

Medical Product OUTSOURCING

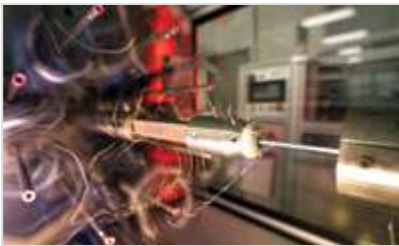
Going the Extra Mile

Tubing Providers Tackle MIS, Other Tricky Needs While Adding Value Through Additional Services and Processes

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Years ago, neurosurgery was a procedure that could evoke nightmares, given what was involved. After drilling several holes into a skull, a surgeon would then remove the skullcap to reach brain matter. It's not difficult to surmise that a long, probably painful patient recovery would follow.

Similarly, patients undergoing spinal procedures used to be sliced open by as much as eight inches—and sometimes the surgeon would have to cut into the front of the body to reach the affected area of the spine.



By changing several factors during the braiding process, the characteristics of the tube can be altered to fit performance requirements. Photo courtesy of Precision Extrusion.

Looking back at these examples of what used to occur in the operating room, it's easy to see why the growth of minimally invasive surgery (MIS) has affected nearly every component-maker in the medical device industry. The extrusion industry especially has benefited from this trend, seeing continued double-digit gains as inventors of the latest sophisticated technology turn to tubing partners for help with everything from design to manufacturing to inventory control.

These days, the motto is, the less trauma to the patient, the better. That's one reason tubing manufacturers say they are seeing a lot of new business focus on single-use sterile devices to aid MIS procedures. Considering the above examples of historically invasive procedures, neurosurgery now often is accomplished by snaking tubes through an artery from the leg or arm rather than removing the skullcap, and spinal procedures are conducted through a tube used as a tunnel that provides a direct portal for surgical instruments and fluids to reach the affected area.

"New product development to leapfrog the current technology on the market appears to be more of a driver than re-engineering existing products," said Rick Bonovitz, director of sales and marketing, healthcare division, for Baraboo, WI-based Teel Plastics. "The trend is toward smaller, thinner, tighter tolerance and more complex tubing designs."

Indeed, in some applications today's medical tubing can be smaller than the stirrer in your coffee cup. Therefore, tight tolerance becomes imperative to the engineers creating these designs. One of the most common questions an extruder is asked by a customer is, "How low can you go?" As such, the need for tight tolerance still tops the list of challenges extrusion providers face every day.

"Five years ago, people expected us to hold tolerance of .005. Now you should add another zero. It's exponentially more difficult," said Patrick Pickerell, president of Pleasanton, CA-based Peridot Corporation. "We've had to refine our techniques, increase our quality and scrutinize processes underway, and, in many cases, we are forced to build an extra sort and screen for these tolerances."

It's this type of expert knowledge of processes, designs and materials that is growing the extruder's role as an extension of a medical device OEM as more product work is outsourced.

A Paradigm Shift

The size of the customer's business often dictates how involved the tubing provider will be in the earlier stages of product development. The largest medical device giants, armed with vast internal resources, usually provide extruders with a detailed design. Smaller companies—particularly startups headed by, say, a doctor with a big idea but little know-how—often come to an extruder with little more than the proverbial design on a napkin.



At the top of the list for challenges for extrusion providers is tighter tolerances. The answer has been refining techniques, increasing quality and scrutinizing processes. Photo courtesy of MRPC.

“Big corporate design teams have dotted all the i's and crossed all the t's and they're certain about what they want. The little guy, on the other hand, is more interested in calling you and talking about what he wants to do because he's not quite sure about materials, hardness, stiffness...the new inventors heading small companies may have come from bigger companies and have an idea they want to capitalize on. They had enough experience or knowledge about the idea that it made sense to do it, but they don't have the fine detail knowledge,” explained Mike Badera, president of Glens Falls, NY-based Precision Extrusion, Inc.

Geary Havran, president of NDH Medical in St. Petersburg, FL, noted that “what's changing with the customer relationship is that companies are asking for more of their suppliers in terms of engineering expertise, full participation in design programs. They are expecting suppliers to be a lot more familiar with the product approval process and are relying more on component suppliers to help specify the finished device rather than previously just producing an engineering drawing.”

Since many new tubing customers are inventors backed by venture capital, these individuals often need the extruder to create a sound product that can be launched and then snapped up by a larger OEM to be commercialized. Therefore, getting in at the ground level is important for a tubing provider—these companies know that once a client has found a service provider it trusts, neither the original inventor nor a new owner would want to shift the work to someone else down the line.

“We view our capabilities as an extension of those of our customers. We are working closer with customers who require validations of all critical elements of the ‘process,’ which means earlier involvement and more definition and detail within the process of manufacturing,” said Scott Pakenham, VP, marketing and sales, for Butler, WI-based MRPC. “The challenge to contract manufacturing companies...is to come up on the learning curve quickly, developing flexibility within the organization, keeping within the new technologies while demonstrating core competency.”

While the mentality among many contract service providers has shifted toward more of one-stop shop, that doesn't mean everyone is looking to be everything to everyone. Many extruders simply are enhancing existing services. MicroLumen in Tampa, FL, for example, found that many customers were asking for certain value-added services, such as hole drilling, multi-durometer constructions and market band embedment. These in-house services save time and prevent clients from having to qualify and use another

supplier for secondary purposes. In addition, tipping or flaring the end of the tube is also offered for customer convenience, said Krissi Heard, who works in technical sales for MicroLumen.

