HBR SMS BA9

BioFreedom™

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

Powered by BA9™ BIOLIMUS A9™

Freedom to treat

BIOSENSORS INTERNATIONAL™

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Freedom to treat

Meeting the Need of High Bleeding Risk (HBR) Patients

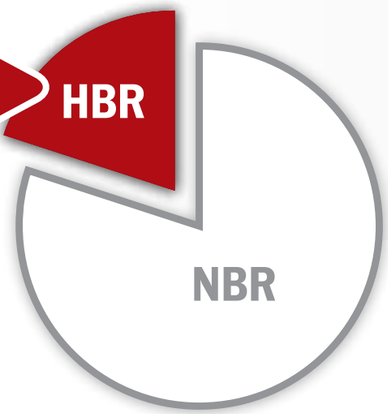
At least 20% of PCI patients are High Bleeding Risk (HBR) where there is a need to avoid prolonged dual antiplatelet therapy (DAPT).[1-9] BioFreedom, as a Drug-Coated Stent (DCS), is safer and more efficacious than BMS in High Bleeding Risk patients.

By directly delivering BA9 - an effective anti-restenotic therapy - without polymer or carrier and becoming a BMS at 28 days, the DAPT regime can be shortened when treating patients with the BioFreedom stent.

High Bleeding Risk (HBR)
Normal Bleeding Risk (NBR)

20%

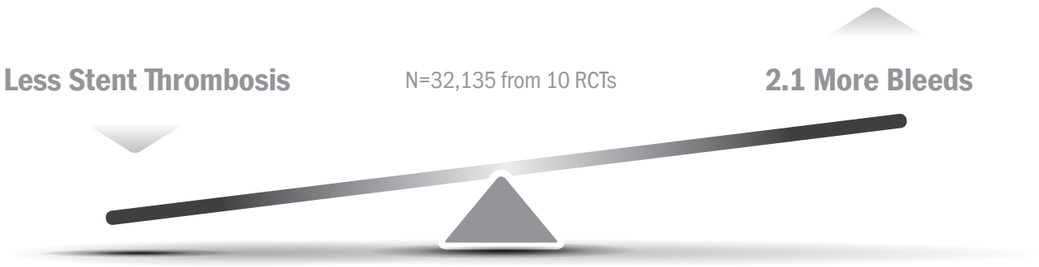
- Age ≥ 75 yrs[1,2]
- Oral Anticoagulation (OAC) after PCI[3]
- Planned major surgery <12 months[4,5]
- History of bleeding/stroke[5,6]
- Anemia (severe)[7]
- Chronic Kidney Disease (CKD)[1]
- Cancer[1]
- Other (DAPT intolerance, poor adherence, Dengue fever)



DAPT = dual antiplatelet therapy

Balancing the Ischemic & Bleeding Risk for HBR Patients with 1 Month DAPT

1 Less Stent Thrombosis N=32,135 from 10 RCTs **2.1 More Bleeds**



Recent meta-analysis[10] indicates that long-term DAPT prevents 1 Stent Thrombosis but increases bleeding by 2.1 events.*

LEADERS FREE

The landmark trial (Prospective, Double Blind Randomised (1:1)) evaluating BioFreedom (DCS) in High Bleeding Risk (HBR) patients with 1 month DAPT

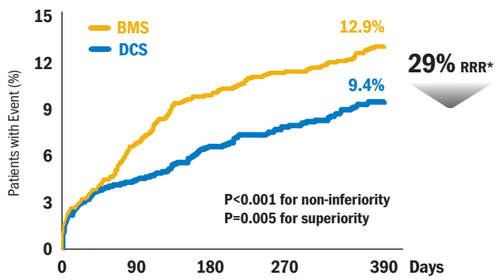
BioFreedom is the only active stent with 1 month DAPT that has demonstrated superior outcomes to BMS[11]

With LEADERS FREE, BioFreedom becomes the standard of care for High Bleeding Risk (HBR) patients[11]

Significantly Safer than BMS[11]

29% Reduction in the Rate of the Composite of Cardiac Death, MI, ST

Primary Safety Endpoint (Composite of Cardiac Death, MI, ST)



Number at Risk

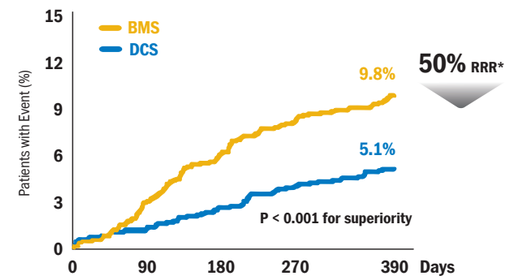
DCS	1221	1146	1105	1081	1045
BMS	1211	1115	1066	1037	1000

