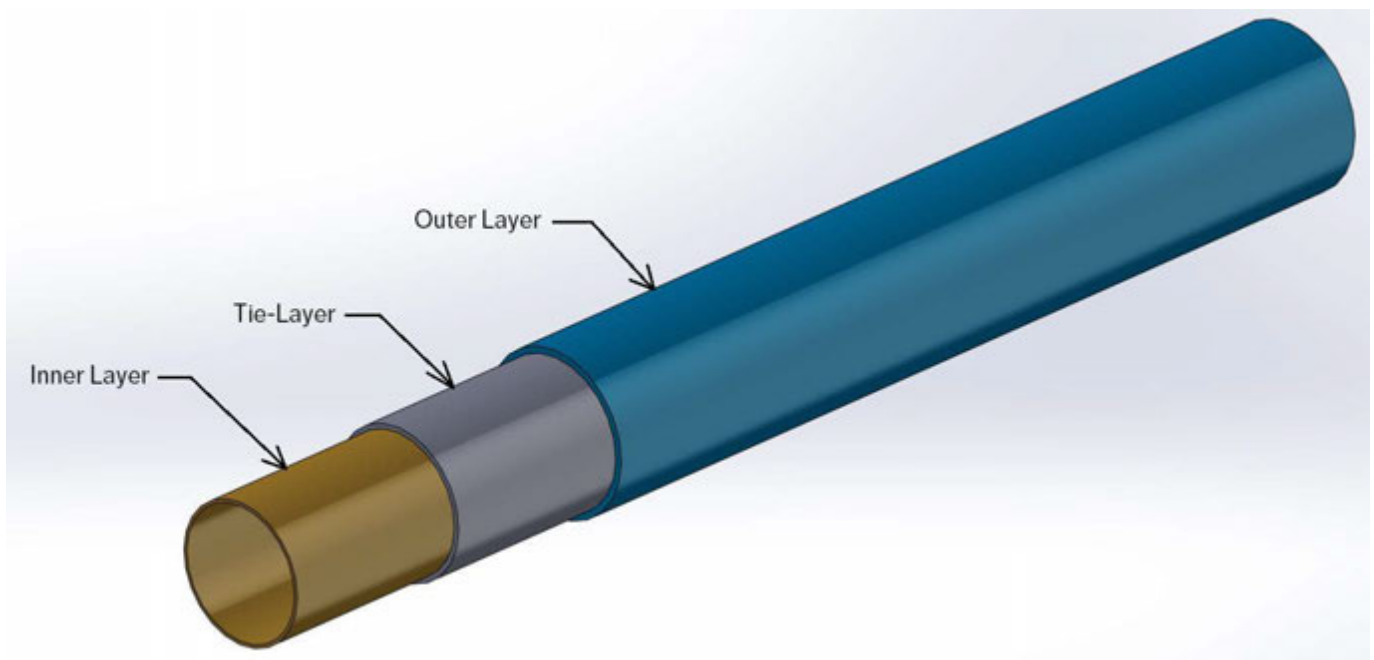


# Multi-Layer Extruded Tubing

## At the Core of Angioplasty & Medical Device Delivery

High Performance Medical Solutions (HPMS), a division of Hitachi Cable America, invites you to take a closer look at the fine art and science of manufacturing thin-walled, multi-layer tubing. Extrusion technologies and processing improvements must keep pace with the growing complexity requirements of this tubing category to produce tighter tolerance and greater precision.

Understanding the subtleties of a design and its manufacturing nuances are crucial to optimizing multi-layer tubing performance. Manufacturers must be well equipped and highly skilled to properly analyze and ultimately optimize the processing intricacies utilizing quick spin tooling and idealized production equipment. Manufacturers must also have critical knowledge of the material properties during the extrusion process and in the annealing phases of tubing production.



