



Ordering Information

Stent diameter (mm)	Stent Length (mm)						
	9	14	19	24	29	33	36
2.25	BFC1-2209	BFC1-2214	BFC1-2219	BFC1-2224	BFC1-2229	-	-
2.50	BFC1-2509	BFC1-2514	BFC1-2519	BFC1-2524	BFC1-2529	BFC1-2533	BFC1-2536
2.75	BFC1-2709	BFC1-2714	BFC1-2719	BFC1-2724	BFC1-2729	BFC1-2733	BFC1-2736
3.00	BFC1-3009	BFC1-3014	BFC1-3019	BFC1-3024	BFC1-3029	BFC1-3033	BFC1-3036
3.50	BFC1-3509	BFC1-3514	BFC1-3519	BFC1-3524	BFC1-3529	BFC1-3533	BFC1-3536
4.00	BFC1-4009	BFC1-4014	BFC1-4019	BFC1-4024	BFC1-4029	-	-

Identify your  
HBR or HBR to become  
patients using the  
ARC-HBR app

Google Play



Apple Store



1. Ueki et al. Validation of Bleeding Risk Criteria (ARC-HBR) in Patients Undergoing Percutaneous Coronary Intervention and Comparison with Contemporary Bleeding Risk Scores. EuroIntervention. 2020 Feb 18. doi: 10.4244/EIJ-D-20-00052

2. Data from BioFreedom Ultra. Bolimus-A9 coated thin Strut Stents in High Bleeding Risk Patients Evidence from the LEADERS FREE III Study. F.R.Eberli et al., Presented at PCR eCourse June 2020

3. Data from BioFreedom in LEADERS FREE: Urban P. et al. Polymer-free Drug-Coated Coronary Stents in Patients at High Bleeding Risk New England Journal of Medicine 2015, October 14, DOI: 10.1056/NEJMoa1503943

4. Data from Gazelle. Urban P. et al. Polymer-free Drug-Coated Coronary Stents in Patients at High Bleeding Risk. New England Journal of Medicine 2015, October 14, DOI: 10.1056/NEJMoa1503943

5. Data from BioFreedom. Garot P et al. 2-Year Outcomes of High Bleeding Risk Patients After Polymer-Free Drug-Coated Stents. JACC VOL.6 9, No.2 , 2017

6. BioFreedom IFU 11677-000 Rev. 01 - Antiplatelet regimen section.

7. Data from BioFreedom. 2017 ESC focused update on dual antiplatelet therapy in coronary artery disease developed in collaboration with EACTS. Euro Heart Journal Vol 39;3, 14 January 2018, Pages 213–260

8. M. W. Krucoff. Global Approach to High Bleeding Risk Patients With Polymer-Free Drug-Coated Coronary Stents: The LF II Study. Circ Cardiovasc Interv. 2020 Apr;13

9. S. Saito. LEADERS FREE Japan study (single BioFreedom DCS arm with 1-month DAPT, compared to BMS arm of LEADERS FREE). ePoster EuroPCR 2017

10. Biosensors International data on file

11. With BioFreedom compared to BMS. BioFreedom is the predicate device of BioFreedom Ultra

12. Data from BioFreedom. Safety and efficacy of polymer-free Biolimus eluting stents in all-comer patients: The RUDI FREE study Sardella G, et al. EuroIntervention. 2018 Sep 20;14(7):772-779.

13. Data from BioFreedom. Angiographic and clinical performance of polymer-free biolimus-eluting stent in patients with ST-segment elevation acute myocardial infarction in a metropolitan public hospital: The BESAMI MUCHO study Gaspardone A Catheter Cardiovasc Interv.2017;00:1-8

14. Mehta LS, Lewis SJ, Duvernoy CS, et al. Burnout and career satisfaction among cardiologists. Presented at: American Heart Association 2017 Scientific Sessions. November 13, 2017. Anaheim, CA

15. Mehta L. Practice factors affecting cardiologists' wellbeing: the American College Of Cardiology 2019 Well Being Study. Presented on: March 28, 2020. ACC 2020

16. Sirolimus analog lipophilicity dictates release kinetics and tissue retention after implantation of polymer free drug eluting stents. R. Tzafirri, Poster Presentation EuroPCR 2017

§. Struts for specific stent diameter (small vessel).

BioFreedom Ultra is a trademark or registered trademark of Biosensors International Group, Ltd. BioFreedom™ Ultra is CE Mark approved.

CAUTION: The law restricts these devices to sale by or on the order of a physician and these products are intended for the use by or under the direction of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Not available in the United States and any other country where applicable health authority product registration has not been obtained. Information contained herein only for presentation outside the US and France. © 2020 Biosensors International Group, Ltd. All rights reserved.

