Putnam Plastics

custom medical
extrusion technologies

putnam plastics corporation

Putnam Plastics Corporation has been a leader in medical tubing for three decades with a focus on small diameters used for life saving vascular catheters and minimally invasive medical devices. We offer the widest range of tubing technologies in the industry, and frequently combine these to create components at the forefront of today's most sophisticated medical devices.

materials

Our range of equipment allows us to process traditional thermoplastics and elastomers, as well as high performance materials such as PEEK, thermoset polyimide, and fluoropolymers.

extrusions

Our extrusion capabilities include traditional multi-lumen and multi-layer extrusions as well as tubes with variable diameters, durometers and reinforcements along the length. We also offer a wide range of thermoset polyimide tubing.

fabrication

Our capabilities to produce finished components from tubing include laser cutting and welding, CNC grinding and lathe turning, thermal forming of tips and flares, over molding, precision drilling of holes, and laser printing.

Putnam Plastics' core competency is the creative application and combination of these technologies to produce advanced tubes used in state-of-the-art medical devices.

facilities

Our two manufacturing facilities in Dayville, CT, totaling over 130,000 square feet, include over 30 extrusion lines in a range of sizes up to 2 inches, 3D modeling and finite element analysis tool design, CNC and EDM tool manufacturing, and 6,000 square feet (557 square meters) of ISO Class 8 clean room space.

Our newest 92,000 square feet (8,547 square meters) facility, completed in 2013, was designed specifically to serve the needs of medical device customers, offering dedicated space for the company's three key growth initiatives: clean manufacturing, product finishing and technology development.

Our facilities are ISO 13485:2003 and 9001:2008 certified, reaffirming our goal of maintaining a quality system of the highest possible standard. This includes a fully equipped laboratory for incoming raw materials and on-line statistical process control, and a vast array of contact and non-contact inspection technologies to ensure that every product requirement is met.

materials

Selecting the appropriate polymer for an optimum catheter design requires an understanding of the biological, physical and chemical characteristics as well as a thorough knowledge of the polymers that are commercially available. During our three decades of serving the medical device market, we have acquired an intimate understanding of the polymers suitable for catheter and minimally invasive devices, and we have first-hand experience processing virtually every available material suitable for commercial use.

thermoplastics We extrude virtually all melt processed thermoplastics including traditional polypropylene, polyethylene, polyvinyl chloride (PVC) and polyamide (nylon), as well as high performance materials such as polyetherimide (PEI), polysulfone, and polyetheretherketone (PEEK). Many of these are extruded in natural or compounded forms, with additives to affect color, radiopacity, lubricity, anti-microbial and other properties. These include rigid materials such as polysulfones to flexible polyamides.

elastomers Thermoplastic elastomers combine some of the properties of rubber with the processing advantages of thermoplastics. Like rubbers, the thermoplastic elastomers key properties are hardness and stiffness or flexibility with the melt processing advantages inherent with thermoplastics. We routinely process a wide range of thermoplastic elastomers, including urethanes and polyether block amides (PEBA), the most commonly used in catheter applications.

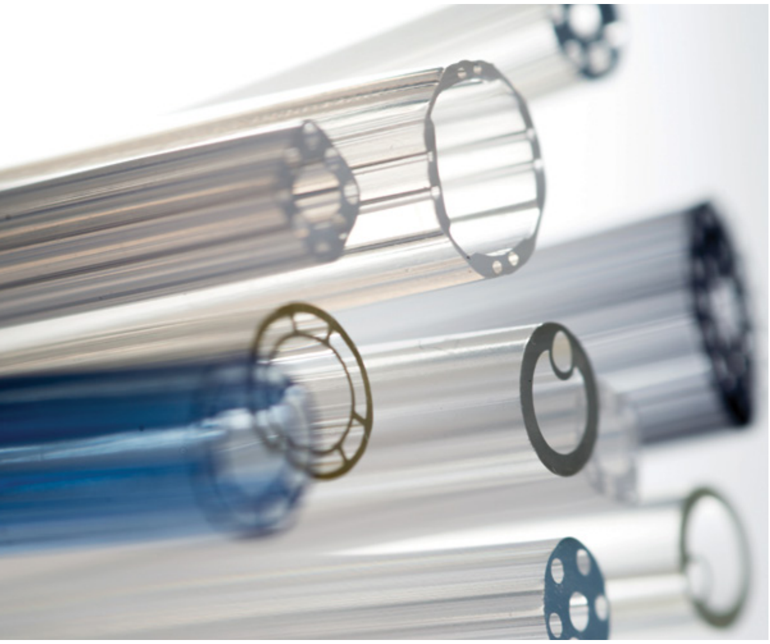
fluoropolymers We manufacture tubing from a range of fluoropolymers used in medical catheters, including polytetrafluoroethylene (PTFE), perfluoroalkoxy (PFA) and fluorinated ethylene-propylene (FEP). We combine fluoropolymers tubing with other technologies to create truly innovative solutions. These include tubes with fluoropolymer liners, wire braid or coil reinforced, and thermoplastic elastomer outer layers.

