JW Medical Systems Ltd.
68 Dalian Road, 264209 Weihai, Shandong Province,
PEOPLE'S REPUBLIC OF CHINA
Tel: +86 (631)5655000
Postal Code: 264209

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BIOSENSORS
INTERNATIONAL™

BioAscend™

Biolimus A9 Coated
PTCA Balloon Dilatation Catheter

INSTRUCTIONS FOR USE

CE 2797

JW MEDICAL SYSTEMS LTD.
a company of the Biosensors International Group

Legal manufacturer: JW Medical Systems Ltd.

68 Dalian Road, 264209 Weihai, Shandong Province, PEOPLE'S REPUBLIC OF CHINA

Manufacturing site: JW Medical Systems Ltd.

68 Dalian Road, 264209 Weihai, Shandong Province, PEOPLE'S REPUBLIC OF CHINA

Contact Details:

Tel: +86(631)5655000

For information, details or assistance with JWMS products, please contact:

Manufacturer: JW Medical Systems Ltd.

Tel: +86(631)5655000

Postal Code: 264209

E-mail: info@jwmsgrp.com

EU REP

NVT GmbH

Address: Lotzenäcker 17, 72379 Hechingen, Germany

Contact information:

Tel: +49 7471 98979-0

CONTENTS

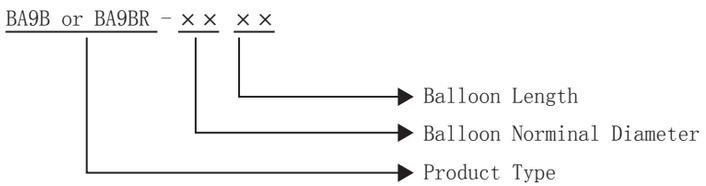
[Warnings]

- Judicious selection of patients is necessary since the use of this device carries the associated risk of thrombosis, vascular complications, and/or bleeding events.
- Patients with known allergy to Biolimus A9 and polyethylene oxide may experience an allergic reaction when using this device.
- Only physicians who have received appropriate training should perform the procedure.
- Balloon inflation pressure should not exceed the maximum recommended pressure (RBP).
- Please inspect the product and verify the expiration date before use. Do not use the product that has exceeded its labeled expiration date.
- Hospitals using this product must have the conditions for prompt, urgent treatment in the event of potential injury or life-threatening complications.
- The product has been sterilized. The product is intended for single use only. Do not re-sterilize or reuse the device.
- Before use, please check the packaging carefully and do not use products with damaged packaging.
- To reduce the risk of balloon overinflation, an inflation device with a pressure gauge (calibrated) is recommended.
- Before using the product, please read this Instructions for Use carefully.
- Due to the lack of supporting data from large-scale, randomized controlled clinical trials, the following conditions are not included as indications for this product: chronic total occlusion lesions, severely calcified lesions, left main coronary artery lesions, triple vessel disease requiring simultaneous treatment, and bypass graft lesions.

[Product Description]

1.Product Name: BioAscend™ Biolimus A9 Coated PTCA Balloon Dilatation Catheter

2.Product Model Description:



Product Types: BA9B are intended for small vessel indication; BA9BR are intended for in-stent restenosis indication.

3.Product Models and Description:

Table 1 provides BA9B models for products intended for small vessel indication, while Table 2 provides BA9BR models for products intended for small vessel and in-stent restenosis indication.

Table 1: BA9B models for products intended for small vessel indication

S/N	Models	Balloon Nominal Diameter(mm)	Balloon Nominal Length(mm)	Nominal Pressure (NP)(atm)	RBP(atm)	Drug Dose (μg)
1	BA9B-2010	2.0	10	6	16	255
2	BA9B-2015	2.0	15	6	16	345
3	BA9B-2020	2.0	20	6	16	450
4	BA9B-2025	2.0	25	6	16	540
5	BA9B-2030	2.0	30	6	16	630
6	BA9B-2210	2.25	10	6	16	300
7	BA9B-2215	2.25	15	6	16	405
8	BA9B-2220	2.25	20	6	16	510
9	BA9B-2225	2.25	25	6	16	615
10	BA9B-2230	2.25	30	6	16	720
11	BA9B-2510	2.5	10	6	16	345

