JWMS 吉威医疗

EXCROSSAL 心跃®

Excrossal Rapamycin Eluting Coronary Stent

Instructions for Use

CE 2797

JW MEDICAL SYSTEMS LTD.

JWMS
吉威医疗

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Safety and clinical performance (SSCP):

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: 69348914ExcrossalAM

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website:https://ec.europa.eu/growth//sectors/medical-devices/con-tacts_en

For additional information, contact your JW Medical Systems LTD. Sales Representative or JW Medical Systems LTD. Customer Service.

The electronic version of the IFU will be provided on the website.

P/N: 03.04.019.017

[Warnings]

- Patient selection must be very careful as the use of the device may result in the risk of subacute thrombosis, vascular complications and/or bleeding events.
- Patients who are hypersensitive to Co-Cr alloy or Sirolimus may have anaphylactic reaction if implanted with this device.
- Surgical operation should be completed by professional who have received trainings.
- The balloon dilatation pressure shall not exceed the rated burst pressure.
- Please check carefully before use. DO NOT use any product that is expired.
- Stent implantation can only be performed in hospitals with the capability of immediate emergency coronary artery bypass grafting.
- For patients with restenosis after stenting, it may be necessary to expand the artery segment where the stent was implanted repeatedly. At present, the long-term results of repeated expansion of endothelialized stent are uncertain.
- This product has been sterilized before delivery. This product is for single use only. DO NOT re-sterilize or reuse.
- Please check the package carefully before use. DO NOT use a product with damaged package.
- The inflation pressure pump with a pressure gauge (calibrated) is recommended in order to reduce the risk of balloon over-inflation.
- Please read the Instructions for Use carefully before use.
- Due to lack of large-scale randomized controlled clinical evidence, the following conditions are not included in the indications: diabetics, acute myocardial infarction, unprotected left main stem lesion, chronic total occlusion lesion, bifurcation lesion, severe calcification lesion and severe tortuosity lesion.

- Cobalt classified as a CMR 1B substance is present in the device in a concentration above 0.1% weight by weight. Leachable substances of stent was performed according to EN ISO 10993-18.

Table 1: Results of Water (50℃) solution of stent

Element	CAS No.	Content (μg/device)	
		Coated stent	Bare stent
Cobalt	7440-48-4	0.24~0.29	0.15~0.19

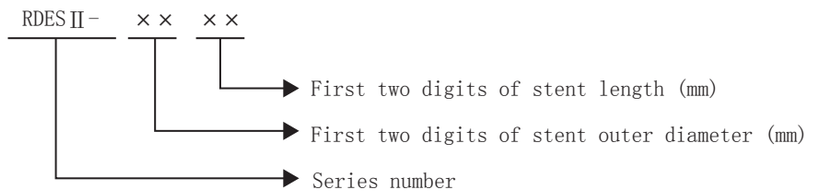
The material of hypotube of delivery system is Stainless steel 304, the Content of Cobalt in hypotube is 0.16% in CMR test.

Residual risk: Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

[Product description]

