▶ BY BILL KENNEDY, CONTRIBUTING EDITOR

Cost Cures

A medical parts maker works to reduce its customers' costs.

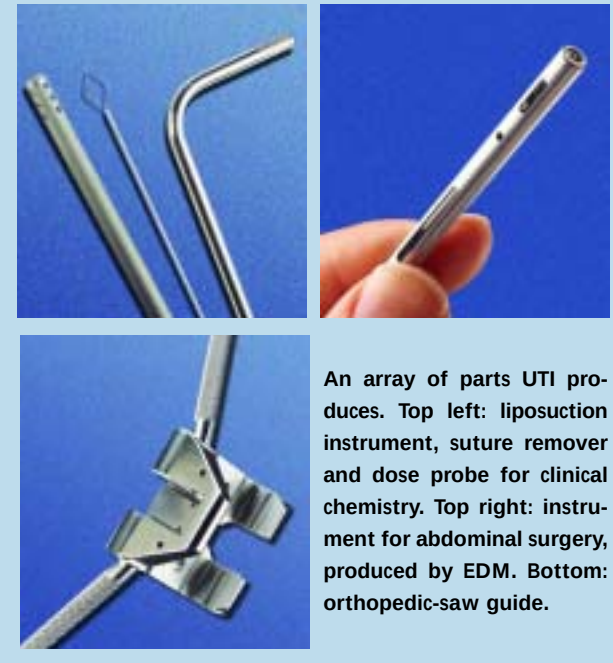
Medical parts manufacturers have long faced rigorous customer requirements and strict regulatory controls. Now, in addition, they are beginning to feel cost-reduction pressures like those affecting most other industries.

One such manufacturer is UTI Corp., Collegeville, Pa., an integrated provider of finished medical devices, assemblies, and metal and plastic components to OEMs. Randy Bormann, general manager of UTI's Design Center, said: "Of course, reliability and quality are critical to our customers. But the medical business has changed in the last 5 years or so. It has a much stronger focus on cost than it ever had before." Bormann said the change reflects heightened public awareness of medical expenses, which have grown to consume more than 15 percent of the U.S. gross domestic product.

The drive for savings has spawned new purchasing relationships. "In the past, the medical industry was selling to the technician, the doctor, the nurse," Bormann said. "Today, it is selling to group purchasing organizations for whom cost is a significant driver."

Manufacturing costs for individual components and inventory expenses are closely scrutinized. "Our customers are looking at every level of their costing structure," Bormann said. "It's the biggest challenge we face. How do we maintain the level of quality—the moral obligation we have to the patients—and still achieve the customer's cost-reduction goals?"

For UTI, the answer is by being innovative in terms of project management, design and application engineering.



An array of parts UTI produces. Top left: liposuction instrument, suture remover and dose probe for clinical chemistry. Top right: instrument for abdominal surgery, produced by EDM. Bottom: orthopedic-saw guide.

All images: UTI

Collective Effort

UTI is comprised of 12 divisions. Their collective capabilities include designing components; contract manufacturing and assembly; CNC machining; electrical discharge machining; and laser cutting.

When a project requires the services of more than one division, it is coordinated through the company's Design Center in Collegeville. The facility has a staff of 25 mechanical and biomedical engineers and customer service representatives, houses a two-shift, full-service machine shop, and has CAD and finite-element-analysis capabilities.

Services are tailored to a customer's needs. For example, UTI works with some of its customers from the earliest development stages. "We have had some projects that literally started as a concept on a cocktail napkin that we managed all the way through to production," Bormann said. (See "From top to bottom" sidebar, page 38.)

Other projects it takes on are beyond the concept stage, but require application-engineering assistance to make a design manufacturable at the lowest possible cost.

"We spend a lot of time in applications engineering, and an equal portion in design engineering, but the primary focus of what we do in the Design Center is the top level of

engineering, which we refer to as 'project management,'" Bormann said.

Management tactics vary to match customer requirements. "For example," Bormann said, "we have some customers who consider 1,000 pieces a year to be normal production volume, while there are others who, although it's fairly rare in the medical device business, consider 750,000 pieces a year normal. The customer who only needs 1,000 pieces a year is looking for the same kind of cost controls as the customer who buys 750,000."

When a low-volume customer seeks cost reductions, UTI presents a two-part solution. First is application-engineering assistance, which is intended to cut costs out of the manufacturing process. While such optimization might be difficult with a low-volume part, UTI sees the effort as a good business practice. Bormann said, "If the customer who only needs 1,000 pieces a year is in a marketplace that is buying 50,000 a year, any contribution that we can make to lowering his costs may be a contribution to increasing his market share, which ultimately will lead to larger volumes for us."

