TECHICAL PAPER

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Micro Molding: Meeting the Challenges of Designing Medical Devices for Minimally Invasive Surgery

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abstract

Minimally invasive surgery (MIS) has been widely adopted for certain surgical procedures but not those that are complex. Manufacturers are seeking to design new devices that will allow open surgeries to be converted to minimally invasive procedures. These devices are highly complex, yet they need to be cost effective in low to moderate production volumes. A majority of device components are machined from stainless steel, ceramic, plastic, or glass and require secondary operations such as gluing, welding, or surface coating to assemble the device. These secondary operations place limitations on the size, complexity, and the material selection of MIS devices. Advances in micro molding technology and material science now make possible a range of cost-effective alternatives for components that are miniature, complex, and require high-precision tolerances. Micro molding technology can be utilized for both new and existing MIS devices, providing a solution to common hurdles now present in designing and manufacturing them. Micro molding technology will allow device designers and manufacturers the catalyst to innovate and create breakthrough products.

terms

Micro Molding, Minimally Invasive Surgery, Medical Devices, Surgery Costs

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Micro Molding: Meeting the Challenges of Designing Medical Devices for Minimally Invasive Surgery

Looking for new technologies to help reduce the complexity of minimally invasive surgical devices? Micro molding technology can provide the technological edge you need.

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The rising cost of healthcare continues to be a concern for individuals, employers, and benefit providers. The pressure to decrease the cost of medical treatment provides opportunities for medical device designers and manufacturers to develop lower cost products.

For more than two decades, minimally invasive surgery (MIS) has made successful inroads in reducing the costs of healthcare by permitting selected surgeries to be performed through small ports rather than large incisions, often resulting in shorter recovery times, fewer complications, and reduced hospitalization costs. MIS has been widely adopted for certain surgical procedures but not within complex surgical procedures. It is estimated that only 25% of all surgical procedures are performed minimally invasively. Manufacturers are seeking to design new devices that will allow open surgeries to be converted to minimally invasive procedures. These devices are highly complex yet they need to be cost effective enough to be widely adopted.

One of the main contributors to the price of MIS devices is the cost to manufacture them. A large percentage of MIS devices are still manufactured using a microscope. The manufacturing of these devices requires highly skilled labor (artisans). To establish qualified personnel to perform these operations requires a long training period and a trained ‘qualitative’ eye to determine if a completed process meets specifications.

A majority of the components used in MIS devices are machined from stainless steel, ceramic, plastic, or glass and require secondary operations such as gluing, welding, or surface coating to assemble the device. Many in manufacturing battle the complexity of assembling these miniature devices into a finished product. Obtaining an acceptable yield can often be a long and challenging process. Machined components and the utilization of secondary operations place limitations on the size, complexity, and material selection of MIS devices. As a result, manufacturing low to moderate volume MIS devices has been a costly challenge for MIS manufacturers.

The design and manufacturing of MIS devices, like all other products, is limited by the technology capable of producing them. Machining, molding, and assembly limitations coupled with the trend toward miniaturization of medical devices provide an excellent opportunity to develop alternative manufacturing processes. We believe micro molding technology is the solution. Advances in micro molding technology and material science now make possible a range of cost-effective alternatives for components that are miniature, complex, and require high-precision tolerances.

Micro molding technology has the potential to change the landscape of minimally invasive surgery. Micro molding technology is still in the introductory stage of its product life cycle; therefore, it is what I would like to call a ‘disruptive’ technology. Medical device designers and manufacturers are just beginning to realize that there is a need for this technology and are looking to fill this technology gap. It will change the way designers and buyers look at developing new products and redesigning existing products. Micro molding technology coupled with the trend toward miniaturization of medical devices and less-invasive procedures will provide ample opportunity for designers to develop new and innovative products.

