Balloon Tubing – The Key to Good Balloons

Apur Lathiya

As more medical device OEMs invent new ways to navigate the tortuous anatomy and open up clogged arteries, one constant remains—without high quality balloon tubing, producing high quality balloons consistently can be a real challenge. This article will highlight some of the considerations in manufacturing balloon tubing from Polyamide or Polyamide co-polymer materials.

Producing high quality balloons consistently requires high quality balloon tubing.

What differentiates a “good” balloon tube from a poorly manufactured one? Is it the ability to achieve tight tolerances? Is lot-to-lot consistency in mechanical properties the primary factor? Some might ask if it is exceptional process control. Others may wonder if it means producing tubing that is free of visual impurities. The answer is that all of these, as well as other characteristics are required in order to make a “good” balloon tube that will consistently yield quality balloons for the OEM.

Many of the critical dimensions for tubing manufactured for catheter shafts, strain reliefs, or lead tubing can be inspected to ensure the tubing will meet the defined functional requirements of the product. However, with balloon tubing, one of the most critical characteristics is the mechanical properties of the tubing. Since testing for the mechanical properties of a tube is a destructive test, validating a consistent, capable, and stable process is paramount to ensure the manufacture of a high quality balloon tube.

There are many elements in the extrusion process that can affect the quality of the

balloon tubing and, therefore, the outcome of a blown balloon. Some of the factors include processing parameters, screw design, tooling size and condition, and filtration techniques. An experienced extrusion professional manufacturing a balloon tube must take extra care in choosing the appropriate tooling and processing parameters to develop the highest quality, repeatable balloon manufacturing method possible.

Two critical requirements for a balloon tube are the tensile and elongation properties of the tube. While the physical properties of the raw material must be capable of achieving the mechanical properties of the tubing, the extrusion process itself must be robust to ensure a good balloon tube. Once the desired mechanical property specifications have been identified the extrusion contractor should provide a stress/strain curve or data with each shipment of the balloon tube.

Extrusion Variables
There are three specific variables that extrusion operators must be diligent in controlling to ensure a repeatable and high quality balloon tube. They are moisture content of the material, tooling, and extrusion process parameters.

Moisture
It is essential to ensure that the moisture content of the raw material is dried at or below the manufacturer’s recommendations for moisture content percentage prior to starting the extrusion. Typically, materials will require several hours of drying at a predetermined temperature in a dehumidifying desiccant-type dryer to remove the moisture from the raw material. The percentage of moisture content can then be measured using a moisture analyzer to confirm the material is sufficiently dry prior to the start of extrusion. If the extrusion process itself is not in a humidity controlled environment, moisture can be absorbed by the material from the ambient air. In these cases, using a closed material conveying system or a dryer mounted directly on to the extruder is recommended.

If tubing is extruded with too much moisture, it is likely that there will be reduced mechanical properties in the balloon tubing. The reduction in tensile properties will result in lower rated burst pressure as well as lowering the elongation, thereby making it difficult to blow acceptable balloons.

In addition to lowered mechanical properties, inadequate drying of the material can also result in the formation of visual defects, such as bubbles. These defects may be small in the tubing itself but when the balloon is blown, the defect will enlarge and could create a weak spot on the balloon.

Tooling
Manufacturing high quality balloon tubing requires extruder tooling that is in good shape. The barrel, feed throat, adaptors, and crossheads must all be free of nicks and voids to ensure the tubing is free of foreign materials that can create a weak spot for the blown balloon. It is also important to choose a screw that will provide consistent metering of the extrudate to meet the tight dimensional tolerances prevalent in most balloon tubes. Where the specifications allow, the extruder operator will want to avoid using a melt pump and rely on a good screw design for

dimensional stability, improving compliance with the cosmetic specifications of the balloon tube. In addition to the tooling components of the extruder itself, choosing the right tubing tooling set is also critical to the mechanical properties of a precision balloon tube. The draw down ratio as determined by the ratio between the size of the tip and die directly correlates to the elongation and tensile properties of the tube. As covered previously, the tensile and elongation properties will affect both the rated burst pressure and the ability to blow acceptable balloons.

Extrusion Processing Parameters
Manufacturing balloon tubing that performs consistently from lot-to-lot requires stringent process parameters and controls. The melt temperature of the extrudate is a critical variable to the production of a high quality balloon tube. Being able to consistently extrude the tubing at the same melt temperature range will contribute to more consistent mechanical properties of the tube.

Additionally, the mechanical properties of the tubing are also influenced by the air gap between the extruder and the water bath, as well as the puller line speed. Both of these variables influence the level of crystallinity of the tubing and thus, the mechanical properties of the tubing.

Another important consideration for the balloon tube is to maintain a wall concentricity of greater than 90%. Having a concentric (balanced) wall is important to ensure that the balloon blows evenly with no thin spots, which can be failure modes for the balloon. Wall balance is dependent upon having both a good quality tool set (tip and die) and a skilled operator in achieving the concentricity of the wall prior to collecting product.

Conclusion
In order to manufacture high quality balloons consistently, the medical device OEM must receive high quality balloon tubing from its tubing supplier. The nuances in extruding high quality balloon tubing differ from extruding other types of tubing. To reduce the time to market and have a consistent supply chain, the medical device OEM will benefit by partnering with an extrusion subcontractor who has the experience and deep understanding of the juxtaposition between a balloon tube and the outcome when the tube is blown.

Apur Lathiya is the VP and GM of the Thermoplastics Division at Vesta [1], a leading medical device contract manufacturer. He is responsible for the growth of the division.

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