Shunmei®

CE 2696

INSTRUCTION FOR USE

Coronary Drug Eluting Stents

CAUTION

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

PRODUCT NAME

Coronary Drug Eluting Stents

INTENDED USE

This product is expected to be suitable for patients who are eligible for percutaneous transluminal coronary angioplasty (PTCA). This product is used to enlarge the diameter of coronary artery cavity and reduce restenosis in coronary intervention therapy.

DEVICE DESCRIPTION

The Coronary Drug Eluting Stents is composed of balloon-expandable stent, drug coating and delivery system. See figure: 1 for Coronary Drug Eluting Stents.

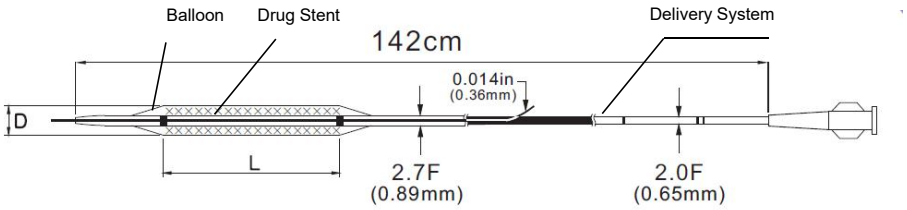


Fig.1 Coronary Drug Eluting Stents

Coronary Drug Eluting Stents

The stent is manufactured from cobalt chromium (CoCr). A range of sizes is available, as described in table 1.

Table 1: Range of size (Stents)

Diameter (mm)	Length (mm)											
	8	12	16	20	24	28	32	36	40	44	48	52
φ2.0	√	√	√	√	√	√	√	√	×	×	×	×
φ2.25	√	√	√	√	√	√	√	√	√	√	√	√
φ2.5	√	√	√	√	√	√	√	√	√	√	√	√

φ2.75	√	√	√	√	√	√	√	√	√	√	√	√
φ3.0	√	√	√	√	√	√	√	√	√	√	√	√
φ3.5	√	√	√	√	√	√	√	√	√	√	√	√
φ4.0	×	√	√	√	√	√	√	√	√	√	√	√
φ4.5	×	√	√	√	√	√	√	√	√	√	√	√
φ5.0	×	√	√	√	√	√	√	√	√	√	√	√

Drug Coating

The drug coating is a blend of sirolimus and polymers. Sirolimus performs the function of anti-proliferation and immunity restraint, inhibiting vascular smooth muscle cell proliferation and migration effectively. The polymers function to delay drug release and provide excellent biocompatibility.

Delivery System

The delivery system is a rapid exchange balloon-expandable catheter. The usable length of the delivery system is 142cm.

There are two proximal delivery system shaft markers (90 cm and 100 cm from the distal tip). These markers indicate the relative position of the delivery system to the end of a brachial or femoral guiding catheter. Also, there are two radiopaque markers, located underneath the balloon, which fluoroscopically mark the working length of the balloon.

Near the tip, there is a notch for the guide-wire. The usual guide-wire, no more than 0.014″ (0.36mm), can pass the guide-wire lumen of catheter smoothly.

Lubricious coating in the catheter shaft surface, together with stent's tiny diameter and flexibility enable its advance to the site of narrowing with more ease and efficiency.

The stent nominal pressure is 10atm. The rated burst pressure (RBP) of all balloons, except the φ4.0-φ5.0mm, is 16atm. The RBP of the φ4.0-φ5.0mm balloon is 14atm.

INDICATIONS

The Coronary Drug Eluting Stents is used for the treatment of ischemic heart disease. The product indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to de novo native coronary artery lesions, and the length of chosen product under nominal pressure(8mm, 12mm, 16mm, 20mm, 24mm, 28mm, 32mm, 36mm, 40mm, 44mm, 48mm, 52mm) should be longer than the length of target lesions with reference vessel diameters of ≥2.25 mm to ≤ 5.00 mm.

