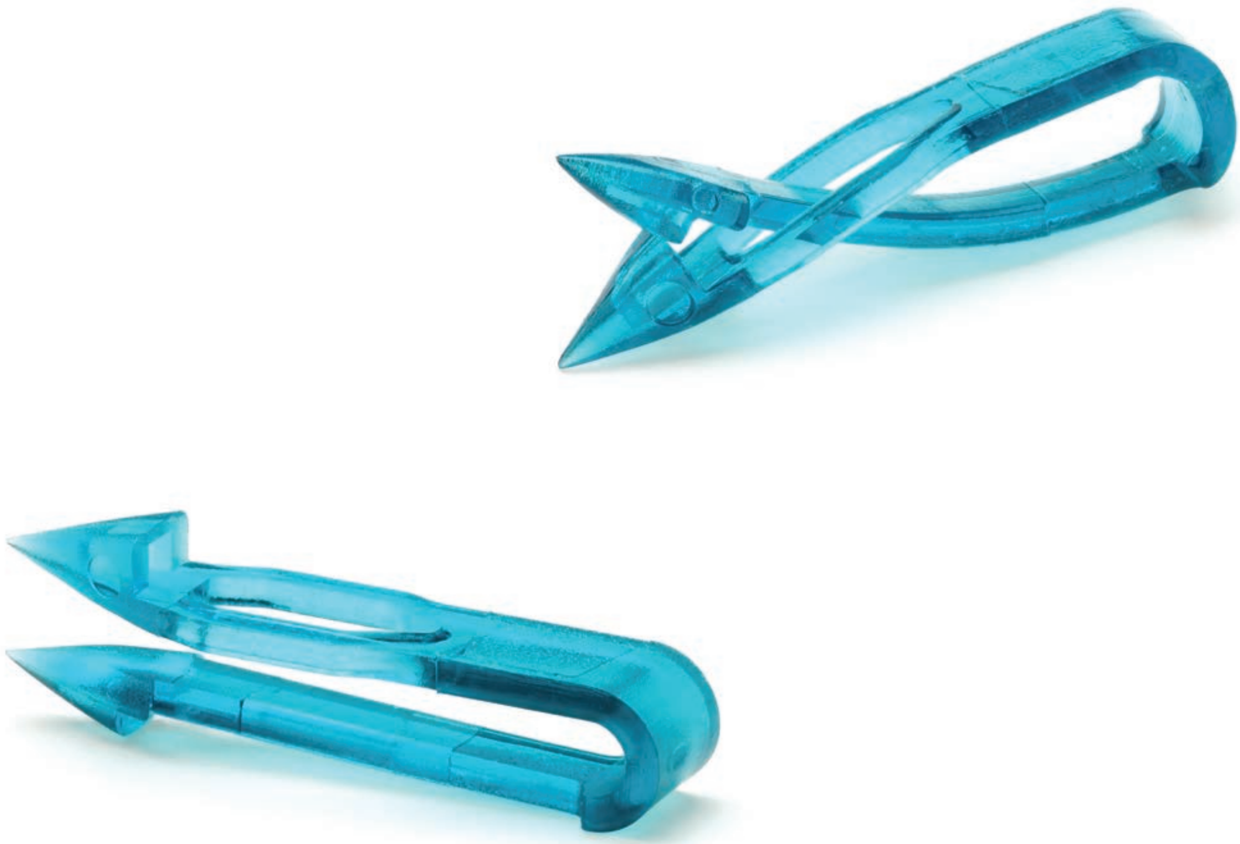
DESIGN FOR MANUFACTURING BREAKTHROUGHS:

Producing Innovative Micro Medical Devices



Finding Your Micro Medical Breakthrough Idea

Everyone wants to be innovative, to find the next big idea in their field. Innovation doesn't strike like a lightning bolt out of the blue. It takes collaboration and a deliberate search process. In *Stand Out,* a book about finding your breakthrough idea and becoming known as an expert, author Dorie Clark recommends asking yourself the following questions:

- What are others overlooking?
- What are the assumptions underlying your field? Have they been questioned or tested? If so, how long ago–and have circumstances changed in the interim?
- What questions do "newbies" in your field often ask that get shot down or dismissed? Is there a way you could take their questions seriously? What would that look like?
- What's the conventional wisdom about how to do things "the right way" in your field? What if it were actually the opposite? What would that look like?
- What do most people in your field think would be impossible? Is it really? Or is it just difficult?
- What research project or initiative would–if you successfully undertook it–change how your field operates?

