NOVEMBER 1, 2019 | MEDICAL | TUBING & EXTRUSION [/MDB/TOPIC/MATERIALS-MANUFACTURING/TUBING-EXTRUSION]

Reducing Risk with Geometric Transition Extrusion

In an effort to design smaller, more intricate and complicated medical devices without running afoul of increasingly stringent national and international regulations, many designers are looking to geometric transition extrusions manufactured of high consistency rubber (HCR) silicone. This process reduces total cost of ownership for the original equipment manufacturer while improving part quality and greatly enhancing the types of devices being sought by healthcare providers.

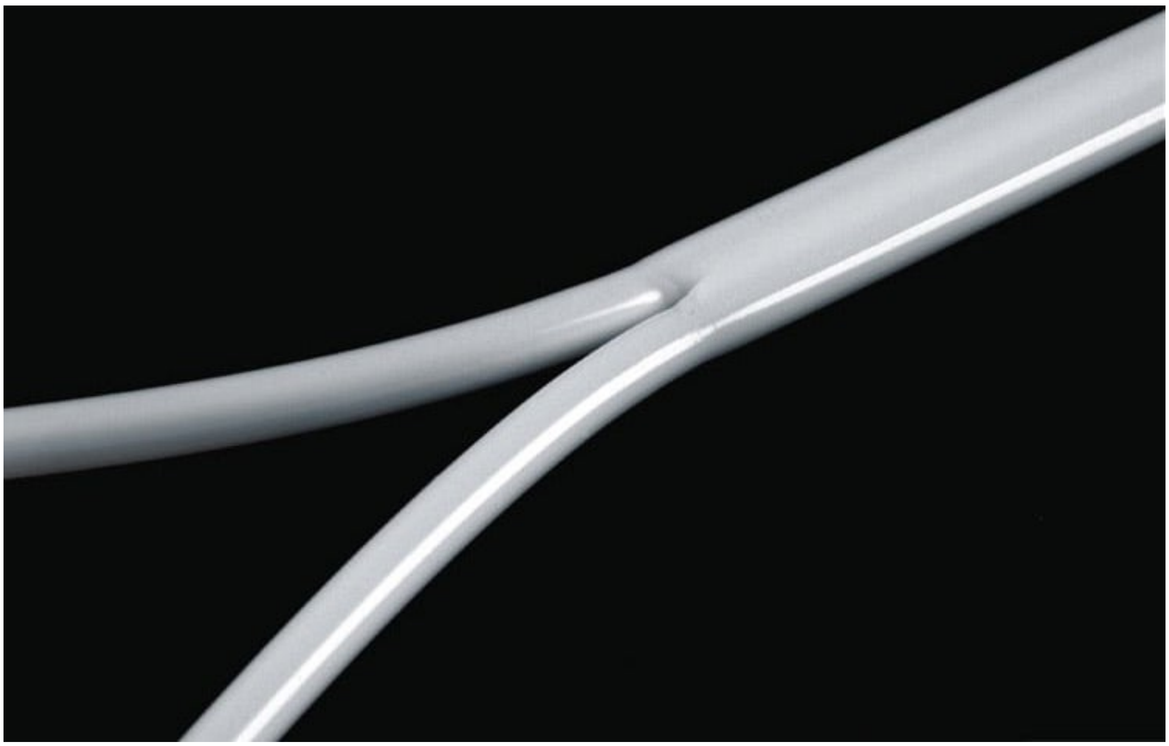

Fig. 1 - A tube can transition from single to multiple lumens or split from a multi-lumen tube into two or three single lumen tubes.

Silicone is a proven material of choice for medical devices because of its purity and biocompatibility. It is also highly customizable, allowing it to be optimized for a wide range of devices that require radiopacity, conductivity, and physical properties such as high tensile strength.

HCR silicone's unique green strength — the strength of rubber in its unvulcanized state — allows for highly complex geometries in continuous extrusion processes, setting it apart from other types of polymers, such as polyurethanes, thermoplastics, and room-temperature vulcanizing (RTV) silicones (see the sidebar, "Complex Geometries"). Used with a geometric transition extrusion process, such as Trelleborg's Geo-Trans™, HCR extrusions can change cross-sections dramatically, opening up new possibilities in a wide range of medical devices, including wound drains, catheters, and hemodialysis tubing.