Coronary Drug Eluting Stents can be used for the following indications:

• Improve coronary luminal diameter in patients with symptomatic ischemic disease due to discrete de novo lesions of length < 52 mm in native coronary arteries with a reference vessel diameter of ≥2.0 to ≤ 5.0 mm.

• One or more stenosis in one-vessel.

• Protected left main coronary artery stenosis.

• Acute or threatened closure of PTCA.

• Prominent residual stenosis after PTCA.

• Coronary artery re-stenosis after PTCA.

CONTRAINDICATIONS

The Coronary Drug Eluting Stents is contraindicated for use in:

- Patients in whom antiplatelet and / or anticoagulant therapy is contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon.
- Patients with a known hypersensitivity or contraindication to Sirolimus, cobalt, chromium, nickel, tungsten and biodegradable polymers may have an allergic reaction to this implant; therefore, the implant is not recommended for such patients.

ADVERSE EVENTS

Adverse events may be associated with the use of a coronary stem.

- Abrupt closure
- Acute myocardial infarction
- Allergic reaction to contrast
- Aneurysm
- Arterial perforation
- Arterial rupture
- Arteriovenous fistula
- Arrhythmias, including atrial and ventricular
- Bleeding complications, which may require transfusion
- Coronary artery spasm
- Coronary or stent embolism
- Coronary or stent thrombosis
- Death
- Dissection of the coronary artery
- Distal emboli (air, tissue or thrombotic)
- Drug reactions to antiplatelet agents / contrast medium
- Emergent or non-emergent Coronary Artery Bypass Graft Surgery
- Fever
- Hypotension / Hypertension
- Hypersensitivity reactions
- Infection and pain at insertion site

- Injury to the coronary artery
- Ischemia, myocardial
- Myelosuppression
- Nausea and vomiting
- Palpitations
- Peripheral ischemia (due to vascular or nerve injury)
- Pseudoaneurysm
- Restenosis of stented segment
- Stroke / cerebrovascular accident (CVA)
- Total occlusion of coronary artery
- Unstable or stable angina pectoris
- Vascular complications, including entry site, which may require vessel repair
- Ventricular arrhythmias including ventricular fibrillation and ventricular tachycardia
- Vessel dissection

Adverse events associated with daily oral administration of Sirolimus:

- Abdominal pain
- Acne
- Anemia
- Coagulopathy
- Diarrhea
- Edema
- Hemolysis
- Hypercholesterolemia
- Hyperlipidemia
- Hypertension
- Hypertriglyceridemia
- Hypogonadism male
- Leukopenia
- Liver function test abnormal
- Lymphocele
- Myalga
- Nausea
- Pain
- Pneumonia
- Pyelonephritis
- Rash

- Renal tubular necrosis
- Sepsis
- Surgical wound complication
- Thrombocytopenia
- Urinary tract infection
- Venous thomboembolism
- Viral, bacterial and fungal infections
- Wound infection

WARNINGS

- Judicious selection of patients is necessary since the use of this device carries the associated risk of stent thrombosis, vascular complications and / or bleeding events.
- Oral administration of Sirolimus in combination with cyclosporine have been associated with increased serum cholesterol and triglycerides. Therefore, patients should be monitored for changes in lipidprofiles.
- Persons allergic to L-605 cobalt chromium alloy, biodegradable polymers, or Sirolimus may suffer an allergic reaction to this implant.
- Do not expose the product to organic solvent, for example alcohol.
- Do not use the contrast medium which incorporates the components of Ethiodol, Lipiodol or same kind of agents.
- Never advance the guide wire briskly and/or force it into the catheter when the catheter is bent or twisted. This may cause breakage/separation of the catheter, resulting in damage to the vessel.
- To reduce the incidence rate for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and / or damage / separation of the catheter.
- Do not resterilize and / or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.
- A manual pressure expansion device should be used, rather than an automatic expansion device.
- Do not alter this device.

PRECAUTIONS

1. Stent Handling – Precautions

- For single use only. Do not reuse. Note the product "Use by date". Do not use this device if it is out of date or damaged.
- Do not remove the stent from the delivery system as removal may damage the stent. The stent system is intended to perform together as a system.

