

A Better Tomorrow For All

In pursuit of Preservation of that priceless self, we have endeavoured through our commitment to Environmental Protection and Affordable Healthcare to achieve: "A better tomorrow for all". Kamal's dedicated 400+ workforce, through Amalgamation of Innovation and Technology, has enabled introduction of world class quality Products and Devices which have found ready acceptance and sustained support across a broad spectrum of users worldwide. Our Healthcare vertical is committed to your success with Best in Class Medical Devices and Services.



Kamal Encon Industries Limited

EN ISO 13485:2016 Certified Company

Phone:
+91 129 4198707
+91 70659 50917

E-mail
E : info@kamalmedtech.com
W : www.kamalmedtech.com

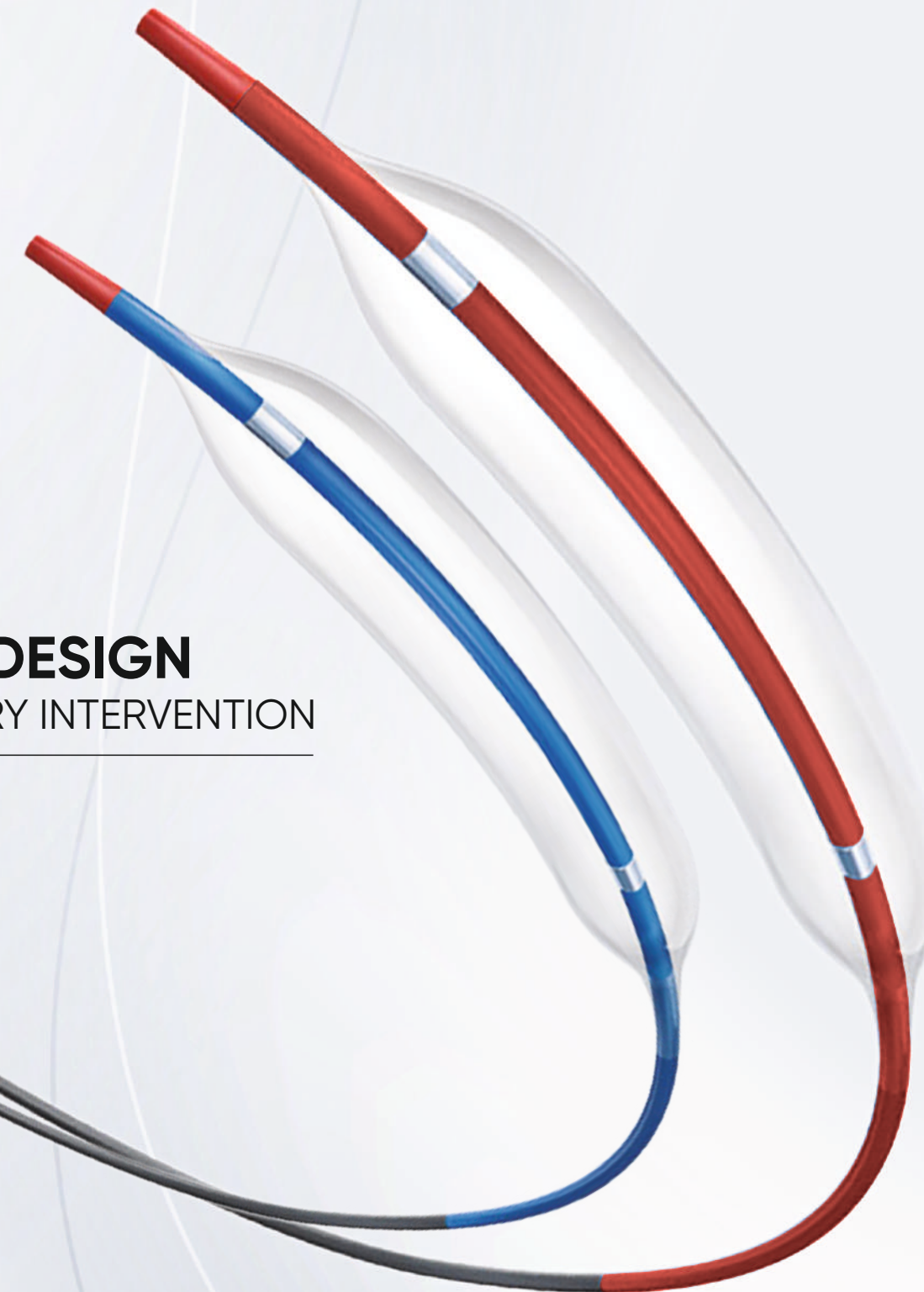
Address:
Plot No. 917, Sector 68,
IMT Faridabad-121001,
Haryana, India

