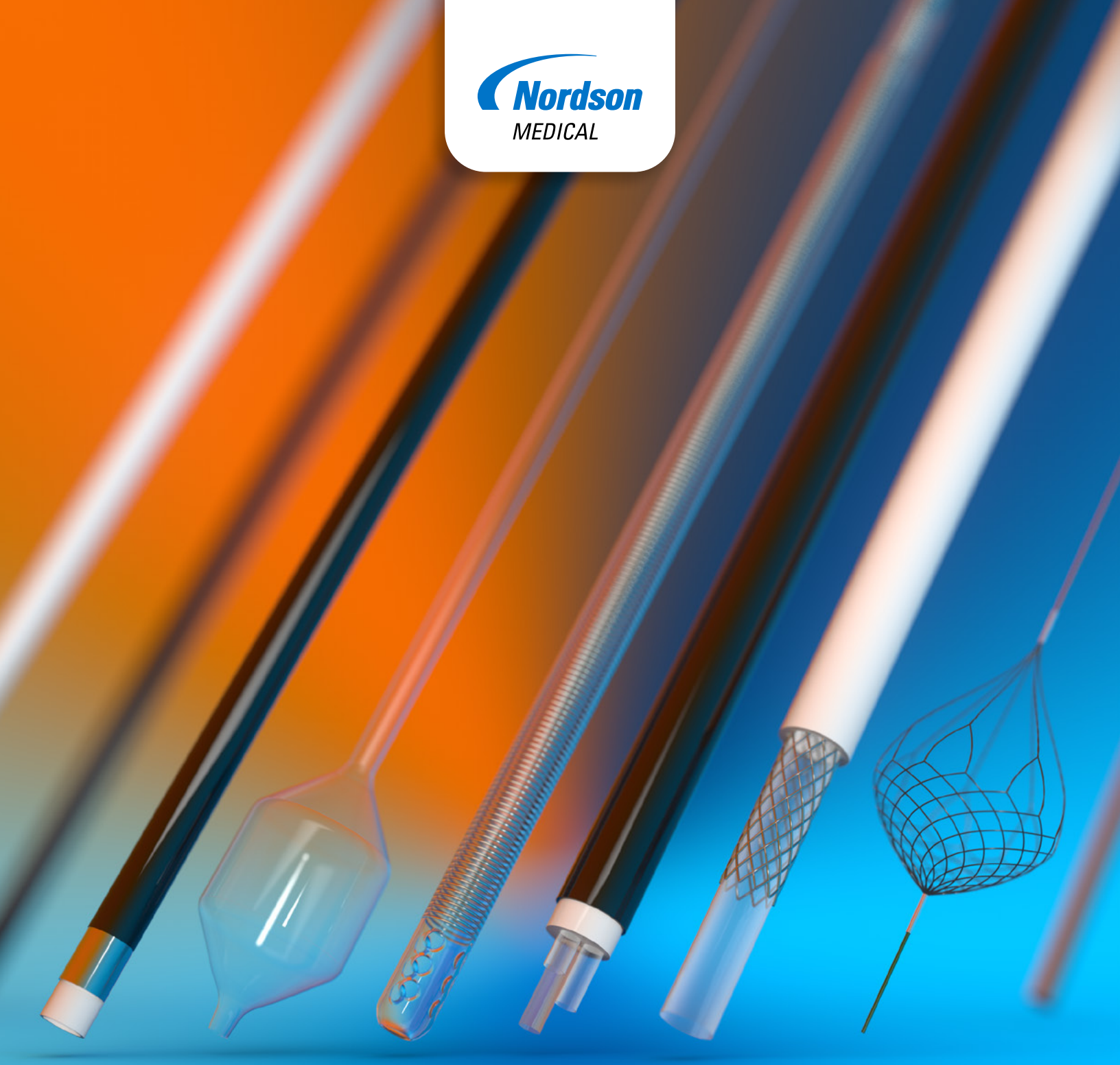
Nordson MEDICAL



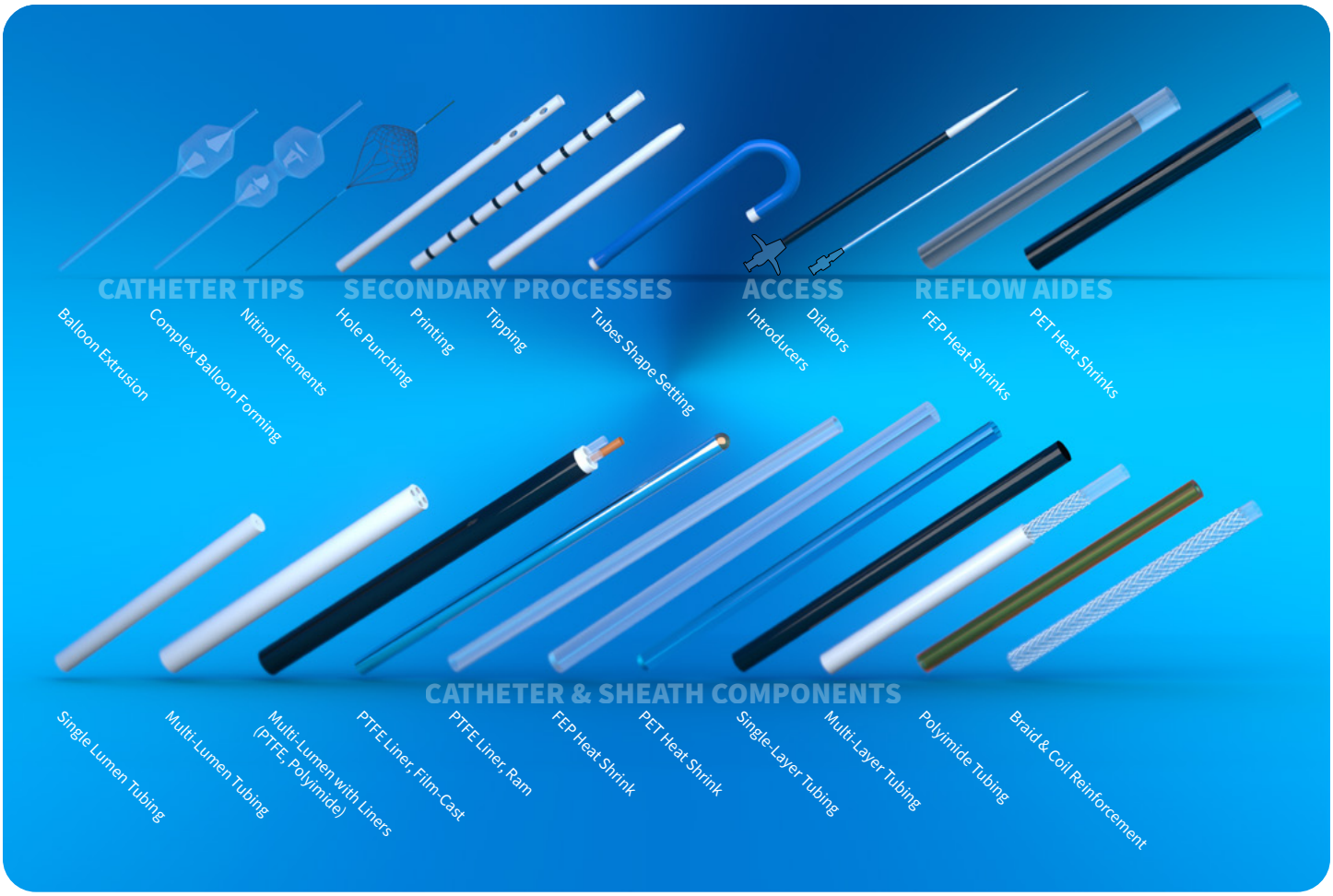
Engineering Interventional Solutions

ADVANCED POLYMER COMPONENTS
FOR CATHETER-BASED INNOVATION

Table of Contents

Engineering Interventional Solutions

Advanced Polymer Components for Catheter-Based Innovation



Nordson MEDICAL Interventional Solutions brings together advanced polymer technologies and deep application expertise to support the development of catheter-based devices across a wide range of interventional markets. From cardiovascular and electrophysiology to neurovascular and structural heart, we partner with device manufacturers to deliver critical components that enable innovation and improve patient outcomes.

We support the full spectrum of device development, from early concept through commercialization, helping to streamline sourcing and simplify vendor strategies. Our comprehensive capabilities include precision extrusion, balloon forming, and heat shrink tubing, all engineered for performance and reliability. With a broad portfolio of high-performance components and both in-stock and custom solutions, we help simplify supply chains and accelerate development.

Nordson MEDICAL

GLOBAL CAPABILITIES

Integrated Solutions

Nordson MEDICAL is a Global Integrated Solutions Partner for the design, engineering and manufacturing of complex medical devices and components. We enable our customers' success through superior products and services differentiated by industry leading innovation, quality, reliability and responsiveness.

11
FACILITIES DOMESTIC & INTERNATIONAL

2,400+
EMPLOYEES

400K+
SQUARE FEET MANUFACTURING SPACE

COMPONENTS & TECHNOLOGIES

- Range of differentiated, proprietary technologies
- Focus on interventional & surgical applications
- Advanced polymer technologies
- 24/7 online store
- In-stock and custom options
- Medical-grade fluid handling solutions
- Single-source partner
- Deep component expertise

FINISHED SURGICAL DEVICES

- Advanced patient care and streamlined procedures
- Specialized innovations that elevate surgical standards
- Precisice, adjustable cardioplegia delivery
- Split septum technology

A Strategy of Delivering Value

INNOVATION

- Proprietary components
- Internal R&D investment
- Innovative surgical devices

QUALITY

- ISO 13485 registered
- Class I, II & III devices
- 100+ audits per year

SERVICE

- Leading responsiveness
- 24/7 online store
- Field service team

VALUE

- Simplify your supply chain
- Global manufacturing sites
- Focus on lean culture

Global Footprint

United States
Allen, TX
Arab, AL
Chattanooga, TN
Eagan, MN
Easton, PA
Loveland, CO
Salem, NH
St. Petersburg, FL

Ireland
Boyle

Israel
Katzrin

Mexico
Guaymas

Markets & Applications

Fluid Components

- BioProcessing
- Diagnostics
- Drug Delivery
- Intravenous
- Inflation & Volumetric Containers
- Non-Medical
- Patient Care
- Surgical

Interventional Solutions

- Cardiovascular
- Electrophysiology
- Gastrointestinal
- Neurovascular
- Peripheral Vascular
- Robotic Surgery
- Structural Heart

Surgical Solutions

- Cardiovascular
- Hemodialysis
- Infusion Therapy
- Ophthalmology

COMPONENTS &
Technologies

Nordson MEDICAL

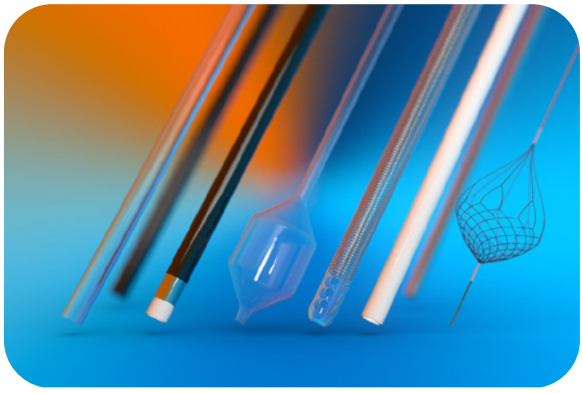
COMPREHENSIVE SOLUTIONS FOR MEDICAL DEVICES & PROCEDURES

Fluid Components

- Aseptic Disconnects
- Bag Ports
- Build-A-Part Fittings
- Check Valves
- Custom Fluid Components
- Gaskets
- Inflation Products
- ISO 80369-Compliant Parts
- Luer Fittings
- Manifolds
- Needlefree Swabable Valves
- Pressure-Relief Valves
- Quick Connect Couplings
- Sanitary Clamps
- Sanitary Fittings
- Stopcocks
- Tapered Seal Connectors
- Threaded Fittings
- Tube Clamps
- Tube Fittings
- Tubing
- Tubing Retainers

Interventional Solutions

- Biomaterial Delivery Devices
- Cannulae
- Extruded Tubing
- FEP Heat Shrink Tubing
- Film-Cast PTFE Tubing
- Inflation Devices
- Medical Balloons
- Nitinol Components
- Peelable Polyester Heat Shrink Tubing
- PET Heat Shrink Tubing
- Polyimide Tubing
- Ram-Extruded PTFE Tubing
- Reinforced Tubing



Surgical Solutions

- Aortic Punches
- IV Extension Sets
- IV Manifolds
- Myocardial Protection Systems
- Needlefree Access Devices
- Needlefree Connectors
- Ophthalmology Balloon Catheters
- Safety Valves
- Securement Bands
- Vascular Loops

VISIT OUR ONLINE STORE: www.nordsonmedical.com

5 Characteristics to Consider

WHEN DESIGNING AN ENGINEERED SHAFT OR DELIVERY SYSTEM

5 Characteristics to Consider

When Designing an Engineered Shaft or Delivery System

Introduction:

The medical device industry is continuously advancing the standard of care for patients. As new procedures, devices, implants and therapeutics come to market, one of the primary objectives is to develop systems that are as minimally invasive as possible. Novel technologies require high-performance delivery systems today more than ever.

There are several factors to consider when designing reinforced catheters and delivery systems. Nordson MEDICAL has the capabilities, expertise, equipment, and systems to help guide the product development of complex delivery systems to ensure clinical performance and user requirements are consistently achieved.

Nordson MEDICAL utilizes engineering expertise along with a software platform, SimShaft™, to balance key characteristics to optimize the performance of delivery systems. Five key features to consider will be discussed in greater detail. These include:

1. Tensile Strength
2. Ovalization Resistance
3. Torsional Rigidity
4. Flexural Rigidity
5. Profile

Performance Feature #1:

TENSILE STRENGTH & COMPRESSION RESISTANCE

Many applications for implant delivery require the delivery system to resist very high tensile and compressive forces. It is common to utilize a push-pull mechanism to deploy an implant. As a result, tensile strength is needed to ensure the ID of the reinforced shaft avoids necking and allows for advancement of the implant. Compression strength is needed to avoid buckling of the shaft during deployment.

Nordson MEDICAL can maximize compression resistance and tensile strength of delivery systems by leveraging the following:

TRI-AXIAL REINFORCEMENT WITHIN THE BRAID:

All our braiders are set up to allow for a longitudinal wire or fiber to be woven within the braid. This allows for significant improvement in tensile resistance with additional positive impact on compression force.

MULTI-LAYER BRAIDING & COILING:

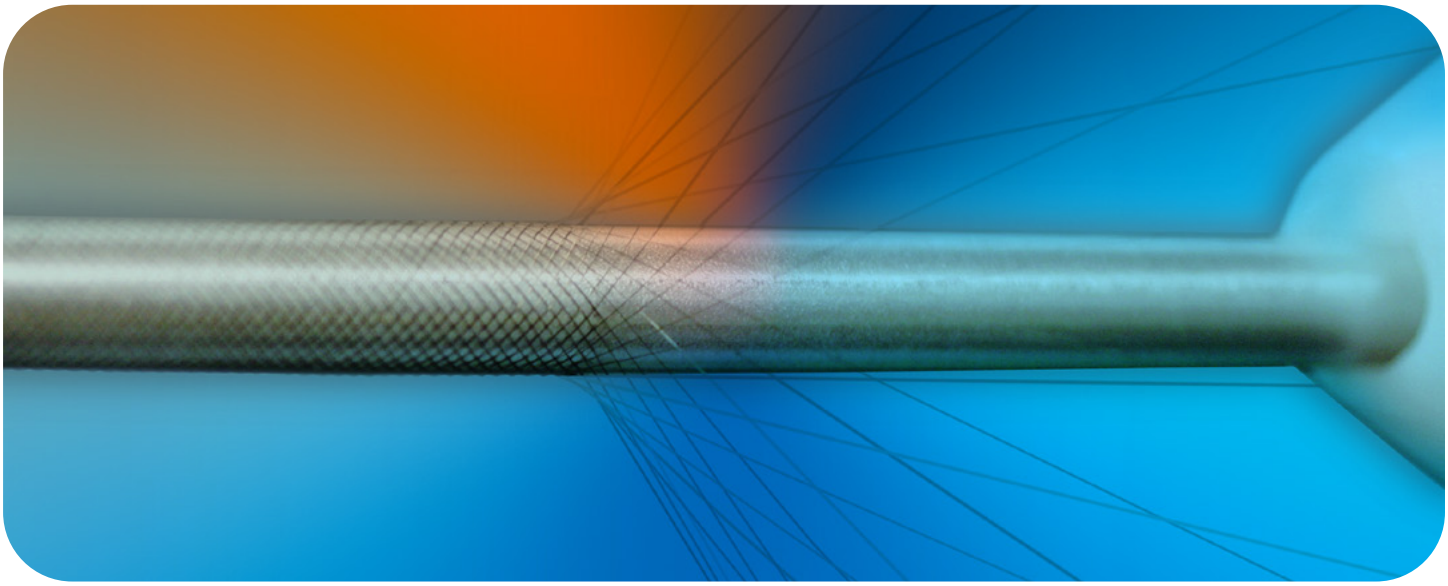
Utilizing our many coil winding capabilities along with our 16-, 32- and 48-carrier braiders, we can leverage multiple layers of reinforcement to significantly improve tensile resistance and compression force.

LASER-CUT HYPOTUBE ENCAPSULATION:

Nordson MEDICAL can laminate a laser-cut hypotube with cut features designed to optimize tensile strength and compression resistance between polymeric layers.

MULTI-FILAR BRAID REINFORCEMENT:

We are able to run multiple wires off of each bobbin. This capability allows us to increase tensile performance without compromising other performance features such as flexibility or torque.



Performance Feature #2:

OVALIZATION RESISTANCE

Ovalization resistance is a critical feature that needs to be considered when there are multiple components closely mated together within a delivery system. Often the forces to deploy an implant will be significantly increased if the system is not designed to minimize ovalization. There are several variables to be considered to avoid ovalization.

BRAID CONFIGURATION:

All of Nordson MEDICAL's braiders are capable of running variable pitch braid. This means the delivery system can have multiple segments that exhibit unique performance characteristics. For instance, the proximal end of the shaft could be reinforced with a very open braid pattern to increase the rigidity of the system while the distal end could have a very dense braid coverage profile to minimize ovalization and to increase flexibility.

COIL REINFORCEMENT:

Nordson MEDICAL has several different coil winders. Utilizing a coil reinforcement can significantly improve the ovalization resistance of a catheter. Coiling can be done continuously through the full length of the catheter, or in a discrete section where ovalization resistance is critical. Nordson MEDICAL also has point winding capabilities, which can be leveraged to eliminate the spring-back of the coil in discrete cases. This helps to ensure the coil is wound tightly over the substrate. Nordson MEDICAL can use variable-pitch coiling to optimize performance for various sections along the length of a single reinforced shaft.

WIRE/FIBER OPTIONS:

Several different reinforcement options exist to help achieve performance characteristics while minimizing impact to profile. Nordson MEDICAL can utilize round or flat wires, varying grades of SS, Tungsten or various types of fibers such as UHMWPE.

Performance Feature #3:
TORSIONAL RIGIDITY

Alignment and orientation of the delivery system can be of paramount importance for allowing the system to navigate to the target anatomy and to allow for a successful procedure. Nordson MEDICAL has a wide range of material options that can be utilized to optimize the torque response of a reinforced catheter in addition to the various reinforcement elements. We manufacture extrusions with various grades of Pebax, Nylon, Polyurethane, Polyester, Polyethylene, Polyimide and PEEK (in addition to several other less common materials).

In addition to selecting the right material for the outer jacket, it can be equally as beneficial to ensure the right liner is utilized. Nordson MEDICAL has a unique offering that includes liners with a strike layer of polymer to enable the reinforcement layer to be more fully encapsulated by the two layers of thermoplastic. This can significantly improve the torque response of the system.

WHAT IS A STRIKE LAYER?:

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.

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.