- This delivery system should not be used in conjunction with other stents.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during catheter removal from packaging, placement over the guide wire and advancement through the rotating hemostatic valve adapter and guiding catheter hub.
- Do not manipulate, touch or handle the stent with your fingers as this may cause coating damage, contamination or dislodgement of the stent from the delivery balloon.
- 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.
- This device should be used only by physicians who have received appropriate training.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent.

2. Stent Placement - Precautions

- Do not prepare or pre-inflate the delivery system prior to stent deployment other than as directed. Use balloon purging technique described in "Delivery System Preparation".
- When treating multiple lesions, stent the distal lesion prior to stenting the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent, and reduces the chance of dislodging the proximal stent.
- 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 (ABG, further dilatation, placement of additional stents, or other).
- Do not expand the stent if it is not properly positioned in the vessel. (See 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. Balloon pressures should be monitored during inflation. Use of pressures higher than specified on product label may result in a ruptured balloon with possible intimal damage and dissection.
- An unexpanded stent may be retracted into the guiding catheter one time only. An unexpanded stent should not be reintroduced into the artery once it has been pulled back into the guiding catheter. Subsequent movement in and out through the distal end of the guiding catheter should not be performed otherwise the stent may be damaged when retracting the undeployed stent back into the guiding catheter. Should any resistance be felt at any time during withdrawal of the Coronary Stent System, the entire system should be removed as a single unit.
- Stent retrieval methods Use of additional wires may result in additional trauma to the coronary vasculature and / or the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.

- When multiple drug eluting stents are required, only Sirolimus Eluting Coronary Stents must be used. Potential interactions with other drug eluting stents or coated stents have not been evaluated and should be avoided.

  If multiple stents are required (resulting in stent-to-stent contact), stent materials should be of si milar composition. Placing multiple stents of different metals in contact with each other may increase the potential for corrosion. The risk of in vivo corrosion does not appear to increase based on in vitro corrosion tests using an L-605 CoCr alloy stent in combination with a 316L stainless steel alloy stent.
- The extent of the patient's exposure to drug and polymer is directly related to the number of stents implanted. A patient can receive up to 4 Sirolimus Eluting Coronary Stents depending on the number of vessels treated and the lesion length. Those patients receiving bailout stenting will receive additional Sirolimus Eluting Coronary Stents. The use of multiple Sirolimus Eluting Coronary Stents will result in the patient receiving larger amounts of drug and polymer.
- The safety and effectiveness of the stent in patients with prior brachytherapy of the target lesion or the use of brachytherapy to treat in-stent restenosis in a Sirolimus Eluting Coronary Stent have not been established. Both vascular brachytherapy and the Sirolimus Eluting Coronary Stent alter arterial remodeling. The synergy between these two treatments has not been established.

3. Stent / System Removal – Precautions

Should any resistance be felt at any time during either lesion access or removal of the delivery system post-stent implantation, the entire system should be removed as a single unit.

When removing the delivery system as a single unit:

- DO NOT retract the delivery system into the guiding catheter.
- Position the proximal balloon marker just distal to the tip of the guiding catheter.
- Advance the guide wire into the coronary anatomy as far distally as safely possible.
- Tighten the rotating hemostatic valve to secure the delivery system to the guiding catheter, then remove the guiding catheter and delivery system as a single unit.

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

If it is necessary to retain guide wire position for subsequent artery / lesion access, leave the guide wire in place and remove all other system components.

4. Post Implant – Precautions

When crossing a newly deployed stent with a guide wire, balloon or delivery system, exercise care to avoid disrupting the stent geometry.

5. MRI Statement

Coronary artery cobalt chromium alloy polymer coated sirolimus drug-eluting stent system has been

shown in non-clinical testing to be MRI safe immediately following implantation. MRI test conditions used to evaluate this stent were:

- The static magnetic field strength of 3 Tesla;
- With a maximum spatial gradient strength of less than or equal to 80 mTesla/meter;
- A maximum whole body averaged specific absorption rate (SAR) of 3.7 W/Kg or lower for 20 minutes of MRI scanning;

  Based on non-clinical testing, under the above conditions: Stent displacement force is less than the gravity, therefore it is consider that the risk of the displacement force is less than that produced by normal daily activities, no torque, while a single stent produced a temperature rise of less than 2.16 ℃.