POLARIS

PTCA Balloon Dilatation Catheter

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PTCA Balloon Dilatation Catheter



ULTIMATE DESIGN
FOR CORONARY INTERVENTION





The Ultimate Design For Coronary Intervention, Designed & Developed For Ultimate PTCA Experience

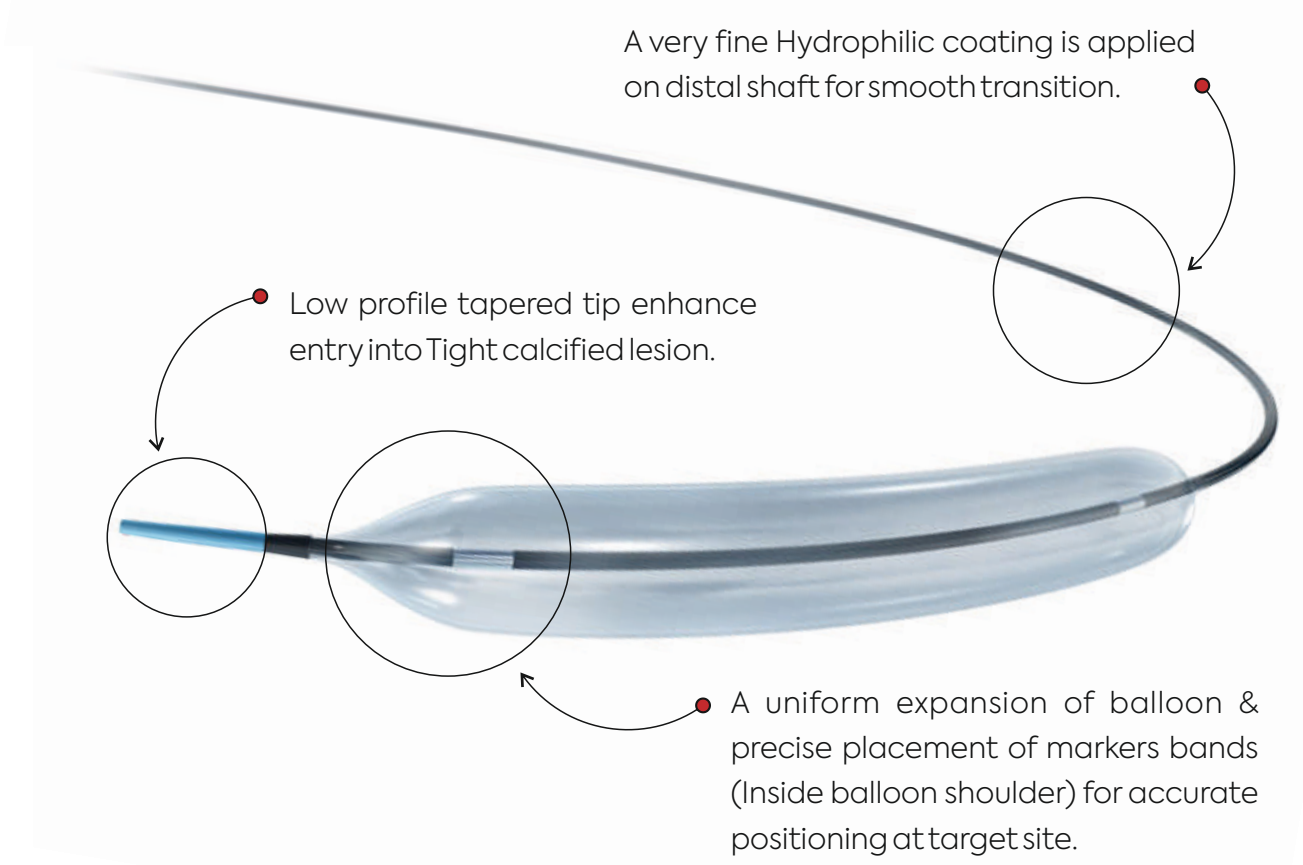
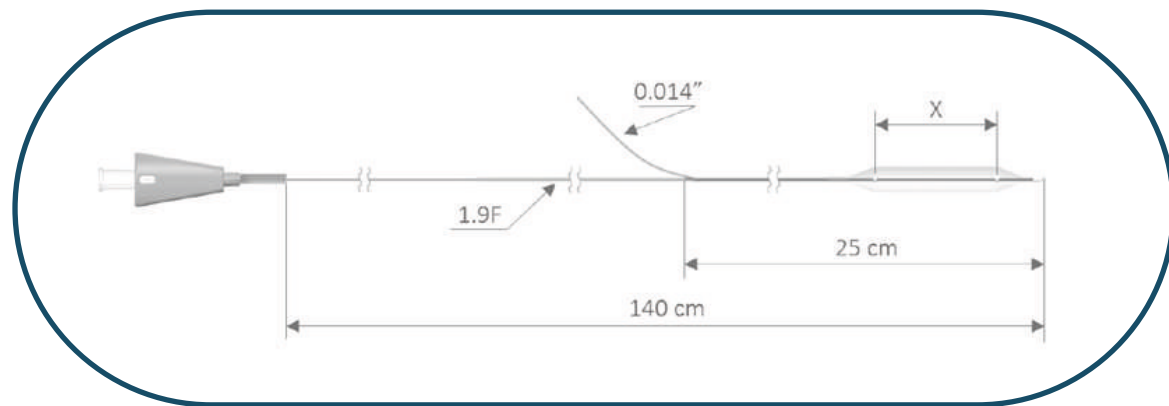
Polaris – Semi Compliant PTCA Balloon Dilatation Catheter

