English
INSTRUCTIONS FOR USE
BioFreedom™ Drug Coated Coronary Stent System

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1. DEVICE DESCRIPTION

The BioFreedom™ Drug Coated Coronary Stent System (BioFreedom DCS) is a combination product consisting of two key components: the stent coated abluminally with the active ingredient BA9™ (Biolimus A9), and the delivery system.
BioFreedom DCS is a polymer and carrier free Drug Coated Coronary Stent System.

1.1. DEVICE COMPONENT DESCRIPTION

- The device components consist of a balloon expandable intra-coronary 316L stainless steel stent abluminally coated with the BA9™ drug and pre-mounted onto a semi-compliant rapid exchange balloon delivery system.
- The delivery system has two radiopaque markers, which fluoroscopically mark the ends of the stent to facilitate proper stent placement.
- At the proximal end of the delivery system is a female Luer Lock connector hub. This hub connects to the balloon inflation lumen.
- The guidewire enters the distal tip of the catheter and exits 23±0.5 cm proximal to the tip of the delivery system.

The device component characteristics are summarized in Table 1
Table 1: Device Description

Stent Pattern:	6-crown model	9-crown model
Stent Diameters (mm):	2.25 – 3.0	3.5 – 4.0
Stent Lengths (mm):	8, 11, 14, 18, 24, 28, 33*, 36*	
Stent Material / Coating:	316L stainless steel stent / BA9 drug coating	
Delivery System Design:	Working length: 142 cm Rapid Exchange (RX) compatible with 0.014" guide wires.	
Balloon Catheter	Semi-compliant balloon with two radiopaque markers located on the catheter shaft	
Balloon Inflation Pressure:		
Nominal Inflation Pressure (NP):	*(for all sizes)* 6 atm / 608 kPa	
Rated Burst Pressure (RBP):	*(stent Ø. 2.25 – 3.0 mm)* 16 atm / 1621 kPa	*(stent Ø. 3.5 – 4.0 mm)* 14 atm /1418 kPa

**** BioFreedom DCS with a length of 33 and 36 mm is only available for stent diameters from 2.5 to 3.5mm.***

1.2. DRUG COMPONENT DESCRIPTION

- The BA9 drug (USAN/INN: *umirolimus*) is a semi-synthetic sirolimus derivative with high lipophilicity. The BA9 drug, as provided on the BioFreedom DCS, inhibits smooth muscle cell proliferation within the stent proximity.
- The drug coating consists of the active ingredient BA9 (Biolimus A9), which is then applied to the abluminal surface of the stent with no polymer or carrier.

Table 2: Nominal BA9 Drug Dosage

Product Code	Nominal Expanded Inner Diameter (mm)	Nominal Unexpanded Stent Length (mm)	Nominal Dose of BA9 drug (µg)
BFR1-2208	2.25	8	133
BFR1-2211	2.25	11	178
BFR1-2214	2.25	14	225
BFR1-2218	2.25	18	292
BFR1-2224	2.25	24	384
BFR1-2228	2.25	28	453
BFR1-2508	2.5	8	133
BFR1-2511	2.5	11	178
BFR1-2514	2.5	14	225
BFR1-2518	2.5	18	292
BFR1-2524	2.5	24	384
BFR1-2528	2.5	28	453
BFR1-2533	2.5	33	521
BFR1-2536	2.5	36	566
BFR1-2708	2.75	8	133
BFR1-2711	2.75	11	178
BFR1-2714	2.75	14	225
BFR1-2718	2.75	18	292
BFR1-2724	2.75	24	384
BFR1-2728	2.75	28	453
BFR1-2733	2.75	33	521
BFR1-2736	2.75	36	566
BFR1 -3008	3.0	8	133
BFR1-3011	3.0	11	178
BFR1-3014	3.0	14	225
BFR1-3018	3.0	18	292
BFR1-3024	3.0	24	384
BFR1-3028	3.0	28	453
BFR1-3033	3.0	33	521
BFR1-3036	3.0	36	566
BFR1-3508	3.5	8	133
BFR1-3511	3.5	11	178
BFR1-3514	3.5	14	225
BFR1-3518	3.5	18	292
BFR1-3524	3.5	24	384
BFR1-3528	3.5	28	453
BFR1-3533	3.5	33	521
BFR1-3536	3.5	36	566
BFR1-4008	4.0	8	133