S/N	Models	Balloon Nominal Diameter(mm)	Balloon Nominal Length(mm)	Nominal Pressure (NP)(atm)	RBP(atm)	Drug Dose (μg)
12	BA9B-2515	2.5	15	6	16	465
13	BA9B-2520	2.5	20	6	16	585
14	BA9B-2525	2.5	25	6	16	690
15	BA9B-2530	2.5	30	6	16	810
16	BA9B-2710	2.75	10	6	16	390
17	BA9B-2715	2.75	15	6	16	525
18	BA9B-2720	2.75	20	6	16	645
19	BA9B-2725	2.75	25	6	16	780
20	BA9B-2730	2.75	30	6	16	930

Table 2: BA9BR models for products intended for small vessel and in-stent restenosis indication

S/N	Models	Balloon Nominal Diameter(mm)	Balloon Nominal Length(mm)	NP(atm)	RBP(atm)	Drug Dose (μg)
1	BA9BR-2010	2.0	10	6	16	255
2	BA9BR-2015	2.0	15	6	16	345
3	BA9BR-2020	2.0	20	6	16	450
4	BA9BR-2025	2.0	25	6	16	540
5	BA9BR-2030	2.0	30	6	16	630
6	BA9BR-2210	2.25	10	6	16	300
7	BA9BR-2215	2.25	15	6	16	405
8	BA9BR-2220	2.25	20	6	16	510
9	BA9BR-2225	2.25	25	6	16	615
10	BA9BR-2230	2.25	30	6	16	720
11	BA9BR-2235	2.25	35	6	16	825
12	BA9BR-2510	2.5	10	6	16	345
13	BA9BR-2515	2.5	15	6	16	465
14	BA9BR-2520	2.5	20	6	16	585
15	BA9BR-2525	2.5	25	6	16	690
16	BA9BR-2530	2.5	30	6	16	810
17	BA9BR-2535	2.5	35	6	16	930
18	BA9BR-2540	2.5	40	6	16	1050
19	BA9BR-2545	2.5	45	6	16	1170
20	BA9BR-2710	2.75	10	6	16	390
21	BA9BR-2715	2.75	15	6	16	525

S/N	Models	Balloon Nominal Diameter(mm)	Balloon Nominal Length(mm)	NP(atm)	RBP(atm)	Drug Dose (μg)
22	BA9BR-2720	2.75	20	6	16	645
23	BA9BR-2725	2.75	25	6	16	780
24	BA9BR-2730	2.75	30	6	16	930
25	BA9BR-2735	2.75	35	6	16	1050
26	BA9BR-2740	2.75	40	6	16	1170
27	BA9BR-2745	2.75	45	6	16	1290
28	BA9BR-3010	3.0	10	6	16	435
29	BA9BR-3015	3.0	15	6	16	585
30	BA9BR-3020	3.0	20	6	16	720
31	BA9BR-3025	3.0	25	6	16	870
32	BA9BR-3030	3.0	30	6	16	1020
33	BA9BR-3035	3.0	35	6	16	1140
34	BA9BR-3040	3.0	40	6	16	1290
35	BA9BR-3045	3.0	45	6	16	1425
36	BA9BR-3510	3.5	10	6	14	540
37	BA9BR-3515	3.5	15	6	14	705
38	BA9BR-3520	3.5	20	6	14	870
39	BA9BR-3525	3.5	25	6	14	1050
40	BA9BR-3530	3.5	30	6	14	1200
41	BA9BR-3535	3.5	35	6	14	1380
42	BA9BR-3540	3.5	40	6	14	1530
43	BA9BR-3545	3.5	45	6	14	1695
44	BA9BR-4010	4.0	10	6	14	660
45	BA9BR-4015	4.0	15	6	14	840
46	BA9BR-4020	4.0	20	6	14	1050
47	BA9BR-4025	4.0	25	6	14	1230
48	BA9BR-4030	4.0	30	6	14	1410
49	BA9BR-4035	4.0	35	6	14	1605
50	BA9BR-4040	4.0	40	6	14	1785

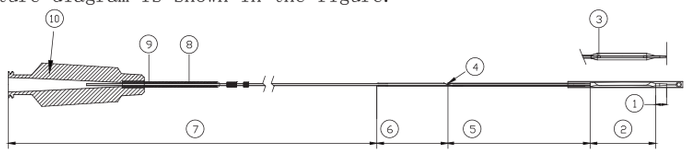
[Product Purpose, Structure and Indications]

1. Product Purpose:

The product is mainly used by inserting the catheter through the femoral or radial artery via the appropriate interventional device, to treat stenotic lesions in human coronary arteries via rapidly releasing the drug coated on the balloon to the lesions.

