



# Micro Molding: An Alternative to Offshoring Medical Devices for Minimally Invasive Surgery

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**abstract**

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Medical device companies have long benefited from the global outsourcing of labor and manufacturing and are now expanding the role of global outsourcing to include product design and development. However, many of the benefits of moving labor and manufacturing could be short term and may be detrimental to the long-term growth of a company. One alternative that will reduce costs and still retain sustaining competitive advantages is to find or develop new manufacturing technologies. Advances in micro molding technology and polymer science now allow a range of cost-effective alternatives for components and subassemblies that are miniature, complex, and require high-precision tolerances. Utilizing micro molding for medical products used in minimally invasive surgery (MIS) can permit companies to improve their manufacturing processes and not jeopardize sustaining competitive advantages. These changes can reduce the number of components, overall size, assembly complexity, and time required to assemble the device under a microscope. This paper attempts to challenge the basic principles of outsourcing and to bring a different outlook on this highly publicized and challenging subject.

**terms**

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Micro Molding, Medical Devices, Minimally Invasive Surgery, Outsourcing, Competitive Advantages

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# Micro Molding: An Alternative to Offshoring Medical Devices for Minimally Invasive Surgery

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## Introduction

It's not uncommon today to open any medical device trade magazine and see an article touting the benefits and pitfalls of outsourcing or offshoring the labor and manufacturing of medical devices. Medical device companies have long benefited from the global outsourcing of labor and manufacturing and are now expanding the role of global outsourcing to include product design and development.

However, many of the benefits of moving labor and manufacturing could be short term and could erode over time and be detrimental to the long-term growth of a company. Proponents and critics of outsourcing or offshoring miss one very important point. Companies may be losing a key aspect of their business: a sustaining competitive advantage (SCA).

There are a number of ways to reduce costs and still retain sustaining competitive advantages. One alternative is to find or develop new manufacturing technologies that reduce or eliminate labor-intensive manufacturing operations. Advances in micro molding technology and polymer science now allow a range of cost-effective alternatives for components and subassemblies that are miniature, complex, and require high-precision tolerances. Utilizing micro molding for medical products used in minimally invasive surgery (MIS) can permit companies to improve their manufacturing processes and not jeopardize sustaining competitive advantages. These changes can reduce the number of components, overall size, assembly complexity, and time required to assemble the device under a microscope.

The purpose of this paper is not to identify whether insourcing or outsourcing is best, nor to identify the pros and cons of each. This paper will attempt to challenge the basic principles of outsourcing and to bring a different outlook on this highly publicized and challenging subject. For the purpose of this paper, the term outsourcing will be used to refer to both outsourcing regionally and offshoring to another country.

## A Sustaining Competitive Advantage

Medical devices for minimally invasive surgery are small-volume, complex, high-precision multicomponent assemblies manufactured using highly skilled manual labor. Many of these devices are assembled under a microscope and assembled using qualitative manufacturing operations such as bonding and welding.

Companies spend years developing and perfecting products that enable them to ensure compliance, quality, reduced risk, lower costs, and profitability. Due to the nature of these products, perfecting a stable manufacturing process requires a significant amount of time and effort. Processes are perfected and developed into a series of skill sets or knowledge that is accumulated over time. The company might have had to endure a period of high costs of quality associated with poor production yields. Over time, this accumulated knowledge (intellectual property) develops into a sustaining competitive advantage.

The term sustaining competitive advantage (SCA) can be defined as a core competency that can yield a long-term advantage to a company. An SCA allows a company to differentiate itself from the competition by creating manufacturing capabilities with a prolonged benefit that cannot be duplicated or imitated by competitors. It establishes barriers to entry that creates disadvantages for new competitors attempting to

enter the market and maintains pricing power. Figure 1 identifies the five characteristics that make up an SCA.

Figure 1. What is a Sustaining Competitive Advantage (SCA)?



A sustaining competitive advantage can be developed through the development of intellectual property. Intellectual property can consist of patents, trademarks, copyrights, and trade secrets. A trade secret is a confidential practice, method, process, design, or other information used by a company to compete and provide an economic advantage over other businesses. Trade secrets are also referred to as ‘confidential information’ or ‘classified information.’

