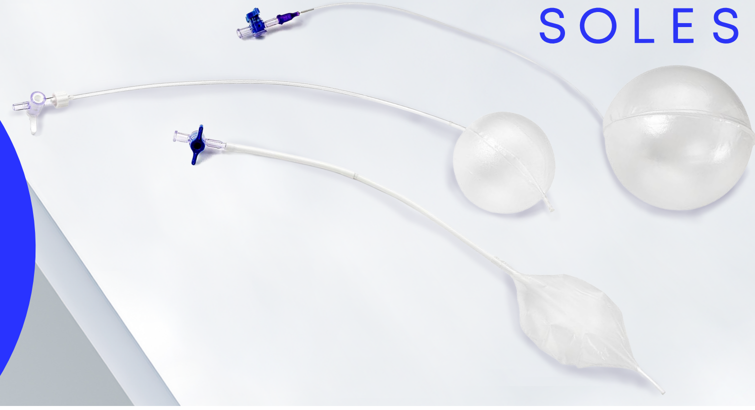
Developing Low-Pressure Balloons for General Surgery



Supporting next-generation surgical delivery systems with compliant balloon solutions optimized for minimally invasive procedures.

Medical device delivery systems are being designed to navigate increasingly complex anatomy while minimizing trauma and improving procedural control. In many of these systems, low-pressure balloons play a critical role, not as precision dilators, but as compliant, adaptive components that support positioning, occlusion, tissue separation and device deployment.

Specialized, custom-shaped low-pressure balloons are commonly used in general surgery, drug delivery and select catheter-based applications, among others, and paired with catheter sheaths to deliver critical devices through smaller access points, working channels and luminal anatomy.

Designing these balloons requires a different engineering mindset than high-pressure balloon development. Compliance, geometry and material behavior take precedence over strict dimensional control, and early design decisions directly influence clinical performance and manufacturability.

What Is a Low-Pressure Balloon?

Low-pressure balloons are structures designed to expand significantly under relatively low inflation pressures — up to 600% of their predetermined diameter. This allows them to conform to surrounding anatomy, making them particularly effective in applications where gentle, adaptive interaction with tissue is required rather than controlled dilation against resistance.

In minimally invasive general surgery, that compliance can support device positioning, temporary occlusion, tamponade, tissue separation and access through constrained endoscopic or laparoscopic pathways.

What Is Balloon Compliance?

Compliance refers to how much a balloon will stretch beyond a predetermined diameter under an applied force. Low-pressure balloons are considered compliant. This means that increased pressure will expand the balloon in areas of low resistance in the balloon and in the body, unlike non-compliant balloons, which maintain a fixed diameter.

High-pressure, or "non-compliant" balloons, will not stretch beyond a predetermined diameter. Non-compliant balloons maintain their profile and shape with repeated inflations and can rupture before permanently deforming. Here is an overview of the compliance scale:

- A low-compliance, high-pressure balloon expands 5-10% beyond a predetermined diameter.
- A high-compliance, high-pressure balloon expands 18-30% beyond a predetermined diameter.
- A low-pressure balloon can stretch 100-600% and recover close to its original size; however, it cannot tolerate high pressures.

Developing Low-Pressure Balloons for Minimally Invasive General Surgery *cont.*

How Low-Pressure Balloons Are Used in Medical Procedures

Low-pressure medical balloons are used across a range of minimally invasive general surgery procedures and delivery system applications, where controlled expansion and conformability are required.

General Surgery Applications

- **Balloon dilatation:** Supporting controlled expansion in luminal anatomy or constrained access paths
- **Temporary occlusion:** Creating a temporary seal in ductal, intestinal or other luminal structures
- **Tamponade support:** Applying compliant pressure to help control localized bleeding or fluid movement
- **Tissue separation:** Creating space between anatomical structures during treatment or device placement
- **Organ retraction:** Providing gentle, temporary positioning support during minimally invasive procedures
- **Endoscopic and laparoscopic positioning:** Supporting device placement through working channels and tight anatomical spaces
- **Stent delivery and expansion:** Supporting placement and controlled expansion in select general surgery applications
- **Drug delivery:** Supporting localized delivery approaches when therapy requirements call for compliant balloon interaction

These applications place unique demands on low-pressure balloon design, particularly in endoscopic, laparoscopic and luminal environments where access paths may be narrow, curved or difficult to navigate. Balloon performance is often defined by:

- Controlled inflation and deflation to help minimize rupture risk
- High compliance and flexibility to conform to anatomy
- Improved resistance to fatigue and burst during repeated inflation
- Smaller profiles for tight working channels and challenging access paths
- Material architectures, including multi-layer or hybrid constructions, to balance compliance and durability

Materials Commonly Used in Low-Pressure Balloons

Material selection plays a central role in defining balloon compliance, durability and manufacturability. Traditionally, latex balloons have been considered the standard for medical device applications.