Main Features

- ☑ Crossability: Reduced tip & balloon profile
- ☑ Pushability: Improved Tensile resistance
- ☑ Trackability: Shorter & redesigned tip
- ☑ Low Compliance <8%
- ☑ Proprietary Hypotube for Smooth navigation at Target Lesion

Above features enable outstanding efficiency and performance on elder & diabetic patients as well as those with chronic total occlusions (CTO) or angulated, calcified & tight lesions.

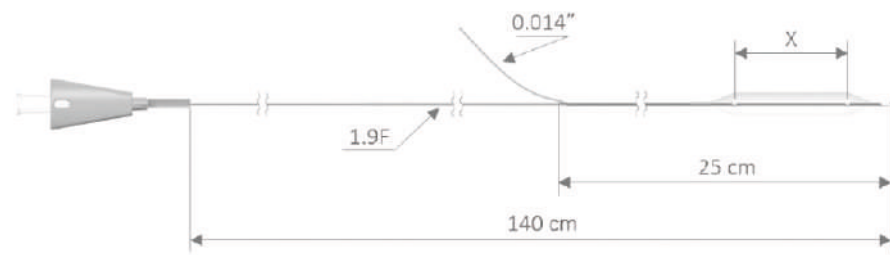
Super Combination between Hypotube & Distal shaft to enhance performance of Trackability & Pushability in tortuous path.