Trade secrets are not protected in the same manner as patents. Probably one of the most significant differences is that a trade secret is protected without disclosure of the secret. Patents, on the other hand, are often costly to produce, and when the patent is issued it becomes public information and can be imitated cheaply. Trade secrets can extend indefinitely, and in that respect they offer an advantage over patent protection, which lasts for only a specific period. The key variables are shown in Table 1.

These differences can be extremely important for companies designing and manufacturing medical devices for minimally invasive surgery (MIS). The unique processes developed for manufacturing these products can be identified as trade secrets and adequately secured from being made public, making it difficult to replicate, hence creating a number of potential sustaining competitive advantages.

Table 1. Patents vs. Trade Secrets

Variable	Patent	Trade Secret
Not known to the public		✓
Provide economic benefit	✓	✓
Effort made to maintain secrecy		✓
Does not expire		✓

### A History Lesson

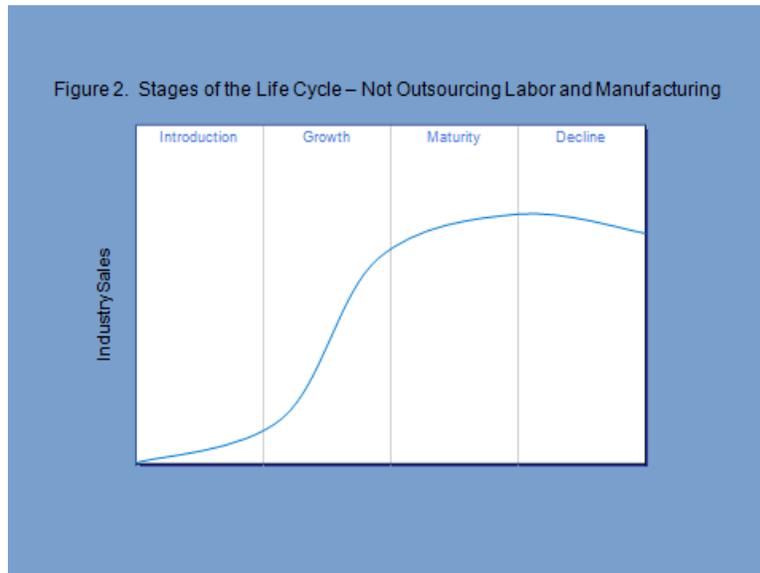
Efforts to cut the cost of labor-intensive manufacturing processes in medical devices for minimally invasive surgery may result in the decision to outsource labor and manufacturing of medical devices to a

contract manufacturer, but doing so may be a strategic error of relinquishing a sustaining competitive advantage. Companies risk reducing long-term growth and profitability of the product and company. A contract manufacturer’s appeal is lower costs and the ability to utilize common components and processes to obtain economies of scale in purchasing and manufacturing. However, a contract manufacturer obtains the intellectual property of the company with very little effort and cost. Once the process knowledge is disclosed to the contract manufacturer, it becomes publicly known and makes it easy for competitors to obtain and replicate (similar to a patent). Contract manufacturers will then make a strategic decision to promote this new knowledge to competitors with similar products lines in the hope of capitalizing on it.

**Outsourcing Components and Subassemblies Only, Not Labor and Manufacturing**

Suppose a company wants to design and manufacture a medical device and strategically identifies only components and subassemblies that should be outsourced. The chart shown in Figure 2 resembles a common product life cycle pattern. The market for medical devices for minimally invasive surgery is currently in the growth stage of the product life cycle, with the main drivers of growth being the aging population and the focus on a higher quality of life. This is evident by the way the medical industry is holding up so well during the global economic recession. The growth stage is accentuated by increasing sales, high profit margins, and the entry of new competitors.

Figure 2. Stages of the Life Cycle – Not Outsourcing Labor and Manufacturing



**Outsourcing Entire Manufacturing Process**

Now suppose a company wants to design a medical device and outsource the entire manufacturing to a contract manufacturer. Some important consequences emerge from this strategic decision.

First, let’s assume the company determines that it needs to reduce costs and decides to outsource the entire medical device. Second, the company outsources the medical device to a contract manufacturer and consequently relinquishes one of more sustaining competitive advantages. In addition, the contract manufacturer receives technical know-how at little or no cost. Third, the contract manufacturer promotes its newly acquired knowledge to competitors. This allows knowledge to become public, permitting access to the intellectual property (in the form of trade secrets) and allowing the competition to gain a wider experience and knowledge of manufacturing these types of medical devices. Lastly, new competitors enter the market.