1. Product name: Excrossal Rapamycin Eluting Coronary Stent

2. Naming rules for product model/specification



3. Specification/model and description: see Table 2.

Table 2: Specifications/models and description

#	Model/ Specification	Nominal OD (mm)	Nominal length (mm)	Nominal pressure (atm)	Rated burst pressure (atm)	Drug content (μg)	#	Model/ Specification	Nominal OD (mm)	Nominal length (mm)	Nominal pressure (atm)	Rated burst pressure (atm)	Drug content (μg)
1	RDES II-2209	2.25	9	8	16	52	20	RDES II-2524	2.5	24	8	16	134
2	RDES II-2509	2.5	9	8	16	52	21	RDES II-2724	2.75	24	8	16	134
3	RDES II-2709	2.75	9	8	16	52	22	RDES II-3024	3.0	24	8	16	134
4	RDES II-3009	3.0	9	8	16	52	23	RDES II-3524	3.5	24	8	14	134
5	RDES II-3509	3.5	9	8	14	52	24	RDES II-4024	4.0	24	8	14	134
6	RDES II-4009	4.0	9	8	14	52	25	RDES II-2229	2.25	29	8	16	162
7	RDES II-2214	2.25	14	8	16	78	26	RDES II-2529	2.5	29	8	16	162
8	RDES II-2514	2.5	14	8	16	78	27	RDES II-2729	2.75	29	8	16	162
9	RDES II-2714	2.75	14	8	16	78	28	RDES II-3029	3.0	29	8	16	162
10	RDES II-3014	3.0	14	8	16	78	29	RDES II-3529	3.5	29	8	14	162
11	RDES II-3514	3.5	14	8	14	78	30	RDES II-4029	4.0	29	8	14	162
12	RDES II-4014	4.0	14	8	14	78	31	RDES II-2533	2.5	33	8	16	184
13	RDES II-2219	2.25	19	8	16	107	32	RDES II-2733	2.75	33	8	16	184
14	RDES II-2519	2.5	19	8	16	107	33	RDES II-3033	3.0	33	8	16	184
15	RDES II-2719	2.75	19	8	16	107	34	RDES II-3533	3.5	33	8	14	184
16	RDES II-3019	3.0	19	8	16	107	35	RDES II-2536	2.5	36	8	16	201
17	RDES II-3519	3.5	19	8	14	107	36	RDES II-2736	2.75	36	8	16	201
18	RDES II-4019	4.0	19	8	14	107	37	RDES II-3036	3.0	36	8	16	201
19	RDES II-2224	2.25	24	8	16	134	38	RDES II-3536	3.5	36	8	14	201

Note: atm is a unit of standard atmosphere, which means 1 standard atmosphere is equal to 101325 Pascals.

[Product performance, structure and Intended purpose]

1. Product performance:

The product is mainly used for implantation with the aid of the corresponding interventional therapy device into the segment of human coronary artery with stenosis via the femoral artery or radial artery in order to support the vascular wall. The drug coated on the stent is used to prevent the proliferation of vascular smooth muscle cells to prevent restenosis.

2. Product structure:

The product is mainly composed of balloon, coated stent (stent + drug coating), radiopaque mark, balloon lumen catheter, distal catheter, proximal catheter, dynamic support needle pole, catheter reinforcement and hub, as shown in the schematic diagram.

1 - Tip	2 -Balloon	3 - Drug Eluting stent(metal stent+drug coating)	4 - Radiopaque marker Bands	5 - Distal shaft	6 - Core wire
7 - Inner lumen	8 - Exit Port	9 - Middle Shaft	10 - Hypotube	11 - Strain Relief	12 - Hub

The stent is made of cobalt chromium alloy, which has good corrosion resistance and biocompatibility. When implanted into human body, it can reduce adverse reactions due to tissues, blood and organs around the implantation site; its chemical inertia can reduce the stimulus response, allergic response and immune response. The stent is applied with a certain amount of coating, which contains biodegradable poly (lactic acid) polymer and the drug rapamycin (Sirolimus). The drug has strong anti-proliferation and immunosuppressive action and can effectively inhibit the proliferation and migration of smooth muscle cells. Polylactic acid is completely degraded after achieving drug carrier function.

The delivery system is the balloon dilatation catheter. There are two marks at the proximal catheter shaft

to determine the position of dilation catheter relative to the front end of guide catheter in different puncture conditions of femoral artery and brachial artery. There are two radiopaque marks on the distal inner catheter, through which the position of the stent can be identified under X-ray, thus facilitating the accurate positioning of the stent.

The nominal pressure of the balloon is 8 atm. The rated burst pressure of the balloon with a stent diameter of 3.5 mm and above is 14 atm, and the rated burst pressure of balloons with other specifications is 16 atm.