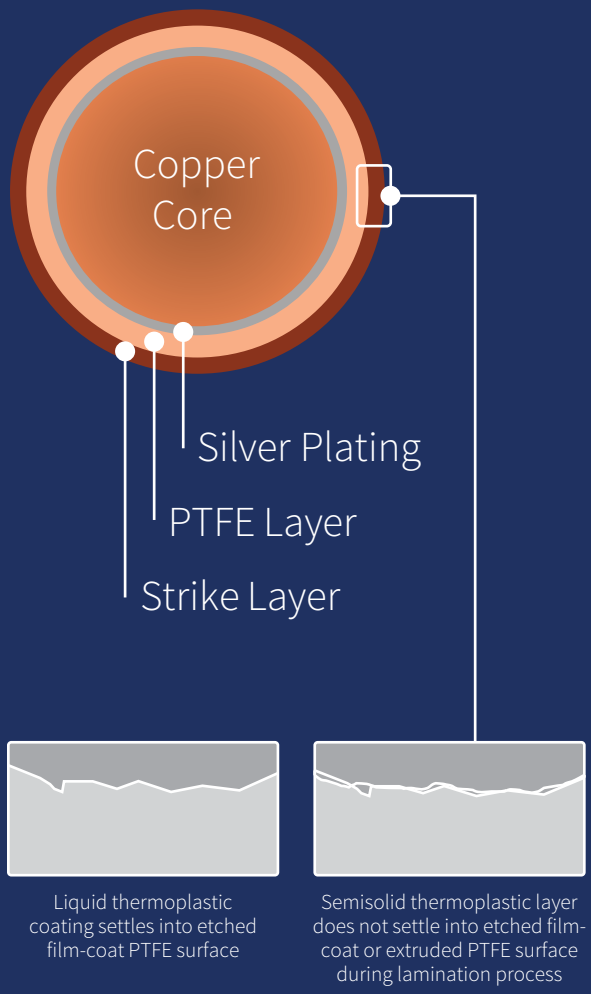


Fig. 1: A Comparison of Liquid vs. Semisolid Thermoplastic Adhesion During Lamination

By coupling material selection with reinforcement selection, Nordson MEDICAL is able to produce reinforced catheters that exhibit high degrees of torsional rigidity. However, torsional rigidity of a reinforced shaft can also have an inverse effect on flexural rigidity. Balancing these performance features is critical.

Performance Feature #4:

FLEXURAL RIGIDITY/FORCE TO FLEX

Flexural rigidity is a very important feature to consider when designing a delivery system to navigate through very tortuous anatomy. This also becomes extremely important when developing steerable/deflectable catheters. Nordson MEDICAL utilizes SimShaft™ software as a platform tool to enable our engineers to predict the impact of reinforcement and material selections. This allows for the balance of torsional rigidity and flexural rigidity to be evaluated early in the design process.

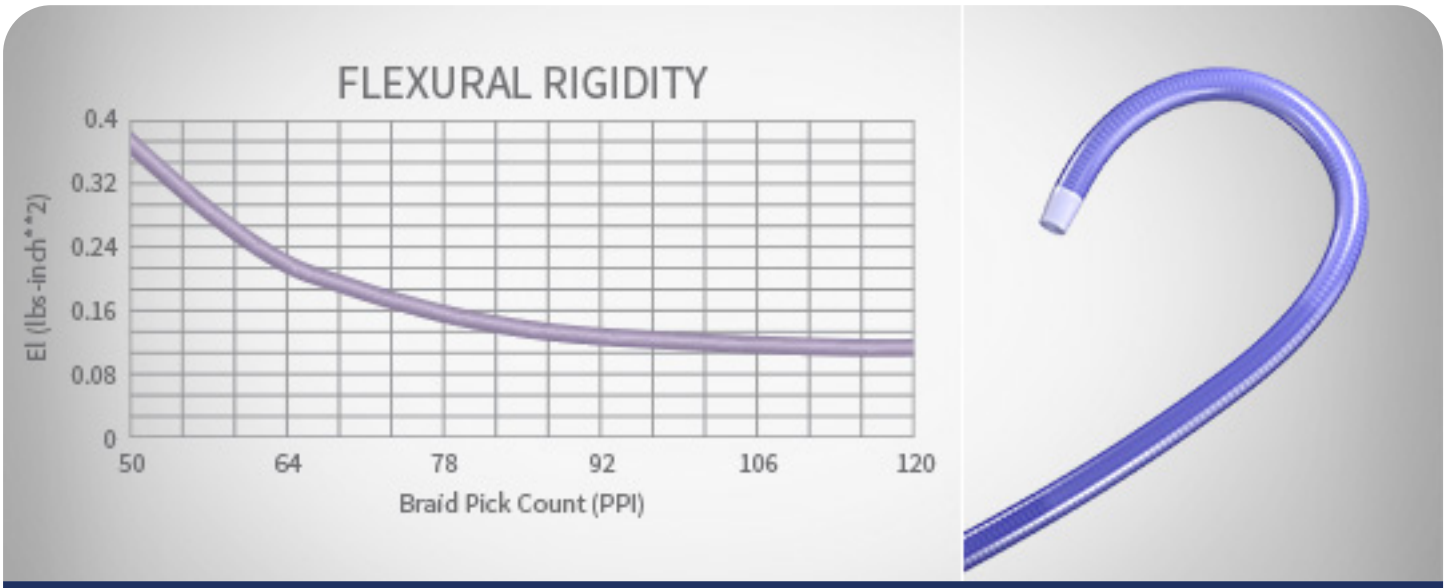
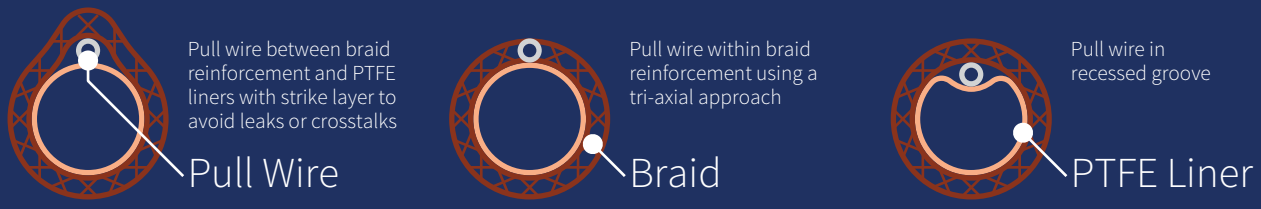


Fig. 2: SimShaft™ Simulated Shaft Performance Characteristics

Another factor that plays heavily into the force to flex is pull wire orientation. Nordson MEDICAL is able to embed pull wires in a number of different configurations that can be tailored to meet our customer's design intent. Pull wires can be aligned within a groove in the ID of the device, between the liner and the reinforcement layer, within an additional lumen in a multi-lumen configuration, over the reinforcement layer, or within the braid using a tri-axial approach. Additionally, we can design steerable systems with round pull wire assemblies, flat pull wire assemblies or even with fibers utilized as the pull mechanism. Nordson MEDICAL also manufactures film-cast PTFE liners which can be utilized to help reduce the force to flex for a system.

CONFIGURATIONS OF PULL WIRES FOR SINGLE STEERABLE ENGINEERED SHAFTS:



Performance Feature #5:

PROFILE

Minimally invasive systems continue to have more and more demanding requirements for minimizing profile. Nordson MEDICAL understands this demand and has put a high level of focus on pushing the boundaries of process capability for all of the components utilized in reinforced shaft construction. We have state-of-the-art capabilities for extrusion tolerances. Film-cast tubing exhibits wall thickness tolerances down to two tenths of a thousandth of an inch (0.0002”).

A LOOK AT THE FILM-CAST MANUFACTURING PROCESS: 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.

Nordson MEDICAL is able to push the limits on system profile by balancing all performance features in accordance with the design intent and clinical requirements.

Conclusion

When designing an engineered shaft, there are several factors to consider in order to meet clinical performance and user requirements. These include tensile strength, ovalization resistance, torsional rigidity, and flexural rigidity, all while maintaining a low profile.

Nordson MEDICAL is uniquely positioned to help you best balance these factors. Our vertically-integrated offering includes ultra-thin PTFE liner tubing, extrusions in a range of materials, and in-house design, development, and manufacturing. We will ensure that you get to market efficiently and with the highest quality.

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.

Visit Nordson MEDICAL at **nordsonmedical.com**

Nordson MEDICAL

Nordson MEDICAL

Choosing PTFE Tubing:

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

Choosing PTFE Tubing:

A Comparison of Film-Cast and Ram-Extruded PTFE Tubing

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:

1. Film-Cast Process
2. 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, ultrathin-walled 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

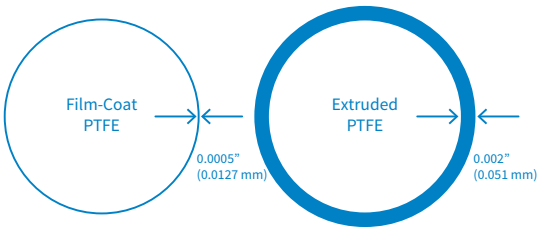


FIGURE 2. COMPARISON OF ID/OD TOLERANCE FOR FILM-CAST AND EXTRUDED PTFE LINER TUBING

	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 micro-texture 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?:

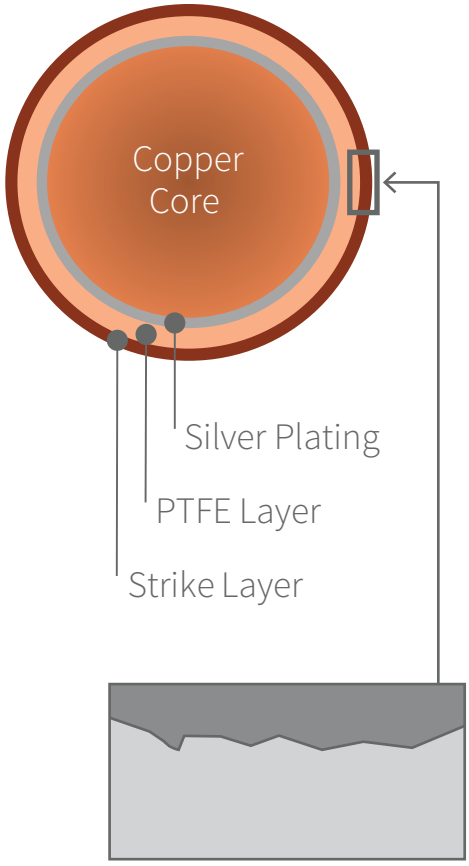
Film-cast PTFE is supplied in straightened cut lengths or in continuous spooled lengths with and without a core wire.

WHAT MATERIALS ARE AVAILABLE FOR STRIKE LAYERS?:

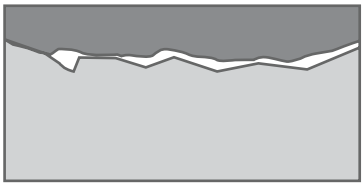
Strike layers are available in a wide range of thermoplastic materials, including:

- Nylon (11 and 12)
- Pebax® (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 film-coat or extruded PTFE surface during lamination process

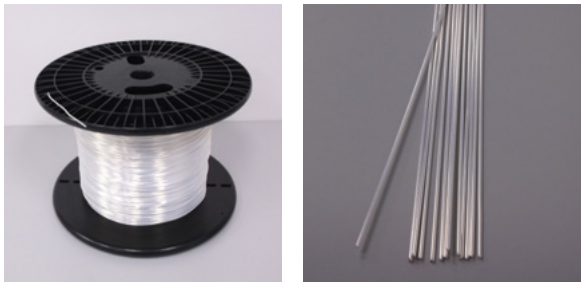
Ram-Extruded Process:

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.

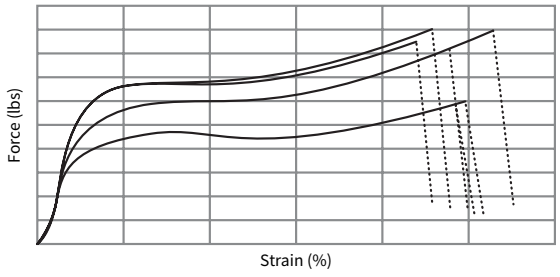
ADD RADIO-OPAQUE FILLERS:

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, ram-extruded 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:

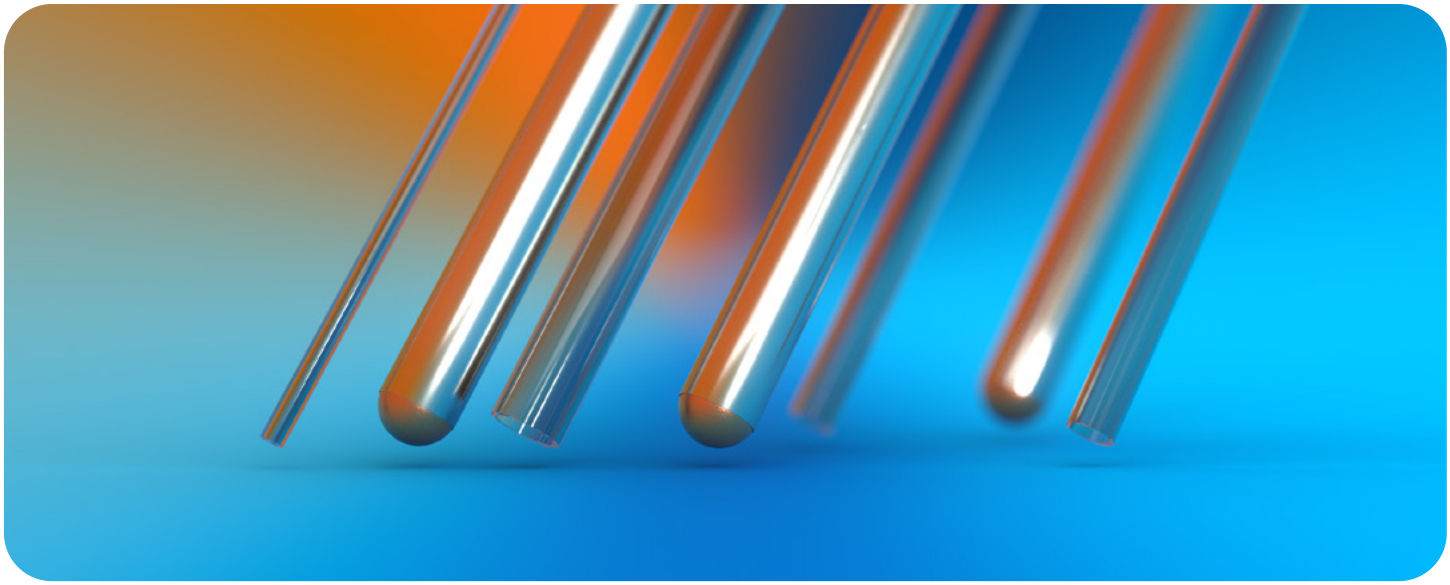
With film-cast and ram-extrusion capabilities, Nordson MEDICAL offers a versatile solution for PTFE tubing in terms of sizes and application-based mechanical requirements. The table below summarizes the differences between film-cast and ram-extruded PTFE, to serve as a guide to determining the ideal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

FIGURE 7. PTFE LINER WITH A BRAID-REINFORCED LAYER AND OUTER JACKET

	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	• Maximized flexibility • Low modulus of elasticity • High elongation at break • High lubricity	• High tensile strength range • Maximized stiffness • High lubricity
Materials	• Natural • Pigmented (not common)	• Natural • Pigmented • Radio-opaque fillers
Extrusion Profiles	• Round tube • Over-the-wire	• Round tube • Monofilament • Multi-lumen • Over-the-wire • Beading
Product Availability	• Spooled over SPC • Cut to length	• Cut to length • Spooled • Spooled over SPC

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.

Visit Nordson MEDICAL at **nordsonmedical.com**

Nordson MEDICAL

Top 5 Applications for Ultrathin-Wall Heat Shrink Tubing

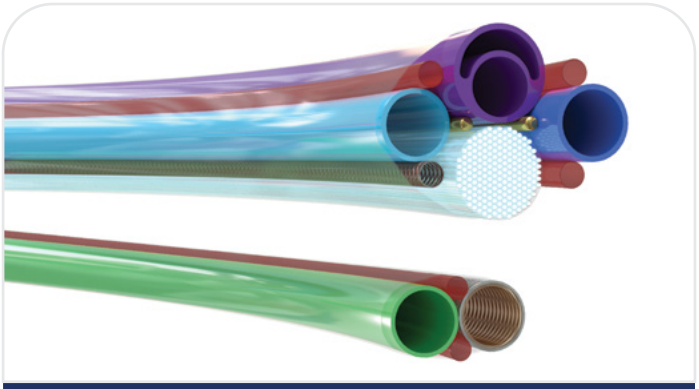
IN MEDICAL DEVICE DESIGN & MANUFACTURING

Top 5 Applications for Ultrathin-Wall Heat Shrink Tubing

In Medical Device Design & Manufacturing

Medical device engineers are always looking for new ways to make devices smaller and thinner, especially catheters, endoscopes, and other devices for minimally invasive procedures. The industry is also under pressure to build more features into devices without increasing their profile (size). Ultrathin-wall heat shrink tubing can help engineers meet this demand by reducing diameters and by improving production processes.

Nordson MEDICAL has developed a proprietary process for manufacturing ultrathin-wall heat shrink tubing from Polyester (specifically, polyethylene terephthalate, or PET) that exhibits extraordinary tensile strength, even with walls as thin as 0.00015".



TUBING BUNDLED TOGETHER WITH CLEAR HEAT SHRINK

THIS WHITE PAPER WILL GIVE MEDICAL DEVICE ENGINEERS IDEAS FOR APPLICATIONS THAT ARE IDEALLY SUITED FOR ULTRATHIN-WALLED PET HEAT SHRINK TUBING:

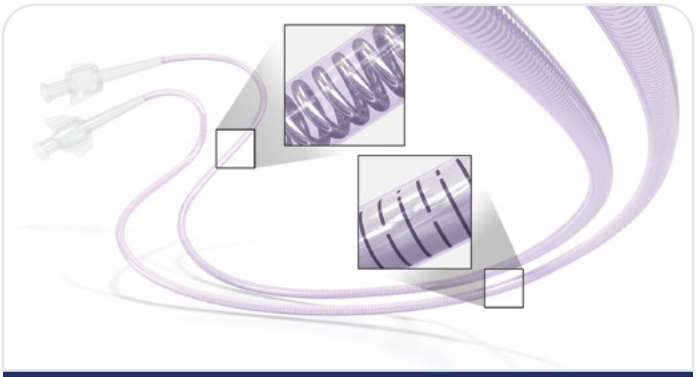
1. Variable-Stiffness Catheters
2. Protective Covering/Coating & Bundling
3. Reinforcement
4. Tube Marking & Printing
5. Electrical Insulation

Application 1:

VARIABLE-STIFFNESS CATHETERS:

Because of its ultrathin walls, PET heat shrink tubing can be used to add stiffness to catheters without significantly adding to the profile of the device. By using different thicknesses of heat shrink tubing along the length of the catheter, you can achieve varying degrees of flexibility for improved control of the device.

For example, you could use heat shrink tubing with a one-mil wall at the back end of a catheter, a half-mil wall in the middle, a quarter-mil wall near the end, and none at the tip for full flexibility.



LASER-CUT HYPOTUBE (BOTTOM) & SPRING COILS (TOP) COVERED WITH A PURPLE HEAT SHRINK

CLEAR HEAT SHRINK USED FOR BRAID TERMINATION

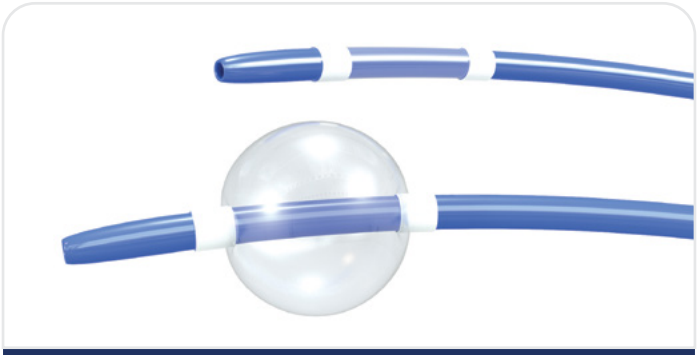
Application 2:

PROTECTIVE COVERING/COATING & BUNDLING:

PET heat shrink tubing is often used to cover laser-cut hypotubes, braided catheter shafts, spring coils, radiopaque marker bands, and other parts that require a thin but very strong outer layer. The tubing provides a smooth transition over sharp edges and can be sealed against fluid leakage. PET heat shrink tubing also can be used to cover tapered structures—such as tapered coils—that cannot easily be covered using conventional techniques.

