## A Better Tomorrow For All

n pursuit of Preservation of that priceless self we have endeavored 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.

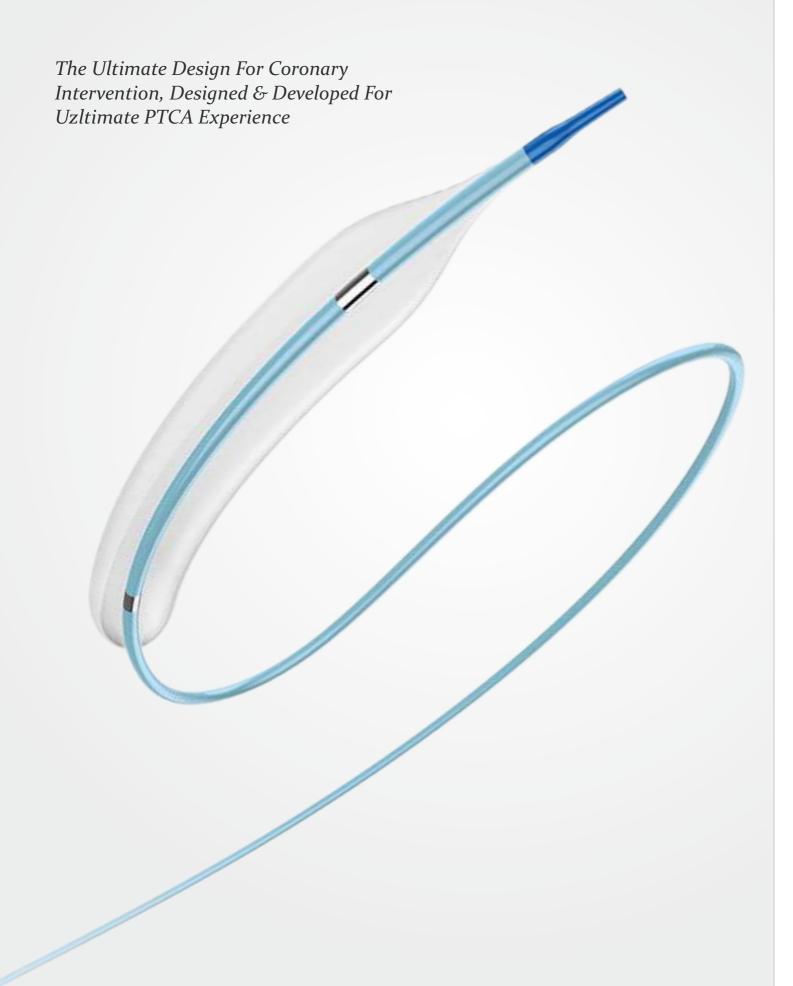


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POLARIS **ULTIMATE DESIGN** FOR CORONARY INTERVENTION

# POLARIS



Polaris – Semi Compliant PTCA Balloon Dilatation Catheter

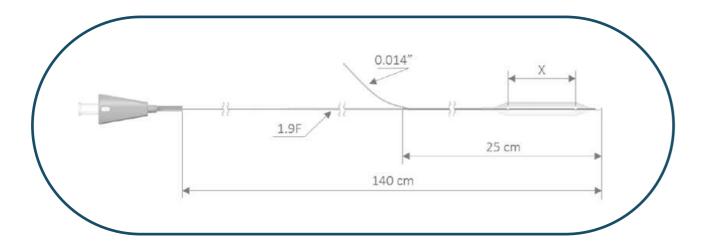
#### **Main Features**

- ✓ Crossability: Reduced tip & balloon profile
- ✓ Pushability: Improved Tensile resistance
- ☑ Trackability: Shorter & redesigned tip
- ✓ Low Compliance <8%</p>
- ✓ 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 (this is to use below schematic diagram of catheter)
- ✓ Low profile tapered tip enhance entry into Tight calcified lesion (use tip picture)
- A very fine Hydrophilic coating is applied on distal shaft for smooth transition (to use picture)
- ✓ A uniform expansion of balloon & precise placement of markers bands (Inside balloon shoulder) for accurate positioning at target site (use balloon expansion picture)



Polaris – PTCA Dilatation Balloon



## **Catheter (Semi-Compliant)**

### **INTENDED USE**

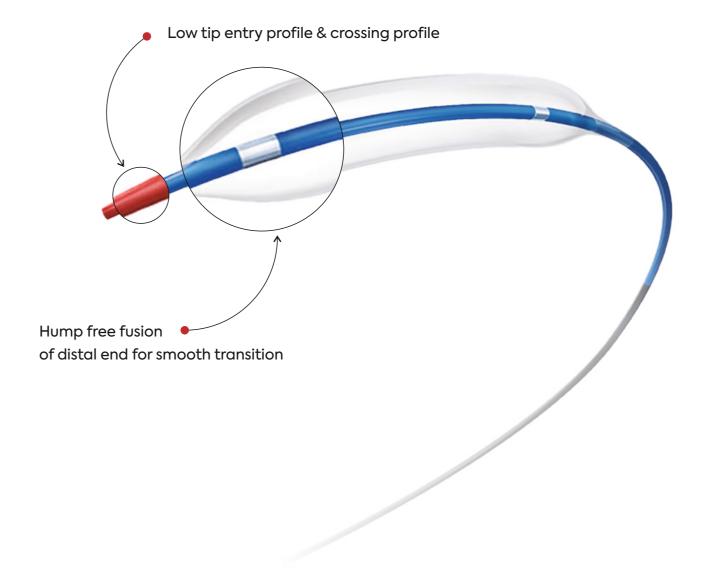
## Polaris PTCA Semi Compliant Dilatation Catheter is indicated for:

Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion.

