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Challenging Channels: Successfully Designing Multi-Lumen Tubing

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The purpose of a multi-lumen tube is to enable different functions within the smallest diameter possible in order to promote less invasive procedures. The complexity of the tubing can vary from multi-lumen extruded tubing to reinforced and steerable catheters. This article provides information on the construction of these catheters.

By Linda Maher

A multi-lumen catheter can be a critical element to the success of a minimally invasive device. Its fabrication, however, can prove to be a significant challenge. To ensure that the finished, multi-lumen catheter meets a user's functional needs, it is important to define the design, material, and performance requirements as accurately as possible with the available information. Clearly articulating these requirements with knowledgeable material selection and specifying the desired application will provide the optimum successful outcome within the shortest delivery time.

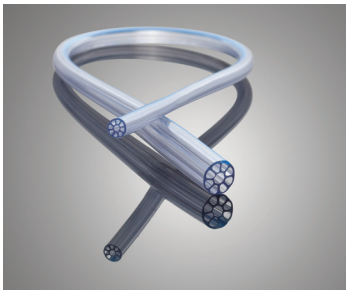
Specifications: The Importance of Communication

Any gaps in information, due to confidentially concerns or key facts that are not available, can greatly impact the material and design selection process. Specifications that are not accurately defined will most likely lead to elongated program timelines with an associated increase in costs. Spending the time to clearly define the requirements and partnering with a qualified manufacturer who is able to achieve the goals set for the project will save both time and money.

As expected, there are numerous configurations available that are based on the requirements of the component tubing and/or finished device. A successful outcome will be accomplished through the communication, imagination, and technical capabilities of the designers and manufacturers.

Design Considerations

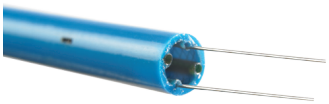
In order to develop and produce a multi-lumen catheter, the genesis is in the specifications for the required tubing. The catheter could be generated from a single or multiple extrusions to achieve the desired result.



9 lumen co-extruded bump tubing (Fig. 1)

Figure 1 details 9 lumen co-extruded "bump" tubing where the larger proximal end facilitates easier assembly of individual extension lumens.

Other alternate construction techniques may be employed in the "building up" of individual layers of materials and tubing (Figure 2 below). This complex extrusion incorporates diverse materials not chemically compatible, such as braid/coil reinforcement, PTFE liners, etc.



Complex catheter assembly (Fig. 2)

The following information outlines considerations that, when taken into account before manufacturing, lead to a functional and cost effective outcome for the medical device customer.

Biomaterial Selection

Any material, surface, or construct that interacts with biological systems

• Biocompatibility - Consider anatomical areas of use and length of time in contact with the body

• Hardness - Single or multiple combinations of materials with different hardness along the shaft, measured in durometer, affect compressibility, column strength, kinking, stretch, etc.

• Temperature sensitivity - What impact will temperature have on the performance of the catheter?

• Sterilization - The method of sterilization will have a critical bearing on the materials used and the packaging concepts employed

Mechanical Requirements

Acceleration and deformation (both elastic and plastic) of devices/components under known forces or stress

• Torque - Rotation of the catheter about its axis (twist)

• Ability to push or advance tubing - A determined advance against opposition; column strength (the ability to advance a catheter within body structures or catheter guides)

• Kink Resistance - Maintaining the inner bore diameter over a specified bend radius (resistance to collapse)

Functional Requirements

Fulfilling the purpose of the device or component

• Co-efficient of friction of the outer/inner lumens - Incorporating PTFE or FEP liners to provide a lower co-efficient of friction in order to deploy or pass a device through one of the inner lumens with ease

• Bend radius - Incorporating spiral coils to achieve the required bend radii and maintain the inner bore diameter (kink prevention)

• Steering - The steering wires may be incorporated into the smaller lumens. Steering capability allows the operator directional control at the distal end of the catheter

Construction

The translation of design into reality

• Varying flexibility (incorporation of different material durometers)

• Braid/coil construction (for reinforcement of the tubing)

• Varying diameters (inner or outer)

• Incorporation of additional components (e.g., hypo-tubing, wires, electrical conductors, and marker-bands)

• Material stack-up for reinforced catheters - The outer jacket must have enough coverage (i.e., wall thickness) to ensure that there are no exposed wires, or that the surface of the catheter will not be compromised due to manipulation of the catheter during the procedure

Tolerance

Permissible limit(s) of variation in devices/components

• The tolerance specification must be functional and manufacturable

• Too tight a tolerance - Does not allow for variation, which is evident in complex parts

• Too great a tolerance - Accessories (i.e., handles) will not have an adequate fit to the part

Validation

Confirming that the medical product/component meets the needs of its users

The key component for accurate, repeatable catheter construction is attributed to quality extrusion capabilities together with robust validated processes. Validation of extrusion is a difficult task, even for simple single-lumen tubing. The introduction of ultrasonic capabilities has made it possible to verify the product rather than validate the process itself. It is possible to verify OD, ID, concentricity, ovality and wall thickness 100% of the time. However, ultrasonic verification does not work for all of the attributes of multi-lumen tubing. Therefore, the traditional validation process needs to be carefully considered.

When considering the validation of a multi-lumen tube, careful attention should be paid to the following:

- Functional requirements of the product need to be considered in order to prevent over-engineering that may lead to manufacturing and validation difficulties.
- Tolerances involved are tied to the specific materials used to produce the catheter. When specific Cpk values are required, it is necessary to pay very close attention to specifications and tolerances. As less invasive medical procedures utilizing smaller catheters have entered the market, extrusion tolerances have become tighter and tighter, leading to challenging validation processes.
- Dimensional specifications are critical and need to be considered. For example, wall thickness is usually stated with ± tolerances. It may be perfectly acceptable to only set a minimum specification on the wall thickness, rather than having a two-sided tolerance.
- Materials employed need to be deliberated when discussing validation. Softer materials and thin-walled materials are much more difficult to manufacture and, therefore, more difficult to validate.

As with most medical devices, the route taken for validation of a multi-lumen tube should consider the IQ, OQ, and PQ processes. When it comes to validation of extrusion, the process can be carried out in a slightly different format. The OQ process can be avoided, going from IQ straight to PQ verification runs. The reason is that extrusion tends to run in a closed-loop control process, where the dimensional inspection readings of the OD (taken from SPC software) are used to feed information back to the extruder, thereby making continual adjustments of the processing parameters of the extruder. This ensures that the dimensional specifications of the product are maintained 100% of the time. Thus the requirement of an OQ is not deemed necessary.

Conclusion

The key components for accurate repeatable catheter construction are attributed to excellent communication; acceptance of requirements and specifications; and repeatable, quality extrusion capabilities - all together with robust validated processes.

A distinct advantage for developing complex catheter devices is realized when the provider has the key knowledge, process capabilities, and resources in-house to facilitate rapid project turn-around, in addition to meeting all quality requirements and providing the customer an attractive and acceptable cost/value ratio.

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