Extrusion p. 62-69.qxd 2/21/06 4:33 PM Page 62

Stretching Thin: Extruders Facing Multiple Pressures

As challenges mount, the extrusion industry examines alternatives to previous approaches.



High temperature extruders reaching 800°F are required to extrude melt-processable fluoropolymers. Photo courtesy of Zeus, Inc.

One word can sum up the current state of the extrusion industry: challenging. Tolerances are tightening, lead times are shrinking and the cost of plastics are rising due to higher petroleum prices. Thus, extruders are faced with new obstacles in timing, scheduling and maintaining their bottom line.

As OEMs increasingly turn to extruders for help in finding cost-saving alternatives and time-saving solutions, extrusion companies are building trust and relationships with customers as they face the challenges head on.

Lead Time Is Money

As any extruder knows, OEMs constantly need their products manufactured quickly in an attempt to rush them to market before their competition. And the factors that contribute to these ever-shortening lead times are varied. For example, since the research and development phase for OEMs is being shortened, production schedules are consequently being ramped up, forcing extruders to bear some of the burden as OEMs decrease time to market in an attempt to maintain a competitive edge.

With lead times dwindling and pressures mounting, many have responded to the faster cycle by designing and manufacturing their own dies and tooling in-house. Furthermore, other extruders have either improved their communication channels with raw material suppliers or modified their production schedules to handle last-minute requests.

"We are turning parts around in two to three weeks, and we can go the next day if we have tooling; it depends on not who the customer is, but on what we have scheduled," said Bob Poirier, vice president of Manchester, NH-based Dunn Industries. "If someone comes to us on a Monday and says, 'We need something tomorrow,' and it's early in the morning, we can probably set that up at the end of the day and run it."

For extruders that rely on outside vendors for tooling and materials, communication is key in handling the shorter lead times that OEMs demand. Jim Ward, president of Birmingham, AL-based FBK Medical Tubing, Inc., noted, "If it's a new [material] that no one has ever made before, then we've got to work with [those suppliers] to get that compounded and there's a time factor in that."

Rick Bonovitz, director of Sales &

Chris Trembath
Associate Editor

Extrusion p. 62-69.qxd 2/21/06 5:18 PM Page 64

Marketing for Baraboo, WI-based Teel Plastics's Healthcare Division, believes that an extruder's lead time is directly affected by the complexity of the customer's design as well as whether new equipment and compounding will be required to make a device component.

"There is no standard turnaround time as it relates to product development and design, but the most successful companies will be those that can react quickly with a reliable product," said Bonovitz.

Tolerating the Need for Precision

As minimally invasive surgical trends continue to grow in the medical industry, items such as catheters are being designed much smaller to reach parts of the body at the neurological level. As a result, extruders are being pressured to push the limits of what is possible.

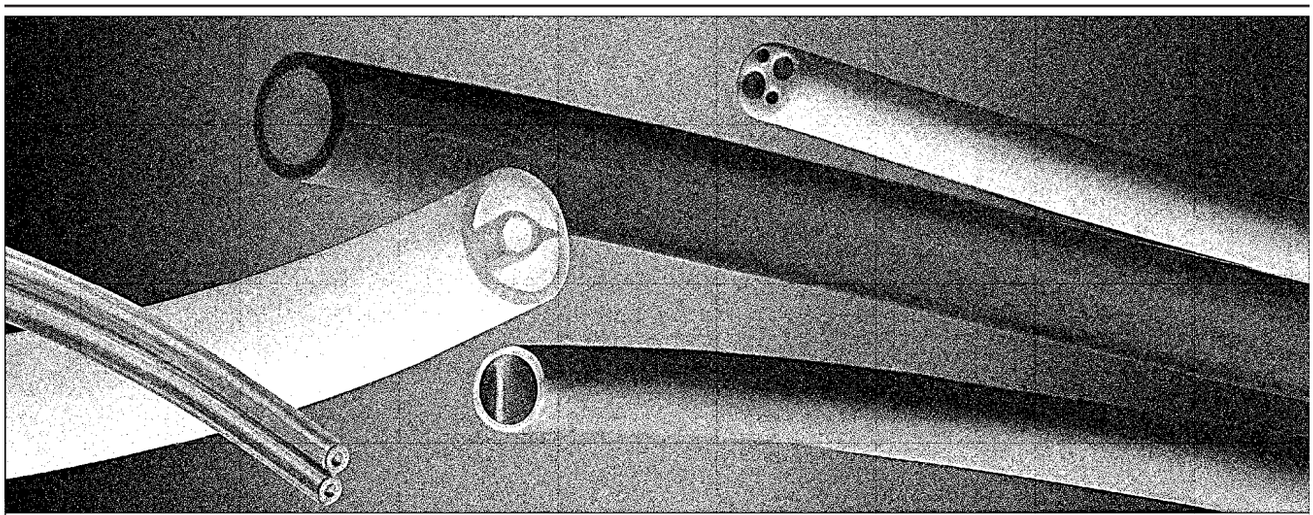
"People are trying new procedures in never before explored areas of the human body, and to get into those areas, they're trying to put more into a smaller catheter," said Mike Badera, president of Glen Falls, NY-based Precision Extrusion.

