

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

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



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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
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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).

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



ULTRA RESPONSIVE
FOR ALL STEPS
OF THE PATIENT JOURNEY

BIOSENSORS
INTERNATIONAL™

Ultra

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%¹
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

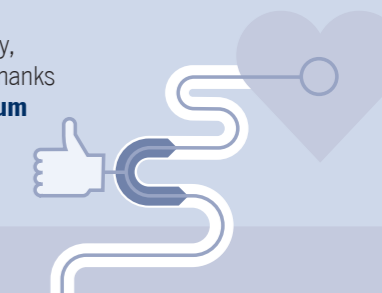


99%²
DEVICE
SUCCESS

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)[§], **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 year²
0.1% very late ST at 2 years⁵

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 month⁶ 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 ² (n=401)	DCS StS LF I ³ (n=1221)	BMS LF I ⁴ (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

BA9™

BIOFREEDOM™
Ultra

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 guidelines⁷

PATIENTS GLOBALLY

Positive outcomes reproducible to all patients

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

3000 HBR patients¹⁰ 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

350'000 patients¹⁰ treated

during implantation

Efficient procedure

Improved deliverability to shorten procedure time. BioFreedom™ Ultra enhances procedure success for the benefit of the patient²

ULTRA DELIVERABLE

Quality of life

51% reduction in Cardiac Death with BioFreedom™^{3,11}

1% ST at 1 year in HBR patients with BioFreedom™ Ultra²

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** registry¹²

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** registry¹³ 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^{14,15}. 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

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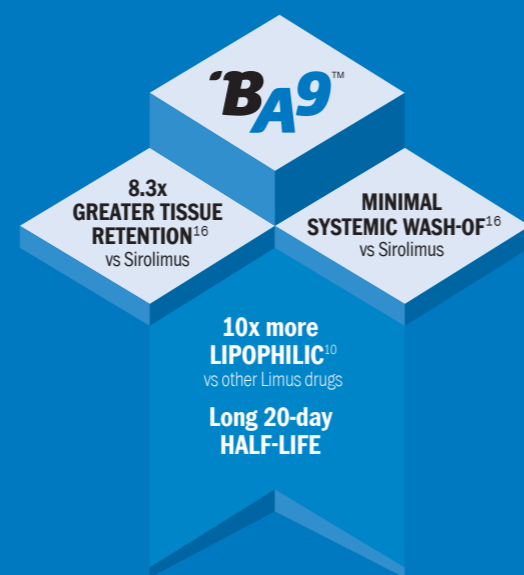
'BA9™

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



OPTIMIZED PROCEDURE

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

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
<p>Nominal Diameter 2.25, 2.5, 2.75, 3.0 mm</p>	<p>Nominal Diameter 3.5, 4.0 mm</p>
<p>Max. exp. outer diameter 4.76* mm</p>	<p>Max. exp. outer diameter 5.95* mm</p>
<p>Max. opening 2.08** mm</p>	<p>Max. opening 2.34** mm</p>

* 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