



SOLESIS



Developing Low-Pressure Balloons for Vascular Procedures

Supporting next-generation vascular 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 vascular, general surgery and drug delivery applications, among others, and paired with catheter sheaths to deliver critical devices to save lives.

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.

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.

How Low-Pressure Balloons Are Used in Medical Procedures

Low-pressure medical balloons are used across a range of vascular procedures and catheter-based applications, where controlled expansion and conformability are required.

Vascular Applications

- **Fixation:** Stabilizing the position of a catheter within a vessel
- **Occlusion and occlusion testing:** Temporarily sealing a vessel and assessing tolerance for occlusion
- **Cardioplegia support:** Facilitating temporary heart arrest during select cardiac procedures
- **Ablation support (radiofrequency or cryo):** Creating space or enabling positioning during treatment
- **Vessel preparation and angioplasty support:** Supporting targeted expansion and pre- and post-dilation steps
- **Stent delivery and expansion:** Supporting placement and expansion within the vessel
- **Drug-coated balloon applications:** Supporting localized drug delivery approaches intended to reduce restenosis risk
- **Balloon-assisted coiling and flow diversion assistance:** Supporting aneurysm treatment, wall apposition, and device positioning
- **Balloon septostomy:** Creating or enlarging an opening between heart chambers in specific cardiac procedures

These applications place unique demands on low-pressure balloon design, particularly in vascular pathways that are calcified or tortuous. 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 distal lesions and challenging access
- 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 peripheral vascular and interventional cardiology applications, these characteristics are especially critical. Low-pressure balloons are increasingly used for delicate vessel sizing, temporary occlusion and drug delivery, where compliant expansion and consistent material behavior support performance in calcified or tortuous pathways.

As cardiovascular balloon technologies continue to evolve, 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 in-patient applications.

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 in-patient applications like gastrointestinal balloons, which must be seamless to help reduce the risk of tearing or rubbing in the patient's stomach. Liquid processing can also support the evaluation and integration of specialty chemistries when application requirements call for them.

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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 ultimately impact patient care.

In peripheral vascular and interventional cardiology device development, that ability to match materials,

forming methods and processing conditions is increasingly what enables the newest balloon innovations — especially as manufacturers pursue lower profiles, more controlled compliance behavior and advanced drug delivery approaches.

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 next-generation vascular devices.