| Product Specifications | |
|--------------------------------|--|
| Generic Name | PTCA Semi-Compliant Rapid Exchange Dilatation Catheter |
| Product Name | Polaris PTCA Semi-Compliant Rapid Exchange Dilatation Catheter |
| Available lengths (mm) | 6, 8, 10, 12, 15, 20, 25, 30, 33, 38, 41 |
| Available Diameters (mm) | 1.50, 2.00, 2.25, 2.50, 2.75, 3.00, 3.25, 3.50, 3.75, 4.00, 4.50 |
| Balloon Material | Polyn® |
| Catheter Design | Rapid Exchange delivery system |
| Usable Shaft Length (cm) | 140 |
| Rapid Exchange length | 25cm |
| Guide wire Compatibility | 0.014" |
| Tip entry profile | 0.017" (0.43mm) |
| Sheath Compatibility | Minimum of 5F |
| Guiding catheter Compatibility | Minimum of 5F |
| Balloon Fold | 3 -fold memory |
| Radio opaque markers | Zero profile |
| Markers on the proximal shaft | 90cm and 100cm |
| Hydrophilic Coating | On the distal shaft |
| Shaft Diameter | Proximal 1.95F, Distal 2.70F |
| Balloon Properties | Nominal Pressure (NP): 8 atm Rated Burst Pressure (RBP): 14 atm & 16 atm depending on balloon size |

