

# The only vertically integrated provider of outsourced solutions for balloon catheter manufacturing

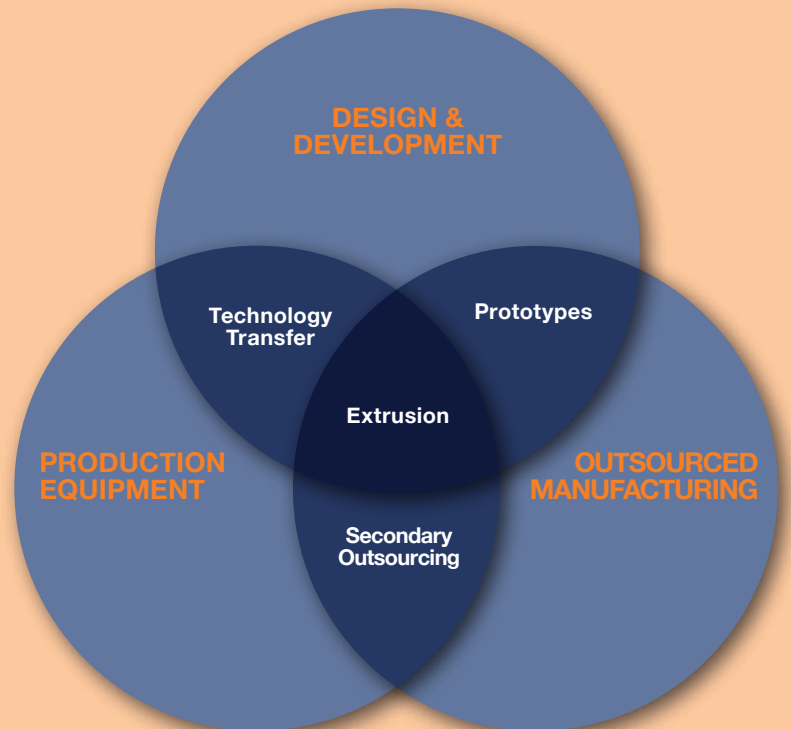


- Balloon Design and Development
- Balloon Prototype and Production Manufacturing
- Balloon Forming Equipment
- Catheter Production and Testing Equipment
- Extruded Tubing Exclusively for Balloon Production

INTERFACE has been solely focused on the balloon catheter market since 1995, and is the only vertically integrated provider of outsourced solutions for balloon catheter manufacturing. Our long-term experience means we can handle all of your needs from proof of concept to production manufacturing. With more than 20 engineers on staff, we offer a comprehensive range of engineering capabilities that will help you solve complex issues to shorten your time to market.

Our offering of products and services include:

- Balloon design and development
- Prototype and production manufacturing of balloons
- Balloon forming equipment
- Catheter assembly and testing equipment
- Welding sleeves
- Extruded tubing designed for balloon production
- In-house custom mold design and production
- Materials analysis including DMA, DSC and UTM
- PTCA and PTA catheter production lines for technology transfer, including a complete equipment line and validation services



With three facilities in Southern California and multiple Class 7 and 8 clean rooms, we are ISO 13485:2003 certified and maintain complete control over all aspects of the production process.

Whether you are looking to increase yields, improve performance properties, develop new products, upgrade your production capabilities, or engage a manufacturing partner, Interface provides vertically integrated solutions for balloon catheter manufacturing.

**I**NTERFACE offers a comprehensive line of equipment for balloon production, catheter manufacturing and testing. All of our equipment has been internally designed based upon extensive feedback from our customers, as well as our own manufacturing team. This reinforces our commitment and expertise in providing balloon catheter solutions to the medical device industry.

### **Balloon Forming Equipment**

Our computer-controlled balloon forming equipment produces the longest and largest medical balloons to meet today's increasing requirements. Interface is known for creating balloon forming equipment that delivers consistent performance, reduced cycle times, increased yields and higher quality, along with real-time balloon forming profiling.

