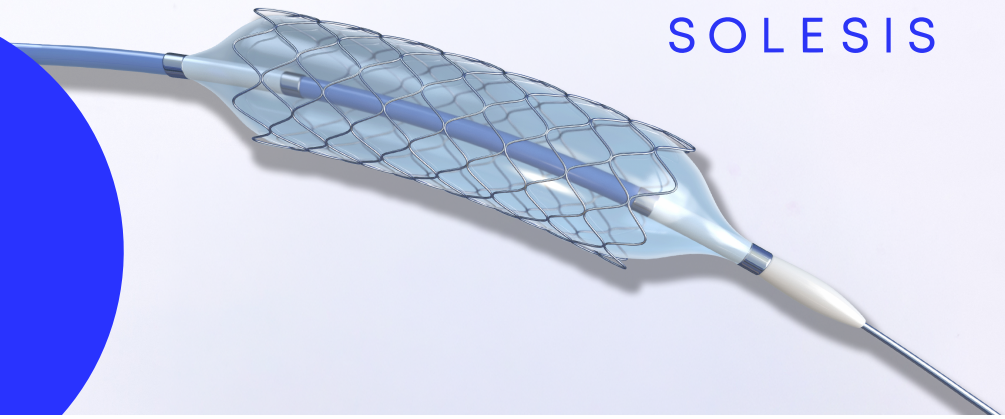

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Designing Catheter Sheaths for General Surgery

Advancing general surgery device performance through optimized low-pressure balloon design.

As minimally invasive procedures continue to replace open surgery in many general surgery applications, delivery systems are being asked to do more than ever before. Rapid advancements in endoscopic and laparoscopic techniques are expanding what clinicians can treat through smaller access points, longer instrument paths and tighter anatomical spaces.

Procedures that involve balloon dilatation, endoscopic and laparoscopic access, occlusion, organ retraction, tamponade, tumor embolization and stent delivery now demand catheter sheaths that can navigate complex anatomy while maintaining flexibility, durability and biocompatibility. These devices must pass through smaller access points and travel longer distances through challenging anatomy, often with little margin for error. At the center of this challenge is the delivery system catheter sheath.

While often viewed as a supporting component, the catheter sheath plays a critical role in protecting tissues, enabling smooth navigation and ensuring reliable device deployment. Today, sheath design has become a sophisticated engineering discipline in its own right, requiring careful material selection, precision manufacturing and system-level integration with balloons and implantable devices.

What Is a Delivery System Catheter Sheath?

A delivery system catheter sheath is the polymer-based outer covering applied to a catheter used for diagnostic or therapeutic procedures. The sheath is typically fitted over a braid- or coil-reinforced polytetrafluoroethylene (PTFE) liner — the structural core of the catheter — and is responsible for many of the functional attributes clinicians rely on during a procedure.

These functions include flexibility, kink resistance, durability and surface lubricity. In many cases, catheter sheaths are also coated with hydrophilic materials to reduce friction and improve navigation through tortuous anatomy. Rather than being a passive layer, the sheath is an engineered interface between the device, the delivery system and the patient.

General Surgery Access Paths and Procedural Considerations

Catheter sheath requirements are closely tied to how and where devices enter the body. In general surgery, delivery systems are often designed for endoscopic and laparoscopic access paths, including navigation through luminal anatomy and working channels, as well as percutaneous entry points used in select minimally invasive procedures. Each access route introduces unique constraints related to anatomy, pathway length, bending and tissue interaction.

For example, endoscopic and laparoscopic procedures often require sheaths that maintain flexibility and kink resistance while navigating curved pathways and tight anatomical spaces. In these settings, surface properties and low friction can help support smoother advancement, repositioning and device placement.

General surgery applications can also place additional demands on sheath geometry and performance, particularly when sheaths are used to support balloon dilatation, luminal occlusion (such as ductal, intestinal or other occlusion use cases), tamponade, organ retraction, tumor embolization or stent delivery and expansion.