Product Code	Nominal Expanded Inner Diameter (mm)	Nominal Unexpanded Stent Length (mm)	Nominal Dose of BA9 drug (µg)
BFR1-4011	4.0	11	178
BFR1-4014	4.0	14	225
BFR1-4018	4.0	18	292
BFR1-4024	4.0	24	384
BFR1-4028	4.0	28	453

2. INDICATIONS

The BioFreedom DCS is indicated for improving coronary luminal diameter for the treatment of de-novo lesions in native coronary arteries with a reference diameter ranging from 2.25 mm to 4.0 mm. Stents with length of 33mm and 36mm are only available for artery diameters ranging from 2.5mm to 3.5mm.

3. CONTRAINDICATIONS

The BioFreedom DCS is contraindicated for use in:

- Patients in whom anti-platelet and/or anti-coagulant therapy is contraindicated.
- Patients with lesion(s) that prevent complete inflation of an angioplasty balloon.
- Patients with known sensitivity to the BA9 drug or its derivatives.
- Patients with a known allergy to stainless steel, nickel or other metal ions found in 316L stainless steel.
- Patients with known sensitivity to contrast agents that cannot be controlled prophylactically prior to BioFreedom stent implantation.
- Off-label use (i.e. outside of the approved indications for use). Patient outcomes may not be the same as the results observed in clinical trials.

4. ANTIPLATELET REGIMEN

Administration of appropriate anticoagulant, antiplatelet and coronary vasodilator therapy is critical for a successful long term result of the implantation.

Physicians should take into consideration information from clinical trials with BA9 DCS[1,2], other BA9 DES trials[3,4,5] as well as the most recently updated ESC/AHA/ACC/SCAI Guidelines for percutaneous coronary intervention and the specific needs of individual patients to determine the antiplatelet / anticoagulation regimen to be used for their patients .

In patients with high bleeding risk (HBR), physicians may choose a 1 month dual antiplatelet regimen based on results of the randomized, double-blind LEADERS FREE1 trial conducted in 2 466 PCI patients demonstrating superior safety and efficacy outcomes for the BA9 DCS versus a BMS with one month of dual antiplatelet therapy followed by single antiplatelet therapy alone.

High bleeding risk (HBR) may include patients with any of the following:

- ≥ 75 years old
- Oral anticoagulation use (including vitamin-K antagonists or factor Xa-inhibiting drugs) planned to continue for > 1 month post PCI
- Hemoglobin <11 g/dL or anemia requiring transfusion in the previous month
- Platelet count <100,000/mm^3 in the previous month

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[1] *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*

[2] *Ricardo A. Costa et al.: Polymer-Free Biolimus A9-Coated Stents in the Treatment of De Novo Coronary Lesions: 4- and 12-Month Angiographic Follow-up and Final 5-Year Clinical Outcomes of the Prospective, Multicenter BioFreedom FIM Clinical Trial. JACC Cardiovascular Interventions (2015), doi: 10.1016/j.jcin.2015.09.008.*

[3] *Windecker S, Serruys PW, Wandel S and al. Biolimus-eluting stent with biodegradable polymer versus sirolimus-eluting stent with durable polymer for coronary revascularisation (LEADERS): a randomized non-inferiority trial. The Lancet: Published online September 1st, 2008*

[4] *Stefanini GG, Kalesan B, Serruys PW, Heg D, Buszman P, Linke A, Ischinger T, Klauss V, Eberli F, Wijns W, Morice MC, Di Mario C, Corti R, Antoni D, Sohn HY, Eerdmans P, van Es GA, Meier B, Windecker S, Jüni P. Long-term clinical outcomes of biodegradable polymer biolimus-eluting stents versus durable polymer sirolimus-eluting stents in patients with coronary artery disease (LEADERS): 4 year follow-up of a randomised non-inferiority trial. Lancet. 2011 Dec 3;378(9807):1940-8.*

