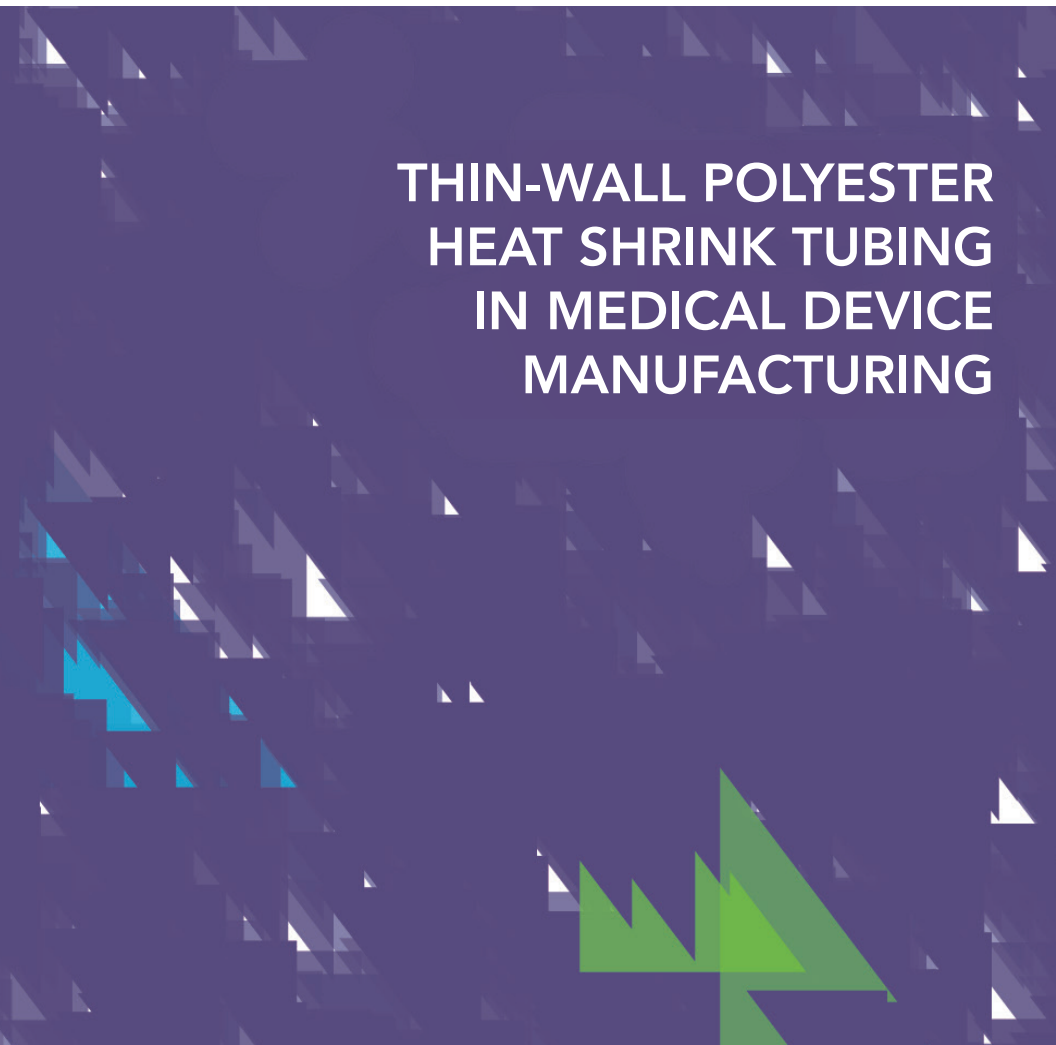


The logo for Vention Medical, featuring the word "VENTION" in a large, bold, dark blue font with three horizontal bars in the "E", and "MEDICAL" in a smaller, dark blue font to the right, with a registered trademark symbol (®) above it.

