THE 6 SCIENCES OF MEDICAL MICRO MOLDING:

How to Achieve Better Long-Term Results and Faster Speed to Market

MICROMOLDING

Background

The medical micromolding industry is still fairly young, but is rapidly growing and evolving. Being aware of shifts in trends and changes in technology helps to see where –and how– the next major innovations and breakthroughs will occur.

In the medical device world, it's often the smallest parts that carry the greatest importance relative to the functionality and safety of a medical device. More than ever, embracing the best proven processes and tools for manufacturing is critical to successful product development.

Market Trends

"As diagnostic technology continues to advance, doctors and scientists are able to explore and treat places in the body that were not possible just a few years ago," explains Rick Campo, founder of West-Tech Materials, a company which represents leading manufacturers specializing in the design and engineering of medical products. "As a result, medical devices are now requiring micro manufacturing technologies to produce components and assemblies that allow for the effective treatment and cure of an ever-increasing range of indications. From cameras that can be swallowed in a pill form to micro stents implanted into the eye to cure glaucoma, micro- and nanotechnology will continue to advance the medical device market, resulting in products that will save and improve the quality of patient lives."

35% of thermoplastic micromolded products are for the medical and healthcare market

65% of polymers used for micro injection molding are thermoplastics

According to *Transparency Market Research*, medical and healthcare micro molding has emerged as the leading market within the thermoplastics industry, accounting for 35% of total thermoplastic micromolded products in 2012 — greater than applications for automotive, telecom fiber optics, and micro drive systems. It is also expected to be the fastest growing market for micro injection polymer molding, at an estimated CAGR of 15.2% from 2013 to 2020.

Thermoplastics are the most widely used polymers for micro injection molding and accounted for over 65% of market revenue in 2012, according to *Grand View Research*. Medical and healthcare emerged as the leading application segment for micro injection polymer molding industry and accounted for just over 33% of total revenue in 2012. The same report highlights a couple shifts in trend:

- Replacing polymers containing phthalates such as PVC with thermoplastics coupled with increasing demand for micro materials has prompted the use of micro molding in medical industry.
- Adoption of micro-sized components in the medical industry, due to the increase of minimally invasive surgeries (MIS), is expected to drive micro injection polymer demand for healthcare applications over the next six years.

Industry Trends

The micromolding industry is getting smaller and smaller with tighter and tighter tolerances. Ken, president of KunLun Micro Molding, asserts, "The evolution we are witnessing is that medical devices are being designed to take advantage of new and advancing technologies." Here are just a few recent trends in the micro medical device industry seen by KunLun:

- 3D printing might have an influence as it becomes more refined and able to be used in more applications.
- "Smarter" camera systems and robotics.
- Bioabsorbable materials in molded medical devices.
- Combining micro products with a macro piece as an assembly.
- Injection molding a second material onto a micro part.
- Custom compounded resins and special recipe materials to meet exact needs of applications, including pharmaceutical filled materials
- Larger device manufacturers outsourcing critical manufacturing technologies at the component and assembly level.

Industry Challenges

Because of how new (and expensive) many of the micromolding tools, technologies, and materials are, there are few micro molders who are fully equipped or experienced enough to provide OEMs with the ability to create product breakthroughs. This is because medical micro molding is such a highly specialized field. Methods that conventional molders have relied on for years simply do not apply to medical micro molding.

"With the ever-changing landscape of our healthcare system," Campo notes, "the demands to lower costs are driving the OEMs to put more pressure on their suppliers to come up with ways to lower costs through technical innovation and reduced Cost of Manufacturing (COM).

It has become even more critical for the medical device manufacturer to develop reliable and technologically advanced suppliers that not only allow them to engineer and produce cost-effective solutions, but are able work together and leverage manufacturing know-how to push the boundaries of technology. A true supplier partnership results in the supplier becoming an extension of the medical device company itself. With this type of cooperative relationship, I have seen amazing accomplishments and products developed that have served to save and improve the quality of life of patients throughout the world. In addition, the high cost of getting to market through the FDA requirements is putting even greater demand on maintaining strong manufacturer-supplier partnerships in order to meet stringent, time-dependent clinical validation requirements."