Filtrona Extrusion also has been ramping up some of its capabilities. “We’re finding as outsourcing grows, we’re not only being called on to do extrusion anymore,” said Richard Brooks, vice president, sales and marketing, for Filtrona Extrusion’s Athol and Northborough, MA facilities. “We’ve evolved and are called to do more subassemblies. Our core competency is extruding, but customers will ask if we can provide certain assemblies as well.”

Superior Tube Company, Inc., based in Collegeville, PA, has been adding value through its nondestructive testing process. “We can ensure that at finish or at an in-process size, our process controls are maintaining quality—defect-free—to meet or exceed what that tube is intended to do. Process control is something we’ve been pushing very hard with and have made a lot of strides,” said Jeff Warden, vice president of business development.

Along with these tasks, OEMs need more help with inventory control and ensuring just-in-time delivery. Devising a smart inventory setup has grown increasingly important for tubing providers, since more customers want their outsourcing partner to store the inventory and be able to provide product at a moment’s notice.



Precision thermoplastic medical extrusions are being produced in this cleanroom. Photo courtesy of Filtrona Extrusion.

Jim Dandeneau, president of Dayville, CT-based Putnam Plastics, said, “As companies continue to outsource, we are working closely with supply chain managers and purchasing personnel to manage their inventory through kanban and integrated software programs.”

On top of all these examples of bells and whistles that give extrusion providers an extra edge in the marketplace, the best strategy is the simplest: it’s all about exceptional customer service.

“We pride ourselves on quality and delivery and ease of customer service,” said Bob Poirer, VP of sales for Dunn Industries in Manchester, NH. “If you service the customer, you’re going to get a lot of business. You can’t say you’re going to deliver a product in two weeks and then not correspond and get it to them in six weeks. You can’t promise the world and give them nothing. If you don’t react quickly, they will go to your competitor.”

Time Is Money

Poirer’s comments raise an important evolution in the medical device industry that affects just about any supplier. As any tubing professional will tell you, purchasing agents for OEMs want to get more product for less money and in less time.

Additional labor shifts, leased space and equipment purchases are some of the solutions extrusion companies are incorporating to meet these demands.

Pickerell of Peridot recalled one client who had an upcoming clinical trial scheduled in Mexico, where a number of prominent gynecologists would participate, and needed her tubing components made within an

extremely tight time frame. The customer told Pickerell that these physicians have packed schedules and, thus, could not accommodate any rescheduling if the product weren't ready in time. If she didn't get her product made on time—and couldn't complete the trial—she would lose her next round of venture capital...and lose any chance of getting the product to market.

"It got down to an amazing crunch time, and we delivered," Pickerell recalled. "We poured so much overtime into the project. I presented my staff the same plea that she did—I had to rally the troops."

In many cases, clients don't fine-tune their tubing designs until the end of the planning stage; thus, tubing providers often face customers who have eaten up their lead times with other processes and then look to the component maker to make up the lost time.

Timing issues also abound in the form of customer forecasting. Usually an OEM can't precisely predict how much product will be needed in a coming year, which means an extruder is left to calculate how much capacity to reserve.

"As a contract manufacturer, you learn to incorporate variables into your planning process and do the best you can to compensate for fluctuations or lack of forecasting ability. It all boils down to communicating with customers. If we don't ask, we're likely not to be told," Havran explained.

Along with timing, the rising cost for raw materials has impacted some extruders and their customers. In general, the issue of price often rests with the product being made. If an application requires a small tube that doesn't weigh much, a spike in the price for raw materials won't affect the suppliers as much. However, companies making larger tubes often have to pass along their cost increases to their customers.

"The increase in raw material is being felt in the higher-volume tubing area," said Dandeneau. "We have adopted a strategy of partnering with our customers to secure longer-term contracts, which, in turn, permits us to lock in pricing on raw materials for a longer time frame. The smaller specialty extrusion market is not as affected by raw material, as the material is a smaller percentage of the overall cost."

That doesn't mean attention isn't being paid toward offsetting any increases through innovative means. As any extruder knows, the faster you can extrude, the more feet per minute are produced and the cheaper the charge. Thus, increasing production output is one method to decrease cost. Filtrona has been double- and triple-stranding its extrusion process—that is, having two or three strands come out of the same machine at once.

Knowledge can really aid a company looking to keep costs down. Some tubing providers are keeping costs low by searching in-house for any inefficiencies in their internal manufacturing processes. "From a quality standpoint, we're looking to identify any flaw in our process that could create rejects," noted Heard of MicroLumen. "We've monitored and measured areas where we could improve yields and salvage raw materials."

The bottom line is that today's extrusion specialists are proactively approaching their clients' needs with knowledge, skill, sophisticated technology and processes as well as any number of value-added services. They understand that OEM customers are burdened enough with maintaining market share and coming up with the next great innovative design that will take the medical device industry by storm.

"Tubing is complicated enough...if you want tubing for any application where people's lives are at risk, you want specialists to help you. That's what we do, and our knowledge is ingrained," said Warden of Superior Tube.