



Technical Specifications

Catheter Type	: Over-The-Wire	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	: 4.5 mm
Balloon Lengths (mm)	: 20 to 100mm (20, 40, 60, 80 and 100mm)	Tip Entry Profile	: 0.044"
Balloon Diameters (mm)	: 4.50 to 10.00 mm (4.50, 5.00,6.00, 7.00, 8.00, 9.00,10.00mm)	Distal Coating	: Hydrophilic
Nominal Pressure (NP)	: 6 atm: 4.50 to 7.00mm 7 atm: 8.00 to 10.00 mm	Minimum Introducer Sheath Size	: 4.50-7.00 mm: 6 Fr 8.00-10.00 mm: 7 Fr
Rated Burst Pressure (RBP)	: 12 atm	Maximum Guide Wire Compatibility	: 0.035" guide wire
Balloon Crossing Profile:		Shelf Life	: 24 months
4.5 mm < 0.061"			
5.0 mm < 0.071"			
6.0 mm < 0.071"			
7.0 mm < 0.076"			
8.0 mm < 0.081"			
9.0 mm < 0.0915"			
10.0 mm < 0.0915"			

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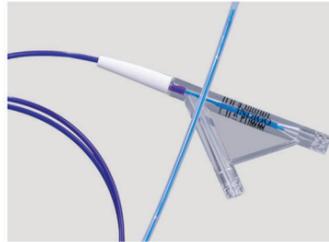
Compliance Chart
OTW PTA Balloon Compliance

Balloon Diameter (mm)	Inflation Pressure (atm)							
	2 atm	4 atm	6 atm	7 atm	8 atm	10 atm	12 atm	14 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
8.00	6.60	7.15	7.70	8.00	8.20	8.30	8.70	9.10
9.00	7.65	8.20	8.80	9.00	9.25	9.60	10.00	10.40
10.00	8.31	9.13	9.82	10.00	10.32	10.71	11.06	11.47
Nominal Pressure				Rated Burst Pressure				



INDIGO OTW™
PTA Balloon Catheter

Designed for smooth movement through long, tight peripheral lesions



Indigo OTW 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 rigidity of over-the-wire design and high-pressure balloon to allow clinicians a device for optimal balloon performance during peripheral interventions.

Targets lesions post-deployment and post-dilation incorporating the rigidity of over-the-wire design and high pressure balloon.

Key System Attributes:

■ Unique Exchangeability Feature :

Dual-port hub supports a dedicated channel for the guidewire along the entire catheter, providing the option to exchange with another or remove the catheter entirely while maintaining the wire's position, or remove the wire entirely and use the port for the injecting of dyes or medication. Providing flexibility to clinicians' during procedures.

■ High Pressure Dilation:

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 12 atm.

■ Enhanced Pushability & Navigation:

Continuous support of the wire allows the balloon to pass through tight stenoses and complex anatomy without kinking or bending.

■ Superior Visibility:

Dual platinum-iridium marker bands offer excellent radiopacity for clear, unambiguous positioning under fluoroscopy

Advanced Engineering for Clinical Excellence

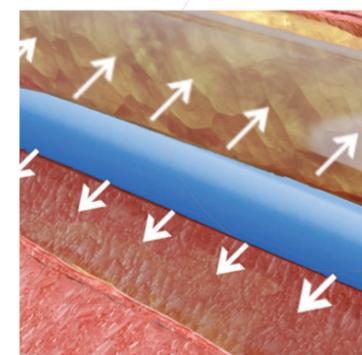
This page details the core technical features of the Catheter system and their direct clinical benefits during an angioplasty procedure

1. Lesion Crossing & System Deliverability

Feature	Technical Detail	Clinical Benefit
Tapered Tip Design	4.5 mm tapered tip length with a leading entry profile of 0.044" .	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 ≤0.0915	Greater variability in profile. 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.



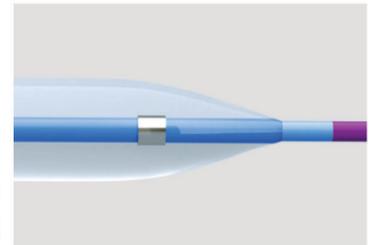
2. Controlled & Powerful Dilation



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 12 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 7 atm (balloon diameters; 8.00 to 10.00 mm) and 6 atm (balloon diameters: 4.50 to 7.00mm) , and a Rated Burst Pressure (RBP) of 12 atm .	Provides the necessary force to effectively dilate lesions, post stent deployment and/or standard post-dilation
Optimized Inflation	Dual-port hub allowing for simultaneous or separate management of balloon inflation/deflation, guide wire management, and/or fluid delivery.	dual-port design with larger lumen specifically for rapid deflation of the balloon, reducing the time the vessel is occluded during angioplasty

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.
Over-The-Wire System	Industry-standard Over-The-Wire (OTW) design with a 130cm total working length	Provides superior pushability, trackability, and exchangeability for wires, making it essential for complex, tortuous, or long, calcified lesions where maximum support and control are needed.



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