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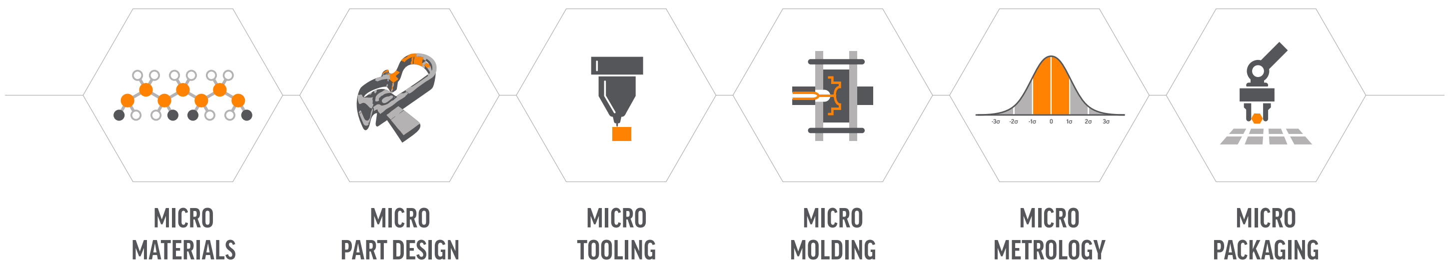
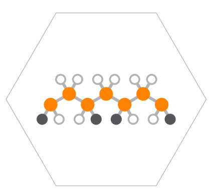


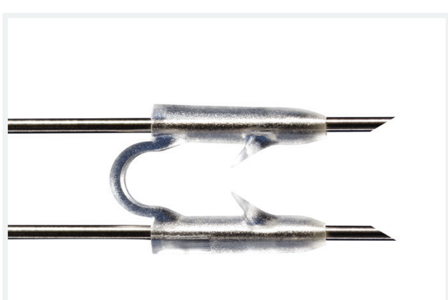
The Six Sciences

Embracing a proven micromolding approach can yield better long-term results, both with part functionality and speed to market. And most importantly, it can solve the problems faced trying to manufacture a micro component with traditional molding techniques. This is why these six sciences have become critical to the success of product development and consistent manufacturability in micro molding.



1: Micro Materials

Select the right materials for the application. Material selection has a direct impact on the outcome of a project. The correct material drives tolerance, dimension, strength, usability, design, speed to market, critical features, and cost. When working with a range of thermoplastic and bioabsorbable materials, it is important to find the most appropriate material to yield the best results for the intended application.



REABSORBABLE SUTURE

This suture device is made of PLG (L-lactide/glycolide copolymer).

The product design has minimal inherent viscosity loss and crisper features, optimizing functionality.