3. Intended purpose

The EXCROSSAL Rapamycin Eluting Coronary Stents are suitable for improving the coronary artery lumen diameter in patients with myocardial ischemia or angina caused by primary coronary artery stenosis or occlusion with the aid of the corresponding interventional therapy device. These patients are caused by lesions with a length ⩽ 36 mm in coronary arteries with reference vessel diameters ranging from 2.25 mm to 4.0 mm. The drug coated on the stent is used to prevent the proliferation of vascular smooth muscle cells to prevent restenosis.

[Stent composition and medication information]

1.Stent Composition

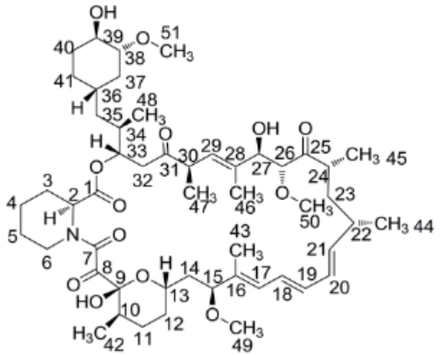
The material of Stent is MP35N conforming to ASTM F562.

2. Medication information

The Sirolimus on the stent can inhibit the proliferation of vascular smooth muscle cells, preventing in-stent restenosis. Polylactic acid (PLA) acts as carrier to control the release of Sirolimus from the stent.

Sirolimus (Rapamycin)

1) Chemical structure:



2) Molecular formula:$C_{51}H_{79}NO_{13}$

3) Formula weight:914.19

[Intended clinical benefits]

The basic mechanisms underlying coronary stenting are relief of obstruction (lumen enlargement) and maintenance of patency thereby ameliorating myocardial ischaemia. The intended clinical benefits of EXCROSSAL Rapamycin Eluting Coronary Stent made by JW Medical include:

- Symptom relief - alleviating Myocardial ischemia or angina pectoris for patients who are symptomatic despite medical therapy.
- Prognostic benefit - preventing cardiac death, recurrent myocardial infarction and heart failure in patients with high ischemic burden or acute coronary syndromes.

[Target Patient population]

The device is intended for use in adult patients with myocardial ischemia or angina caused by De Novo coronary artery stenosis or occlusion.

[Intended users]

This device should only be used by professional surgeon who have capability of performing Coronary Stent deployment surgery.

[Intended using environment]

The device is only designed for use in surgical operating room and catheter lab of hospitals.

[Indications]

- Myocardial ischemia or angina caused by primary coronary artery stenosis or occlusion;
- The diameter of the lesion is between 2.25 mm and 4.0 mm, and the length of lesion is 36 mm or less.

[Contraindications]

Use of the Excrossal Stent System is contraindicated in patients with the following:

- Patients who cannot receive recommended anti-platelet and/or anticoagulant therapy;
- Patients who cannot undergo percutaneous balloon angioplasty;
- Patients known hypersensitive to the contrast agents;
- Patients known hypersensitive to rapamycin and its derivatives;
- Patients known hypersensitive to Cobalt, Chromium, and Co-Cr alloy;
- Patients known hypersensitive to polylactic acid;
- Patients with only a single coronary artery supply of viable myocardium;
- Patients with extremely curved or angulated lesion;
- Other lesions that are not conducive to stent delivery or balloon dilatation;

[Installation, instructions for use and precautions]

1. Inspection Prior to Use:

Before opening the product package, carefully check: the expiration date of the product and intactness of the product package;

Do not use if any defects are noted.

See Table 3 for the materials required (not included in Stent Delivery System package)

Table 3

Quantity	Material
1	Percutaneous access needle
2-3	Arterial sheath and dilator of 5F-8F
2-3	Appropriate guide catheter(5F = 1.7 mm, 6F = 2.0 mm, 7F = 2.3 mm, 8F = 2.7 mm)
1	0.014 inch (or smaller) x 175 cm guidewire
1	3-4 lead connector
1	"Y-shaped" adapter
1	Inflation pressure pump with pressure sensor and 3-way stopcock
1	Pre-dilation balloon catheter
2-3	10-20ml (cc) syringe
1000U/500cc	Heparin saline (HepNS)
1	Rotating hemostatic valve

2. Inspection Prior to Operation:

After opening the product package, carefully check the delivery system for curve, break or other damage, and confirm that the stent is between the two radiopaque markers of the balloon.