Advantages of Using Micro Molding Technology for MIS Devices and Instruments

There are a number of benefits that can be achieved using micro molding technology for designing minimally invasive devices and instruments. In addition to the cost savings, micro molding technology can also provide MIS designers and manufacturers one or more of the following benefits:

Table 1. Benefits of Using Micro Molding for MIS Devices

BENEFITS
• Decrease the overall size of products
• Incorporate additional complex features
• Reduce complexity of assembling the product
• Reduce the number of components
• Identify design and process innovations that lead to converting open surgical procedures
• Dimensionally stable production process
• No particle contamination
• Use alternate resins or fillers to improve mechanical and/or electrical properties
• Better surface finish
• Likely reduction in part cost compared with other forming techniques

There are a number of ways micro molding technology can be effectively incorporated into MIS devices. Here are a few examples of how micro molding technology can offer solutions to some common manufacturing issues.

1. Medical devices that require visibility under an X-ray are typically made from metal. The density of the material provides the contrast needed to accurately locate the position of the device inside the body during the procedure. Plastic resins filled with radiopaque compounds can be visible under X-ray imaging and can be used to replace metal components. Materials typically added to base resins to add radiopacity are barium, bismuth, and tungsten.
2. Medical devices that carry current (amperes) need to be isolated from the main body of the instrument. This additional component increases the diameter of the product. Moving to a molded plastic component can remove the need to add isolation to metal components, thereby reducing the size of the device.
3. Plastic with metal or ceramic filler can be a suitable replacement for metal injection molding (MIM). It eliminates the need for secondary operations associated with MIM.
4. Micro molding can be suitably vertically integrated into an entire manufacturing assembly process that may include stamping, insert molding, bonding, or conventional molding.
5. Ceramic is traditionally very brittle. If a device is dropped, it could break and be rendered unusable. Substituting ceramic for a plastic resin with ceramic filler for ceramic can increase the toughness.

Micro molding technology can provide a significant impact to both existing and new MIS designs.

Existing MIS Devices

For devices already in production, micro molding technology can prolong product life with cost-effective upgrades, enhancements, and other value-adding features providing a better defense to existing competitor's products. This is accomplished by eliminating secondary operations that are extremely difficult to control, such as gluing, coating, and welding to name a few. Many of these secondary operations place limitations on material selection, size, complexity, and quality of the device. Removing these secondary operations creates a more robust assembly. It also improves quality by reducing the reliance on artisans to manufacture product.

Attempting to convert existing products to micro molding may appear to be difficult due to the nature of the undertaking. It can require a number of actions depending on the significance of the change. It may require as little as a 30-day notice for a process change, or as much as a 90-day 510(k) submission that may require further information, including clinical data. Action items may include a cost and investment analysis, assistance from several functional departments, capital investment, testing, and FDA approval. However, the benefits might far outweigh the undertaking required to convert to micro molding. Obviously, not all potential conversions will have the same impact, however, it might behoove MIS manufacturers to review existing product lines and perform a cost and capital investment analysis to determine which products are good candidates for conversion. The cost savings might well justify placing strategic resources to those products that present a significant cost savings (benefit).

It may take a lot of effort to remove resistance to change once a product design is frozen and in production due to the amount of time and resources that were required to get there. If converting existing devices seems like an insurmountable task, then taking the path of least resistance and switching over to micro molding technology on new designs may be the best alternative.

New MIS Devices

Micro molding technology can provide a significant impact to new MIS products in the design and development stage. It can help produce the next-generation product that can drive market leadership from within in your organization. It can help in getting the product right the first time and getting it to market on time by reducing the number of start-up problems associated with manufacturing complexity.

Micro molding technology gives designers the flexibility to design smaller more complex devices while not compromising manufacturability, thereby enhancing their ability to create new and more innovative products and establish product leadership. If designers can enhance the performance of the device and/or add more features (benefits) to allow doctors to utilize the devices more effectively and lessen the trauma to the patient, the doctor will be more inclined to use the device again. It can also potentially increase the growth of the MIS market by creating products leading to the conversion of open surgical procedures to MIS procedures.