[5] *Serruys PW et al. Improved Safety and Reduction in Stent Thrombosis Associated With Biodegradable Polymer-Based Biolimus-Eluting Stents Versus Durable Polymer-Based Sirolimus-Eluting Stents in Patients With Coronary Artery Disease Final 5-Year Report of the LEADERS (Limus Eluted From A Durable Versus Erodable Stent Coating) Randomized, Non-inferiority Trial. JACC : Cardiovascular Interventions, vol 6, n°8, 2013*

- Hospital admission for bleeding in the previous12 months
- Stroke in the previous12 months
- Any prior intracerebral hemorrhage
- Severe chronic liver disease defined to include the following diseases or symptoms: variceal hemorrhage, ascites, hepatic encephalopathy or jaundice
- Creatinine clearance <40 ml/min in the previous month
- Cancer (non-skin) in the previous 3 years
- Major surgery planned in the 12 months post-PCI
- Glucocorticoids or NSAID planned to continue > 1 month post-PCI
- Other medical reasons that would preclude treatment with >1 month dual antiplatelet therapy which may include: congenital conditions, high risk of trauma, history of falling

Physicians should consider the bleeding versus ischemic risk when determining the most beneficial antiplatelet regimen for an individual patient.

5. WARNINGS

- Before use, ensure that the inner package has not been damaged or opened prior to use as this may indicate a breach of the sterile barrier.
- Judicious selection of patients is necessary since the use of this device carries the associated risk of thrombosis, vascular complications and/or bleeding events. Hence, patients should be maintained on clinically adequate post-procedural antiplatelet therapy (refer to section 4: Antiplatelet Regimen).
- Only physicians who have received appropriate training should perform implantation of the stent.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Care should be taken to the preparation of the delivery system (refer to section 6.3. Stent Placement – Precautions).
- Subsequent thrombotic blockage of the stented segment may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- This delivery system must not be reused in another procedure. The performance characteristics of the balloon are degraded during use.
- The “crushing” technique in bifurcations has not been attempted with BioFreedom DCS. No information is available regarding BioFreedom DCS abluminal surface exposure to the blood stream.
- When multiple tandem stents are required, stent materials should be of similar composition to avoid dissimilar metal corrosion.
- The safety and effectiveness of overlapping BioFreedom stents have not been established.
- Direct stenting has not been evaluated in clinical studies. Therefore direct stenting is not recommended (refer to section 9.4. Stent Delivery Procedure).
- This product is not intended or approved for use in peripheral applications.
- DO NOT resterilize and/or reuse this device or related delivery system, as this can compromise performance and can lead to device/delivery system failure and procedure complications with severe injury or patient death. Reuse, reprocessing and resterilization bear the risk of cross contamination and patient to patient infection.

6. PRECAUTIONS

6.1 DRUG INTERACTIONS

Consideration should be given to the potential for drug interactions when deciding to place a BioFreedom stent in a patient who is taking a drug that could interact with the BA9 drug or when deciding to initiate therapy with such a drug in a patient who has recently received a stent coated with BA9 drug. The effect of BioFreedom DCS drug interactions on safety or efficacy has not been determined.

There is no specific clinical data available for the interactions of the BA9 drug with other drugs. However, drugs like Tacrolimus that may act through the same binding proteins (FKBP) may interfere with the efficacy of the BA9 drug. Drug interaction studies have not been performed. The BA9 drug is metabolized by CYP3A4. Strong inhibitors of CYP3A4 (e.g. ketoconazol) might cause increased BA9 drug exposure to levels associated with systemic effects, especially if multiple stents are deployed. Systemic exposure of the BA9 drug should be taken into consideration if the patient is treated concomitantly with systemic immunosuppressive therapy.