The second part of the solution balances delivery with manufacturing efficiency. "We work with that 1,000-piece customer on guarantees regarding what he will accept over the course of a 12-month period," Bormann said. "As a result of that guarantee, we build that product in whatever is our best lot size. We may have semifinished or finished goods sitting on our shelves for 3 to 6 months, but the benefits of building a strong customer relationship far outweigh the potential financial risk."

On the other hand, UTI's high-volume customers realize that a large inventory of finished goods will ultimately increase their costs, so they look to push inventory levels down.

Tim Hoklas, vice president of manufacturing at UTI's Spectrum Manufacturing Division, in Chicago, said UTI works closely with its customers, determining demand "on a monthly basis, weekly basis or daily basis, for that matter, and adjusting accordingly."

UTI will physically alter its manufacturing setup to maximize efficiency on long production runs. "For high volumes, we actually pick up machines and move them around to create a cell," he said.

However, it's not as simple as just calling a rigger and shuffling equipment. Hoklas explained: "There are some things that have to happen in the medical field. We have to notify the customer and let him know we are moving equipment and make sure that nothing has changed once we've moved it. We then have to revalidate the machine itself and the process."

Machine Investments

UTI is "not shy" about acquiring new equipment to boost capacity and productivity. For example, Bormann described the manufacture of a skin-piercing device called a trocar, which was machined from 17-4 stainless steel at UTI's Spectrum facility. The part had been produced on a Swiss-style screw machine and took about 1 minute and 40 seconds to complete.

Advances in Swiss machining technology prompted UTI to upgrade to a Traub TNL12 11-axis, sliding-head CNC Swiss lathe. The new machine cost twice as much as its predecessor, but because the Traub can run at higher speeds and is heavier and more rigid, it can remove larger quantities of material faster. "We doubled our capital investment, but we reduced cycle time on that part down to 26 seconds," Bormann said. "We gain-shared the cost savings with the customer, even though we took the risk of buying capital equipment and performing the validation and testing that was necessary to prove the customer was getting an equivalent part."

The fairly simple part was costing the customer less than $2 each; the upgraded machine enabled UTI to reduce the customer's cost by 30 percent.

Acquiring new equipment has allowed UTI to assist customers other ways, too. One is by helping them deal with the increasingly short life cycles of their products. As an example, Bormann described the evolution of coronary stents—tiny metal tubes placed in arteries to keep them open. Johnson & Johnson introduced metal stents in the 1990s. Within a year, competitors introduced similar products, and in less than 3 years, the market was divided among a few major players. The technology was maturing and becoming cost-driven.

Now, Bormann said, Johnson & Johnson is marketing a new family of stents with timed-release drug coatings. Competitors are within months of offering similar products, and the market is already reflecting the impact this will have on the sale price. "Because product life cycles are very short," he said, "when we enter a manufacturing relationship, we have to be thinking how we can control product costs so

From tube maker to supply-chain manager

A.H. Mainwaring founded Uniform Tubes Inc. in 1940 to produce miniature nonferrous tubing. Uniform Tubes formed UTI Corp. in 1969 as a holding company whose purpose was to acquire companies and become an integrated resource for designers and manufacturers. Today, it consists of 12 divisions, located throughout North America and overseas.

UTI built its organization to address customer demand for an integrated provider of design and manufacturing services. In many cases, the relationship is not unlike that of the automakers to their Tier 1 suppliers.

"You'd be surprised by the number of people that the medical industry has intentionally sought from the automotive and electronics industry because of their background in inventory control and cost reduction," said UTI's Randy Bormann.

UTI's structure is a response to industry's overall trend toward supplier consolidation. "Our customers no longer have the resources to go out and seek 25 vendors for 25 different components to go into an assembly," Bormann said. "They are looking for someone to take that responsibility over for them. They are looking for someone to manage the supply chain."

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that our customer can maintain a cost advantage, even when they no longer have a technical advantage."

Continuous Improvement

In the same way that increased cost pressures have infiltrated the medical parts industry, so have quality initiatives from other industries. One such initiative is Six Sigma, which started at Motorola.

"Six Sigma is beginning to roll through the medical industry like a tank right now," Bormann said, noting that Six Sigma is part of the companywide quality initiative at UTI. "That's the direction everyone is talking about going. Again, it's not just a matter of a good quality part; it's a matter of a good quality system that is effective from the highest levels of management to the person responsible for shipping the product. Our responsibility is to provide our customer with the confidence that our system precludes their need to duplicate our quality-assurance efforts. The only way to accomplish that is via a system that affects our processes from top to bottom."