Do not use if any defects are noted.

Precautions:

For single use only. DO NOT re-sterilize or reuse this product.

Please pay attention to the "expiration date" of the product. The product must be used before the labeled expiration date.

Do not rub or scratch the coating on the stent.

Do not use the product if the stent coating is worn out due to physical or chemical damage.

The stent and its stent delivery system are to be operated as an integral. Please do not rotate the stent by hand or dismantle the stent at will, otherwise the part between the stent and the balloon will loose and deform, which will cause shedding of drug coating or the stent dislodgement during implantation.

3. Operation procedures

1)Prepare the delivery system:

Connect the pressure pump containing diluted contrast agent to the delivery system, open the piston of the stent delivery system and keep the pressure at zero.

Note: At this time, do not pressurize or pump back the balloon to produce negative pressure.

2)Delivery procedure:

Pre-dilate the lesion with PTCA (Percutaneous Transluminal Coronary Angioplasty) balloon.

Keep the pressure of the inflation pressure pump at zero and turn the rotating hemostatic valve to fully open.

Deliver the radiopaque segment of the guidewire to the distal end of the target vessel, and insert the proximal end of the guidewire into the guidewire lumen of the delivery system through the tip of the delivery system.

Advance the stent delivery system into the blood vessel through the guidewire, and position the stent by angiography and according to the radiopaque marks of the balloon.

3)Deployment procedure:

Before Stent deployment, reconfirm whether the position of stent relative to target lesion is correct or not by the radiopaque marks of the balloon.

First, keep the inflation pressure pump under negative pressure to remove the air in the balloon, and then start dilation.

Note: This procedure can only be performed when it is confirmed that the stent is positioned at the target lesion.

Inflate the balloon with at least the nominal pressure and expand the stent. However, the pressure used to expand the stent shall not exceed the rated burst pressure indicated.

Balloon compliance is shown in Table 4 and Table 5:

Table 4: Excrossal Stent System Compliance (stent length ≤ 29 mm)

Pressure (atm)	8 NP	10	12	14 RBP	16 RBP
Nominal diameter of balloon (mm)	Tolerance of balloon OD: ±10%				
2.25	2.25	2.31	2.37	2.43	2.49
2.5	2.50	2.56	2.62	2.68	2.74
2.75	2.75	2.81	2.87	2.93	2.99
3.0	3.00	3.06	3.12	3.18	3.24
3.5	3.50	3.56	3.62	3.68	—
4.0	4.00	4.06	4.12	4.18	—

Table 5: Excrossal Stent System Compliance (stent length: 33mm and 36mm)

Pressure (atm)	8 NP	10	12	14 RBP	16 RBP
Nominal diameter of balloon (mm)	Tolerance of balloon OD: ±10%				
2.5	2.50	2.56	2.62	2.68	2.74
2.75	2.75	2.81	2.87	2.93	2.99
3.0	3.00	3.08	3.16	3.24	3.32
3.5	3.50	3.60	3.70	3.80	—

RBP =Rated Burst Pressure. Don Not Exceed Rated Burst Pressure

The most ideal expansion is that the stent completely fits the artery wall. Therefore it is required that the stent diameter should match the reference vascular diameter.

Pump back the inflation pressure pump to return the balloon to negative pressure, and confirm that the balloon is under negative pressure before any attempt to move the balloon catheter.

Perform angiography with the guide catheter to confirm proper stent expansion.