The next section will provide three case studies demonstrating how micro molding technology can be utilized to produce more sophisticated MIS devices. The case studies will identify how existing manufacturing processes can be converted to micro molding resulting in improved devices as well as cost savings.

Case Studies

Illustrated below are three examples currently under development that provide insight into the possibility of using micro molding technology. The first example shows a direct conversion from machining to micro molding, while the other two examples show a conversion and the elimination of secondary operations. Please note that the illustrations of the components depicted in these case studies have been altered to protect the confidentiality of the customers.

Example 1

Example 1 illustrates a potential cost-savings project we are currently working on with a medical device original equipment manufacturer (OEM). The component is part of a medical device used for a cardiology procedure. The device is currently in production.

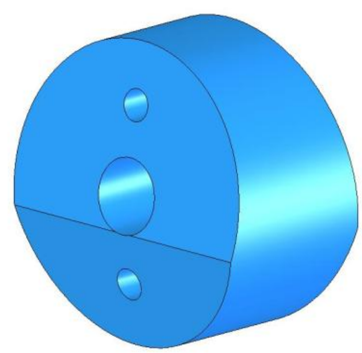
The component is machined from beryllium copper. We are proposing to convert to liquid crystal polymer (LCP). It is currently in production and has a life expectancy of another five years. The estimated annual usage (EAU) is 30,000. The company is paying $12.49. The equivalent cost for a micro-molded component would be approximately $4.75.

This example uses net present value (NPV) for the cost and capital investment analysis. The NPV is based on a minimum five-year life expectancy and a required internal rate of return of 10% (IRR). The project will have an immediate outlay of $39,000 for the mold and inspection tooling and an estimated cost of $35,000 for product revalidation. The revalidation cost includes samples of the component, manufacturing product assemblies, performing design verification, and submitting a 510(k) submission. A large commitment from the OEM is needed because it will draw a number of resources from functional departments such as purchasing, engineering, and quality to complete the conversion. Figure 2 illustrates the potential cost savings for the project.

Figure 2. Optical Ring

Part Description:
Optical Ring

Beryllium Copper ⟶ LCP



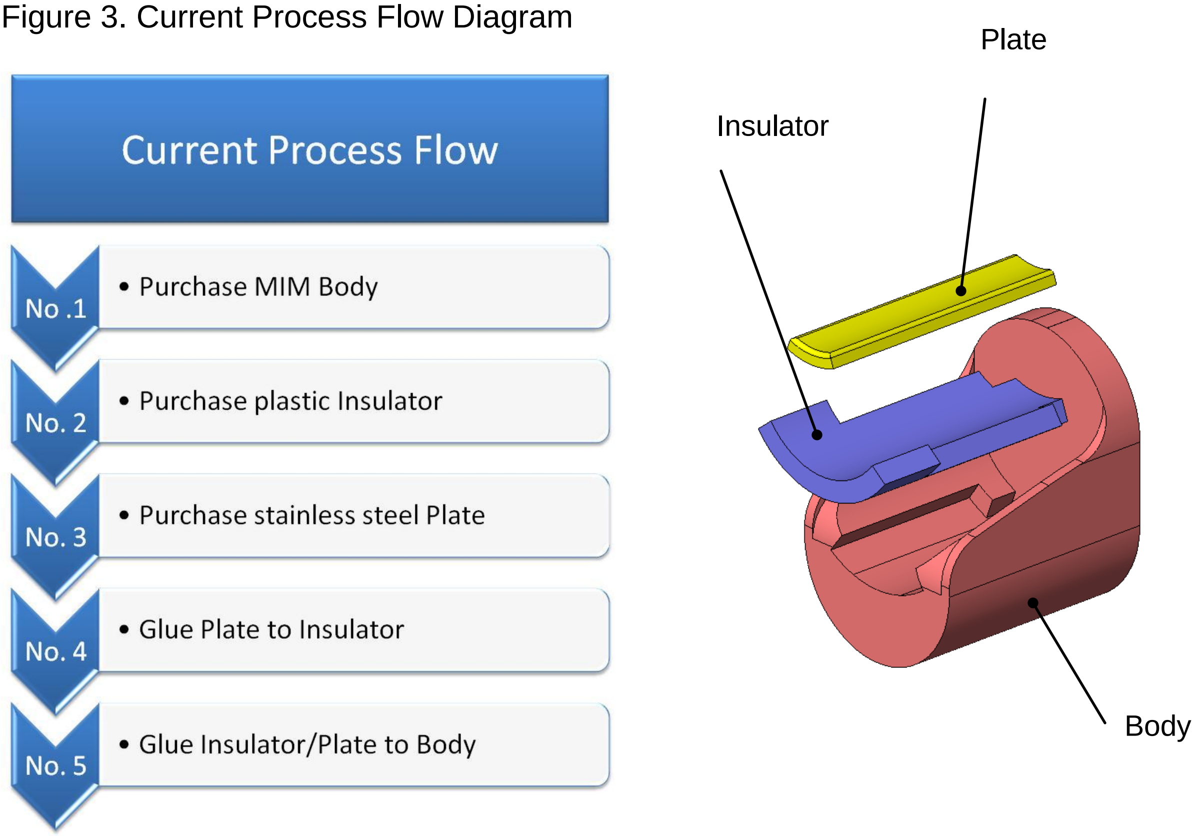
EAU	30,000
Machined Cost	$12.49
Micromolded Cost	$4.75
Annual Savings	$232,200
Tooling Cost	$39,000
Re-validation cost (est.)	$35,000
5 Year NPV	$806,221
IRR	10%

