

Product Specification

Balloon

Balloon Material	Nylon 12
Nominal Pressure	6 atm
Rated Burst Pressure*	16 atm
Sheath Compatibility	4 Fr
Compliance	< 13% between nominal and rated burst pressure
Deflation Time	< 10 seconds
Fold	Tri-fold

Range of Balloon Sizes

Diameters	2.5 to 4 mm (0.5 mm size increments available)
Lengths	10 to 35 mm

Catheter Shaft

Entry Tip Profile	0.019", 0.48 mm
Overall Catheter Length	140 cm ± 2.5 cm usable length
Distal Shaft Material	Nylon 12
Proximal Shaft Material	Pebax® jacketed stainless steel 304
Guidewire	Maximum wire diameter 0.014"

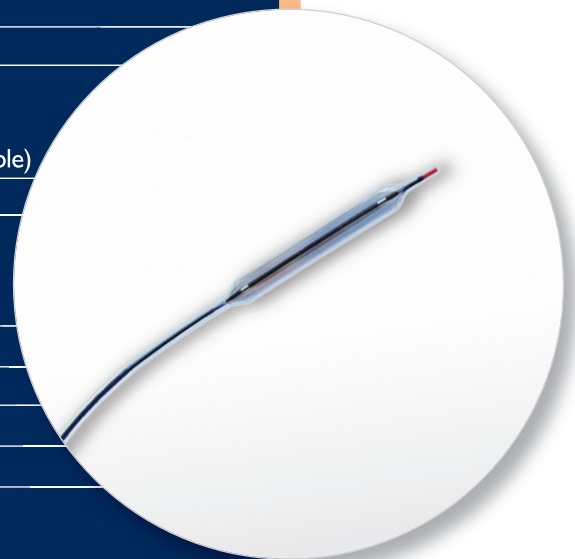
Hub

Polycarbonate female luer lock

Marker Bands

Swaged platinum/iridium marker bands

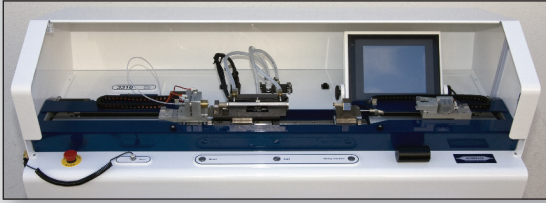
*95% Confidence, 99.9% Reliability



Customer is responsible for FDA submission clearance and CE mark prior to product sale.

Interface Catheter Solutions Technology Transfer

Interface Catheter Solutions extensive experience in balloon catheter contract and equipment manufacturing provides customers complete PTCA and PTA production line solutions. The balloon catheter production lines include a full-range of equipment, production drawings and procedures, along with validation services. Interface has a successful track record of training companies throughout the world on PTCA and PTA technology through its technology transfer program. Consulting services offered by Interface help companies to quickly enter the balloon catheter market.



The technology transfer product lines are designed to give our customers the ability to offer a high-quality main stream product that is reliable and robust. Product lines can also be customized per client specifications. Clients are introduced to many special assembly and fabrication techniques that increase productivity and improve quality. By having access to Interface expertise and manufacturing proficiency, clients can greatly reduce time-to-market and be able to initiate their own production of attractively priced, high quality catheters.

Recommended Equipment for PTCA Catheter Production

1. **Computerized Balloon Forming Machine, Model BFM-3310** – This system is designed to produce a variety of high strength polymer balloons using a stretch, blow molding process. Optional features include parison deionizer, light curtain safety cover and bar code scanner.
2. **Cooling Water Tank and Chiller Assembly** – Accessories to Balloon Forming Machine.
3. **Balloon Visual Inspection System, BVIS-2000** – Automated balloon visual inspection system provides both visual inspection/dimensional measurements of medical balloons in a single operation. Inspection includes classification and size of defects with pass/fail analysis based on user-selected criteria.
4. **Length Diameter Measurement System, LDS-320** – Non-contact, air-pressurized balloon dimensional measurement system.
5. **Computerized Parison Stretcher, Model CPS-1000** – The machine pre-forms balloon tubing to optimize balloon properties as well as to allow large balloon to neck diameter ratios.
6. **Hydraulic Pressure Tester, Model HPT-1000** – Performs pressure testing of balloons and catheters including tests such as burst, fatigue and compliance. Use with optional Compliance Test Fixture, Water Bath and Printer to quickly and accurately determine the compliance characteristics of the balloon. (Equipment upgrade available to Model PT-3070).
7. **Marker Band Swager, Model MBS-200** – Swages metal marker bands on shafts. Use with Marker Band Positioning and Pre-Crimp Fixture for precise positioning.
8. **Tubing Welding Machine, Model TBW-500** – Performs fuse-welding of proximal balloon neck, distal balloon neck, and proximal to distal shaft. Optional Vision System available to aid catheter positioning for optimal welds.
9. **Slitting Fixture** – Performs distal tube skiving.
10. **Hot Air System, Model HB-700** – Timer/Controller Module and Fuse-Weld Module are used to perform conversion bonds (guidewire entry fuse-welds). Also Timer/Controller Module and Tipping Attachment for tip forming.
11. **Extrusion Die Stretching Machine, Model EDS-3X68** – Performs hot die draw down of plastic tubing to reduce O.D./I.D. Performs hypo-tube jacketing. Produce custom size welding sleeves and balloon sheaths from standard off-the-shelf tubing.
12. **Gas pressure Leak Tester, Model GPL-501** – Performs non-destructive leak testing of finished catheter.
13. **Dual Fluter and Wrapper, Model DFW-1000** – Flutes and wraps balloons in preparation for sheathing.
14. **Heat Setting Oven, Model HSO-250** – Performs post fluting and wrapping heat setting to improve fold memory retention and reduce wrapped profile after unsheathing.
15. **Spot Welding System** – Performs spot weld of core wire to hypo-tube.
16. **Catheter Stand** – For transferring semi-finished and finished catheters between workstations.