Note:

- Stent deployment may lead to intimal tear, dissection or acute occlusion at the distal and/or proximal end of the stent, thus requiring additional treatment (such as CABG (Coronary Artery Bypass Grafting), further balloon dilatation or stent re-implantation).
- When treating multiple lesions, the distal lesion should generally be stented first, followed by stenting of the more proximal lesion(s). Stenting in this order avoids the requirement to cross the proximal stent when placing the distal stent and reduces the chances of the stent dislodgment.
- If the stent is not delivered to the target lesion, do not expand the stent.
- Stent deployment has the potential risk of affecting the blood flow of adjacent collateral vessels.

4)Balloon Withdrawal:

Make sure that the balloon is completely under negative pressure.

Fully open the rotating hemostatic valve.

Withdraw the stent delivery system while keeping the position of the guidewire unchanged and the inflation pressure pump under negative pressure.

Tighten the rotating hemostatic valve.

Repeat angiography to evaluate the stent expansion. If the stent expansion is not satisfactory, try to inflate the stent with an appropriate balloon again until a satisfactory stent expansion (the stent may be inflated under the guidance of intravascular ultrasound in an adequately equipped catheterization room).

Precautions:

- It is allowed to withdraw a stent that has not been inflated to or out of the guide catheter only once, and it is not allowed to move it in or out repeatedly through the distal end of the guide catheter, so as to avoid damage to the stent and its coating during withdrawal.
- Whenever the coronary stent system is advanced or withdrawn, the whole system should move as a whole and an appropriate amount of resistance should be met.
- In case of stent dislodgement, appropriate methods can be taken to take out the stent, but this operation may cause additional damage to the coronary system and/or vascular access, such as bleeding, hematoma or pseudoaneurysm and other vascular complications.
- Failure to follow the above steps and/or advancement or withdrawal of the delivery system with excessive force may result in the falling off or damage of the stent and/or delivery system accessories.
- If it is necessary to keep the current position of the guidewire in order to treat the next blood vessel or lesion, leave the guidewire in situ and only move all the other accessories of the delivery system.

Precautions:

- Caution must be exercised when passing coronary guidewire, IVUS catheter, balloon or delivery system through a newly implanted stent, so as to avoid damage and destruction to the structure of the stent.

6)Magnetic Resonance Imaging (MRI):

Through non-clinical testing, the Excrossal Stent has been shown to be MR Conditional. The conditions are as follows:

- Static magnetic field strengths of 3.0 T.

Under the condition of magnetic field strengths of 3.0 T and maximum whole-body-averaged SAR (specific absorption rate) not exceeding 2.22 W/kg, the local temperature rise of two overlapping stents does not exceed 1.5 ℃ during 15 minutes of MRI scanning.

Under the magnetic field strengths of 3.0 T, the deflection angle of the two overlapping stents is less than 45° and the magnetically induced displacement force is less than their own gravity.

Under the magnetic field strengths of 3.0 T, the unilateral artifact of the image obtained by using gradient echo sequence is no more than 10.0 mm. The artifact may have an impact if the region of interest (ROI) is close to or at the Stent deployment site during MRI scanning.

Under the magnetic field strengths of 3.0 T, the maximum magnetically induced torque of the two overlapping stents is less than their worst gravitational torque caused by gravity.

- No non-clinical testing has been conducted to evaluate if it is MR Conditional beyond these conditions

[Potential adverse events and complications]

The complications of this product are same as those of general Stent deployment. The main complications occur in the gastrointestinal tract, and a few patients may have vomiting, diarrhea, gastrointestinal ulcer and colitis. The extremely rare complications are interstitial pneumonia, thrombocytopenia, central lymphoid tissue inhibition, testicular atrophy and renal function damage. There is no clear evidence for the potential adverse drug reactions caused by rapamycin coated on the stent.

Adverse events that may be associated with stent use in coronary artery include: acute myocardial infarction; arrhythmia, including ventricular tachycardia (VT) and ventricular fibrillation (VF); death; vascular tear; vascular dissection; vasospasm; infection and pain at the puncture site; cardiac perforation; embolism caused by stent dislodgement; acute and subacute thrombosis; stent segment or intra-stent restenosis; hypotension/hypertension; pseudoaneurysm at the puncture site; stroke/cerebrovascular accident; failure to deliver the stent in place; target lesion revascularization; allergic reaction; pericardial tamponade; poor stent adherence.