Patient's exposure to the BA9 drug is directly related to number of stents used and length of the BioFreedom stent or any other BA9 coated stents implanted.

6.2. STENT HANDLING – PRECAUTIONS

For single use only. Do not resterilize or reuse.

Do not use a product that has exceeded its labeled expiration date.

Do not use if packaging has been damaged or opened. **The sterility and stability of the BioFreedom DCS cannot be guaranteed once the pouch has been opened** and hence the device MUST be used promptly. Un-used devices should be discarded or returned to Biosensors International™ and should not be re-stocked.

DO NOT RUB OR SCRAPE THE STENT COATING.

Do not use if stent coating is subjected to abrasions beyond those of normal insertion and delivery.

Do not use if stent is exposed to abnormal rubbing or contact with objects other than the guide catheter or opened hemostasis valve prior to implantation.

Exposing the stent to fluids before implantation is not recommended. Exposure to fluids prior to implantation may result in premature release of drug.

Special care must be taken not to handle or in any way disrupt the stent on the balloon.
Do not "roll" the mounted stent with your fingers as this action may damage stent coating and loosen the stent from the balloon. Subsequently this could cause dislodgement, or some loss of drug coating

Do not remove stent from its delivery catheter as removal may damage the stent and/or lead to stent embolization. BioFreedom DCS is intended to perform as a system.

The delivery system should not be used in conjunction with other stents.

Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.

Do not attempt to straighten the proximal shaft (hypotube) as it may cause the catheter to break if it is accidentally bent.

Do not expose delivery catheter to organic solvents, e.g. isopropyl alcohol. Such an exposure can degrade delivery catheter performance.

IN THE EVENT THAT THE STENT IS NOT SUCCESSFULLY DEPLOYED, THE STENT AND DELIVERY SYSTEM SHOULD BE RETURNED TO BIOSENSORS INTERNATIONAL.

6.3. STENT PLACEMENT – PRECAUTIONS

Do not introduce negative pressure or pre-inflate the delivery system prior to stent deployment other than as directed. Use balloon purging technique described in section 9.3. Delivery System Preparation.

The labeled stent diameter refers to the expanded stent inner diameter.

Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (CABG, further dilatation, placement of additional stents, or other).

When treating multiple lesions, distal lesions should be stented first followed by proximal lesion stenting. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent and reduces the chances for dislodging the proximal stent.

Do not expand the stent if it is not properly positioned in the vessel. (See section 6.4. Stent / System Removal – Precautions)

Placement of a stent has the potential to compromise side branch patency.

Do not exceed rated burst pressure as indicated on product label. Use of pressures higher than specified on the product label may result in a ruptured balloon with possible intimal damage and dissection.

Do not attempt to pull an unexpanded stent back through the guiding catheter, as dislodgement of the stent from the balloon may occur. Remove as a single unit as described in section 6.4. Stent / System Removal – Precautions.

Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.

6.4 STENT / SYSTEM REMOVAL – PRECAUTIONS

Should unusual resistance be felt at any time during either lesion access or removal of the stent delivery system prior to the stent being implanted, the entire system should be removed as a single unit.

When removing the stent delivery system as a single unit:

- Do not attempt to retract an unexpanded stent into the guiding catheter while engaged in the coronary arteries.
- Stent damage or dislodgement may occur. Advance the guidewire into the coronary anatomy as far distally as safely possible.□
- Position the proximal balloon marker just distal to the tip of the guiding catheter.

NOTE: If it is necessary to maintain guidewire position, the guidewire must either be converted to an exchange wire length or a second guidewire must be inserted. □

- Tighten the rotating hemostatic valve to secure the delivery system to the guiding catheter. Remove the guiding catheter and stent delivery system as a **single unit**.

Do not attempt to pull the guiding catheter and delivery system through the femoral sheath. When the distal tip of the guiding catheter reaches the distal end of the femoral

sheath, remove sheath, guiding catheter, and delivery system as a single unit and replace sheath per hospital protocol.

