Most specifications for medical tubing consist of a drawing of a tube with the material, dimensions and tolerances. For single lumen tubing, the dimensions will usually include two of the following three dimensions; inner diameter (ID), outer diameter (OD) and the tubing wall thickness, along with their associated tolerances. In addition, the tubing length and tolerance would be included unless the tubing is to be provided in a continuous length on a spool. Other notes that may appear on a tubing specification include packaging requirements; a sampling plan for inspection of the dimensional tolerances listed above; and some note regarding tubing cleanliness such as “no dirt, grease, oil, etc. to be present on the tubing surface.” Very few specifiers of medical tubing specify other tubing attributes or process parameters associated with the production of the tubing. It is a common misconception that as long as a lot of tubing is made from the right material and meets the dimensional requirements, it will be the same as, or it is equivalent to, another lot of tubing either made by the same supplier or potentially made by a different supplier. While this may be true, there is also a good chance that the two lots of tubing may be different. These differences are not always obvious or easily recognizable, even when inspected by incoming QC. Oftentimes, the process parameters and the equipment used to extrude the tubing are as important or even more important than the actual dimensions of the tube.

The Extrusion Process and Degradation

The process used to produce medical tubing can be extremely important in high end diagnostic and therapeutic catheters where market pressures have driven catheter manufacturers to design smaller and smaller devices with thinner and thinner walls. Examples of such applications include high pressure catheter tubing; tubing used to make angioplasty and stent delivery catheters; balloon tubing used to fabricate medical balloons, especially high pressure angioplasty and stent delivery balloons; tubing that will be implanted or inserted in the body for long periods of time; and other applications where the mechanical, physical, chemical, electrical, or thermal properties are critical to the function of the finished medical device.

Degradation during the extrusion process can greatly affect the properties of the end-use medical tube. Polymers are very large molecules that derive their unique and useful properties from their size (molecular weight). Degradation is a breakdown of these large molecules. At some point, polymer degradation results in a change in properties such as tensile strength, brittleness, flexibility, discoloration, etc. To understand degradation, it is important to understand the various interactions that take place during the extrusion process. The following figure provides an overview:

Figure 1. Various interactions take place during the extrusion process. A combination of these interactions can result in material degradation. Courtesy of Chris Rauwendaal and Rauwendaal Extrusion Engineering.
overshearing the material (i.e. running the polymer at too high a screw speed or using the wrong screw design), or keeping the polymer in the molten state too long (i.e. long residence time). Such changes occur primarily because of the effect of these factors on the chemical composition of the polymers. Some polymers are very sensitive to process parameters and can degrade easily, such as PET, while other polymers are very forgiving, such as polyethylene.

Another cause of degradation in extrusion is multiple melting process steps. For example, some materials used to make medical tubing must be pre-compounded. In other words, the base material is melted and mixed with other materials, such as colorants, radio-opaque fillers, stabilizers, processing aids, etc. This often takes place in a separate extrusion operation to ensure high quality dispersion and distribution of the components. Compounding is often done in a twin screw or single screw extrusion process. This process step results in a heat history and shear history in addition to the heat history and shear history that will be imparted in the tube extrusion process. It is the combination or total sum of these processes that result in overall loss of molecular weight and polymer degradation. If either one of these steps is carried out incorrectly, detrimental results can occur.

Extrusion Overview

An extrusion line is a combination of several pieces of equipment. The major elements of a medical extrusion line include a resin drying system, the extruder, the die, the cooling tank, a take-up device (puller) and a cutter or winder.

![Figure 2. A typical medical tubing extrusion line.](image)

Drying

Oftentimes, the first step in the extrusion process is drying the polymer. Polymer drying is a critical process in extrusion. Many polymers used in the medical device industry are “hygroscopic”, i.e. they absorb moisture readily from the environment. Hygroscopic polymers must be carefully dried prior to being melt extruded or compounded.

All materials are not dried under the same parameters. Some require high temperatures for long periods of time while other materials may require low temperatures for shorter periods of time. Some materials are extremely sensitive to moisture content
and must be very carefully dried while others are easier to dry and much less critical. For example, drying PET is absolutely critical to the extrusion process. Even a very small amount of moisture can degrade PET beyond use.