390 days chosen for assessing primary endpoint to capture potential events driven by the 360 day follow up contact
Hazard Ratio (HR) 0.71; 95% CI : 0.56 to 0.91; P = 0.005 for superiority
* Relative Risk Reduction

Significantly more Effective than BMS[11]

50% Reduction in the Rate of Restenosis

Primary Efficacy Endpoint (Clinically-Driven TLR)



Number at Risk

DCS	1221	1167	1130	1098	1053
BMS	1211	1131	1072	1034	984

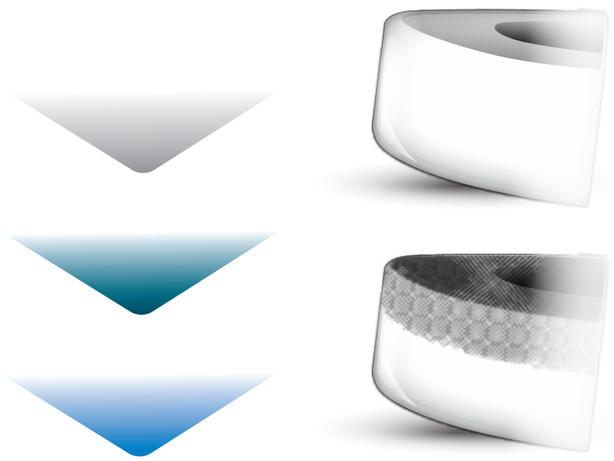
390 days chosen for assessing primary endpoint to capture potential events driven by the 360 day follow up contact
Hazard Ratio (HR) 0.50; 95% CI : 0.37 to 0.69; P<0.001 for superiority
* Relative Risk Reduction

BioFreedom achieves this because of it unique characteristics ... and allows for 1 month DAPT!

SMS, Selectively Micro-structured Surface

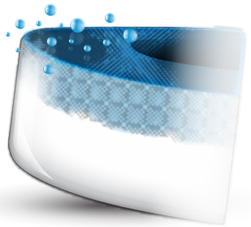
Only the abluminal surface of the stent receives SMS treatment, allowing BA9 to be contained on the micro-structured surface and delivered with high specificity to the vessel wall of the coronary lesions.

With no need for polymer or carrier, BA9 and SMS make BioFreedom a true **Drug-Coated Stent (DCS).**



STENT PLATFORM

SMS TREATMENT (ABLUMINAL SURFACE)



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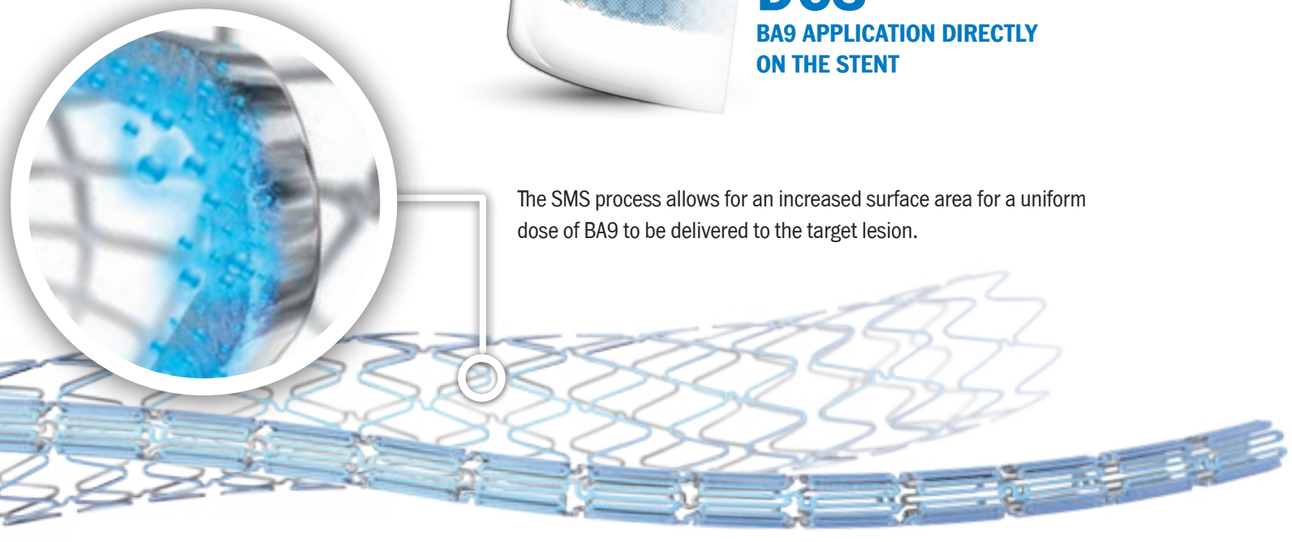
DCS

BA9 APPLICATION DIRECTLY ON THE STENT



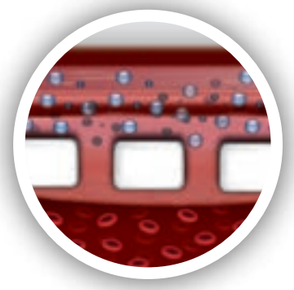
The SMS process allows for an increased surface area for a uniform dose of BA9 to be delivered to the target lesion.