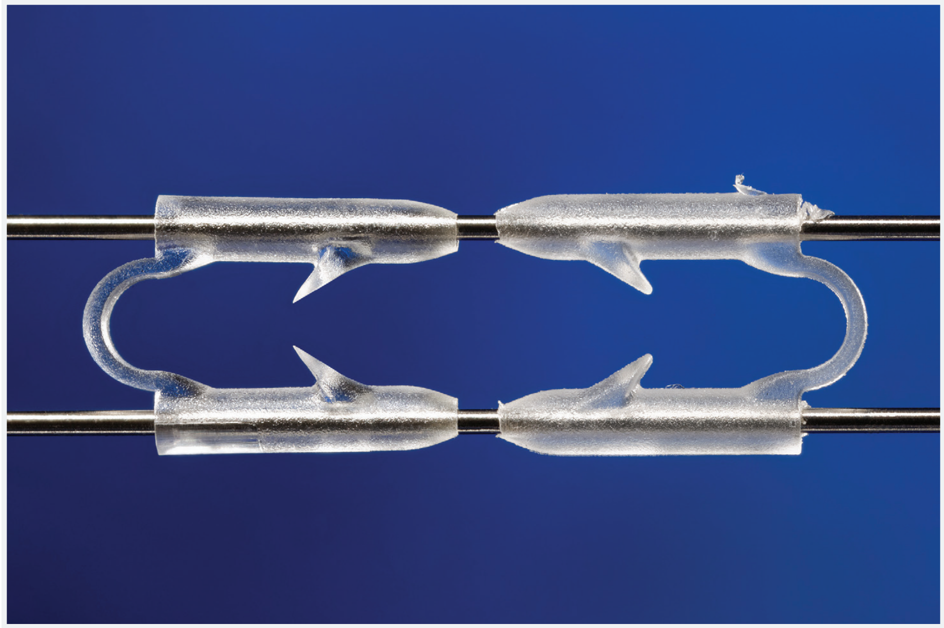
WORKING WITH BIOABSORBABLES

Bioabsorbable materials (also called resorbable or bioresorbable materials) are popular in micro medical applications as the materials can dissolve or absorb into the body. Implantable staples, bioabsorbable micro-screws, tacks, micro-plugs, and medical stents are popular applications.

A successful bioabsorbable micromolding project will meet the following criteria:

- premium part quality from a robust molding process window,
- less invasive devices with increased precision and capability,
- superior post-mold mechanical and functional properties,
- consistent and minimal post-mold IV loss, and
- highly capable critical dimensions.

What's important to keep in mind is that post-mold inherent viscosity (IV) loss is dependent on the micro molder and the material. Even if a micro molder has the equipment to work with a particular material, they may have trouble delivering consistent product with controlled IV loss for each sample run if they are not familiar with the complexities of the material. A micromolding company should have an IV testing machine on-site, so they can determine the impact of processing variables on IV and adjust immediately. This allows the micro molder to optimize molding processes, obtain consistent IV loss, and improve capability.



REABSORBABLE SUTURE

On the left is **Kunlun**'s molded part. On the right is another molder's attempt.

For example, KunLun worked with a customer whose part design was failing with another molder. The failures weren't due to the design, but to the molder's ability to effectively work with the material. Where the competition saw a range of IV loss between 20% and 100%, KunLun averaged a 4% IV loss.

MICRO IMAGING TIP DEVICE

This micro imaging tip device, presented on a gage pin, is made from PC (Polycarbonate).

The device is about one quarter the size of a grain of rice.

WORKING WITH THERMOPLASTICS

Thermoplastics are polymers that become pliable and moldable above a specific temperature, and return to a solid state upon cooling. This property makes thermoplastics an ideal choice for micromolding miniatures like permanent fixation screws and thin-walled micro components.

Know what your part requires out of a material and don't commit to a material for the wrong reasons. Be prepared to evaluate other options for materials based on the mechanical properties you require for your component. Know what you need from your part performance and let your molder guide you on material selection. There might be a less expensive material option that meets your part's needs.

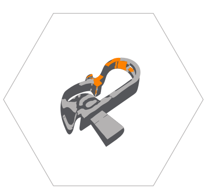
For example, clear advances in micro machining provide a great solution for companies that need a very small quantity of parts, with its quick and straightforward manufacturing process. But once a company is ready to ramp up their volumes to thousands, the likely transition is moving to injection micro molding.

Many customers enter the injection molding process with a part they feel is "stuck" in a certain material, due to the machining success they had with it. After having invested time and resources, it's easy to understand the reluctance to start over, but it can become a more costly decision to not reconsider the best material at this stage. Polyetheretherketone (PEEK) is a common material example for this, because its high melt temperature makes it one of the easiest materials to machine. PEEK is also a popular choice for its strength properties, chemical resistance, and ability to hold up to sterilization. The problem? PEEK is one of the hardest to injection mold.