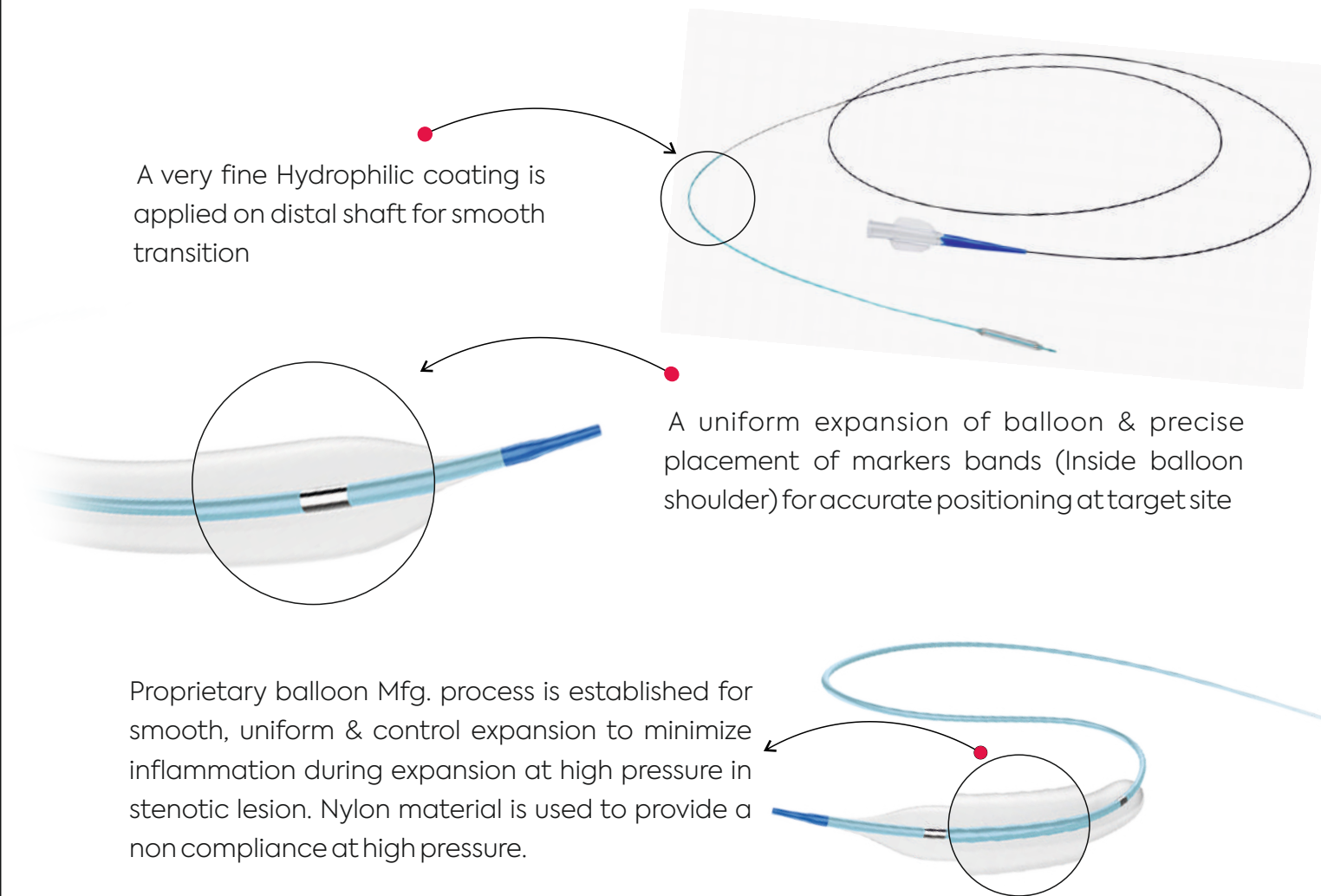
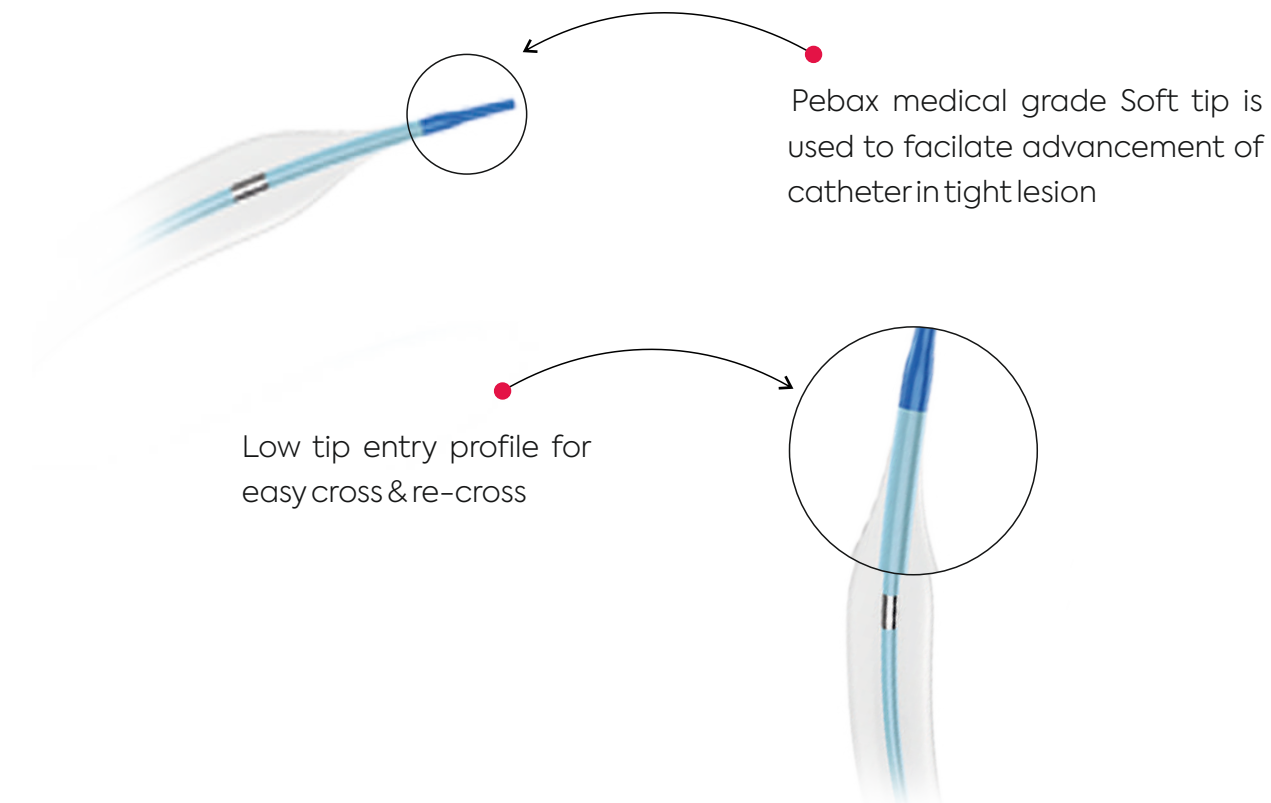
Polaris - Non Compliant PTCA Balloon Dilatation Catheter

