# BioFreedom™

POLYMER- & CARRIER-FREE DRUG-COATED CORONARY STENT SYSTEM

BIOSENSORS INTERNATIONAL™

↔ 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;
- 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:

- 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.

## 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 mmn (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.'[1] 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[2].

## 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) | 0.043" / 1.09 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 | |
| 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 | 120 µm | |
| 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[5]: | 6-crown stent | 9-crown stent |
|---|---|---|
| Stent over expansion outer diameter[3]* | 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[4]* | 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[3]* | 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[4]* | 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 balloon 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:

| | | Stent Internal Diameter (mm) by stent platform | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | For stent lengths from 8 to 28 mm | | | | | | For stent lengths of 33 to 48 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 | 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 | | | | |

## 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



## For further in formation or assistance, please contact:

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