PEEK PEEK offers superior mechanical properties compared to most commercially available polymers. It is biocompatible and fully melt processible, and ideally suited for many medical tubing applications. We offer small diameter tubes for vascular catheters as well as larger diameter, thin wall tubes for non-vascular applications, such as Natural Orifice Transluminal Endoscopy Surgery (NOTES) devices. Our thin wall PEEK tubing can be manufactured semi-transparent or in custom colors.

polyimide The mechanical, thermal, chemical, radiation properties and tight tolerances of thermoset polyimide tubing are unmatched by other materials. Our polyimide tubing is available single lumen configuration with diameters from 0.006 inches to 0.090 inches (0.152 mm to 2.286 mm) and wall thicknesses ranging from 0.0002 inches to 0.010 inches (0.005 mm to 0.254 mm). One or more polyimide single lumen tubes may be incorporated into a multilumen thermoplastic extrusion as lumen lining. Our polyimide tubing can also be reinforced with stainless steel wires in coil and/or braid configurations.

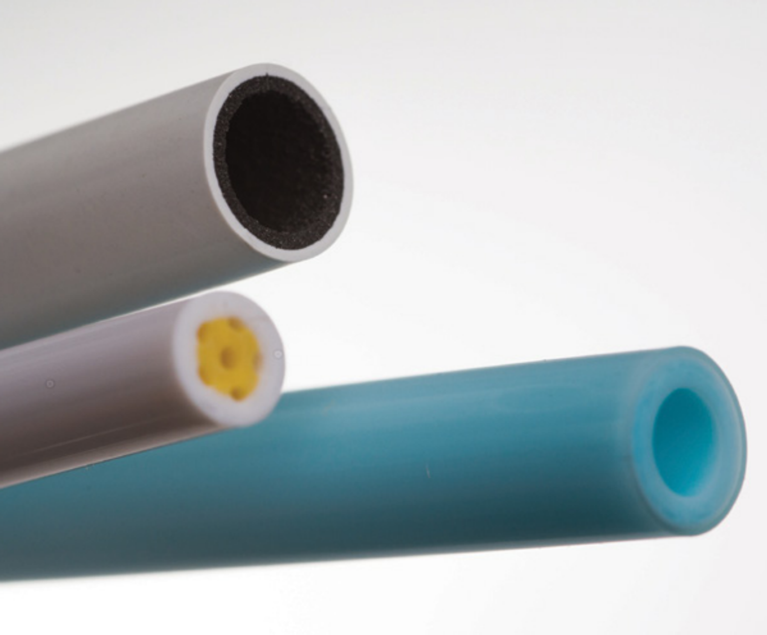
bioresorbables Bioresorbable polymers are a class of materials frequently used for temporary implant applications. These materials degrade over time through hydrolysis, or the splitting of a compound into fragments by the addition of water. Through advanced processing that minimizes premature degradation we are able to produce rods and tubes from a range of these polymers, including polylactide (PLA), poly-L-lactide (PLLA), poly-DL-lactide (PDLLA), polyglycolide (PGA) and copolymers of PLA and PGA (PGLA).

extrusions



single & multi-lumen

Lumens are used to tranport liquids, gases or surgical devices during a medical procedure. The number and configuration of lumens are nearly limitless. We routinely process single lumen tubes for use with guide wires, multi-lumen tubes for peripherally inserted central catheters (PICC), and unsymmetrical multi-lumen tubes for percutaneuous transluminal coronary angioplasty (PTCA) catheter and thermodilution catheters.



