



**BIOFREEDOM™**  
POLYMER- & CARRIER-FREE DRUG-COATED CORONARY STENT SYSTEM

Powered by  
**BA9™**  
BIOLIMUS A9



Freedom to treat  
with the power of Biolimus A9

**Ordering Information**

Stent Diameter (mm)	Stent Length (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. Cell Cycle is a the growth cycle of eukaryotic cells. It is divided into five stages, known as G 0, in which the cell is quiescent, G 1 and G 2, in which it increases in size, S, in which it duplicates its DNA, and M, in which it undergoes mitosis and divides
  2. Virmani Opinion & Tada et al Circulation: Cardiovascular Interventions.2010;3:174-183
  3. Tada et al. Circulation: Cardiovascular Interventions. 2010;3:174-183
  4. Internal BioFreedom Tissue PK Report
- \* Data on File

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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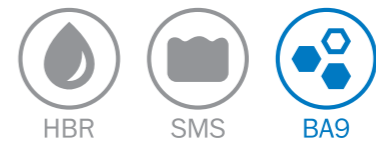
[www.biosensors.com](http://www.biosensors.com)

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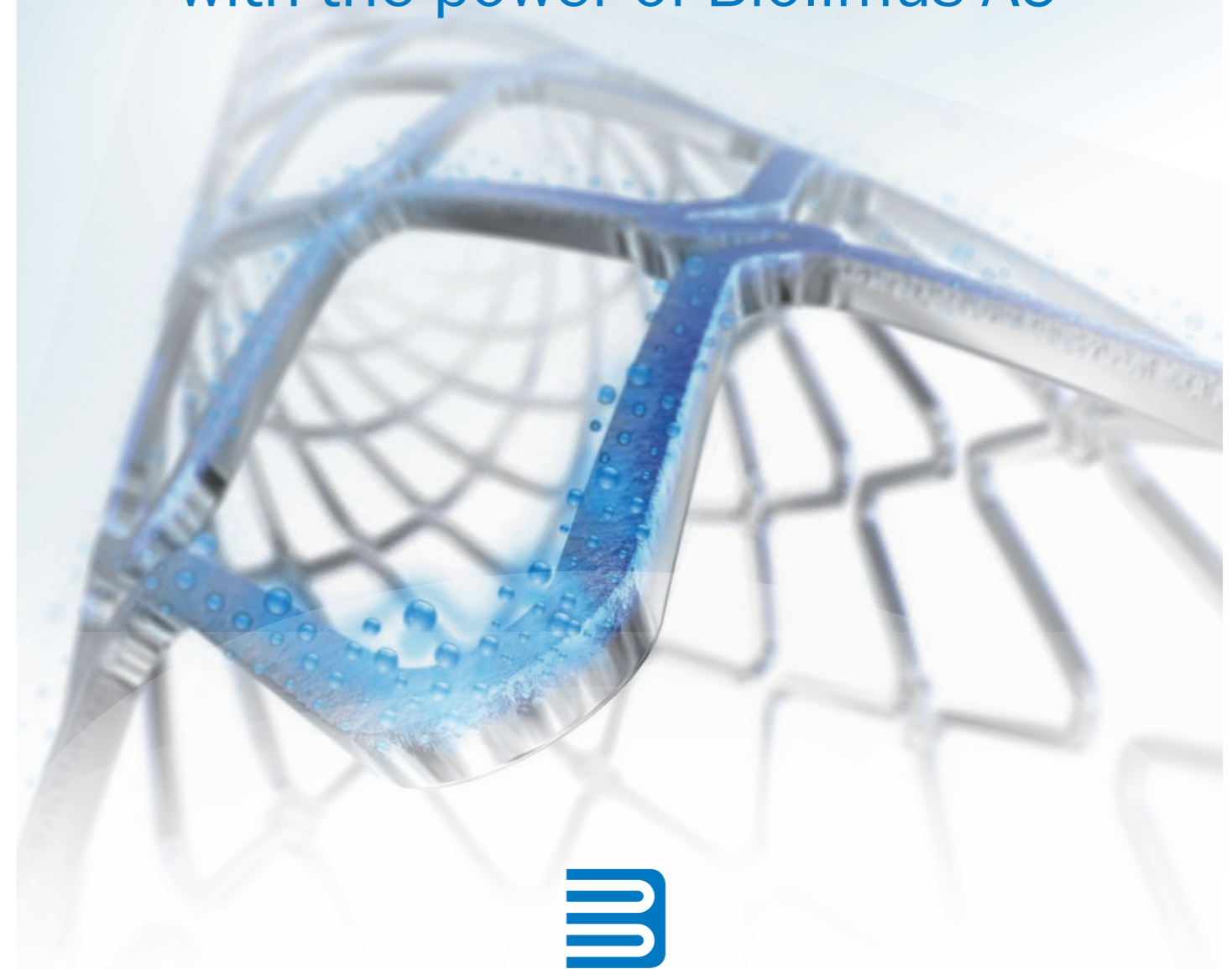
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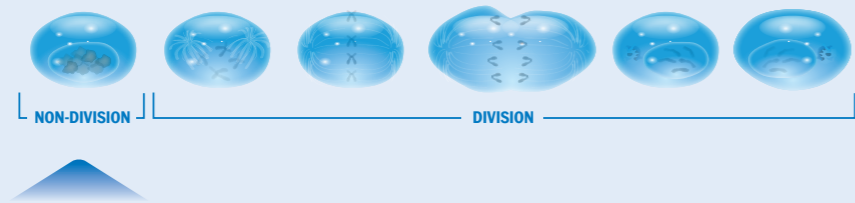
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## Freedom to treat



### BA9, Designed for Vascular Stent Technologies

The design of the BioFreedom stent and inherent properties of BA9 enable sustained drug delivery without the need for a polymer or carrier to control release.

