

# **Choosing PTFE Tubing:**

A COMPARISON OF FILM-CAST AND RAM-EXTRUDED PTFE TUBING

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Nordson MEDICAL is a pioneer and innovator in the design, development, and manufacturing of PTFE (polytetrafluoroethylene) medical tubing and liners for a wide range of applications in the medical device industry. With decades of experience, our processes are comprehensive.

### **An Ideal Catheter Liner:**

PTFE tubing is typically used for split-sheath introducers and dilators, and its chemical stability and low coefficient of friction make it an ideal lubricious catheter liner. That lubricious inner layer is ideal for catheter applications that require low friction for enhanced:

- Guidewire tracking
- Fluid flow
- Passage of other devices
- Irrigation
- Steering wire tracking
- Liners
- Balloon protectors
- Introducer sheaths
- Fluid transfer tubing

### THERE ARE PRIMARILY TWO WAYS OF PRODUCING PTFE TUBING:

- Film-Cast Process
- Ram-Extrusion Process

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

### WHAT MAKES PTFE AN IDEAL MEDICAL DEVICE PLASTIC?:

PTFE has the lowest coefficient of friction of any polymer, making it a popular choice for catheter applications that require lubricity.

#### **PTFE FEATURES:**

- Temperature and chemical resistance
- Biocompatibility
- Precise tolerances
- High dielectric strength
- Excellent insulative properties

### **Film-Cast Process:**

# WALL THICKNESS OF 0.0005" TO 0.002" ID AND OD TOLERANCES OF ±0.0003" TO ±0.0005":

Nordson MEDICAL is at the forefront of the evolving 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 create PTFE liners.

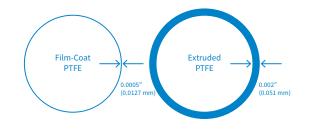
In a film casting process, a liquid coating is created using water, PTFE particles or powder, and a wetting agent to keep the PTFE suspended in the water. This coating is applied to the outer surface of the silver-plated copper wire. Heat is applied to the coated wire, which causes the water and surfactant to vaporize, leaving only a thin coating of PTFE powder. Higher heat is then applied to sinter the individual PTFE particles together into a homogeneous film. 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, ultrathinwalled PTFE tubing remains. PTFE liners manufactured using this process offer some solutions for medical device design challenges like 0.0005" to 0.002" thin walls, precise dimensions achieving tolerances of ±0.0003" to ±0.0005", improved adhesion by a strike layer, and enhanced flexibility.

PTFE film-cast processing is ideal for thin-walled liners. The flexibility of film-cast PTFE is demonstrated by both elongation and elasticity tests. With liners of 5.2 Fr ID and 0.001" wall thickness, film-cast PTFE tested to have 450% elongation while attaining as low as 43,000 psi modulus of elasticity.

### **REAL-LIFE EXAMPLE:**

For a customer designing a catheter for a neurovascular application, flexibility and ultra-low profile were key performance requirements to both navigate the small and tortuous vessels and easily track over the guidewire. Film-cast PTFE was an ideal choice to provide an ultra-thin inner layer that was both flexible and highly lubricious.

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



## FIGURE 2. COMPARISON OF ID/OD TOLERANCE FOR DILM-CAST AND EXTRUDED PTFE LINER TUBING

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

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

	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

#### STRIKE LAYERS FOR MORE STRENGTH:

All PTFE liner processes require outer surface etching to enable further catheter assembly and bonding. Using the film-cast process, a micro-thin layer of thermoplastic can be applied over the etched PTFE surface to optimize the thermal or adhesive bonding of an outer jacket. This thermoplastic "strike layer" adds up to 60% more bond strength between the etched PTFE liner and the catheter assembly compared to the 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. Strike layers using the film-cast process can be applied as thin as 0.0003", therefore not significantly increasing the overall wall thickness of the shaft. Combined, the typical overall thickness of a PTFE liner and thermoplastic strike layer is as little as 0.001".

In the film-cast process, the thermoplastic strike layer is applied to the etched PTFE surface as a liquid coating, enabling the material to flow completely into the microtexture of the surface, resulting in more surface area contact. This creates a higher adhesive bond than an etched PTFE surface without a strike layer.

#### **HOW DOES FILM-CAST PTFE COME?:**

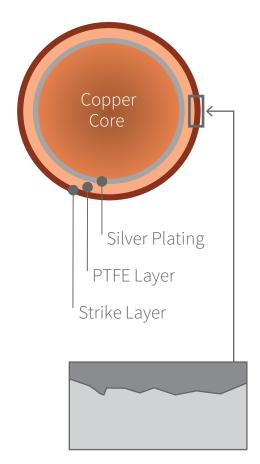
Film-cast PTFE is supplied in straightened cut lengths or in continuous spooled lengths with and without a core wire.

