

'TRIBAL KNOWLEDGE' DEVELOPED OVER SIXTY YEARS

What began as a traditional tool and die shop has now found a niche in the medical contract manufacturing arena – and Oberg Medical shows no signs of abandoning their plans.

Oberg Industries was founded in 1948 and pioneered the use of tungsten carbide in progressive stamping dies. However, having been around for more than 60 years means every so often you have to take a step back, look at your business, and perhaps reinvent some of what you are doing. That is exactly what Oberg did approximately five years ago – they began a strategic planning process that would enable them to carve-out a position within the medical market.

With approximately 650 employees, corporate-wide, Oberg has two main facilities in Pennsylvania, one in Mexico, and one in Costa Rica. Oberg Medical is run out of the Freeport, PA, facility and when talking with Shawn Schafer, vice president sales and market development, a big part of the "Oberg Advantage" is people.

"Oberg has a certified apprentice training program so all of our manufacturing and production employees are trained – with what would amount to a college curriculum – so they all possess very high skill levels, which is really beneficial in the

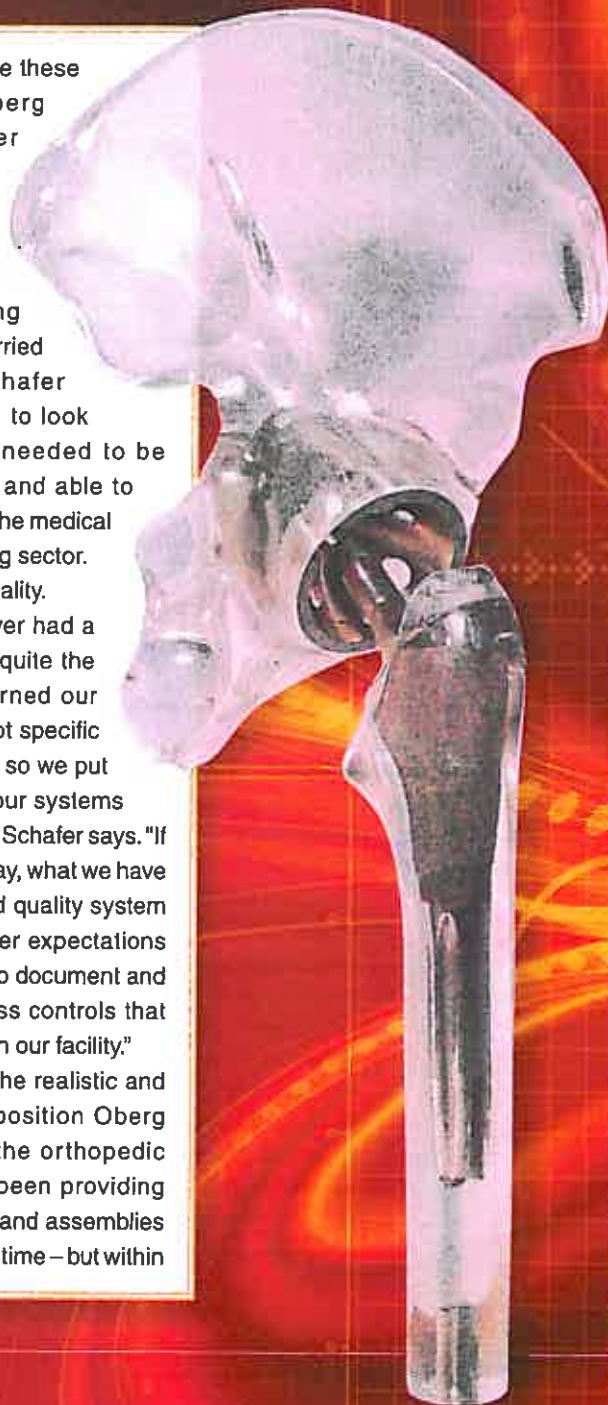
medical market where these skills separate Oberg Medical from other suppliers," Schafer explains.

So, coming out of the strategic planning process and knowing Oberg employees carried high skill sets, Schafer and his team began to look at what more was needed to be competitive, unique and able to hold an advantage in the medical contract manufacturing sector.

