APPLIED PLASTICS

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PTFE is universally used as a coating for medical devices. It is used as a crucial component of products such as interventional catheters and as a lubricious coating to improve the efficiency and longevity of precision tooling used to manufacture those catheters. PTFE has been used in the medical market for over 30 years due to its superior lubricity and heat resistance, which are fundamental to the functional properties of catheter construction and performance.

One of the critical components of a complex interventional catheter is the central lumen or working channel. PTFE and PTFE components are regularly used as lubricious liners comprising the innermost layer of these catheters. These components have direct and indirect contact with other components used in surgical procedures, such as introducers, dilators, guidewires, or other catheters in more complex procedures. Due to their versatility, PTFE liners are the gold standard for catheter construction by providing superior lubricity, durability, and biocompatibility. The high melting point (roughly 620F) of PTFE is unmatched by alternative materials and provides the ideal foundation for catheter construction. PTFE liners can be produced with very thin walls, making them easier and more cost-effective than Polymer liners while meeting customer's specific needs. These liners will usually be used in reflow processes with the outer jacket. Suppose ideal processing parameters are not maintained by using the perfect liner. In that case, there is a potential that during the process, any structures such as braids, coils, or laser-cut components could drift into the liner wall and be exposed.

Complex steerable catheters used in therapy areas such as structural heart, GI, Urology, and other minimally invasive procedures use PTFE as a critical component of their steering mechanism. These catheters use a complex pull-wire system to direct the tip of the catheter to the treatment or implant area of the patient. The control over the catheter tip deflection and tip force are critical design features for a complex catheter. Because these are critical design features, PTFE is used either as a liner to allow for faster assembly and fine direction control or as a coating of the pull wires to allow for smooth travel and critical responsiveness in directing the catheter through tortuous pathways of the body. PTFE is an integral component of a steerable catheter as a liner for the working channel and as a coating for the pull wires needed to withstand the forces experienced in the assembly process and functional use of the end devices.

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Besides using PTFE in standard and steerable catheters, microcatheters use thin layers of PTFE to form the inner layer of the catheter. This thin layer of PTFE is critical in maintaining the inside diameter of the catheter and providing a lubricious surface essential to function. These microcatheters will have an inner lumen diameter that ranges from 0.015” to 0.021” and are used for placement of stents (peripheral/intracranial), flow diverters, devices to prevent strokes, and employed extensively in the treatment for antegrade CTO (chronic occlusions). Due to the extremely small size needed to navigate the cerebral vasculature, PTFE liners are an essential component due to the very thin walls (≈0.00075”) that are bondable to outer jackets and allow for the necessary lubricity for device delivery and trackability during procedures.

Understanding the importance of PTFE in the catheter manufacturing process is also essential. Manufacturing tools such as hypotubes, mandrels, and stylets used to build the catheter are often coated with PTFE for ease of use in the manufacturing process and to improve the durability and longevity of tool life. These tools are used as manufacturing support tooling for catheter construction, fixation mandrels for coating applications, or shipping mandrels.

When PTFE components are replaced with polymer-based alternatives such as nylons, urethanes, and PEBA formulations, production tooling needs to be PTFE coated or sprayed with a release agent to process the catheters.

Release agents are often silicon-based and can interfere with the manufacturing process further down the line. PTFE coating allows for the reuse of production tooling over multiple cycles without re-spraying or the potential of process contamination.

Catheters are often designed with formed distal tips for specific treatments or applications. The tooling must have excellent release properties when forming the catheter's tip. This can be most easily accomplished by utilizing a PTFE-coated metal device. Since mold release can interfere with subsequent processing, such as hydrophilic coating, and because it uses an aerosol propellant, technicians must use care and PPE for repeated processing. These material property requirements and limitations make PTFE the ideal coating solution for these applications.

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PTFE is also used as supportive tooling during the extrusion bonding process. Supportive tooling is necessary to form the final product when un-reinforced plastic extrusions are bonded by heat or RF energy. This tooling supports the inner diameter of the extrusion and can be straight, tapered, or stepped depending on the final product's design. Durable PTFE coatings are the standard for these applications; any dipped coatings or mold release spray will likely leave residual material inside the catheter, potentially causing contamination of the final device.

Applied Plastics is a business focused on the interventional catheter market in the medical device industry. A ban on fluoropolymers will cause a significant disruption in this industry and affect millions of patients' care and well-being. Because of the many international regulations on medical devices, any change to a component within a medical device would require said medical device to go through a new development, validation, and regulatory approval process. This will be very costly for our business and customers, who must redesign their products and manufacturing processes. This will limit the ability of Medical Device Manufacturers to innovate and develop new therapies, ultimately impacting patient care.

Today, Applied Plastics employs over 80 people and ships PTFE-coated products to over 300 customers worldwide, and over 25% of that business is shipped into the European Union. The proposed ban on fluoropolymers will significantly impact Applied Plastics, our customers, and their patients around the globe. We encourage the European Chemical Agency (ECHA) to consider and weigh the patient benefits of this unique fluoropolymer in their decision to ban fluoropolymers.

Regards,

Thomas Barrett, CEO
Applied Plastics