Failure to follow these steps and/or applying excessive force to the stent delivery system can potentially result in stent dislodgement or damage to the stent and/or delivery system components.

6.5. POST IMPLANT – PRECAUTIONS

Care must be exercised when crossing a newly deployed stent with adjunct devices to avoid disrupting stent placement, apposition, and/or geometry.

6.6 MAGNETIC RESONANCE IMAGING (MRI)

Non-clinical testing has demonstrated that the BioFreedom DCS is MR Conditional. A patient with a BioFreedom stent can be scanned safely, immediately after placement of this implant, under the following conditions:

- Static magnetic field of 3-Tesla or less
- Spatial gradient field of 720-Gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning.

In non-clinical testing, the stent platform used for BioFreedom DCS (single and two stents overlapping) produced a temperature rise of less than or equal to 2.1°C at a maximum MR system reported whole body averaged specific absorption rate (SAR) of 3-W/kg for 15-minutes of MR scanning in a 3-Tesla, 128 MHz MR system (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI). The effect of performing MRI procedures using higher levels of RF energy on the BioFreedom stent has not been determined. The effect of heating in the MRI environment on more than two overlapping stents or drug is unknown.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the BioFreedom DCS.

7. INDIVIDUALIZATION OF TREATMENT

The risks and benefits of drug-eluting or drug coated stents should be considered for each patient before use of the BioFreedom stent. Physicians are responsible for assessing patient appropriateness for stent implantation prior to procedure.

8. USE IN SPECIAL POPULATIONS

The safety and effectiveness of the BioFreedom DCS has not been established in the following patient populations:

- Pregnancy: There are no data available for use of the BioFreedom stent in pregnant women.
- During Lactation: The effects of the BA9 drug during lactation have not been evaluated.
- Pediatric use: The safety and efficacy of the BioFreedom stent has not been established.

Carefully consider whether it is appropriate to use in the above patient populations.

The safety and effectiveness of using mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters) or laser angioplasty catheters to treat in-stent stenosis has not been established.

9. OPERATOR'S MANUAL

9.1. INSPECTION PRIOR TO USE

1. Inspect the stent delivery system package for damage to the sterile barrier.
2. Carefully remove the system from the package and inspect the delivery catheter for bends, kinks, and other damage.

3. Carefully remove the stent guard covering the stent /balloon. The pre-attached stylet is automatically removed.
4. Inspect the stent to ensure that it has not been damaged or displaced from its original position on the balloon. Verify that the stent is positioned between the proximal and distal balloon markers.
5. Note the position of the stent relative to the proximal and distal marker bands for use as reference under fluoroscopy.

Do not use if any defects are noted.

9.2. MATERIALS REQUIRED

1	A guiding catheter with a minimum inner diameter of 0.056”
1	Pre-dilatation balloon catheter
1	10-20 cc syringe
1000 IU	Heparin per 500 cc Normal Saline (HepNS)
1	0.014 inch guidewire $\geq$ 175 cm
1	Rotating hemostatic valve
N/A	Contrast diluted 1 : 1 with normal saline
1	Inflation device
1	Three-way stopcock

9.3. DELIVERY SYSTEM PREPARATION

1. Prepare inflation device/syringe with diluted contrast medium.
2. Attach inflation device to the three-way stopcock; attach to balloon inflation port hub.

   NOTE: DO NOT apply negative or positive pressure to the balloon at this time as it can cause premature dislodgement of the stent.
3. Open stopcock to stent delivery system.
4. Leave on neutral.

9.4. STENT DELIVERY PROCEDURE

1. Prepare vascular access site according to standard PTCA practice.
2. Pre-dilate lesion with a balloon diameter 0.5 mm smaller than the stent, and a balloon length equal to or shorter than the target lesion length, and shorter than the length of the stent to be implanted.
3. Immediately prior to backloading the stent delivery catheter onto the guidewire, flush the guidewire lumen of the delivery system with HepNS according to hospital protocol. Avoid contact with the stent.

