

Technical Specifications

Catheter Type	: Rapid Exchange (RX)	Balloon Material	: Nylon
Compliance Type	: High Pressure Semi-Compliant	Marker Material	: Platinum and Iridium
Balloon Folding	: Quad-fold	Radiopaque Markers	: Dual Markers
Total Working Lengths	: 40cm, 60cm, 80cm, 130cm	Tip Length	: 6 mm
Balloon Lengths (mm)	: 20 to 80 mm (20, 40, 60 and 80 mm)	Tip Entry Profile	: 0.033"
Balloon Diameters (mm)	: 4.50 to 7.00 mm (4.50, 5.00, 6.00, and 7.00mm)	Distal Coating	: Hydrophilic
Nominal Pressure (NP)	: 6 atm	Minimum Introducer Sheath Size	: 5 FR for 4.50 to 5.00 mm 6 FR for 6.00 & 7.00 mm
Rated Burst Pressure (RBP)	: 14 atm	Maximum Guide Wire Compatibility	: 0.018" guide wire
		Shelf Life	: 24 months

Balloon Crossing Profile:

- 4.5 mm – < 0.061"
- 5.0 mm – < 0.071"
- 6.0 mm – < 0.071"
- 7.0 mm – < 0.076"

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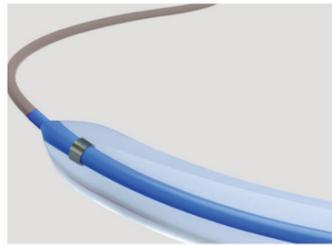
Compliance Chart
RX PTA Balloon Compliance

Balloon Diameter (mm)	Inflation Pressure (atm)							
	2 atm	4 atm	6 atm	8 atm	10 atm	12 atm	14 atm	16 atm
4.50	3.90	4.25	4.45	4.65	4.75	4.85	4.95	5.10
5.00	4.40	4.70	5.00	5.15	5.20	5.30	5.40	5.50
6.00	5.30	5.70	6.00	6.20	6.40	6.65	7.00	7.10
7.00	6.20	6.65	7.00	7.20	7.40	7.60	7.80	8.10
	Nominal Pressure				Rated Burst Pressure			



INDIGO RX™
PTA Balloon Catheter

Designed for smooth movement through long, tight peripheral lesions



Indigo RX is designed for percutaneous transluminal angioplasty procedures of the femoral, iliac, renal arteries, post deployment and dilation of peripheral vascular stents. Also indicated for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Incorporating the flexibility of rapid exchange design with high burst balloons, multiple working lengths and balloon sizes to facilitate usage in most peripheral intervention requirements.

Targets lesions post-deployment and post-dilation incorporating the flexibility of rapid exchange design with high burst balloons.

Key System Attributes:

- Superior Crossability & Trackability:**
 A combination of low-profile tip design, optimized shaft construction, and hydrophilic coating enable smooth navigation through tortuous anatomy, enhances push force transmission, ensuring reliable lesion access
- Enhanced Procedural Control:**
 The unique stainless steel hypotube construction ensures outstanding torque response, pushability, and trackability, giving the operator precise control from the guide catheter to the lesion.
- High Pressure Dilatation:**
 High-pressure, nylon-material made, semi-compliant balloon provides a thicker wall for controlled expansion in longer, tighter lesions during standard vessel dilation and post-stent placement. Controlled expansion up to a Rated Burst Pressure (RBP) of 14 atm
- Superior Visibility:**
 Dual platinum-iridium marker bands offer excellent radiopacity for clear, unambiguous positioning under fluoroscopy.

Advanced Engineering for Clinical Excellence

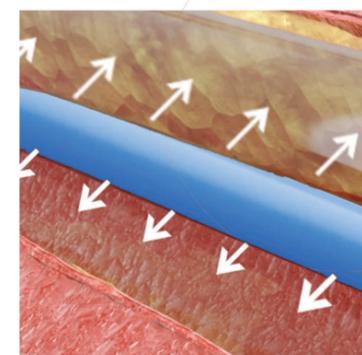
This page details the core technical features of the Catheter system & their direct clinical benefits during an angioplasty procedure.

1. Lesion Crossing & System Deliverability

Feature	Technical Detail	Clinical Benefit
Tapered Tip Design	6 mm tapered tip length with a leading entry profile of 0.033".	Provides an atraumatic, low-profile leading edge for effortless crossing of stented lesions in the femoral, iliac, renal arteries.
Optimized Balloon Fold	Quad-Fold balloon design with low crossing profile ranging from ≤0.061" to ≤0.076".	Ensures the smallest possible profile for long, tight, stented lesions, then re-folds uniformly for smooth withdrawal.
Hydrophilic Coating	The distal outer shaft is coated with a medical-grade hydrophilic layer	Reduces friction against vessel walls and device lumens, enhancing catheter advancement and trackability.
Advanced Shaft Construction	A unique stainless steel 304 hypotube transitions to a flexible distal shaft.	Facilitates a seamless transfer of force from the operator's hand, providing superior pushability and torque control for precise maneuverability through complex vasculature.



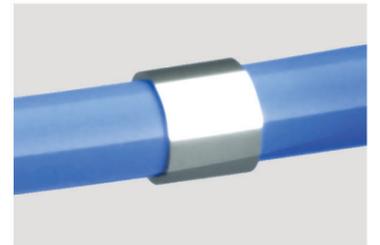
2. Controlled & Powerful Dilatation



Feature	Technical Detail	Clinical Benefit
Semi-Compliant Balloon	Fabricated from a high pressure, puncture-resistant nylon material (USP Class VI).	Delivers predictable, uniform dilation at high pressures (up to 14 atm RBP), ensuring smooth deployment as well as full lesion expansion post-dilation in calcified and fibrotic tissue while minimizing the risk of "dog-boning"
High-Pressure Capability	Nominal Pressure (NP) of upto 6 atm and a Rated Burst Pressure (RBP) of 14 atm.	Provides the necessary force to effectively dilate lesions, post stent deployment and/or standard post-dilation
Optimized Inflation	Distal shaft diameter is engineered for efficient lumen flow.	Facilitates rapid and uniform balloon inflation (<10 seconds) for reduced procedure time and patient discomfort.

3. Enhanced Visualization & Usability

Feature	Technical Detail	Clinical Benefit
High-Definition Markers	Dual Platinum-Iridium radiopaque marker bands are embedded at the balloon shoulders.	Offers exceptional radiopacity for clear and precise visualization under fluoroscopy, ensuring accurate balloon placement relative to the lesion and stent.
Rapid Exchange System	Industry-standard Rapid Exchange (RX) design with a 130 cm total working length.	Enables single-operator use, simplifies wire management, and allows for faster catheter exchanges, improving overall procedural efficiency



Compliance Chart RX PTA Balloon Compliance

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6.00	5.30	5.70	6.00	6.20	6.40	6.65	7.00	7.10
7.00	6.20	6.65	7.00	7.20	7.40	7.60	7.80	8.10
Nominal Pressure				Rated Burst Pressure				