BioFreedom™
DRUG-COATED CORONARY STENT SYSTEM

The world's first polymer-free stent with BA9™

Ordering Information

	Stent Length (mm)							
Stent Diameter (mm)	**8**	**11**	**14**	**18**	**24**	**28**	**33**	**36**
2.25	BFR1-2208	BFR1-2211	BFR1-2214	BFR1-2218	BFR1-2224	BFR1-2228	NA	NA
2.50	BFR1-2508	BFR1-2511	BFR1-2514	BFR1-2518	BFR1-2524	BFR1-2528	BFR1-2533	BFR1-2536
2.75	BFR1-2708	BFR1-2711	BFR1-2714	BFR1-2718	BFR1-2724	BFR1-2728	BFR1-2733	BFR1-2736
3.00	BFR1-3008	BFR1-3011	BFR1-3014	BFR1-3018	BFR1-3024	BFR13028	BFR1-3033	BFR1-3036
3.50	BFR1-3508	BFR1-3511	BFR1-3514	BFR1-3518	BFR1-3524	BFR1-3528	BFR1-3533	BFR1-3536
4.00	BFR1-4008	BFR1-4011	BFR1-4014	BFR1-4018	BFR1-4024	BFR1-4028	NA	NA

1. Clinical studies exploring this potential are in progress
2. In vivo data shows that approximately 2% of BA9 remains on the stent after 28 days. Data on file at Biosensors International
3. Adapted from Grube E., oral presentation TCT 2010

BioFreedom™ drug-coated stent is CE Mark approved.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Not available for sale in the United States and certain other countries.

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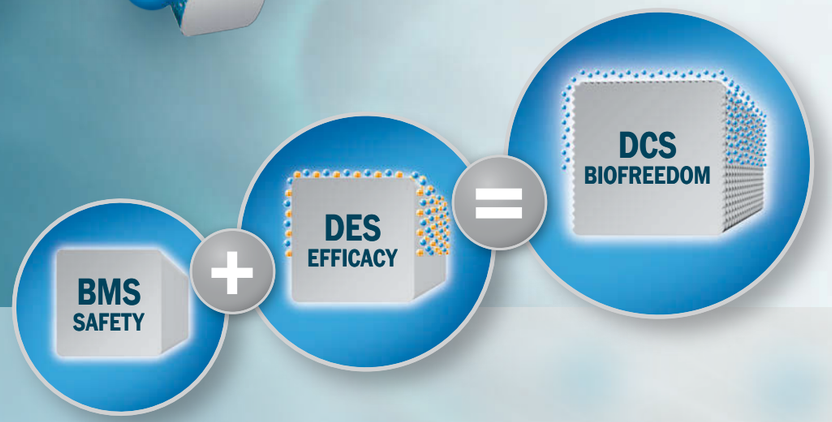
BIOSENSORS INTERNATIONAL™

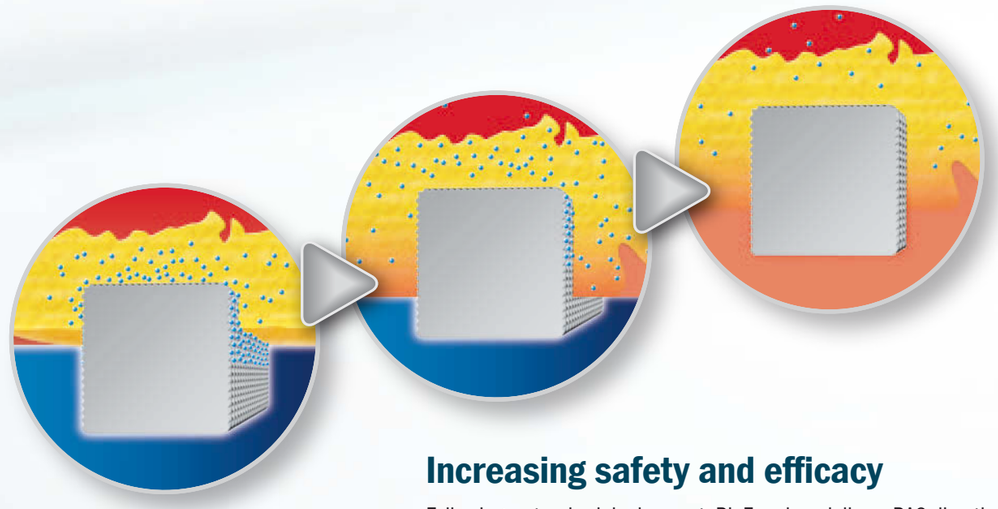
Expanding the therapeutic horizon for physicians

Changing the script

Drug Eluting Stents (DES) are proven to reduce the risk of restenosis and improve outcomes for patients with more complex coronary disease. However, in certain patients where there is a requirement to avoid prolonged Dual Anti-Platelet Therapy (DAPT), Bare Metal Stents (BMS) may be preferred.

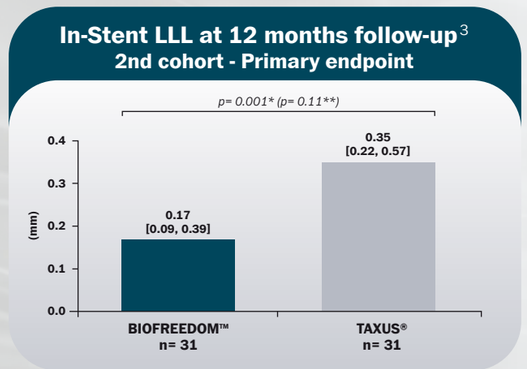
BioFreedom™, as a Drug-Coated Stent (DCS), combines the advantages of both DES and BMS.
It delivers an effective anti-restenotic therapy with Biolimus A9™, and may shorten the required DAPT[1] regime.





Increasing safety and efficacy

Following a standard deployment, BioFreedom delivers BA9 directly from the abluminal surface to the surrounding vessel wall. After about 28 days, when approximately 98% of the BA9 has been transferred, the BioFreedom stent structure remains acting like a Bare Metal Stent[2].



*Non-inferiority tests based on the mean. **Superiority tests. All values are presented as median [IQR].

Delivering true innovation

BioFreedom ensures effective drug release kinetics without the need for a polymer carrier. BioFreedom is a true drug-coated stent, with BA9™ directly coated only on the abluminal metal surface of the platform. This innovation has been made possible by the unique combination of two Biosensors' technologies:

- A stent surface micro-structured treatment (SMS)
- The proprietary BA9 drug developed specifically for use with stents

BA9 has increased lipophilic properties differentiating it from the other limus drugs. This increased lipophilicity delivers improved local action on vascular smooth muscle cells, and aids rapid transfer to cells in the vessel wall,reducing systemic exposure.

Metal and drug – nothing else

The Biosensors' SMS surface treatment technology modifies only the abluminal surface of the stent. The resultant surface structure retains the BA9, allowing controlled and progressive release into the surrounding vessel wall after deployment.

Evidence-based approach

CE Mark approval was supported by strong positive data from the BioFreedom First in Man study[3]. At 12 months, BioFreedom demonstrated non-inferiority to Taxus® Liberté® ($p_{non\text{-}inferiority}$ = 0.001) with a trend towards superior efficacy. Median late lumen loss (LLL) with BioFreedom was 0.17 mm, compared to 0.35 mm in the Taxus® Liberté® group.

BIOFREEDOM™