The end result is that outsourcing has lowered competitive barriers, allowed start-up companies to easily enter the market, and permitted the contract manufacturers to realize economies of scale in purchasing, manufacturing, and so on. In other words, the company has actually subsidized the start-up companies!

As seen in Figure 3, the increase of new competitors entering the market sooner than anticipated will cause the growth stage to contract while the mature and decline stages increase. This will reduce the time the product will spend in the growth stage. This results in a decrease in sales revenue. The growth stage of the product development cycle becomes compressed, hence speeding up the eventual commoditizing of the product. This is the consequence of the loss of one or more sustaining competitive advantages. This was not what was initially intended. The company receives short-term profit gains but sacrifices sales revenue over time. These points are summarized in Table 2.

Figure 3. Stages of the Life Cycle – Outsourcing Labor and Manufacturing

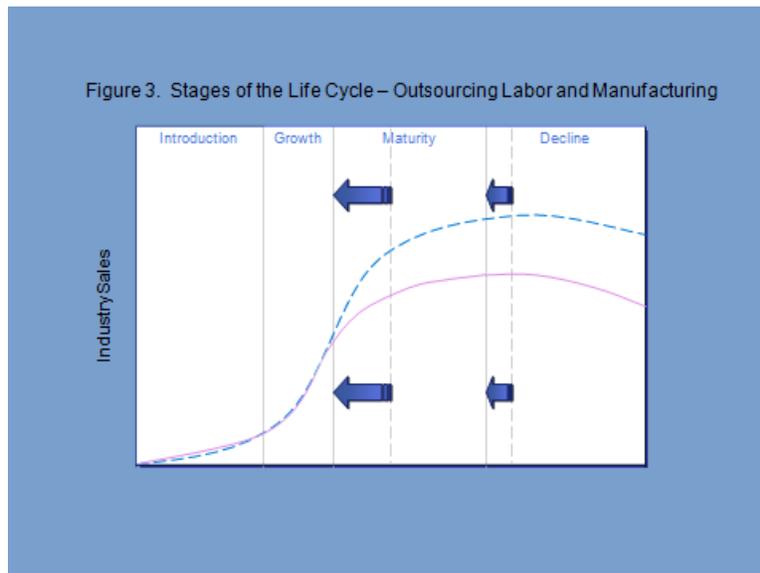


Table 2. Sequence of Events – Outsourcing a Complete Medical Device

Event No.	Action	Reason	Result
1.	Company looks to reduce time and costs	<ul style="list-style-type: none"> <li>• Short-term focus on maintaining costs or increasing profitability</li> <li>• Managerial changes</li> </ul>	<ul style="list-style-type: none"> <li>• Don't thoroughly investigate alternatives</li> <li>• No long-term strategy developed</li> </ul>
2.	Company outsources labor and manufacturing of an entire medical device	<ul style="list-style-type: none"> <li>• No intellectual property strategy</li> <li>• Intellectual property not identified</li> </ul>	<ul style="list-style-type: none"> <li>• Company relinquishes a new or existing sustaining competitive advantage</li> <li>• Company transfers knowledge (intellectual property) to contract manufacturer</li> </ul>
3.	Contract manufacturer promotes new knowledge (intellectual property)	<ul style="list-style-type: none"> <li>• Look for competitors that make similar medical devices</li> <li>• Increase sales revenue</li> <li>• Establish economies of scale</li> </ul>	<ul style="list-style-type: none"> <li>• Access to intellectual property and wider experience and knowledge</li> <li>• Knowledge becomes public</li> </ul>
4.	New competitors enter market	<ul style="list-style-type: none"> <li>• Lower barriers to entry</li> <li>• Mature manufacturing processes established</li> </ul>	<ul style="list-style-type: none"> <li>• Product life cycle reduced</li> <li>• Lose pricing power</li> <li>• Gross margins reduced</li> <li>• Commoditization</li> </ul>

It is not uncommon to hear stories of companies being victimized by contract manufacturers taking previously transferred knowledge (intellectual property) and promoting it to competitors for economic gain. So why would a company want to outsource or offshore labor and manufacturing of a medical device?

Over the last several decades, companies have been transitioning away from manufacturing goods and have instead been moving labor and manufacturing to lower-cost producers. Companies fall prey to the pressure to stay ahead of the competition and have been compelled to abandon manufacturing in favor of managing cost structures. Today, manufacturing is considered passé. If I can buy it cheaper, why would I want to try to manufacture it in-house (commonly referred to today as insourcing).