In addition, you can use PET heat shrink tubing to bundle and compress components such as plastic and metal tubing, wires, and optical fibers into the smallest possible space. Ultrathin-wall tubing allows you to downsize or add features to a device without increasing the profile. For example, using PET heat shrink tubing to bundle components can free up enough space to add another working channel inside an endoscope. It might even enable you to reduce the size of a device by a whole French size.

Another use for PET heat shrink tubing is for bundling common plastic and metal tubes to create a quick, low-cost, multilumen tube, without the need for costly tooling and long lead times.



WHITE HEAT SHRINK TUBING APPLIED OVER LATEX BALLOON ENDS TO ACT AS HOSE CLAMPS

Application 3:

REINFORCEMENT:

With its high hoop strength, PET heat shrink tubing can offer effective reinforcement. For balloon catheters, for example, you can apply a narrow band of heat shrink tubing over the end of the balloon to grip the tube like a micro hose clamp, reinforcing the bond and helping to prevent the balloon from failing under pressure. It also provides a smooth transition without adding significantly to the bond diameter.

In reinforced tubing with a braided layer, PET heat shrink tubing can contain the braid at the end and prevent it from unraveling or poking through the thermoplastic layer, without adding significantly to the profile.

CUSTOM PRINT HEAT SHRINK TUBING IN VARIOUS SIZES AND COLORS

Application 4:

TUBE MARKING & PRINTING:

You can easily add depth marks and printing to catheters and metal shafts with PET heat shrink tubing. Simply order custom printed heat shrink tubing and apply it to the product. This avoids sending the actual devices to a printer for labeling or bringing printing inks and solvents into the manufacturing facility for in-house printing.

Manufacturers who print directly on their products can use clear PET heat shrink tubing as an ultrathin protective layer over the printed area.

ELECTROSURGICAL AND ABLATION DEVICES USE BLACK AND CLEAR HEAT SHRINK FOR ELECTRICAL INSULATION

Application 5:

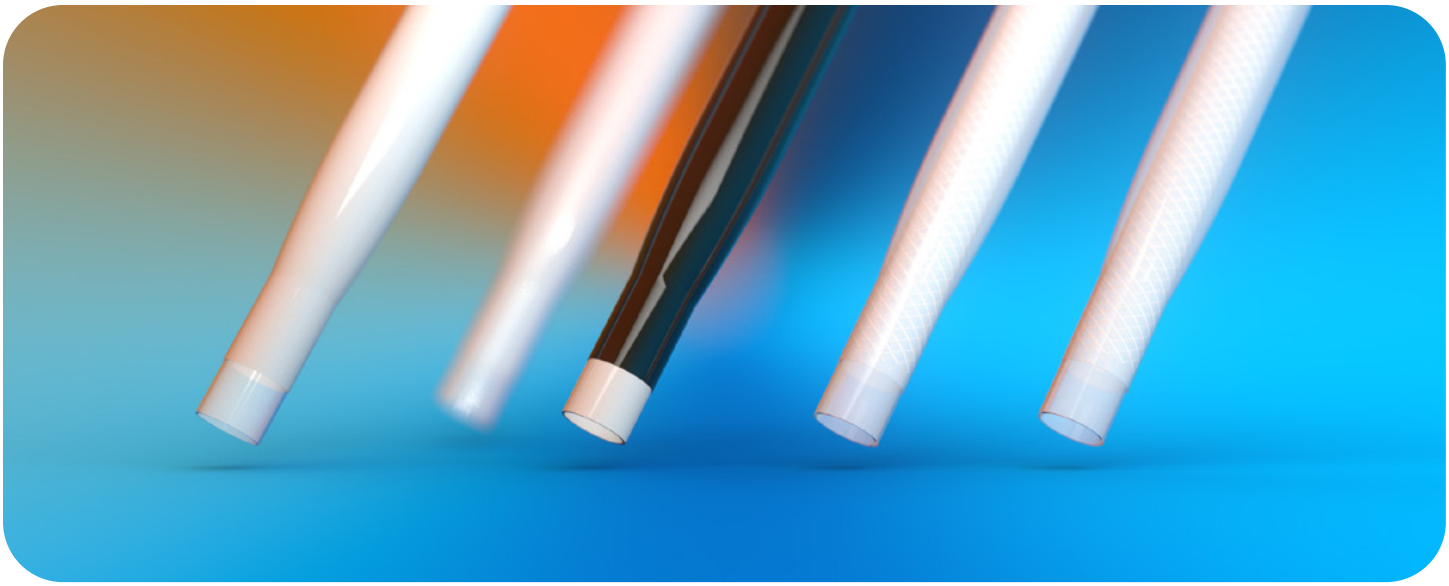
ELECTRICAL INSULATION:

Because of its high dielectric strength, PET heat shrink tubing is an effective electrical insulation material that adds little dimension because of its ultrathin walls. For example, you can use it over needles to protect the surface of the skin from being burned during electrical stimulation, or to insulate electrosurgical devices, electrical components, and wiring on catheters and other products.

PET is the only heat shrink tubing thin enough to replace a coating process for electrical insulation of metal shafts, including needles. Using PET greatly reduces the chance of pinholes that can develop in coated surfaces, leading to a repeatable, consistent, and efficient alternative that eliminates the solvents and chemicals associated with coating processes.

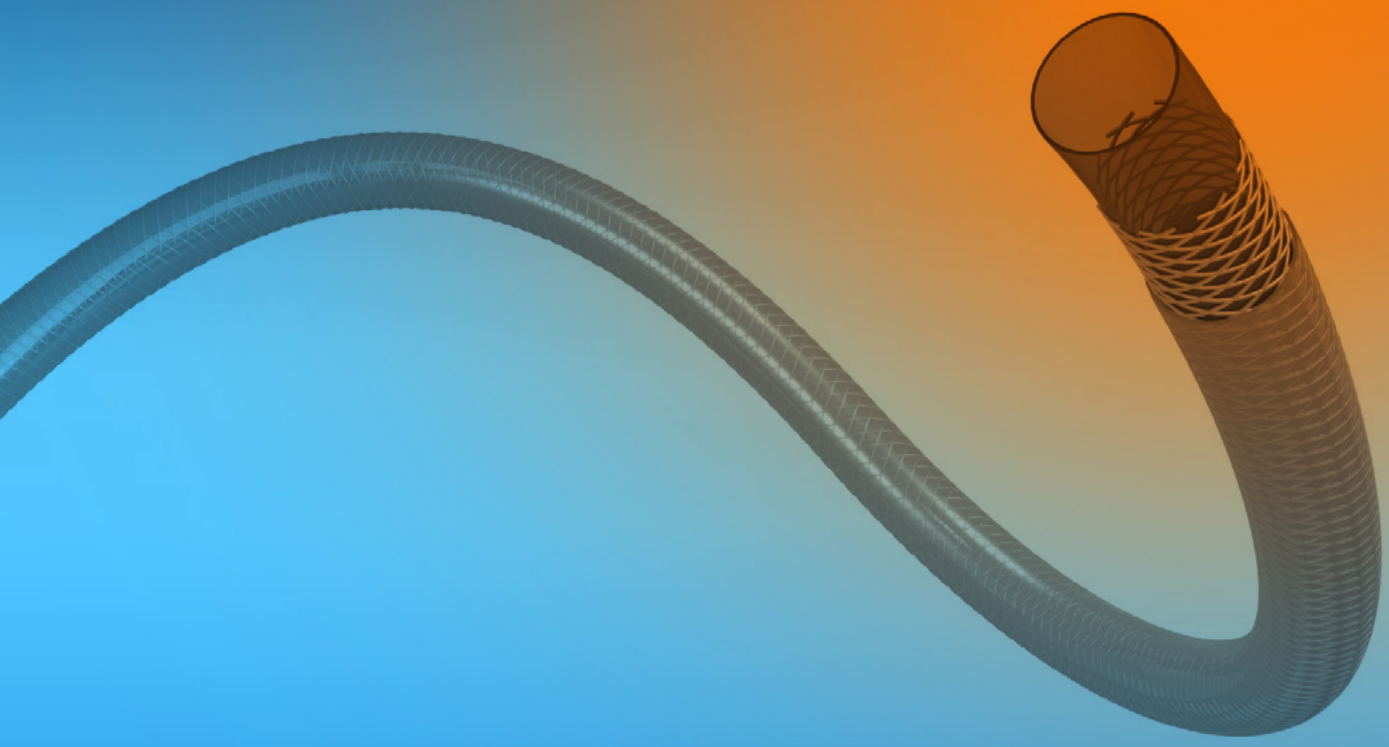
Conclusion:

These are only a few of the many applications that take advantage of the unique properties of PET heat shrink tubing. Other tubes are simply too thick, or lack strength or other features. The ultrathin, yet strong walls of this tubing make it an outstanding material for engineers as they design and build medical devices for today's market requirements and tomorrow's patient needs.



Nordson MEDICAL

Nordson MEDICAL



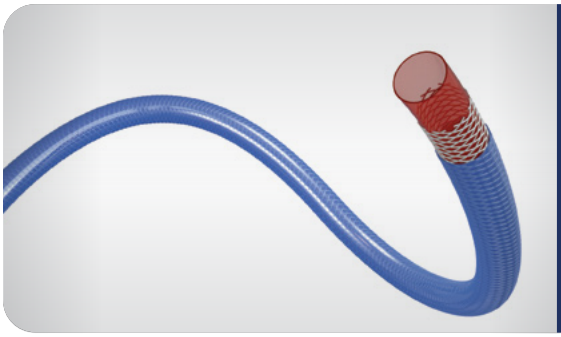
Three Medical Device Design Challenges, Solved:

LEVERAGING THE FILM-CAST PROCESS WITH POLYIMIDE AND OTHER POLYMERS

Three Medical Device Design Challenges, Solved:
Leveraging the Film-Cast Process with Polyimide and other Polymers

Introduction:

Polyimide is a versatile polymer popular for micro-diameter tubing applications that require very thin—yet very strong—walls. It also lends itself to compositing with materials that can add additional performance characteristics to medical tubing and shafts.



Nordson MEDICAL has been working with polyimide for decades and has mastered the film-cast process used to make polyimide tubing (see next page). This process excels at:

- Making tubing with very thin wall thicknesses, very small IDs, and very tight tolerances
- Allowing thin layers of different polymers in various thicknesses to be applied at different depths of the tubing's cross-section

Applying this expertise, we've developed new techniques that use the film-cast process with other polymers—alone or to boost the functionality to polyimide—to achieve advanced performance characteristics that expand the range of solutions to medical device challenges.

This white paper will explore 3 medical device design challenges and how Nordson MEDICAL devised optimal solutions with the innovative use of the film-cast process with polyimide and other polymers.

The Film-Cast Tubing Process

LAYERS OF DESIGN POTENTIAL:

PROCESS:

Film casting is a process for making tubing in which a thin layer of liquid polymer is applied over a solid mandrel. This layer of polymer is solidified with heat, and the process is repeated until the desired tubing wall thickness is achieved. (See Figure 1.)

This process has two advantages over extrusions:

- It can make tubing with very thin wall thicknesses, very small IDs, and very tight tolerances:
  - Wall thickness: .0003" to .006"
  - IDs: .005" to .085"
  - ID and OD tolerances: ± .0002" to .0005"
- The process of building up layers allows for varied thickness of polymers and varied types of polymers or reinforcement materials to be applied at different depths of the tubing's cross-section, expanding the potential function of the tubing or shaft.

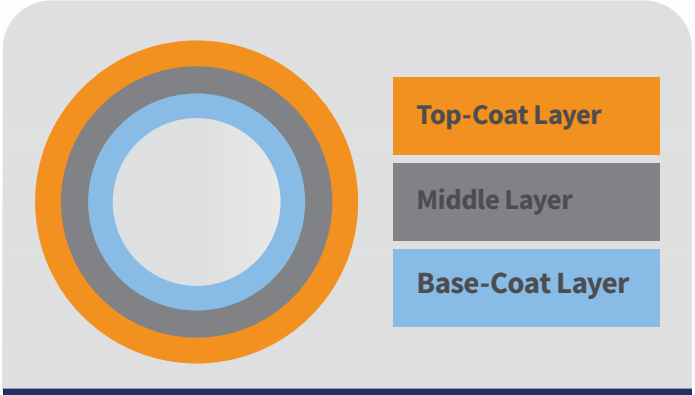
MATERIALS:

The film-cast process has been widely used in the medical device industry to make thermoset polyimide. However, Nordson MEDICAL has developed techniques for using thermoplastic polymers including PTFE and Pebax® in this process. (See Appendix 1 for a list of standard polymers available for film-cast tubing.) These polymers allow new functionality and expand the range of solutions for medical device challenges.

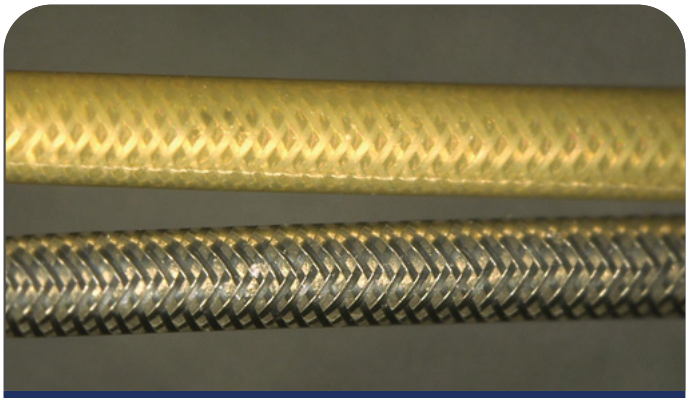
REINFORCEMENT:

Film-cast tubing can be reinforced with several materials, such as braided flat or round stainless-steel wire. Reinforcement is primarily used for increasing tensile strength, but it also provides hoop strength, increases stiffness, and improves torque transmission. The braid density, or picks per inch (PPI), can be varied.

FIGURE 1. FILM CAST LAYERING:



Medical device engineers can visualize the film-cast tubing process as layers of design potential, or opportunities to build in performance characteristics at different depths within the tubing cross section. The tube is built from the inside (ID) out. First, consider the properties the liner or base-coat layer needs to have; for example, low friction. Second, consider what type of reinforcement is needed in the middle layer to make the tube stronger. Third, consider the top coat that comes in contact with tissue. Does it need to be flexible? Does it need the ability to be thermally bonded? Does it need a lubricious material? The combination of these three layers allows engineers to optimize performance characteristics of the device or shaft.



Top tubing shows all three layers.
bottom tube shows base & middle layers.

Tubing Design Challenge #1:

MICRO (1.25 FR) BALLOON CATHETER:

TUBING REQUIREMENTS:

- ✓ Thin wall
- ✓ High burst strength
- ✓ Flexibility/kink resistance at tight bend radius
- ✓ Ability to thermally bond to outer surface

CHALLENGE:

In this application, the catheter needs to navigate a tortuous arterial pathway to deliver a semicompliant nylon balloon to the point of therapy. Once in place, the tubing will act as an inflation lumen to fully expand the balloon to a pressure of 18 atmospheres, or 257 PSI.

SOLUTION:

Nordson MEDICAL designed a multilayer solution that leveraged the burst strength of thermoset polyimide, while adding flexibility and bondability with a top layer of Pebax®.

- Wall construction:
  - Inner liner: .0005” to .001” of polyimide
  - Middle layer: .001” braid reinforcement layer (comprising 16 wires of .0005” x .003” flat-wire stainless steel with 120 PPI)
  - Top coat: .0005” to .001” 55D of 63-durometer Pebax
  - Total wall thickness: .002” to .003”
- Polyimide acts as the structural “backbone” and a pinhole-free liner that will contain the fluid pressure when the balloon is inflated. (See Figure 2.) The polyimide—along with the wire braiding—also helps to provide push and transmit torque.
- The wire braiding helps contain the pressure when the balloon inflates and provides hoop strength to prevent kinking while bending around tortuous pathways.
- The Pebax layer holds down the braid and serves to “carry” the wire braiding, allowing it to elongate and contract as the tubing bends. This significantly reduces bend resistance and increases flexibility compared with a pure polyimide construction. (See Figure 3.)
- The Pebax top layer also provides a thermoplastic surface to which the balloon material can cohesively and/or adhesively bond using thermal techniques.

If the application can handle a thicker wall then a .001” round braid wire could be used. Braiding with round wire and top coating with a lower-durometer Pebax thermoplastic gives the absolute best flexibility for this type of tubing design.

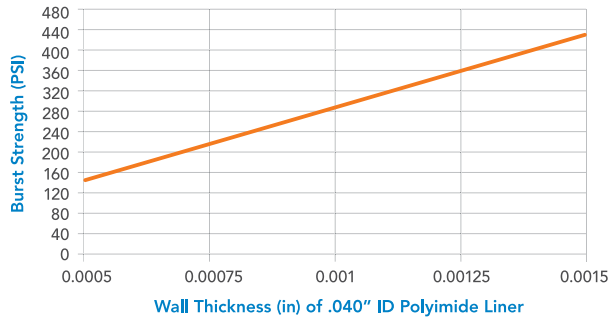


FIGURE 2. INTERNAL BURST STRENGTH AS A FUNCTION OF POLYIMIDE WALL THICKNESS:

Test data on polyimide liner only; adding braid reinforcement and top coat will add burst strength.

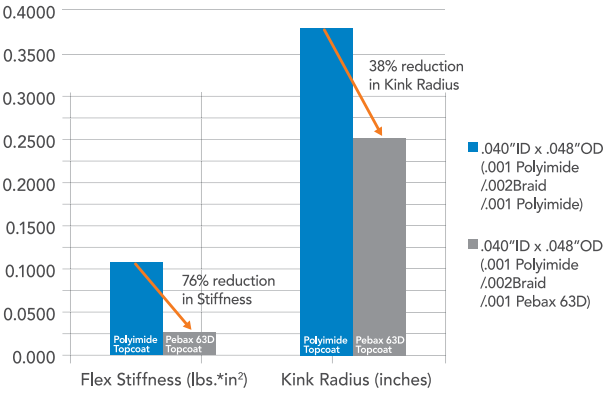
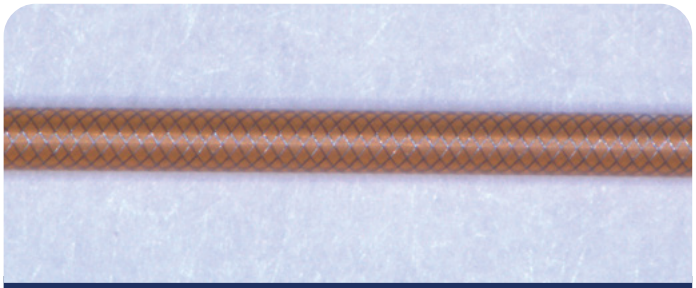


FIGURE 3. SIGNIFICANT CHANGE IN FLEXIBILITY



Thin-wall balloon delivery catheter. Wall construction = .0005” polyimide liner + .002” braid layer of .001” diameter round wire + .001” top coat of Pebax 72D.

TUBING Design Challenge #2:

NOVEL SELF-EXPANDING STENT DELIVERY CATHETER:

TUBING REQUIREMENTS:

- ✓ Strong, thin wall
- ✓ Ability to effectively bond dissimilar materials using thermal techniques

CHALLENGE:

A self-expanding stent delivery catheter used in the peripheral arteries requires a strong, thin-wall polyimide tube to contain the pressure of the collapsed stent without stretching out. Due to OD limitations, this polyimide tubing also has to serve as the outer shaft of the final catheter product. This outer shaft has a thermoplastic proximal tip and distal hub insert molded to it. These insert-molded parts must achieve effective thermal bonds to the outer surface of the polyimide shaft.

SOLUTION:

Nordson MEDICAL designed a multilayer solution that leveraged the strength and thin walls of polyimide, while adding a very thin bondable layer with virtually no increase in OD.

- Using the film-cast process, we apply an ultrathin thermoplastic bond-coat or tack-down layer over the outer surface of the polyimide tubing, for an overall wall thickness of only .002."
- We thermally bonded the catheter's tip and distal hub to this thermoplastic outer surface that covers the polyimide tube.

Pure polyimide is a thermoset polymer, so it doesn't remelt or reflow when heated. The top coat layer of thermoplastic polymer (like Pebax or Nylon) provides a surface that remelts and reflows to create a thermal bond, even if it is only .00025" thick.