VENTION MEDICAL[®]

Advancing your innovations for health

A large, abstract background graphic consisting of a dense pattern of overlapping triangles and squares in various shades of blue, purple, and green, creating a complex, geometric pattern.

**THIN-WALL POLYESTER
HEAT SHRINK TUBING
IN MEDICAL DEVICE
MANUFACTURING**

Mark Saab, Chief Technology Officer

THIN-WALL POLYESTER HEAT SHRINK TUBING IN MEDICAL DEVICE MANUFACTURING


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INTRODUCTION

The demand for less-invasive medical procedures is a major driving force in the medical device industry today. Smaller and thinner is better, especially in catheters, endoscopes, and other devices inserted into the body. Designers are looking for new ways to downsize existing devices and satisfy the requirements of minimally invasive procedures. The industry is also under pressure to build more features into devices without increasing their profile (size). Thin-wall heat shrink tubing can help designers meet this demand across a range of applications by reducing diameters and improving production processes.

Vention Medical has developed a proprietary process to manufacture thin-wall heat shrink tubing from Polyester (specifically, polyethylene terephthalate, or PET) that exhibits extraordinary tensile strength, even with walls as thin as 0.00015”.

This paper begins with a brief comparison of the key properties of thermoplastic materials used in the manufacture of high-end medical heat shrink tubing, then discusses the advantages of PET for thin-wall heat shrink tubing for the following applications:

- ▶ Creating Variable-Stiffness Catheters
 - ▶ Electrical Insulation
 - ▶ Protective Covering/Encapsulation & Bundling
 - ▶ Tube Joining & Transitioning
 - ▶ Tube Marking and Printing
 - ▶ Catheter Shaft Lamination
 - ▶ Catheter Tip Forming
 - ▶ Micro Hose Clamps
 - ▶ Masking Procedures
- 

MATERIALS COMPARISON – PROPERTIES OF HEAT SHRINK TUBING

This table compares the properties of the primary materials used for thin-wall heat shrink tubing.

MATERIAL	WALL THICKNESS	SHRINK TEMP.	SHINK RATIO	STERILIZATION	STRENGTH	COST
PVC	>.0.005"	Medium	2:1	Most	Low	Low
Polyolefin	>.0.005"	Medium	2:1 to 4:1	Most	Low	Low/Medium
PET	0.00015 to 0.004"	Low/Medium	1.1:1 to 3:1*	Most	High	High
FEP	>.0.002"	High	1.13:1 to 1.6:1	No Gamma	Low	High
PTFE	>.0.002"	Very High	1.3:1 to 4.1	No Gamma	Low	High

* Recovery greater than 20% can be accomplished by drawing while shrinking

PET is the clear leader in terms of thin walls and high strength. It is 10 to 100 times thinner than all other heat shrink tubing and more than 10 times stronger. Tube walls of 0.00015" to 0.004" can be produced from PET and still maintain high hoop strength. That compares with >.0.002" for Fluoropolymers (FEP, PTFE) and >.0.005" for Polyolefin and PVC. PET also has the lowest shrink temperature (185°F/85°C) of the group, which enables processing of delicate substrates without heat degradation.

As noted in the chart above, the cost of PVC is low, Polyolefin is low to medium, and Fluoropolymers and PET are higher. However, the cost of tubing for high-end medical devices is generally outweighed by other factors, such as the need for unique mechanical characteristics, product quality, precise sizing, availability across a broad range of diameters and wall thicknesses, and supplier delivery and reliability.. In addition, cost savings can often be realized by using high-end components that eliminate upstream or downstream processes, reduce defect rate, or deliver functional performance that warrants a premium price in the marketplace.