coextrusion

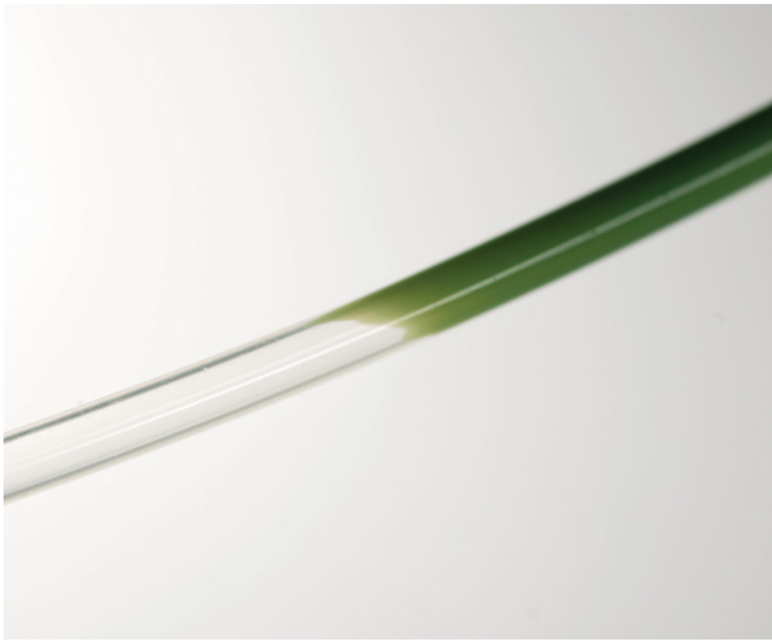
Coextrusion is the extrusion of multiple materials simultaneously to provide unique attributes to discrete areas of the tube. The most common form of coextrusion is multilayered tube, in which different materials on the inner and outer surfaces provide unique performance attributes. Coextrusion can also be used for discrete properties along the length of a tube, such as radiopaque or color coding stripes. Coextruding precision medical tubing has been one of our core competencies since our founding over thirty years ago.

tri-layer extrusions

When the inner and outer layer of a coextruded tube are not melt compatible, a middle ‘bonding layer’ is required to minimize delamination. These tri-layer extrusions are common in catheters that require a highly lubricious inner surface and soft, flexible outer surface such as those used in conjunction with guide wires. Since our early development of the tri-layer process for catheter tubing we have continued to innovate the process for increasingly smaller, thinner wall tubing used in cardiovascular and neurovascular applications.

Total Intermittent Extrusion (TIE™)

Coextrusion of two materials in sequence such that material properties change along the length of the tube is known as intermittent extrusion. For catheters, this allows for variable flexural rigidity from the distal to proximal end of the shaft. Prior to our development of the TIE™ total intermittent extrusion process, variable flexibility was commonly achieved by manually assembly and bonding tubes end-to-end on a mandrel. TIE™ extrusions reduce labor required to build these assemblies and provides a more consistent shaft without bonded joints.