An important consideration is the quality or effectiveness of the bond between the thin layer of thermoplastic and the thermoset polyimide. If the thermoplastic top coat is not bonded effectively to the polyimide surface, it won't matter how well the two layers of thermoplastic are bonded.

What makes this polyimide-to-thermoplastic bond effective is that the thermoplastic is applied as a liquid coating with carefully controlled viscosity. This allows the thermoplastic material to flow into the microsurface texture of the polyimide tubing's outer surface and essentially "wet" the surface, establishing more surface contact. Once this liquid coat solidifies, it establishes a superior adhesive bond between thermoplastic and thermoset polyimide, which allows cohesive bonding between the two layers of thermoplastic material.

Tubing Design Challenge #3:
RADIOPAQUE POLYIMIDE CATHETER WITH LOW-FRICTION OD:

TUBING REQUIREMENTS:

- ✓ Thin walls
- ✓ Tight tolerances
- ✓ Radiopacity
- ✓ Low-friction top layer

CHALLENGE:

A catheter-based application requires thin-wall, tight-tolerance tubing. This tubing slides inside a guide lumen, so for ease of movement, the outer surface needs to have low sliding friction properties to avoid "sticking." It also needs to be visible under fluoroscopy so the physician can see the tubing move within the guide catheter. These 4 functions must be incorporated into a single tube with a wall thickness of only .0025."

SOLUTION:

Nordson MEDICAL designed a solution that exploited the thin walls and tight tolerances of polyimide, while adding radiopacity and a low-friction top layer.

- Polyimide can be composited with particulate materials quite easily. And thanks to the layering process, two different composite materials can be used within one single tubing cross-section. Loading or compositing polyimide with submicron tungsten particulate (powder) provides a radiopaque image. The clarity of this image depends on the wall thickness of the polyimide layer. A wall thickness ≥ .002" provides a good, clear fluoroscopic image that lightens as the wall thins, but is still visible when the wall is as thin as .0008." (See Figure 4.)
- To achieve a low-friction outer layer, the tubing is then top-coated with a layer of polyimide that has been composited with PTFE powder. While pure polyimide has a coefficient of friction (COF) of .250, this COF value drops by 50% to .125 when PTFE powder is mixed into polyimide and applied over the top surface.

Particulates are often thought of as coatings or surface elements. But since the PTFE composite layer uses the same polyimide polymer matrix, this low-friction top layer is more like part of the tubing than simply a surface coating, making it less prone to flaking or scrapes.

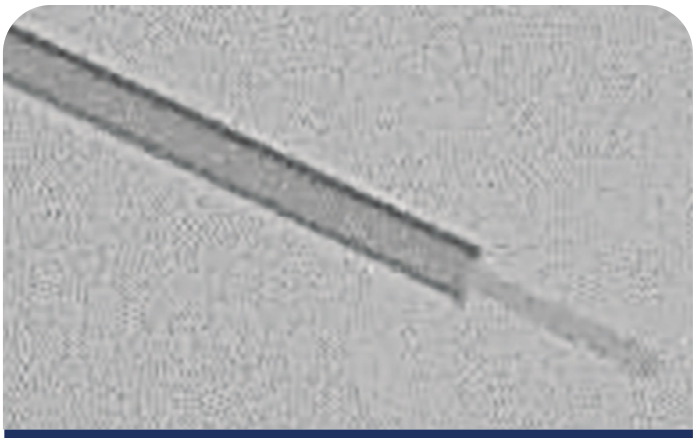


FIGURE 4. TUNGSTEN-LOADED POLYIMIDE WITH A WALL THICKNESS OF .002" AND A STAINLESS-STEEL GUIDEWIRE RUNNING THROUGH THE MIDDLE OF THE LUMEN:

The tungsten-loaded polyimide provides a better fluoroscopic image than the stainless-steel guidewire running through the middle of the tubing.

APPENDIX 1. STANDARD MATERIALS FOR FILM-CAST TUBING PRODUCTS:

Item #	Polymer Name	Polymer Type	Primary Purpose(s)	Thermoplastic Durometer(s)
1	Polyimide	Thermoset	Thin-wall, micro ID tubing	Approximately 95 to 100D
2	Polyimide + PTFE particle composite	Thermoset	Creates low-friction coating on OD &/or ID	n/a
3	Polyimide + tungsten particle composite	Thermoset	Radiopaque with X-ray & fluoroscopy	n/a
4	PTFE	Thermoplastic	Low-friction inner liner	50D
5	Radel® polyphenylsulfone	Thermoplastic	High-durometer thermoplastic & top coat	86D
6	Pebax® polyether block amide	Thermoplastic	Thermoplastic top coat	55D, 63D, 70D, & 72D
7	Rilsan® nylon 11	Thermoplastic	Thermoplastic top coat	72D
8	Vestamid® nylon 12	Thermoplastic	Thermoplastic top coat	55D
9	TecoFlex® polyurethane	Thermoplastic	Thermoplastic top coat	80A, 93A, & 60 D

Conclusion:

Leveraging its expertise in film-cast polyimide tubing, Nordson MEDICAL has developed new techniques using the film-cast process with other polymers to enhance the functionality of polyimide. The evolution of this technology opens new opportunities for optimizing design characteristics to create innovative solutions to customers' medical device design challenges.

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.

Visit Nordson MEDICAL at **nordsonmedical.com**

Nordson MEDICAL

Nordson MEDICAL

Six Innovative Uses for Polyimide Tubing

IN MEDICAL DEVICE APPLICATIONS

Six Unexpected Uses for Polyimide Tubing

In Medical Device Applications

Polyimide has been used in a wide range of microdiameter tubing applications for more than 30 years (see Box 1, Common Applications). However, some of the innovative ways that this exceptionally strong and durable polymer can be used—specifically in catheters and other medical devices used in minimally invasive procedures—might actually surprise medical device engineers.

This white paper will explore 6 such innovative uses for microdiameter polyimide tubing in medical devices, all of which are made possible by a film-cast manufacturing process (see the sidebar on the next page).

1. As a discrete length polyimide coating sleeve

For applications that require a discrete length of tubular polyimide coating, specially engineered polyimide tubing offers a possible solution. This sleeve of tubing, which is not fully polymerized, can be reduced in size with the application of heat.

For example, consider a hypotube that needs to be partially coated with polyimide. A section of thermoset polyimide tubing can be engineered to fit the portion of the hypotube that is to be coated. This heat-formable polyimide can then slide over the hypotube like a sleeve. When exposed to a variable temperature profile, the tubing will cure and shrink slightly, effectively covering that portion of the hypotube with polyimide.

Polyimide Coating Sleeve—the inner and outer diameters of which will shrink by 0.003 to 0.005 inches—is ideal for applications such as covering exposed braiding or covering a joint between two pieces. It would also be useful for adding a tip to a product that has been machined to have an inconsistent profile. It is important to note, however, that there is one key limitation: The walls must be at least 0.002 inches thick.

COMMON APPLICATIONS FOR POLYIMIDE TUBING:

- Retention sheath for self-expanding stents
- Inflation lumen for balloons
- Suction lumen for atherectomy devices
- Liner material for lumens containing catheter-steering wires
- Low-diameter guidewire designs or guidewire outer sheaths
- High-temperature or gamme radiation-resistant tubing applications
- Applications requiring high tensile strength, torque transmission, or column stiffness

2. In microdiameter hydraulic fluid or liquid delivery lines

Polyimide is a thermoset polymer. This means that once it is formed, it's solid—it will not remelt or reflow when exposed to a high-temperature environment. It is also very stable, able to withstand exposure to corrosive and acidic chemicals that would typically harden or degrade other thermoplastics. In addition, polyimide tubing that is reinforced with stainless-steel braiding can resist high pressures.

These desirable qualities make polyimide tubing a suitable option for use in lines that convey hydraulic fluid or other liquids. Materials such as mineral oil, aromatic hydrocarbons, and polyalkylene glycols can be delivered safely through lines made from polyimide, which will not fail in high-heat and even nuclear environments. For example, many microrobotic medical tools rely on hydraulics.

3. As heat-exchange or cooling system tubing

Thermal conductivity is paramount in materials used in tubing for heat exchange or cooling systems. As a dense material that conducts heat at a rate of .471 W/m·K, polyimide is ideal for such applications. It also is well suited for particle and fiber compositing, which means that it is possible to extend the thermal conductivity of the tubing beyond polyimide's standard capacity.

When polyimide is in its liquid, viscous state, it is easy to add particulate materials that augment functionality. In this case, a material such as ceramic or graphitic powder can be added to the polymer matrix, increasing the thermal conductivity level of the tubing by 70% to 90%.

For example, such a polyimide composite would be ideal for surgical tools used for ablation procedures in which heat must be conducted away from tissue that does not need to be treated. Because polyimide can be manufactured with thin walls and small inner diameters, it also can be used to make microdiameter tubing that can be bundled together in a specialized cooling system.

THE FILM-CAST MANUFACTURING PROCESS: WHAT MAKES IT ALL POSSIBLE?

The film-cast process begins by applying a thin layer of liquid polyimide resin to a solid mandrel. The resin is cured until solid using high-temperature polymerization. The process is then repeated, adding layers of material until the desired tubing wall thickness is achieved.

This film-cast process makes it very easy to customize tubing. Different polymers, filament reinforcements, and particulate material additives can be layered onto the tubing's cross-section. The film-cast process also allows for the manufacture of tubing with much thinner walls and smaller outer diameters (OD)—walls down to 0.0003 inches and ODs down to 0.005 inches—and with more dimensional stability than tubing made via extrusion.

4. In electromagnetically shielded coaxial cable

Catheter-based ultrasound imaging applications often rely on microdiameter coaxial cables. These cables can benefit from the use of polyimide to provide electromagnetic shielding, thanks to the ease with which polyimide can be composited.

In roughly the same way that graphite powder can be added to the polymer matrix to enhance thermal conductivity, a material that provides electromagnetic shielding, such as powdered silver or copper, can be mixed in with polyimide in its liquid, viscous state. When cured, the composited tubing will act as an electromagnetic shield for the inside conductor.

5. To create a multilumen shaft

Combining several microdiameter tubes together in one bundled, multilumen shaft can take advantage of several polyimide functionalities. For example, a multilumen shaft could include both an electromagnetically shielded tube and one that has been composited with metallic tungsten to become radiopaque, for viewing via X-ray or fluoroscopy, thus giving the shaft dual capabilities.

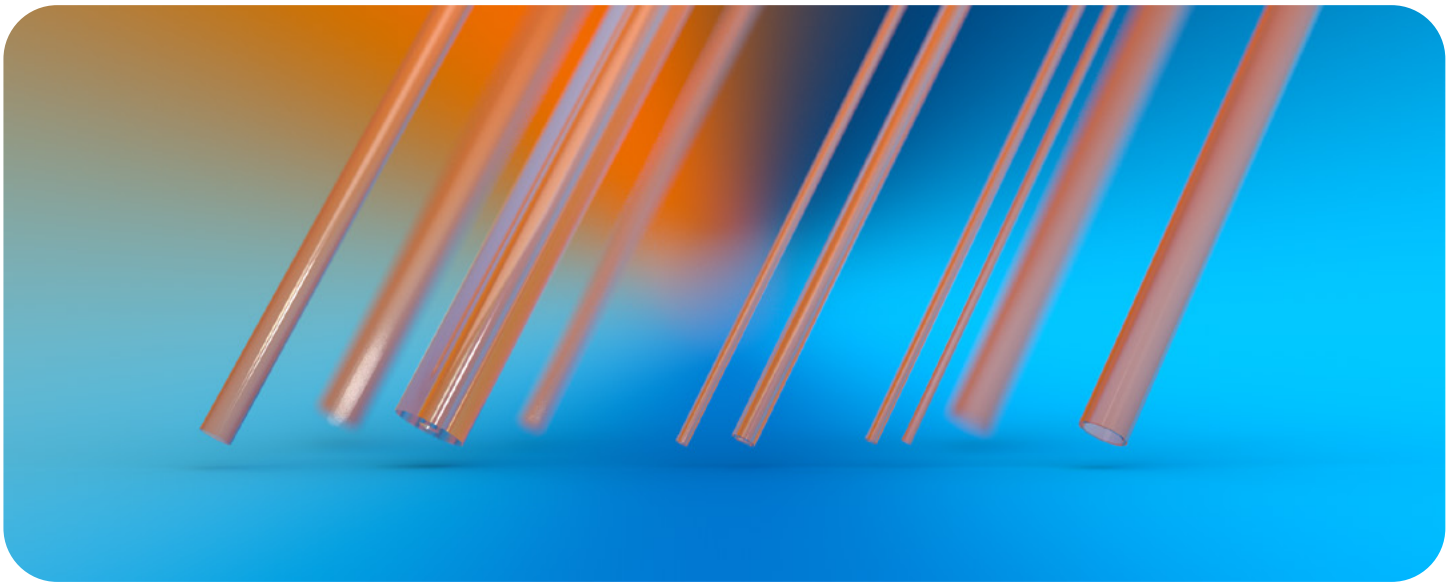
It is also possible to bundle together several microdiameter tubes that have been manufactured via the film-cast process to create a single shaft with several lumens. Overcoats of nylon or Pebax® can be applied to the tubes being joined; these overcoats are then fused together to bind the tubes to one another. A multilumen shaft that incorporates several polyimide tubes easily could be used in place of typical extruded multilumen shafts in many catheter applications.

6. As a polymer needle or puncture tool:

With a tensile strength of 20 to 40 Kpsi and a modulus of elasticity ranging from 300 to 500 Kpsi, polyimide is so strong and stiff that it can actually be used to make a tube that will function as a blade-like cutting or puncture tool. A tube with a wall thickness of 0.002 to 0.004 inches could slice through different types of tissue, serving as a polymeric substitution for a metallic blade.

Conclusion:

Polyimide is a versatile polymer with a wide range of desirable properties that can be used to great effect in many different microdiameter tubing applications. Thanks to the novel film-cast tubing process, medical device engineers can take full advantage of this stable, durable polymer in ways that might not be obvious at first glance.



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.

Visit Nordson MEDICAL at **nordsonmedical.com**

Nordson MEDICAL

Nordson MEDICAL

A Comparison of Lubricious Materials & Additives

FOR EXTRUDED MEDICAL TUBING

A Comparison of Lubricious Materials & Additives

For Extruded Medical Tubing

1.0 Introduction:

1.1 BACKGROUND:

For medical device designers looking for a lubricious surface for catheter-based devices, PTFE, FEP, and HDPE have traditionally been the go-to materials for extrusions.

As a contact layer for interfacing devices, these lubricious materials can ease insertion into the body or into another device, increase sensitivity of movement, and boost pushability.

However, these materials may not always be the optimal choice for a particular application, due to cost, performance, or process considerations.

To provide medical device designers with additional options, leading material manufacturers have developed low-friction additives that can be blended with medical polymers to significantly decrease surface friction and give extruded tubing a more lubricious surface.

Additives can be used with most existing medical polymers without significantly affecting the original properties of the primary material.

These lubricious materials can be used:

- As a tubing liner
- As an alternative to hydrophilic coatings
- As a way to improve bonding to other components

1.2 PURPOSE:

The next question for medical device designers is which lubricious material or additive is right for their project. This can be a challenge due to a lack of data in the marketplace. Data from manufacturers of lubricious additives is generally limited to how their products affect the lubricity and mechanical properties of the medical tubing they are blended with. However, test results cannot be accurately compared across manufacturers.

Nordson MEDICAL's technical staff conducted independent testing to understand the performance of several market-leading lubricious additives to common extruded medical polymers. Table 1 and Table 2 show the selected additives and materials, respectively. We tested these extrusions for:

- Extrusion capability
- Dimensional stability
- Lubricity
- Elongation
- Tensile strength
- Adhesive bond strength

We also tested the lubricious additives to determine the effects of aging, sterilization, and pad printing processes. The results are summarized in this technical paper.

2.0 Materials:

2.1 SELECTED ADDITIVES:

As shown in Table 1, we tested 4 market-leading additives from 4 manufacturers.

TABLE 1. SELECTED ADDITIVES:

Lubricious Product	Percent Additive	Manufacturer	Additive Material Composition
EverGlide®	8%	Polymer Dynamix	Modified polysiloxane
Mobilize	3%–7%	Compounding Solutions	Proprietary
PEBASlide	6.7%	IPC	Nanotechnology based
ProPell S™	3%	Foster	Proprietary

2.2 SELECTED MATERIALS:

All of the lubricious additives in Table 1 can be combined with a wide range of commonly used engineering thermoplastics, including nylon, Pebax®, TPU, polyethylene, polypropylene, PET, ABS, and polycarbonate.

We compared these lubricious additives with 2 fluoropolymers, which are inherently lubricious. Both are manufactured by Daikin:

- NEOFLON™ EFEP RP-5000
- NEOFLON™ PFA AP-210

These fluoropolymers share some characteristics with PTFE but offer several advantages: they are easier to extrude, easier to bond to, and can be gamma sterilized.

As shown in Table 2, our control samples were Pebax 4033 SA 01 MED Natural, Tecoflex™ EG-80A Natural, and PTFE.

All materials were extruded to the same dimensions:

- Outer diameter: 1.95 mm
- Inner diameter: 1.35 mm
- Length: 450 mm

TABLE 2. SELECTED MATERIALS:

Base Material	Additive Material	Type
Pebax 4033 SA 01 MED, Natural	None	Nonlubricious control
Tecoflex EG-80A, Natural	None	Nonlubricious control
PTFE	None	Lubricious control
Pebax 4033 SA 01 MED	EverGlide	Lubricious additive
Pebax 4033 SA 01 MED	Mobilize	Lubricious additive
Pebax 4033 SA 01 MED	PEBASlide	Lubricious additive
Pebax 4033 SA 01 MED	ProPell S	Lubricious additive
Tecoflex EG-80A	ProPell S	Lubricious additive
Tecoflex EG-80A	Mobilize	Lubricious additive
NEOFLON EFEP RP-5000	None	Fluoropolymer (inherently lubricious)
NEOFLON PFA AP-210	None	Fluoropolymer (inherently lubricious)

METHODOLOGY:

Nordson MEDICAL staff extruded the materials in Table 2 using a conventional ¾" extruder (PTFE was ram extruded by an external source). First, we extruded the natural materials and recorded all extrusion settings and parameters as a baseline.

Second, we extruded the materials with additives using parameters as close as possible to the natural versions to minimize process variation that could have an impact on testing results.

We used the manufacturers' recommended processing conditions in the set-up when available. Our results are based on limited trials, conducted to provide initial guidance for materials selection (For specific applications, we would work with the customer to analyze and optimize the process for their needs).

RESULTS:

We observed little to no difference between extrusions of the materials with additives and extrusions of the natural versions of the materials. The Tecoflex showed slight instability during the extrusion process, but that was to be expected because of the material's natural tackiness.

3.0 Dimensional Stability:

METHODOLOGY:

We tested each of the materials in Table 2 for dimensional stability with a sample size of 20, based on an acceptable quality limit (AQL) of 2.5%. Outer diameter (OD) dimensional capabilities were measured using an offline laser scan micrometer (Scantron XLS 35XY). The results are given as OD Tolerance, which is the Range divided by 2 or (maximum - minimum)/2 for the 20 samples tested.

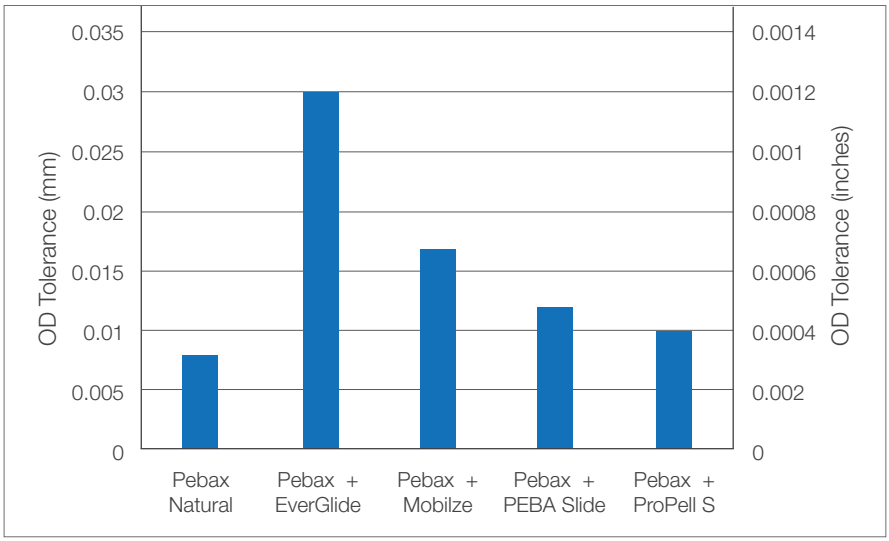
RESULTS:

The following graphs show the dimensional stability based on final inspection data from the extrusion runs.