Understanding these anatomical and procedural variables is essential when defining sheath geometry, length, material composition and surface treatment.

How Catheter Sheaths Work With Balloons and Delivery Devices

Catheter sheaths rarely function in isolation. In many delivery systems, they serve as the pathway for balloons and implantable devices, making coordination between components essential. Sheath materials, coatings and attachment methods must be compatible with balloon compliance, deployment mechanics and device positioning requirements.

When sheath and balloon components are developed in isolation, compatibility issues often surface late in development — affecting deployment reliability, device placement and overall system performance. The most robust delivery systems are those where sheath construction, balloon specification and attachment method are engineered together from the outset. Thin-film welding is one technique that supports reliable sheath-to-balloon attachment and plays an important role in integrated delivery system assembly.

Designing catheter sheaths with these interactions in mind helps ensure reliable deployment, smooth transitions during procedures and consistent performance across the entire delivery system.

Key Performance Requirements for Catheter Sheaths

Balancing Inner Diameter and Outer Diameter

One of the most important design considerations for catheter sheaths is the relationship between inner diameter (ID) and outer diameter (OD). A narrow OD can significantly reduce access-related constraints and tissue interaction, particularly in minimally invasive procedures that require smaller working channels or tighter anatomical access. At the same time, the ID must be large enough to accommodate increasingly complex devices.

Achieving this balance depends on the precision of the manufacturing process. Blown film and lay-flat extrusion technologies are capable of producing thin-wall tubing at wall thicknesses as low as 0.0005”, with tight dimensional tolerances that allow designers to maximize the functional ID while holding OD to an absolute minimum. This tradeoff is commonly evaluated using the French (Fr) scale, which measures catheter outer diameter and continues to drive innovation toward smaller profiles.

Sheath Length and Structural Support

Sheath length is closely tied to the target anatomy and procedure type. In general surgery, sheath length and construction must often account for longer endoscopic paths, laparoscopic access requirements and the need for controlled positioning during device delivery. When procedures involve balloon dilatation, occlusion or stent delivery and expansion, sheaths must provide sufficient

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support for device advancement while maintaining flexibility to navigate curved anatomy.

As sheath length increases, so does the need for reinforcement. Without appropriate structural support, long sheaths are prone to kinking or loss of control, particularly in curved or tortuous anatomy. Laminated film constructions — which combine multiple material layers, including embedded meshes, fabrics or metallic elements — offer a way to tune stiffness and reinforcement along the sheath length without sacrificing the low-profile geometry required for minimally invasive access. Reinforcement strategies must be balanced carefully to preserve flexibility while maintaining stability.

Surface Properties and Lubricity

Surface performance is another defining feature of catheter sheaths. Hydrophilic coatings are commonly applied to reduce friction, minimize insertion force and support smoother navigation through luminal anatomy and tighter access paths, while enabling more controlled device placement. Beyond hydrophilic coatings, antimicrobial and anti-thrombogenic surface treatments are increasingly relevant in general surgery applications where extended dwell time or repeated device placement is part of the procedural workflow.

Typical Materials Used in Catheter Sheath Design

Material selection is essential to sheath performance and manufacturability. Common materials include:

- **Pebax®:** Widely used in catheter applications due to its biocompatibility, low coefficient of friction, coating uptake and compatibility with assembly processes
- **Polyurethane:** Valued for its biodurability, flexibility, ease of assembly and ability to accept coatings
- **Polyethylene (PE):** Lightweight and moisture resistant, offering durability in liquid-rich environments
- **Thermoplastic elastomers (TPEs):** Provide excellent flexibility, though care must be taken to manage risks such as pinholes
- **Neusoft™:** Ultra-soft TPU blends offering good elasticity, abrasion resistance and heat stability; evaluated selectively depending on application requirements
- **Chronoprene®:** Soft, compliant elastomer with high tensile strength and elongation; referenced as an alternative material but not commonly used in catheter sheath programs

Manufacturers generally avoid latex due to allergy concerns. Instead, material selection often prioritizes other polymers that can be produced consistently, scaled for manufacturing and integrated with downstream processes such as coating, bonding, welding and assembly. Custom polymer formulations are also becoming more common in complex sheath programs, allowing properties such as durometer, melt behavior, adhesion and surface characteristics to be tuned to specific procedural requirements.meet performance requirements.