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ULTRA RESPONSIVE  
FOR ALL STEPS  
OF YOUR PATIENTS JOURNEY



BIOSENSORS  
INTERNATIONAL™

# LEADING THE WAY AT DECISIVE MOMENTS

What if the choices you make today, could allow you to focus on what matters most to you?



**40%**<sup>1</sup>  
OF PATIENTS  
ARE HBR

WHEN  
**BLEEDING  
RISK**  
IS DECISIVE

**It is all about when patients become HIGH BLEEDING RISK**  
Use the ARC HBR App to identify your patients

ULTRA EFFICACY

**LEADERS FREE LEGACY**  
WITH LONG TERM DATA

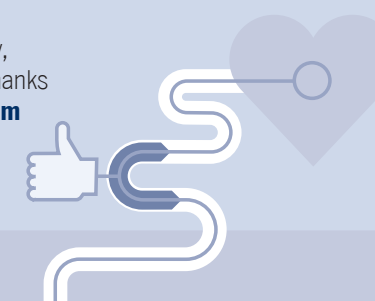


**99%**<sup>2</sup>  
DEVICE  
SUCCESS

WHEN  
**AN EFFICIENT  
PROCEDURE**  
IS DECISIVE

**EASE OF NAVIGATION**  
THROUGH TORTUOUS VESSELS

Ease of navigation through tortuous anatomy, while maintaining **longitudinal strength** thanks to the combination of **thin Cobalt Chromium struts** (84 µm)<sup>§</sup>, stent **design** and **improved delivery system**



**Ease of delivery**



**1 Month  
DAPT**

WHEN  
**FLEXIBILITY  
IN DAPT**  
IS DECISIVE

**BA9™ UNIQUE DRUG  
PROPERTIES**

ULTRA SAFETY

**Long term safety**

**1%** ST at 1 year<sup>2</sup>  
**0.1%** very late ST at 2 years<sup>5</sup>

**Most BA9™ is released from the stent in 1 month**

For patients in whom DAPT longer than >1 month poses safety concerns, you could shorten the DAPT down to 1 month<sup>6</sup> thanks to the BioFreedom™ Family concept  
With this advanced design, you get the best of both worlds:  
**Safety benefit** = BMS like  
**Efficacy benefit** = DES like

## Clinical outcomes at 1 year

	DCS CoCr LF III <sup>2</sup> (n=401)	DCS StS LF I <sup>3</sup> (n=1221)	BMS LF I <sup>4</sup> (n=1211)
Primary Safety Endpoint*	8.0%	9.2%	12.7%
Cardiac Death	3.7%	4.1%	5.1%
Myocardial Infarction	4.4%	5.9%	8.7%
Def/Prob. Stent Thrombosis	1.0%	2.0%	2.2%
Clinically-Driven TLR**	4.2%	4.9%	9.3%
BARC 3-5	5.4%	7.2%	7.2%
All Death	6.4%	7.5%	8.7%

## Procedural characteristics

Lesion Success	99%	98%	98%
Device Success	99%	98%	98%
Procedure Success	97%	94%	94%

\* p-value for non-inferiority vs DCS LF I: 0.0006 (non-inferiority margin: 3.9%)  
\*\* p-value for superiority vs BMS LF I: < 0.0001

**ALL-COMER HBR: HBR, HBR-ACS, UNCERTAIN**

**BIOFREEDOM™**  
Ultra

**BA9™**

Ultra

## FOCUS ON WHAT MATTERS

In your patient journey, BioFreedom™ Ultra is designed to simplify device related concerns, so that you can focus on what matters to You!

### Peer recommendation

To date BioFreedom™ is the only commercially available DCS stent referenced in the ESC DAPT guidelines<sup>7</sup>

### Positive outcomes reproducible to all patients

The **LEADERS FREE global clinical trial program (I, II, III, Japan)**<sup>2,8,9</sup> proves a significant improvement of outcomes across a broad spectrum in HBR patients

**3000 HBR patients**<sup>10</sup> studied in Randomized Clinical Trials

**13 publications** covering all presentations from the LEADERS FREE trial program. They include detailed subgroup analysis showing the patient benefit brought by BioFreedom and covering most patients encountered in the cath lab.