For questions more specific to the micro medical industry, KunLun recommends asking:

- How can a material be used in a new, unexpected way?
- How could a medical device benefit from miniaturization?
- How could design changes improve manufacturing cost?
- What device only operates as "good enough"? Where are the opportunities for increased functionality?
- Where have there been too many compromises waiting to be resolved?
- What new advancements in other areas could be applied to or combined with a micro medical component?
- How has a new micro molding technology opened a new opportunity?

> **"Innovation is the practical exploitation of any novel idea. Novel ideas can be inventions in the strict definition of the term, which means they didn't exist before, but most often they're not. Instead, they're based on taking an idea that's been developed somewhere else – or combining a number of existing ideas – and introducing them to a market that hasn't seen those combinations before."**
>
> **– Andrew Hargadon, author**

Material Breakthroughs

POPULAR CHOICES

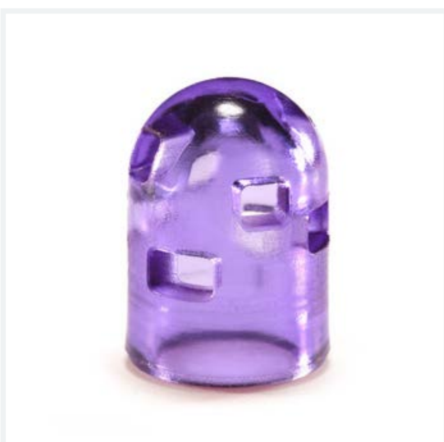
Many OEMs start with PEEK as their material for creating new medical devices. It's a popular choice because of the implant data that accompanies it. It is also one of the easiest materials to machine, which makes it convenient for their prototyping phase. The problem with PEEK occurs when higher production volumes justify moving into the injection molding process for significant cost savings. The benefit is that micro injection molding takes a fraction of the time to mold components and uses less costly materials in comparison to micromachining. The problem is that micro injection molding with PEEK can be challenging, placing further stress on timing and budget.

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

Instead, consider materials that may be unfamiliar, out of your comfort zone, or even beyond your initial wishlist. There are benefits to not choosing a material based on its popularity. If you rank your wants and requirements by order of importance for your design and present them to your molding partner and material suppliers,you may find that other materials may be better options.

What attribute is most important for your design?

- **Chemical resistance?** Consider using a material from the Olefin family, such as Polypropylene (PP).
- **Strength or rigidity?** Consider Liquid Crystal Polymer (LCP).
- **Implant biostability data?** Consider other polymers that provide this documentation, such as Polyurethane alloys and Polysulfone (PSU).



DRUG ELUTING IMPLANT

For this drug eluting implant, the micromolded housing is resorbable. The device serves as an innovative alternative to repeat surgeries and routine medical management for patients with a common disease.

NEW CHOICES

The development of bioabsorbable products is evolving quickly. These novel polymers provide new opportunities to implantable components and devices to expand how and where they are used in the human body. The days of only having one or two bioresorbable polymer selections are a thing of the past.

Advancements in drug delivery components are transforming the medical market by making drug delivery devices more convenient, painless, and effective for patients.

The advantages of micromolding drug delivery components include:

- Improved dimensional stability
- Sharply reduced production costs
- Elimination of timely, costly, and inaccurate assembly steps

As the marketplace for point-of-care (POC) drug delivery expands, so does the need for producing designs that previously have not been possible, like cannulas with extremely thin walls, ultra-precise drug delivery components, and bioabsorbable pharmaceutical delivery devices. These device companies are thinking outside the box while solving patients' problems, creating a new platform for pharmaceutical companies to deliver drugs to the masses with ease.