Manufacturing Methods for Catheter Sheaths

Several manufacturing techniques are used to produce catheter sheath films, each offering distinct advantages depending on the application:

- **Extrusion,** including flat-die and lay-flat extrusion, is commonly used to produce thin films suitable for low-profile sheath construction. This approach supports tight dimensional control and scalable production.
- **Thermoforming** allows films to be heated and molded over forms to create specific geometries or localized features, supporting customized sheath designs.
- **Laminated film** combines multiple films to introduce differentiated properties — such as tailored melt points, adhesion characteristics, embedded reinforcement layers or surface friction profiles — within a single sheath structure.

Designing Catheter Sheaths for Minimally Invasive General Surgery *cont.*

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- **Dip molding** enables the creation of long, narrow, seamless sheaths with no parting lines or seams, making it well suited to producing highly compliant, thin-walled sheath geometries for endoscopic and laparoscopic applications. In-house polymer solution formulation and mold development allow for fast prototype turnaround and straightforward scale-up to high-volume production.
- **Thin-film welding** supports sheath assembly and attachment to balloon and device components, and is an important process capability for building fully integrated delivery systems.

These methods can be used to tune thin-film sheath properties such as smaller profiles, surface finish, coefficient of friction, softness, durability, flexibility and biocompatibility, depending on how the sheath must perform in endoscopic and laparoscopic environments.

Emerging Trends in Catheter Sheath Technology

As minimally invasive general surgery procedures continue to expand, catheter sheath design is evolving alongside advances in endoscopic and laparoscopic tools. Device teams are placing greater emphasis on sheath solutions that support smaller profiles, consistent navigation through tight access paths and reliable performance during repositioning and device placement.

Looking ahead, increased integration with robotic platforms and continued refinement of minimally invasive techniques will further influence sheath requirements. Manufacturers are prioritizing sheath materials, coatings and thin-film processing approaches that enable smoother navigation, improved device placement and repeatable manufacturability for complex general surgery workflows.

Design Delivery System Catheter Sheaths With Confidence

Modern catheter sheath design requires a system-level understanding of anatomy, procedural workflows and device integration. Balancing profile, flexibility, durability, surface performance and manufacturability is essential to developing sheath solutions for increasingly demanding minimally invasive procedures.

With deep expertise in polymeric materials and thin-film processing for medical device delivery systems, Polyzen, part of the Solesis family of companies, works with device teams early in development to translate complex requirements into scalable, clinically relevant sheath designs.

Leveraging advanced liquid processing and dip molding technologies, Polyzen offers end-to-end sheath development and manufacturing capabilities. These include blown film and lay-flat extrusion producing wall thicknesses from 0.0005” to 0.010” in a class-10,000 cleanroom, laminated film constructions with embedded meshes and fabrics for tunable reinforcement, dip molding for seamless compliant sheath geometries, and in-house hydrophilic, antimicrobial and anti-thrombogenic coatings. Thin-film welding supports reliable sheath-to-balloon and sheath-to-device assembly.

Polyzen also manufactures balloons in-house, including low-pressure, high-pressure, multi-layer and dilation configurations. This means sheath and balloon compatibility is designed together from the start. A structured stage-gate process with dedicated engineering, quality and regulatory support ensures every design is manufacturable, compliant and ready for full-scale production.

Discover how Solesis partners with device developers to advance minimally invasive surgical technologies.

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