BA9, Designed for Vascular Stent Technologies

- BA9, an effective Cytostatic Limus Drug
- Rapid BA9 Transfer Enhanced by High Lipophilicity
- High Local Bioavailability:
  - Targeted Drug Release
  - Sustained Tissue Release, with Therapeutic Effect up to 100 days[12,13]
  - Longer Half Life than other Commonly used Limus Drugs approximately 20 days in tissue[12,13]
  - Potent Neointimal Suppression

Increasing Safety and Efficacy

By leaving a bare metal stent luminal surface, BioFreedom promotes rapid re-endothelialization and therefore may improve the healing process and allow for very short DAPT regimes.

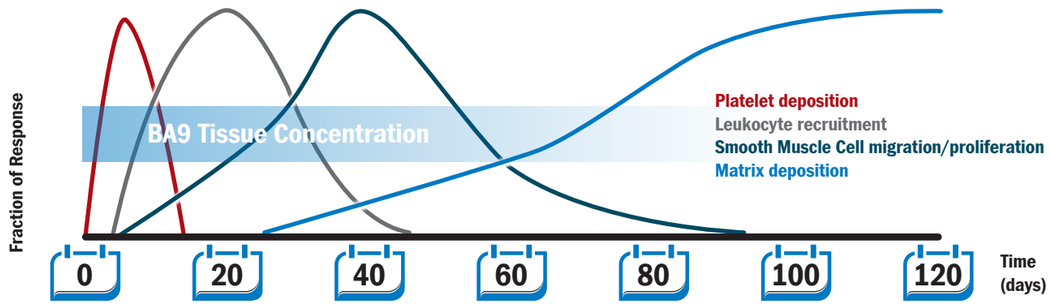


Optimizing Healing to Allow for Very Short DAPT

After about 28 days approximately 98% of BA9 is released from the stent.[12]

From Drug-Coated Stent to Bare Metal Stent

Following Local Tissue Warehousing of BA9, the Bare Metal Stent Heals Rapidly Allowing for Very Short DAPT



Adapted from Garasic J, Rogers C, Edelman ER. Stent design and the biologic response. In: Beyar R, Keren G, Leon MB, et al., eds. Frontiers in Interventional Cardiology. London: Martin Dunitz; 1997:95-100.

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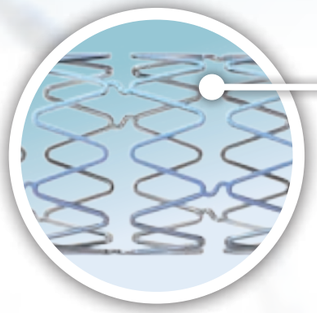
Juno Stent Platform

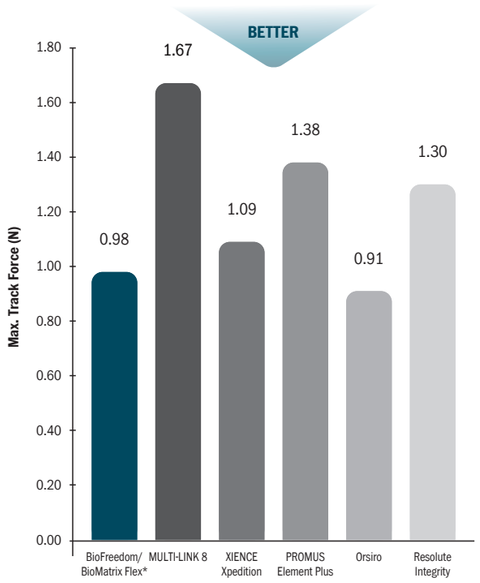
Stent Platform Optimised for Delivery to the Coronary Lesion



Largest Cell Openings & Lowest Longitudinal Stent Deformation of 2nd Generation DES

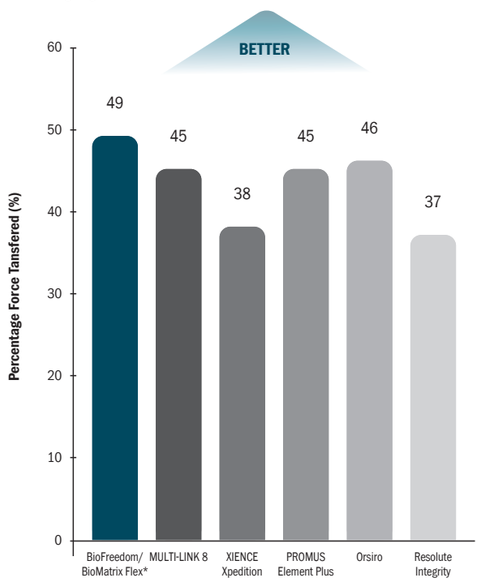
Trackability

Lower peak force represents better trackability, which allows better navigation of the delivery system through the blood vessels



