Tubing and Extrusion Trends Yield More Material Options

The growing demand for minimally invasive medical devices is creating the need for more high-tech tubing and extrusion alternatives. This article examines the challenges facing medical product manufacturers and offers some clear solutions.

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&#149 IV bags and fluid/gas set

TPR offers silkiness, flexibility, and the stretch properties of latex at a much lower cost. It is finding increasing use in chest drainage systems and blood pressure cuff tubing.

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By Richard Brooks and Richard LaFreniere
Medical product manufacturers and their tubing suppliers are facing an array of challenges as medical devices become more sophisticated, lead times shorten for developing product solutions, OEMs increase their outsourcing requirements, and pressures continue to mount on the use of some key traditional, functional, and economically preferable materials.

The demand for more sophisticated medical devices is prompting the need for more high-tech tubing and extrusion products. Medical device manufacturers are especially looking to develop minimally invasive devices. As a result, paired-tubes (paratubing) and multi-lumen tubes are now designed and utilized to carry multiple fluids, gases, or electrical current simultaneously during a single medical procedure

or application.

In one advanced medical procedure for women, a newly developed impedance-controlled endometrial ablation system uses paired tubing and paired electrical conductors that are thermo-bonded together in a procedure designed as an alternative to hysterectomy, conventional endometrial ablation, and hormone therapy.

For a non-surgical procedure, paratubing is used in an assisted breast biopsy device. Irrigation and anesthesia are sent to the biopsy site through the tubing, which also uses air and suction to capture tissue culture. This device is the only one commercially available that operates under MRI guidance and gives women in the “high risk” category for breast disease a fast and easy biopsy option over surgery.

Manufacturers are also demanding tighter specifications and thinner walls for catheters. They need strength and stability combined with thinner walls to reduce the impact of trauma associated with the introduction of the catheter into the vascular system. To meet the demands for ever-thinner walls, tubing has been introduced with a wall thickness of 0.008 in. for use as a vascular catheter.

Outsourcing Increasing

As more OEMs focus on the R&D, design, regulatory issues, and marketing of new medical devices, they are outsourcing much more of their manufacturing and assembly operations to contract manufacturers. Both OEMs and contract manufacturers are requiring shorter lead times from their suppliers for engineering and development projects. As a result, custom medical extrusion companies are facing a strong impetus to become more vertically integrated, offering “one stop shopping”&#151design, development, extrusion, and assembly. This includes the addition of sub-assembly of components and packaging, which provides extra value to the core business of extruding tubing products.

For example, some custom extrusion companies are now more likely to make the base tube for a catheter and also offer all the post-fabrication operations required to complete the catheter including irrigation holes, tipping, and even printing.

Sub-assemblies and other extra value operations need to be provided to service the growing requirements of today’s medical OEMs. To be competitive, however, the assembly operations need to be based in a low labor cost environment such as Mexico or Latin America. As a result, custom extrusion companies may have to shift some production across borders.

PVC Still Prevalent

Polyvinyl chloride (PVC) has been the dominant plastic material used in the medical industry for more than 50 years. Despite the efforts of a variety of environmental organizations, PVC will probably continue to be the medical grade material of choice for tubing, IV bags, and fluid or gas administration sets for some time to come. With

all its inherent qualities and characteristics such as clarity, flexibility, resilience, resistance to chemicals, and bonding properties, there is no other material available today that can offer what PVC does at comparable pricing, which is most significant. Defenders of PVC also point out that there is still no real proof to date of any harmful effects to humans.

There are several reasons for the leading use of PVC in medical tubing. First and foremost, it's one of the least expensive tubing materials on the market. Second, because its grades run from flexible to firm, it can be made into tubes ranging from supple to rigid. Third, unlike some tubing materials that can be troublesome to bond, PVC bonds wonderfully. For example, if you have to bond a tube to a plastic connector, there's no problem using a PVC tube because it can bond to just about every plastic molded component there is. Fourth, because PVC is clear, people can see what's going through tubes used for fluid or gas administration. Fifth, it holds up well to chemical exposure and a wide range of temperatures and sterilization methods.

PVC is particularly well suited for tubes used in high-volume disposable medical devices. For instance, the tubing in an intravenous fluid administration set has to be inexpensive and as clear as possible so that the drug going through it can be seen. PVC is ideal for that application.

However, there are some drawbacks to PVC. Its tackiness can slow down assembly operations. A frost finish can be applied to the outside to make it smooth to the touch, but the finish diminishes the tubing's clarity. It's also not an ideal choice for high-pressure applications.

The most serious concern is that diethylhexyl phthalate plastizer (DEHP), which is used to soften PVC, may leach out of the material. This plasticizer has long been a suspected carcinogen. However, according to reports, no human deaths, injuries, or illnesses have ever been directly linked to the leaching or migration of plasticizers from PVC.

Multiple Material Alternatives

Still, for those device manufacturers who prefer not to use conventional PVC&#151made with DEHP&#151there are a variety of material options. These include non-DEHP PVC and polyolefin thermoplastic elastomer (TPE). PVC can be combined with non-phthalate plasticizers to produce materials with capabilities and properties equal to those of conventional PVC. However, the cost can be 25 percent higher. In addition, since the substitutes don't extrude as well, the tubing may not be as clear or may contain more gels and blemishes than conventional PVC tubing.

Another option is a proprietary polyolefin-based TPE tube that doesn't include plasticizers. It has all the properties and characteristics of PVC but costs five times more than PVC. This may not be a problem when it's used for small, thin tubes because the cost of an expensive material may only amount to 15 percent of the

total cost of the tube. But as tubes get bigger and walls get thicker, the material cost can rise to as much as 50 percent of the total tube cost, making this option impractical.

Polyolefins, such as polyethylene (PE), are the second most popular choice for medical tubing. Like PVC, PE is chemical resistant. It weighs about a third less than PVC and is price competitive. PE tubes are very strong packaging vessels and offer low friction and high lubricity. High-density PE tubing is employed for such applications as guide-wire dispensers used in angioplasty procedures. Polyolefins are also used as film for IV bags.

However, PE isn't as flexible as PVC and doesn't solvent bond to many plastics. It also has a frosted rather than clear appearance, making it difficult to clearly see fluids flowing through these tubes.

Polyurethane, on the other hand, is just as flexible and clear as PVC. It's also more durable and heat resistant than PVC and provides the strength needed for thin-wall and high-pressure tubing applications. It also has exceptional kink resistance. Its problem is cost, which is about seven times that of flexible PVC.

Another tubing option gaining widespread acceptance in a number of applications is synthetic rubber. Thermoplastic rubbers (TPR) combine vulcanized rubber properties with the processing advantages of conventional thermoplastics. Available as a latex-free alternative to avoid allergy concerns, TPR offers silkiness, flexibility, and the stretch properties of latex at a much lower cost. It is finding increasing use in chest drainage systems and blood pressure cuff tubing, where contact with patients and potential allergy concerns have prompted the switch from latex.

A more common rubber tubing alternative is silicone. It has exceptional flexibility and can handle exposure to high heat and corrosive body chemicals. However, it is costly. A blend of TPRs is finding use as a replacement for the much higher priced silicone when the application does not require high heat or implantation.

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