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The Tooling Press Release interviewed Tom Vassallo, president of Helix Medical, LLC, as well as Luis Burgos, general manager. The Carpinteria, CA-based company specializes in the manufacture of medical devices and components using both silicone and thermoplastic materials and serves a global market.

What is your company niche, and what does your company do that is notable, unique or different?

Helix Medical has made a name for itself in silicone for the medical device industry, specifically custom molding of platinum-cured silicones. We work with medical and implant grade silicones from quality suppliers like Dow Corning, Wacker, Nusil and Momentive. Platinum grades we work with include LSR (liquid silicone rubber), HCR (high consistency elastomers), LCR (low consistency elastomers), and bacteriostatic blends (proprietary).

Our custom molding operation handles liquid injection molding (LIM), compression/transfer, insert, thermoplastic, and micro molding. We specialize in patented cold runner technology at all of our U.S. facilities and in two-shot molding at our facilities in Gloucester, MA, and Baldwin Park, CA, whereby two materials are combined into one component – thermoplastic and silicone.

Aside from custom molding, we also offer extrusion, assembly, sterilization, and packaging at our Carpinteria, CA, plant. This facility has ISO 13485 and ISO Class 7 & 8 certified Cleanrooms, and is an FDA-registered medical device facility. Helix Medical also manufactures the HelixMark® brand of platinum-cured silicone tubing and fluid handling components for Big Pharma and biotech.

Helix Medical is much more than just silicone, however, because of the acquisition of APEC, discussed below in Question 6.

When and how did you get into the industry, what attracted you to it?

Helix Medical was founded in 1984 by senior level executives from the medical device industry, from firms such as Heyer Schulte, American Hospital Supply and Baxter Healthcare. The company is headquartered in Carpinteria, CA, near Santa Barbara – a little known hotbed for medical silicone. Other companies in the area include Nusil, Mentor and Allergan.





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Tom: I have worked for more than 30 years in the medical device industry. I started with American Hospital Supply and then worked for one of their divisions, Heyer Schulte, and that's where the silicone expertise started – they were innovators of devices for children that suffered from Hydrocephalus on the brain. That was the beginning of the silicone device industry in the Santa Barbara, CA, region. My expertise is in sales, marketing and general management. The close personal contact we had with the surgeons and medical personnel in the field helped us grow the medical device side of the business because, in those days, that's where the ideas came from.



Luis: I have over 15 years of experience in the medical device industry in management, both domestically and overseas. My technical involvement has been in Quality Assurance in regulatory affairs, manufacturing, engineering and general management.

Relate a notable "best time" for your company.

Tom: Today is the best time and it's because of the Freudenberg-NOK acquisition of Helix. We now have the capital and the technical expertise behind us to be able to grow rapidly in this field. We have the opportunity to put a business case together and all we have to do is execute and perform. Freudenberg is intelligent because now they can utilize all the great automotive technology that they have developed and leverage it into the medical device industry. Now we have the opportunity to go back to many customers we've had in the past and offer them more than just silicone – we now have thermoplastic technology, patented cold runner technology and offshore manufacturing capabilities.



In addition, today's customers are demanding a manufacturing agreement from us that includes a contingency plan in the event of a natural disaster. For example, we are set up with injection molding operations in multiple facilities to ensure minimal downtime in production. This is just one way we've been able to expand the services we offer to those medical device customers.

Luis: I agree with Tom. Opportunities are available to us now in all areas of the medical device industry; plus the technologies are there, and we are growing exponentially. This is the best time for Helix Medical.

The medical device industry is very challenging and competitive and in order to become the best in our niche, we are applying Lean and Six Sigma tools that are helping us to achieve Operational Excellence; this



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is only achieved when each employee knows that the product moves from process A to process B in a specific quantity, at a specific time, to a specific location. We are increasingly doing more with less energy and waste as we are becoming closer to exactly what the customer wants by applying techniques from our proprietary GROWTTH (Get Rid Of Waste Through Team Harmony) program always involving the three links of any process: supplier, processor and customer.

Similarly, relate notable challenges that your company has overcome.

A customer required a product that inhibited the growth of fungus on the silicone. We developed a proprietary process that included the incorporation of the tooling and material that led to the introduction of antimicrobial silicone. This product is now patented and widely available.

