Nordson MEDICAL

Top 5 Reasons to Use Film-Cast PTFE Liner

FOR YOUR NEXT CATHETER DESIGN

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Introduction:

So you're thinking of using a low-friction PTFE inner liner for your catheter-based device. Maybe you're working on a braid-engineered 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:

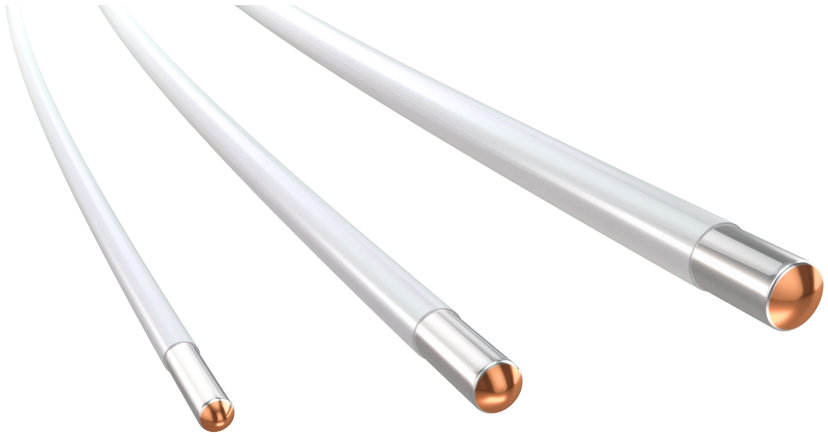
- Film-cast PTFE liner tubing
- Extruded PTFE liner tubing

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.

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

PTFE liner tubing manufactured using the film-cast 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”):

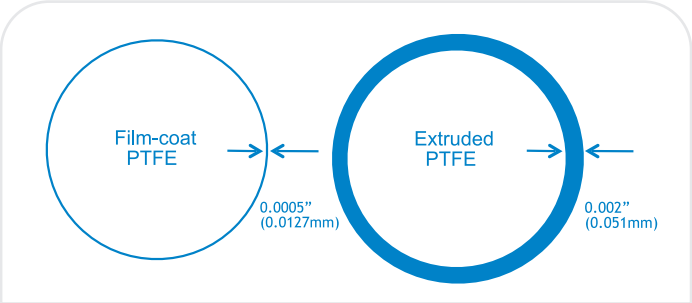


FIGURE 1: Cross-section comparison of film-cast PTFE tube and extruded PTFE tube

MAXIMIZES SPACE IN YOUR DEVICE:

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-cast 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-cast 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 & FILM-CAST PTFE LINER TUBING: WHAT’S THE DIFFERENCE?

FILM-CAST 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-cast 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-cast 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 & OD TOLERANCES OF ±0.0003” TO ±0.0005”:

	ID/OD Tolerance
Film-Cast 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)

FIGURE 2: Comparison of ID/OD tolerance for film-cast and extruded PTFE liner tubing

Precision film-cast 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-cast 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-CAST PTFE LINER ADDS MINIMAL STIFFNESS TO THE CATHETER SHAFT:

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

We conducted 2 tests on both film-cast 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.

	Nordson MEDICAL Film-Cast 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

FIGURE 3: Comparison of elongation at break and modulus of elasticity for film-cast and extruded PTFE liner tubing

Tensile Elongation at Break data points are about the same for both film-cast and extruded PTFE liners. The big difference is the Modulus of Elasticity. The film-cast liner Modulus of Elasticity was 66% more elastic or flexible than that of the extruded liner. This means that using a film-cast 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-cast 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-cast 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-cast 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-cast strike layer to an extruded PTFE liner tube is not possible.

Etched PTFE—whether fabricated via the film-cast 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

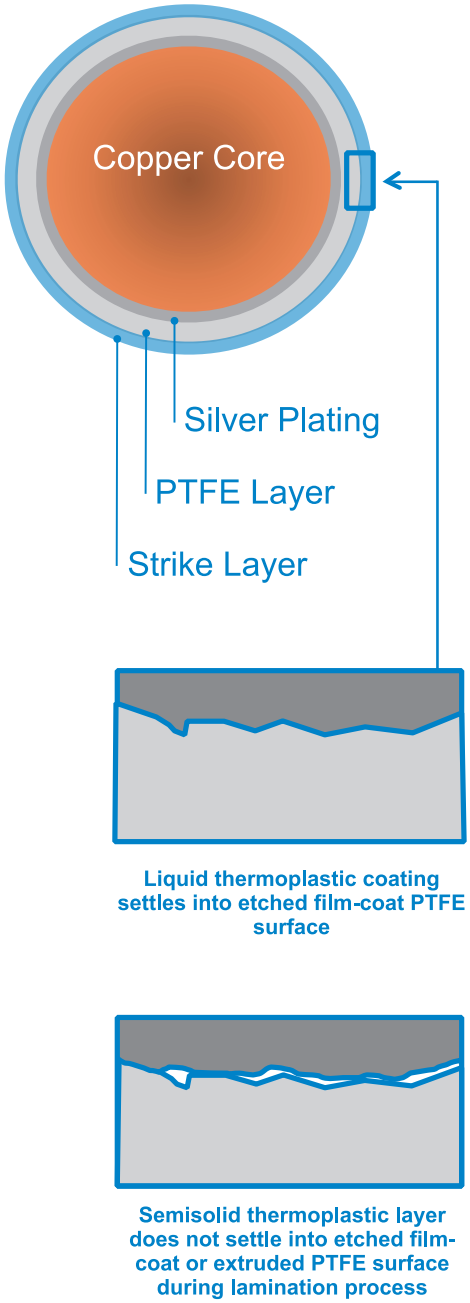


FIGURE 4: Comparison of liquid vs. semisolid thermoplastic adhesion during lamination