Drying a material for too short a time and/or at too low a temperature can result in under-drying. This can leave residual moisture in the polymer which results in hydrolysis during extrusion. Hydrolysis is a degradation process that results in significantly lower molecular weight. Under-drying of polymers also occurs often in medical extrusions because run times can be very short with lots of material change-overs. Customers often request the same size tube to be provided in multiple grades of materials, i.e., three different durometers of the same type of material in order to optimize flexibility for a particular application. If the processor does not have three separate dryers available to pre-dry all three materials, then it is entirely possible that the second and third materials may not be properly dried prior to extrusion. The result could be that the end user evaluates partially degraded material and makes the wrong choice for the application.

Over-drying is another problem that can occur, especially when extruding medical tubing, because many medical extrusion lines run at very low through-puts, i.e. at low pounds per hour. Most commercial resin dryers are oversized for medical extruders. Therefore, the residence time in the dryer can be extremely long. If not properly monitored, this can result in over-drying which can cause thermal degradation in some materials. Many polymers, such as nylon and polycarbonate, can be sensitive to over-drying.

Most resin manufacturers specify specific minimum drying times and temperatures for their materials. These recommendations must be followed very carefully in order to ensure that the materials are properly dried prior to extrusion. Normally, desiccant type dryers are used in the medical extrusion industry to ensure proper drying. These dryers must be well maintained, cleaned, tested and calibrated on a periodic basis to ensure that they are functioning properly.

The Extruder

The extruder is a melting and pumping machine. It converts solid pellets into a uniform, molten state and forces the material through the die, hopefully at a constant rate. Melting is accomplished through frictional heat generated from the mechanical work of the screw and heat conduction from the heated barrel of the extruder. The design of the extrusion screw is critical in achieving uniform melting and pumping of the polymer without over-working (over-shearing) the material. Different materials require different screw designs in order to optimize the extrusion process. Many tube manufacturers use general purpose screw designs and try to run all of their materials using the same screw. This can result in over-shearing and degradation in some materials and improper melting and gels in others.
Extrusion Die

The extrusion die sits at the end of the extruder and is the point where the polymer exits into a cooling tank. The die forms the initial shape of the tube. A tubing die typically consists of two major components; a mandrel or tip that forms the tube ID, and a die, or ring, which forms the tube OD. The die and mandrel are typically contained inside the extrusion “head”. There are literally dozens of manufacturers of extrusion heads and tooling and many extrusion companies have developed their own proprietary head, die and mandrel designs. The design of these components plays a critical role in the extrusion process and the ability of the extruder to produce precise dimensions and maintain proper physical properties of the material. The relationship between the die and mandrel dimensions and the finished tube dimensions is typically referred to as the draw down ratio.

![Image of extrusion die](image)

Figure 3. The extrusion process that creates the draw-down ratio.

Very small diameter medical tubing with very thin walls can be difficult to extrude through a standard extrusion head/die. Oftentimes, the viscosity of these materials in the die is so high and the die gap is so small that the extrusion operator must increase the temperature of the polymer in order to reduce the viscosity of the material so that they can get sufficient flow through the die. This practice can dramatically alter material properties. When extruding thin-walled tubing, specially designed heads are often required to produce high quality tubing without degradation, gels, black specs, or undesirable residual stress.

Many custom extruders overcome the problems producing tight tolerance, small diameter thin walled tubing by using high draw down ratios. This significantly improves dimensional tolerances, increases line speed and makes tooling (dies and mandrels) much easier to fabricate. Unfortunately, running high draw down ratios also imparts significant orientation and residual stress/strain in the finished tubing. This orientation can significantly increase the tensile strength and reduce the elongation of the tubing in the machine direction. It can also reduce the tubing burst pressure due to the loss in hoop
strength. The residual stresses from high drawn down ratios can wreak havoc during subsequent thermal processing, sterilization, or aging (natural or accelerated). These thermal processes can release the stresses built in during extrusion, causing the tubing to shrink significantly in length and increase in diameter and wall thickness.

Cooling

The extrusion cooling process is the next critical step. Cooling of many polymers is critical and significant changes in physical properties and morphological structure can result from different cooling conditions. For example, many polymers are semi-crystalline; in other words, they contain amorphous regions and crystalline regions. When the polymer exits the die and is cooled, rapid cooling / quenching tends to retard crystallization or completely eliminate it; while slow cooling can result in a higher degree of crystallinity and/or very large crystal formation. In some medical applications, such as balloon manufacturing, it is critical that the extruded tubing be amorphous prior to the balloon forming process. Therefore, the cooling parameters 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 achieve a relatively high level of crystallinity when extruded to ensure that the tubing has the outstanding thermal, physical and mechanical properties that PEEK possesses. In materials such as polyethylene and polypropylene, it is desirable, in some applications, to minimize the crystallinity in the tubing for improved clarity and softness while in other applications it is desirable to increase the amount of crystallinity for improved stiffness and lubricity.