DEVICE EXAMPLES

With geometric transition extrusion, tool components can be moved during the extrusion process to change tubing geometry. For example, a tube can transition from single to multiple lumens or split from a multilumen tube into two or three single lumen tubes (see Figure 1). Extruding different geometries in one process eliminates assembled joints that may be weak or create internal misalignments where fluids can become turbulent or stagnate. This in turn reduces labor costs and improves the overall quality of the product. Additional examples of geometric transitions:

- A multiple lumen tube can have one or more lumen stops and restarts, eliminating the need for secondary operations, such as backfilling a lumen after filling a catheter balloon.
- Instead of a wound drain comprising three separate pieces — an extruded tube, a complex cross-section extrusion, and a molded hub as a connecting piece — the drain can be created as a single extrusion with two or more distinct geometric cross-sections and a smooth, integrated transition where the hub had been (see Figure 2).
- Off-ration bump tubing, for applications requiring a variable outer diameter with either a constant or variable inner diameter, can be created with very short (fractions of an inch) transitions (see Figure 3).

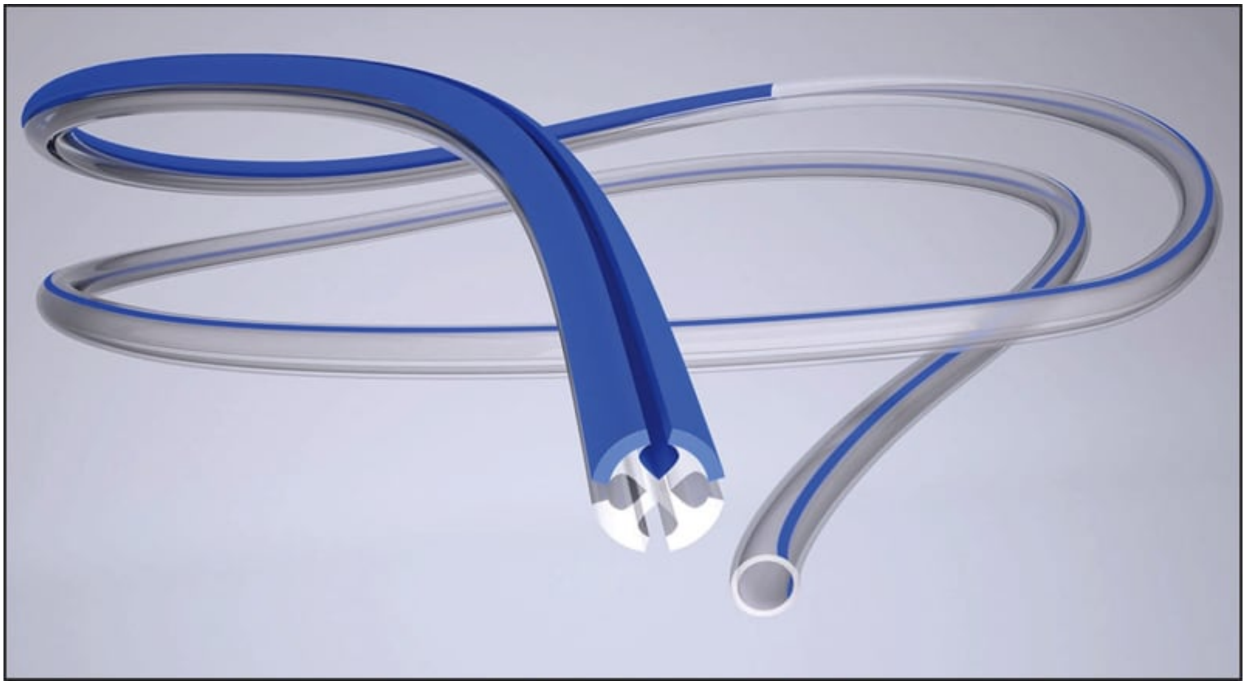

Fig. 2 - A wound drain can be created as a single extrusion with two or more distinct geometric cross-sections and a smooth, integrated transition where the hub had been.

COMPLEX GEOMETRIES

In addition to geometric transition extrusion, several tubing processes may be of interest to medical device designers, including twisted, reinforced, multilumen, and micro-extrusion.

Twisted. This extrusion process produces a continuously twisted tubing for use in applications where implanted power or sensing cables require strain relief from repeat flexing and bending, as with pacemaker leads. The tube cross-section typically consists of a center lumen and multiple outer lumen. The twisting process causes the outer lumen to become spiraled around the center lumen. Wires fed through the outer lumen are then less prone to dynamic flex failures because the stresses are distributed more evenly to the multiple wires. The process does not require the tubing to have a round outer diameter (OD), and features such as grooves can be incorporated on the OD.

Reinforced. Silicone tubes can be made kink resistant by reinforcing them with nylon monofilaments in a double-helix configuration. The monofilaments are embedded in the tube wall to add radial strength and reduce the likelihood the tube will compress. Reinforced tubes are ideal for long-term implantable devices because they allow fluid to flow from the device into the body, or between implanted components, regardless of bodily movement. The tube stays open when muscles flex, keeping fluid transfer consistent in all positions.

