



**Product Specification**

<b>Balloon Material</b>	Nylon 12
<b>Nominal Pressure</b>	6 atm
<b>Rated Burst Pressure*</b>	16 atm (5 - 6 mm); 15 atm (7 - 8 mm); 14 atm (9 - 10 mm)
<b>Sheath Compatibility</b>	5 Fr (5 - 7 mm); 6 Fr (8 - 10 mm)
<b>Compliance</b>	< 10% between nominal and rated burst pressure
<b>Deflation Time</b>	< 30 seconds
<b>Fold</b>	Tri-fold ( $\leq$ 7mm diameter), Penta-fold ( $>$ 7mm diameter)
<b>Range of Balloon Sizes</b>	
Diameters	5 to 10 mm
Lengths	20 to 150 mm
<b>Tip Lead in Profile</b>	.048", 1.22 mm
<b>Usable Catheter Length</b>	80 cm $\pm$ 2 cm
<b>Shaft Material</b>	Pebax® 72D, Bi-lumen
<b>Shaft Diameter</b>	0.066", 1.676 mm
<b>Hub</b>	Polycarbonate female y-luer lock
<b>Guidewire</b>	Maximum wire diameter 0.035"
<b>Marker Bands</b>	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 PTA 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. **Computerized Double-End Stretching Machine, Model CJS-3X12** – The machine pre-forms balloon tubing to optimize balloon properties as well as to allow large balloon to neck diameter ratios.
4. **Programmable Pressure Tester, Model PT-1000** – Microprocessor based unit for pressure testing balloons and catheters. Performs tests such as burst, fatigue, compliance, etc. Use with optional Compliance Test Fixture and printer to quickly and accurately determine the compliance characteristics of the balloon. (Equipment upgrade available to Model PT-3070)
5. **Marker Band Swager, Model MBS-200** – Swages metal marker bands on shafts. Use with Marker Band Positioning and Pre-Crimp Fixture for precise positioning.
6. **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.
7. **Hot Air System, Model HB-700** – Timer/Controller Module and Tipping Attachment for tip forming.
8. **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.
9. **Gas pressure Leak Tester, Model GPL-501** – Performs 100% non-destructive leak testing of finished catheter.
10. **Balloon Fluting Fixture** – Flutes balloons in preparation for wrapping and sheathing.
11. **Balloon Wrapping Fixture** – Wraps fluted balloon.
12. **Heat Setting Oven, Model HSO-250** – Performs post fluting and wrapping heat setting to improve fold memory retention and reduce wrapped profile after unsheathing.
13. **Catheter Stand** – For transferring semi-finished and finished catheters between workstations.