Miniaturization Breakthroughs

As less invasive procedures and technology-driven advancements become more prevalent, the demand increases for smaller yet more effective and powerful medical components that benefit patients and the medical profession alike.

What's driving medical product miniaturization?

- **Pediatric applications** requiring smaller versions of the adult versions
- **Point-of-care technologies** for patient care and comfort, such as wearable devices to manage chronic pain (ex. at-home dialysis, wearable bolus injectors).
- **Minimally invasive surgeries** (vs. larger-scale surgical operations), such as laparoscopic or endoscopic procedures
- **Office-based outpatient surgical procedures** (vs. hospital-based services)
- **Pairing with medtech advancements**, such as optical imaging, robotics, and computer processing

Cost Breakthroughs

Sometimes, OEMs can achieve the biggest cost breakthroughs by switching from a traditional manufacturing method to micromolding. For example, cannulas were once difficult to produce through micro injection molding. With advancements in technology, cannulas are now possible – opening up new possibilities in manufacturing micro medical devices. Figure 1 below provides an example of a significant cost breakthrough in switching from a traditional manufacturing process to micro injection molding.

Reducing or refining the overall geometry is a more obvious way to reduce manufacturing costs. For a micro part design, the molder can point out costly areas

FIGURE 1: Innovative approach to a cannula device

ORIGINAL COST PER DEVICE
$1.50
PLUS ASSEMBLY COSTS

NEW COST PER DEVICE
$0.75
NO ASSEMBLY COSTS

An injectable drug delivery systems company was struggling with the traditional extrusion methods for its drug delivery device. The process included a series of high-risk, cumbersome steps to manually assemble four micro components to combine the cannula and housing. These steps were costly, requiring an entire room of people assembling components at one time.

KunLun worked with the company to define a possible solution: micromolding all the components together at once. This eliminated three assembly steps (which had been assumed to be required as the industry norm) and created huge cost savings for the customer. The geometry-rich cannula was micromolded at $0.75 a unit, in contrast with making four separate components at a cost of over $1.50 for the set—excluding assembly costs. While assembly steps largely contributed to the main failure mode in the final device, molding the device as a single unit removed all possibilities for functional failures.

on a drawing to help facilitate a conversation about what changes can reduce manufacturing and piece part costs immediately or long-term.

Basic changes on a drawing can usually result in a 5-10% overall cost reduction. Examples of small changes include changing a wall thickness, radius, draft, or small feature in order to make the design less difficult and costly to manufacture.

Along with design refinements, allow your molder to help reduce costs by assisting in the process of material selection, creating a customized plan for achieving validated production, and offering solutions for minimizing material waste with tools like runner optimization.

Product teams are cautioned to not approach a molder with the following request for their critical part design: “Can you redesign my part to reduce cost by x%?” While this type of request will typically result in a revised quote, the molded product likely won’t resemble the intended design. The molder or manufacturer does not look at your design in the same lens as you do; they are assessing it from the manufacturability point of view. Your molder doesn’t have a comprehensive understanding of how this product is designed to perform, how it should function, or how it needs to mate and/or interact with other components in a device.