The answer was quality.

"Not that Oberg ever had a poor quality system, quite the contrary, but we learned our quality system was not specific to the medical market so we put added emphasis on our systems and process controls," Schafer says. "If you fast forward to today, what we have in place is a very solid quality system that can take customer expectations and translate them into document and manufacturing process controls that we have in place within our facility."

Schafer feels that the realistic and methodical plan to position Oberg Medical not just in the orthopedic space – Oberg had been providing implants, instruments and assemblies in that market for some time – but within



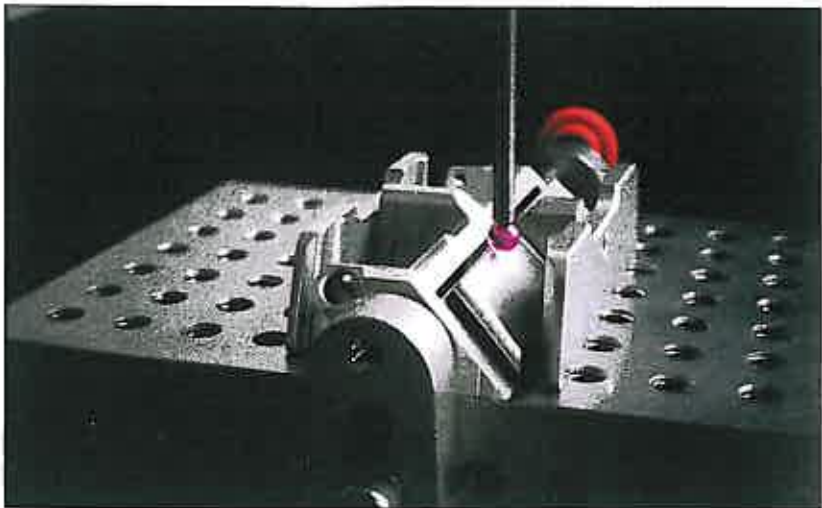
the medical technology space, is what continues to make them attractive to the OEM companies they deal with today. This is especially true as OEMs continue to consolidate their supply base, looking for more services from a fewer number of suppliers in order to manage risk in the supply chain. "We really were diligent and took the time to put these quality systems and processes in place so as these OEMs make supply chain moves, Oberg Medical is able take some of the burden of risk-management off of them, while delivering the services they need," Schafer states.

QUALITY SPEED

Oberg Medical's motto is agility, speed, innovation. However, having a motto and actually living up to it is what matters most in medical manufacturing. Maintaining current certifications and working on continually adding more certifications and registrations is a never-ending process.

Oberg Medical is currently ISO 9001: 2008 certified. In addition, they plan to implement ISO 13485 by January 2010 and are also looking at becoming registered with the Food and Drug Administration (FDA). There is currently a staff of quality engineers who are working exclusively on the FDA registration effort – yet another step Schafer feels will separate Oberg Medical from the pack. Additionally, Oberg's quality assurance organization implements Advanced Product Quality Planning (APQP) techniques and Oberg is also in the process of validating all of their equipment and special processes – heat-treating, cleaning, passivation, laser welding and marking.

After the certifications come the services of a value-added/value-engineering organization.



^ From angles to dimensional features, parts are checked to a resolution of 1micron to maintain consistent part quality.

"There is the traditional model of getting prints and making implants and instruments to customer specification, but today we can offer so much more," Schafer explains. "We look at it as co-development with the OEMs. We offer design engineering services – where our on-staff engineers actually work on customer blueprints and create designs for them – and Oberg is also investigating adding value in the areas of packaging and inspection for customers. Making a part to print that does not meet its' desired function is of little value to medical device OEMs; you must understand how your customers' products function in the field."

The speed at which Oberg can respond to customers is equally as important as the quality they deliver. Rapid turnaround on prototypes and custom components is unique in the sense that Oberg – working with specific OEM customers – offers an internal work cell that modifies standard instrumentation currently in the field for surgeons who may want changes or new features added. Turn-around time for this specialty is 10 days or less.