Pebax:

The Pebax natural material showed the greatest OD stability. Adding additives to the Pebax slightly decreased stability, but the results were still well within acceptable levels given an outer diameter spec of 1.95 mm.

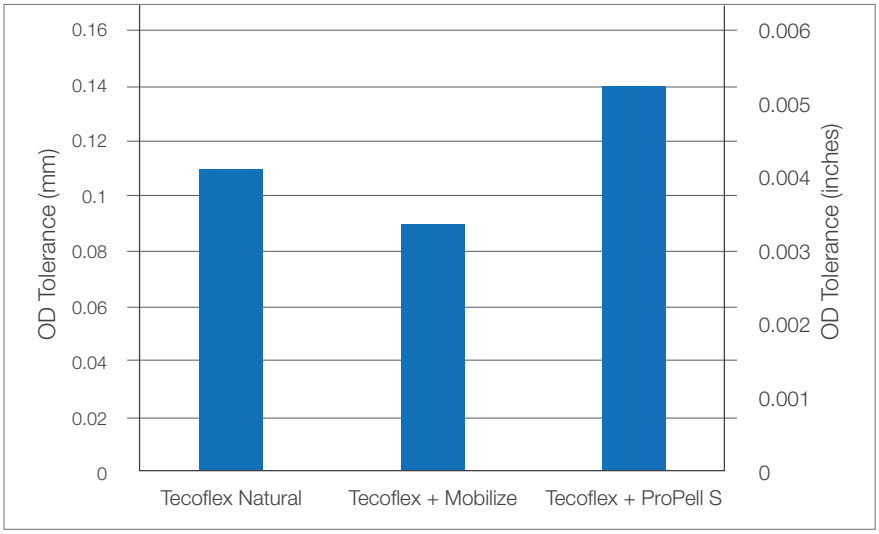
FIGURE 1. OD STABILITY: PEBAX:



Tecoflex:

The OD stability was very similar for the Tecoflex materials with additives compared to the Tecoflex natural material.

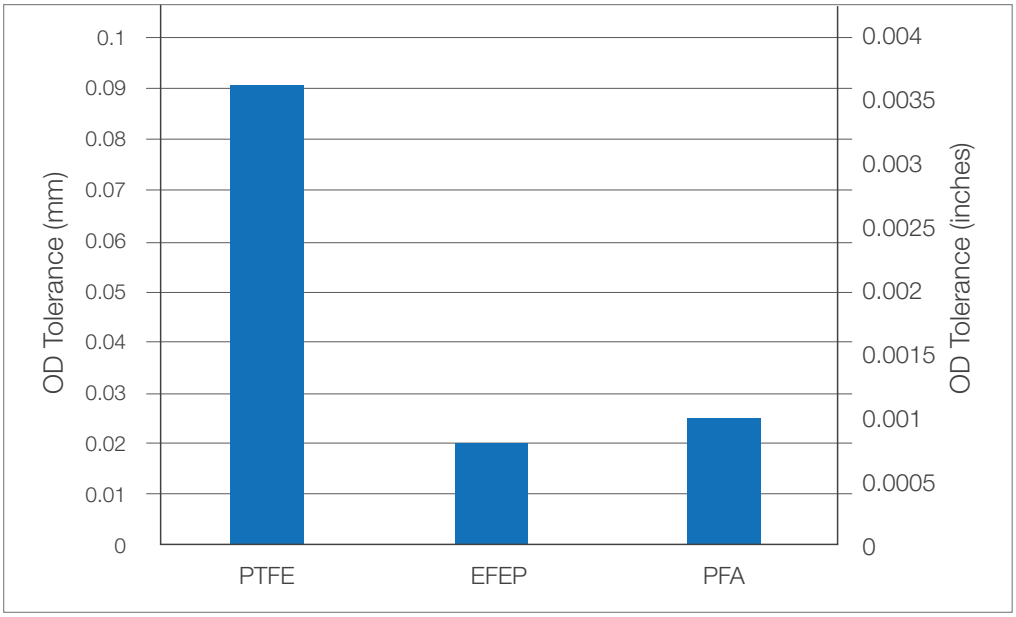
FIGURE 2. OD STABILITY: TECOFLEX:



Fluoropolymers:

The OD range on the EFEP and PFA samples that Nordson MEDICAL extruded was much tighter than the tolerance of the ram-extruded PTFE. The conventionally extruded test samples used vacuum forming, which typically yields tighter tolerances.

FIGURE 3. OD STABILITY: FLUOROPOLYMERS:



CONCLUSIONS:

Dimensional testing showed that OD stability was within acceptable limits for OD ranges and tolerances for medical tubing. Medical device designers considering lubricious additives should not be overly concerned about their effect on dimensional stability.

4.0 Mechanical Testing:

4.1 LUBRICITY:

METHODOLOGY:

A specialized external test laboratory carried out the lubricity testing for Nordson MEDICAL. The sample size was 20, based on an AQL of 2.5%.

A test fixture was fitted to the base of a tensile tester. This was a wet test using deionized water at 37°C. The samples were clamped in the test fixture. The tensile tester pulled the sample horizontally through the grips at a rate of 3 inches/minute. The force required to pull the sample a distance of 75 mm was graphed against the distance travelled. The test was performed with both silicone (GP 60W) grips and PTFE grips. Figures 4–9 show the mean results of the required forces.

RESULTS:

Pebax:

All samples with additives proved to have reduced friction compared to the Pebax natural material. When tested with PTFE grips, the Pebax + EverGlide samples had the best results. When PTFE is pulled against PTFE, the surface interaction can increase friction, which is why some materials had better results when tested with PTFE grips. Of the samples tested with silicone grips, the PTFE samples showed the best results.

FIGURE 4. LUBRICITY: PEBAX - PTFE GRIPS:

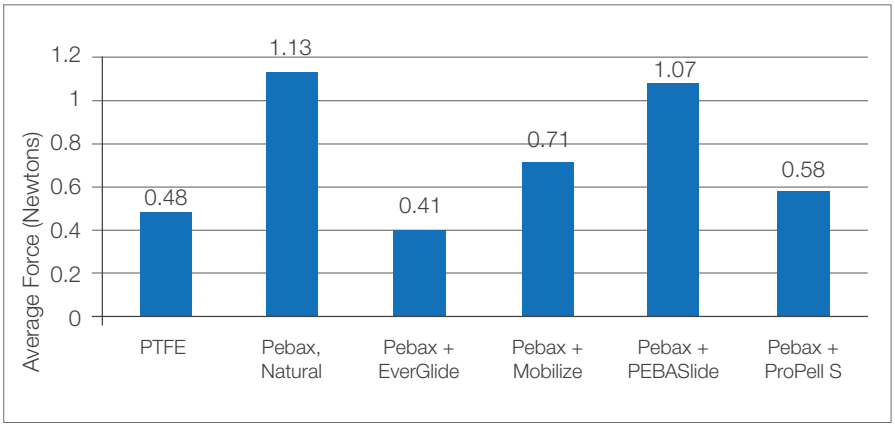
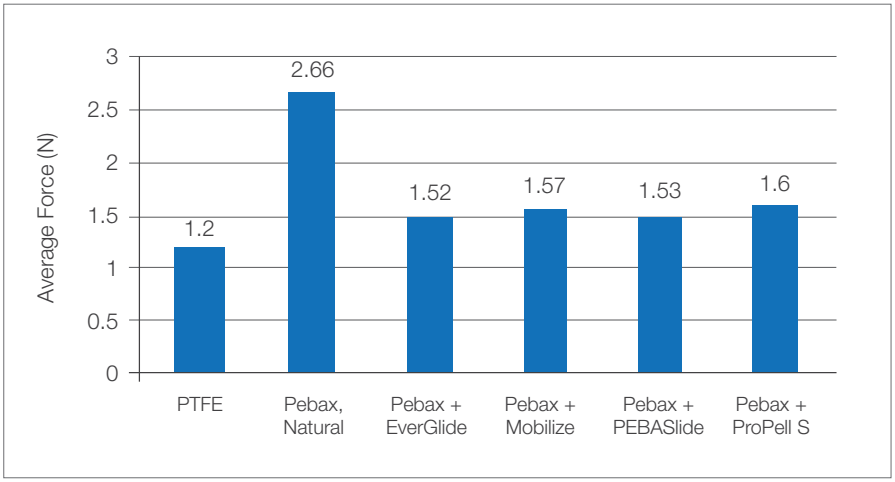


FIGURE 5: LUBRICITY: PEBAX - SILICONE GRIPS:



Tecoflex:

All samples with additives showed reduced friction compared to the Tecoflex natural material, when tested with both PTFE and silicone grips. The results were not close to the PTFE material, which was to be expected due to the inherent tackiness of the Tecoflex material.

FIGURE 6. LUBRICITY: TECOFLEX - PTFE GRIPS:

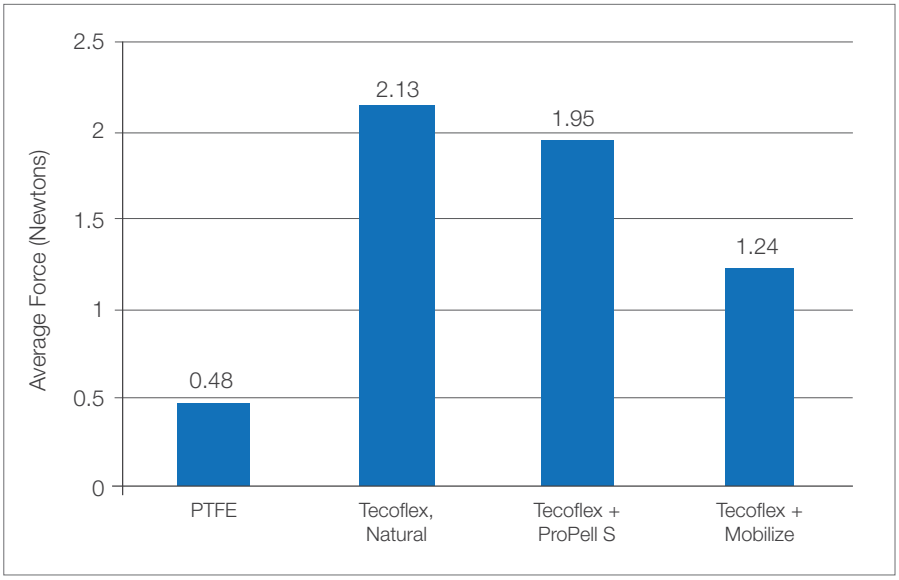
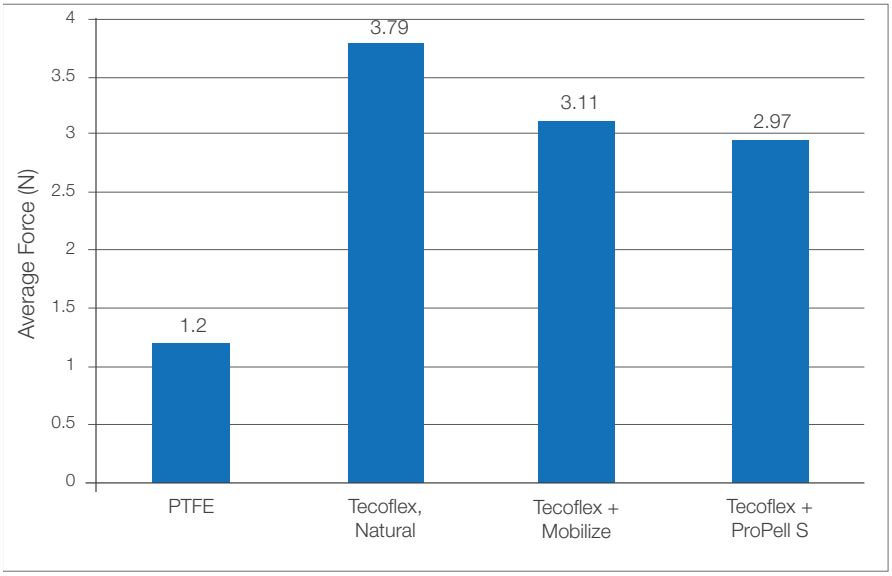


FIGURE 7: LUBRICITY: TECOFLEX - SILICONE GRIPS:



Fluoropolymers:

When tested using PTFE grips, the PFA and PTFE samples had similar results, with PFA showing a 4% greater friction force than the PTFE. Again, the PTFE results were expected due to PTFE/PTFE surface contact. However, the EFEP samples had a 31% reduction in friction compared to the PTFE. When tested with silicone grips, the PTFE samples gave the best results of the fluoropolymers.

FIGURE 8. LUBRICITY: FLUOROPOLYMERS - PTFE GRIPS:

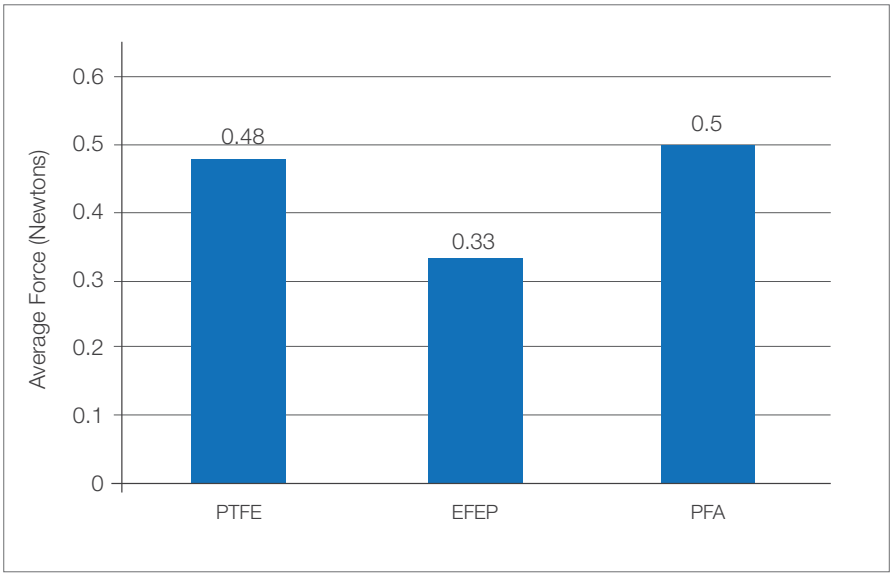
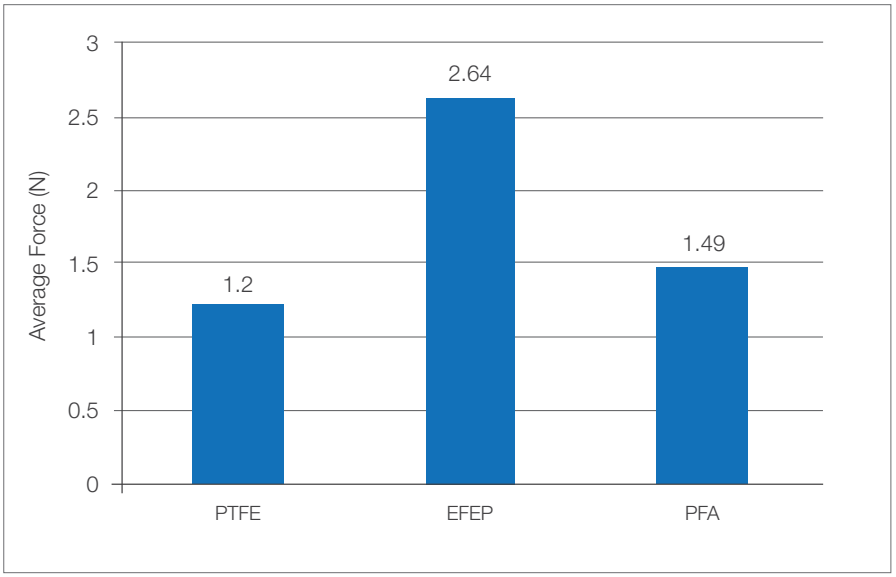


FIGURE 9: LUBRICITY: FLUOROPOLYMERS - SILICONE GRIPS:



CONCLUSIONS:

The EFEP samples tested with PTFE grips showed the greatest reduction in friction compared to PTFE (31%), suggesting that EFEP could perform well as an alternative to PTFE if it were in contact with, for example, a PTFE-coated mandrel. The Pebax + EverGlide sample also performed very well. An advantage of this combination is that it can be extruded on conventional equipment, whereas EFEP requires modified extrusion equipment.

4.2 ELONGATION:

METHODOLOGY:

Each of the materials in Table 2 was tested for elongation at break with a sample size of 20, based on an AQL of 2.5%. We measured elongation using a vertical tensile tester (Tinius Olsen model H10KT).

- Gauge length: 25 mm
- Speed: 250 mm/min
- Clamp pressure: 50 psi
- Temperature: 23°C

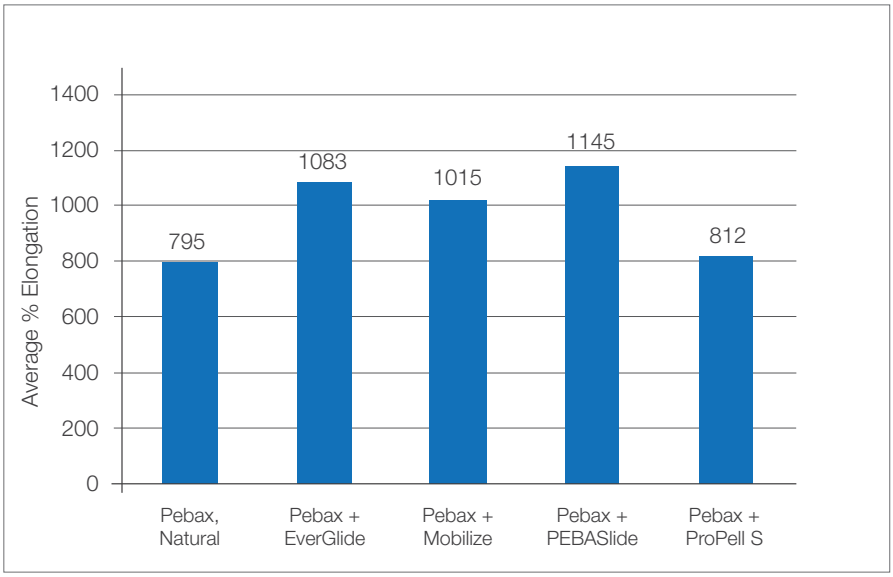
RESULTS:

The following graphs show the elongation results based on final inspection data from the extrusion runs.

Pebax:

We found an increase in elongation on all tubing with lubricious additives compared to the Pebax natural material. The Pebax + ProPell S samples showed elongation very similar to the natural material.

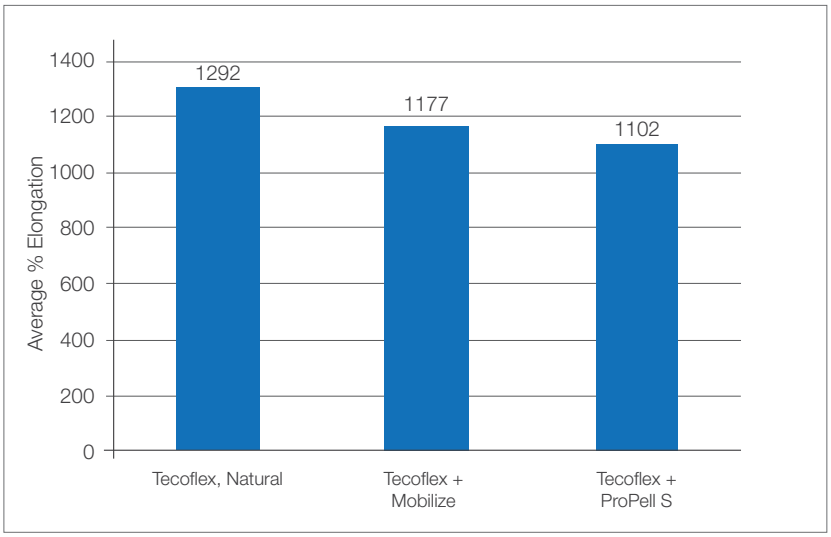
FIGURE 10. ELONGATION: PEBAX:



Tecoflex:

We found a slight decrease in the elongation results (10%–15%) for the Tecoflex materials with additives over the natural version of the material.

