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## Medical molding a healthy prescription for Mack

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Mack Molding Co. has launched a new medical products unit, which it has branded MackMedical. "We have been aggressively developing the medical manufacturing sector of our business for the past nine years by refining quality and supply management systems, hiring specialized staff, and adding new technology," said Jeff Somple, president of Mack Molding's northern division in Arlington, VT.

The medical market now represents 30 percent of Mack's business, including several class III medical devices, surgical equipment and disposables for the orthopedic sector, Somple said. About 50 employees work for Mack's medical side.

Delving into medical manufacturing was a sound business idea, said Somple.

"It was part of our agenda to 'China-proof' our company", he said. "Our strategy is to concentrate on selling products in the Northeast and in the United States, rather than selling everything around the world."

"Medical manufacturing will grow to 50 percent of our business within the next two years, as we anticipate adding large-part clean-room molding and other medical design services," Somple predicted. "The medical-device industry has shown continued growth, even though many other industrial sectors of the economy have been stagnant or weak."

Mack Molding is a leading custom plastics molder and supplier of contract manufacturing services. It specializes in plastics design, prototyping, large-part molding, metal fabrication and medical device manufacturing.

About 50 percent of Mack's products are straight contract manufacturing, Somple said. Mack handles the design, build and assembly specifications for the rest of its products.

MackMedical's manufacturing staff focuses on program management, product development, quality, regulatory, document control, purchasing, sales and production. They manage all medical accounts, from upfront engineering through final manufacturing and distribution.

"This is an engineering-intensive team with a medical manufacturing culture that understands the industry," said Kevin Bradley, business unit director. "The customer doesn't have to spend time bringing us up to speed on the stringent requirements of this market."

That was echoed by company client John Grecco, senior designer for Knee Engineering at Stryker Orthopaedics in New Jersey.

"My experience with Mack is founded on a mutual understanding that quality is everything," Grecco said. "We are in an industry where it is our business to restore the quality of life to those who are in pain. Mack understands this, and has implemented the necessary systems and expertise to assure that they maintain the highest level of quality."

"Stryker, as a company, expects a lot from their suppliers, and Mack has met this challenge," Grecco said. "Forming MackMedical to better serve its medical market customers is yet another positive step along the way."

Other MackMedical customers include GE Medical Systems, Philips Medical Systems and Tyco Healthcare, according to the company's Web site.

While rooted in plastic injection molding since its inception in 1920, Mack has long since been more than a molder. Vertically integrated into a number of other core competencies, Mack offers design, prototyping, metal fabrication, full product assembly and direct-order fulfillment.

The company recently added product refurbishment, complaint investigation and obsolescence management for its medical customers.

"We have demonstrated to the medical market that we're in this business to stay," said Somple, "which is particularly important during this period of economic uncertainty.

"Given the length of the medical product development cycle, it's critical for OEMs (original equipment manufacturers) to deal with contract manufacturers that have the financial and staff bandwidth to stay the course," he said.

Somple pointed out that although Mack only recently announced this major corporate transition, company representatives have already been called upon at the three recognized annual industry trade shows in New York City, Philadelphia and Anaheim, CA to make presentations on how the company is accomplishing this process, and what their experience has been to date.

"Given the severe slump in sectors like automotive and homebuilding, for example, there are already a number of other companies looking to convert into this medical devices sector, because it appears that there will be economic growth here," Somple observed.

"However, there is a long due-diligence protocol needed, which includes regulatory compliance and accountability to the U.S. Food and Drug Administration (FDA). It is unlikely that other companies will be able to make a speedy shift to take advantage of marketplace benefits."

Somple's assessment was confirmed by Sean Fenske, editor-in-chief of Medical Design Technology magazine. Fenske said that it was unlikely companies would be able successfully transition into this sector without knowledge of the regulatory environment.

"Even if an enterprise is not making products that need direct approval or supervision by the FDA, they are contributing their products to devices which still have to undergo FDA inspection," Fenske said.

"So, if they cannot assure with certainty that their component does not negatively impact the approval of the finished product, that business will not be getting work from medical device manufacturers," he said.

The plant at the company's Arlington headquarters has been certified by the International Organization for Standardization (ISO) for medical device production. Its prototyping division, Mack Prototype, Inc., of Gardner, MA, has earned ISO certification as well.

Mack is a privately owned business that operates 10 facilities throughout the U.S. and Mexico totaling 1.5 million square feet of manufacturing space.

Mack has annual sales of more than \$260 million and employs over 1,800 people throughout the U.S., with approximately 450 in Vermont.

The company has earned a 5A1 Dun & Bradstreet rating, the highest available. The corporation has no long-term debt and finances its own acquisitions and growth.