Reason #5: Comes in Cut lengths or Continuous-Spooled Lengths:

ALL PTFE LINERS PROVIDED ON MANDRELS:

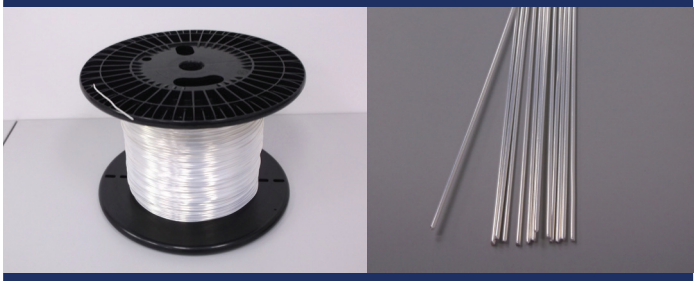


FIGURE 5: Spooled PTFE liner tubing (left) and straightened, cut lengths of PTFE liner tubing (right)

Film-cast 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-cast 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 4: Comparison of liquid vs. semisolid thermoplastic adhesion during lamination

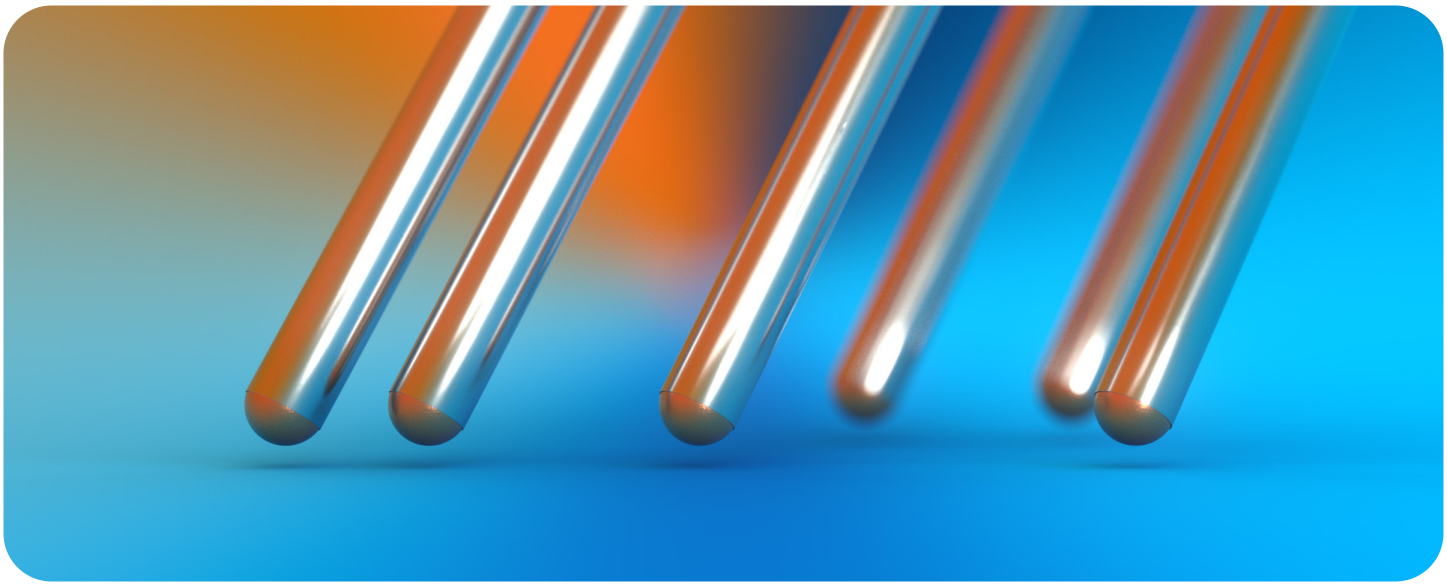
REAL-LIFE EXAMPLE:

Using Nordson MEDICAL’s continuous-spooled, film-cast PTFE liner tubing enabled a customer to reduce the cost of as-sembling 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 pre-lamination steps were eliminated with continuous-spooled film-cast PTFE liner tubing.

Conclusion:

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

Nordson MEDICAL has decades of experience with the film-cast 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.



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Nordson MEDICAL is a global expert in the design, development, and manufacturing of complex medical devices and component technologies. We serve interventional, surgical, and specialized markets with technologies that save or enhance lives. As an integrated, single-source partner, we enable our customers to save costs and speed time to market.

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