However, today, latex is generally avoided due to allergy concerns and the superior properties offered by other materials, such as polyurethane.

Polyurethane is widely used due to its balance of elasticity, durability and process compatibility. It can be thermoformed, dip-molded or welded to support complex geometries and high neck-to-body ratios.

In addition to polyurethane, thermoplastic elastomers can be used to create more flexible balloons. Silicone is also an excellent material for dip molding low-pressure balloons, as it can stretch up to 1000% of its original position and demonstrates excellent strength. Both thermoforming and dip molding are viable solutions for producing low-pressure balloons, depending on material selection and balloon requirements.

Manufacturing Methods for Low-Pressure Balloons

The choice of manufacturing method directly influences balloon geometry, wall thickness and performance.

In minimally invasive general surgery applications, these characteristics are especially critical. Low-pressure balloons may be used for temporary occlusion, tissue separation, tamponade, organ retraction, balloon dilatation or device deployment, where compliant expansion and consistent material behavior support performance in tight access paths and luminal anatomy.

As endoscopic and laparoscopic techniques continue to advance, manufacturers are placing greater emphasis on repeatable processes that can achieve precise, application-specific performance. Against this backdrop, thermoforming and dip molding remain two viable solutions for producing low-pressure balloons — the choice depends on material choice, required geometry and balloon performance requirements.

Thermoforming

Thermoformed balloons are fully 3-dimensional and exhibit a nearly invisible seam on the inside of the balloon, making them ideal for applications that require custom geometry, compact profiles and controlled deployment.

Using the thermoforming process, low-pressure balloons can be produced in almost any size and configuration, ranging from as small as 0.200” with neck-to-body ratios of 1:5, 1:10 and 1:20, depending on the material. These polyurethane balloons are compact and foldable, providing an easier insertion compared to traditional latex balloons. Various thicknesses are achievable depending on the designer’s application and requirements.

These balloons offer more versatility compared to other non-latex, low-pressure alternatives that are limited by 2D forms and extremely low-pressure tolerances.

Dip Molding

Dip molding is another method for creating custom, low-pressure balloons. Because it relies on liquid polymers, it enables seamless, hollow balloon structures by building controlled layers on a mandrel before curing and demolding. Advanced liquid processing capabilities can further refine this approach by improving material distribution and repeatability, supporting tighter control over wall construction and more consistent performance.

Dip-molded balloons can be made of polyurethane, silicone, fluoropolymers and bioabsorbable polymers, among other materials, which opens the process for a wide range of applications. Given the lack of seam, dip-molded balloons are ideal for general surgery applications such as gastrointestinal balloons, where seamless surfaces and compliant geometries can help reduce the risk of tearing or rubbing during placement. Liquid processing can also support the evaluation and integration of specialty chemistries when application requirements call for them.

Develop Low-Pressure Balloons With Confidence

Medical device manufacturers have a variety of methods and materials to consider when designing low-pressure medical balloons. Thermoforming and dip molding have emerged as two reliable and repeatable methods for creating these critical medical device components, which can be customized for optimal construction, deployment, durability, strength and thickness.

Device manufacturers should partner with an experienced medical balloon manufacturer that can match the right materials to the appropriate design and development processes and ensure that polymer-based devices or components meet specified performance criteria to positively impact patient care.

In minimally invasive general surgery device development, that ability to match materials, forming methods and processing conditions is increasingly important as manufacturers pursue lower profiles, controlled compliance behavior and reliable performance in endoscopic, laparoscopic and luminal applications.

With decades of expertise in biomaterials science, Solesis can help you solve your toughest medical device and delivery system challenges with custom polymer, textile and hybrid solutions. From material selection and early development through scale-up and commercialization, Solesis can help bring your next therapeutic breakthrough to life.

Discover how Solesis supports the development of low-pressure balloon technologies for minimally invasive procedures.