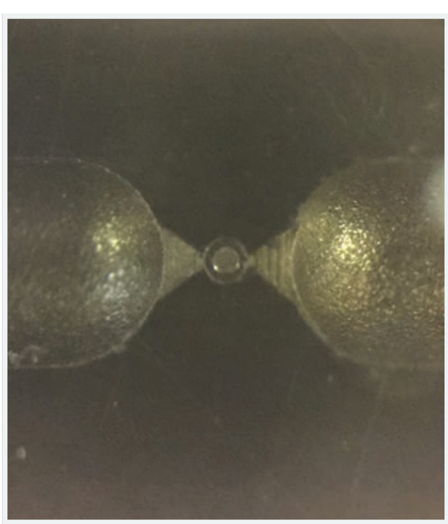
Technology Breakthroughs

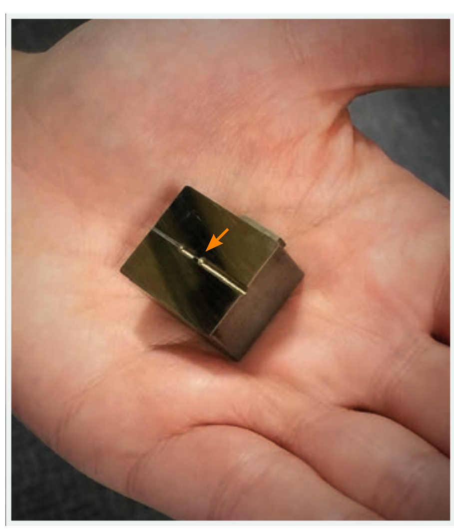
Advancements in technology and equipment often allow major breakthroughs for the most innovative medical device products.

Consider the “smallest part in the world” — the donut-shaped part pictured below (left) under 100X magnification. Even at 100X, the part is hardly visible. When looking at the one-cavity mold (center), the small dot between the lines is the area that creates the part geometry.

From late 2010 to 2012, MTD successfully molded this EVA ophthalmic implant, weighing in at 0.00000313 grams with a gate measuring .0018" x .0008".

Advanced micro EDM technology was needed to precisely mold such a tiny part. MTD had recently brought this capability in-house in 2009 when we invested in a Sarix 3D micro EDM milling machine (right). In fact, we were the first mold-making manufacturer in North America with this technology, and still one of only a few. Without this advanced





in-house equipment and expertise, this ophthalmic micro medical breakthrough would not have been possible.

If you are struggling with making a breakthrough device, you may need to look further than your existing supplier base. The solution for your innovative micro design may not be on your AVL list. Keeping up to speed on new technologies and developing relationships with the leading-edge micro manufacturers will allow you to have a complete list of capable suppliers in the industry.

> "If you always do what you've always done, you will always get what you've always got."

Production Breakthroughs

Nothing is more frustrating for micro part designers than to spend countless hours on a new drawing, only to get to the manufacturing phase and find out they need to make significant revisions or compromises.

PROTOTYPE VS. PRODUCTION

Understanding what can be created in the prototype phase (often steel) versus what can be manufactured in production volume is one key to being successful. Lean on your supplier to understand why machined prototype parts perform differently than the injection molded versions.

With scalability being the ultimate goal, be sure to engage your production vendor during (or before) the prototyping phase to allow for seamless transition from prototyping to production.

DESIGN FOR MANUFACTURABILITY

Through design for manufacturability (DFM), your supplier's engineers should offer design assistance to improve manufacturability of your product. This critical process will determine what is possible and scalable.

Most compromises that are made with a micro part design are with dimensions and tolerances that suppliers do not believe to be possible or manufacturable. Finding a molding partner who can vastly reduce or eliminate design compromises is the key to bringing a part to life as it was originally designed.

How can you improve the production process?

- Eliminating timely, costly secondary operations.
- Eliminating quality issues that require sorting and result in high fall-out rates
- Improving functionality of the device, such as building in flexibility to a once-always rigid part to support proper healing.
- Choosing a supplier with expertise in a very specialized materials, such as bioabsorbable resins.

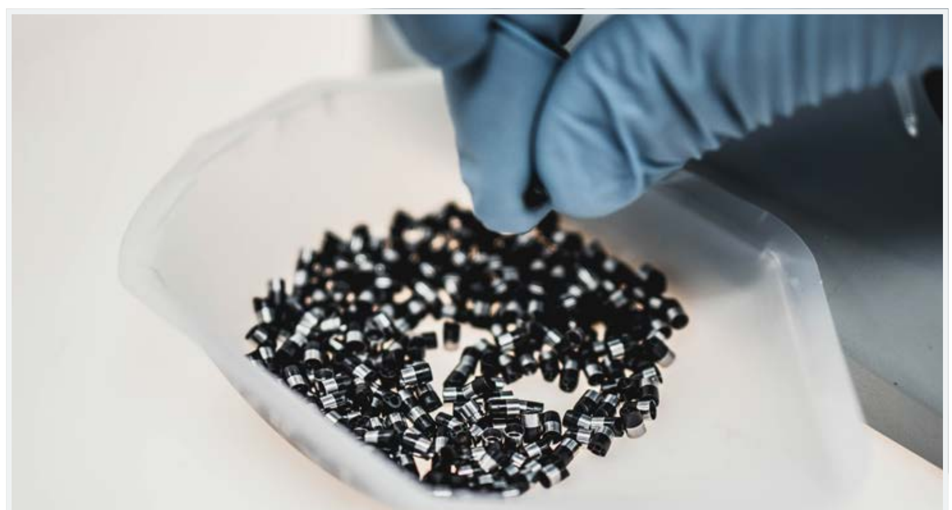
- Offering a solution to manual assembly. Precision overmolding (below) can be a consistent solution, eliminating the quality issues, need for gluing, assembling, and part inconsistencies.

