BIOFREEDOM™ ultra

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

ULTRA RESPONSIV

FOR ALL STEPS
OF THE PATIENT JOURNEY

BIOSENSORS INTERNATIONAL™

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Date: 2022.10.08 11:34:02 EEST
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Location: Moldova

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

LEADERS FREE LEGACY WITH LONG TERM DATA

99%[2] DEVICE SUCCESS

WHEN **AN EFFICIENT PROCEDURE** IS DECISIVE

EASE OF NAVIGATION THROUGH TORTUOUS VESSEL

1 Month DAPT

WHEN **FLEXIBILITY IN DAPT** IS DECISIVE

BA9™ UNIQUE DRUG PROPERTIES

ULTRA **EFFICACY**

It is all about when patient become HIGH BLEEDING RISK

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Use the ARC HBR App to identify your patients

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LEADERS FREE LEGACY

It is all about when patient become HIGH BLEEDING RISK

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

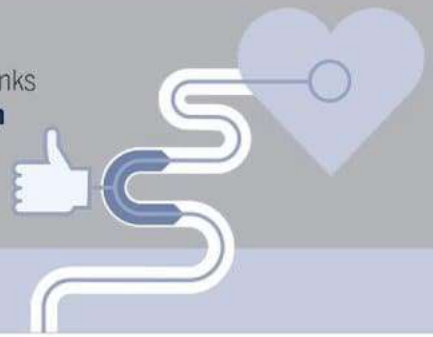
ULTRA **DELIVERABLE**

99%[2] DEVICE SUCCESS

WHEN **AN EFFECTIVE 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

ULTRA SAFE

1 Month DAPT

BA9™ UNIQUE DRUG PROPERTIES

WHEN **FLEXIBILITY IN DAPT** IS DECISIVE

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[6] 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

Long term safety

1% ST at 1 year[2]

0.1% very late ST at 2 years[5]

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!

before implantation

Peer recommended

To date BioFreedom™ is the only commercially available DCS stent referenced in the ESC DAPT guidelines[7]

350'000 patients[10] treated

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

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**

ULTRA **DELIVERABLE**

during implantation

Efficient procedure

Improved deliverability to shorten procedure time. BioFreedom™ Ultra enhances procedure success for the benefit of the patient[2]

350'000 patients[10] treated

PATIENTS **GLOBALLY**

REAL LIFE

after implantation

350'000 patients[10] treated

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[12]

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[13] adds more evidence to the **increased benefit** seen for BA9™ stents in AMI patients.

Quality of life

51% reduction in Cardiac Death with BioFreedom™[3,11]

1% ST at 1 year in HBR patients with BioFreedom™ Ultra[2]

OTHER **SERVICES**

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 ev
can to reduce complexity. The experience a
of all our staff is there to support you espec
important moments.

**Everything we do, from the design of n
to our high-quality customer service, a
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OPTIMIZED PROCEDURE

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

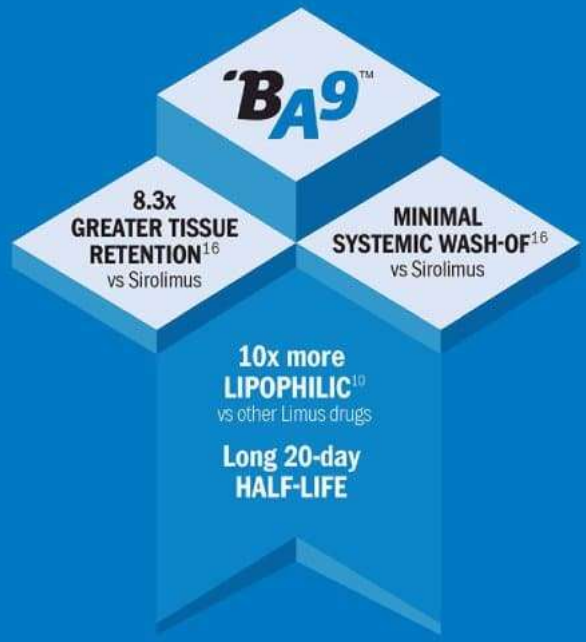
BA9™

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.



ULTRA **PLATFORM**

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.

BARE STENT | SMS TREATMENT | DRUG COATED

Stent overexpansion

Strut thickness: 84 µm	Strut thickness: 88 µm
Nominal Diameter **2.25, 2.5, 2.75, 3.0 mm**	Nominal Diameter **3.5, 4.0 mm**
Max. exp. outer diameter **4.76⁺ mm**	Max. exp. outer diameter **5.95⁺ mm**
Max. opening **2.08⁺⁺ mm**	Max. opening **2.34⁺⁺ mm**

* 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.

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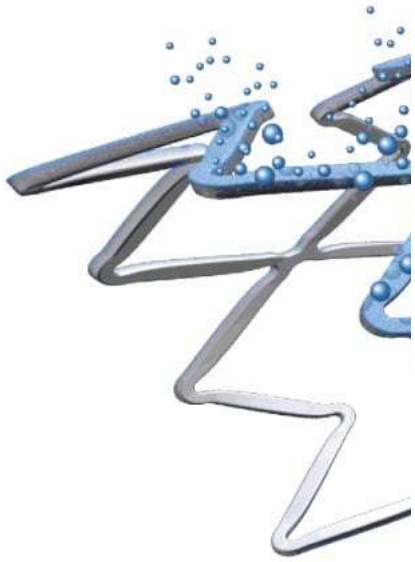
STRAIGHT CONN



ULTRA **RESISTANCE**

Excellent radial and longitudinal for with optimal struts thickness

ULTRA INFORMATION

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	-	-

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ULTRA **INFORMATION**

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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. Tzafriri, Poster Presentation EuroPCR 2017

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

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