To accommodate these needs, extruders are often being asked to ensure the utmost precision by creating components with extremely tight tolerances. As a result, extruders are often using highly engineered materials to maintain sturdiness and durability while maintaining smaller diameters and thinner walls. Even though tolerances have reached parameters as small as two thousandths of an inch (and often less), the difficulty is sustaining the tolerance over long production runs. Therefore, many extruders simply try to live within an acceptable range of tolerance, which averages around five thousandths of an inch.

Although minimally invasive surgery (and minimizing trauma) to the patient is the primary catalyst for low tolerances, it is not the only one. Machinery used to join extruded components to other devices often requires extrusions that adhere to specific dimensions. According to Ward of FBK Medical Tubing, "if these parameters are not met, assembly might not proceed or machinery could possibly jam, bringing production to a halt."

Price Concerns Elevating

The main material used by extruders is plastic, which is derived from petro-



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Extrusion p. 62-69.qxd 2/21/06 4:33 PM Page 65



A technician monitors extrusion equipment at Oscor's Palm Harbor, FL facility. Photo by James Johannessen, provided courtesy of Oscor, Inc.

leum. As anyone who drives a car (and has paid at the gas pump lately) knows, petroleum has become increasingly expensive.

According to Sean Lynn, associate director for extrusion R&D at the Ireland-based facility of Teleflex Medical OEM (headquartered in Bannockburn, IL), "Virtually all commercially used medical plastics are derived from oil."

While Lynn believes the high costs associated with petroleum affect every extruder using plastics derived from this resource, he also noted these costs are even more problematic for companies that manufacture high volume, commodity medical tubing for applications such as extension sets for IVs.

While some extruders have been able to absorb the increasing cost of plastics by either refining their tooling operations, investing in automated equipment to reduce labor costs or minimizing yield losses, others see the increase as marginal based on the type and volume of tubing they extrude.

"The cost of the plastic itself in the really high tech, low volume applications is very small compared to the setup time and labor that goes into making the tube," Badera noted.

Other companies that do not extrude petroleum-based plastics have not been directly affected by the elevated petroleum prices, but they still have been faced with increasing shipping costs (due to fuel prices) and higher utility bills due to the energy needed to extrude

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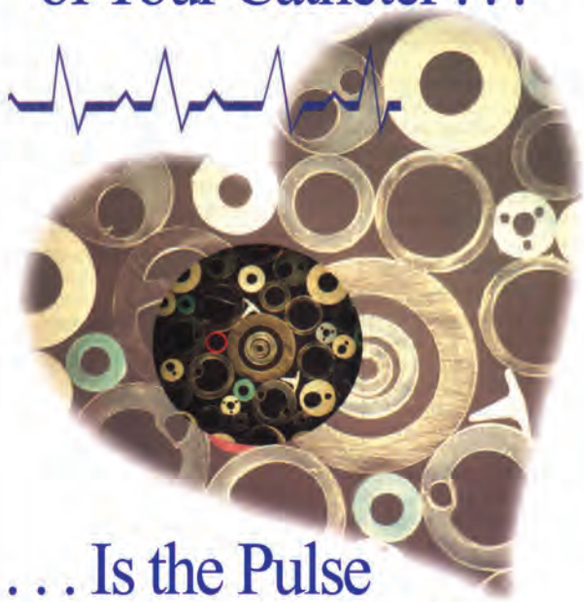

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Extrusion p. 62-69.qxd 2/21/06 4:33 PM Page 66

those materials.

Regardless of the methodology used to curtail rising resin costs, the increase has forced extruders to formulate new price structures or streamline manufacturing processes to minimize the cost to their OEMs.

