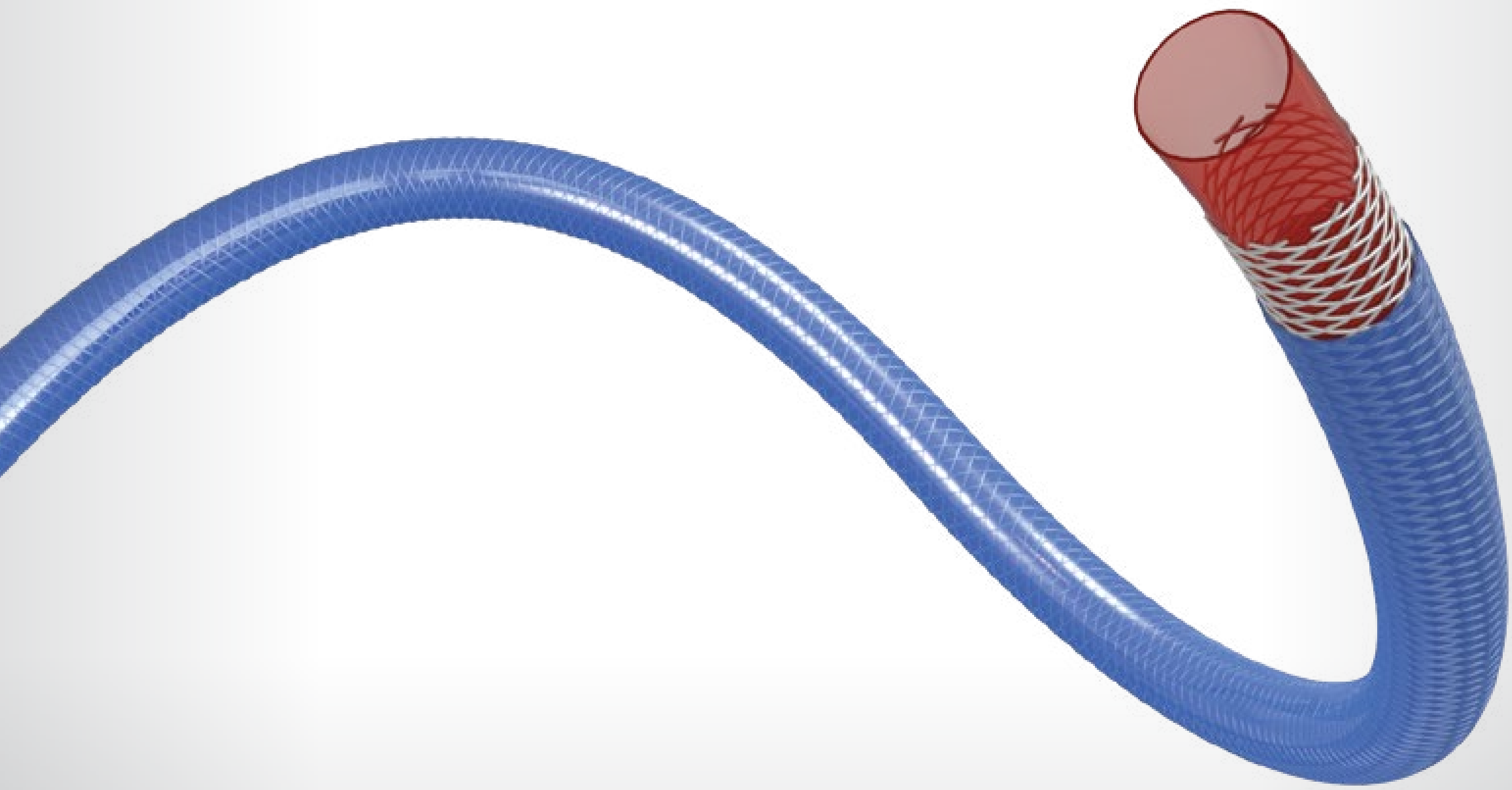
Three Medical Device Design Challenges, Solved:

Leveraging the Film-Coat Process with Polyimide and other Polymers



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THREE MEDICAL DEVICE DESIGN CHALLENGES, SOLVED: LEVERAGING THE FILM-COAT PROCESS WITH POLYIMIDE AND OTHER POLYMERS