While Fluoropolymers offer outstanding lubricity, a significant drawback is their very high shrink temperature (420°F - 650°F/215°C - 343°C). For FEP, this can lead to process inefficiencies and increased defect rates. In the case of PTFE, it precludes many catheter and plastic component applications altogether. Fluoropolymers cannot be sterilized with gamma radiation, which is a negative in an industry that is moving away from ethylene oxide sterilization. In addition, the walls cannot be made nearly as thin as PET tubing, and Fluoropolymers would fail to retain any useful strength at that dimension. Wall thickness

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tolerances also tend to be quite high, which must be compensated for in device design. Because of these constraints, Fluoropolymer heat shrink tubing is typically used as a processing aid, or as an insulative and protective covering for metal components and devices.

PET heat shrink tubing offers several key advantages over other materials, including dimensional stability, ultra-smooth surface finish, and the ability to achieve extremely thin walls and maintain a very high tensile strength.. PET is able to maintain high strength in both the hoop and axial directions through a proprietary process that biaxially orients the PET during production of the tubing. Because of its mechanical properties, PET tubing can be made very thin, yet still perform as well as—and in some cases better than—tubing that is 10 times thicker. The tubing also has outstanding flex fatigue properties and toughness.

KEY PROPERTIES OF POLYESTER (PET) HEAT SHRINK TUBING

Wall Thickness	Ultra-thin (0.00015" - 0.004")
Tensile Strength	Very high (>20,000 PSI)
Electrical Insulation	One of the highest dielectric strength ratings of any thermoplastic material Dielectric strength: >4,000 V/mil (60Hz) Dielectric constant: 3.3 Dissipation factor: 0.0025 Volume resistivity: 1018 Ohm-cm Surface resistivity: 1014 Ohm/square
Shrink Temperature	185°F to 374°F (85°C to 190°C)
Melt Point	High, 473°F (245°C)
Shrink Ratio	5%-15% shrinkage is typical if unconstrained – recovery up to 3:1 can be achieved if drawn or stretched during application
Surface Finish	Ultra smooth, hard, glossy finish
Color/Clarity	Optically clear or can be pigmented
Bondability	Can be bonded using a wide range of adhesives (surface treatment recommended)
Flex Fatigue	Very high
Biocompatibility	Meets all requirements for disposable devices

With PET tubing, shrink rate is a function of temperature: the higher the temperature, the higher the material recovery. The shrinking temperature ranges from approximately 185°F to 374°F (85°C to 190°C). Unrestricted, the tubing will shrink both radially and axially, and the best overall performance is achieved with minimal shrinkage (15% or less). Whenever very high radial shrinkage is required (up to 3:1), the PET heat shrink tubing can be drawn axially while it is being heated.

APPLICATIONS & ADVANTAGES OF POLYESTER (PET) HEAT SHRINK TUBING

Creating Variable-Stiffness Catheters

Because of its ultra-thin walls, PET heat shrink tubing can be used to add stiffness to catheters without significantly adding to the profile (size) of the device. By using different thicknesses of heat shrink tubing along the length of the catheter, varying degrees of flexibility can be achieved for improved control of the device. This quick and easy tubing application eliminates the need for joining dissimilar materials or adding braid to sections of a catheter to achieve multiple zones of stiffness. For example, some manufacturers use heat shrink tubing with a one-mil wall at the back end of a catheter, a half-mil in the middle, a quarter-mil near the end, and none at the tip. This provides varying degrees of stiffness along a catheter's length and full flexibility at its tip.

Key advantages of using PET tubing in creating variable-stiffness catheters are:

- ▶ Very thin; adds very little device dimensions
- ▶ High-flex modulus provides needed stiffness
- ▶ Can be applied in thicknesses as low as 0.00015"
- ▶ Multiple stiffness zones can be created by adjusting thickness rather than changing materia

Electrical Insulation

High dielectric and resistive properties make PET heat shrink tubing an effective electrical insulation material that adds little dimension because of its ultra-thin walls. It can be used over needles to protect the surface of the skin from being burned during electrical stimulation, or used to insulate electrical components and wiring on catheters and other devices. Some



VARIOUS COILS COVERED WITH CLEAR PET HEAT SHRINK TUBING FOR INSULATION.

