is stable and in control. With the overall capability Ppk being 3.91 for this critical dimension, the process meets the customer's specifications.



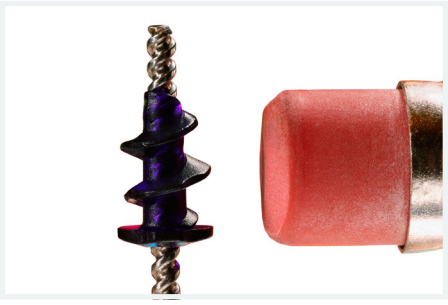
4: Minimal and Consistent IV Loss

MTD process technician testing for Inherent Viscosity (IV).

Post-mold IV loss is dependent on the micro molder and the material. More specifically, it depends on whether the micro molder has both the equipment and expertise to work with a particular material's complexities. On-site IV, gas chromatography, and DSC testing capability enables a micro molder to immediately adjust the impact of process variables on these outputs, allowing for a better optimized molding process, minimal and consistent IV loss, and improved capability.

Without consistent IV loss, an OEM cannot be confident that its parts will achieve repeatable quality and functionality.

One of MTD's high-volume production lines is a bioabsorbable fixation screw molded from PLDL. Over 170,000 parts are produced each week with a 7.5% average IV loss—achieving a historical post-mold IV variation of less than 2%. This diligence to monitoring and optimizing IV loss translates into significant cost savings for the OEM.



BIOABSORBABLE FIXATION SCREW

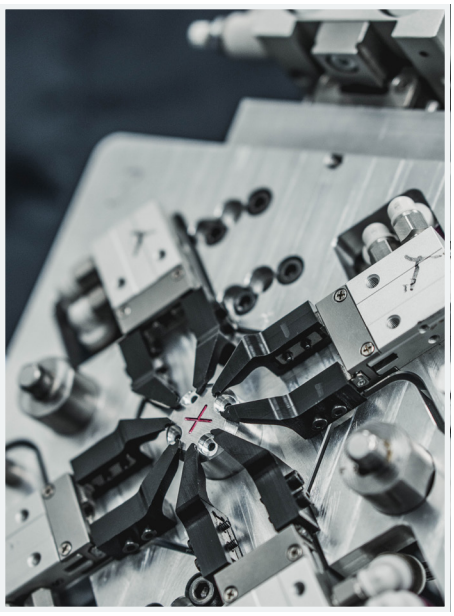
5: Controlled Handling and Packaging

Storage of sensitive bioabsorbable materials and molded inventory in temperature-controlled environments is critical. Temperature should be constantly monitored and logged with alert limits with all manufacturing occurring in environmentally-controlled cleanrooms. Micro molders should also implement specialized shipping procedures to control and monitor temperature for sensitive materials.

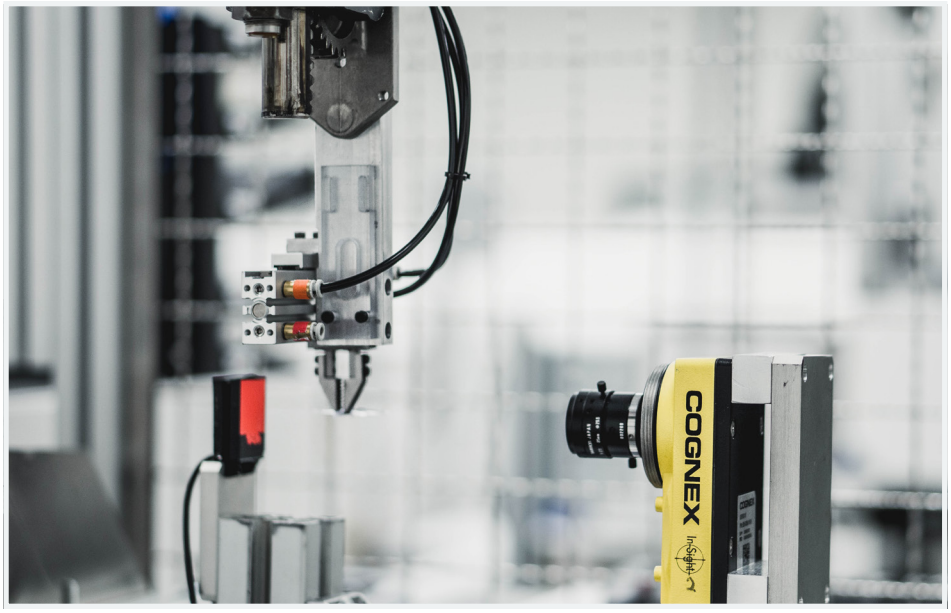
> “To be successful, there needs to be an intimate knowledge of the full manufacturing picture. In-house design is required to keep communication flowing between all departments as tool makers, process engineers, and others all have upfront input that needs to be relayed quickly and concisely during the design phase.”
>
> **– Kyle Kolb, tooling supervisor**

6: Customized, Specialized Equipment

A micro molder should invest in very specialized micromolding equipment to control critical bioabsorbable processing factors such as residence time, shear, and degradation rate of material. This equipment can be further customized and optimized to best serve the needs of medical micromolding.