### Consider the Application

Multi-layer tubing is used in a broad range of medical devices for a wide array of applications involving diagnostics, fluid transportation, and highly specialized surgical procedures. Angioplasty tubing is one area in particular that has significantly benefited from multi-layer tubing advancements. Angioplasty catheter tubing, also known in the industry as percutaneous transluminal catheters (PTCs), are suitable for treating coronary artery disease (CAD) and peripheral artery disease (PAD). These multi-layer tubes require extreme precision. They rely on very small extrusion tooling geometries to deliver a uniform and consistent product with strong

ultra-thin walls and individual layer wall thicknesses on the order of 0.001 inches (0.0254 mm) in order to keep the size of the catheter as small as possible given the area of the body that it is intended to treat.

The challenge with multi-layer designs is creating tubing with highly uniform wall thicknesses along the length of the extruded product, as well as creating strong adhesive bonds between the layers. A poor bond can result in the delamination of one or more layers which will change the characteristics of the tube and potentially impact the performance during a surgical procedure.

There are many factors that must be considered when designing a tri-layer tube. Features such as flexibility, steerability, rigidity, kink resistance, concentricity, and wall thickness to name a few, will all impact the tubes performance characteristics. By design, a tube's properties can be uniform along the length of a catheter or it can have different properties and durometers resulting in sections that behave differently. Common applications for this multi-layer tubing include angiography, light-sensitive therapies, procedural and drug delivery devices, structural heart (valve replacement), implantable, intravenous, infusion and contrast injection.

Multi-layer and co-extruded thin walled tubing are used for a wide variety of reasons:

- Applications requiring reduced secondary operations such as braiding reinforcement
- Applications requiring assembly cost reduction to minimize components or processes
- Applications that benefit from unique material enhancements when certain materials are combined.
- Creating tubing with material layers such as antimicrobial additives, drug-eluting properties, and specialty coatings
- As preforms for stent delivery balloons and high pressure formed balloons

## How Multi-layer Tubing Is Made

Multi-layer tubing can be manufactured separately, with all resins being processed simultaneously (often different production lines and different dates), or it can be run in tandem where one extruder directly feeds in to the back of another, or it can be run as a co-extrusion using a single extrusion head assembly that forms all the layers.

To manufacture a co-extruded multi-layer tube two or more materials, be they similar or dissimilar, are extruded through multiple deflectors /cones inside a single die body, creating a tube that is a laminate of the thermoplastic resins selected. Each polymer layer quickly fuses to its adjoining layer forming a structural bond. The completed tube functions as a blend of the property characteristics of the base layer materials. These characteristics can be uniform along the length of a catheter or they can vary as is the case with durometer changes that enable a device to be soft and flexible at the distal tip while being more rigid at the proximal end.

If cost is the predominate driver, then tight tolerances and high precision geometries may need to be relaxed in order to achieve the desired target price. If patient safety is the predominate driver, then quality and precision, not cost, should take the lead. Multi-layer tubing, be it coextruded or sequentially extruded, requires a much greater level of precision and eye for quality. There is a lot more that can go wrong and a lot more that needs to be taken into consideration especially when velocity to market matters.

Consideration number one; the inner layer. The inner layer is the delivery / guide chamber for the application. It typically needs to be smooth, lubricious and chemically inert so that the catheter can advance over the guide wire or so that devices and fluid materials may easily pass through without sticking. It is often desirable to make the inner geometries as small as the design will allow, so that the completed multi-layer tubing O.D. does not become excessive. Ideally these tubes need to be strong and small enough to navigate hard to reach areas of the body, while being thin, tough and resilient enough to withstand any media passing through it. The same factors that make it ideal for delivery also make it difficult for bonding, especially when using fluoropolymer (non-stick, low friction) materials such as PTFE, FEP, EFEP, PFA and HDPE. These materials along with Polyimide are the traditional materials of choice for catheter liners.

Consideration number two is the outer layer. This is the primary layer that contacts the body and bloodstream. Its function is to protect the patient and to provide support with catheter visualization. The outer layer not unlike the inner layer, must also resist certain chemicals and molecular materials, such as proteins which can bind to the material and in time lead to thrombosis or infection.

The adhesive layer, also called the “tie-layer”, is the third consideration. It is often the structural support and scaffolding that holds the inner and outer layers together while providing critical to function performance characteristics such as bendability, kink resistance and steerability. This layer is sometimes neglected but has many important considerations and will be discussed in the section, ***The Tie That Bonds***.

