

DynamX™ Coronary Bioadaptor System TECHNICAL SPECIFICATIONS

Bioadaptor Implant			
Stent Material	Cobalt Chromium, L-605		
Strut Thickness*	71 µm		
Drug and Drug Dose	Novolimus, a Sirolimus analogue - 5 µg / mm		
Polymer	Base Coat - PLLA-based Bioresorbable Polymer (~ 6 µm) Top Coat - PLGA Bioresorbable Polymer (~ 3 µm)		
Crossing Profile**	0.040", 1.02 mm		
Post dilatation limit	Stent Diameter	Post-dilatation Limit per IFU	Bench Testing Limit
	2.25 mm	2.75 mm	4.0 mm
	2.5 mm	3.0 mm	4.0 mm
	2.75 mm	3.25 mm	4.0 mm
	3.0 mm	3.5 mm	4.0 mm
	3.5 mm	4.0 mm	4.5 mm
Delivery System			
Balloon Material	Nylon Copolymer		
Working Catheter Length	140 cm		
Tip Entry Profile	0.017", 0.43 mm		
Marker Bands	Platinum Iridium, swaged		
Catheter Shaft Diameter	Distal Outer Shaft OD 2.7F / 0.89 mm Intermediate Shaft OD 2.5F / 0.85 mm Proximal Hypotube OD 1.95F / 0.65 mm		
Nominal Pressure	10 atm for 2.5, 3.0, 3.5 mm diameters 11 atm for 2.25 and 2.75 mm diameters		
Rated Burst Pressure	16 atm for 2.25 – 3.5 mm diameters		
Guide Wire Compatibility	0.014", 0.36 mm		
Guiding Catheter Compatibility	5F (min I.D. 0.058", 1.47 mm)		

* DynamX Bioadaptor diameters 2.25 mm – 3.0 mm

** DynamX Bioadaptor 2.5 mm diameter

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COMPLIANCE CHART

PRESSURE	2.25 mm	2.5 mm	2.75 mm	3.0 mm	3.5 mm
6 ATM	n/a	2.22	2.39	2.77	3.19
7 ATM	2.05	2.30	2.47	2.85	3.27
8 ATM	2.11	2.37	2.54	2.92	3.35
9 ATM	2.17	2.43	2.61	2.98	3.41
10 ATM	2.22	2.48 [nom]	2.67	3.03 [nom]	3.47 [nom]
11 ATM	2.26 [nom]	2.52	2.73 [nom]	3.07	3.52
12 ATM	2.31	2.56	2.78	3.11	3.57
13 ATM	2.34	2.60	2.82	3.15	3.61
14 ATM	2.38	2.64	2.86	3.19	3.65
15 ATM	2.42	2.67	2.90	3.23	3.69
16 ATM	2.46 [RBP]	2.70 [RBP]	2.94 [RBP]	3.26 [RBP]	3.72 [RBP]
17 ATM	2.49	2.74	2.98	3.30	3.76
18 ATM	2.53	2.77	3.01	3.34	3.79

Compliance for Bioadaptor lengths 14 mm – 38 mm
Not all sizes available in all geographies

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