Super Combination between Hypotube & Distal shaft to enhance performance of Trackability & Pushability in tortuous path.



Intended Use

Intended to dilate a stenotic portion of a native coronary artery or a bypass graft stenosis for the purpose of improving myocardial perfusion and to be used for post-dilatation of stents.



| Specifications Polaris PTCA Non-Compliant Dilatation Catheter | |
|---|--|
| Generic Name | PTCA Non-Compliant Dilatation Catheter |
| Product Name | Polaris PTCA Semi-Compliant Rapid Exchange Dilatation Catheter |
| Available lengths (mm) | 6, 8, 10, 12, 15, 20, 25, 30, 33, 38 |
| Available Diameters (mm) | 1.50, 2.00, 2.25, 2.50, 2.75, 3.00, 3.25, 3.50, 3.75, 4.00, 4.50, |
| Balloon Material | Polyn® |
| Catheter Design | Rapid Exchange delivery system |
| Usable Shaft Length (cm) | 140 |
| Rapid Exchange length | 25cm |
| Guide wire Compatibility | 0.014" |
| Tip entry profile | 0.017" (0.43mm) |
| Sheath Compatibility | Minimum of 5F |
| Guiding catheter Compatibility | Minimum of 5F |
| Balloon Fold | 3 -fold memory |
| Radio opaque markers | Zero profile |
| Markers on the proximal shaft | 90cm and 100cm |
| Hydrophilic Coating | On the distal shaft |
| Shaft Diameter | Proximal 1.95F, Distal 2.70F |
| Balloon Properties | Nominal Pressure (NP): 12 ATM and Rated Burst Pressure (RBP): 20 ATM |

Product Performance Qualification of SC & NC Balloon Dilatation Catheter

- ☑ Series of In - Vitro Engineering Bench test as per ISO 25539-2 & ISO 10555-4 have been performed: Pushability & Trackability, Balloon fatigue test, Guide wire friction test, Bond Strength, Corrosion resistance, pullback, Balloon Compliance, etc.
- ☑ Series of Biocompatibility Study have been performed as per ISO 10993
- ☑ Both devices (SC & NC) extensive Clinical studies has been carried out per MEDDEV guideline. Various criteria such as Pushability, trackability, crossing profile, kink resistance, soft tip, Radiopacity, deflation time, Balloon rewinding have been established in different types of tortuous lesion

Ordering Information

PTCA Semi Compliant Balloon Dilatation Catheter

| Diameter (mm) | Balloon Length (mm) | | | | | | | | | | |
|---------------|---------------------|---|----|----|----|----|----|----|----|----|----|
| | 6 | 8 | 10 | 12 | 15 | 20 | 25 | 30 | 33 | 38 | 41 |
| 1.5 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 2.0 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 2.25 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 2.5 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 2.75 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 3.0 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 3.25 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 3.5 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 3.75 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 4.0 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 4.5 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