An example of how these layers might be used in a finished device is with a percutaneous angioplasty (PTA) balloon catheter. These catheters are used to enlarge or dilate a narrowed vessel and place a stent during a minimally invasive procedure. They use two manufactured multi-lumen tubes. One that makes up the long body of the device and the other that is formed into a balloon component that is secured and assembled via a secondary operation near the distal tip, ultimately forming the completed PTA balloon catheter that is used to enlarge a narrowed vessel and place a stent.

The angioplasty is done in a catheterization laboratory (“cath lab”) where the doctor injects a special dye (a contrast medium) through a small, thin high pressure braided tube (a multi-layer catheter) into the bloodstream. The dye allows the doctor to view the arteries on the X-ray monitor and thread a guidewire through the arteries to the point of the occlusion. Once in place, the catheter with the balloon at the tip is fed over the guide wire and into position so that the balloon can be inflated to treat the area and/or apply the stent to restore blood flow. When complete, the balloon is deflated and removed from the body along with the guide wire.

For the main body of the catheter, designers might use a lubricious high-density polyethylene (HDPE) as the inner liner to facilitate the advancement of the catheter over the guidewire, a nylon as the outer layer to reduce cost and provide strength and bendability, and a linear low-density polyethylene (LLDPE) for the tie layer since it bonds well to both. For the balloon structure they might use TPU or Nylon, or a combination of the two. TPU because of its flexibility and excellent processing characteristics and Nylon for its toughness, abrasion resistance, and the ability to withstand repeated stress over extended periods without tearing or fatigue.

## **The Tie That Bonds**

All extruded thermoplastics behave differently when subjected to extrusion stresses. Processing expertise is crucial to providing strong and reliable composites. A material failure or layer delamination could be catastrophic to the success of a medical procedure, so understanding the root cause is important.

A common cause of multi-layer tubing failure is from delamination triggering a change in the composite's properties. Delamination can occur due to a wide variety of circumstances triggering a change in the performance of a multi-layer tube.

When melt temperatures are not well matched, delamination can occur because one of the materials is too cool to form a strong adhesive bond before it exits the extrusion head. When flow velocity and viscosities are not well matched, delamination can occur because the outer material inevitably acts as a dragline on the inner material, and the inner material slows within the extrusion head. Because the plastics are flowing, much like a thick water, it is easy to visualize two currents joining and fighting to find a new homeostasis. The faster flowing current impacts the slower moving current and an eddy current (a disturbance) is formed. This disturbance, if significant enough, will cause a poor bond and result in nonuniform wall thicknesses since the materials moving at different chaotic rates will either bunch up, or become thin and inconsistent.

Spot defects can impact a tube's mechanical performance, or they can cause potential failure points within the tubing, which pose a significant risk especially when it comes to high pressure balloon tubing applications and the manufacturing of those tubes. For example, when mixing color or additives into a base resin, it's necessary to mitigate gel defects. These "gel/color globules" create weak points in a design that can lead to failures and are mitigated by the proper blending and filtration of the material.

To manufacture a multi-layer balloon, a preform tube is shaped in a secondary operation using a process like blow molding. Large OEMs often use highly automated equipment to manufacture their balloons. These systems do not have the same ability to catch the subtle defects that slower more manual labor might offer. Defects such as delamination, material voids, and material contamination will impact a tube's final performance.

The preform tubing must be of a much higher caliber than other non-inflatable single layer or multi-layer components. The preforms require uniform wall thicknesses and properties throughout the length of the tubing in order to provide final balloons that will function as required.

For the process, the multi-layer preforms are often significantly expanded within a cavity of the desired shape and size. Once expanded, the material reflows and cools into the final shape necessary for the procedural style. Proper material selection and elongation considerations must be made in order to obtain a strong and uniform product. Any defect or visual anomaly is greatly exaggerated in this expanded portion of the tube.

Another means of applying a tie-layer is by extruding over an existing extruded tube. This conventional extrusion is done when certain materials require surface treatment to prepare the surface for bonding.