NOTE: Stent contact with fluid has the possibility of initiating drug release. Fluid contact time should be limited to immediately prior to loading the delivery catheter on the guidewire.

4. Backload stent delivery system onto the proximal portion of the guidewire while maintaining guidewire position across target lesion.
5. Open rotating hemostatic valve on the guiding catheter hub as widely as possible, and close when the stent has been advanced safely inside the guide catheter.
6. Advance the stent delivery system over the guidewire to the target lesion under fluoroscopic guidance. Utilize the radiopaque balloon markers to position the stent across the lesion. Perform angiography to confirm stent position.

NOTE: If resistance is felt, DO NOT FORCE PASSAGE. Resistance may indicate a problem and may result in damage to the vessel or stent, or in stent dislodgement if it is forced. Remove the

stent delivery system and the guiding catheter as a single unit (see section 6.4. Stent / System Removal - Precautions).

9.5. DEPLOYMENT PROCEDURE

1. Consult the balloon compliance chart on the compliance card or at the back of the product box in order to determine the balloon inflation pressure appropriate for the target vessel diameter.

CAUTION: Different compliance charts apply for different stent lengths.

2. Before deployment, reconfirm the correct position of the stent relative to the target lesion via the balloon markers.
3. Ensure that the three-way stopcock on the stent delivery system is open to the inflation device and apply negative pressure to purge the balloon of air.
4. Turn the three-way stopcock on the stent delivery catheter off to the balloon port and purge the inflation device of air. Open the side port of the three-way stopcock to the delivery system.
5. Under fluoroscopic visualization, inflate the balloon to at least 6 atm to deploy the stent at nominal diameter, but do not exceed the labeled rated burst pressure (RBP). Optimal expansion requires the stent to be in full contact with the artery wall with the stent internal diameter matching the size of the reference vessel diameter. **ENSURE THAT THE STENT IS NOT UNDERDILATED**.
6. Deflate the balloon with appropriate time reported below by pulling a vacuum with the inflation device. Make sure the balloon is fully deflated before attempting any movement of the system.

Balloon Diameter (mm) / Balloon length (mm)	Time for Deflation
2.25 to 2.75 / all lengths 3.0 up to 25 mm lengths	maximum 15 seconds
3.0 from 30 mm to 38 mm 3.5 to 4.0 / all lengths	maximum 20 seconds

7. Confirm adequate stent expansion and balloon deflation by angiographic injection through the guiding catheter.
8. If more than one stent is needed to cover the lesion and balloon treated area, adequately overlap the stents (at least 2 mm) to avoid potential gap stenosis.

9.6. REMOVAL PROCEDURE

1. Ensure that the balloon is fully deflated.
2. Fully open the rotating hemostatic valve.
3. While maintaining guidewire position and negative pressure on inflation device, withdraw the delivery system.
4. Tighten rotating hemostatic valve.
5. Repeat angiography to assess the stented area.

9.7. FURTHER DILATATION OF STENT SEGMENTS

1. If an adequate expansion has not been obtained, re-advance the stent delivery system or exchange for another balloon catheter of appropriate balloon diameter to achieve proper stent apposition to the vessel wall.

NOTE: Post-dilatation should be performed within the stented segment. DO NOT dilate beyond the stent edges.

2. Reconfirm stent position and angiographic result. Repeat inflations until optimal stent deployment is achieved. Final stent diameter should match reference vessel.

10. POTENTIAL ADVERSE EVENTS

Adverse events that may be associated with the use of a stent in native coronary arteries include but not limited to:

- Abrupt stent closure or failure to expand the stent.
- Abrupt vessel closure or spasm
- Acute myocardial infarction
- Allergic reaction to anti-coagulation and/or anti-thrombotic therapy, contrast material, or stent and/or delivery system materials
- Aneurysm, pseudoaneurysm or arteriovenous fistula
- Arrhythmias, including ventricular fibrillation and ventricular tachycardia
- Cardiac tamponade
- Cardiogenic shock
- Death
- Dissection, perforation, or rupture of the artery
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergency coronary artery bypass grafting (CABG) as a result of damage to the stent or injury to the vessel
- Fever
- Hematoma at insertion site
- Hemorrhage requiring transfusion
- Hypotension/hypertension
- Infection and/or pain at insertion site
- Late stent thrombosis/stent thrombosis/occlusion
- Perforation or rupture of the artery
- Peripheral ischemia or peripheral nerve injury
- Stroke or transient ischemic attack
- Renal failure
- Restenosis of stented segment
- Stent migration or stent embolization
- Total occlusion of coronary artery
- Unstable angina

Adverse events that may be associated with BA9 drug coating:

BA9 drug administration is limited to intra-coronary stent delivery. The adverse effects of using this drug have not been fully characterized and may have additional side effects / complications associated with the use of the BA9 drug at significantly higher doses than what would be delivered via the BioFreedom DCS.

They include the following:

• Nausea

• Lymphadenopathy

• Mouth ulcers
• Chest heaviness
• Dizziness

11. HOW SUPPLIED

STERILE, NON-PYROGENIC. This device is sterilized via e-beam sterilization.
CONTENTS: One Biosensors BioFreedom Drug Coated Coronary Stent System.
STORAGE: Store in a cool dark dry place. Do not store above 25°C.
DISPOSAL: Dispose device in accordance with local regulations.
NOTE: This product does not contain phthalates

12. SYMBOLS USED IN LABELING

	Legal Manufacturer		Keep away from sunlight or heat
	Date of Manufacture		Keep Dry
REF	Catalog number		Do not use if package is damaged or open
LOT	Batch code		Stent Length
	Caution, consult accompanying documents		Stent Diameter
	Do not re-sterilize		Maximum Guidewire Outer Diameter (OD):
	Do not reuse		Minimum Guiding Catheter Inner Diameter (ID):
	This device has been sterilized using irradiation		Do not store above 25°C
	Use by date Do not use this device after the indicated date (Year-month-day):		Consult Instruction for use
NP	Nominal Pressure	RBP	Rated Burst Pressure
	MR conditional		

13. WARRANTY

Biosensors International warrants that its products are manufactured to the specifications set forth on its packaging, instructions for use and related literature.

This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied, by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.

Biosensors International neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this product.

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CE Mark: CE 0344	

ECO #	Rev	Brief Description of Changes	Author
ECO-9726	01	New Release of BioFreedom IFU wording in English	Guylaine Dudley-Casses
ECO-10492	02	Update of the English wording document to include the legal manufacturer and individual countries addresses as well as logo and history of the changes. The rev 02 of the English document is wording equivalent to rev01 of other languages.	Julie Heubi / Teresa Bianchi
ECO-12159	03	Updated following sections: 1.2 Drug component description – Reflect proper description of BA9 drug 5.0 Warning – Add in detailed description on risk of resterilizing and reuse of device 6.2 Stent Handling – Exposing delivery catheter to organic solvent 6.5 Post implantation precautions – Generalise paragraph 6.6 MRI – Effect on heating in the MRI environment on more than two overlapping stents or drug is unknown. 9.3 Delivery system preparation - DO NOT apply negative or positive pressure to the balloon 9.4 Stent delivery procedure – Amend guidewire lumen to guidewire lumen of the delivery system. Remove flushing the delivery catheter to ensure that damage to the stent does not occur. 12 Symbol – Add in MRI Conditional	Shermaine Png / Teresa Bianchi
ECO-12868	04	Change of guiding catheter inner diameter dimension from 0.070” to 0.056” (6F to 5F)	Samantha Ong / Shu-Ying Huang
ECO-13501	05	Change of DAPT recommendation duration in section 4. ANTIPLATELET REGIMEN	Guylaine Dudley-Casses
ECO-14027	06	Updated Spanish address	Muhammad Amsyar
ECO-16452	07	Removal of CE Mark and BA9 logo at the end of the IFU following IA17-S-08/01. Uprev of the Spanish address.	Julie Vergez