Cash inflows (savings) are expected to be $232,200 for years 1 through 5. The net present value for the sum of the years is $806,221. That savings would double if the life reached 10 years. Because the NPV is greater than zero, the company should invest in this conversion project. The results show that the total savings would be enough to offset the costs associated with revalidation and seeking regulatory approval.

Example 2

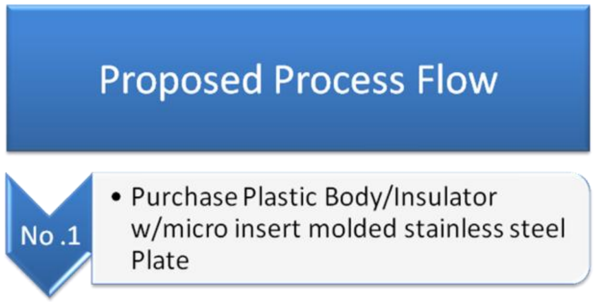
Example 2 illustrates a potential cost-saving project we are currently working on with a contract design house for a new device. The three components are part of a medical device used for a laparoscopic procedure. This device is currently in development but is a replacement for a device currently in production. The Body is metal injection molded, the Insulator is plastic injection molded, and the Plate is stamped stainless steel. In the current process, the Plate is glued to the Insulator and then the Plate/Insulator is glued to the Body. Figure 3 identifies the current process flow diagram. It has five process steps.

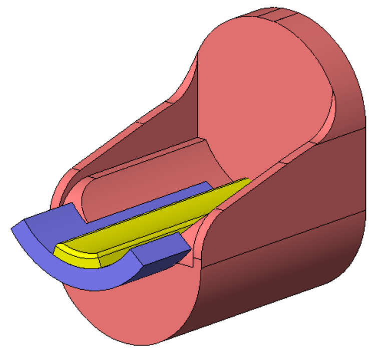
Figure 3. Current Process Flow Diagram



We are proposing to combine the Body and Insulator into one component and convert to liquid crystal polymer (LCP) and simultaneously insert-mold the Plate. Figure 4 exhibits what the process flow diagram would look like if micro molding was introduced to the design and manufacturing of the assembly. The proposed solution eliminates cost contributors such as ordering, carrying, assembly, and design. The revised process flow eliminates four steps, or 80%, of the work. There would be one part to order vs. three, therefore, only one part to carry and inventory. It eliminates the gluing operation entirely and simplifies the assembly of the device.

