TOP 5 REASONS TO USE **FILM-COAT PTFE LINER** TUBING FOR YOUR NEXT CATHETER DESIGN

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TOP 5 REASONS TO USE FILM-COAT PTFE LINER TUBING FOR YOUR NEXT CATHETER DESIGN

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So you're thinking of using a low-friction PTFE inner liner for your catheter-based device. Maybe you're working on a braid-reinforced shaft and need to optimize guidewire tracking. Or maybe you're looking to maximize fluid flow.

You have a choice of PTFE liners for your catheter shaft:

- *Film-coat PTFE liner tubing*
- *Extruded PTFE liner tubing*

Both types of liner tubing involve the sintering of PTFE powder particles together into a homogeneous mass. But each fabrication method results in a different set of characteristics. It's important to understand these characteristics to determine which type of liner tubing is best for your design and application.

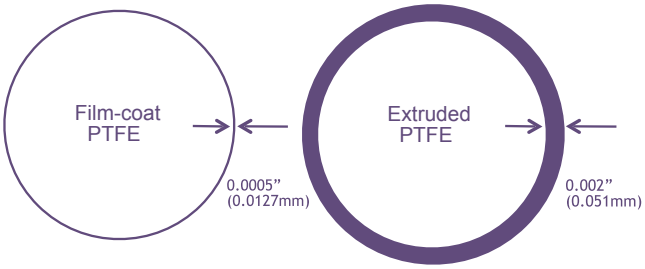
Vention Medical is at the forefront of the evolution of the film-coat process. With decades of experience using a similar technique to fabricate polyimide tubing, Vention has further developed the film-coat process to fabricate PTFE and other thermoplastic tubing.

PTFE liner tubing manufactured using the film-coat process offers some important advantages for medical device design challenges:

1. ULTRATHIN WALLS (0.0005"-0.002")
2. PRECISE DIMENSIONS
3. HIGH FLEXIBILITY
4. IMPROVED ADHESION WITH A STRIKE LAYER
5. OPTION OF CUT LENGTHS OR CONTINUOUS-SPOOLED LENGTHS

REASON #1: ULTRATHIN WALLS (0.0005" TO 0.0020") *MAXIMIZES SPACE IN YOUR DEVICE*

FIGURE 1. CROSS-SECTION COMPARISON OF FILM-COAT PTFE TUBE AND EXTRUDED PTFE TUBE



Using an ultrathin PTFE liner is all about optimizing the cross-section of your catheter-based device. An ultrathin PTFE liner can maximize inner diameter (ID) and give you space to do more with your device, whether it's adding reinforcement or adding additional layers. A thinner liner can also minimize the outside diameter (OD), resulting in a shaft that takes up less space.

Using the film-coat process, we can fabricate PTFE liner tubing with a wall as thin as 0.0005" (0.0127 mm), or even as thin as 0.0003" (0.0076 mm), depending on the design.

Real-Life Example

One customer was able to improve insertion force and reduce the profile of its catheter shaft by 10% by using a film-coat PTFE liner with a wall thickness of 0.0005" (0.0127 mm) instead of a thicker extruded PTFE liner.

In contrast, extruded PTFE liner tubing has much thicker walls—an average of 0.002" (0.051 mm). To create thinner walls (0.001" and less) in extruded PTFE tubing, the liner must undergo an additional processing step of heating and elongating over a straightened stainless steel mandrel. In this process the PTFE's wall thickness is first thermally softened, then mechanically reduced.

FABRICATING EXTRUDED AND FILM-COAT PTFE LINER TUBING: WHAT'S THE DIFFERENCE?

Film-coat PTFE liner tubing

A liquid coating is created using water, PTFE particles or powder and a wetting-agent to keep the PTFE suspended in the water. This coating is applied to the outer surface of a silver-plated copper wire. Heat is applied to the coated wire, which causes the water and surfactant to vaporize, leaving only a thin coating of PTFE powder. Higher heat is then applied to sinter the individual particles of PTFE together into a homogenous film. Film-coat PTFE is supplied in straightened cut lengths or continuous-spooled lengths. The wire on which the PTFE was fabricated can be left in place and used as a mandrel for the catheter assembly process. Once the mandrel is removed, ultrathin-wall PTFE tubing remains.

