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XIENCE Xpedition™ 48

Everolimus Eluting Coronary Stent System

Description: XIENCE Xpedition™ 48 Everolimus Eluting Coronary Stent System is comprised of four main components: 1) the efficacious low dose of the everolimus drug, 2) the cobalt chromium MULTI-LINK stent platform, 3) the fluorinated coating technology, and 4) a delivery system designed for improved deliverability to reach and cross lesions in the coronary artery.

System Highlights:

XIENCE Xpedition™ 48 Stent Features:

- Few and smooth transitions from the hypotube to the catheter tip for excellent support and flexibility.
- Superb tactile feel and less force is a required to cross challenging anatomy.
- An integrated tip for smooth tracking around sharp bends in tortuous anatomy.
- A transitionless design from the hypotube to the distal shaft for improved pushability.

Stent Technical Specifications

Material composition	L-605 Cobalt Chromium (Cobalt, Chromium, Tungsten, Nickel)
Degree of radiopacity	Comparable to XIENCE V™, XIENCE PRIME™, MULTI-LINK VISION™, MULTI-LINK 8™ Stents
MRI compatibility	Non-ferromagnetic (MRI compatible at field strengths up to and including 3 Tesla)
Metallic surface area (expanded)	13.3% Metal to artery ratio at 3.0 mm diameter
Stent design	Slotted tube stent, based on the MULTI-LINK stent design. There are two stent designs to maximize the flexibility, conformability, and expansion range of the various diameters. <ul style="list-style-type: none"> • The 2.50 – 3.25 mm diameter stent design has 6 crests, connected by non-linear links • The 3.50 mm diameter stent design has 9 crests, connected by non-linear links Both stent designs have a proximal end ring with symmetric crests and bar arms for improved pull back into the guide catheter

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Stent Technical Specifications	
Strut dimensions	Strut Thickness: 0.0032" for minimal vessel injury ¹
Longitudinal stability / deformation	Not prone to longitudinally deforming when an external force is applied to the stent
Percentage shortening on expansion (not longitudinal stent compression)	3.1% for 3.0 x 48 mm at nominal (stent lengthens 3.1%)
Degree of recoil of stent diameter	2.4% for 3.0 x 48 mm at nominal
Radial strength	3.0 x 48 mm - Nominal 1075 mmHg
Currently available diameters	2.5, 2.75, 3.0, 3.5 mm
Maximum stent expansion with post-dilatation:	2.5 mm diameters: 3.25 mm 2.75 - 3.00 mm diameters: 3.75 mm 3.5 mm diameters: 4.5 mm
Maximum circular unsupported area (MCUSA)	1.01 mm ²
Maximum circular access diameter (MCAD) (Largest diameter that can fit through struts)	1.13 mm
Available length	48 mm
Mechanism of deployment	Balloon expandable
Pre-mounted on delivery catheter	Yes
Balloon characteristics	The XIENCE Xpedition™ Stent System is delivered via a Pebax ¹ based balloon specifically designed to maximize the flexibility of the stent

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1- C.M. Agrawal, et al. Evaluation of poly (L-lactic acid) as a material for intravascular polymeric stents. Biomaterials 1992.

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Stent Delivery System Specifications	
Catheter	Rapid exchange
Max. guidewire diameter	0.014"
Tip entry profile (Average)	0.016" (3.00 x 48 mm)
Tip construction (laser bounded, tapered, etc.)	Tapered, integrated with distal shaft
Delivery balloon compliance	See compliance chart
Average crossing profile	2.5 x 48 mm: 0.048" 2.75 – 3.00 x 48 mm: 0.049" 3.5 x 48 mm: 0.053"
Nominal pressure	11 atm
Rated burst pressure (RBP)	18 atm
Position of radiopaque markers	Proximal and distal dual swaged markers clearly indicate both the position of the expanded stent and the balloon working length
Placement of stent on Markers	The stent edges are crimped on the middle of the Markers for stent placement accuracy
Width of markers	1.51 mm
Distance of marker from balloon shoulder	The outside edge of both the distal and proximal markers cannot lie more than 0.5mm into the balloon taper. The outside edge of the distal marker cannot be more than 1.0mm into the balloon working length.
Number of markers	All diameters have 2 markers
Marker material	Platinum Iridium
Delivery system shaft markers	95 cm and 105 cm proximal to the distal tip
Balloon taper length	2.02 mm for 3.0 x 48 mm
Stent-to-Balloon shoulder length	1.08 mm (3.0 x 48 mm)
Mechanism of expanding	The balloon of the stent delivery system has either three or five folds based on stent diameter to ensure uniform stent deployment
Balloon material	Multi-layer Pebax [†]
Folding of balloon	The 2.0-2.5 mm balloon has 3 folds configuration while the 2.75-4.0 mm has 5 folds configuration
Minimal internal diameter of guiding catheter	0.056" (5F) compatible for all lengths