  Coronary Drug Eluting Stents under the static magnetic field strength of 3 Tesla MRI scanning, the test sample maybe present problem if MR image area of interest is in or near the area where the test sample is located.

  MRI response of overlapping stents or stents with fractured struts is unknown.

  Non-clinical testing at field strength greater than 3 Tesla has not been preformed to evaluate stent migration and heating.

6. Drug Interactions

Sirolimus is extensively metabolized by the CYP3A4 isoenzyme in the gut wall and liver. Therefore, a bsorption and subsequent elimination of sirolimus may be influenced by drugs that affect this isoenzyme. CYP3A4 inhibitors can slow down the metabolism of sirolimus and Increase blood levels of Sirolimus, but the inducer of CYP3A4 will cause the opposite situation. Formal drug interaction studies have not been performed with Coronary Drug Eluting Stents. Therefore, due consideration should be given to the potential for both systemic and local drug interactions in the vessel wall when deciding to place the Sirolimus Eluting Coronary Stent in a subject taking a drug with known interaction with Sirolimus.

Sirolimus, when prescribed as an oral medicine, may interact with the following drugs:

- CYP3A4 isozyme inhibitors (ketoconazole, itraconazole, ritonavir, erythromycin, clarithromycin, fluconazole, calcium channel blockers)
- Inducers of CYP3A4 isozyme (rifampin, rifabutin, carbamazepin, Phenobarbital, phenytoin)
- Antibiotics (ciprofloxacin, ofloxacin)
- Glucocorticoids
- HMGCoA reductase inhibitors (simvastatin, lorvastatin)
- Digoxin
- Cisapride (theoretical potential interaction)
- Sildenafil (Viacra®) (theoretical potential interaction)
- Antihistamines (terfenadine, astemizole)
- Grapefruit juice

7. Production Waste handling attention

The production is sterile and pyrogen-free, single-use only. After use, dispose the device according to hospital, administrative or government policies.

8. Use in Special Populations

- There are no adequate and well controlled studies in pregnant women. Effective contraception should be initiated before implanting a stent and for one year after implantation. The stent should be used during pregnancy only if the potential benefit outweighs the potential risk to the embryo or fetus.
- Use during lactation: A decision should be made whether to discontinue nursing prior to stent implantation, taking into account the importance of the stent to the mother.
- Pediatric use: The safety and efficacy of the stent in pediatric patients below the age of 18 years have not been established.
- Elderly people use: Clinical studies of the did not find that patients age 65 years and over differed with regard with regard to safety and efficacy compared to younger patients.

9. Users

Only surgeons who have received appropriate training and are familiar with the principles, clinical applications, side effects and hazards should use this device.

INSTRUCTIONS FOR USE

1. Inspection Prior to Use

Prior to using the Coronary Drug Eluting Stents, carefully remove the system from the package and inspect for bends, kinks, and other damage. Verify that the stent does not extend beyond the radiopaque balloon markers. Do not use if any defects are noted.

Note: The outside of the inner pouch is NOT sterile.Open the inner pouch aass or drop the product into the sterile field using an aseptic technique.

2. Materials Required

- Appropriate guiding catheter(s)
- syringes (10 - 20 cc)
- Heparinized Normal Saline (HepNS)
- Guide wire
- Rotating hemostatic valve with minimum inner diameter
- 60% contrast diluted 1:1 with normal saline
- Inflation device
- Three-way stopcock
- Torque device

- Guide wire introducer

3. Preparation

1) **Guide Wire Lumen Flush**

① Remove the protective sheath from the tip.

② Flush the guide wire lumen with HepNS until fluid exits the guide wire exit notch.

2) **Delivery System Preparation**

① Prepare an inflation device / syringe with diluted contrast medium.