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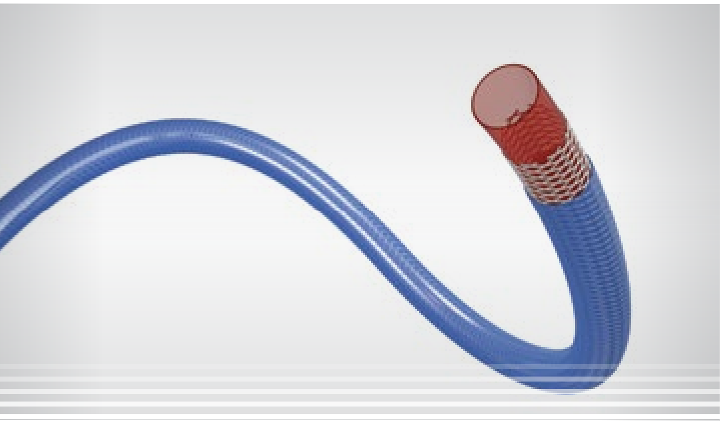
Polyimide is a versatile polymer popular for microdiameter tubing applications that require very thin—yet very strong—walls. It also lends itself to compositing with particulate materials that can add additional performance characteristics to medical tubing and shafts.



Vention Medical has been working with polyimide for decades and has mastered the film-coat process used to make polyimide tubing (see page 3). 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-coat 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 Vention Medical devised optimal solutions with the innovative use of the film-coat process with polyimide and other polymers.

THE FILM-COAT TUBING PROCESS: LAYERS OF DESIGN POTENTIAL

PROCESS

Film coating 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:
  - o Wall thickness: .0003" to .006"
  - o IDs: .005" to .085"
  - o 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.

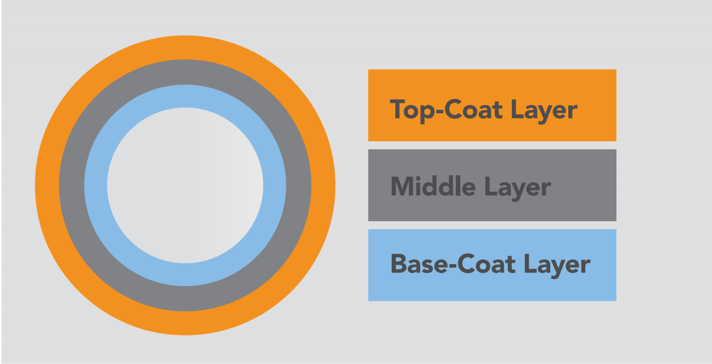
MATERIALS

The film-coat process has been widely used in the medical device industry to make thermoset polyimide. However, Vention 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-coat tubing.) These polymers allow new functionality and expand the range of solutions for medical device challenges.

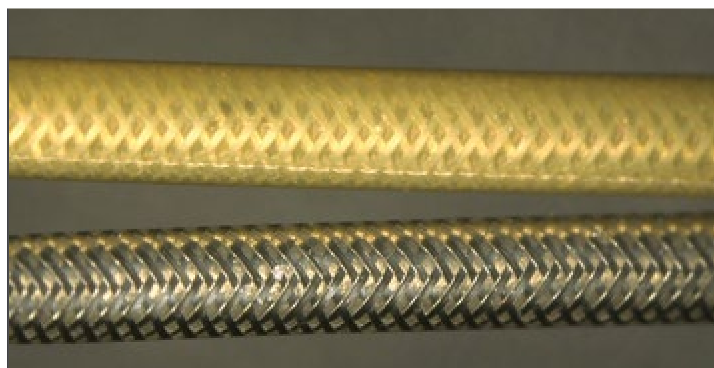
REINFORCEMENT

Film-coat 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 COAT LAYERING



Medical device engineers can visualize the film-coat 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.
The bottom tube shows the base and 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

Vention 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:
    - o Inner liner: .0005" to .001" of polyimide
    - o Middle layer: .001" braid reinforcement layer (comprising 16 wires of .0005" x .003" flat-wire stainless steel with 120 PPI)
    - o Top coat: .0005" to .001" 55D of 63-durometer Pebax
    - o 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.)

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.