PTCA Non Compliant Balloon Dilatation Catheter

| Diameter (mm) | Balloon Length (mm) | | | | | | | | | | |
|---------------|---------------------|---|----|----|----|----|----|----|----|----|---|
| | 6 | 8 | 10 | 12 | 15 | 20 | 25 | 30 | 33 | 38 | |
| 1.5 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 2.0 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 2.25 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 2.5 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 2.75 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 3.0 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 3.25 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 3.5 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 3.75 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 4.0 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 4.5 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

Compliance Chart

PTCA Semi Compliant Balloon Dilatation Catheter

| Pressure (atm) | Balloon Diameter (mm) | | | | | | | | | | |
|----------------|-----------------------|------|------|------|------|------|------|-------|-------|-------|------|
| | 1.50 | 2.00 | 2.25 | 2.50 | 2.75 | 3.00 | 3.25 | 3.50 | 3.75 | 4.00 | 4.50 |
| 2 | 1.21 | 1.71 | 1.96 | 2.21 | 2.46 | 2.71 | 2.96 | 3.21 | 3.46 | 3.71 | 4.16 |
| 4 | 1.31 | 1.81 | 2.06 | 2.31 | 2.56 | 2.81 | 3.06 | 3.31 | 3.56 | 3.81 | 4.28 |
| 6 | 1.41 | 1.01 | 2.16 | 2.41 | 2.66 | 2.91 | 3.16 | 3.41 | 3.66 | 3.91 | 4.4 |
| 8 | 1.50 | 2.00 | 2.25 | 2.50 | 2.75 | 3.00 | 3.25 | 3.5 | 3.75 | 4.00 | 4.5 |
| 10 | 1.54 | 2.06 | 2.31 | 2.56 | 2.81 | 3.06 | 3.31 | 3.56 | 3.78 | 4.08 | 4.58 |
| 12 | 1.58 | 2.12 | 2.37 | 2.62 | 2.87 | 3.12 | 3.37 | 3.62 | 3.89 | 4.16 | 4.66 |
| 14 | 1.62 | 2.18 | 2.43 | 2.68 | 2.93 | 3.18 | 3.43 | 3.68* | 3.96* | 4.24* | 4.74 |
| 16 | 1.66 | 2.24 | 2.49 | 2.74 | 2.99 | 3.24 | 3.49 | 3.74 | 4.02 | 4.3 | 4.8 |
| 18 | 1.69 | 2.27 | 2.52 | 2.78 | 3.03 | 3.29 | 3.55 | 3.8 | 4.08 | 4.36 | 4.86 |
| 20 | 1.72 | 2.30 | 2.55 | 2.82 | 3.07 | 3.34 | 3.6 | 3.86 | 4.14 | 4.42 | 4.92 |

Note: Gray Background: NP (Nominal Pressure) Blue Background: RBP: Rated Burst Pressure

Measured at 37.5°C, tolerance +/-0.1mm between nominal & RBP for balloon ≤ 41mm tolerance +/-0.2mm between nominal & RBP for balloon 45/49mm

* RBP = 14 for diameter 3.50, 3.75 with length>35mm and diameter 4.00 with length>30mm