Material Choices Abound

With many resins at an all-time high, a renewed interest has been sparked in exploring new materials. Traditionally, PVC has been the most popular choice of resin for medical extrusions. However, it is not without concerns. Some are minor, such as offensive odors and taste, while others are major—such as possible carcinogenic potential (though there is no conclusive evidence to support this) and disposal issues (ie, environmental impact). In addition, some types of "softeners" used to make PVC more flexible in tubing components present similar concerns. Therefore, extruders reported that many medical device manufacturers are turning to them for alternative solutions.

"The industry is trying to get away from PVC because when it's disposed of, it's burned and it releases chlorine gas, an environmental toxin," said Poirier.

Though the trend might be to shift away from PVC, many extruders believe it will be difficult to find a direct replacement that offers the many benefits this plastic provides at the same price.

"Some alternatives are out there that cost 10 times as much, but customers won't pay for it," said Badera.

Bonovitz agreed, noting, "There is always an interest in finding an alternative for PVC. [Opportunities are] always on the horizon, but matching the properties of PVC at the same or lower cost is the challenge."

Some extruders believe that the shift away from PVC is purely a mater of economics. Ward pointed out that as the cost of PVC increases due to rising petroleum prices, alternate materials are becoming more attractive.

"While PVC is still the least expensive resin, you're starting to see more and more people going away from PVC partly because the recent increase in cost makes it easier to justify using a different material." said Ward.



Extrusion p. 62-69.qxd 2/21/06 4:34 PM Page 67

How Far Does Extrusion Stretch Offshore?

In years to come, extruders need to decide whether the ever-growing issue of offshore outsourcing to China or Mexico will be an advantage or a downside to their industry.

Currently, offshore outsourcing consists primarily of high-volume, low technology, commodity extrusions such as IV tubing and syringes. Additionally, secondary operations such as over-molding, tipping, hole punching, and turnkey packaging have been outsourced offshore.

However, low-volume, higher technology extrusion remains here in the United States, and most extruders agree that quality is the key factor in keeping that business.

"My customers come to me because they're looking for a high tech extrusion—they're looking for someone who can consistently meet their lean time requirements, who can consistently meet their quality and tolerance requirements…and the tighter those get, the harder those are to outsource, especially out of the country," said Mike Badera, president of Glen Falls, NY-based Precision Extrusion.

To that end, Bob Poirier, vice president of Manchester, NH-based Dunn Industries, noted that China will take five to 10 years before it can compete with the United States on a technological and quality level.

While some extruders deal with offshore outsourcing domestically, others have actually embraced the concept by opening facilities on foreign soil. For instance, Oscor, Inc. recently opened a 15,000 square-foot plant in the Dominican Republic that helps the company stay competitive in the global arena.

"Since opening the offshore facility, we've seen a dramatic increase in our business," said Tom Osypka, president and CEO of Palm Harbor, FL-based Oscor, Inc. "Once [OEMs] have a product approved and it's ready for mass production, they're very happy that we can offer them a cost savings by providing high volume assembly services instead of them having to switch companies."

Aside from a cost benefit, offshore outsourcing has its downside. Communications between parties is often difficult because of language barriers, shipping issues and intellectual property concerns that come into play due to a lack of protection laws between China and the United States. Further, supply chain concerns such an inventory play a part in determining offshore outsourcing decisions.

"Companies like to keep their inventories low. If, for some reason, an offshore supplier can't get the shipment to you in time, then you're out of product," said Jim Ward, president of Birmingham, AL-based FBK Medical Tubing, Inc. "Most people who deal with offshore manufacturers keep a significant amount of inventory here in the United States, and there's a cost associated with that."

Conversely, some extruders see China as a growing market because, as its healthcare system improves and the population ages, the nation will become more dependent on US technology.

Regardless of how offshore outsourcing is categorized, the sooner US extruders factor China and Mexico into their long-term business plans, the better off they'll probably be.—*CT*

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Extrusion p. 62-69.qxd 2/21/06 4:34 PM Page 68



Operators tend to a PTFE extruding machine. Photo courtesy of Zeus, Inc.

To help anticipate OEM challenges for more cost-effective (and less environmentally taxing) solutions, extruders are increasingly evaluating the potential of materials such as silicone, nylons and polyurethanes.

"These material groups provide easy processing and at the same time have a great biocompatibility and approval history," explained Tom Osypka, president and CEO of Palm Harbor, FL-based Oscor, Inc.