Multilumen. Extrusion with multiple lumen are commonly used to carry multiple wires or fluids to, or within, the body. Such tubes typically have four to five lumens but have been manufactured with 20+ lumens. The lumens are often symmetrical within a round tube, but they can also be asymmetrical, varying in size and position within the extrusion. Even ribbons consisting of tubes connected tangentially can be extruded if a lower profile is required. Inspection methods become more critical as lumen numbers increase and as the number of inspected dimensions multiply to include all walls between lumen and between lumen and OD. This is especially true as these extrusions become smaller with implanted smart devices of increasing complexity, such as those incorporating power, sensors, and/or and drug delivery.

Micro-Extrusion. Silicone tubes in diameters down to 0.014 in. OD and 0.007 in. ID can be produced to accommodate precise drug delivery or as scaled-down devices for neonatal applications. Measurement methods become especially critical for these products and often require custom innovations to measure ever-shrinking sizes and tolerances with accuracy.

DESIGN CONSIDERATIONS

Fig. 3 - For applications requiring a variable outer diameter with either a constant or variable inner diameter, off-ration bump tubing can be created with very short transitions.

The first aspect for consideration in design of geometric transition extrusion is the hardness required. Although HCR silicones are available from approximately 20 to 80 Shore A, the extremes of the hardness spectrum are challenging for highly technical extrusions.

The ideal target for GeoTrans extrusions is between 50 and 70 Shore A. The green properties of HCR silicone materials are ideal to facilitate the control of the material and forming of geometries in the critical transition areas. There is also a greater availability of suitable materials from silicone suppliers in this hardness range.

Size, combined with the expected cross sections, is the second consideration. The GeoTrans extrusion process has been used to manufacture products between 7 and 24 French (on the catheter scale). This size range is ideal to minimize initial and maintenance costs. Reducing the complexity of the cross sections also speeds time to market.

The third design consideration is tolerance targets. Transitioning from one cross section to another creates pressure differentials within the raw silicone as it flows, causing variations in size due to tapering along the length of the tube. Therefore, with complex extrusions, one section can be manufactured to very tight tolerances and the others would need to have more flexibility in dimensional tolerances.

To eliminate further tolerance and measurement correlation issues, it is important to define where the extrusion will be cut for dimensional inspection. Close collaboration between designer and manufacturer is critical to ensure that the final specifications and tolerances support design for manufacturability.

BENEFITS

The benefits of geometric transition extrusion include reduced processing time and cost, lower risk of mechanical failure, less validation cost, fewer regulatory issues, and overall improvement to performance and quality.

The tooling costs for this process are considerably higher than traditional extrusion. Despite this, for some devices, total cost of ownership is reduced by eliminating one or more components, secondary processes, and/or assembly steps.

Device designers and manufacturers are increasingly inclined to pursue a solution with this method because the strength improvement dramatically enhances the device's longevity and robustness. For example, eliminating secondary bonds can greatly increase a device's ability to withstand cycle loading, reducing risk of failure and increasing device life expectancy.

Processing time can be significantly reduced when devices are redesigned to take advantage of this technology. Although running a simple extrusion is faster than running a geometric transition extrusion, assembly time is often cut in half. For instance, the production volume of many long-term implants does not justify complex, automated assembly. However, a redesign to include a geometric transition can eliminate the need for manual assembly of a portion of the device. Additionally, the design validation process may be significantly shorter, with fewer components and assembly processes.

An excellent example is bifurcated tubing, which traditionally has four components: a two-lumen tube extruded and cut to length, two single-lumen tubes extruded and cut to length, and a molded hub. In the past, each of these pieces had to be bonded together in a secondary step, after which each bond and secondary process step had to be tested. In contrast, using geometric transitioning, one extrusion process can produce the bifurcation, cut the extrusion to length, and stack complex extrusions in bundles, minimizing the secondary processes required during final device assembly.

As mentioned earlier, reducing the risk that a device will run afoul of a U.S. or international regulation is top of mind for designers these days. The more components and secondary processes involved with a design, the greater the risk. Thus, medical device manufacturers are seeing great benefit from partnering closely with component suppliers to identify how sophisticated technologies like GeoTrans can contribute to risk mitigation.

Indeed, the redesign of catheters, drains, and tubing often comes from a collaboration between the manufacturer and a component supplier experienced in geometric transitioning, with a variety of devices being evaluated to see whether this method could be used to eliminate components.

This article was written by Dan Sanchez, a product manager at Trelleborg Healthcare & Medical, Fort Wayne, IN. He has been working closely with customers on GeoTrans projects for 21 years. For more information on GeoTrans, visit here [http://www.tss.trelleborg.com/healthcare] .