PTFE is ideal as an inner lubricious liner, but it does not bond well to thermoplastics and so requires surface treatment such as Plasma Enhanced Chemical Vapor Deposition (PECVD). Subsequently another material such as PEBAX might be extruded over the treated PTFE, to form the next layer or the final tube. In the case of multi-layer tubing with four or more layers, there may be multiple tie-layers working together for the tube's functionality. But this is true only if internal layers are not compatible.

Improperly made tie-layer(s) can fail anytime during a product's lifecycle. It's important to properly identify the root cause. Was it due to a poor design or did it happen because of the manufacturing process? The designer must understand the risks of incorporating incompatible materials or the process risks of "hard-to-obtain" feature geometries. Regardless of design ownership, those with extrusion expertise should always communicate those risks upfront before ever proceeding with a build. Otherwise it will be very difficult to discern whether a delamination occurred due to processing or the design parameters.

## **Design Consideration & Metrology**

Without inline testing and post processing measurement, it is difficult to find flaws in tight tolerance multi-layer designs. Interlayer flow instabilities can be hard to detect on micro tubing with diameters as small as .020 inches (0.5 mm). When extruding, finding these flaws quickly enough will prevent material scrap, wasted capacity, and it will save customers money.

At HPMS, for example, we are investigating new technologies to maximize our quality and throughput. We have implemented a highly specialized measurement system to ideally allow us to see through 5 layers at a time while taking continuous cross-sectional wall measurements. Inline sensors directly tied to a central processing unit will help to identify defects and make the necessary adjustments or alert when corrective actions are required. This should enable the production line to run at an ideal efficiency rate for the materials being extruded, resulting in tubing with better dimensional characteristics, tighter tolerance controls, and far thinner walls than previously achieved.

In addition to inline measurement, inline inspection such as foreign object detection can be implemented along with a cutting operation and a pneumatic blow off system, to remove non-conforming tubing without impacting the production stream. In this way we can diagnose a problem during the run, and we can also identify variations in the product lot to lot. By establishing robust procedures to minimize characteristic deviations this will better allow for unique material combinations in the future and consistent product quality.

## **SUMMARY**

Over the past 50 years, the transition from invasive surgery required for patients with blocked arteries, to minimally invasive same day procedures, has revolutionized the treatment of coronary artery disease and peripheral artery disease. The fact that there have been over 60 million angioplasty procedures validates this dramatic improvement in the quality of patient care.

Hospital stays of a week or more have become a thing of the past. Thanks to new procedures and diagnostics, patients are living longer and receiving better care than ever before.

Disposable devices are being used to minimize the risk of infection and patients are being treated in a matter of hours, not days.

Multi-layer catheter tubing advances and the vendors that produce them are “at the heart” of social innovation. Suppliers who have invested in strong teams with the necessary tooling and production equipment with strict in-line controls have delivered the necessary quality and reliability while reducing maintenance and production expenses critical to lowering costs. These advances have been transformative to the medical industry and have made it possible for the revolution to happen.



Paper written and edited by Richard Roth and Joseph lamartino.

### **About High Performance Medical Solutions (HPMS)**

HPMS, a Hitachi company, is a medical device manufacturer that specializes in the production of medical devices for diagnostic and interventional procedures. We have over 30 years of extrusion and assembly experience with a diverse portfolio of medical tubing and cable technologies. Our manufacturing facilities and expertise provide precision catheter components and assemblies to many medical OEMs worldwide. These devices are critical for the cutting-edge applications requiring increased functionality and performance with a reduction in size. HPMS offers ISO-13485:2016 compliant operations in Rhode Island and Connecticut U.S.A., and Suzhou, China serving many medical markets like endoscopic, cardiovascular, ultrasound and neurovascular OEMs. Complimentary to our medical device production, the Hi-Tech Machine and Fabrication team excels in the production of defense components, critical to life and mission systems.

**For more information, visit:**

[www.hca.hitachi-cable.com](http://www.hca.hitachi-cable.com) or contact: +1 (866) 972-2077 U.S.A. toll free or +1 (401) 315-0654

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