A custom EOAT.



A standard molding cell at MTD, equipped with custom end-of-arm tooling (EOAT), robotics, in-line camera systems, and automated part collection.

CASE STUDY

Consistency and Control in Bioabsorbable Process Development

An OEM designed an innovative bioabsorbable suture fixation device and worked with a molding partner who said they could manufacture the device.

Over the span of five years, the molder had limited success and could not produce the part represented in the drawing.

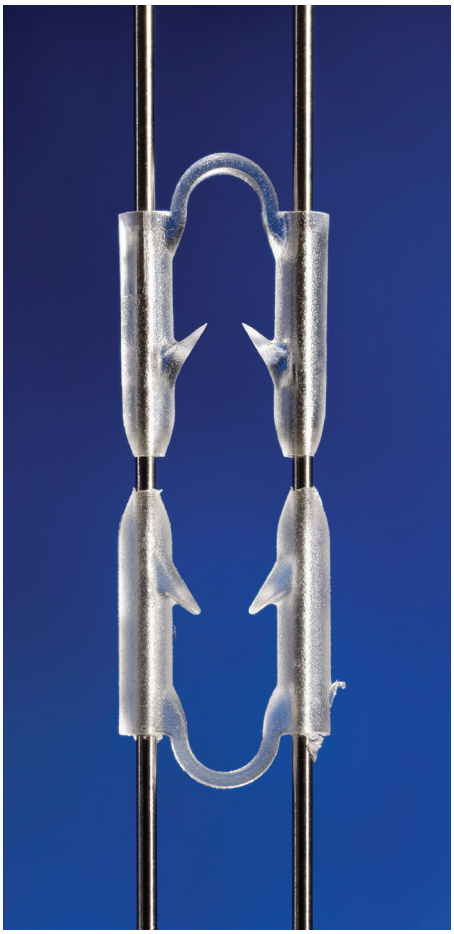
There was 30% IV loss with consistency issues. To assess part functionality, a secondary operation was required to heat and bend the part into the final shape and orientation. This secondary process meant further IV loss and introduced stresses into the product, causing more inconsistency.

With quality being the customer's top priority, they needed to transition to a different path. They reached out to MTD Micro Molding.

The tool design for this part was so complex and challenging that it took approximately two months for MTD to design the mold—much longer than the usual one-week process. Furthermore, typical side action clearance for steel movement is approximately .125" to eject the part out of the mold, but this design allowed for .001". *(See Figure 8 below.)* Creative side action techniques were utilized to accomplish proper part ejection from the tool.

By guiding the customer through material characterization and developing the unique tooling construction concept to reduce secondary operations, parts achieved minimal and consistent IV loss and were much more consistent shot to shot. This confidence in the repeatability of device function allowed reliable testing and successful proof of concept to take place.

FIGURE 8: SIDE CLEARANCE SIZE COMPARISON (10X MAGNIFICATION)



BIOABSORBABLE FASTENER

On the top is MTD's molded PLG part. On the bottom is another molder's attempt.

Tips for Working with Molders for Bioabsorbable Success

- Involve the micro molder as early in the project as possible—including material selection.
- Lean on your expert molder and their knowledge of materials, processing, strategy, techniques, and development requirements to get the best outcome possible in the least amount of time.
- Understand the requirements of the part in terms of consistency. The two things we have found to be most important to our customers with bioresorbable products:
  - **Consistency.** The percentage of IV loss is often less important than achieving consistent IV loss.
  - **Control.** Select a micromolder that has in-house equipment and measurement systems to support the development and validation of the bioabsorbable molding process. It is imperative for a molder to have a means for establishing a baseline and performing internal testing.

ABOUT THE COMPANY

Founded in 1972, **MTD Micro Molding** is your single-source partner for micro medical manufacturing, from material selection to assembly and packaging. With our exclusive focus on the medical market, we offer unparalleled bioabsorbable expertise, breakthrough drug delivery molding capabilities, and advanced overmolding services.

Bring us your most challenging micro medical designs and our team of engineers will get your products to market faster with improved manufacturability.

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

Questions? Contact Lindsay Mann: lmann@mtdmicromolding.com