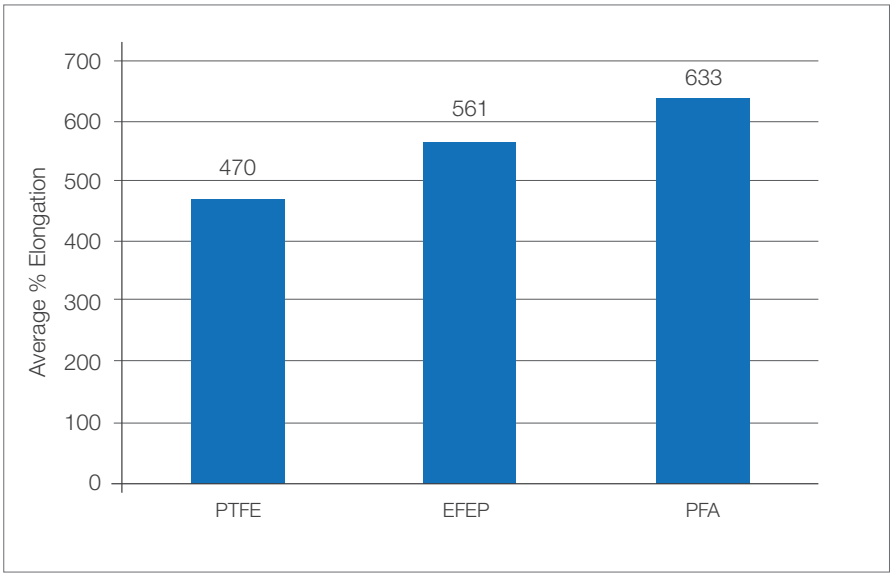
FIGURE 11. ELONGATION: TECOFLEX:



Fluoropolymers:

Elongation results for samples of the 3 fluoropolymers were relatively similar to one another.

FIGURE 12. ELONGATION: FLUOROPOLYMERS:



CONCLUSIONS:

The data showed no major changes in elongation with lubricious additives or fluoropolymers compared to the base materials. This suggests that medical device designers should not be overly concerned about the effects of additives on elongation. If a customer needs a tube to have a certain elongation, we can optimize the mechanical properties by adjusting the extrusion process.

4.3 TENSILE STRENGTH:

METHODOLOGY:

Each of the materials was tested for tensile strength at break with a sample size of 20, based on an AQL of 2.5%. We measured tensile strength using a vertical tensile tester (Tinius Olsen model H10KT):

- Gauge length: 25 mm
- Speed: 250 mm/min
- Clamp pressure: 50 psi
- Temperature: 23°C

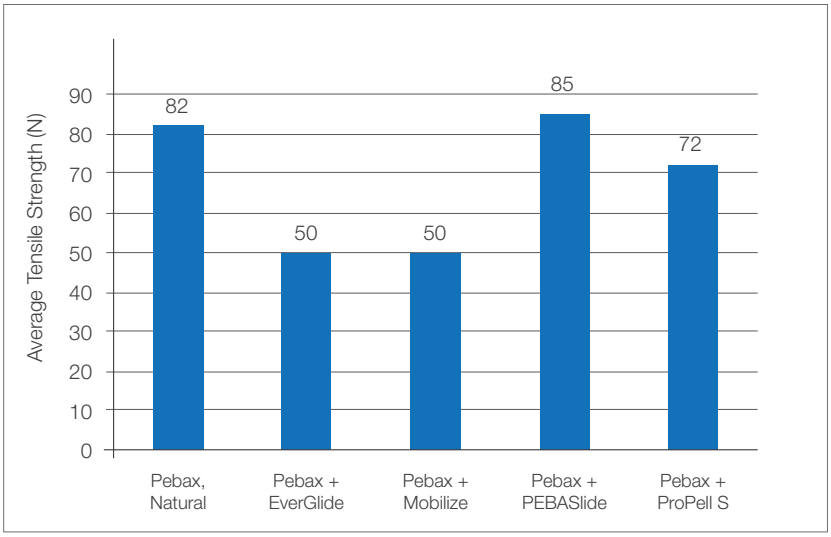
RESULTS:

The following graphs show the tensile strength results based on final inspection data from the extrusion runs.

Pebax:

We found a decrease in tensile strength on Pebax tubing with EverGlide and Mobilize when compared to the Pebax natural material. The Pebax + PEBASlide samples showed a slight increase in tensile strength, and the Pebax + Propell S samples had results similar to the natural material.

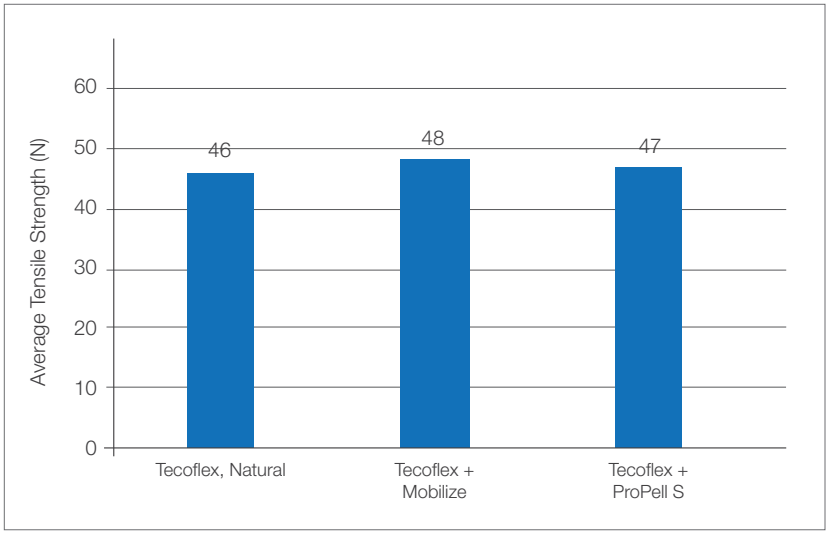
FIGURE 13. TENSILE STRENGTH: PEBAX:



Tecoflex:

The Tecoflex material with additives had tensile strength results very similar to the Tecoflex natural material.

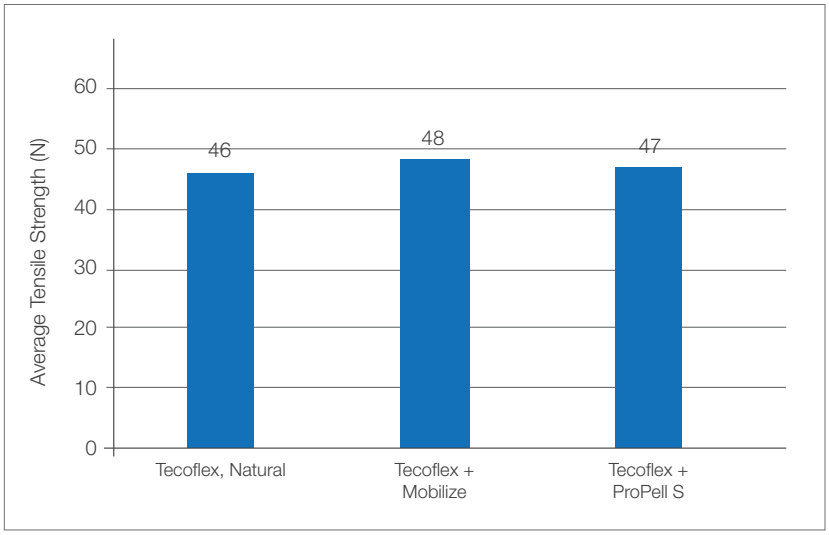
FIGURE 14. TENSILE STRENGTH: TECOFLEX:



Fluoropolymers:

The EFEP samples gave the highest tensile strength reading. The PFA and PFTE samples had similar tensile strength results.

FIGURE 15. TENSILE STRENGTH: FLUOROPOLYMERS:



CONCLUSIONS:

According to the data, some additives with Pebax show a significant decrease in tensile strength compared to natural Pebax. If strength is a critical design feature in a Pebax device, designers should consider materials that behave the most like natural materials; for example, Pebax + ProPell S or Pebax + PEBASlide, as opposed to Pebax + EverGlide or Pebax + Mobilize.

However, the tensile strength of the Tecoflex with additives was almost identical to the natural version, and the tensile strength of the fluoropolymers (PFA and EFEP) increased compared to the PTFE. Therefore, designers considering these materials can be confident that the tensile strength would be the same if not better than the natural materials.

4.4 ADHESIVE BOND STRENGTH:

METHODOLOGY:

To determine if the materials with the lubricious additives were capable of bonding in the same way as the natural materials, we bonded standard Luer lock fittings to each extrusion using Loctite® 4310 Flashcure Light Cure Adhesive. As the goal was to compare the lubricious additives, we only tested Pebax, which is the only material that was combined with all additives. Three types of Luer materials were used in this test: ABS, PC, and PVC.

The sample size was 10. We tested the samples using a tensile strength tester (Instron):

- Test speed: 200 mm/min
- Gauge length: 10 mm
- Clamp pressure: 30 psi
- Temperature: 23°C

RESULTS:

All failures were adhesive failures. The Pebax + ProPell S samples had results very similar to the Pebax natural material, when tested with all 3 Luer materials. The Pebax + PEBASlide samples had the next best results, with bond strength actually increasing slightly for the PC Luer and decreasing 20% on average across the 2 other Luer materials. The results for the Pebax + EverGlide and Pebax + Mobilize samples were lower than the Pebax natural material, with an average reduction in bond strength of 45% for the Mobilize and 30% for the EverGlide.

FIGURE 16. ADHESIVE BOND STRENGTH: ABS LUER:

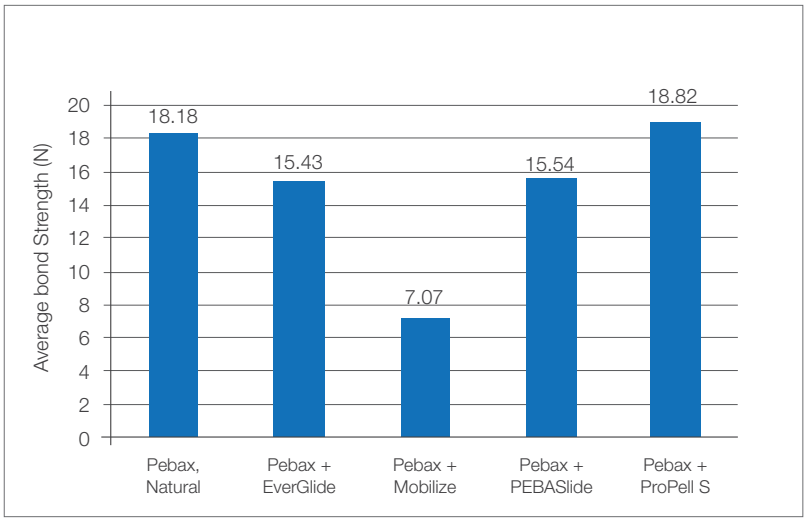


FIGURE 17. ADHESIVE BOND STRENGTH: PC LUER:

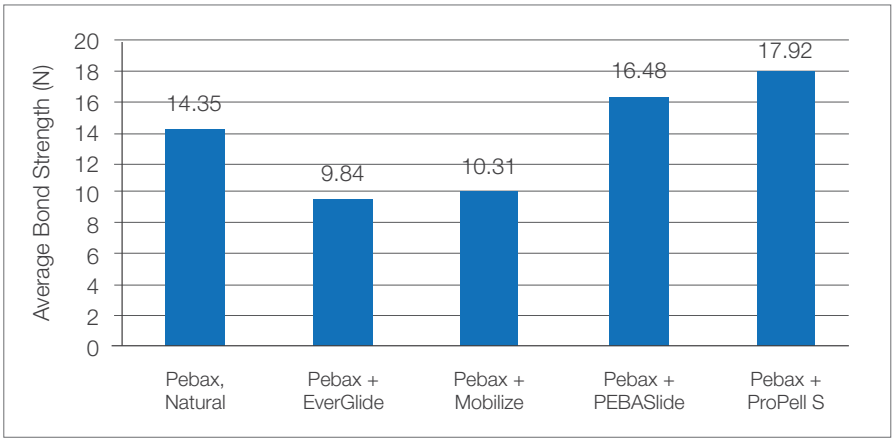
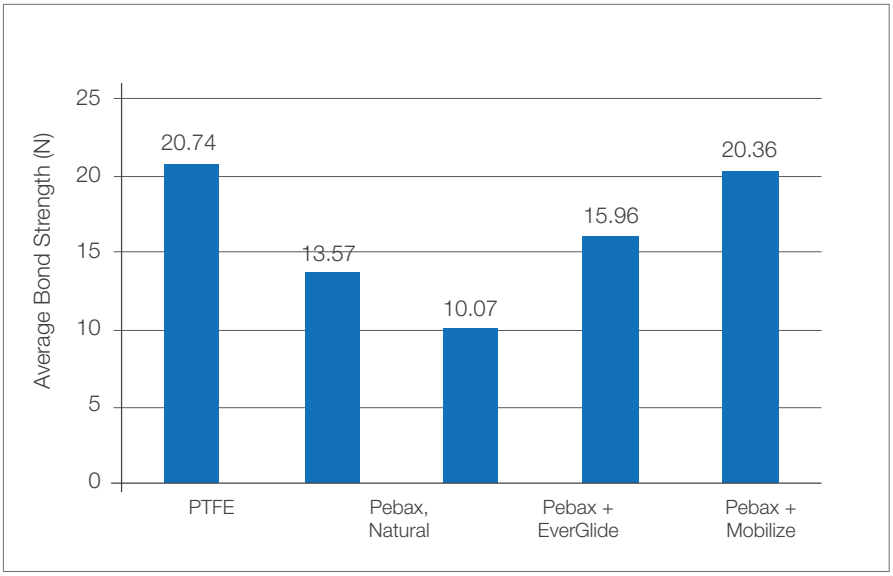


FIGURE 18: ADHESIVE BOND STRENGTH: PVC LUER:



CONCLUSIONS:

Before selecting a lubricious additive, designers should consider whether the tubing would be bonded to other components. If so, they should be aware that some additives, such as EverGlide and Mobilize, show much lower bond strength than the Pebax natural material, Pebax + PEBASlide, or Pebax + Propell S.

Table 5 in the Appendix shows the full results of testing for dimensional stability, elongation, lubricity, tensile strength, and bonding for all materials.

4.5 PAD PRINT TESTING:

METHODOLOGY:

We wanted to determine whether the materials with lubricious additives were capable of being pad printed upon in the same manner as the natural materials. We printed the materials using a pad printer (TAMPOFLEX model # TF 150 E) and Tampa® Star TPR ink (Black 980). The temperature was 23°C. Sample size was 5.

All tubing was wiped down with 100% alcohol before printing to achieve better print quality. We performed a standard adhesive tape test 48 hours after printing. A section of tape was pressed onto the print and removed quickly. If the print were well adhered, the tape would not remove any part of the print.

RESULTS:

All tubing samples showed good print quality right after printing. We found that the tape test had little or no effect on the print quality 48 hours after printing. The exceptions were one Pebax + ProPell S tube and one Pebax + EverGlide tube, for which the tape removed a small amount of the print.

We observed that the tubing with the lubricious additives had printing properties very similar to the natural materials. However, all printing was done on untreated tubing. If the tubing had been subjected to corona or plasma treatments before printing, it might have shown even better print quality and adherence.

CONCLUSIONS:

The results showed that the materials with the lubricious additives were as capable of being pad printed with depth markers or logos as the natural materials. Decreasing surface friction with these lubricious additives does not significantly affect print quality.

5.0 Aging Testing:

METHODOLOGY:

We replicated 6 months of aging to determine whether the materials with lubricious additives were as capable of withstanding the aging process as the natural version of the material. We placed samples of all tubing with the additives, including the fluoropolymer materials, in Nordson MEDICAL's environmental test chamber (ECO HTCL CL 400) at 55°C with a relative humidity of 6% for 20 days. The sample size was 10 based on an AQL of 10.0%.

RESULTS:

Table 3 shows the results of tests for dimensional stability, elongation, and tensile strength after simulated aging. We observed very little variation in the dimensional stability after aging. The difference between the tensile strength and elongation after extrusion and after aging for the materials with the additives is also roughly in line with the Pebax natural material. Tensile strength and elongation are given as averages of the 10 samples tested.

TABLE 3. AGING: DIMENSIONAL AND MECHANICAL RESULTS:

Material	Baseline OD Stability	OD Stability Post Aging	Baseline Elongation	Elongation Post Aging	Baseline Tensile Strength	Tensile Strength Post Aging
Pebax 4033 SA 01 MED, Natural	±0.008 mm	±0.009 mm	795%	704%	82 N	82 N
Pebax 4033 SA 01 MED + EverGlide	±0.03 mm	±0.026 mm	1083%	1141%	50 N	50 N
Pebax 4033 SA 01 MED + Mobilize	0.017 mm	±0.017 mm	1015%	1037%	50 N	50 N
Pebax 4033 SA 01 MED + PEBASlide	±0.012 mm	±0.011 mm	1145%	1137%	85 N	85 N
Pebax 4033 SA 01 MED + ProPell S	±0.010 mm	±0.010 mm	812%	728%	72 N	72 N
NEOFLON EFEP RP-5000	±0.019 mm	±0.017 mm	561%	557%	82 N	82 N
NEOFLON PFA AP-210	±0.025 mm	±0.026 mm	633%	804%	65 N	65 N

CONCLUSIONS:

We can conclude that adding lubricious additives to the natural materials has no major adverse effects on the dimensional properties of the tubing after a simulated aging process. While there was a slight difference in the mechanical properties, the difference was relatively small, so designers can have confidence in the stability of these extrusions.

6.0 Sterilization Testing:

METHODOLOGY:

We conducted tests to determine whether the materials with lubricious additives were as capable of withstanding sterilization as the natural version of the materials. We confirmed with the manufacturers that all additives and materials could be EtO sterilized. However, no manufacturer provided test results for gamma sterilization. For this reason—and because PTFE cannot be sterilized by gamma radiation—we passed the lubricious additives and the fluoropolymer materials through gamma sterilization.

We used the same samples that had previously been age tested, with a sample size of 10 based on an AQL of 10.0%. The samples were treated with a standard dose of 25–40 kGy. Table 4 shows the results of tests for dimensional stability, elongation, and tensile strength after gamma sterilization.

RESULTS:

According to the certificate of irradiation from the sterilization company, the calculated minimum dose was 34.8 kGy and the calculated maximum dose was 35.9 kGy. We observed little difference in the dimensional stability compared to the natural materials when the tubing was inspected after sterilization. However, the gamma sterilization process did affect the mechanical properties of the tubing, increasing the elongation in almost all samples and decreasing the tensile strength in all samples. We also observed these changes in the natural materials.

TABLE 4. STERILIZATION: DIMENSIONAL AND MECHANICAL RESULTS:

Material	OD Stability Post Aging	OD Stability Post Sterilization	Elongation Post Aging	Elongation Post Sterilization	Tensile Strength Post Aging	Tensile Strength Post Sterilization
Pebax 4033 SA 01 MED, Natural	±0.009 mm	±0.011 mm	704%	925%	82 N	82 N
Pebax 4033 SA 01 MED + EverGlide	±0.026 mm	±0.025 mm	1141%	1289%	50 N	50 N
Pebax 4033 SA 01 MED + Mobilize	±0.017 mm	±0.017 mm	1037%	1244%	50 N	50 N
Pebax 4033 SA 01 MED + PEBASlide	±0.011 mm	±0.011 mm	1137%	1293%	85 N	85 N
Pebax 4033 SA 01 MED + ProPell S	±0.010 mm	±0.012 mm	728%	817%	72 N	72 N
NEOFLON EFEP RP-5000	±0.017 mm	±0.019 mm	557%	574%	82 N	82 N
NEOFLON PFA AP-210	±0.026 mm	±0.026 mm	804%	662%	65 N	65 N

CONCLUSIONS:

The data showed that, while gamma sterilization did not significantly impact the dimensional properties of the tubing, it did affect the mechanical properties. It increased elongation in almost all samples and decreased tensile strength in all samples. We also observed these changes in the natural materials, indicating that the changes were due to the sterilization process rather than the lubricious additives.

