Micro Molding: Reduce the Cost to Manufacture a Medical Device

John Whynott, Technical Product Manager, Mikrotech, LLC

On January 1, 2013, a new 2.3% tax went into effect on the sale price of medical devices. As companies look for ways to offset the cost of the medical device tax, they should consider the use of new technologies to reduce the cost of manufacturing medical devices used in minimally invasive surgery (MIS).

MIS designers and manufacturers have difficulty creating and maintaining reliable manufacturing processes as many devices 1) use expensive machined components; 2) require highly skilled labor (artisans) using a microscope; and 3) require complex secondary operations to assemble them. These methods of manufacturing place limitations on size, complexity, material selection, production yields, and profitability.

Micro molding can provide an excellent alternative for designing and manufacturing medical devices used in minimally invasive surgery. Micro manufacturing processes overcome the limitations of established technologies, facilitating smaller components, incorporating complex features, reducing the number of components, eliminating outdated processes, reducing manufacturing costs, and increasing production yields.

No.	Criteria
1.	Expensive machined components
2.	Dependency on microscope for assembly
3.	Secondary operations - bonding and welding
4.	Poor lot-to-lot consistency
5.	Poor production yields
6.	Long manufacturing cycles
7.	Complicated geometry

The key to success is utilizing best-in-class plastic micro molding equipment with twice the precision and repeatability as conventional equipment. It enables suppliers to achieve tolerance targets on complex products that conventional equipment cannot maintain and streamline the manufacturing process to create a more robust and reliable design for manufacturing.

Optimal Conversion Criteria

What type of component or subassembly makes a good fit? Table 1 identifies seven variables that make a component or subassembly a good candidate for conversion to micro molding.

Weighing the Costs and Benefits

So how does one justify moving to a different manufacturing process? A widely used method is performing a cost and capital investment analysis using NPV (net present value) or NPW (net present worth) comparisons.

	Tube
EAU	15,000
Machined cost (Stainless steel)	$20.00
Micro molded cost (Pebax®)	$2.50
Annual savings	**$262,500**
Tooling cost	$25,000
Revalidation cost (est.)	$30,000
5 Year NPV	**$940,081**
IRR	**10%**

Table 2 illustrates an example of a cost savings project. The subassembly is part of a medical device used for a cardiology procedure and is currently in production. The customer approached Mikrotech [1] looking for a way to manufacture a subassembly in a more cost-effective manner. The subassembly consisted of a machined 0.007" wall by 0.500" long stainless steel tube and an extruded 0.215" O.D. Pebax tube.

Attaching the two required a pre-treatment, primer, and adhesive to bond them together.

Mikrotech converted the machined stainless steel tube to micro molding utilizing a Pebax polymer similar to the extruded tube. Utilizing similar materials in the subassembly eliminated the pre-treatment and the primer steps utilized for the stainless steel tube.

The NPV was based on a minimum five year life expectancy and a required internal rate of return of 10%. The project had an immediate outlay of $25,000 for mold and inspection tooling and an estimated cost of $30,000 for product revalidation and regulatory approval. Cash inflows (savings) were expected to be $262,500 for years one through five.

With a discount rate of 10% and a span of five years, the projected cash flows are worth $995,081 today, which is greater than the initial $55,000 investment in tooling and revalidation. The resulting positive NPV of the project is $940,081 ($995,081 minus $55,000), which indicates that the above project should be pursued.

No.	Steps	Questions
1.	Identify conversion candidates	Machined components? Microscopic assembly? Welding/bonding? Poor lot consistency? Poor production yields? Long mfg. cycles? Complicated geometry?
2.	Evaluate material alternatives	Functional requirements? Material certification? Single-use device? Contact w/body fluids? Implantable? Sterilization?
3.	Conduct cost/benefit analysis	Existing cost to mfg.? IRR? Tooling/inspection cost? Biocompatibility test? Process validation cost? Revalidation cost?

How to Get

Started

So how do you get started? Table 3 provides a simple three step process to help establish potential opportunities and make an informed decision on whether or not to convert to micro molding.

Evaluating material alternatives is extremely important. Engineers need to determine what properties are critical to the functionality of the component so that an equivalent polymer replacement can be selected. Does it have to be sterilized? What method? How often? Does it have to be biocompatible?

There are a number of USP Class VI compliant polymers already on the market that are biocompatible and can be sterilized. If considering a polymer that has not been biocompatibility tested, the cost of testing will need to be included in the analysis of whether or not to convert. However, keep in mind that once the polymer has been tested, it can be used for multiple products.

Many companies try to use polymers that are already specified in their existing products. Regulators are familiar with those polymers, increasing the likelihood of approval. On the flipside, it might limit the ability to make a better device.

Conclusion

Micro molding can be an excellent lower cost alternative to machining. It can also be a nice alternative to outsourcing offshore, eliminating the complexities associated with logistics, quality control, and the potential risk of losing intellectual property.

Links:
[1] http://www.mikrotech.com/