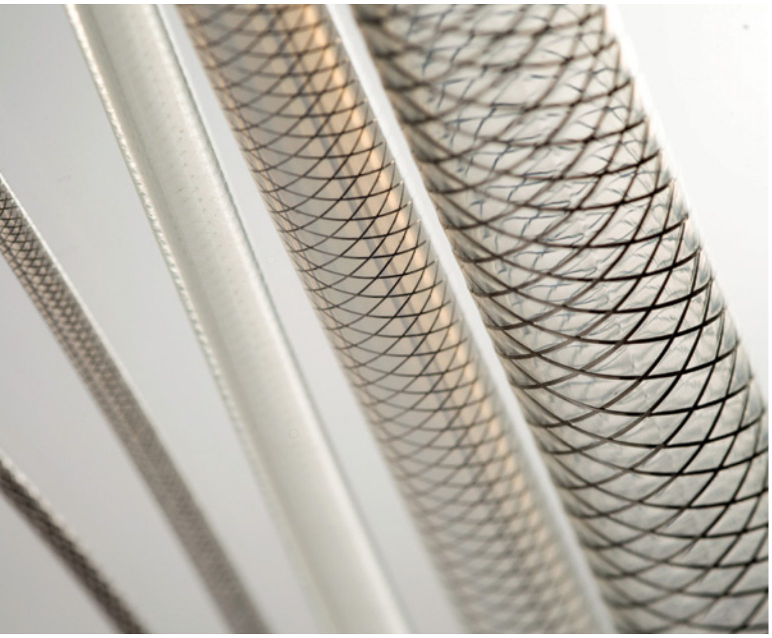
tapered tubing

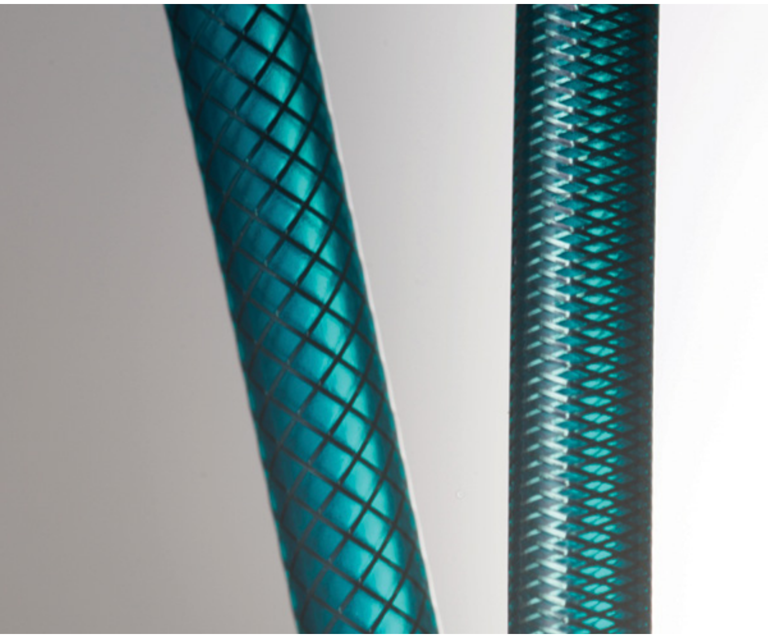
Extrusion cross sections can vary in size along their length. Such tapered extrusions are commonly used to create variable stiffness from proximal to distal ends or to ease connections at the proximal end. Our tapered extrusions include tapering diameters with consistent wall thickness and tapered wall thickness with consistent inside diameters.

monofilament

Oriented, large diameter fibers offer substantial strength properties to replace metals in applications that require x-ray transparency or non-magnetic properties for magnetic resonance imaging (MRI) applications. Our proprietary extrusion process for custom monofilament manufacturing controls voids and diameters, resulting in more consistent product performance in large diameter medical monofilaments between 0.025 inches (0.64 mm) and 0.100 inches (2.54 mm).

reinforced tubing





braiding

The addition of braided reinforcement to the wall of plastic tubing can improve burst pressure resistance, column strength and torque transmission. Braid angle and percent coverage are important, as well as size, shape, and strength of the reinforcing material. Braid angle is measured from the longitudinal axis of the tube. Typically, a lower angle creates a stiffer tube that can deliver more torque and reduce stretching, while a higher angle creates a more flexible kink-resistant tube with somewhat lower torque transmission.

Our braiding machines can change braiding rates during operation to create tubing with different braid flexibility between the proximal and distal sections of a shaft to allow for variation in picks per inch (ppi) without the expense or risk of a molded joint.

coiling

The addition of spiral reinforcement, or coiling, to a tube can improve kink and crush resistance. High angled spirals (almost perpendicular to the longitudinal axis of the tube) provide improvements in kink and crush resistance. High-angle spiral design provides almost no torque transmission improvement and does not restrict longitudinal movement of the tube. Our coiling machines are also capable of variable coiling along the length of a tube to provide variable reinforcement.

linear wire reinforced

Longitudinal wires or fibers incorporated into an extrusion cross section provide specific benefits, such as structural support or electrical data transmission. Wires can also be employed to discretely limit stretch or flexibility depending on the number and location of reinforcing members. We offer a wide range of reinforcement materials and sizes to match specific application requirements. High-tensile stainless steel round wire is commonly used for wire reinforcing; however, in thin wall sections, flat wire provides an excellent alternative. Other materials, such as aramid fiber or polymer monofilaments, can also be used for specialty linear reinforcement applications.

wire coating

We offer custom wire coating for a wide range of performance applications, including thermoplastic elastomer coating of guide wires and fluoropolymer coating of electrical wires. Continuous jacketing of thermoset polyimide lumen linings, wires, fiber optics, aramid fiber reinforcement, and more are available. Discrete jacketing of tapered guide wires (including pre-cut Nitinol* or stainless steel), laser cut and/or tapered hypotubes, and micro-coils, are also available.

