Extrusion, Balloons, and Catheter Finishing

Tightly Controlled Inputs Deliver Optimal Performance

The extrusion process and catheter finishing processes are inextricably linked and balancing these processes can be a complex undertaking. There are a number of variables that can ultimately affect the performance of the finished product; these include the properties of the raw material and the extrusion process itself. Careful consideration of the process is essential to ensure consistency and repeatability.

The manufacture of high quality extrusions used in sophisticated catheter systems is greatly affected by tight control of the “inputs”. The greater the control of the inputs to the extrusion process the higher the probability of achieving the desired “outputs” necessary to develop and manufacture high quality extrusions.

Inputs

- extrusion environment
- raw material
- storage conditions
- resin drying
- extrusion equipment
- auxiliary equipment
- tooling
- personnel

Outputs

Process stability, in order to consistently meet the agreed upon customer specifications, such as:

- dimensional
- visual
- mechanical properties
- physical properties
- functional specifications

The tolerance expectations from customers are constantly challenging the boundaries of extrusion capability. It has become more significant than ever for tubing manufacturers to maintain close control of their inputs and close control of the extrusion process.

A good understanding of polymer science and material behaviour is undeniably crucial for producing high-quality catheters and balloons. The morphological structure of the thermoplastic material can change with varying thermal conditions which, in turn, determines key physical properties such as strength and flexibility. The polymer exits the die head of an extruder in an amorphous state and the rate and length of the cooling downstream from an extruder controls the degree of crystallinity of the final product.

Fig 1: Braid to coil delivery system

In some medical applications, such as balloon forming, it is critical that the extruded tubing is amorphous prior to the balloon forming process. Therefore, the cooling parameters and cooling method used are critical to ensure that crystallization does not occur in the tubing during the extrusion process. In other applications, such as the extrusion of PEEK tubing, it is critical that the PEEK tubing achieves a relatively high level of crystallinity during extrusion to ensure that the tubing utilizes the outstanding properties that PEEK possesses.

To produce high quality balloons and catheter systems it is fundamental to have all the extrusion inputs under control. Extremely tight dimensional tolerances for tubing must be maintained for consistent balloon quality and desired performance. A sophisticated extrusion process with precise in-line monitoring and control is crucial to achieving high quality balloon tubing. Small process variations can undoubtedly hinder the quality and performance of the final product. These variations potentially impact melt homogeneity and can result in variability in balloon tubing performance.

Polymers can degrade due to excessive temperatures or high shear stress causing deterioration in the material molecular weight which, in turn, compromises the material's performance. An important first step in achieving optimal catheter performance is to choose the right materials for the catheter delivery system. In recent years leading-edge polymers have begun to replace traditional materials and these new polymers are being integrated into the design of next-generation catheters. For optimal performance, engineers need to consider the biological, physical, and chemical characteristics of polymers and the growth of new break-through manufacturing processes.

In order to enhance catheter performance and achieve optimum results several features should be incorporated:

- Braid/coil reinforcement for strength, rigidity, and torque control along the length of the catheter while balancing the need for flexibility and kink resistance to navigate tortuous pathways
- Use of hydrophilic coatings delivers high lubricity for low insertion force or a reduction in friction for a specific delivery application
- Soft tip and multi-durometer segments along the length of the catheter provide excellent atraumatic entry and manoeuvrability
- Radiopaque contrast at the tip and key segments offers better visibility for the physician to visualize accurate anatomical placement
- Steerability and deflection for optimal navigation

To achieve some of these attributes, a number of design aspects can affect performance and design:

- Varying material durometer along the outer jacket length will provide a number of flexibility options
- Different levels of flexibility and kink resistance can be achieved by varying the pitch of the braid on the shaft. Braid patterns (e.g. diamond pattern) will effect flexibility and torque response. Wire options (e.g. flat or round) can also effect catheter performance; round wire will provide a more flexible shaft while flat wire will deliver a lower profile and less flexibility
- Hybrid coil-braid designs can also offer the best balance between torque, flexibility, and a thin wall solution

Requests are on the rise for braided shafts with the lowest possible wall thickness while maintaining adequate levels of track and kink resistance. Controlled extrusion inputs combined with a robust extrusion process play a key role in achieving these next-generation catheters.

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