We also noted that mechanical properties of the EFEP showed very little change after the sterilization process. This suggests that EFEP could be a good lubricious option for a device that cannot be EtO sterilized but still needs to maintain most of its original mechanical properties.

7.0 Conclusion:

The findings from this report indicate that lubricious additives and materials are capable of being extruded on conventional extrusion equipment with no significant stability or processing issues over the natural versions of the materials.

The data shows that the lubricious additives and materials have comparable—and in some cases, better—dimensional stability than the natural materials. However, the mechanical properties of the materials with the additives are affected in some cases. We recommend that designers consider the critical mechanical requirements of the end device before selecting a material, so as not to compromise important design characteristics.

The results of testing also show that all the additives show reduced friction compared to the natural materials. This is more pronounced in some additives. When tested with the PTFE grips, the PFA material performed almost as well as PTFE, and the EFEP material performed even better. These materials could prove to be good options for designers for applications that require increased lubricity when PTFE is not an option.

We also found that all materials were capable of being bonded, printed, aged, and gamma sterilized. Some of the additives and materials performed better than others in each of these tests. So again, we recommend that designers carefully consider the processes to which the final device will be subjected when selecting materials.

From the findings of this report, we feel that these lubricious additives and materials give medical device designers additional options and flexibility in developing new and improved medical devices.

8.0 Appendix:

8.1 DIMENSIONAL AND MECHANICAL TESTING RESULTS TABLE:

As noted in section 4.4.3, Table 5 shows the full results of testing for dimensional stability, elongation, lubricity, tensile strength, and adhesive bond strength for all materials.

TABLE 5. DIMENSIONAL AND MECHANICAL TESTING: FULL RESULTS:

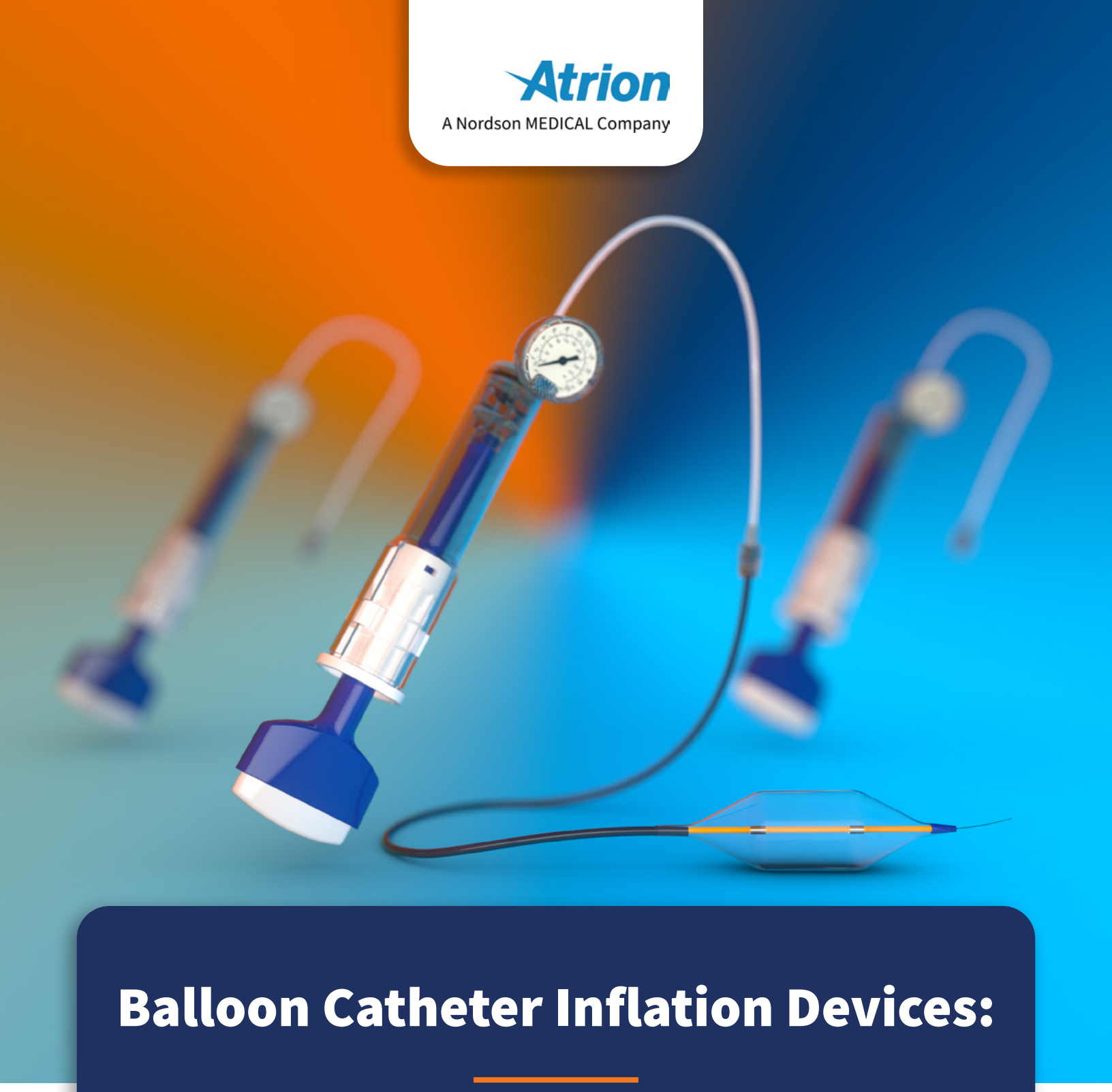
Extruded Material	Dimentional Stability (±mm)	Elongation (%)	Frictional Force (Lubricity) PTFE Grips (N)	Frictional Force (Lubricity) Silicone Grips (N)	Tensile Strength (N)	Adhesive Bond Strength (N) ABS Luer	Bonding (N) PC Luer	Bonding (N) PVC Luer
Pebax 4033 SA 01 MED, Natural	0.008	795	1.13	2.66	82	18.18	14.35	20.74
Tecoflex EG 80A, Natural	0.11	1292	2.13	3.79	46	N/A	N/A	N/A
PTFE	0.09	470	0.48	1.20	54	N/A	N/A	N/A
Pebax 4033 SA 01 MED + ProPell S	0.010	812	0.58	1.60	72	18.82	17.92	20.36
Pebax 4033 SA 01 MED + PEBASlide	0.012	1145	1.07	1.53	85	15.54	16.48	15.96
Pebax 4033 SA 01 MED + Mobilize	0.017	1015	0.71	1.57	50	7.07	10.31	10.07
Pebax 4033 SA 01 MED + EverGlide	0.03	1083	0.41	1.52	50	15.43	9.84	13.57
Tecoflex EG-80A + ProPell S	0.14	1102	1.95	2.97	47	N/A	N/A	N/A
Tecoflex EG-80A + Mobilize	0.09	1177	1.24	3.11	48	N/A	N/A	N/A
PTFE	0.09	470	0.48	1.20	54	N/A	N/A	N/A
NEOFLON EFEP RP-5000	0.019	561	0.33	2.64	82	N/A	N/A	N/A
NEOFLON™ PFA AP-210	0.025	633	0.50	1.49	65	N/A	N/A	N/A

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.

Visit Nordson MEDICAL at **nordsonmedical.com**

Atrion
A Nordson MEDICAL Company



Balloon Catheter Inflation Devices:

SUPPORTING CARDIOVASCULAR, GASTROINTESTINAL, UROLOGICAL, AND STRUCTURAL INTERVENTIONS

Balloon Catheter Inflation Devices:

Supporting Cardiovascular, Gastrointestinal, Urological, and Structural Interventions

Introduction

Inflation devices are recommended for use with balloon catheters to create and monitor the pressure in the balloon and to deflate the balloon.

Balloon catheters are critical tools in interventional medical procedures. They are used to mechanically dilate specific anatomical structures and to deliver stents, drugs, therapeutics and implants.

Balloon catheter inflation devices provide precise, controlled delivery of fluid volume and pressure to ensure that balloons achieve the desired diameter and shape without causing vessel or structural damage.

Therapeutic Applications

Balloon catheters that require high pressure balloon inflation and pressure monitoring are used in a wide range of interventional procedures

CORONARY ANGIOPLASTY (PERCUTANEOUS CORONARY INTERVENTION)

Balloon catheters are used to open stenotic (narrowed) or blocked coronary arteries in patients with atherosclerosis or coronary artery disease. After a pre-dilation to open the blocked artery, a second balloon catheter is often used to deploy/expand a stent into the vessel. A stent is a small, mesh-like tube implanted to keep the artery open and improve blood flow. A third balloon can be used to post-dilate the stent to optimize stent expansion, improve stent apposition and potentially reduce the risk of complications such as stent thrombosis and restenosis. Drug coated balloons (DCBs) are an emerging alternative to permanent stent implantation. DCBs are coated with a drug-excipient matrix that delivers anti-proliferation medication directly to the vessel wall during balloon inflation.

PERIPHERAL ARTERY DISEASE (PAD)

Balloon catheters are used to treat blockages in the legs (i.e. femoropopliteal or below-the-knee) and arms (i.e. arteriovenous fistula/graft). Similar to coronary angioplasty, the balloon dilates narrow vessels to improve blood flow. Peripheral balloons are often longer in length and larger in diameter vs. coronary balloons to accommodate bigger peripheral vessels. The larger balloons require more fluid volume to inflate and, in some cases, have a rated burst pressure up to 40ATM.

STRUCTURAL HEART

Transcatheter heart valve replacement is a minimal invasive procedure to replace diseased heart valves with an artificial heart valve. In balloon expandable transcatheter aortic valve replacement (TAVR), the artificial valve is mounted on a metal frame which is crimped on a balloon catheter and the artificial valve is then guided into the aortic annulus via a transfemoral catheter. The balloon is inflated to expand the metal frame and anchor the heart valve implant, replacing the stenotic (narrowed) or regurgitant (leaky) valve. In some cases, valvuloplasty, a balloon dilation to expand the valve leaflet and widen the opening, is performed prior to valve replacement.

ESOPHAGEAL

An esophageal stricture is a narrowing of the esophagus that leads to difficulty swallowing foods and liquids. Esophageal balloon dilation involves inserting a large balloon catheter into the esophagus and inflating it to stretch the narrowed area.

GASTROINTESTINAL

Balloon dilation is performed during endoscopic retrograde cholangiopancreatography (ERCP) procedures to widen narrowed or obstructed bile or pancreatic ducts. It involves inserting a balloon catheter through the endoscope and inflating it to expand the duct, allowing for stone removal, stent placement, or other interventions.

UROLOGY

Balloon dilation for urethral stricture treatment is a minimally invasive procedure that uses a balloon catheter to widen the urethra, relieving the narrowing caused by scar tissue. It's an effective treatment for short strictures and can be a good option for recurrent strictures, particularly when combined with DCBs, which can reduce the risk of recurrence. DCBs are also used to treat Benign Prostatic Hyperplasia (BPH). In these procedures, a balloon catheter coated with an antiproliferation drug is used to treat lower urinary tract symptoms (LUTS) caused by an enlarged prostate.

KYPHOPLASTY

Kyphoplasty is a minimally invasive procedure used to treat vertebral compression fractures in the spine, often caused by osteoporosis. A balloon is inserted into the fractured vertebra and inflated to compact the surrounding bone to create a defined cavity for cement injection. The space is filled with bone cement to stabilize the fracture and restore vertebral height.

BALLOON SINUPLASTY

Balloon sinuplasty is a minimally invasive procedure used to treat chronic sinusitis by widening the sinus openings and improving drainage. It involves inserting a small balloon catheter into the nasal passages, inflating it to reshape the sinus, and then deflating and removing the balloon. This technique aims to restore normal sinus function without the need for cutting or removing bone and tissue like traditional sinus surgery.

Balloon Catheter Inflation Devices

FEATURES AND FUNCTIONS

Balloon catheters that require high pressure balloon inflation and pressure monitoring are used in a wide range of interventional procedures:

LOCKING MECHANISM

Balloon catheter inflation devices feature a locking mechanism, integrated into the inflation syringe, allowing clinicians to engage and disengage the screw-driven plunger threads. The plunger threads are unlocked/disengaged to fill the syringe with fluid and to prepare the device for use. To generate the high pressure required by many balloon catheters, the screw driven plunger must be locked/engaged, allowing the user to rotate the screw plunger clockwise to precisely deliver fluid to dilate the balloon. Once balloon dilation is complete, the threads are disengaged/unlocked so the user can pull a vacuum to quickly deflate the balloon catheter.

PRESSURE MEASUREMENT

Balloon diameter is often correlated to a specific inflation pressure. Two critical specifications that define the operational limits of a balloon during interventional procedures are nominal pressure and rated burst pressure. Nominal pressure is the pressure at which the balloon catheter achieves a specified diameter or shape as designed by the manufacturer for optimal performance. The rated burst pressure is the maximum pressure the balloon is designed to withstand before there is a risk for significant failure or balloon rupture. Inflation devices have a pressure gauge to measure and display the balloon pressure so the clinician can properly dilate the balloon.

CLEAR SYRINGE BARREL

A clear syringe barrel allows clinicians to see fluid levels during device preparation to ensure all air bubbles have been cleared prior to use and then to monitor fluid dispensing during balloon dilation. The syringe must have durable construction to accommodate high pressure balloon catheter dilation.

TUBING AND CONNECTOR

High-pressure braided tubing connects the device to the balloon catheter with a Luer-lock ensuring a secure, leak-free interface. The rotating luer-lock connection should be ISO 80369 compliant.

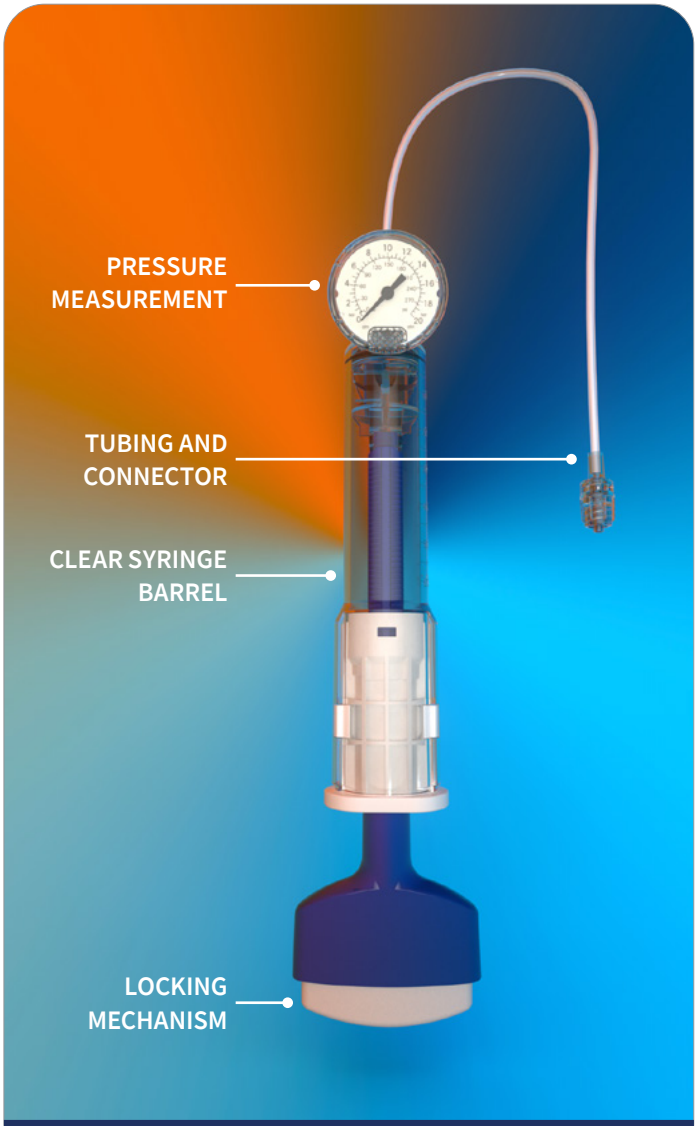


FIGURE 1: Inflator features

Balloon Catheter Inflation Devices

CRITICAL PERFORMANCE CHARACTERISTICS

One device does not fit all applications. Specialty clinical applications have unique inflation device requirements.

INFLATION/DEFLATION SPEED

Balloon catheters used in heart valve replacement procedures must be rapidly inflated and deflated as the expanded balloon blocks blood flow through the heart valve. The need for speed prohibits users from engaging the locking mechanism and dilating the balloon with the use of the threaded plunger. The inflation device must have a small-bore diameter to minimize user input force and allow the balloon to be dilated manually. In addition, heart valve balloons are often large diameter and require up to 45ccs of fluid volume to fully dilate at pressures up to 15ATM. In order to meet the large capacity requirement of these balloon catheters, while still allowing for rapid manual inflation, the length of the device must increase, complicating the design requirements and manufacturing processes. A quick latch locking mechanism, that allows the plunger threads to remain in the unlocked/disengaged position, is often preferred for structural heart procedures versus a spring-loaded locking mechanism that automatically returns to the locked position.

ULTRA HIGH PRESSURE

Balloon catheters, used to dilate severely calcified lesions or compact bone material to create a cavity, often require 40ATM or 55ATM of pressure for the balloon to reach the proper diameter and shape. In some cases, the force required to inflate a balloon catheter could be as much as 300lbf (1300N). Therefore, inflation devices require reinforced plunger threads, braided tubing, high pressure gauges and a robust locking mechanism to accommodate inflating and deflating ultra high pressure balloons multiple times during a procedure.

LARGE FLUID CAPACITY

Large capacity balloon catheters require inflation devices to accommodate up to 60ccs of fluid volume and generate up to 20ATM of pressure, while promoting ergonomics and clinical usability. Deflating large balloons can prove to be especially challenging as the large diameter syringe requires higher user force to create negative pressure. The latching mechanism should be easy to activate so the user can lock the device in the vacuum position while the balloon is deflating.