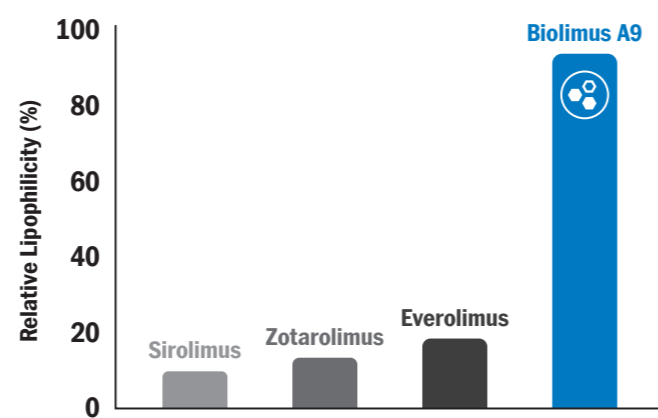


### BA9, an Effective Cytostatic Limus Drug

BA9 inhibits cell proliferation by arresting the Cell Cycle.<sup>1</sup>  
BA9 acts on several cell types, including vascular smooth muscle cells.

### Rapid BA9 Transfer Enhanced by High Lipophilicity

- Due to its chemical structure, BA9 has very high lipophilicity resulting in:
  - Rapid transfer of BA9 from the abluminal surface of the polymer free BioFreedom stent to the arterial wall
  - Minimising systemic loss and maximising the amount of drug available to the tissue
- BA9 has demonstrated safety and efficacy with no evidence of cellular necrosis and minimal inflammatory response in animal studies.<sup>2</sup>



+/- 2.8% (valid for all drugs tested). Data on file at Biosensors.

BA9 is designed for targeted local applications such as with drug eluting or drug-coated stents.

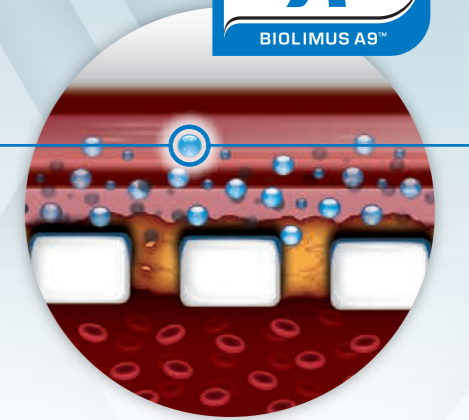
Up to 10x the Lipophilicity of other common limus drugs used on current DES

### High Local Bioavailability:

#### - Targeted Drug Release

BA9's combination of high lipophilicity and long half life allow it to be warehoused in the vessel wall, resulting in targeted and sustained local drug release.

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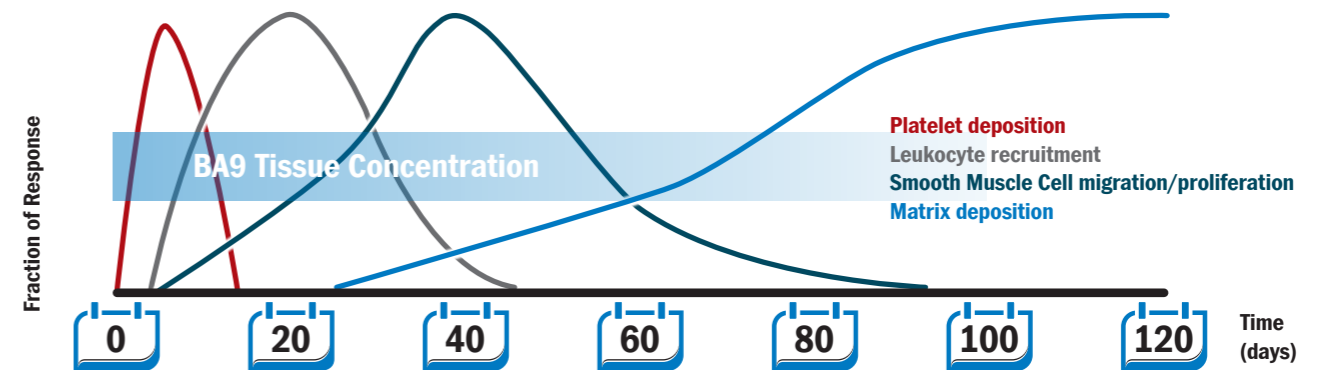
#### - Optimizing Healing to Allow for Very Short DAPT

After about 28 days approximately 98% of BA9 is released from the stent.<sup>3</sup>



From Drug-Coated Stent to Bare Metal Stent

#### - Sustained Tissue Release up to 100 days with Therapeutic Effect<sup>3,4</sup>



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.

#### - Longer Half Life than other Commonly used Limus Drugs

- Approximately 20 days in tissue<sup>3,4</sup>
- BA9 is broken down slower than other limus drugs, due to its chemical structure

#### - Potent Neointimal Suppression

BA9 acts on several cell types, including vascular smooth muscle cells;

- Pre-clinical models have shown a significant reduction in neointimal proliferation\*
- Early trials in man have shown low levels of Lumen Late Loss and no episodes of Stent Thrombosis out to 5 years\*