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.

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*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
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). BioFreedom, as a Drug-Coated Stent (DCS), is safer and more efficacious than BMS in High Bleeding Risk patients.

By directly delivering B9 - 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)

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

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

Significantly Safer than BMS
- 29% Reduction in the Rate of the Composite of Cardiac Death, MI, ST

Significantly more Effective than BMS
- 50% Reduction in the Rate of Restenosis

Recent meta-analysis indicates that long-term DAPT prevents 1 Stent Thrombosis but increases bleeding by 2.1 events.*
BioFreedom achieves this because of its 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).

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

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**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
  - Longer Half Life than other Commonly used Limus Drugs approximately 20 days in tissue
- 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**

Juno Stent Platform

Stent Platform Optimised for Delivery to the Coronary Lesion

**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.

* Shows same metal platform and delivery system.
Freedom to treat

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