Extruded PTFE liner tubing

A paste composed of a lubricant and PTFE powder particles is pushed through a die to form continuous tubing. This PTFE-paste tubing is exposed to high heat, which causes the lubricant to vaporize, and the individual particles in the PTFE powder to sinter together in one interconnected mass of material. Extruded tubing is supplied in cut lengths only and is not supplied on a mandrel.

Both film-coat and extruded PTFE liner tubing must undergo an etching process to allow for further assembly and bonding steps. This etching process is standard for both types of PTFE liner tubing.

REASON #2: PRECISE DIMENSIONS
ID AND OD TOLERANCES OF ±0.0003" TO ±0.0005"

FIGURE 2. COMPARISON OF ID/OD TOLERANCE FOR FILM-COAT AND EXTRUDED PTFE LINER TUBING

	ID/OD Tolerance
Film-Coat PTFE Liner	**0.0003"-0.0005" (0.0076 mm-0.0127 mm)**
Extruded PTFE Liner	**0.001"-0.002" (0.0254 mm-0.0508 mm)**

Precision film-coat PTFE liner tubing starts with a spool of precision-drawn, silver-plated copper wire. The PTFE liner is then formed or molded around this mandrel. The wire-drawing process creates a wire with an extremely consistent OD throughout the length of the mandrel. This consistent diameter and tight OD tolerance is passed on to the PTFE liner's ID.

PTFE liner tubing on a mandrel is then ready for additional lamination. Building your catheter shaft over the same mandrel on which the PTFE liner was formed helps you to maintain tight tolerances throughout your device.

In the extrusion process, tight tolerances can be difficult to maintain due to the need to control the complex interaction of variables including temperature, pressure, and flow rate. The typical extruded PTFE liner has an ID and OD tolerance of ±0.001" to 0.002".

In most cases, film-coat PTFE liners can be used with standard catheter-building techniques that use a stainless steel mandrel. Even if you remove the PTFE liner from the silver plated, copper-core mandrel and slide it over the standard stainless steel mandrel, you still form a very tight fit between liner and mandrel. Since the PTFE liner ID has a tolerance of ±0.0003" to ±0.0005", the clearance between the liner ID and the mandrel OD needs to be only 0.001" (0.025 mm), instead of the common 0.0025" (0.063 mm) clearance exhibited with an extruded PTFE liner.

REASON #3: HIGH FLEXIBILITY
FILM-COAT PTFE LINER ADDS MINIMAL STIFFNESS TO THE CATHETER SHAFT

If your goal is to create the most flexible catheter shaft possible, a film-coat PTFE liner is a better choice than an extruded PTFE liner.

We conducted 2 tests on both film-coat PTFE liners and extruded PTFE liners with similar dimensions: Elongation at Break and Modulus of Elasticity (flexibility). Both test outcomes had good to excellent CpK, which indicated the tight distribution of all data points.

FIGURE 3. COMPARISON OF ELONGATION AT BREAK AND MODULUS OF ELASTICITY FOR FILM-COAT AND EXTRUDED PTFE LINER TUBING

	Vention Film-Coat PTFE Liner (5.2 Fr ID; 0.001" wall)	*Extruded PTFE Liner (5.7 Fr ID; 0.001" wall)*
Elongation at Break	**450%**	**390%**
Modulus of Elasticity (psi)	**43,000**	**130,000**

Tensile Elongation at Break data points are about the same for both film-coat and extruded PTFE liners. The big difference is the Modulus of Elasticity. The film-coat liner Modulus of Elasticity was 66% more elastic or flexible than that of the extruded liner. This means that using a film-coat PTFE liner will improve your finished catheter's overall flexibility compared with using an extruded PTFE liner.

Real-Life Example

For a customer designing a catheter-based device for a neurological application, flexibility was a key performance requirement to navigate tortuous vascular pathways and easily track over the guidewire in a very small space. Film-coat PTFE was an ideal choice to provide an ultrathin inner layer that was flexible and highly lubricious.