The other service that is offered along the lines of speed is what Oberg calls the Quick Turn Medical

(QTM) area. "This area offers sets of instruments and or implants, in four weeks or less," Schafer states. "It is not necessarily a launch, but the components are ready to use in cadaver labs, qualification runs, etc. So, once finalized, they are ready to take to production."

Finally, the third piece of the puzzle is Oberg's High Volume Machining (HVM) area, which is where launch manufacturing take place. "Here, the lead time is not always the major concern, as long as we are meeting the critical time lines laid out by our customers," Schafer explains.

PARTS, PROCESSES

A dedicated orthopedic service focuses solely on implants and instruments made of both metal and plastic, but Oberg is involved in other areas. Oberg looks at their client's products from the design for manufacturing angle through evolution of the final product. This enables them to react quickly to manufacture a variety of products.

"In addition to the machining work we offer, we have the stamping business – which means we are talking about higher volume lots, which lends itself to our work in endoscopic

and laparoscopic instrumentation," explains Neil Ashbaugh, senior market specialist. "Then the precision grinding Oberg offers enables us to produce needles – both biopsy and intravenous – and sharps, which can be used in diabetes care, trocars and various blade devices."

The last area that Oberg can mention they active in is the cardiac rhythm management (CRM) device industry – pacemakers, defibrillators, guidewires, leads, etc.

As far as machining, Schafer considers Oberg to be a very multi-axis milling intensive and wire EDM operation. Boasting more than 20 machines in each of these disciplines enables Oberg to respond to the high-volume production requirements. "We perform Swiss operations, and turning is a big component that we are continuing to grow. We are proficient with milling and turning combinations where we utilize Mazak's Integrex machines," Schafer says. "We have also brought many time-critical operations in-house, such as passivation, laser marking and welding and non-sterile packaging, to better serve our customers from a lead-time and cost perspective. OEM's are looking for more services to compliment manufacturing and assembly."

In addition to Mazak, Oberg works with Charmilles, Mitsubishi and Sodick wire EDMs, Deckel-Maho's for their multi-axis milling, Siemens PLM for their programming, and a full line of CMM capabilities with the latest in Zeiss equipment. "Obviously, with the medical projects, Oberg has critical internal documentation controls for our reports to assure that inspection data is gathered and stored properly," Ashbaugh explains. "We are holding device history records (DHR's) on the items we produce for customers for roughly 55 years. So, we understand

that in this market we have to have everything: the best quality, the best parts and the best processes."

KNOWLEDGE

When asked what sets Oberg Medical apart from other contract manufacturers, Schafer is quick to say, "tribal knowledge." The tribal knowledge Schafer refers to is the 60 years of manufacturing techniques which Oberg has developed.

"You can imagine the types of techniques that we have developed for finishing hard materials and, if you look at the materials in the medical industry, you are talking titanium, cobalt chromium, titanium carbide, nitinol and more. As implants continue to move to materials that are harder and longer-lasting, Oberg adds value because we have already worked with very hard materials and we know how to machine them, we know how to grind them, and we bring our 60 years of experience," Schafer explains. "I feel this is one main offering that separates our products from the others."

A final piece of the complexity of Oberg Medical that enables them to continue their growth is their internal R&D test bed – which is not strictly for medical customers. "Any customer can come to us with the next latest and greatest material they want to use to produce their part," Ashbaugh explains. "We have the know-how and the processes setup to do test cuts, to see how the material will react in wire EDM operations. So again, we become an extension of our customer's product development."

At the end of our talk, the parting thoughts from Schafer, was a friendly caution to others looking to enter this market, and that was to make sure that they have a sound quality system



^ Multi-axis machining centers with state-of-the-art controls are dedicated to launch volume medical manufacturing.



^ EDM work cells, used in conjunction with Oberg's multi-axis milling centers, provide them with a strong competitive advantage.

in place, rather than trying to go in and offer capabilities they cannot prove. "I think companies will have a quick exit from the market if they fail to address the quality aspect. By ignoring quality, they may risk not working in the medical contract manufacturing field. This is not an Oberg-centric thought, but medical contract manufacturing is not everything to everybody and companies really have to make sure they fully understand what this market demands of quality assurance before they invest their time and effort," Schafer concludes. **tmd**

Oberg Medical

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