When you are working on projects with your customers, what aspects would you like them to better recognize?

Tom: The extent of the capabilities that we have here at Helix and that we're a professional team able to solve their problems via communications and technical involvement.

Luis: We have the benefit of applying concurrent engineering by involving representatives from Helix, the customer, and our suppliers in the early stages of every project. This ultimately saves time and money and ensures the success of the project. Project management is formalized and key to that success. Helix Medical has a well-defined, cross-functional team that is ready to work with customers for the best outcomes.



List newly acquired technology, equipment or key personnel (in last year).

As a result of an acquisition made by Helix Medical earlier this year, Helix Medical now oversees the operations of APEC, a Baldwin Park, CA-based thermoplastic and silicone injection molder. With APEC, Helix Medical gained the resources of a respected manufacturer of medical device components and subassemblies. APEC, in business since 1997, operates a 72,000-square-foot, state-of-the-art facility in



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southern California in addition to a manufacturing operation in Shenzhen, China, APEC ASIA, which is a 35,000-square-foot facility. APEC is strong in thermoplastic injection molding, utilizing top-of-the-line ARBURG and TOYO presses ranging from 28 – 300 ton, and also offers advanced silicone injection molding with 7 silicone (LIM) cells with the unique ability to manufacture both thermoplastics and silicone in the same ISO Class 8 cleanroom.



Has your company recently expanded? Plans to expand or form partnerships/alliances?

Helix Medical has recently been certified ISO Class 7 & 8 for cleanrooms within its Carpinteria, CA, facility. Currently the Carpinteria facility has 10,000 square feet of cleanroom space and will be expanding that area by another 3,000 square feet in the next six months. The Company is also in the process of adding an ISO Class 8 assembly room to its Baldwin Park, CA, facility. Both improvements are due to be operational by early next year.

The Helix Medical – Gloucester Operations has recently expanded its manufacturing facility by 9,000 square feet to meet an increase in the volume of business. New equipment was also added.

In addition, APEC ASIA has just passed an ISO 13485:2003 certification audit, conducted at the company's medical manufacturing facility in Shenzhen, China. APEC ASIA is one of a small number of firms in mainland China to carry this certification. It attests to a quality management system designed and implemented specifically for medical devices.



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Are you involved in any industry organizations or educational programs related to the trade?

We have a mentorship program through affiliations between our engineering & R&D departments and the University of California at Santa Barbara and Cal Poly in San Luis Obispo. We engage students with interests in biomedical engineering as interns and we also support senior student projects in biomedical engineering.

In addition, many of our employees belong to professional engineering, quality, and regulatory trade organizations as well.

What do you think about changes occurring in the industry due to globalization? How has it affected the way you do business?



Tom: From the medical device industry side of things, medical device technology is really a U.S.-based operation in terms of product development. What's been moving off shore is the assembly side of operations and that hasn't hurt us. As the population continues to age, and with the shrinking world we live in, there is more opportunity to research and develop devices that will help people get and stay healthy. Globalization is not a negative for Helix because we are part of a global organization (Freudenberg-NOK) and that's a comfort area for us. That's what we do – manage our business globally for the benefit of our employees, our customers and their patients.

What will the industry look like in 3 to 5 years?

Luis: The medical device R&D technology will continue to be developed in the U.S. The labor intensive jobs are going to go off-shore, but that is not our focus. To me, the future is very good. I think we'll continue to grow through more robotics and other technologies.

Tom: The market will continue to experience double digit growth and we? will make further acquisitions of innovative companies that have IP of their own. I believe we will see the blending of Big Pharma, Biotech and Medical Devices into a common, therapeutic segment.



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Additional Background Information:

Number of years in business: 24

Current number of employees: cannot disclose

Current square footage: 185,000 sq. ft. spread over four medical device manufacturing operations worldwide

Additional locations: Gloucester, MA; Baldwin Park, CA and Shenzhen, China



Website: www.helixmedical.com

Types of tools built and/or run:

From single cavity prototypes to 128-cavity high production tooling, silicone and thermoplastic tools, cold runner and hot runner tooling, compression, and transfer technology.

Industries served: medical device, health care, pharmaceutical, biotech, and IVD.

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