2. Product Structure:

The product consists of a balloon catheter (hereinafter referred to as a catheter) and a drug coating on the balloon. Its structure diagram is shown in the figure.



1- Tip	2- Balloon (with coating)	3- Radiopaque markers	4- Innerlumen shaft	5- Distal shaft
6- Distal to proximal transition shaft	7- Proximal shaft	8- Strain relief	9- Bonding point	10- Hub

The balloon is coated with a certain amount of coating containing Biolimus A9 drug and polyethylene oxide. The drug has strong anti-proliferative and immunosuppressive effects and can effectively inhibit the proliferation of smooth muscle cells.

The catheter is a balloon dilatation catheter, and there are two markers on the proximal catheter shaft to determine the position of the dilation catheter relative to the tip of a femoral or brachial guiding catheter, respectively. There are two radiopaque markers on the distal innerlumen shaft, which can be used to identify the position of the balloon under fluoroscopy and aid in accurate positioning of the balloon.

The NP of the balloon is 6 atm and the RBP is 16 atm (for diameter 3.0mm and below) and 14 atm (for diameter 3.5mm and 4.0mm).

3. Product Indications

The BA9 DCB is indicated for Percutaneous Transluminal Coronary Angioplasty (PTCA) in the coronary arteries to treat in-stent restenosis (ISR) and de novo lesions including small vessel disease.

[Intended Purpose]

1. Intended Use:

The BA9 DCB is intended for use in patients undergoing Percutaneous Transluminal Coronary Angioplasty (PTCA) procedures.

2. Intended Patient Population:

Patients with small vessel coronary artery disease.
Patients with in-stent restenosis in coronary arteries.

3. Intended User:

Only physicians who have received appropriate training should perform the procedure.

[Contraindications]

The balloon catheter is contraindicated for the following conditions:

- Patients with contraindications to antiplatelet and/or anticoagulant therapy;
- Patients who are unable to undergo percutaneous balloon angioplasty;
- Patients who are allergic to contrast agents;
- Patients who are allergic to Biolimus A9 and its derivatives;
- Patients who are allergic to polyethylene oxide;
- Patients with viable myocardium supplied by a single coronary artery;
- Severely tortuous or angulated lesions;

- Other lesions that are not favourable to balloon delivery or balloon expansion (e.g.: severe calcified lesions, tortuous target lesions, etc.);
- Patients with bleeding tendencies or other conditions with a high risk of bleeding, such as gastrointestinal ulcers that limit the use of antiplatelet and anticoagulant therapies;
- Patients with liver, kidney, brain and other vital organ failure;
- Patients with cardiogenic shock;
- Contraindications to any required concomitant medications;
- Women during pregnancy or lactation;
- Target lesion remained completely occluded after lesion preparation, preventing the passage of the balloon;
- Lesions that are not suitable for interventional techniques.

[Expected Clinical Benefits]

1.BioAscendTM biolimus A9 coated PTCA balloon dilatation catheter is expected to perform at least as well and be as safe and performance as the identified state-of-the-art PTCA balloon catheters available on the market

2.Flexibility: Pass the product through the coronary vessel

3.Trackability: Along the guide wire, it shall be easy to pass the product through the coronary vessel

4.BA9 Load Content: Drug loading is 3.0 (±0.9) μg/mm^2 of the balloon

5.Very large size matrix

[Instructions for Use and Precautions]

1.Inspection Prior to Use:

Before unpacking the product, please check carefully: the expiration date of the product, whether the packaging of the product is damaged;

Refer to Table 3 for accessories that should be equipped with this product.