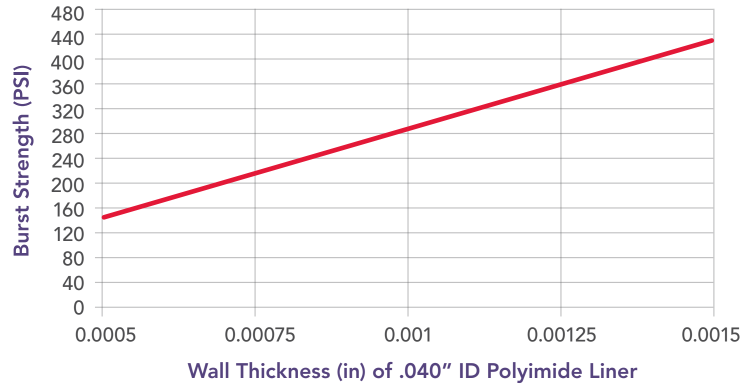
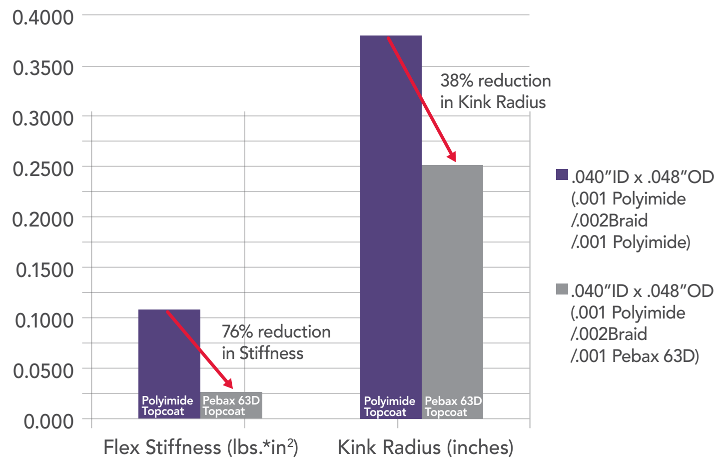
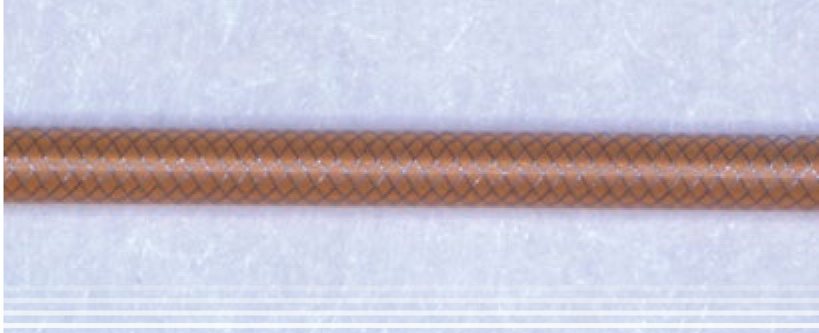


FIGURE 3. SIGNIFICANT CHANGE IN FLEXIBILITY





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

Vention 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-coat 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

Vention 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.

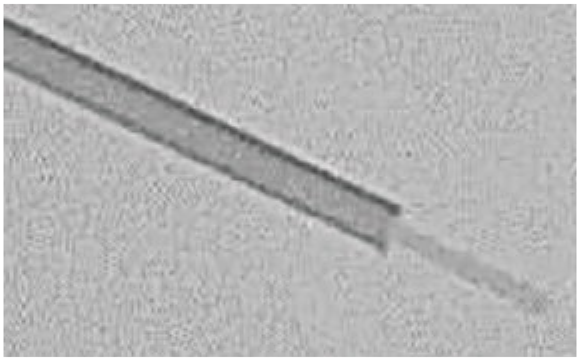
  Loading or compositing polyimide with submicron tungsten particulate (powder) provides a radiopaque image. The clarity of this image depends on the wall thickness of the polyimide layer. A wall thickness ≥ .002″ provides a good, clear fluoroscopic image that lightens as the wall thins, but is still visible 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-Coat 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-coat polyimide tubing, Vention Medical has developed new techniques using the film-coat 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 VENTION MEDICAL

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

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