

Balloon Manufacturing

Balloon Manufacturing

- ◆ Experienced engineering team
- ◆ Rapid prototype to full production
- ◆ Substantial balloon manufacturing capacity
- ◆ State-of-the-art balloon forming equipment
- ◆ In-house mold and die fabrication

Interface Balloon Design, Development and Manufacturing Expertise

As a medical balloon contract manufacturer for more than 15 years, Interface Catheter Solutions has accumulated substantial expertise and understanding of the issues linked to balloon quality and balloon production yields. We have extensive experience in producing medical balloons to client specifications for a variety of clinical applications, either on a prototype or contract manufacturing basis.

Our long history in balloon design and development is built upon extensive product and project expertise in the development of more than 2,100 different balloon designs. Interface Catheter Solutions is your proven partner from concept development and prototyping to full-scale production.

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Engineering Design and Manufacturing Capabilities

Interface has an extensive range of catheter balloon engineering and development expertise, from the development of balloon forming and testing equipment to extruded balloon tubing along with mold and die fabrication.

Resources available include substantial balloon manufacturing capacity with expansive clean room facilities and an extensive array of state-of-the-art balloon forming equipment. Interface has highly-skilled balloon design, development and manufacturing engineers, quality engineers and trained operators to insure the utmost balloon quality and production. They work with your team to provide the optimal design, materials and tooling for high-yield balloon production along with quick turnaround.



In-house production capabilities include:

- ◆ Rapid response prototyping to full production
- ◆ Experienced engineering team to reduce time to market
- ◆ State-of-the-art facilities and equipment for successful production yields

Balloon Production Quality

Interface develops and monitors balloon manufacturing process parameters that include temperature, pressure, expansion and stretch to achieve and maintain consistent and predictable results. Computer software programs maintain stress and strain ratio control to meet burst and compliance requirements. Customer specific production parameters are maintained and monitored throughout the balloon production process.

Balloon production quality includes:

- ◆ Uniform consistent wall thickness
- ◆ Increased burst pressures and improved fatigue
- ◆ Tight tolerance and defect-free balloons
- ◆ Tested and certified balloons



Balloon Technical Capabilities

Interface has extensive experience in a variety of balloon clinical applications and meeting market demands. We produce long-length balloons up to 320 mm with high-quality performance standards. These longer balloons are produced with sharp, well-defined cone transitions, no warping or banana shaping and even wall thickness throughout the body.

Interface creates high pressure balloons that meet and exceed current market demands to reach higher-rated burst pressures.

No project is too big or too small; Interface has an extensive portfolio of balloon design capabilities for a wide variety of clinical applications. These include angioplasty, cardiovascular, dilatation, distraction, ear/nose and throat, endotracheal and esophageal, high pressure, intra-aortic balloon pump (IABP), neurovascular, occlusion, orthopedic/spinal, stent delivery and valvuloplasty.

Standard and Sample Balloon Programs

Standard and sample balloon programs are available for quick-turnaround requirements and for research and development.



The sample balloon program offers immediate shipping for sizes available and the standard balloon program is a quick turnaround production run with a large inventory of sizes available. Both balloon programs offer market-competitive balloon material, sizes and specifications. Balloon program specifications are available online through the Interface web site.

Extruded Balloon Tubing

Interface balloon tubing extrusion process offers significant benefits for balloon production, including:

- ◆ Superior high-quality tubing for consistent balloon performance characteristics
- ◆ Minimal wall thickness and improved burst pressure
- ◆ Higher production yields and minimal defects
- ◆ Greater control over the balloon manufacturing process



Interface has the expertise and in-house capability for all of your balloon production requirements.



Interface Commitment to Quality

Interface is an ISO 13485:2003 certified contract component and finished device manufacturer with multiple Class-8 clean rooms. Our vertically integrated production capabilities allow us to maintain control over all aspects of the production process. Interface provides a Certificate of Compliance with each balloon lot and completes both in-line and post production rigorous quality testing. Following ISO standards, our focus is always on quality and on-time delivery.



Specifications

Our extensive experience allows us to offer you:

- ◆ **Balloon sizes from 0.5 mm to 50 mm in diameter and lengths up to 320 mm**
- ◆ **Wide range of shapes – cylindrical, spherical, oval, conical, stepped, tapered, offset and more**
- ◆ **Materials expertise with Nylon, Pebax®, PET, Polyurethane and more**
- ◆ **Non-compliant, semi-compliant and compliant balloons developed and produced for a wide variety of clinical applications**





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