Although successful micro molding with PEEK is possible and yields a much more homogenous product than machining, the medical grade PEEK required for injection molding is very expensive (compared to the formed rods and sheets commonly used in machining) and its high melt temperature makes for extremely difficult processing conditions. Polypropylene (PP) is a material that has proven to be a great alternative to PEEK for many micromolding applications. It is inert, has great flow, is far less expensive to purchase and process, and can be a viable material consideration, if in the early stages of a project. *(See Figure 1.)*

FIGURE 1: Material comparison

MATERIAL	MICRO MOLDING EASE (1=HARD, 5=EASY)	COST ($–$$$$)	NOTES
PEEK (Polyetheretherketone)	2	$$$$	Easy to get black specs, quick degradation, extensive and rigorous flowpath clean required, high temperature molding.
PP (Polypropylene)	5	$	Does not have to be dried prior to molding, great flow.

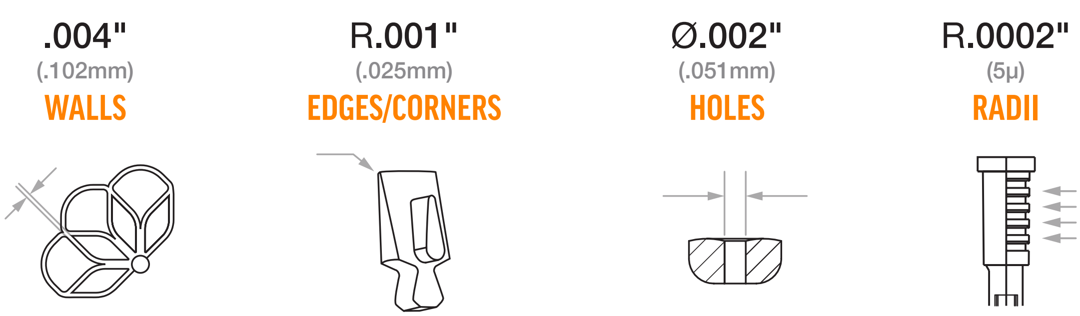


2: Micro Part Design

What micro part design is feasible? Understanding what can be created in steel versus what can be manufactured in production volume is the key to being successful. In addition to a part's reproducibility, consider the required features:

- Does the design have wall stocks in the range of .002" to .004"? *(See Figure 2 below.)*
- Does it have aspect ratios in the range of 250:1?
- Is the part weight so low that 520 parts could be made from a single pellet of plastic?

FIGURE 2: Micro features



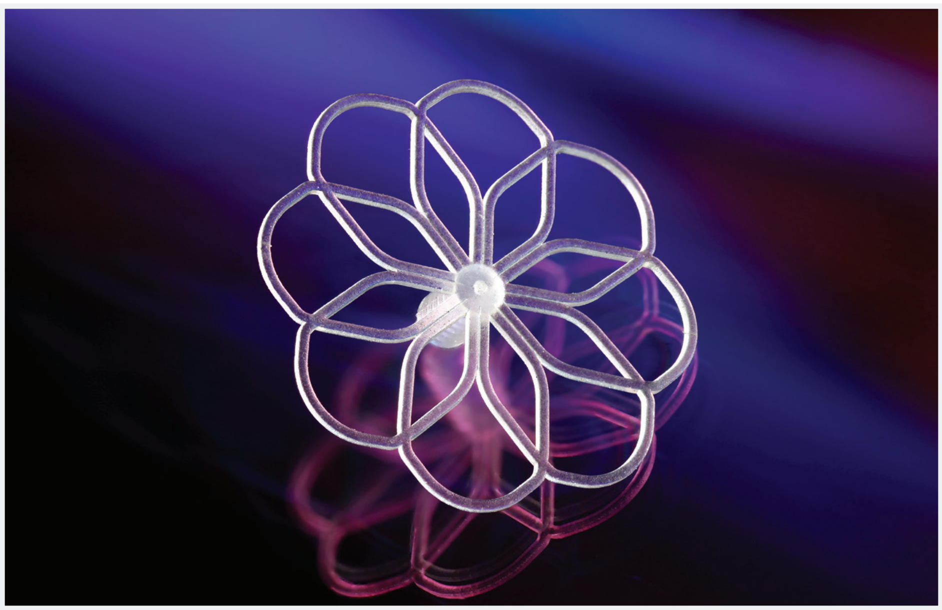
Each of the micro design features are accomplished by micro molding and are generally recognized by the industry as features that require highly specialized tools to be possible. One of the greatest myths in the medical device industry is that a part needs to be microscopic to be considered a micro part — this is not the case.