manufacturers are using PET heat shrink tubing to replace a coating process for electrical insulation of metal shafts. Due to the extremely thin layers that can be achieved with coatings, PET was found to be the only heat shrink tubing that was viable for this application. Using PET in this way also greatly reduces the chance of pin holes that can develop in coated surfaces,

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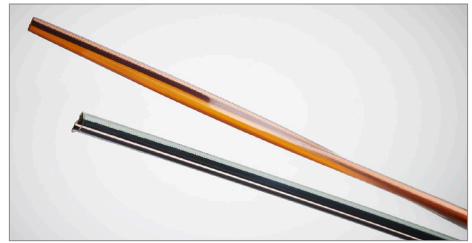
leading to a repeatable, consistent, and efficient alternative that eliminates the solvents and chemicals associated with coating processes.

Key advantages of using PET tubing as an electrical insulator are:

- ▶ Outstanding toughness
- ▶ High dielectric and resistivity properties
- ▶ Very thin; adds very little device dimensions

Protective Covering/Encapsulation & Bundling

PET heat shrink tubing is often used to cover braided catheter shafts, spring coils, radiopaque marker bands, and other parts that require a thin but tough outer layer. The tubing provides smooth transitions over sharp edges and can be sealed against fluid leakage. One manufacturer uses PET over a rotary spring cutter to keep debris from clogging the coils and to act as a bearing surface inside the device. It provides a fluid seal, yet the cutter remains flexible, and the very thin walls add virtually no dimensional increase to the device.



POLYIMIDE TUBINGS BUNDLED TOGETHER (TOP) AND HYPOTUBE AND POLYIMIDE TUBING BUNDLED TOGETHER (BOTTOM)

Ultra-thin-wall tubing allows designers to downsize or add features to endoscopes and other devices without a size increase. Unique devices can be produced using PET heat shrink tubing to bundle various components into the smallest possible space. Components such as plastic and metal tubing, wires, and optical fibers can be compressed and protected. Connecting tubes at the ends of a device also can be made of thin-wall PET to save valuable space. Using PET heat shrink tubing can free up enough space to add another working channel inside an endoscope. Or it might enable the designer to reduce the size of a device by a whole French catheter size.

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Key advantages of using PET tubing as a protective cover or encapsulation material are:

- ▶ Very thin; adds very little device dimensions
- ▶ Smooth transitions over sharp edges
- ▶ Strain relief to prevent kinking
- ▶ Quick, easy application

- ▶ Repeatable and consistent
- ▶ Adhesive can be UV-cured through clear tubing

Tube Joining & Transitioning

Clear PET heat shrink tubing can be used effectively in fusing tubes together. Typically, tubes of dissimilar properties—one stiff and one flexible—are joined. An easy way to accomplish this is to insert a wire mandrel in the tube ends to keep them from collapsing, butt the two ends together, and shrink a piece of tubing over them. Since PET tubing has a low shrink temperature, a broad range of materials can be joined without causing distortion.

The shrinking process squeezes the tubes and holds them together tightly during fusing. Because of PET's high melt temperature, the heat applied to fuse the tube ends does not melt the heat shrink tubing. After the tubes are joined, the heat shrink tubing can be left on or peeled off to leave an ultra-smooth surface finish.

Nicking the shrink tubing at an end before shrinking facilitates removal. Since the PET tubing is clear, the operator can see when the tubes are fused. The ability to monitor the process is very useful in product development and production to avoid applying too much or too little heat.