Figure 4. Proposed Process Flow Diagram



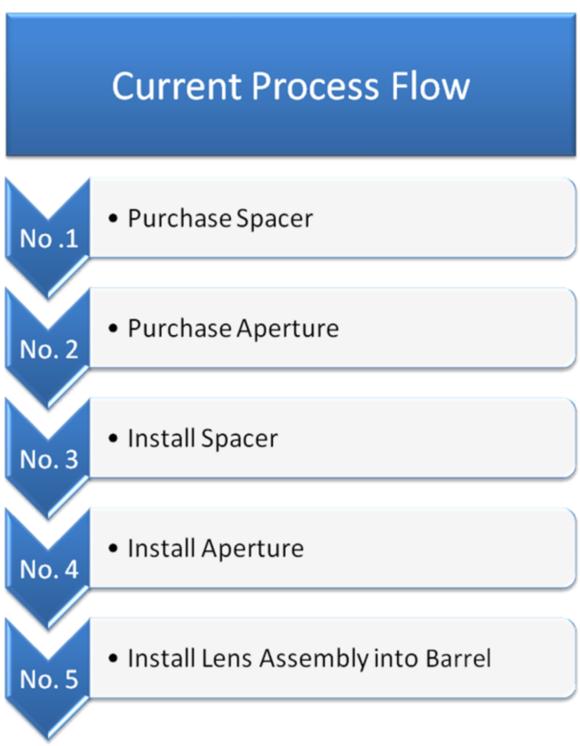


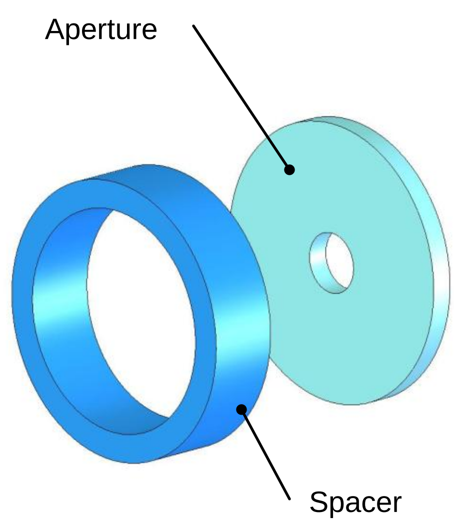
This new design is in the early stage of development, however, this approach will undoubtedly offer significant cost savings and drastically reduce the number of operations required to assemble.

Example 3

Example 3 illustrates a potential cost-saving project we are currently working on with a medical device original equipment manufacturer (OEM). The two components are part of a device used for a urology procedure. The device is currently in production and has a life expectancy of another five years. The Aperture is machined out of nickel and the Spacer is machined out of stainless steel. The estimated annual usage (EAU) is 10,000. The company is paying approximately $12.00 for both components. The equivalent cost for a micro-molded component would be approximately $2.85. Figure 5 identifies the current process flow diagram. It has five process steps.