Most processors cool the polymer as it exits the die in a cooling tank filled with water. This is typically done in free extrusion or through a vacuum sizing tank. However, in both methods, the polymer cools through contact with water in the cooling tank. The variables that can affect the cooling process include water temperature; the circulation of the water in the tank; the length of the cooling tank; and the line speed. All of these variables can affect the physical properties of the resultant tubing.

Control of the water temperature in the cooling tank can be critical in many applications; however many processors do not use temperature controllers at all or have very crude temperature control of their cooling water. This can result in significant variations in the cooling rate of the polymer from one lot/batch to another and from the beginning to the end of a lot. Processors that use tap water for cooling can see incoming water temperatures change 30°F or more from summer to winter. In addition, hot spots can be created in the cooling tank especially in the area where the polymer first enters. This is why proper circulation of the water in the cooling tank is also critical, even if precise temperature controllers are used. If there is not sufficient flow in the water tank, hot spots can develop over time and be unknown to the processor.

Many medical extrusion lines are sold with very small, undersized cooling tanks that may not be well-suited for long production runs or for extruding larger diameter and/or thick walled tubing; or extruding small, thin-wall tubing at higher line speeds where there is insufficient time in the tank to properly cool the tube. High line speeds or short cooling tanks can result in insufficient residence time in the cooling tank. This can
further result in tubing that exits the extrusion process where the inside of the tube may be still warm or hot and insufficiently set up. Once the tube exits the cooling tank, the cooling process can reverse itself and the tube can begin to re-warm itself from the inside out since the center of the tube was not sufficiently cooled. This can create varying physical properties in the tube.

**Extrusion Equipment and Its Importance in the Success of the Tube**

It is of extreme importance that purchasers ensure their tube manufacturer has the expertise and equipment to manufacture a high end tube for use in the medical device industry. In recent years, many industrial extrusion houses have decided to enter the medical device extrusion business because they see higher profit margins than are available in industrial applications. However, often these manufacturers have extruders that are oversized for the production of tubes used in the medical industry. Using an oversized extruder to make a medical tube can result in very long residence time. In many materials, the residence time is important because excessively long residence time will lead to thermal degradation of the polymer.

In addition, some tubing manufacturers use old equipment or equipment that may not be maintained to the standards desired in the medical device industry. Many older extrusion lines do not have state of the art controls and therefore processing temperatures and other parameters can vary widely resulting in inconsistent thermal history and therefore inconsistent properties within a run or from run to run. This can also be true for equipment that is properly designed, however not well maintained or equipment that is not properly calibrated. For example, a temperature controller on an extrusion line may operate in a temperature range from 300° to 600°F or more. If that temperature controller is off by one (1) percent, that is equivalent to five degrees at 500°F. If it is off by 5%, that is 25 degrees at 500°F. With some materials, a process change of 10 degrees can result in a dramatic difference in the properties of the tube being manufactured.

Medical tube manufacturers typically have very small extruders, however oftentimes, medical devices require larger diameter tubing than these small extruders were actually designed to produce. In these cases, processors may be running the extrusion lines at their maximum output with high screw speeds. This can be detrimental to many polymers that are shear sensitive. Shear sensitive polymers run at high screw RPM can suffer the same type of degradation found when a polymer is heated for too long or too hot. It is important to recognize and understand that there are numerous interactions taking place during the extrusion process.

**Conclusion**

The performance characteristics of medical extrusions are only partially determined by the tubing dimensions. As demonstrated in this article, process parameters, equipment and material characteristics all play an important role in determining the end-properties of an extruded tube. When choosing a tubing supplier, the specifier should take into account the criticality of the application in the finished medical device and the importance of the performance characteristics of that tube in ensuring the proper function of the device. Since it is not possible or practical to specify
or even measure every critical characteristic of a given tube, it is desirable to seek out suppliers that have a demonstrated history extruding similar materials in similar sizes that are used in similar applications. The tubing specifier should also ensure that the tubing supplier has appropriate level of understanding, process controls and expertise for the intended tube application/materials.

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