Key properties of PET heat shrink tubing in tube joining are:

- ▶ Low shrink temperature, allowing initial application without part distortion
- ▶ High melt temperature, allowing use of a high enough temperature to get the substrates to melt and flow together
- ▶ Axial shrinkage that tends to draw components together, resulting in superior butt welds
- ▶ Very smooth surface finish after joining
- ▶ Easy to removed if required
- ▶ Does not stick to most materials
- ▶ Clear material that enables monitoring of the process

Tube Marking & Printing

Depth marks and printing can easily be added to catheters and metal shafts with heat shrink tubing. Typically, thin bands of colored heat shrink tubing are used for marking. They can be accurately positioned using the proper techniques. Labeling information can be added by

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PAD PRINTED HEAT SHRINK TUBING

preprinting on the heat shrink tubing then applying it to the product, which avoids the need to send the devices themselves to a printer for labeling or to bring printing inks and solvents into the manufacturing facility for in-house printing. Some products, such as catheters made from high-density Polyethylene, cannot be readily printed without surface treatment, adding more complexity. Manufacturers who print on their products can use clear heat shrink tubing over the printed area to protect it. The ultra-thin wall of PET heat shrink tubing does not increase the diameter of the product substantially.

Key properties of PET heat shrink tubing influencing marking and printing are:

- ▶ Can be printed with any color and graphic
- ▶ Available in a variety of colors
- ▶ Very thin; adds very little device dimensions
- ▶ High-gloss surface provides quality appearance
- ▶ Can be accurately placed using proper techniques
- ▶ Can be used to protect printing on the product

Catheter Shaft Lamination

Manufacturers of reinforced, variable-stiffness catheters have a constant need for heat shrink tubing that can be easily loaded onto a catheter assembly, processed through a heat source to fuse components together, then removed and discarded without imparting any undesired effects to the substrate. PET heat shrink tubing currently satisfies most requirements for long, continuous-reflow applications. Most notably, its low recovery temperature and thin walls allow for gentle melting of substrate materials without affecting cycle time and smooth ID transfers to processed components (resulting in a superior surface finish). In addition, and the ability to draw during recovery means a wide range of diameters can be accommodated on a single part (up to 3:1 recovery ratio if actively tensioned during heating). Due to its thin walls, traditional removal techniques such as lengthwise skiving are not easily employed with PET heat shrink tubing. Specially designed skiving fixtures may be required. The material readily peels in a spiral fashion, allowing for simple manual removal from any assembly, without skiving.

See the chart below for recommended processing parameters.

Sizing	- Shrink ratios: - Tight fit is best: - Wall thickness range (in):	1.1:1 up to 3:1* 15% gap or less** 0.00015 – 0.004
Reflow Settings (Hot Box, Laminator or Oven)	- Material shrink temp range: - Material melt temp: - Recommended set temp range	185°F to 374°F (85°C to 190°C) 473°F (245°C) 300°F to 450°F (149°C to 232°C)
Material Compatibility	PET releases easily from the most common thermoplastics. However, urethanes and some low-durometer materials tend to tack to the PET and may require a resting period (~1hr) or may not be compatible. Run test samples with these materials.	

Key properties of PET heat shrink tubing in catheter shaft lamination are:

- ▶ Low shrink temperature for gentle recovery of common thermoplastics
- ▶ Ultra-smooth surface finish on ID that transfers to processed part
- ▶ Releases well from most materials
- ▶ Clear material enables visible monitoring of the process
- ▶ High shrink ratio can be achieved with drawing, accommodating variable-diameter

Catheter Tip Forming



PET HEAT SHRINK USED TO CREATE A SMOOTH, TAPERED TIP ON DISTAL END OF CATHETER

The low shrink temperature and high melt temperature of PET heat shrink tubing enables it to be used very effectively to form smoothly tapered tips on the ends of catheters. In the initial operation, a rod is inserted in a catheter to support the ID; a section of heat shrink tubing is slid over the end of the catheter, leaving a portion

extended beyond the tip of the support rod; and heat is applied to shrink the tubing to the substrate. Once attached, additional heat causes the substrate to melt and flow. Pulling on the shrink tube draws the catheter tube to a very thin, smooth tip. Since the shrink tubing is clear, the operator can monitor the process. The shrink tubing is peeled off and the support rod is removed to reveal the finished product.