In many instances, the micro features on a part that are seen with the naked eye require more specialized tools and techniques than what's required to create a microscopic part with simple geometry. Some of the most difficult parts to manufacture are larger parts with micro features. Three micro technology tools are available to optimize micro part design:

MicroFill – Determine the material's sheer sensitivity by using a spiral mold at selected melt temperature.

MicroFlow – Determine realistic wall thicknesses for certain materials by running multiple injection velocities while measuring flow length at various thicknesses.

MicroRunner – Determine minimum runner size required to fill the volume of your part, with the goal of sizing a runner system to adequately mold a product without unnecessarily sacrificing material. This tool is particularly important when working with expensive materials.



MICROMOLDED CARDIO SURGICAL CATHETER TIPPED ABLATION HEAD

This "flower" design demonstrates the need for MicroFlow and MicroFill technology. Molded in an experimental shape-memory material, the part is approximately 0.300" (7.62mm) in diameter with .009" (0.23mm) wide webbing. This 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 micro technology tools.

These technologies, coupled with extreme material conditioning control, allow conventional micro runner systems to produce 10,000 shots per pound of material. If there is a struggle to maintain consistency, the importance of controlling said factors may not be understood or practiced by the micro molder.

3: Micro Tooling

A successful micromolded component starts with an exact mold. Advanced workpiece accuracy target should near 42 millionths of an inch (.000042"). At MTD, workpiece accuracy is defined as what the actual molded part looks like when it comes out of the machine, not what the machine itself is designed to do. The medical device OEM and

Ultra-precision micro inserts are the result of exact tooling execution.

Sarix 3D EDM milling technology in action.KunLun has the Sarix machine in factory being utilized for creating micro mold inserts.

molding partner might share the same plan going in, but exact execution makes all of the difference.

3D EDM milling machines are unique pieces of tooling equipment that enable extremely detailed cavity geometry in micro molding by following a tool path similar to CNC milling, but the major difference is that the end mill is actually an electrode that can be as small as 5 microns.

FIGURE 3:

4. Micro Molding

Advanced medical micromodling and conventional molding are very different. *(See Figure 4 on next page.)*

Once the mold is built, it is important to perform installation qualification on the technologically advanced micromolding cell. It is vital to ensure that the mold is functioning properly when mounted into the press.

Dependable and accurate equipment is essential when working with such small numbers. The plunger resolution of a micromolding machine can be compared to a

FIGURE 4: Molding Comparison

ADVANCED MEDICAL MICRO MOLDING

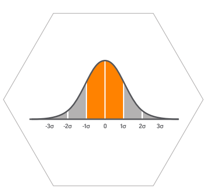
- Optimized runner systems
- [Unrecoverable] minimal material waste, by volume
- Violent molding process (fast, high temp, high shear rates)
- Tight/stringent process windows
- Macromolding guidelines do not apply
- Without EOAT, robots, and cameras, there is a high risk of mold and cell damage
- Tightly married tooling and molding processes – key to success
- Cold runner systems more common
- No material regrind option
- Good fit for Engineering/Exotic/Bioabsorbable materials
- Highly complex detail achievable

CONVENTIONAL MOLDING

- Long/larger runners
- Increased material waste
- Less-violent molding process
- More latitude in process window development
- Macromolding guidelines do apply
- Robotic part removal does not always add value
- Less shear sensitivity
- Hot runner systems more common
- Material regrind is common
- Bad fit for Engineering/Exotic/Bioabsorbable materials – normal material waste too expensive to justify
- Highly complex detail not achievable

human hair: 25% of the diameter of a human hair on position is the difference between a full shot, a short shot, or a flashed shot.