Table 3: List of accessories

Quantity	Item
1	Percutaneous needle
2-3	5F-8F arterial sheath and dilator
2-3	Guiding catheter (5F=1.7mm, 6F=2.0mm, 7F=2.3mm, 8F=2.7mm)
1	Guidewire, 0.014" maximum diameter x 175 cm length
1	3-4 port manifold
1	Y connector
1	Inflation device with pressure gauge and 3-way stopcock
1	Pre-dilatation balloon catheter
2-3	10-20 mL syringe
1000U / 500cc	Heparin saline (HepNS)
1	Rotating hemostatic valve

2.Pre-procedure Inspection

After unpacking the product, inspect the catheter for bends, kinks, and other damage.

Do not use the product if any defects are noted or if there is any doubts about the product!

Notes:

- This product is a single use medical device and cannot be re-sterilized or reused. Pay attention to the "expiration date" of the product, it must be used before the labeled expiration date.

- Do not rub or scratch the coating on the balloon.

- Do not use if the balloon coating is worn due to physical or chemical damage.

3.Product Operational Procedure

1) Preparation of Balloon Catheter:

i.Open the package, take out the drug balloon catheter, do not take off the protective sleeve on the balloon;

ii.Prepare a pressure inflation device with balloon inflation solution, usually a mixture of contrast medium/sterile saline (1:1);

iii.Remove air from the balloon:

a.Prepare a 20mL syringe (or pressure inflation device) and draw about 4mL of balloon inflation solution;

b.Connect the syringe (or pressure inflation device) to the balloon catheter with the syringe and distal end of the catheter facing down;

c.Apply negative pressure, hold for 15 seconds, and then slowly restore the pressure to normal pressure, so that the balloon inflation solution is filled into the catheter and balloon;

d.Detach the syringe (or pressure inflation device) from the catheter, expel the air from the syringe (or pressure inflation device), and then reconnect, repeat step c until no air bubbles are seen, and then restore the syringe (or pressure inflation device) to normal pressure;

e.Detach the syringe (or pressure inflation device) from the catheter and connect the catheter to the pressure inflation device prepared in step ii.

2) Delivery Procedure:

i.Prepare the vascular access device according to standard PTCA procedures;

ii.Insert a guiding catheter with a hemostatic valve;

iii.Insert a 0.014" (0.36 mm) guidewire into the guiding catheter, the length of the guidewire should be sufficient to reach the distal end of the stenotic lesion;

Note: In order to prevent the drug coating on the balloon from peeling off when the drug balloon is passed through the stenotic vessel, it is recommended to pre-dilate the lesion with a PTCA balloon;

iv.Carefully remove the protective sleeve from the balloon;

v.Insert the proximal end of the guidewire through the tip of the catheter into the innerlumen of the catheter;

vi.Open the hemostatic valve, insert the balloon catheter into the guiding catheter, and close the hemostatic valve;

vii.Under X-ray monitoring, push the drug balloon catheter to the lesion site over the guidewire. Position the balloon with the guidance of angiography and balloon radiopaque markers.

3) Balloon Dilatation

i.Refer to the balloon compliance table on the outer label of the box, and select the balloon inflation pressure that is suitable for the diameter of the diseased blood vessel;

ii.Before inflation, reconfirm the correct balloon position with the radiopaque markers inside the balloon;

iii.Rotate the three-way valve to ensure that the passage between the balloon catheter and the pressure inflator is open;

iv.Under X-ray monitoring, inflate the balloon with a pressure of at least 6 atm, but not exceeding the RBP, and maintain the balloon inflation time for at least 30 seconds;

v.Withdraw the inflation pressure to make the balloon back to a negative pressure state. Confirm that the balloon is in a negative pressure state before moving the balloon catheter.