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Key properties of PET heat shrink tubing in catheter-tip forming are:

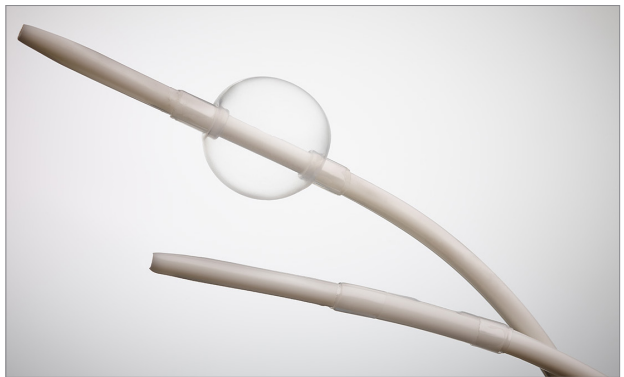
- ▶ Low shrink temperature allows initial application without part distortion
- ▶ High melt temperature allows use of a high enough temperature to cause the substrate to melt and flow
- ▶ Very smooth surface finish after forming
- ▶ Easily removed
- ▶ Does not stick to most materials
- ▶ Clear material enables visual monitoring of the process
- ▶ Shrink tube can be drawn down when heated to get a very thin smooth taper

Micro Hose Clamps

Bands of heat shrink tubing can be used as micro hose clamps on balloon catheters to reinforce bonds and help prevent failure under pressure.

A narrow band of heat shrink tubing is applied over the end of the balloon. The PET tubing, with its high hoop strength, grips the part much like a hose clamp, reinforcing the bond and keeping it from lifting off.

It also provides a smooth transition without adding significantly to the bond diameter. The tubing can also be used to terminate braiding, spring coils, and other parts to provide a smooth transition.



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

Key properties of PET heat shrink tubing in micro hose clamp applications are:

- ▶ Adds substantial hoop strength to reinforce bonds
- ▶ Very thin; adds very little device dimensions
- ▶ Can help smooth diameter transitions
- ▶ Can be used to terminate braiding, springs, etc.
- ▶ Adhesive can be UV-cured through the clear tubing

Masking Procedures

This is a simple but very effective application of PET heat shrink tubing for masking areas during coating operations. One manufacturer requires a white coating over a clear balloon, but the neck must remain uncoated so that a UV-curable adhesive can be used to bond it to the catheter. A piece of heat shrink tubing is applied to the neck, then the balloon is dipped in the coating. After it dries, the heat shrink tubing is peeled away, leaving the neck uncoated. The key to this application is the thinness of the PET tubing. Thicker heat shrink tubing would leave a thick edge of coating material on the balloon, unlike the ultra-thin-wall PET tubing.

Another manufacturer applies a slippery coating to a length of wire that has a fine spring coil at the end. PET heat shrink tubing is used to mask the spring to keep it from being coated during the dipping process. The low shrink temperature permits the masking operation without heat distortion, and the tight heat shrink fit prevents the coating from flowing into the spring. Afterwards, the PET tubing is easily peeled away.

Key properties of PET heat shrink tubing in masking applications are:

- ▶ Very thin wall to prevent thick buildup at edge
- ▶ Low shrink temperature allows application without heat distortion
- ▶ Easily removed
- ▶ Tight heat shrink fit on substrate

CONCLUSION

Many of the applications discussed here are made possible because of the unique properties of PET heat shrink tubing. Other tubes are simply too thick, or lack unique features like smooth surface finish and low recovery temperature. Designers often do not have enough space to incorporate heat shrink tubing with walls of 0.005" thick or sometimes even 0.001" thick in their novel devices. The alternative would be to do the job in some other way, or to accept a bulkier product. But the ultra-thin walls and related properties of this tubing make it an enabling technology for designers as they design and build medical devices for today's market requirements and tomorrow's patient needs.

ABOUT VENTION

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



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