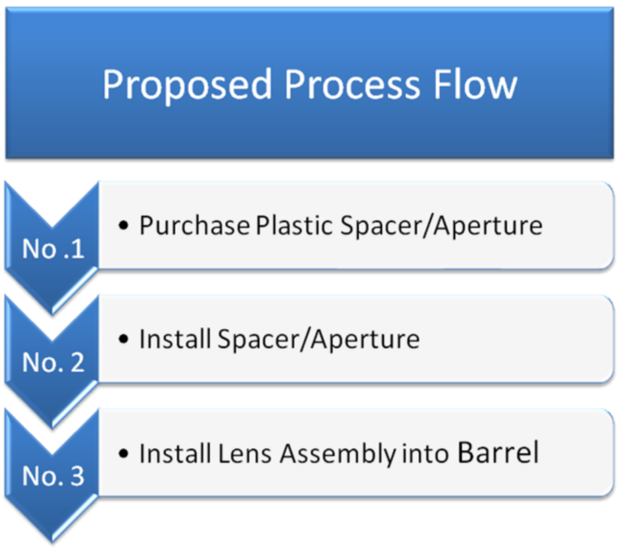
Figure 5. Current Process Flow Diagram

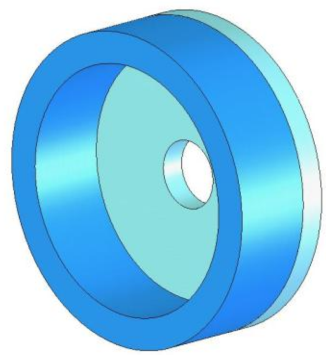




We are proposing to combine the Spacer and Aperture into one component and convert to liquid crystal polymer (LCP). Figure 6 exhibits what the process flow diagram would look like if micro molding was introduced to the manufacturing of the assembly. The proposed solution eliminates cost contributors such as ordering, carrying, and assembly. The revised process flow eliminates two steps, or 40%, of the work. There would be one part to order vs. two, therefore, only one part to carry and inventory. It eliminates the gluing operation entirely and simplifies the assembly of the device.

Figure 6. Proposed Process Flow Diagram





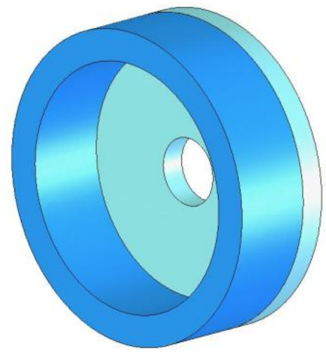
This example uses net present value (NPV) for the cost and capital investment analysis. The NPV is based on a minimum five-year life expectancy and a required internal rate of return of 10% (IRR). The project will have an immediate outlay of $17,750 for mold and part removal/inspection tooling and an estimated cost of $30,000 for product revalidation. The revalidation cost includes samples of the component, manufacturing product assemblies, performing design verification, and submitting a 510(k) submission. A large commitment from the OEM is needed because it will draw a number of resources from functional departments such as purchasing, engineering, and quality to complete the conversion. Figure 7 illustrates the potential cost savings for the project.

Figure 7. Aperture/Spacer

Part Description:
Aperture/Spacer

Aperture
Nickel ⟶ LCP

Spacer
Stainless Steel ⟶ LCP



EAU	10,000
Machined Cost (2 Parts)	$12.00
Micromolded Cost	$2.85
Annual Savings	$91,500
Tooling Cost	$17,750
Re-validation cost (est.)	$30,000
5 Year NPV	$299,107
IRR	10%