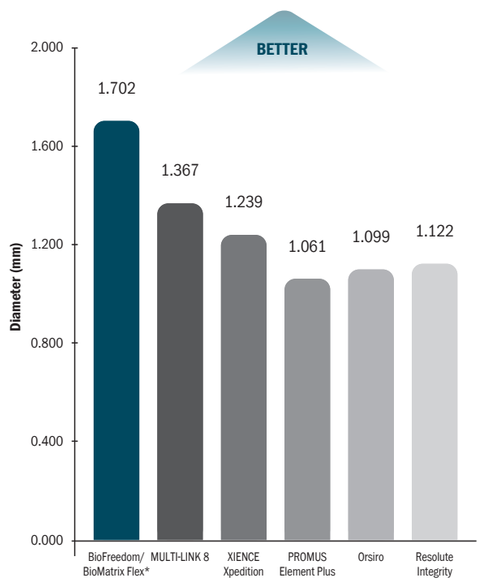
Pushability

Higher pushability is desired to increase the efficiency of the force exerted by the clinician to move the catheter through blood vessels and advance through tight lesions

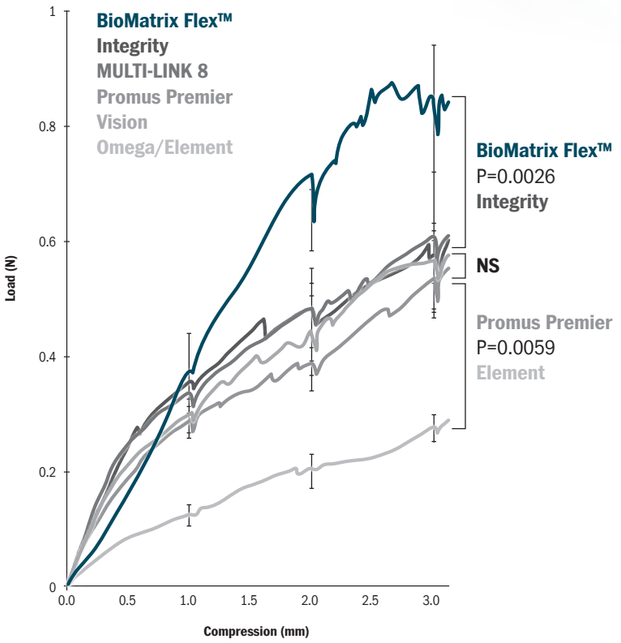


Cell Opening Diameter

Large cell opening diameter is desirable, as it provides better access to side branch for subsequent stents



Longitudinal Compression Lowest Longitudinal Stent Deformation of 2nd GEN[14]



* Shares same metal platform and delivery system.

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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	BFR1-3028	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. Rao et al. AHJ 2013;166:273-281.e4
2. Rittger H et al. Herz 2014;39(2):212-8
3. Faxon et al. Circ Cardiovasc Interv 2011;4:522-34
4. De Biase et al. Transl Med 2015;11(3):14-23
5. To et al. Circ Cardiovasc Interv-2009;2:213-21
6. Wiviott et al. NEJM 2007;357:2001-15
7. Pilgrim et al. Circ Cardiovasc Interv. 2012;5:202-210
8. Shanmugam VB et al. Journal of Geriatric Cardiology 2015;12:174−184
9. Urban P. et al. Am Heart J 2013;165:704-9
10. Guistino et al. JACC 2015;65:1298−310
11. Urban et al. New England Journal of Medicine 2015; published ahead of print October 14. DOI: 10.1056/NEJMoa1503943
12. Tada et al. Circulation: Cardiovascular Interventions. 2010;3:174-183
13. Internal BioFreedom Tissue PK Report
14. Ormiston, John A., et al. "Stent Longitudinal Strength Assessed Using Point Compression Insights From a Second-Generation, Clinically Related Bench Test." Circulation: Cardiovascular Interventions 7.1 (2014): 62-69.

* Bleedings were defined as: 1) TIMI major or minor 2) type 3 or 5 BARC; 3) STEEPLE major bleeding; or 4) GUSTO moderate or severe bleeding

BioFreedom™ Drug-Coated Stent is CE Mark approved. Data on file at Biosensors International for any sustained claims in this brochure.

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.

www.biosensors.com

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