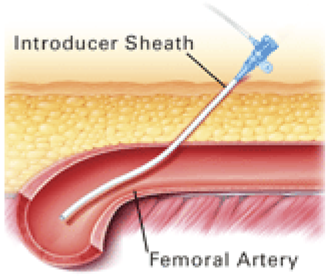
Considerations for Introducers

Dilators and Sheaths

Dilators and sheaths are a pair of extruded components included in a vascular introducer set. An introducer set contains devices used to access blood vessels for the insertion of vascular catheters. After a needle is inserted through the skin and into the blood vessel, the dilator and sheath are passed together into the blood vessel. The long tapered tip of the dilator acts to stretch the opening in the skin and blood vessel to allow for the insertion of the larger sheath. The dilator is then removed, leaving only the sheath inserted into the blood vessel, providing a port through which a variety of catheters can be inserted. Some introducers incorporate a proximal seal to allow catheters to be repeatedly inserted and removed while preventing blood from escaping. Other introducers are designed to split in half and peel away after insertion, leaving behind only the catheter device.



The use of introducer dilators and sheaths is common for intravascular catheter applications. A wide variety of sizes are available for common procedures such as central lines. Unique and innovative catheters may require a custom introducer set that is matched to the size and application technique of the catheter device.

Component Requirements

Ease of Insertion and Movement with Minimal Gap – A guide wire must fit inside the dilator with minimal gap, yet must be free to move easily. Likewise, the dilator must fit inside the sheath with minimal gap, yet must be free to move easily. This is achieved with tight extrusion tolerances on the diameter and roundness of both dilator and sheath. Ease of movement is also achieved by the use of lubricious polymers such as polypropylene, polyethylene, FEP, and ETFE.

Atraumatic – The dilator and sheath assembly must be inserted through a small hole in the skin and stretch it to the outer diameter of the sheath. After the procedure is complete and the catheter is removed, the hole must recover to as small as possible to speed healing. For insertion to be conducted with minimal tissue trauma, both the dilator and sheath must have smooth radius tips free of burrs or sharp edges. Lubricious polymers also minimize tissue stress during insertion. Some introducers feature tips of a softer polymer to reduce tissue trauma further, while preserving the pushability and ease of movement of the rest of the shaft.

Kink Resistance – After insertion the sheath must be able to bend slightly with the body during insertion of catheters without kinking or buckling. High concentricity of the sheath extrusion improves kink resistance, as does the utilization of lower durometers polymers such as LDPE or FEP.

Visibility Under Fluoroscopy – Fluoroscopy may be used to ensure proper positioning of the introducer and catheter inside the body. The use of radiopaque polymer compounds makes the dilator and/or sheath highly visible under fluoroscopy. Some introducers feature radiopaque compounds only in the soft tip polymer to minimize the use of the more expensive polymer compound.

Curve Memory – Depending on the anatomy of the insertion point, the doctor may shape the introducer into a curve by hand before insertion. The curve memory is provided primarily by the thick walled dilator. The dilator must be extruded from a polymer that can be cold formed such as polyethylene or polypropylene.

Polymer Selection

Polypropylene **–** The stiffest of the polymers used, it is commonly used for insert molded connectors and dilators requiring high strength such as those used in bariatric applications. It is the least lubricious of the polymers listed here, but is more lubricious than common elastomers used for catheters. It easily accepts color pigments and radiopaque fillers and is among the least expensive polymers available.

Polyethylene **–** High density (HDPE) and low density polyethylene (LDPE) are moderately stiff polymers with durometers of approximately 50D and 40D respectively. HDPE, LDPE, or a blend of the two, may be used for standard dilators and sheaths. Polyethylene has good lubricity and easily accepts color pigments, radiopaque fillers and is among the least expensive polymers available.

FEP **–** The softest of the polymers used, it is used to produce sheath components where lubricity is important. FEP is a melt extrudable fluorinated polymer with very good lubricity, second only to ETFE (PTFE is the most lubricious fluoropolymer but it is not melt processible). Radiopaque fillers and color pigments are more difficult to incorporate in FEP, and it is much more expensive than polypropylene or polyethylene.

ETFE – With higher stiffness than FEP, it is commonly used to produce sheath components where lubricity is most important and higher stiffness required. ETFE is the most naturally lubricious extrudable polymer. Like FEP, it is incorporating radiopaque fillers and color pigments presents some challenges and it is much more expensive than polypropylene or polyethylene and comparable to FEP.

Radiopaque Fillers

Barium Sulfate was the first radiopaque filler widely used in medical formulations. It is a relatively inexpensive white powder that has excellent process stability. High loadings are required for comparable radiopacity to other fillers. Because it has poor tinting strength, it is relatively easy to color.

Bismuth Subcarbonate offers greater radiopacity that barium sulfate and can be added in less quantity to achieve comparable results. It is a white powder with high tinting strength, thus limiting color matching in some instances. It is limited by processing temperatures (yellows at 400 F) and in some polymers (not compatible with thermoplastic polyurethanes).

Bismuth Trioxide also offers excellent radiopacity in comparably lower loadings and is compatible with most polymers. It is yellow in color and can turn brown at elevated processing temperatures, limiting color matching. Gritty surfaces in finished parts limit use in thin wall and critical surface components.

Bismuth Oxychloride provides excellent radiopacity and is compatible with a wide range of polymers. It is more temperature stable than bismuth subcarbonate. White ‘platelet-like’ particles provide a smooth, pearlescent finish on components. This can provide limitations to exact color matches.

Tungsten is a very heavy metal powder that is compatible with virtually all polymers at very high loadings by weight. It is dark gray in color and produces a matte finish in high concentrations, providing substantial restrictions for color matching. Polymer compounds with tungsten can be very abrasive on processing equipment. However, it is a filler of choice in very thin walled devices where radiopacity is critical.

Extrusion

Vacuum Sizing – Vacuum sizing technology is critical to achieve the tight tolerances and roundness required for both dilator and sheath tubing extrusion. Dilators and sheaths present extrusion challenges due to very thick and very thin walls respectively.

Fluoropolymer – Special extruders and tooling are required to achieve the high processing temperatures required for FEP and EFTE tubing extrusion. Especially for radiopaque compounds, carefully designed precision tooling is required to minimize polymer degradation and filler discoloring.

Extrusion Finishing Operations

Precision Cutting - Precise cut lengths are required for proper alignment of the dilator and sheath tips in the final assembly. Offline cutting equipment is used to achieve length tolerances as tight as +/- 0.010”.

Tipping - Precision RF tipping tooling is required to achieve smooth atraumatic tips on both dilators and sheets without burrs or sharp edges. Sheaths tips are challenging to form due to their thin walls. The addition of a soft tip increases process complexity due to the introduction of dissimilar polymers. Dilator tips are challenging due to their length and extremely thick walls which require the tipping process to move a large volume of polymer. Process optimization is required to minimize cycle times and cost to maximize profit margins for introducers often considered to be non critical accessory devices.

Insert Molding - Molding of sheath connectors is challenging due to the thin tubing walls. Tooling inserts may be used to produce connectors featuring product codes. Multi cavity molds are required to minimize cycle times and cost to maximize profit margins for introducers often considered to be non critical accessory devices.

About Putnam

For over two decades, Putnam Plastics has provided comprehensive extrusion technologies for medical catheters and minimally invasive devices. Technologies include thermoplastic and fluoropolymers extrusions, polyimide tubing, printing, and tipping and machining tubes. Putnam offers development through validated manufacturing services.

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