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)	1.25, 1.50, 2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50					
Balloon Material	Polyn <sup>®</sup>					
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					

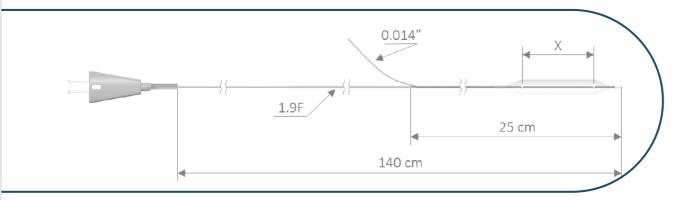
Pressure	Balloon Diameter (mm)											
atm	1.25	1.5	2	2.25	2.5	2.75	3	3.25	3.5	3.75	4	4.5
2	1	1.21	1.71	1.96	2.21	2.46	2.71	2.96	3.21	3.46	3.71	4.16
4	1.18	1.31	1.81	2.06	2.31	2.56	2.81	3.06	3.31	3.56	3.81	4.28
6	1.21	1.41	1.01	2.16	2.41	2.66	2.91	3.16	3.41	3.66	3.91	4.4
8	1,25	1.5	2	2.25	2.5	2.75	3	3.25	3.5	3.75	4	4.5
10	1.29	1.54	2.06	2.31	2.56	2.81	3.06	3.31	3.56	3.78	4.08	4.58
12	1.33	1.58	2.12	2.37	2.62	2.87	3.12	3.37	3.62	3.89	4.16	4.66
14	1.36	1.62	2.18	2.43	2.68	2.93	3.18	3.43	3.68*	3.96*	4.24*	4.74
16	1.39	1.66	2.24	2.49	2.74	2.99	3.24	3.49	3.74	4.02	4.3	4.8
18	1.41	1.69	2.27	2.52	2.78	3.03	3.29	3.55	3.8	4.08	4.36	4.86
20	1.43	1.72	2.3	2.55	2.82	3.07	3.34	3.6	3.86	4.14	4.42	4.92

**Note:** Grey background: NP (Nominal Pressure), Blue background: RBP (Rated Burst Pressure) Measured at 37.5C, tolerance +/-0.1mm between nominal & RBP for balloon  $\le 41$ mm\* RBP = 14 for diameter 3.50, 3.75 with length>35mm and diameter 4.00 with length>30mm



# Polaris – PTCA Dilatation Balloon Catheter (Non-Compliant)

- Super Combination between Hypotube & Distal shaft to enhance performance of Trackability & Pushability in tortuous path (this is to use below schematic diagram of catheter)
- Pebax medical grade Soft tip is used to facilate advancement of catheter in tight lesion (use tip picture)
- ✓ Low tip entry profile for easy cross & re-cross (use this feature along with above)
- A very fine Hydrophilic coating is applied on distal shaft for smooth transition (to use picture)
- A uniform expansion of balloon & precise placement of markers bands (Inside balloon shoulder) for accurate positioning at target site (use balloon expansion picture)
- Proprietary balloon Mfg. process is established for smooth, uniform & control expansion to minimize inflammation during expansion at high pressure in stenotic lesion. Nylon material is used to provide a non compliance at high pressure (used balloon expansion picture).



#### **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): 8 atm Rated Burst Pressure (RBP): 14 atm & 16 atm depending on balloon size						

Pressure	Balloon Diameter (mm)									
atm	1.5	2	2.5	2.75	3	3.5	4	4.5		
6	1.33	1.85	2.32	2.5	2.77	3.24	3.67	4.13		
7	1.36	1.88	2.36	2.55	2.81	3.29	3.72	4.21		
8	1.38	1.91	2.39	2.60	2.85	3.33	3.78	4.27		
9	1.4	1.94	2.42	2.64	2.88	3.37	3.83	4.33		
10	1.45	1.96	2.44	2.68	2.91	3.4	3.87	4.38		
11	1.47	1.99	2.47	2.72	2.95	3.44	3.92	4.43		
12	1.49	2.01	2.5	2.75	2.98	3.48	3.98	4.48		
13	1.51	2.03	2.52	2.76	3.01	3.51	4.01	4.53		
14	1.53	2.05	2.54	2.77	3.03	3.54	4.04	4.57		
15	1.55	2.07	2.56	2.78	3.06	3.56	4.08	4.61		
16	1.56	2.08	2.57	2.79	3.08	3.58	4.11	4.64		
17	1.58	2.1	2.59	2.81	3.09	3.6	4.13	4.67		
18	1.59	2.11	2.6	2.83	3.11	3.62	4.15	4.69		
19	1.61	2.13	2.61	2.85	3.12	3.64	4.17	4.72		
20	1.62	2.14	2.62	2.86	3.13	3.66	4.19	4.74		
21	1.64	2.15	2.64	2.88	3.15	3.67	4.21	4.76		
22	1.65	2.16	2.65	2.89	3.16	3.68	4.23	4.79		

Note: Grey background: NP (Nominal Pressure), Blue background: RBP (Rated Burst Pressure) Measured at 37.5C