"Micro Medical Device Market"

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INTRODUCTION:

WOW! In over 20 years in medical device design and manufacturing (10+ years of those specifically in micro), I've been saying, "this is the year, this is the year of the micro boom" and each year comes and goes with growth, but not the boom that was anticipated. Well, this year finally boomed and micro and specifically micro medical manufacturing REALLY took off and is now reaching the potential it was expected to reach all these years. With all of the talk about economics and worldwide recession, a bright and shining star called medical device manufacturing glows keeping hopes alive for any country or any company that has invested in the how-tos and where-tos to get micro components manufactured in a scaled-up fashion.

It seems that everyone from material manufacturers to machine shops and fabricators to equipment suppliers that supply to the medical device community are all smiling and not just busy but "swamped" as they describe it. With that said, they are all holding their breath too, and not oblivious to the fact that they need to be smart about investing and re-investing their profits in the right places. They also are cognizant of the fact that when the economy picks up, they should be even busier than they are now. Or will they?

Here's a random and non-financially educated thought….what happens in a down economy is that people get stressed and when people get stressed, they get sick and when they get sick, hospitals get busier and use more medical devices. Because of this, medical device manufacturers have an influx of cash that they can use to develop new products and the new product engine is what keeps us all busy with new and innovative products to supply to the medical device community. Now, everybody knows that medical devices take 2-3 years to develop and get onto the market so what happened in the early 2000-2001 eras with respect to the economy are just getting to reverberate around the world and are now turning into new medical device production orders. (I told you it was non-educated but a theory that I'm sticking to because all others aren't logical enough to explain why medical device subcontractors are so very busy in a bad economy)

GLOBAL MARKETS:

The materials used in micro medical devices are influenced by regulatory requirements, compliance (less pain, easy to use) in the medical industry, and global price competition. The medical device industry is extremely competitive and as with any market, it is critical to be the first ON the scene with new products.

Some of these new products can be seen in Figure 1.1 and 1.2.

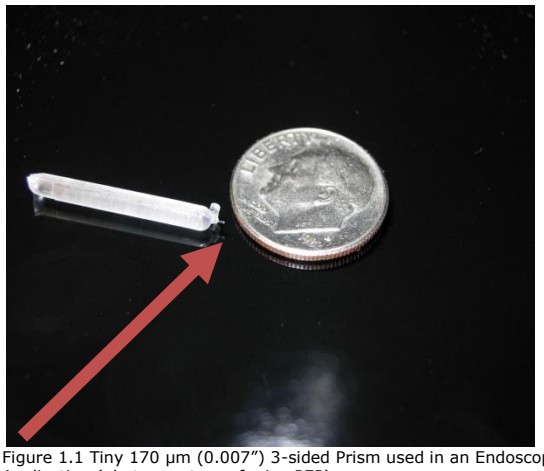

Figure 1.1 Tiny 170 µm (0.007") 3-sided Prism used in an Endoscopy Application (photo courtesy of microPEP)

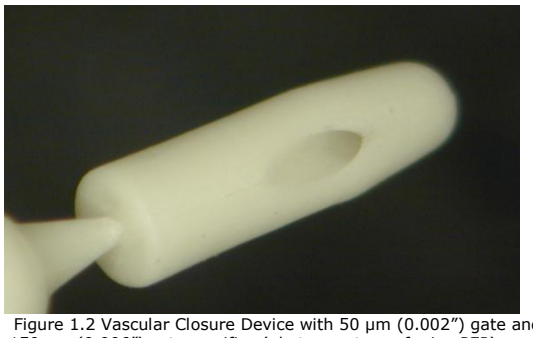

Figure 1.2 Vascular Closure Device with 50 µm (0.002") gate and 150 µm (0.006") suture orifice (photo courtesy of microPEP)

According to BCC Research, a global market analysis firm, the global market for minimally invasive surgery devices and instruments is expected to reach $19Billion U.S. by 2011. Many of these devices are enabled by micro components and assemblies to fire their tiny mechanisms internally in the body. Approximately 60% of the medical devices are designed in the United States and even still some OEMs are shifting production and assembly operations to other countries. FDA compliance responsibility and ensuring product integrity is in the hands of the contract manufacturer OR in the hands of the regulatory-aligned body and with Intellectual Property now aligning with scale-up, more and more medical device companies are keeping this technology "close to their belts" by internally manufacturing it OR strategically partnering with a full service contract manufacturer to produce both their challenging micro assemblies and their straight-forward conventionally sized assemblies.

MICRO MANUFACTURING SUPPLY CHAIN OPPORTUNITIES:

So, where is this boom happening and what are the applications in micro medical devices that are fueling this growth? In spite of mounting operating expenses, the medical device industry has experienced substantial growth during the past decade. Medical Device OEMs have managed to maintain profitability by supporting an extraordinarily high level of commitment to product innovation and by adopting a variety of creative cost-cutting measures— including the increasingly popular strategy of outsourced manufacturing. This is most evident in micro manufacturing as re-inventing this wheel is not the best use of their multi-billion dollar research and development budgets. Additional reasons for outsourcing medical devices are:

1. **Quicker, More-Efficient Product Launches.** Engaging full-service contract manufacturers in the design and development phase of a product's life cycle condenses launch timelines. Manufacturing experts working in conjunction with product designers are able to achieve higher productivity by developing DFM (Design For Manufacturability) solutions that drive out production inefficiencies over the long haul.
2. **Ability to Focus on Core Competencies.** Medical device manufacturers obtain greater ROI by investing in product development and marketing rather than in manufacturing. Developin methods for micro manufacturing capacity are both capital intensive and slow for medical OEMs, resulting in lower capital returns over time.
3. **Access to Specialized Capabilities.** Contract micro manufacturers have become experts in their niches in the market, allowing manufacturers the option to use these specialized production capabilities without spending valuable R&D dollars on projects that distract from their core competencies.

Although the argument for outsourced manufacturing is compelling, there are instances in which manufacturers choose to handle projects for which they would otherwise rely on contract manufacturers or micro manufacturing consultants. Such reasons include:

1. **Surplus Capacity.** Due to the fixed-cost nature of manufacturing, manufacturers may look to leverage underutilized resources before outsourcing work.
2. **Manufacturing Control.** Device manufacturers may keep projects in-house to interact with existing assembly equipment or to protect their Intellectual Property. IP in micro manufacturing is historically linked with scale-up processes versus making the first several thousand parts and therefore the IP becomes tightly integrated into the supply chain and may include co-development of products.
3. **Liability Issues.** OEM Device manufacturers are ultimately liable for products they market. There may be instances, such as pharmaceutically-induced materials that would necessitate ownership of the manufacturing process.

CONCLUSION:

The medical device market is never stagnant, is recession-proof, and is full of challenges and innovation. Many medical OEMs are using a combination of outsourcing, internally sourcing, and niche supplier strategic sourcing. As the outsourcing continues, medical OEMs will either move toward a full-service manufacturing provider or start to develop their own outsourcing network to provide the additional services. To the extent that their existing suppliers have micro manufacturing capabilities, they will be the likeliest candidates for the new business.

[Donna Bibber is President/CEO of Micro Engineering Solutions, a solutions-based company serving small to Fortune 50 companies. She is also technical partner for microPEP, a full service micro manufacturing company. She has written and lectured hundreds of technical papers on micro manufacturing associated topics worldwide and was recently voted onto the List of 100 Notable People in Medical Devices for 2008.

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