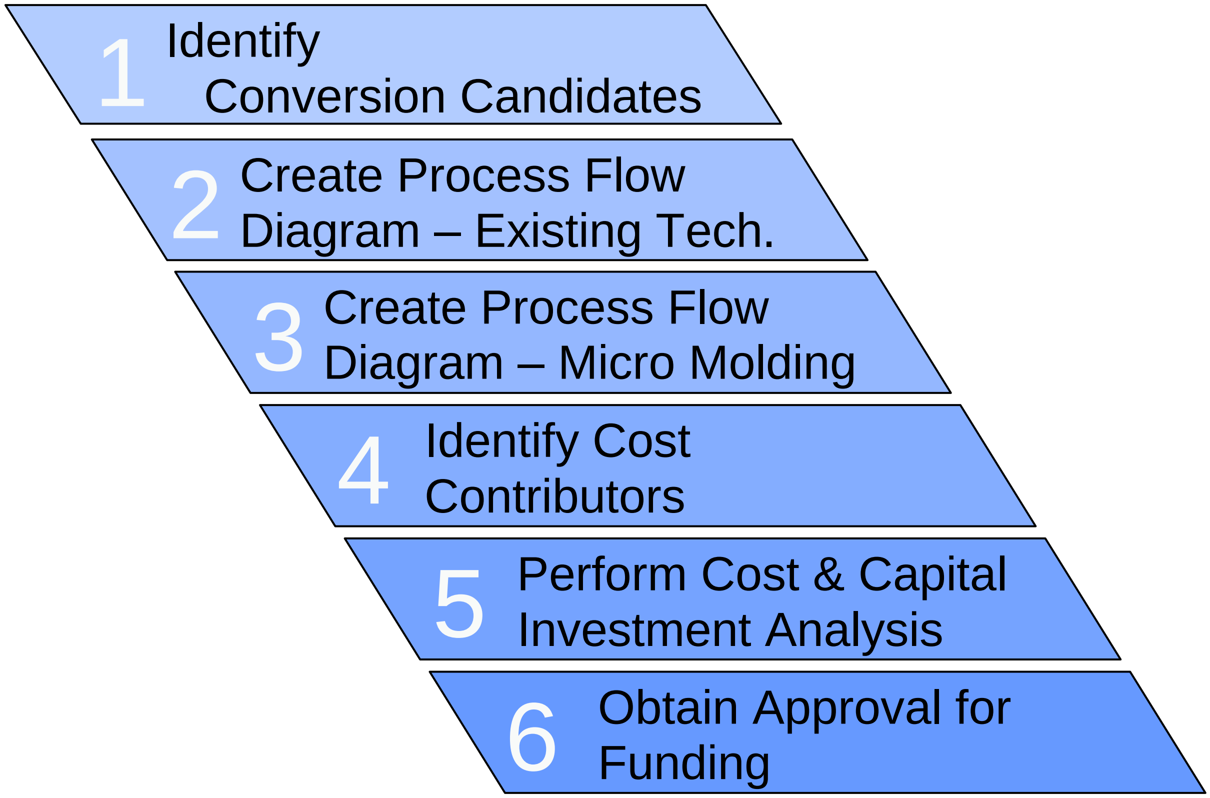
Cash inflows (savings) are expected to be $91,500 for years 1 through 5. The net present value for the sum of the years is $299,107. That savings would double if the life reached 10 years. Because the NPV is greater than zero, the company should invest in this conversion project. The results show that the total savings would be enough to offset the costs associated with revalidation and seeking regulatory approval.

How to Get Started

So how do you get started? Figure 8 provides a simple six-step process to help establish potential opportunities and allow you to make an informed decision on whether or not to utilize micro molding technology for your MIS devices. The process flow chart and the net present value calculation are tools that can assist you with understanding the impact of converting to micro molding and obtaining capital budget approval. The internal rate of return (IRR) is an optional capital budgeting method that can be used.

Every company has a different internal rate of return (IRR). Contact your accounting department for the value they find to be acceptable. Cost contributors may include non-value-added activities, such as material movements, inventory transactions, in-process inspection, labor reporting, labeling, etc. For simplicity, these activities were not included in the examples, but they are very important to consider and collectively can add significant cost to the device.

Figure 8. Conversion Guidelines for MIS Designers



Conclusion

Micro molding technology can be an excellent lower-cost alternative to designing and manufacturing MIS devices. Micro molding technology can be utilized for both new and existing MIS devices, providing a solution to common hurdles now present in designing and manufacturing them. It may also provide the catalyst to move additional complex open surgical procedures to minimally invasive procedures.

As with any new technology, there is skepticism as to whether or not it can work, and micro molding technology is no exception. Because this technology is in its infancy, many designers and buyers have little or no experience with micro molding technology. There is always an element of risk with any new technology, and not all projects will be successful. However, to maintain product leadership, MIS designers and manufacturers need to stretch the limits of technology, both in products and processes. That is a company's chief strategic means of remaining a product innovation leader. Micro molding technology will allow MIS device designers and manufacturers the catalyst to innovate and create breakthrough products. Consider the benefits your company can achieve by utilizing micro molding technology in your MIS devices.