BioMatrix Flex™
DRUG ELUTING STENT SYSTEM

BIOSENSORS INTERNATIONAL™

TECHNICAL SPECIFICATIONS

DESCRIPTION:

The BioMatrix Flex™ Drug Eluting Coronary Stent System (BioMatrix Flex™ 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 23 cm proximal to the tip of the delivery system.

COATING COMPONENT DESCRIPTION:

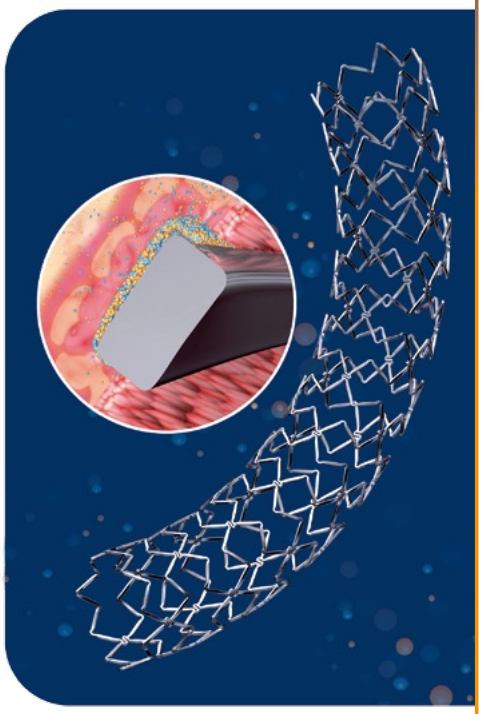
- BA9™, a proprietary formulation of umirolimus, is a semi-synthetic sirolimus derivative with enhanced pharmacokinetic properties
- BA9™ drug on the BioMatrix Flex™ DES, inhibits muscle cell proliferation within the stent proximity
- Poly-lactic acid (PLA) acts as a carrier for the drug and biodegrades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

INDICATIONS:

The BioMatrix Flex™ 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 Flex™ 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	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 / 0.037” / 0.94 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	5 F (min I.D. 0.056") / 1.42 mm for 6-crown stent	
	6 F (min I.D. 0.070") / 1.78 mm for 9-crown stent	
Guide wire compatibility	0.014"/ 0.36 mm	
Hydrophilic coating	W-II 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 (3.5 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

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	BMX-2208	BMX-2211	BMX-2214	BMX-2218	BMX-2224	BMX-2228		
2.50 mm	BMX-2508	BMX-2511	BMX-2514	BMX-2518	BMX-2524	BMX-2528	BMX-2533	BMX-2536
2.75 mm	BMX-2708	BMX-2711	BMX-2714	BMX-2718	BMX-2724	BMX-2728	BMX-2733	BMX-2736
3.00 mm	BMX-3008	BMX-3011	BMX-3014	BMX-3018	BMX-3024	BMX-3028	BMX-3033	BMX-3036
3.50 mm	BMX-3508	BMX-3511	BMX-3514	BMX-3518	BMX-3524	BMX-3528	BMX-3533	BMX-3536
4.00 mm	BMX-4008	BMX-4011	BMX-4014	BMX-4018	BMX-4024	BMX-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: 24 months

Storage Conditions:

Store between 0°C and 25°C

For further information or assistance, please contact:

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