By implementing in-line inspection systems, micro molders can verify the absence or presence of details down to .0001", providing peace of mind that every part is 100% correct. Other lines of defense include process monitoring and control systems for plastic injection molding applications, which will speed up the visual inspection process and can tighten the window on how a cavity is packed, sort good from bad, and predict dimensions.



5. Micro Metrology

Although each micro-manufacturing cell is considered autonomous, quality assurance techniques must be depended on in micro molding, which come in the form of micro metrology and testing. Because of the typical part size and tight tolerances of medical micro parts, it is important that a molder's processes and tools focus on perfecting the measurement system early on in a project. Custom measurement fixtures and non-contact, optical vision systems should be created and validated for each part. Measurement systems should be validated for inspecting all critical dimensions with a passing gage repeatability and reproducibility (Gage R&R), ensuring that the data is valid and captured with accuracy.

Goals of Gage R&R:

- establish a measurement system that is capable of detecting dimensional defects
- provide evidence that multiple operators can use the measurement system interchangeably

- establish confidence internally and externally in the data collected and used in reporting process capability

At KunLun, we achieve .001–.002" tolerances every day. But passing a GRR with these tolerances can be extremely difficult. The chances of passing a GRR decreases considerably as the tolerance minimizes. For example, for a ±0.001" tolerance, with optimal gage variability (r bar=.0001) and operator variability (x bar=.0001) assumed, the best case expected Total R&R% outcome is 23.7%, which we accept with close monitoring of the dimension. *(See Figure 5.)*

FIGURE 5: Total Gage R&R ±0.001 tolerance

GAGE RANGE	OPERATOR RANGE 0.0001	0.00015	0.0002	0.00025	0.0003	0.00035
0.0001	23.70%	29.49%	36.07%	43.08%	50.33%	57.75%
0.00015	30.91%	35.55%	41.17%	47.43%	54.10%	61.06%
0.0002	38.82%	42.60%	47.39%	52.92%	58.98%	65.42%
0.00025	47.07%	50.24%	54.36%	59.24%	64.71%	70.63%
0.0003	55.52%	58.23%	61.82%	66.15%	71.09%	76.52%

<10% World Class Gage

10–20% Accept

>20–30% Accept with Close Monitoring

>30% Quarantined for Measurement & Inspection

Even with an extremely accurate gage, operators, and methods, passing a Gage R&R (<=30%) for a dimension with a tolerance of ±0.001 is extremely difficult.

The chance for a World Class <10% Total R&R outcome is nearly impossible with the extremely small tolerances that we work with daily. This further underlines the need for a reliable fixture, well-trained operators, and a robust inspection program.

One key point to remember is that the goal of a Gage R&R is not to determine if the part is within specification. It tells if a measurement system can accurately and consistently measure your parts.

For example, KunLun's Product Realization methodology resembles what you would normally find in the industry, following a standard IQ/OQ/PQ (Installation/Operational/ Performance Qualifications). But because of the typical part size and tight tolerances, we have adapted our processes and tools to focus on perfecting the measurement system early on in your project.