REASON #4: INCREASED ADHESION WITH STRIKE LAYER

ADDING A MICROTHIN THERMOPLASTIC LAYER BOOSTS BOND STRENGTH

Using the film-coat process to apply a microthin layer of thermoplastic over an etched PTFE surface can optimize thermal or adhesive bonding. This thermoplastic "strike layer" adds up to 60% more bond strength between the etched PTFE liner and the catheter assembly, compared with bond strength without a strike layer. The strike layer material is typically selected to match the successive layers in the catheter which ensures a strong thermal bond between the liner and the rest of the catheter design.

A microthin strike layer of only 0.0003" (0.0076 mm) does not significantly increase the overall wall thickness of the shaft. A common wall construction for a PTFE liner with an outer thermoplastic strike layer is a 0.0007" (0.0178 mm) layer of PTFE and a 0.0003" (0.0076 mm) layer of nylon or Pebax®, for a total liner wall thickness of 0.001" (0.0254 mm).

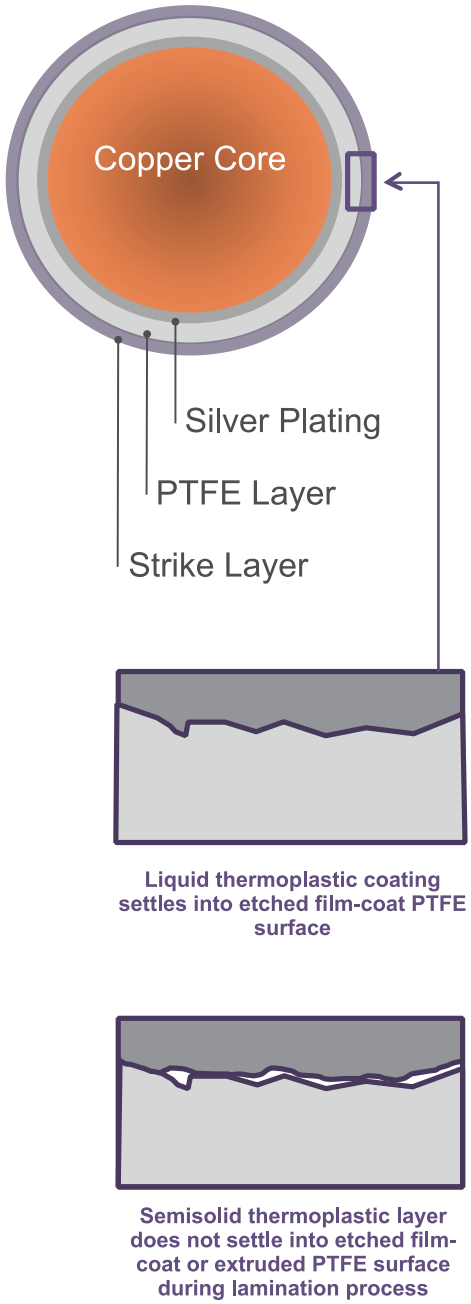
Why does an etched PTFE liner with a thermoplastic strike layer produce such high thermal bond strength? In the film-coat process, the thermoplastic strike layer is applied to the etched PTFE surface as a liquid coating. This enables the material to flow completely into the microtexture of the surface, resulting in more surface area contact and hence a higher adhesive bond than an etched PTFE surface without a strike layer. Adding a film-coat strike layer to an extruded PTFE liner tube is not possible.

Etched PTFE—whether fabricated via the film-coat process or extrusion—has a bond surface that degrades over time and with exposure to environmental conditions. An additional benefit of a strike layer is that it preserves and prevents the degradation of surface adhesion properties of an etched PTFE liner.