### **Catheter Manufacturing Equipment**

The key to insuring repeatability in the production of high-quality medical balloons and catheters is precision production equipment. Our equipment is designed with your production goals in mind: increased throughput, reliability and fast turnaround.

### **Testing Equipment**

Our range of testing equipment is designed to test catheters, balloons and crimped stents for burst, leaks, fatigue, dimensions and compliance characteristics.

### **Technology Transfer**

We offer PTCA and PTA production lines, including a complete range of equipment, production drawings and procedures, and validation services.

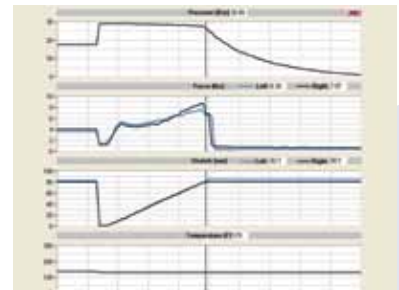
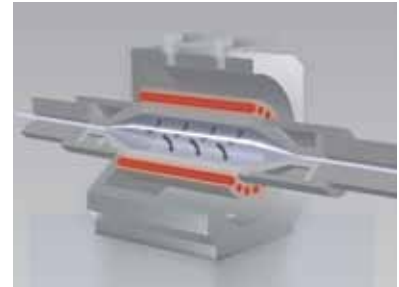


INTERFACE offers a comprehensive array of engineering capabilities ranging from customized mold and end plug design to the design and development of complex medical balloons. Our long history in balloon design and development is built upon extensive product and project expertise in the development of more than 2,000 different balloon designs over the last 15 years. Interface is your proven partner from concept development and prototyping to full-scale production.

## Design and Development

Our services include:

- Standard and custom balloon designs
- Material testing and analysis capabilities – DMA, DSC and UTM
- State-of-the-art machine shop for building standard and proprietary tools, dies and molds
- Experienced balloon development engineering team



INTERFACE is an FDA-compliant and ISO 13485:2003 certified contract component and finished device manufacturer with multiple Class 7 and 8 clean rooms. With our vertically integrated production capabilities, we maintain control over all aspects of the production process. Following ISO standards, our focus is on quality and on-time delivery.

### Balloon Production

Balloon production capabilities cover all phases of manufacturing including prototyping to complete production manufacturing. Our extensive experience allows us to offer you:

- Balloon sizes from 0.5 mm to 50 mm in diameter and lengths up to 250 mm
- Wide range of shapes – cylindrical, spherical, oval, conical, stepped, tapered, offset and more
- Materials expertise with Nylon, Pebax®, Polyurethane, PET and more
- Increased burst pressures and improved fatigue
- Wall thicknesses ranging from 0.0002" to 0.007" (0.005 mm to 0.178 mm)



INTERFACE offers in-house extrusion capabilities specifically designed for balloon production. Our custom balloon tubing extrusion process was developed on a foundation of extensive experience in balloon design and development. We focus on the consistent production of defect-free tubing to provide increased production yields and superior balloon performance characteristics. Interface provides complete documentation for every lot including a certificate of compliance, dimensional and visual inspection reports, and tensile test report.

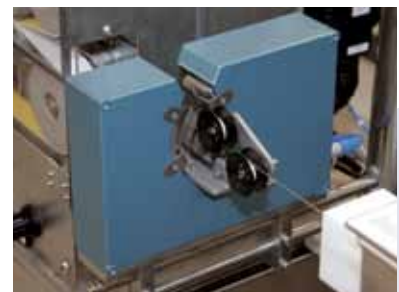
### Balloon Tubing Extrusion Process

Our balloon tubing extrusion process offers significant benefits, 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
- Complete documentation for each lot

#### Quality Policy

*Interface Catheter Solutions is committed to consistently provide high-quality products with on-time delivery and superior service to our customers. We will maintain and continuously improve our Quality Management System to assure its effectiveness and comply with all applicable requirements.*



CATHETER SOLUTIONS

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