[Storage conditions and methods]

1. The product is sterilized with E-beam or ethylene oxide. Please do not use the product if the package is open or damaged. The product must be used immediately once the package is opened. The product is for single use only. Do not re-sterilize or reuse.

2. Storage condition: The product shall be stored in a shady, dry, clean and well-ventilated environment where there is no corrosive gas and the temperature is 0-25℃.

3. The product has a shelf life of 24 months under the specified storage conditions. The duration of transportation at a temperature as high as 40 ℃ should not be more than 2 weeks. Please use the product within the shelf life indicated, and do not use expired product. If the product is beyond the expiration date or cannot be used even though it is within the shelf life, please return the product to JW Medical Systems LTD. for disposal.

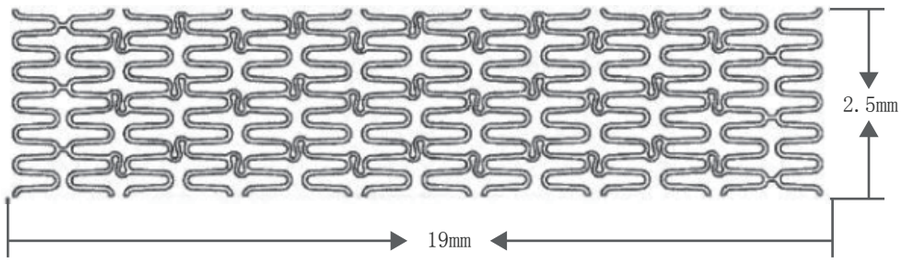
4. If the product is exposed to a temperature > 60 ℃, do not use the product and return it to JW Medical Systems LTD.

[DISPOSAL of used device]

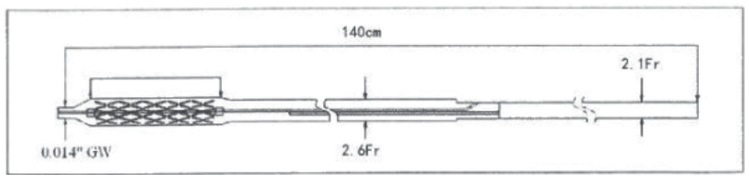
The product can be disposed with normal clinical waste or according to local regulations.

[Diagrams, symbols and abbreviations of labels]

1. Stent diagram: The stent length and outer diameter after expansion are indicated, as shown in the figure: 19 mm is the length of the stent, and 2.5mm is the outer diameter after expansion of the stent.



2. Diagram of the stent and its delivery system: The total length of the catheter is 140 cm, and 0.014″ GW indicates that the diameter of the guidewire is 0.014 inch.



3. RDES II-XX XX is the specification/model of this product.

4. Symbols

	Do not re-use	CN	Country of manufacture		Non-pyrogenic		Consult Instructions for Use
LOT	Batch code	STERILE R	Sterilized using irradiation, single sterilebarrier system with protective packagingoutside		Use-by date	REF	Catalogue code
2 STERILIZE	Do not re-sterilize		Do not use if package is damaged		Caution	0℃ 25℃	Temperature limit
MD	Medical device	EC REP	Authorized representative		Importer	CE 2797	CE marking and Notified Body Code
	Manufacturer	UDI	Unique device identifier		Contains a medicinal substance	MR	MR Conditional
	Contains hazardous substances		Keep dry		Keep away from sunlight		Patient information website
#	Patient number		Health care centre or doctor	31	Date		

5. Abbreviations in the compliance table: NP represents the pressure used to inflate the stent to the reference outer diameter, i.e. the nominal pressure; RBP is the rated burst pressure of the balloon.

6. P/N is the IFU number.

[Production date]: See the label

[Expiration date]: See the label

[Shelf life]: 24 months

[Revision date of Instructions for Use]: June 2024

[Rev]: 01