The balloon compliance table is shown in Table 4 and Table 5 below:

Table 4: Balloon compliance table (for balloon length 30mm and below)

Pressure(atm)	6 NP	8	10	12	14 RBP	16 RBP
Balloon Nominal Diameter(mm)	The tolerance of the outer diameter of the balloon is ±10%					
2.0	2.00	2.04	2.08	2.12	2.16	2.20
2.25	2.25	2.31	2.37	2.43	2.49	2.55
2.5	2.50	2.56	2.62	2.68	2.74	2.80
2.75	2.75	2.81	2.87	2.93	2.99	3.05
3.0	3.00	3.06	3.12	3.18	3.24	3.30
3.5	3.50	3.56	3.62	3.68	3.74	-
4.0	4.00	4.06	4.12	4.18	4.24	-

Table 5: Balloon compliance table (for balloon length above 30mm)

Pressure(atm)	6 NP	8	10	12	14 RBP	16 RBP
Balloon Nominal Diameter(mm)	The tolerance of the outer diameter of the balloon is ±10%					
2.25	2.25	2.31	2.37	2.43	2.49	2.55
2.5	2.50	2.56	2.62	2.68	2.74	2.80
2.75	2.75	2.81	2.87	2.93	2.99	3.05
3.0	3.00	3.08	3.16	3.24	3.32	3.40
3.5	3.50	3.60	3.70	3.80	3.90	-
4.0	4.00	4.10	4.20	4.30	4.40	-

The most ideal dilatation is when the balloon is completely apposed to the arterial wall, so the balloon diameter selected is required to match the diameter of the reference vessel.

Precautions:

- Before performing balloon dilatation, it is necessary to confirm the selection of the appropriate product model specification.

- Extreme care must be taken when removing the balloon catheter from the packaging and passing it through the hemostatic valve to ensure that the balloon system remains intact or remains sterile at all times.

- Do not inflate the balloon prematurely. Do not exceed the RBP for the balloon.

- If resistance is felt during the procedure, do not force passage. The resistance can damage the balloon catheter. Should unusual resistance be felt during the advancement of the balloon catheter through the guide catheter, remove the entire system as a single unit.

- If necessary, the same balloon can be inflated twice. To avoid drug overdose, do not use a second balloon for repeated dilation at the same lesion.

4) Balloon Withdrawal:

i.Deflate the balloon catheter according to the PTCA standard operating procedures to ensure that the balloon is fully under negative pressure;

ii.Fully open the hemostatic valve;

iii.Withdraw the catheter while maintaining the position of the guidewire and the inflation device at negative pressure;

iv.Tighten the hemostatic valve;

v.Repeat angiography to confirm treatment outcome.

Precautions:

Failure to follow the steps above and/or pushing or retracting the catheter with excessive force may result in dislodgement of catheter accessories or catheter damage.

If it is necessary to retain the current position of the guidewire for the next vessel or lesion, leave the guidewire in place and move only all other accessories of the catheter.

[Potential Adverse Events and Complications]

(including but not limited to the following)

- Side effects caused by concomitant
- Infection
- Hematoma at insertion site
- Hypotension
- Palpitations
- Pseudoaneurysm
- Ventricular fibrillation
- Coronary artery spasm
- Angina pectoris
- Arterial perforation
- Cerebral circulation dysfunction
- Thrombosis
- Arterial rupture
- Coronary artery dissection
- Localized hemorrhage
- Arteriovenous fistula
- Vascular complications requiring surgical management
- Total occlusion of coronary artery
- Systemic bleeding
- Acute myocardial infarction
- Death

[Product Storage Conditions, Storage Methods]

1.This product is sterilized by ethylene oxide. If the product package is open or damaged, please do not use it; the product must be used immediately after opening the package. This product is a single use product and cannot be re-sterilized or reused.

2.Storage requirements: The product should be stored in a dry, clean and well-ventilated environment at 0-25℃.

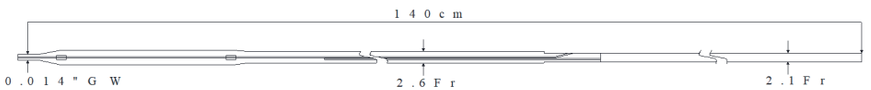
3.The product shelf life is 2 years when stored under the specified storage conditions. Transportation at 40℃ should not exceed 2 weeks. Please use the product before the labeled expiration date and do not use product that have expired. If the product exceeded the shelf life or cannot be used even though it is within its shelf life, please send the product to JWMS.

[Incident Reporting]

The user and/or patient shall report any serious incident that has occurred in relation to the device to JW Medical Systems Ltd. and the competent authority of the EU Member State in which the user and/or patient is established.