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Stent Delivery System Specifications			
Recommended deployment pressure	In vitro nominal pressure is 11 atm for all diameters in saline. Clinically, recommended deployment pressure is between nominal and 18 atm according to lesion characteristics and to angiographic outcome		
Post-dilatation recommendation	At physician's discretion. The stent delivery system can be used for post-dilatation		
Distal shaft coating (not including working length of balloon)	Hydrophilic		
Length of catheter shaft	145 cm		
Stiffness of distal shaft	Soft		
Kinking resistance in transition zone	Transitionless design (skive)		
Minimum guiding catheter	5 French (0.056")		
Sterilization method	EtO (Ethylene Oxide Gas) sterilized		
Storage recommendation	15 - 30 °C		
Latex free declaration	Latex Free		
Heavy metals	No		
Chlorine bleached materials	No		
Shelf Life	36 months		
Shaft measurements	Proximal Max: 0.028"	Mid-Shaft Min: 0.035" Max: 0.038"	Distal Min: 0.032" Max: 0.034"

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Drug and Coating Technical Specifications										
Drug coating	Coating Technology: <ul style="list-style-type: none"> • Durability, flexibility and elasticity for stent coating use¹ • Attracts albumin to surface for thromboresistance^{2, 3} • Minimal inflammation⁴ • Fast and functional endothelialization^{5, 6, 7} 									
Drug dose	100 µg/cm ²									
Elution profile	80% at 30 days, 100% at 120 days									
Nominal total amount on stent (µg):	<table border="1"> <thead> <tr> <th>Stent Diameter (mm)</th> <th>Stent Length (mm)</th> <th>Drug Amount (µg)</th> </tr> </thead> <tbody> <tr> <td>2.5, 2.75, 3.0</td> <td>48</td> <td>227</td> </tr> <tr> <td>3.5</td> <td>48</td> <td>290</td> </tr> </tbody> </table>	Stent Diameter (mm)	Stent Length (mm)	Drug Amount (µg)	2.5, 2.75, 3.0	48	227	3.5	48	290
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Compliance Chart:

Pressure (atm)	Stent Diameter			
	2.5 mm	2.75 mm	3.0 mm	3.5 mm
8	2.35	2.65	2.81	3.31
9	2.40	2.71	2.87	3.38
10	2.45	2.76	2.92	3.45
11 (Nominal)	2.49	2.81	2.98	3.50
12	2.54	2.86	3.02	3.56
13	2.58	2.90	3.07	3.60
14	2.61	2.93	3.11	3.65
15	2.64	2.97	3.14	3.68
16	2.67	2.99	3.17	3.71
17	2.69	3.01	3.19	3.74
18 (RBP)	2.71	3.04	3.21	3.76
19	2.73	3.06	3.23	3.79
20	2.75	3.08	3.25	3.81

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1. Ding, N. I., et al. "XIENCE V™ Stent Design and Rationale." Journal of Interventional Cardiology 2009; 22: S18-S27.
2. Szott, L. M., et al. "Blood compatibility assessment of polymers used in drug eluting stent coatings." Biointerphases 2016; 11(2): 029806.
3. Panchalingam V., et al. ASAIO J 1993;39:M305-M309.
4. Otsuka, et al. JACC: Cardiovasc Interv 2015; 8: 1248-1260.
5. Perkins, et al. Journal of Interventional Cardiology 2009; 22: S28-S40.
6. Chinn, et al. J Biomed Mater Res, 1998; 39: 130-140.
7. Joner, et al. JACC, 2008;52: 333-342.

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