BioMatrix NeoFlex™

BIOSENSORS INTERNATIONAL™

TECHNICAL SPECIFICATIONS

DESCRIPTION:

The BioMatrix NeoFlex™ Drug Eluting Coronary Stent System (BioMatrix NeoFlex™ DES) is a Drug Eluting Stent (DES) System for coronary use with a biodegradable polymer coating. The DES is a combination product comprised of two key components: the stent, which includes the active BA9™ pharmaceutical ingredient (Biolimus A9™) incorporated into a polymer coating, and the delivery system.

COMPONENT DESCRIPTION:

- A balloon expandable intra-coronary 316L stainless steel stent with an abluminal biodegradable polymer coating containing BA9™ drug pre-mounted onto 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 proper stent placement
- At the proximal end of the delivery system is a female luer lock connector hub which connects to the balloon inflation lumen
- The guidewire enters the distal tip of the catheter and exits 27.5 cm proximal to the tip of the delivery system.

COATING COMPONENT DESCRIPTION:

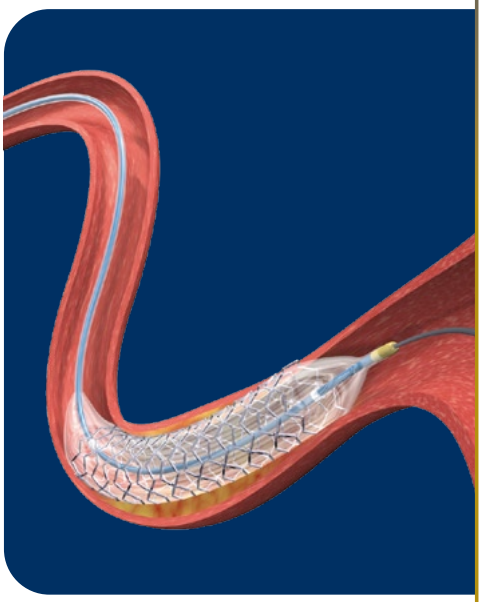
- BA9™, a proprietary formulation of umirolimus, is a semi-synthetic sirolimus derivative with enhanced pharmacokinetic properties
- BA9™ drug on the BioMatrix NeoFlex™ DES, inhibits muscle cell proliferation within the stent proximity
- Poly-lactic acid (PLA) acts as a carrier for the drug and biodegrades along with the drug elution.

INDICATIONS:

The BioMatrix NeoFlex™ abluminal biodegradable polymer DES is indicated for improving coronary luminal diameter and reducing stent restenosis 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.
The BioMatrix NeoFlex™ DES with stent lengths up to 28 mm is also indicated for use in patients with **ST Elevated Myocardial Infarction** (STEMI), **Acute Coronary Syndromes** (ACS, including ACS-STEMI, ACS-NSTEMI and Unstable angina) and **Diabetes Mellitus**.

STENT DELIVERY SYSTEM:

Catheter design	Rapid Exchange	
Usable shaft length	142 cm	
Proximal shaft design	Hypotube	
Proximal shaft coating	Polyamide Jacket	
Proximal shaft profile	2.1 F / 0.0274" / 0.70 mm	
Shaft markers placement	90 and 100 cm from tip	
Distal shaft profile	3.0 mm	2.4 F/0.031”/0.79 mm (2.25-3.00 mm)
	4.0 mm	2.6 F/0.034”/0.86 mm (3.50-4.00 mm)
Lesion entry profile	0.016” based on bench test results*	
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	0.5/0.9mm (distal/proximal)	
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	5 F - 2.25 - 3.00 mm	
	6 F - 3.50 - 4.00 mm	
Guide wire compatibility	0.014"/ 0.36 mm	
Hydrophilic coating	W-II coating	



STENT PLATFORM:

Stent material	Stainless steel 316 L
Strut design	Corrugated rings
Link design	Quadrature Link™ (with "S" connector)
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)
Stent crossing profile (max)	0.045" / 1.14 mm (3.0 mm, ≤ 28mm stent length)
Flexibility	Very good
Radiopacity	Good
Ferromagnetism	Non ferromagnetic (MRI safe)
Open cell diameter 6-crown model (3.0 mm)	1.56 mm
Foreshortening	≤ 10%
Elastic recoil	≤ 5%
Radial strength	> 0.67 bar / 500 mmHg

* Bench test data on file at Biosensors International (3.00mm x 18mm)

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DRUG:

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

POLYMER:

PLA (Poly-Lactic Acid)	Biodegradable polymer

COATING:

Coating formulation	PLA/BA9™ drug
Nominal coating thickness	11 µm
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	BMXP-2208	BMXP-2211	BMXP-2214	BMXP-2218	BMXP-2224	BMXP-2228		
2.50 mm	BMXP-2508	BMXP-2511	BMXP-2514	BMXP-2518	BMXP-2524	BMXP-2528	BMXP-2533	BMXP-2536
2.75 mm	BMXP-2708	BMXP-2711	BMXP-2714	BMXP-2718	BMXP-2724	BMXP-2728	BMXP-2733	BMXP-2736
3.00 mm	BMXP-3008	BMXP-3011	BMXP-3014	BMXP-3018	BMXP-3024	BMXP-3028	BMXP-3033	BMXP-3036
3.50 mm	BMXP-3508	BMXP-3511	BMXP-3514	BMXP-3518	BMXP-3524	BMXP-3528	BMXP-3533	BMXP-3536
4.00 mm	BMXP-4008	BMXP-4011	BMXP-4014	BMXP-4018	BMXP-4024	BMXP-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:	12 months

Storage Conditions:

Store between 0°C and 25°C

For further information or assistance, please contact:

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