

↔ 42&48 mm

## TECHNICAL SPECIFICATIONS

### DESCRIPTION:

The BioFreedom™ Drug Coated Coronary Stent System (BioFreedom™ DCS) is a **polymer-free** and carrier-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; (*abluminal coating, - angl.*);
- 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.

*-limus klasės vaistu stentas padengtas be polimerinio sluoksnio; limus klasės*

### COATING COMPONENT DESCRIPTION:

- The BA9™ drug (USAN/INN: umirolimus) is a semi-synthetic sirolimus derivative with increased lipophilicity;
- 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. (*vaistas pritvirtintas tiesiogiai ant specialiai paruošto stento viso paviršiaus*)

### INDICATIONS:

The BioFreedom™ polymer-free and carrier-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 models above 28mm are only available for artery diameters ranging between 2.5 mm and 3.5 mm.

### ANTIPLATELET REGIME - CE Mark one month DAPT

In patients at High Bleeding Risk (HBR), physicians may choose a **one month dual antiplatelet regimen** for an active stent, based on results of the randomized, double-blind LEADERS FREE trial, conducted in 2'466 patients demonstrating superior safety and efficacy outcomes for the BA9™ DCS versus a BMS with one month of dual antiplatelet therapy, followed by single antiplatelet therapy alone.<sup>11</sup> BioFreedom now listed as stent of choice in ESC DAPT guidelines, for 1 month-ultra short DAPT in patients with stable CAD in whom longer DAPT regimes pose safety concerns<sup>2</sup>.

*gydymą dviem antiagregantais nutraukti po vieno mėnesio*

### STENT DELIVERY SYSTEM:

Catheter design	Rapid Exchange	
Usable shaft length	142 cm <i>visos sistemos ilgis - ne mažesnis kaip 140 cm;</i>	
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)	0.043" / 1.09 mm*	
Lesion entry profile	0.018" / 0.46 mm	
Balloon material	Polyamide Elastomer	
Balloon compliance	<b>Semi-compliant</b> <i>balionėlis, ant kurio užmautas stentas - dalinai kintamo diametro (semi-compliant, - angl.)</i>	
Balloon folding	Tri-Fold	
Balloon cone	30 degrees	
Radiopaque markers	2 swaged platinum/iridium marker bands <i>balionėlio rentgeno kontrastiniai žymekliai įspausti į kateterį (neišsikiše).</i>	
Length of balloon markers	1 mm	
Nominal pressure	6 atm (608 kPa) <i>nominalusis slėgis - ne didesnis nei 6 atm</i>	
<i>darbinis slėgis - ne mažesnis 16 atm;</i>	16 atm (1621 kPa)	2.25-3.00 mm
Rated Burst Pressure	14 atm (1418 kPa)	3.50-4.00 mm
Guiding catheter compatibility	5 F (min I.D. 0.056") / 1.42 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 <i>žiedinės struktūros su</i>	
Link design	Quadrature Link™ <i>ketvirtinėmis jungtimis</i>	
Strut thickness	<b>120 μm</b> <i>stento sienelės storis (strut thickness, - angl.) - ne didesnis kaip 0,0047" (0,12 mm);</i>	
Strut length	1.2 mm (6- and 9-crown model)	
Stent crowns	6 crowns: 2.25-3.00 mm	9 crowns: 3.50-4.00 mm
Crossing profile (3.0mm stent)	0.043" / 1.09 mm*	
Flexibility	Very good	
Radiopacity	Good	
Ferromagnetism	Non ferromagnetic (MRI safe)	
Open cell diameter 6-crown model (3.0 mm)	1.68 mm*	
Foreshortening	0.96%*	
Elastic recoil	3.02%*	
Radial strength	> 0.67 bar / 500 mmHg	

### CELL OPENING<sup>3\*</sup>:

	6-crown stent	9-crown stent
Stent over expansion outer diameter <sup>3*</sup>	4.60 mm (stent post-dilated with 4.5 mm balloon)	6.05 mm (stent post-dilated with 6.0 mm balloon)
Cell over-expansion perimeter <sup>4*</sup>	17.25 mm (stent post-dilated with 3.5 mm balloon)	15.80 mm (stent post-dilated with 4.0 mm balloon)
Maximum cell opening <sup>3*</sup>	2.61 mm (stent post-dilated with 4.5 mm balloon)	2.25 mm (stent post-dilated with 6.0 mm balloon)
Cell over-expansion diameter <sup>4*</sup>	3.58 mm (stent post-dilated with 3.5 mm balloon)	3.18 mm (stent post-dilated with 4.0 mm balloon)

\* Biosensors International Group Ltd. Internal bench testing report report SR-10401.

1. BioFreedom IFU 10870.3-000 - Rev.07, 12102-000 - Rev.01 - 2. Page 19 European Heart Journal (2018) 39, 213-254. - 3. BioFreedom™ stent 3.0x18 mm, N=1, BioMatrix NeoFlex™ stent 4.0x18 mm, N=1.

4. BioMatrix Flex™ stent 3.0 mm, N=1, BioMatrix Flex™ stent 3.5 mm, N=1 - All balloons used for cell over-expansion were deployed at NP.

5. **Caution:** In vitro testing only. Overexpansion increases stent stiffness which may increase the risk of metal fatigue and the potential risk of fractures over time. Dilatation beyond stent labelled is not recommended as mechanical efficiency and drug delivery efficiency both remain unknown under such extreme overexpansion. Physicians should refer to the product IFU.

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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:

Pressure (atm)	Stent Internal Diameter (mm) by stent platform										
	For stent lengths from 8 to 28 mm						For stent lengths of 33 to 48 mm				
	2.25	2.50	2.75	3.00	3.50	4.00	2.50	2.75	3.00	3.50	
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 diameter	Stent Length (mm)									
	8	11	14	18	24	28	33	36	42	48
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	BFR1-2542	BFR1-2548
2.75 mm	BFR1-2708	BFR1-2711	BFR1-2714	BFR1-2718	BFR1-2724	BFR1-2728	BFR1-2733	BFR1-2736	BFR1-2742	BFR1-2748
3.00 mm	BFR1-3008	BFR1-3011	BFR1-3014	BFR1-3018	BFR1-3024	BFR1-3028	BFR1-3033	BFR1-3036	BFR1-3042	BFR1-3048
3.50 mm	BFR1-3508	BFR1-3511	BFR1-3514	BFR1-3518	BFR1-3524	BFR1-3528	BFR1-3533	BFR1-3536	BFR1-3542	BFR1-3548
4.00 mm	BFR1-4008	BFR1-4011	BFR1-4014	BFR1-4018	BFR1-4024	BFR1-4028				

*diametrai - 2,25 mm, 2,50 mm, 2,75 mm, 3,00 mm, 3,50 mm ir 4,00 mm*

### 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:

Do not store above 25° C

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CAUTION: The law restricts these devices to sale by or on the order of a physician and these products are intended for the use by or under the direction of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Not available in the United States and any other country where applicable health authority product registration has not been obtained. Information contained herein only for presentation outside the US and France. © 2020 Biosensors International Group, Ltd. All rights reserved.

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