Resolution of detail or quality issues can negatively affect the assembly process, expectations of function, and use of the part. When these are compromised, the device doesn't function as designed and can push designers back to drawing board or push an inferior product into the marketplace.

PART'S MODEL GEOMETRY

You don't have to compromise on your design. While many suppliers will only quote to produce 70–75% of a part's model geometry, MTD quotes to produce more than 95% of a part's model geometry without exception. It's possible, with the right equipment, expertise, and experience.

The catheter tip is comprised of a stainless steel insert overmolded with Ultem.



The tip design required extreme micro tooling precision to accomplish the tiny through-holes required for this application. Extremely thin walls in this overmolded tip design measuring .005" at the overmolded section of the metal ring and features +/- .001" tolerances throughout were enabled by micro injection molding technology.

Producing Your Micro Medical Breakthrough

> **"…I found that the most innovative firms aren't necessarily any more creative or even better at solving problems than most. Rather, what set them apart was how they aggressively sought out new problems to solve. The truth is that if you want to create a truly innovative culture, it isn't ideas you should glorify, but problems."**
>
> **– Greg Satell, author of *Mapping Innovation***

How do you overcome roadblocks?

When trying to produce an innovative micro medical design, you may come to a roadblock. What can you do to move forward and get the project back on track? First, determine the source of the problem. Is your supplier having problems? Is there an issue with your design? Figure 2 below provides some common warning signs.

FIGURE 2: Common signs of where a project is failing

YOUR SUPPLIER MAY BE FAILING

- Failing validation
- Not achieving lot-to-lot consistency
- Told your design is "impossible"
- Asked to make numerous design compromises
- Lack of communication
- Same issues cropping up
- Time between communication is getting longer and longer
- Feeling you know more than your vendor
- Lead times between samples getting longer – showing disinterest

YOUR DESIGN MAY BE FAILING

- Notes on the drawing (ex: "no flash")
- Specifications
- Material selection
- Polymer issues
- Aesthetic or crystallinity issues
- Can only run part with a one-point molding process

INTERDEPARTMENTAL COLLABORATION

When kunlun is working on producing a breakthrough medical device design, it's all hands on deck. Engineering, tooling, molding, quality management, project management, and process development departments team up under the same roof to engineer a process that allows for successful manufacturing of complex micromolded medical components.

OVERCOMING SUPPLIER ROADBLOCKS

If your supplier is failing, it's time to ask the tough questions. Is it truly feasible for your supplier get your product back on track, or will you spend months or years without making progress? Even though you've invested time and money with your current supplier, sometimes the best strategy to get your product to market faster is to find a new supplier who is better equipped to address your product's specific needs and challenges. While it seems like a major expense to change suppliers, it will likely save you money in the long run if your product gets to market faster and efficiently.

Sometimes the molder simply doesn't have the specialized medical micro molding equipment needed to produce a particular design. Sometimes they don't have experience or expertise in working with a certain material or challenging design. Other times, a supplier may excel at low volume or on-demand production, but cannot efficiently ramp up production.