[Description of Product Label Graphics, Symbols, Abbreviations]

1.Illustration of the balloon catheter system: the overall effective length of the catheter is 140 cm compatible with 0.014inches diameter guidewire.



2.BA9B-XXXX and BA9BR-XXXX are the models of this product.

3.Symbol Description:

	Do not re-use		Batch code		Consult instructions for use		Sterilized using ethylene oxide		Date of manufacture
	Temperature limit		Use-by date		Caution		Manufacturer		Authorized Representative in the European community/ European Union
	Medical Device		Do not use if package is damaged and consult instructions for use		Unique device identifier		Contains a medicinal substance		CE mark
	Do not resterilize		Single sterile barrier system with protective packaging outside		Keep away from sunlight		Keep dry		Non-pyrogenic

4.English abbreviation in the compliance table: NP indicates Nominal Pressure which is the pressure used to expand the balloon to the reference outer diameter.

5.P/N indicates the part number. 03.04.019.048

[Date of manufacture]: Refer to label

[Expiration date]: Refer to label

[Shelf life]: 2 years

[Summary of Safety and Clinical Performance]:The summary of safety and clinical performance (SSCP) will be made available to the public at https://ec.europa.eu/tools/eudamed

[Basic UDI-DI]: 69348914BA9BT2

Pre-market Clinical Trial Information for DCB

Clinical Trial Objective	To evaluate the clinical performance, safety, and efficacy of the BA9-coated coronary balloon catheter in treating patients with small vessel coronary artery disease.	To compare the safety and efficacy of the BA9-coated coronary balloon catheter with the paclitaxel-releasing coronary balloon catheter (SeQuent® Please Neo) in the treatment of in-stent restenosis in coronary arteries.
Clinical Trial Design	This study is a prospective, multicenter, randomized, controlled, blinded, parallel-group, non-inferiority trial. Participants with primary coronary artery lesions and vessel diameters ≥2.0 mm and ≤ 2.75 mm will be enrolled and randomly assigned in a 1:1 ratio to the experimental group and the control group. All participants will undergo clinical follow-up at postoperative, 30 days, 6 months, 9 months, and 12 months, with angiographic follow-up at 9 months.	This trial consists of a randomized controlled group and a long balloon observation group: 1) Randomized Controlled Group: Participants with in-stent restenosis lesions will use balloons with lengths of 10/15/20/25/30/35/40 mm. They will be randomly assigned in a 1:1 ratio to the experimental group or the control group. 2) Long Balloon Observation Group: A total of 30 participants will be consecutively enrolled, using a 45 mm BA9-coated coronary balloon catheter. All participants will undergo clinical follow-up at baseline, surgery, discharge, 1 month, 6 months, 9 months, 1 year, 2 years, and 3 years after the procedure, with angiographic follow-up at 9 months.
Sample Size	206 participants	310 participants
Efficacy Evaluation	The late lumen loss (LLL) at the lesion segment 9 months post-surgery is significantly lower than that of the plain balloon; Intervention success rate: 94.29%; Restenosis rate at 9 months post-surgery: 7.69%.	The late lumen loss (LLL) in the target lesion segment at 9 months post-surgery is non-inferior to that of the paclitaxel-releasing coronary balloon catheter (SeQuent® Please Neo). There is no difference in the neointimal area at 9 months post-surgery.
Safety Evaluation	15 major adverse cardiovascular events (MACE) were reported, with no cases of all-cause mortality; No thrombosis occurred at the lesion dilation site; 1 case of device malfunction.	In the experimental group, the incidence of device-related cardiovascular clinical composite endpoints at 30 days, 6 months, 9 months, and 1 year post-surgery were 0%, 0.7%, 11.8%, and 13.3%, respectively. The incidence of in-stent thrombosis in the experimental group at 30 days, 6 months, 9 months, and 1 year post-surgery was 0% at all time points.
Conclusion	The results of this clinical trial indicate that the product is safe and effective for the treatment of de novo coronary artery lesions with vessel diameters ≥2.0 mm and ≤ 2.75 mm.	The results of this clinical trial indicate that the product demonstrates reliable efficacy and safety for the treatment of in-stent restenosis in coronary arteries.