finishing operations

Our wide variety of value added fabrication capabilities bring your extruded medical tubing one step closer to a turnkey solution, shipped bulk, non-sterile to your facility for final assembly into your medical device.

laser welding

Laser welding is a highly reliable and repeatable thermal bonding technology for joining of catheter components, such as soft tips to more rigid catheter shafts. Laser thermal bonding differs from traditional thermal bonding in that heat is generated through material absorption of laser light, which results in a more efficient application of heat. This makes it possible to create very small bonds between catheter device components without melting the surrounding surfaces. Our lasers produce a wavelength with similar resonance frequency to the polymers commonly used in catheters, which allows it to be absorbed by opaque and transparent components. It also provides for outstanding bond strength and smooth joint surface between mating components.

laser machining

UV laser machining is a non-thermal material removal process that utilizes high resolution, short wavelength light. This allows for medical devices to be manufactured with the smallest features in accordance with the most demanding specifications, with a process that is reliable and repeatable. Applications in catheter design include drug delivery access ports, selective removal of material, position markings and drug delivery openings. Our nanometer ultraviolet (UV) cutting laser is capable of drilling, cutting or marking polymer components made from extremely hard polymers, such as polyimide or PEEK, and delicate materials, such as elastomers and urethanes. Our state-of-the-art laser can produce precision openings in thin wall catheters. These include square, round, oval or irregular shaped blind holes or through holes. Arrays of hundreds or even thousands of precision holes can also be created.

tipping

Our radiofrequency (RF) equipment is capable of producing custom tips on wide range of catheter sizes and configurations. Tips may include open or closed ends, radius on inner and outer diameters, irregular shapes, and even lumen specific.

RF welding

Radiofrequency (RF) thermal heating can be applied to the formation of tips as well as the bonding of two components in a uniform weld. Applications include bonding of soft tips on catheter shafts and thermal reflowing of catheter terminations.

precision cutting

Most tubing components can be cut to length online during extrusion to tolerances of approximately +/- 0.080 inches (+/- 2.032 mm). When tighter cut length tolerances are required, specialty cutting equipment is used offline which is capable of finished cut length tolerances as tight as +/- 0.005 inches (+/- 0.27 mm).

precision machining

Utilizing both CNC grinding and lathe turning methodologies, we have the capabilities to machine custom profiles into the outer surfaces of extruded tubing. Our CNC hole cutting equipment can produce through-and-through holes or blind holes into a specific medical catheter lumen.

insert molding

Our ability to mold connectors such as luers or hubs directly over an extruded component can eliminate manual assembly steps and provide a strong polymer-to-polymer bond. Insert molded connectors are an ideal match for complex multi-lumens where access to each lumen is required and standard connectors are insufficient.

printing

Catheter devices often require printing along the length and around the circumference of the shaft with markers for use in medical procedures. Instructional markings, device company information, or other information may also be required on the shafts. Our printing equipment is located in a climate controlled room capable of maintaining temperature and humidity to ensure repeatable printing processes. Dedicated pad printers are capable of printing catheter shafts up to 80 cm (32 inches) in length with 360 degree printing roll options.

plasma etching

PEEK, thermoset polyimide and other chemically resistant polymers are increasingly being used for minimally invasive applications due to inherent strength and chemical resistance properties.   These same material properties create greater challenges for pad printing. Our plasma pre-treatment makes the outer surface temporarily receptive to chemical adhesion of the pad printing ink. Within a few days of being printed, the polymer surface recovers its chemical resistance for optimal performance in the field.   While plasma pre-treatment increases ink adhesion on all plastics, it is of greatest value when used on polymers inherently resistant to thermal and chemical degradation such as PEEK and thermoset polyimide.

annealing

Our walk-in annealing oven is capable of applying customized heat cycles to extruded medical tubing up to two meters in length. Incorporating annealing into the manufacturing process provides a dimensionally stable finished product.

advanced technologies

Demand for smaller shaft diameters, reduced wall thicknesses, improved functionality, variable properties along the length and variable properties within the cross section are just some of the factors leading to an increase in composite shaft constructions. At the same time, demand for improved manufacturing economies and process validations are shifting the focus from manual assembly to continuous manufacturing technologies.