FIGURE 2: Detailed photo showcasing the gauge for precise measurements

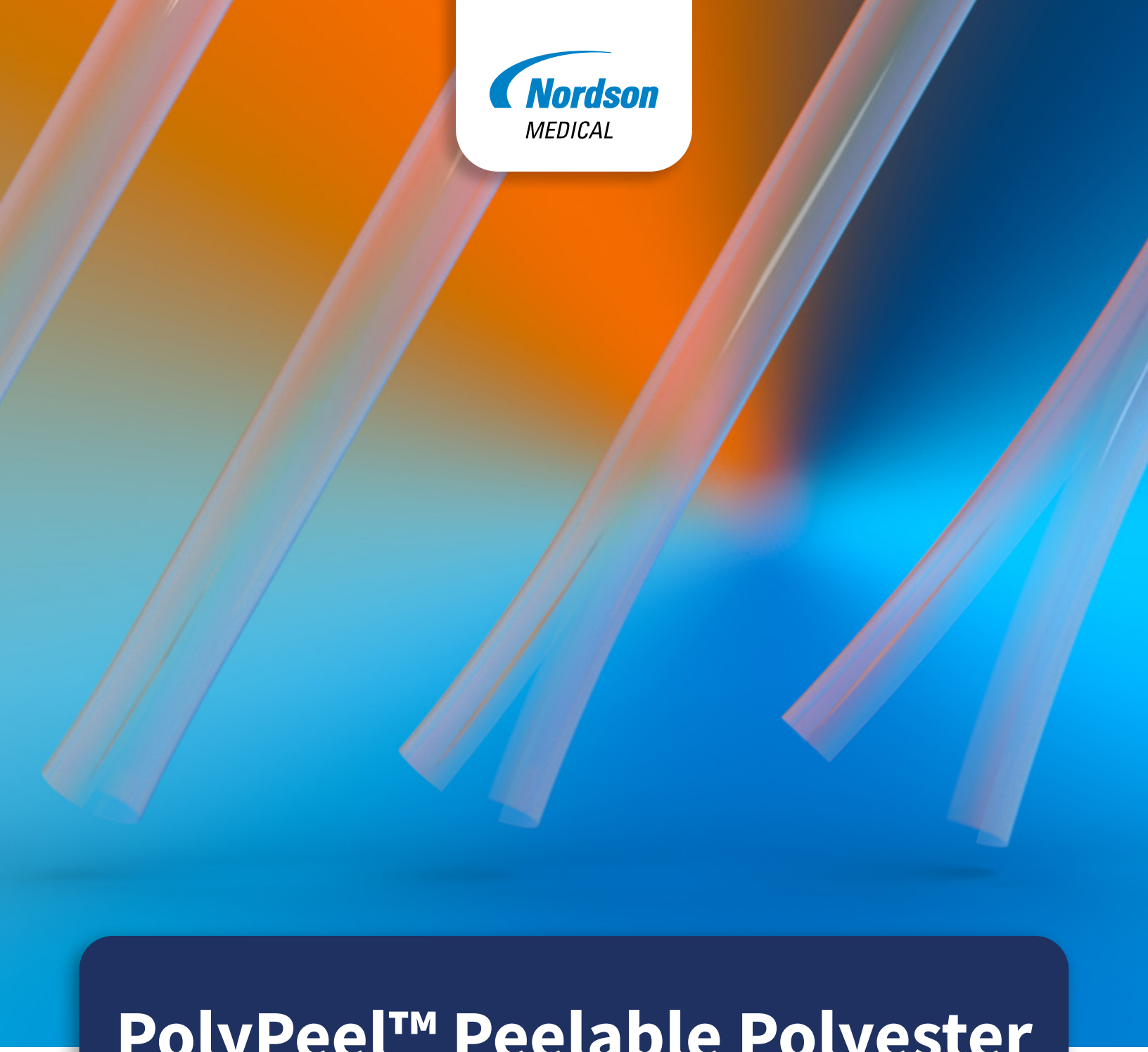
PRESSURE GAUGE ACCURACY

To ensure balloon catheters are inflated to the appropriate shape and diameter, pressure accuracy is paramount. Premium pressure gauges have a minimum accuracy of +/- 1ATM over the pressure range and have a luminescent background to improve visibility in dark procedure rooms. Analog gauges are the most popular gauge type and serve as a practical, cost-effective and reliable tool to measure and display pressure.

Conclusion

Balloon catheter inflation devices play a critical role in a wide range of therapeutic procedures, from cardiovascular interventions to structural heart repairs and gastrointestinal treatments. Their design must meet the demanding requirements of high-pressure performance, rapid inflation and deflation, and precise fluid control to ensure optimal clinical outcomes. As medical applications continue to evolve, so too must the engineering behind these devices—tailoring features to meet the specific needs of each procedure. Understanding the nuances of inflation device functionality and performance characteristics is essential for clinicians and device developers alike, driving innovation and improving patient care across diverse therapeutic domains.

FIGURE 3: Atrion's inflators: A snapshot of innovation and versatility



Nordson MEDICAL

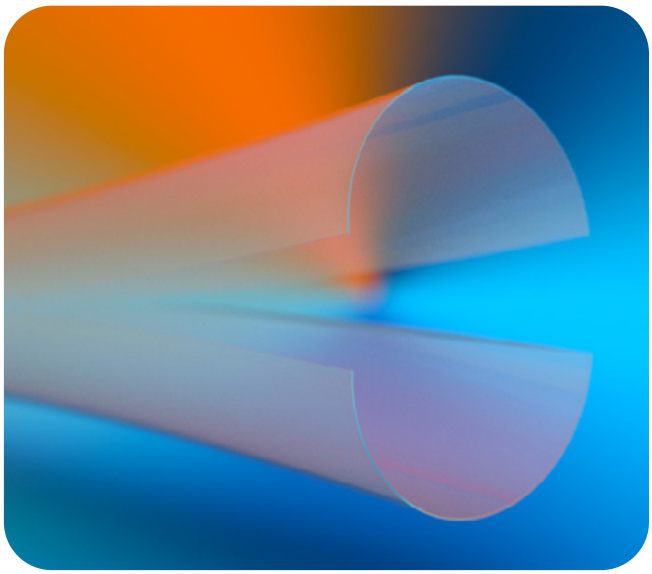
PolyPeel™ Peelable Polyester Heat Shrink Tubing:

SOLVING A FOUR-DECADE PROBLEM

PolyPeel™ Peelable Polyester Heat Shrink Tubing:

Solving a Four-Decade Problem

Introduction



Introduced more than four decades ago, polyethylene terephthalate (PET) heat shrink is a highly effective protective barrier for medical devices. More recently, PET heat shrink's application as a disposable manufacturing aid have multiplied exponentially.

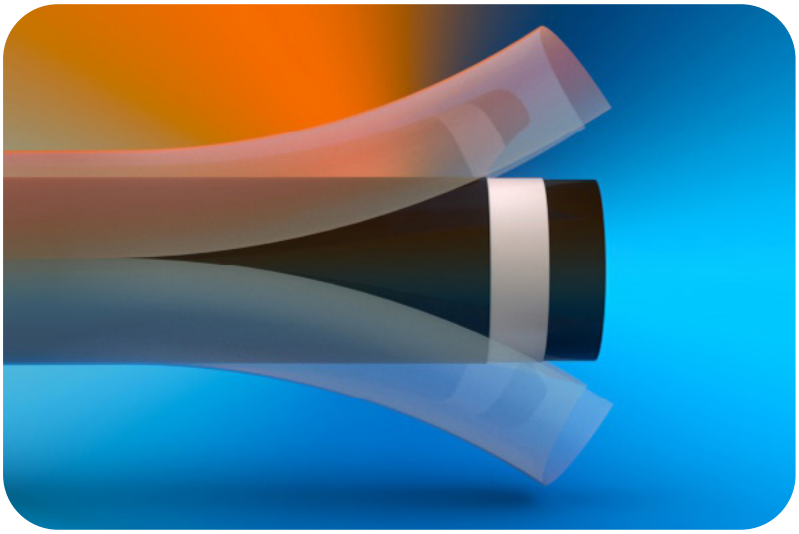
However, because PET is naturally strong, yet thin, it can be difficult to remove during manufacture or from finished medical devices. It often comes off in pieces or operators on the manufacturing line must carefully skive it for removal. This adds to manufacturing time, diminishes throughput, and increases the risk of damage to the sensitive substrate underneath — in some cases, the damage is severe enough that the device must be discarded.

PET That Peels Back With No Drawbacks

To address these shortcomings, Nordson MEDICAL developed PolyPeel™ Peelable Polyester Heat Shrink Tubing. As the industry's premier provider of medical-grade PET heat shrink, we are committed to helping with issues experienced by customers and better serving current and future PET applications in manufacturing.

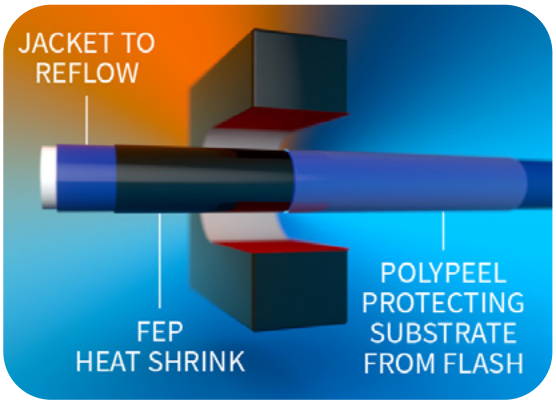
PolyPeel's patent-pending design easily releases from common thermoplastic jacket materials, such as Pebax® and nylon. Removal is as simple as holding the PET heat shrink in two places while pulling them apart in different directions.

We developed PolyPeel to offer the same reliable performance our customers expect from our standard PET heat shrink tubing. PolyPeel is free of per- and polyfluoroalkyl substances (PFAS) and meets ISO 10993 requirements. It also exhibits the same tolerances, wall thicknesses, and inner diameter (ID) ranges as our standard PET heat shrink tubing.



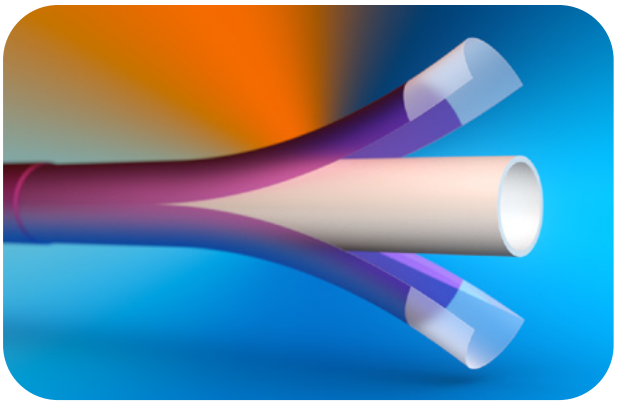
This consistency is critical because many customers have used standard PET heat shrink for decades, and its dependable performance is integral to their applications. This includes the ability to achieve ultra-thin walls and to enable significantly lower-temperature recovery of PET heat shrink tubing versus fluorinated ethylene propylene (FEP). While these attributes make PolyPeel heat shrink ideal for an ever-expanding number of purposes, four primary applications are most prominent:

1. WRAPPING



Wrapping applications are among PET heat shrink tubing's most common uses and benefit from the material's low temperature recovery (shrink ratios of at least 1.1:1). FEP tubing requires nearly double the heat to recover versus PolyPeel, whose heat shrink recovery range is 185°F to 374°F. This range enables safer usage in existing applications and offers opportunities for new uses by reducing the risk of heat damage to temperature-sensitive substrates. PolyPeel's peak melt temperature is 489°F.

Consider, as an example, a stent mounted on a balloon with a tight wrap. Device engineers must maintain or improve the wrap's low profile when updating materials. The low profile enables a smaller hole at the puncture site, reduces the risk of puncture site complications, and makes it easier to navigate the device through the vasculature. Additionally, the wrapping material must maintain a tight wrap during storage. If that product sits on a shelf waiting to be finished, sterilized, and/or packaged before being sent to a hospital, a material that relaxes over time will increase the profile, perhaps even enough to draw the product out of spec for use.

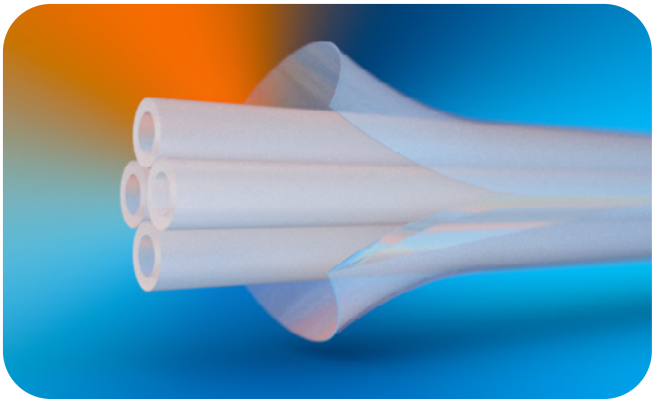


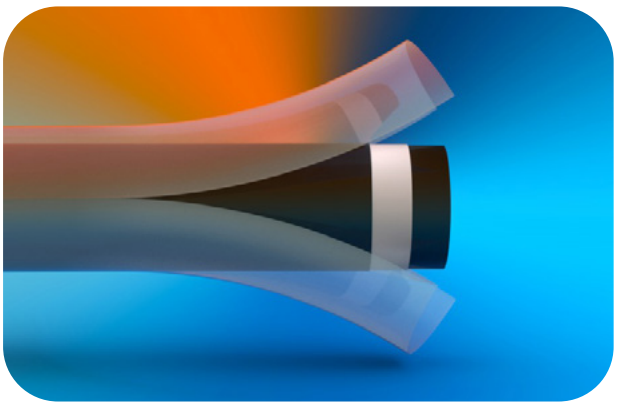
2. MASKING

Thin-wall PET heat shrink tubing allows for all-but-seamless transitions between coated and uncoated catheter sections in masking applications. For example, PET heat shrink is applied over the area to be protected, the coating is applied, the heat shrink is removed, and a smooth transition is created between the coated and uncoated surfaces. A thicker coating, like FEP (about 0.01" thick), might cause coating to build up at the edge of that wall, creating a bumped transition in the catheter. PolyPeel is available in wall thicknesses from 0.00025" to 0.001" and IDs ranging from 0.080" to 0.300".

3. BUNDLING

Ultra-thin walls also enable tight-tolerance bundling of various wires and catheters. For example, a catheter may comprise tubing, electrical wires, and/or a complex, articulating tip. Thin-walled PET heat shrink or PolyPeel enable the operator to insert that bundle into a tight-tolerance outer jacket, push it all the way through, and then remove the heat shrink from the other end. The result is a low-profile outer jacket with a tight tolerance wrap around all the various components inside. Again, FEP heat shrink would create a thicker outer wall and thus a larger outer diameter (OD) on the jacket, as well as potentially a larger profile.





4. REFLOW

Currently, almost all reflow laminating processes use FEP heat shrink, which contains PFAS. However, our PET heat shrink and PolyPeel provide a PFAS-free alternative. Recommended reflow temperatures range from 185°C to 235°C, depending upon jacket material, but much higher temperatures can be used by increasing reflow run speeds. This is possible because heat transfers through the PET's thin walls more quickly and efficiently. So, the same temperature heat can be used to laminate multilayer catheters in a reflow process, but run at a much faster speed, increasing throughput and reducing manufacturing costs.

Time's Up For "Forever Plastics"

The FDA acknowledges that PFAS materials, particularly polytetrafluoroethylene (PTFE), are valuable substances that not only support but also often enable the functionality of medical devices. However, the FDA also has stated the use of PTFE should be avoided in food-contact applications, paving the way to curtailed use in medical applications.

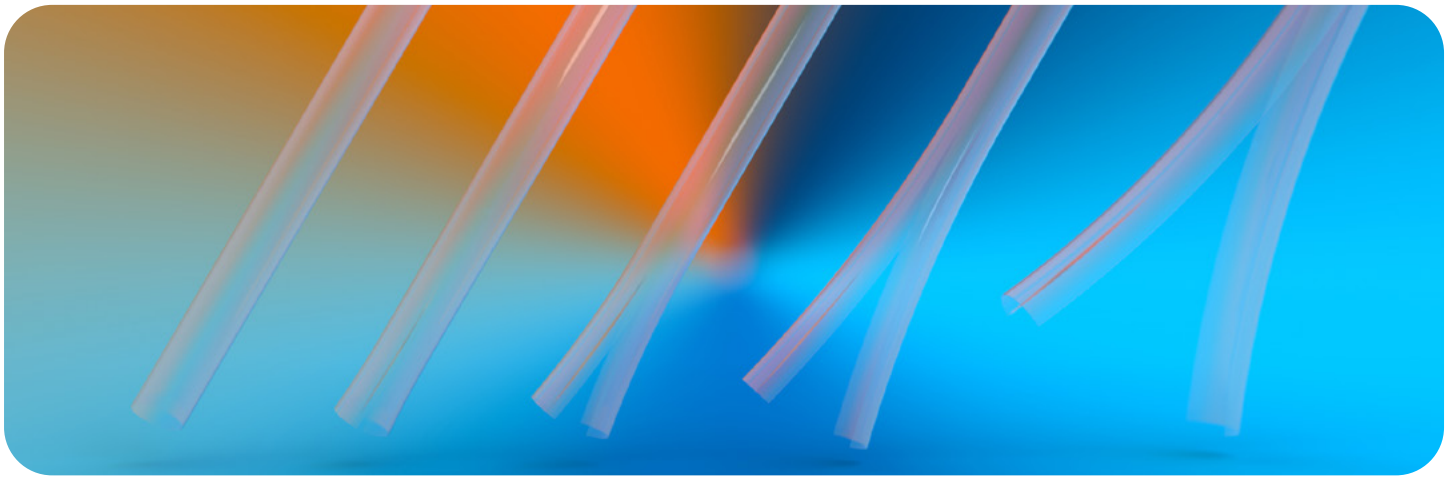
Moving away from the use of PFAS — dubbed "forever chemicals" or "forever plastics" because of their high resistance to breakdown — is environmentally responsible and minimizes humans' exposure risk, as some PFAS have been determined to be toxic. If a defective device is discarded wearing a PTFE liner, as many catheter-based devices do, the operator or user is throwing away a PFAS material. This also applies to hospitals discarding single-use devices.

Additionally, device materials and components typically are cleaned during manufacture, and the resulting wastewater is tainted with microplastics that contaminate drinking water. The European Commission has proposed adding numerous PFAS to its lists of water pollutants (in addition to PFAS like PFOA, already on that list), as well as releasing a chemicals action plan that includes the creation of an EU-wide PFAS monitoring system. Therefore, reducing this scrap is imperative for both sustainability and regulatory compliance.

A Novel Product Informed By Industry Heritage

Over Nordson MEDICAL's decades of operation, hundreds of customers have discovered the benefits of PET heat shrink across a multitude of applications and thousands of different part specifications. Usage has increased so steadily that we now supply nearly all the PET heat shrink used in the global medical device market, amounting to 20 to 30 million feet annually.

In fact, we recently doubled the production capacity of our Salem, NH, facility — our PET Heat Shrink Center of Excellence — meaning we have ample capacity to support future growth in service of new and existing customers. This capability extends to PolyPeel, which is available in high-volume production, empowering Nordson MEDICAL to support significant market demand or growth.



Conclusion

In addition to 40+ years of technical experience, Nordson MEDICAL customers benefit from the trust we have earned and industry relationships we have established during that time. We regularly consult with customers to understand their needs and to resolve challenges they encounter, both in product development and on the manufacturing line.

Providing solutions can mean modifying PET heat shrink's dimensions, tweaking processing parameters, changing how the heat shrink is manipulated during use, or, with the advent of PolyPeel, making polyester heat shrink tubing removal easier and safer. Nordson MEDICAL's knowledge of polyester's morphological structure, during manufacture and use, enables us to "dial in" these specifications with precision.

We encourage and support our customers' innovation in how they use heat shrink, and we look forward to breaking new ground with PolyPeel's implementation into existing applications and use in novel operations. To learn more, contact the authors and visit https://interventional-solutions.nordsonmedical.com.

About Nordson MEDICAL

Nordson MEDICAL (Nasdaq: NDSN) is a global expert in the design, development, and manufacturing of complex medical devices and component technologies. As a single-source partner, we enable our customers to save costs, speed time to market, and simplify supply chain management.

We work with companies at any point in the product lifecycle, from concept to launch and beyond. With our flexible business model, we can provide a solution that meets the scope and scale of any project to bring innovative ideas to life.

Contact Information

Ireland		
Boyle, Ireland	Abbeytown Boyle, County Roscommon	Phone: 353.71.966.3038 IRE.CustomerServices@nordsonmedical.com

Irael		
Katzrin, Israel	20 Street Katzrin 1290000	Phone: 972.4.6738600 VTN-CustomerService@nordsonmedical.com

Mexico		
Guaymas, Mexico	Carretera Int No. 15 Km129 Salida Norte Parque Industrial Roca Fuerte, Edificio 21 Guaymas, Sonora C.P. 85400	

United States		
Arab, AL	1426 Curt Francis Road Arab, AL 35016	256.586.1580 info@atrionmedical.com
Chattanooga, TN	4701 Wilson Road, Suite E Chattanooga, TN 37410	Phone: 423.551.8700 CTN-Sales@nordsonmedical.com
Easton, PA	12 McFadden Road Easton, PA 18045	Phone: 610.559.9000 ETNcustomerservice@nordson.com
St. Paul, MN	1270 Eagan Industrial Road, Suite 120 St. Paul, MN 55121	Phone: 651.452.1977 customerservice@nordsonmedical.com
Salem, NH	29 Northwestern Drive Salem, NH 03079	Phone: 603.327.0600 VTN-CustomerService@nordsonmedical.com

About Nordson MEDICAL

Nordson MEDICAL (Nasdaq: NDSN) is a global expert in the design, development, and manufacturing of complex medical device components. As a single-source partner, we enable our customers to save costs, speed time to market, and simplify supply chain management.

We work with companies at any point in the product life cycle, from concept to launch and beyond. With our flexible business model, we can provide a solution that meets the scope and scale of any project to bring innovative ideas to life.

Visit Nordson MEDICAL at **nordsonmedical.com**

Nordson MEDICAL

SHOP OUR ONLINE STORE

interventional-solutions.nordsonmedical.com/Shop