UTI constantly seeks ways to optimize its machining operations. "Once a project has graduated to a production environment, we look for continuous improvement," Hoklas said. "We sit down as a team, decide on where to start and over 6 months to a year, track

From top to bottom

A medical part manufactured at UTI crosses a range of engineering, design and manufacturing disciplines, as well as testing and regulatory checkpoints, on its path from concept to full production.

At the initial meeting, the customer and UTI's R&D design and manufacturing engineers define the basic concept and scope of the project. For an existing endoscopic surgical device, for example, the goal might be improvements in ergonomics and performance, such as better cutting ability and tighter maneuverability. UTI names a project manager—an engineer—to serve as the single point of customer contact until full production is achieved.

Focusing on meeting functional requirements, UTI employs 3-D computer modeling to combine basic product specifications with the desired improvements. This part of the process typically consumes 2 to 10 weeks, depending on the complexity of the design.

The customer reviews the electronic model and may also evaluate a nonfunctional, tangible prototype produced via the stereolithography process.

At this point, functional requirements meet cost considerations. "Sometimes, the impact can be dramatic, with the new version costing twice as much as the existing design," said UTI's Randy Bormann.

Next, UTI's Design Center makes a series of working prototypes from materials suitable for the product's function. "Typically, we use stainless steel that is close to the final requirement and various machinable plastics that imitate the performance of molded plastics," Bormann said.

Depending on how the customer plans to test the part, UTI may produce one prototype or as many as 50. The prototype phase can take 2 to 6 weeks. Initial testing of the prototypes follows. If the part is an instrument, basic tissue testing may be performed.

After final modifications, UTI builds a final group of prototypes, which may consist of 100 to 250 pieces, depending on the amount of destructive testing necessary. The final prototyping process can involve five or more UTI facilities: one or more facilities for raw materials in the form of tubing, the Chicago facility for secondary manufacturing, and the California facility for plastic and mold tooling expertise. The contract manufacturing facility in Texas may provide assembly guidance. After final prototype testing, which may involve animal or anatomical model testing, the design is frozen—no more changes are made.

UTI's various divisions work together to provide a complete package for its customers—everything from design to prototyping to production.

Test data are used to build clinical testing products at the manufacturing facility where the part ultimately will be produced. "By the time our customers get to the clinical trial stage, they want devices produced using methodologies that are an exact replication of the production intent," Bormann said. "A heart valve, for example, may require thousands of parts in various sizes for testing purposes." The result is a package of data that prove product effectiveness.

When the product is deemed ready for production, the Design Center transmits accumulated product information to the manufacturing facility that will build the clinical testing products. The project manager retains responsibility until the product has been manufactured for 3 consecutive months without any quality issues arising and 100 percent on-time delivery. Results are confirmed through random inspections. When the quality and delivery goals have been achieved, responsibility shifts to the production facility.

During production, UTI works with the customer to provide continuous improvement and cost reductions. UTI often contracts a gain-sharing program, wherein it takes responsibility for finding, testing and validating improvement opportunities. Under a gain-sharing agreement, UTI and the customer split the cost-reduction benefits 50-50.

Bormann said the entire concept-to-production process could take from 6 months to 2½ years, depending on project complexity. A typical timeframe is 18 to 24 months.

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down bottlenecks and address them."

However, optimization doesn't necessarily mean machining at extremely high speeds and feeds. "If you go pedal to the metal, you may be burning up tools and changing them constantly to get your process back on track," Hoklas said.

UTI takes a moderate approach, seeking to minimize the time spent changing tools, making corrections and setting offsets. "That provides a more stable process, which gives you a higher C_pk (a measure of process capability) and better parts," Hoklas said.

This ability to make "better parts"—and make parts better through continual process improvements—keeps UTI healthy in today's highly competitive, demanding medical market.

Better materials create machining challenges

A significant portion of UTI's application-engineering work deals with a stream of new materials employed by medical part designers to improve product performance.

An example is L-605, a tough, corrosion-resistant cobalt-nickel alloy. Joint replacements manufactured from L-605 last a long time, but the material is difficult to machine. Because the parts are cast near-net shape, machining operations are usually of the low-feed, high-precision finishing variety. UTI's Tim Hoklas said UTI generally cuts the alloy with coated-carbide cutters, some of which incorporate special UTI-developed geometries.

Another material that is growing in medical applications is NiTinol, a nickel-titanium shape-memory alloy that changes shape when heated, exhibits superelasticity at body temperature and is biocompatible. It is an excellent material for coronary stents, but its characteristics also pose a machining challenge. UTI employs noncontact techniques such as EDMing for most of its machining of NiTinol and uses power settings that "are fairly low, because you can't put a lot of heat into the part," Hoklas said.

—B. Kennedy