We leverage a wide range of material expertise, in-house tool making and tube processing technologies to offer the latest in continuously manufactured composite shafts. These include integration of novel materials such as polyimide, PEEK or fluoropolymers for liners, variable wire reinforcements along the shaft length, variable durometer outer layers along the shaft length and variable diameters along the length.

Tri-TIE™ technology

Guide catheters are commonly used to access endovascular sites and deliver balloons, stents, guide wires, contrast media and other devices. Traditionally, these complex shafts have been manually assembled from discrete components and heated to create the final component. This is costly and presents challenges for validating a highly manual manufacturing process.

Our Tri-Tie™ technology incorporates the traditional three-layer approach while enhancing performance and reliability. The lubricious inner layer is designed with a fully bondable outer surface that penetrates the middle braid layer and securely bonds to the outer layer. Discrete outer layer segments and hinge points are eliminated with Putnam's proprietary TIE™ intermittent extrusion process whereby polymers of varying durometer are applied along the length of the shaft in a single extrusion.

Taper-TIE™ technology

Diagnostic and interventional catheter devices can be over 100cm (39in) in length to reach vascular sites deep within the body. The forward, or distal, end of the catheter must be soft and flexible to navigate complex vascular pathways while minimizing trauma. The end held by the physician, or proximal end, must be more rigid to allow the physician to advance and steer the catheter shaft. Variable stiffness properties can be achieved by changing materials, wall thicknesses or shaft diameters along the length of the shaft.

Our Taper-Tie™ technology is a continuous manufacturing method that produces a catheter shaft with variable properties along the length, and eliminates the need for manual assembly of discrete segments. Putnam's proprietary extrusion process can quickly change from rigid to soft grades for a designated polymer along the shaft length, while simultaneously reducing wall thickness of the shaft. The result is a highly flexible distal end and more rigid proximal end in a single extruded tube.

variable braid & coil

In order to navigate to vascular regions, many catheters require enhanced rigidity at the proximal end for pushability and torque, and increased flexibility at the distal end. Traditional manual assembly of shaft segments with varying flexibility can be costly to manufacture and performance can be compromised at the bonded segment joints. Putnam Plastics' variable flexibility shaft technologies are designed to reduce costs with continuous manufacturing methods and improve product performance by eliminating bonded components.

Our variable wire reinforcement technology includes variable wire coiling for improved kink resistance and variable braiding for improved torque performance. Reinforcement wires including stainless steel, Nitinol, and copper can be incorporated into extruded tubing ranging from 0.010 to 0.450 inches in diameter. Reinforcing coils can transition from complete coverage up to 5 wraps per inch, and braided wires can transition from complete coverage up to approximately 1 pick per inch.

polyimide shaft liners

The success of minimally invasive procedures has accelerated the use of balloons and stents in a wide range of interventional radiology and cardiology applications. These new procedures often require reduced diameter tubes for smaller vascular openings, thinner tube walls to allow for larger lumen openings, and higher pressures for balloon and stent delivery.

Due to its high tensile properties, polyimide is an ideal material for catheter tubing that must resist high pressure. However, the material's high modulus suggests potential limitations for catheters that require flexibility. We are able to leverage the benefits of polyimide while maintaining flexibility of the shaft by using polyimide as an inner liner within softer, more flexible outer shaft materials. With the higher modulus material closer to the center of the tube structure, the moment of inertia is greatly reduced resulting in reduced rigidity of the finished catheter tube.

polymer marker bands

A traditional catheter marker band is a short, thin-wall tube made from gold or platinum that is placed on the tip of a catheter shaft to provide high levels of visibility under fluoroscopy (radiopacity). These metal marker bands require a multi-step forming process to create seamless small diameter tubes. Specialized manufacturing equipment is used to crimp or swage metal bands to the polymer shaft tip such that they do not fall off during the medical procedure.

Our polymer marker bands are made from tungsten filled polymers, such as nylons, urethanes and thermoplastic elastomers. Bands are customized using the same polymer specified for the catheter shaft to allow heat bonding of the band for a more secure assembly. Tungsten loadings range from 65% to 80% by weight to meet radiopacity requirements. Using proprietary co-extrusion technology, Putnam applies an unfilled polymeric outer surface to these bands similar to the surface of the catheter shaft to ensure minimal trauma to blood vessel walls.

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