### WHAT MATERIALS ARE AVAILABLE FOR STRIKE LAYERS?:

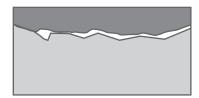
Strike layers are available in a wide range of thermoplastic materials, including:

- Nylon (11 and 12)
- Pebax<sup>®</sup> (55D, 70D, and 72D)
- Polyurethane (Pellethane® and Tecoflex®)
- Polyimide

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



Liquid thermoplastic coating settles into etched film-coat PTFE surface



Semisolid thermoplastic layer does not settle into etched filmcoat or extruded PTFE surface during lamination process

### **Ram-Extruded Process:**

### WALL THICKNESS AS LOW AS 0.001" TOLERANCES AS LOW AS ±0.0005":

During the ram-extruded process, a powdered PTFE is combined with a processing aid to form a paste that is pushed out of a tooling combination to form a continuous profile. This extruded paste passes through heat which vaporizes the processing aid. The extrusion then passes through high heat where the PTFE powders sinter together in one interconnected sleeve of material. Ram extrusion enables free extrusion and does not need a silver-plated copper wire. However, the flexibility of the process does allow for the inclusion of a wire. Multi-lumen tubing, monofilament, and beading are all capable of using this process.

The PTFE ram-extruded process offers advantages over film cast with a broader dimensional product range. Ram extrusion can extrude walls as low as 0.001" at outer diameters as high as 0.400", with tolerances as low as ±0.0005". Ram extrusion can produce thicker-walled tubing than the film-cast process, which is important for the demands of larger-bore delivery systems or for any device requiring high tensile strength and durability.

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





#### **HOW DOES RAM-EXTRUDED PTFE COME?:**

Extruded tubing can be supplied in cut lengths, continuous spooled lengths, and spooled over SPC.

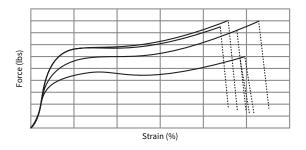
### **ADD RADIO-OPAQUE FILLERS:**

Nordson MEDICAL's expertise in the PTFE ram-extrusion process has enabled us to incorporate radio-opaque fillers, ideal for many applications such as sheaths and dilators, and anywhere precise catheter positioning is critical for procedural success. As with the film-cast process, ramextruded PTFE tubing must undergo an etching process to allow for further assembly and bonding. Nordson MEDICAL offers both continuous and discrete etching solutions.

#### **REAL-LIFE EXAMPLE:**

A customer for a PTFE legacy product wanted to optimize the tensile strength requirement. Their biggest constraint was that the dimensions were fixed and could not be changed. Our ram-extrusion SMEs used their process experience and expertise to offer a range of tensile strengths for the same size PTFE tubing. This enabled the customer to find the optimum tensile property to best fit their application.

#### FIGURE 6. COMPARISON OF FORCE AND STRAIN



### **Find Your Ideal Process:**

### **FILM-CAST VS RAM-EXTRUSION:**

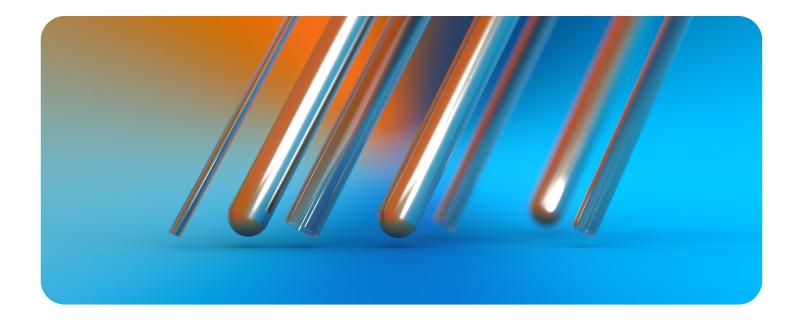
With film-cast and ram-extrusion capabilities, Nordson MEDICAL offers a versatile solution for PTFE tubing in terms of sizes and application-based mechanical requirements. The table below summarizes the differences between film-cast and ram-extruded PTFE, to serve as a guide to determining the ideal process that meets the needs of your device design.



	Film-Cast Coating	Ram Extrusion
Tubing Inner Diameter Range	0.014" - 0.096"	0.002" - 0.350"
Wall Thickness Range	0.0004" - 0.002"	0.001" and up
Tolerances	0.0003" - 0.0005"	0.0005" - 0.001"
Mechanical Aspects	<ul><li>Maximized flexibility</li><li>Low modulus of elasticity</li><li>High elongation at break</li><li>High lubricity</li></ul>	<ul><li> High tensile strength range</li><li> Maximized stiffness</li><li> High lubricity</li></ul>
Materials	Natural     Pigmented (not common)	<ul><li>Natural</li><li>Pigmented</li><li>Radio-opaque fillers</li></ul>
Extrusion Profiles	Round tube     Over-the-wire	<ul><li>Round tube</li><li>Monofilament</li><li>Multi-lumen</li><li>Over-the-wire</li><li>Beading</li></ul>
Product Availability	Spooled over SPC     Cut to length	<ul><li>Cut to length</li><li>Spooled</li><li>Spooled over SPC</li></ul>

### Conclusion

Nordson MEDICAL has decades of experience with PTFE and has mastered its extrusion and film-cast techniques. We are continuing to innovate with these processes to expand the range of solutions for medical devices.



### **About Nordson MEDICAL**

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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