PTCA Non Compliant Balloon Dilatation Catheter

| Pressure (atm) | Balloon Diameter (mm) | | | | | | | | | | |
|----------------|-----------------------|------|------|------|------|------|------|------|------|------|------|
| | 1.50 | 2.00 | 2.25 | 2.50 | 2.75 | 3.00 | 3.25 | 3.50 | 3.75 | 4.00 | 4.50 |
| 4 | 1.28 | 1.80 | 2.00 | 2.26 | 2.48 | 2.69 | 3.00 | 3.16 | 3.40 | 3.55 | 4.01 |
| 5 | 1.30 | 1.82 | 2.03 | 2.29 | 2.51 | 2.73 | 3.06 | 3.20 | 3.43 | 3.61 | 4.07 |
| 6 | 1.33 | 1.85 | 2.06 | 2.32 | 2.56 | 2.77 | 3.09 | 3.24 | 3.48 | 3.67 | 4.13 |
| 7 | 1.36 | 1.88 | 2.09 | 2.36 | 2.59 | 2.81 | 3.14 | 3.29 | 3.54 | 3.72 | 4.21 |
| 8 | 1.38 | 1.91 | 2.12 | 2.39 | 2.63 | 2.85 | 3.16 | 3.33 | 3.58 | 3.78 | 4.27 |
| 9 | 1.40 | 1.94 | 2.15 | 2.42 | 2.66 | 2.88 | 3.18 | 3.37 | 3.63 | 3.83 | 4.33 |
| 10 | 1.45 | 1.96 | 2.18 | 2.44 | 2.69 | 2.91 | 3.21 | 3.40 | 3.67 | 3.87 | 4.38 |
| 11 | 1.47 | 1.99 | 2.20 | 2.47 | 2.72 | 2.95 | 3.23 | 3.44 | 3.70 | 3.92 | 4.43 |
| 12 | 1.49 | 2.01 | 2.23 | 2.50 | 2.74 | 2.98 | 3.25 | 3.48 | 3.74 | 3.98 | 4.48 |
| 13 | 1.51 | 2.03 | 2.25 | 2.52 | 2.75 | 3.01 | 3.28 | 3.51 | 3.77 | 4.01 | 4.53 |
| 14 | 1.53 | 2.05 | 2.27 | 2.54 | 2.76 | 3.03 | 3.3 | 3.54 | 3.8 | 4.04 | 4.57 |
| 15 | 1.55 | 2.07 | 2.29 | 2.56 | 2.77 | 3.06 | 3.31 | 3.56 | 3.82 | 4.08 | 4.61 |
| 16 | 1.56 | 2.08 | 2.31 | 2.57 | 2.79 | 3.08 | 3.32 | 3.58 | 3.84 | 4.11 | 4.64 |
| 17 | 1.58 | 2.10 | 2.32 | 2.59 | 2.80 | 3.09 | 3.33 | 3.60 | 3.86 | 4.13 | 4.67 |
| 18 | 1.59 | 2.11 | 2.34 | 2.60 | 2.81 | 3.11 | 3.34 | 3.62 | 3.88 | 4.15 | 4.69 |
| 19 | 1.61 | 2.13 | 2.35 | 2.61 | 2.82 | 3.12 | 3.35 | 3.64 | 3.90 | 4.17 | 4.72 |
| 20 | 1.62 | 2.14 | 2.36 | 2.62 | 2.83 | 3.13 | 3.36 | 3.66 | 3.92 | 4.19 | 4.74 |
| 21 | 1.64 | 2.15 | 2.37 | 2.64 | 2.84 | 3.15 | 3.37 | 3.67 | 3.93 | 4.21 | 4.76 |
| 22 | 1.65 | 2.16 | 2.38 | 2.65 | 2.85 | 3.16 | 3.38 | 3.68 | 3.95 | 4.23 | 4.79 |
| 23 | 1.66 | 2.17 | 2.39 | 2.66 | 2.86 | 3.17 | 3.39 | 3.70 | 3.97 | 4.25 | 4.81 |
| 24 | 1.68 | 2.19 | 2.40 | 2.68 | 2.87 | 3.19 | 3.40 | 3.71 | 3.99 | 4.27 | 4.84 |
| 25 | 1.69 | 2.20 | 2.41 | 2.69 | 2.88 | 3.20 | 3.41 | 3.73 | 4.00 | 4.30 | 4.87 |

Note: Gray Background: NP (Nominal Pressure) Blue Background: RBP: Rated Burst Pressure

Measured at 37.5°C, tolerance +/-5% between nominal & RBP