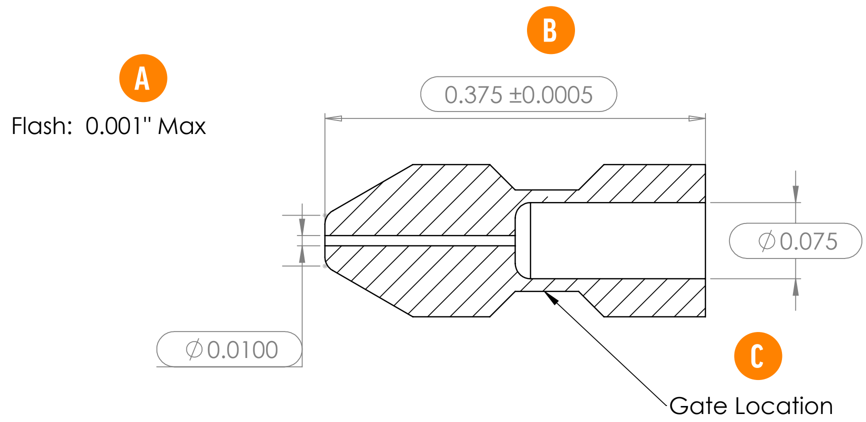
What does it cost to not do it right the first time? We worked with one of our customers to calculate what it actually cost their company to have their project rescued from a failing supplier. This OEM had developed a concept for a bioabsorbable fixation device that generated excitement and positive comments from reviewing surgeons. Although the company worked with a reputable molder, after five years of labor, the molder had limited success and could not produce the part represented in its drawing with sufficient quality.

After the five years, the OEM decided to cut its losses and start fresh with a different molder. When the OEM tallied its losses, the results were staggering.

Factoring in an estimated one-year delayed market entry, the loss of potential product sales, the time unnecessarily spent in process development, and the cost of restarting their project with a new molder, the sum came to about $1.5 million.

> "If you don't have time to do it right, when will you have time to do it over?"
>
> **– John Wooden**

FIGURE 3: Common design roadblocks



OVERCOMING DESIGN ROADBLOCKS

Are you requesting “no flash” (Figure 3, A)? Requiring extremely tight or challenging tolerances (B)? Assigning a challenging gate location (C)? If so, you may be causing your supplier to chase their tail to solve the problem – or you may be incurring a huge increase to budget and lead time. Is it worth it? Sometimes simple drawing concessions can help.

Inadequate material choice frequently leads to manufacturing issues. There are polymers that demonstrate high compressibility, poor fill properties, poor long term dimensional stability. Tight tolerances like +/- .001" may be difficult to achieve with these materials. Your design and drawing will dictate what materials can be used.

If you’re tackling design roadblocks, talk to your supplier. They should be able to guide you on better material choice or simple design concessions that will help meet the goals of your part’s functionality.

How can you determine what’s completely unrealistic vs. pushing boundaries?

Engage early. Get a clear understanding of whether your design can translate to injection molding by engaging your molder as soon as possible – and if it can’t, understand why not.

Push the boundaries. Go to industry experts to understand what elements of your design are realistically possible and what boundaries can be pushed. When requesting quotes for a micromolding project, ask molders to show similar examples of parts they have created that are similar to your design.

Go with the “true positive.” A molder that is open with concerns and can present options for manufacturing success should be more comforting than a molder with zero concerns or interest in drawing optimization.

Don’t make assumptions. Bring your grand ideas to your molding partner and discuss your wishlist for your design(s). If you allow the molder to evaluate what is possible and realistic as a long-term molding solution, they can listen to your expectations and provide substantive feedback.

How can you efficiently work with a molder to produce your breakthrough idea?

Consult early. Consult your molder early in the development process and, if possible, be open to some flexibility in material, dimensions, and timing in order to increase speed to market.

Come prepared. Know what you need for your part with a high level of understanding about the product's requirements. Express areas of the design you feel are challenging and/or have concerns about to your molder. You understand the limits of your design and the edges of success and failure. This information allows the supplier to assess how they can help from the most productive angle.

Be mindful. Extremely difficult geometries typically require some kind of unconventional approach to the project in order to be successful. Having an understanding of the technology, experience, and knowledge required to create these complex geometries in plastic will help you save you time in your supplier qualification process.