Additionally, the industry is seeing increased interest in a material called PEEK. Despite its higher price tag, Lynn noted that PEEK has excellent mechanical properties, chemical resistance and can be extruded to very tight tolerances.

One particular challenge that extruders face is the request for tubes to have less friction (lubricity), because minimally invasive procedures now require more instruments and guide wires to be inserted into smaller tubing.

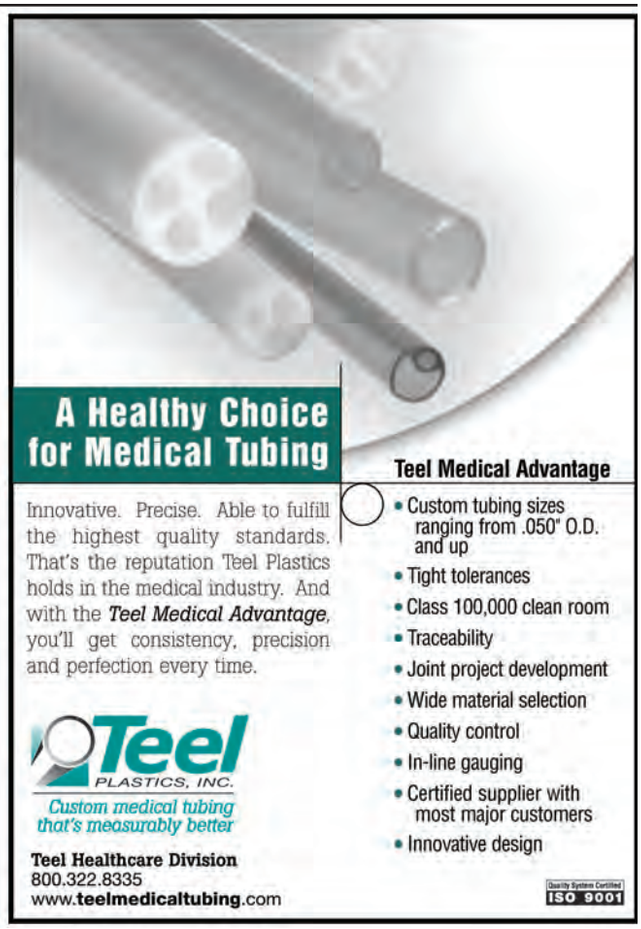
To accommodate these requests, extruders are constantly trying to identify new methods to help reduce friction problems, such as by lining the inside of catheters with Teflon-based materials. (This is known in the industry as co-extrusion.) As may be expected, these additional efforts can further elevate costs to the OEM but minimize friction problems.

Obtaining and Maintaining Customers

For most extruders, getting in at the inception of an OEM's design is key to obtaining new business.

"If we're the ones doing the R&D





Extrusion p. 62-69.qxd 2/21/06 4:34 PM Page 69

from the extrusion side for that medical OEM at the beginning, then odds are when it's time to go to market, our name is going to be on the specification as the supplier for that tube, and we will get that business," said Richard Brooks, vice president of Sales and Marketing for the Northborough, MA plant of Atlanta, GA-based Filtrona Extrusion, Inc."

Extruders also try to vertically integrate themselves into the entire production cycle of a device from concept to fulfillment. Helping an OEM with design concepts, choosing appropriate resins, prototyping and testing are just a few ways an extruder can help secure business. And by providing assembly, post-extrusion and fulfillment services, OEMs are finding that a "one stop shop" offers cost advantages.

But once an extruder secures the business, the challenge is keeping it, and the resounding reasons that keep OEMs partnered with their outsourcing counterparts are quality, trust and expertise.

"We have very good relationships with our medical device manufacturers and they know us very well," said Karl Graffte, director of marketing Zeus Industrial Products in Orangeburg, SC. "They understand that we have quality systems in place and we have a very good, very established quality system."

In the end, what extruders and OEMs are looking for is a win-win situation, and once they can ignore the fact that two ownerships exist, a strong partnership takes root and grows into trust.

"If the customer is able to work on a multilevel basis with your company and quality and service meets or exceeds expectations, then trust evolves," Bonovitz said.

One Invariable Truth

Amid all the new resins, techniques and business strategies, one concept remains steadfast: choice. The outsourcing trend is growing and OEMs can choose from many extrusion providers.

As Bonovitz summarized the industry: "Many things have changed over time but the key to gaining and maintaining business is still price, quality and service. If you add value, it is more difficult to be replaced." ❖

