

TECHNICAL SPECIFICATIONS

DESCRIPTION:

The BioFreedom™ Drug Coated Coronary Stent System (BioFreedom™ DCS) is a polymer-free combination product consisting of two key components: a stent coated abluminally with the active ingredient BA9™ (Biolimus A9™), and a delivery system for intracoronary use.

COMPONENT DESCRIPTION:

- A balloon expandable intra-coronary 316L stainless steel stent abluminally coated with BA9™ drug pre-mounted on to a semi-compliant rapid exchange balloon delivery system;
- The delivery system has two radiopaque markers that fluoroscopically mark the ends of the stent to facilitate accurate placement;
- At the proximal end of the delivery system is a female luer lock connector hub which connects to the balloon inflation device;
- The guidewire enters the distal tip of the catheter and exits 23 cm proximal to the tip of the delivery system.

COATING COMPONENT DESCRIPTION:

- BA9™, a proprietary formulation of umirolimus, is a semi-synthetic sirolimus derivative with enhanced pharmacokinetic properties;
- BA9™ drug on the BioFreedom™ DCS, inhibits smooth muscle cell proliferation within the stent proximity;
- BA9™ is directly coated onto the microstructured abluminal surface of the stent

INDICATIONS:

The BioFreedom™ polymer-free DCS is indicated for improving coronary luminal diameter for the treatment of *de novo* lesions in native coronary arteries with a reference diameter ranging from 2.25 mm and 4.00 mm (see "Instructions For Use" for more details). Stents with length 33 mm and 36 mm are only available for artery diameters ranging between 2.5 mm and 3.5 mm.

STENT DELIVERY SYSTEM:

Catheter design	Rapid Exchange	
Usable shaft length	142 cm	
Proximal shaft design	Hypotube	
Proximal shaft coating	PTFE	
Proximal shaft profile	2.0 F / 0.0265" / 0.67 mm	
Shaft markers placement	90 and 100 cm from tip	
Distal shaft profile (3.0 mm)	Length 8-18 mm	2.6 F / 0.034" / 0.86 mm
	Length 24-36 mm	2.8 F / 0.036" / 0.92 mm
Lesion entry profile	0.018" / 0.46 mm	
Balloon material	Polyamide Elastomer	
Balloon compliance	Semi-compliant	
Balloon folding	Tri-Fold	
Balloon cone	30 degrees	
Radiopaque markers	2 swaged platinum/iridium marker bands	
Length of balloon markers	1 mm	
Nominal pressure	6 atm (608 kPa)	
Rated Burst Pressure	16 atm (1621 kPa)	2.25-3.00 mm
	14 atm (1418 kPa)	3.50-4.00 mm
Guiding catheter compatibility	6 F (min I.D. 0.070") / 1.78 mm	
Guide wire compatibility	0.014" / 0.36 mm	
Hydrophilic coating	W-ll coating	



STENT PLATFORM:

Stent material	Stainless steel 316 L	
Stent platform	Juno™ Stent	
Strut design	Corrugated rings	
Link design	Quadrature Link™	
Strut thickness	0.0047" / 0.12 mm	
Strut length	1.2 mm (6- and 9-crown model)	
Stent crowns	6 crowns (2.25 mm-3.00 mm)	
	9 crowns (3.50 mm-4.00 mm)	
Crossing profile (3.0 mm)	Length 8-28 mm	0.045" / 1.14 mm
	Length 33 & 36 mm	0.047" / 1.19 mm
Flexibility	Very good	
Radiopacity	Good	
Ferromagnetism	Non ferromagnetic (MRI safe)	
Open cell diameter 6-crown model (3.0 mm)	1.56 mm	
Foreshortening	0.39%*	
Elastic recoil	2.46%*	
Radial strength	> 0.67 bar / 500 mmHg	

* Bench test data on file at Biosensors International N=10 (3.0x28 mm stents)

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DRUG:

Drug name	BA9™ (Biolimus A9™)
BA9™ drug dosage	15.6 µg/mm stent length

COATING:

Coating formulation	BA9™ drug
Coating configuration	Abluminal

COMPLIANCE TABLE:

		Stent Internal Diameter (mm) by stent platform									
		For stent lengths from 8 to 28 mm						For stent lengths of 33 and 36 mm			
Pressure (atm)	6 Nominal Pressure (NP)	2.25	2.50	2.75	3.00	3.50	4.00	2.50	2.75	3.00	3.50
	7	2.28	2.53	2.78	3.03	3.53	4.03	2.53	2.78	3.04	3.55
	8	2.31	2.56	2.81	3.06	3.56	4.06	2.56	2.81	3.08	3.60
	9	2.34	2.59	2.84	3.09	3.59	4.09	2.59	2.84	3.12	3.65
	10	2.37	2.62	2.87	3.12	3.62	4.12	2.62	2.87	3.16	3.70
	11	2.40	2.65	2.90	3.15	3.65	4.15	2.65	2.90	3.20	3.75
	12	2.43	2.68	2.93	3.18	3.68	4.18	2.68	2.93	3.24	3.80
	13	2.46	2.71	2.96	3.21	3.71	4.21	2.71	2.96	3.28	3.85
	14 Rated Burst Pressure (RBP)	2.49	2.74	2.99	3.24	3.74	4.24	2.74	2.99	3.32	3.90
	15	2.52	2.77	3.02	3.27			2.77	3.02	3.36	
16 Rated Burst Pressure (RBP)		2.55	2.80	3.05	3.30			2.80	3.05	3.40	

ORDERING INFORMATION:

		Stent Length (mm)							
Stent Diameter		8	11	14	18	24	28	33	36
2.25 mm	BFR1-2208	BFR1-2211	BFR1-2214	BFR1-2218	BFR1-2224	BFR1-2228			
2.50 mm	BFR1-2508	BFR1-2511	BFR1-2514	BFR1-2518	BFR1-2524	BFR1-2528	BFR1-2533	BFR1-2536	
2.75 mm	BFR1-2708	BFR1-2711	BFR1-2714	BFR1-2718	BFR1-2724	BFR1-2728	BFR1-2733	BFR1-2736	
3.00 mm	BFR1-3008	BFR1-3011	BFR1-3014	BFR1-3018	BFR1-3024	BFR1-3028	BFR1-3033	BFR1-3036	
3.50 mm	BFR1-3508	BFR1-3511	BFR1-3514	BFR1-3518	BFR1-3524	BFR1-3528	BFR1-3533	BFR1-3536	
4.00 mm	BFR1-4008	BFR1-4011	BFR1-4014	BFR1-4018	BFR1-4024	BFR1-4028			

Class III device, Rules 8, 13; MDD 93/42/EC:

Single Use Product
Sterile unless package is open or damaged
Do not reuse or resterilize
The product is LATEX & PVC FREE

Sterilization method: E-BEAM

CE certification: DEKRA 0344

Shelf life: 18 months

Storage Conditions:

Store between 0°C and 25°C

For further information or assistance, please contact:

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