Along with dimensional testing, various other tests may be required to meet a part's desired specification to provide evidence of successful form, fit, and function. Our in-house testing includes:

CHEMICAL: Inherent Viscosity

THERMAL: Differential Scanning Calorimetry, Melt Flow Index, Moisture Content Analysis

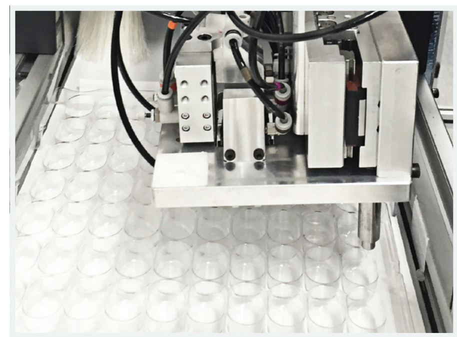
MECHANICAL: Tensile Test, Ultimate Elongation, Custom Failure Testing

6. Micro Packaging

Handling, assembling, or packaging micro-sized parts is far more challenging and the solutions far different, than producing macro-sized parts. Every machine should have a custom end-of-arm tool made specifically for each molded part. That way, parts are always handled and packaged with extreme care and precision, and no parts are simply ejected into a bin.

LEFT: Looking at the variety of shapes and sizes of micro-sized parts, it's easy to see why custom solutions are necessary for packaging.

RIGHT: An end-of-arm tool is ready to carefully place parts into clear wells for packaging – all within a certified cleanroom environment.



Steps to Successful R&D and Product Launch

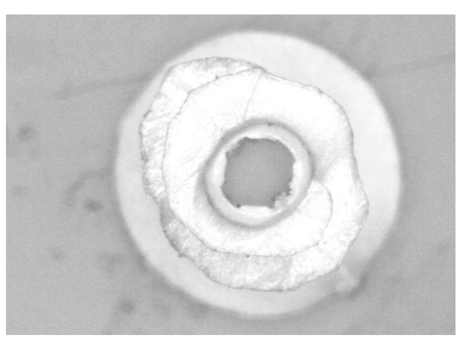
One OEM wanted to create a bioabsorbable part. The way they approached the challenge was sensible. Before they invested in molding a bioabsorbable material, they wanted to find a reasonable thermoplastic "surrogate material" that could tell them whether or not they could have a likelihood for success with bioabsorbable. The surrogate material was identified as polycarbonate and when they built the mold and tried to run product, the initial molder could not fill the part.

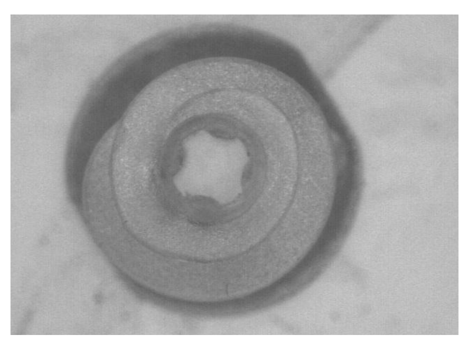
The next step for the molder was trying a host of other materials. Perhaps polycarbonate was not the best material choice. The results proved that the molder could not fill the part in *any* material. After six months of trying different materials, the closest they got was using a high-flow acrylic, which is pictured below on the left.

DIFFERENT APPROACHES TO THE SAME DESIGN

On the left is a molder's best attempt to produce the part.

On the right is KunLun's solution.





BIOABSORABLE TACK

The OEM eventually came to KunLun and after we analyzed the tacks from the other vendor, it was clear the first vendor approached the mold construction like a macro part. This resulted in gas traps throughout. With KunLun's MicroFill technology (as explained earlier) and understanding of materials, we knew we had to build the mold differently.

Weeks later, our first shots looked exactly like the drawing.

Fast forward to today where we are in full production mode, producing over 170,000 parts per week with a 7.5% average IV loss. We have been able to pass down a cost savings of 38% to the customer over four years.

The path we encourage our clients to take when they are starting a challenging R&D project is to always start at proof of concept and scale the program using the following steps:

STEP 1 **Prove** the design is viable.

STEP 2 **Create** a prototype mold that can sustain early production.

STEP 3 **Maximize** cavitation based on what you learn from that prototype tool.

STEP 4 **Build** production cavities at maximum cavitation to reduce cost and consider multiple molds to achieve your volume requirement.