The problem lies with short-term strategic thinking and the propensity to move in the direction of least resistance. It requires less time and capital to outsource or offshore than to try and improve or develop a new and unique manufacturing process.

## Potential Solution

If companies wish to retain their sustaining competitive advantages, they must avoid outsourcing the entire medical device assembly. Companies must only outsource components and subassemblies used to manufacture the medical device. By allowing the sourcing of components and subassemblies only, the company can still realize the benefits of obtaining 'best practices' while still retaining its SCAs. By working with strategic suppliers, companies can still manufacture more efficiently without compromising their sustaining competitive advantages.

So what can a company do? Are there economical manufacturing methods available that allow companies to reduce costs and time without jeopardizing their sustaining competitive advantages? The answer to that question is yes.

Micro molding can be an excellent lower-cost alternative to outsourcing medical devices for minimally invasive surgery. Utilizing micro molding can reduce or eliminate labor-intensive manufacturing processes and have a significant impact on the development of new MIS devices.

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

- Manufacture medical devices more efficiently without compromising sustaining competitive advantages
- Reduce costs by reducing the number of components, assembly complexity, cycle time, and production yield
- Spur continuous improvement and innovation
- Use supplier base to ascertain best practices and incorporate in design and manufacturing
- Do not have to 'shop around' for the labor

These benefits will allow companies to reduce their dependency (time) on a microscope to assemble devices, reduce or eliminate expensive machine components, and reduce or eliminate complex secondary operations, all of which result in higher production yields.

## How to Get Started

A two-step process is required to ensure that companies create and retain sustaining competitive advantages. The first step requires a company to establish an effective organizational structure that promotes three key factors:

- Continuous improvement of product, process and service
- Continuous exploitation of existing knowledge to develop new and different products, processes, and services
- Innovation

Innovation with regard to patents is often costly to produce and is easily imitated. As a result, firms operating in competitive market structures have difficulty realizing the full benefits of their innovative efforts and thus maximizing returns on R&D investments. Unlike patents, innovations with regard to trade secrets are not generally known to the public and can provide a longer-lasting return on investment.

The second step requires companies to adequately identify and document their existing competitive advantages and sustaining competitive advantages. In addition, they must be accessible to the personnel responsible for outsourcing. The decision to outsource is normally made at a strategic level. The process begins with the company identifying the activity to be outsourced and generally using a make-buy analysis to justify the decision. Before a decision is made to outsource, management should ask the four following questions:

- Are competitive and sustaining competitive advantages documented and accessible for a strategic make-buy analysis?
- Are any of the components we are considering for outsourcing relinquishing a competitive advantage? A sustaining competitive advantage?
- Will this new product launch provide us the opportunity to obtain and grow a new competitive advantage? A sustainable competitive advantage?
- Will this product allow the company to retain and strengthen a sustainable competitive advantage?

Companies need to evaluate outsourcing not only to see if it will reduce costs and time, but also to see if they are relinquishing a potential or an existing sustaining competitive advantage. For an intellectual property strategy to be truly effective, it must be properly maintained and personnel must be properly trained to know what is and what isn't intellectual property and how to safeguard it. These questions will ensure that existing sustaining competitive advantages will remain in-house.

## **Conclusion**

There are many ways to compete successfully in the global marketplace. To create sustaining competitive advantages, it is important to develop a competitive strategy that includes a wide spectrum of techniques to gain advantage. You can compete on a technology, but you can also compete on time, reputation, values, images, experience, service, design, innovation, quality, information, knowledge, loyalty, and process.

As for medical device companies, they need to explore new manufacturing technologies to help reduce the complexity of minimally invasive surgical devices. Micro molding technology can be an excellent lower-cost alternative to designing and manufacturing components and subassemblies for MIS devices. It allows MIS devices to be manufactured efficiently without compromising knowledge and sustaining competitive advantages. Micro molding can be an alternative that provides many of the same short-term benefits while also maintaining longer-term strategic advantages.

Manufacturing can play a vital role in the success of a company. The decision to outsource should not be based solely on the product type, cost, quality, and time. At the end of the day, sustaining competitive advantages are what make companies strong and able to compete in the global marketplace.