ULTRA REPRODUCIBLE

before implantation

during implantation

### Efficient procedure

Improved deliverability to shorten procedure time. BioFreedom™ Ultra enhances procedure success for the benefit of the patient<sup>2</sup>

ULTRA DELIVERABLE

350'000 patients<sup>10</sup> treated

PATIENTS GLOBALLY

### Quality of life

**51% reduction in Cardiac Death** with BioFreedom™<sup>3,11</sup>

**1% ST at 1 year** in HBR patients with BioFreedom™ Ultra<sup>2</sup>

### Real life data

BioFreedom™ demonstrated a very **favorable safety** (0.4% ST) and **efficacy profile** (1.4% TLR) at one year in real world clinical setting in the all-comer **RUDI FREE** registry<sup>12</sup>

In all-comer STEMI patients BioFreedom demonstrated a **low 4.6% MACE** rate at one year with only **0.6% Cardiac Death** and **1.1% def/prob ST**. The **BESAMI MUCHO** registry<sup>13</sup> adds more evidence to the **increased benefit** seen for BA9™ stents in AMI patients.

after implantation

## SIDE BY SIDE IN DEMANDING MOMENTS

As job requirements become more complex, the burden on individuals increases. When we add the pressure of everyday life, it impacts significantly on our decision making and our ability to manage decisive moments.

We know that health care professionals are particularly exposed<sup>14,15</sup>. They must deal, in a short time, with a large volume of work and a great complexity of tasks. In the cath lab, staying calm is vital during those decisive moments that matter to you and ultimately, the patient.

At Biosensors International, we are doing everything we can to reduce complexity. The experience and interaction of all our staff is there to support you especially at important moments.

**Everything we do, from the design of new devices to our high-quality customer service, aspires to contribute to the well-being not only of patients, but also of the medical community.**

BIOFREEDOM™  
Ultra



## OPTIMIZED PROCEDURE

BioFreedom™ Ultra  
polymer and carrier-free  
Drug-Coated Stent

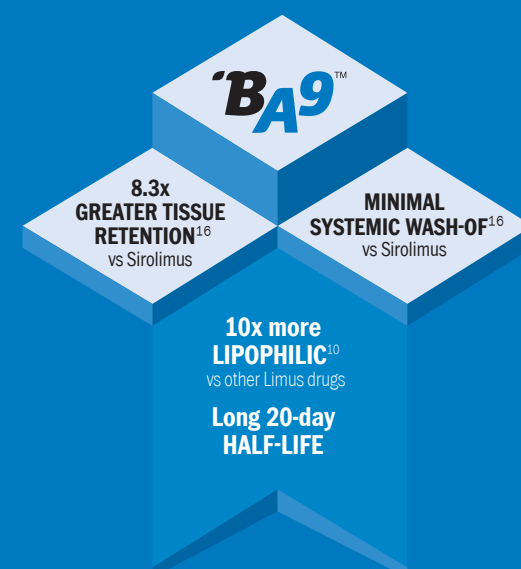
# 'BA9™

**BA9™ (Biolimus A9™) is the only drug designed specifically for coronary stent application**

After many years of research and up to 11 iterations, BA9 was selected for properties that would support healing and re-endothelialization.

An enhanced lipophilicity makes the drug hydrophobic, allowing for a rapid transfer of the drug to the vessel wall, in the absence of a polymer or carrier and with no loss to the systemic system.

With greater local bioavailability and a longer in-tissue residence time of 20 days, BA9 is a unique drug and is proprietary of Biosensors International Group, Ltd.



AFTER IMPLANT

AFTER 30 DAYS

AFTER 100 DAYS



### SMS: Selectively Microstructured Surface

Only the abluminal surface of the stent receives the SMS treatment, allowing BA9™ to be contained in the microstructured surface and delivered with high specificity to the vessel wall of the coronary lesions.

With no polymer or carrier, BA9+SMS makes 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.



### ULTRA RESISTANCE

Excellent radial and longitudinal force  
with optimal struts thickness

### Stent overexpansion

Small Vessel 84 µm	Medium Vessel 88 µm
 Nominal Diameter <b>2.25, 2.5, 2.75, 3.0 mm</b>	 Nominal Diameter <b>3.5, 4.0 mm</b>
 Max. exp. outer diameter <b>4.76* mm</b>	 Max. exp. outer diameter <b>5.95* mm</b>
 Max. opening <b>2.08** mm</b>	 Max. opening <b>2.34** mm</b>

\* BioMatrix Alpha stent: 3.0x19 mm (n=1) - Limited sample size. Post-dilated with a 5.0 mm balloon at nominal pressure. \*\* BioMatrix Alpha stent: 4.0x19 mm (n=1) - Limited sample size. Post-dilated with a 6.0 mm balloon at nominal pressure.

+ BioMatrix Alpha stent: 3.0x19 mm (n=1) - Limited sample size. Post-dilated with a 6.0 mm balloon at nominal pressure. ++ BioMatrix Alpha stent: 4.0x19 mm (n=1) - Limited sample size. Post-dilated with a 5.0 mm balloon at nominal pressure.

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. All figures from bench test data on file Biosensors International Group, Ltd.

**BIOFREEDOM™**  
Ultra