Strike layers are available in a wide range of thermoplastic materials, including:

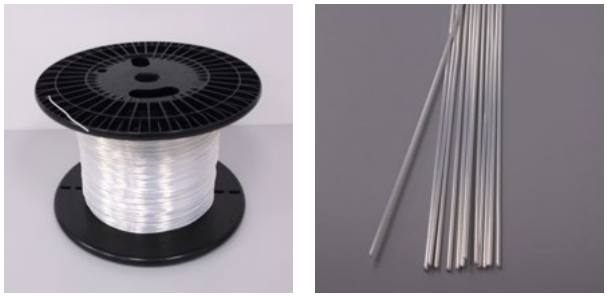
- Nylon (11 and 12)
- Pebax® (55D, 70D and 72D)
- Polyurethane (Pellethane® & Tecoflex®)
- Polyimide

FIGURE 4. COMPARISON OF LIQUID VS SEMISOLID THERMOPLASTIC ADHESION DURING LAMINATION



REASON #5: COMES IN CUT LENGTHS OR CONTINUOUS-SPOOLED LENGTHS *ALL PTFE LINERS PROVIDED ON MANDRELS*

FIGURE 5. SPOOLED PTFE LINER TUBING (LEFT) AND STRAIGHTENED, CUT LENGTHS OF PTFE LINER TUBING (RIGHT).

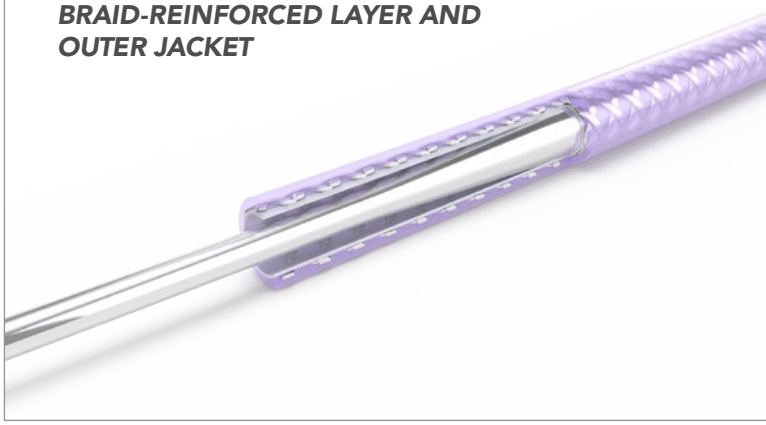


Film-coat PTFE liner is fabricated around a solid, silver-plated, copper-core mandrel. The mandrel remains in place throughout the catheter assembly process. It also helps maintain the surface quality of the PTFE liner, as tubing with only a 0.001" (0.025 mm) wall is susceptible to kinks and surface imperfections.

Sourcing film-coat PTFE liner tubing on a continuous mandrel already on the spool means it's ready for high-volume, reel-to-reel manufacturing processes like braid- or coil-wire reinforcement.

Extruded PTFE liner tubing is not offered in continuous spooled lengths nor available over a mandrel, as either a cut-to-length or continuously spooled package.

FIGURE 6. PTFE LINER WITH A BRAID-REINFORCED LAYER AND OUTER JACKET



Real-Life Example

Using Vention's continuous-spooled, film-coat PTFE liner tubing enabled a customer to reduce the cost of assembling its catheter by 30% while improving quality and simplifying the assembly process. Before, the extruded PTFE had to be heated, pulled down, and secured over the mandrel by hand to form a liner. Each mandrel was then passed through a braiding machine to apply a 16-wire braid, and the ends of the braid had to be secured by hand. All these prelamination steps were eliminated with continuous-spooled film-coat PTFE liner tubing.

CONCLUSION

When it comes to PTFE liner tubing, you have a choice between film-coat and extruded PTFE liner tubing, each with its own set of performance characteristics. Film-coat PTFE liner tubing offers key advantages that can be leveraged in a wide range of medical device designs.

Vention Medical has decades of experience with the film-coat process and has mastered this technique for polyimide, PTFE, and other polymers. We are continuing to innovate with this versatile technique to expand the range of solutions for medical device challenges.

ABOUT VENTION MEDICAL

Vention Medical is a global integrated solutions partner with more than 30 years of experience in design, engineering, and manufacturing of complex medical devices and components. Vention Medical specializes in components and services used in interventional and minimally invasive surgical products including catheters, balloons, extrusions, polyimide and composite tubing, heat shrink tubing, braid-reinforced shafts, cleanroom injection molding, and finished device assembly and packaging. Visit Vention at ventionmedical.com.

Visit ventionmedical.com to learn more and check out our film-coat PTFE liner tubing in our online store.

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