② Attach an inflation device / syringe to stopcock; attach it to the inflation port.

③ With the tip down, orient the delivery system vertically.

④ Open the stopcock to delivery system; pull negative for 30 seconds; release to neutral for contrast fill.

⑤ Close the stopcock to the delivery system; purge the inflation device / syringe of all air.

⑥ Repeat steps 3 through 5 until all air is expelled.

Note: If air is seen in the shaft, repeat Delivery System Preparation steps 3 through 5 to prevent uneven stent expansion.

⑦ If a syringe was used, attach a prepared inflation device to the stopcock.

⑧ Open the stopcock to the delivery system.

⑨ Leave on neutral.

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

3) **Delivery Procedure**

① Prepare the vascular access site according to standard practice.

② Pre-dilate the lesion with a balloon catheter.

③ Maintain neutral pressure on the inflation device. Open the rotating hemostatic valve as wide as possible.

④ Backload the delivery system onto the proximal portion of the guide wire while maintaining guide wire position across the target lesion.

⑤ Advance the delivery system over the guide wire to the target lesion. Utilize radiopaque balloon markers to position the stent across the lesion; perform angiography to confirm stent position.

Note: Should any resistance be felt at any time during either lesion access or removal of the Delivery System post-stent implantation, remove the entire system as a single unit. See Stent / System Removal - Precautions for specific delivery system removal instructions.

⑥ Tighten the rotating hemostatic valve. The stent is now ready to be deployed.

4) **Deployment Procedure**

① CAUTION: Refer to product label for in vitro stent inner diameter and RBP.

Deploy the stent slowly by pressurizing Delivery System in 2 atm increments every 5 seconds, until stent is completely expanded. Maintain pressure for 30 seconds. If necessary, the Delivery System

can be repressurized or further pressurized to assure complete apposition of the stent to the artery wall. Do not exceed RBP.

FURTHER EXPANSION OF THE DEPLOYED STENT:

If the deployed stent size is still inadequate with respect to reference vessel diameter, a larger balloon may be used to further expand the stent, if the initial angiographic appearance is sub-optimal, the stent may be further expanded using a low profile, high pressure, non-compliant balloon dilatation catheter.

Expanded stents should not be left under-dilated in the vessels.

CAUTION: Do not dilate the stent beyond the following limits.

② Deflate the balloon by pulling negative on the inflation device for 30 seconds.

5) **Removal Procedure**

① Ensure the delivery system is fully deflated.

② Fully open the rotating hemostatic valve.

③ White maintaining guide wire position and negative pressure on the inflation device, withdraw the delivery system.

Note: Should any resistance be felt at any time during either lesion access or removal of Delivery System post-stent implantation, the entire system should be removed as a single unit. See Stent / System Removal - Precautions for specific Delivery System removal instructions.

④ Tighten the rotating hemostatic valve.

⑤ Repeat angiography to assess the stented area.

If post dilatation is necessary, ensure the final stent diameter matches the reference vessel diameter. Assure that the stent is not under-dilated.

PATIENT SELECTION AND TREATMENT

- **Individualization of Treatment**

The risks and benefits described above should be considered for each patient before using the Coronary Drug Eluting Stents. Patient selection factors to be assessed should include judgment regarding risk of antiplatelet therapy. Special consideration should be given to those patients with recently active gastritis or peptic ulcer disease.

Antiplatelet drugs should be used in combination with Sirolimus. Physicians should, according to the current DES literature and the specific needs of individual patients, determine the specific Antiplatelet / Anticoagulation regimen to be used for their patients in general practice.

It is very important that the patient is compliant with the post procedural antiplatelet recommendations. Premature discontinuation of prescribed antiplatelet medication could result in a higher risk of thrombosis, myocardial infarction or death. Prior to PCI, if a surgical or dental procedure is anticipated that requires early discontinuation of antiplatelet therapy, the interventionalist and patient should carefully consider

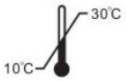
whether a Drug Eluting Stent and its associated recommended antiplatelet therapy is the appropriate PCI choke. Following PCI, should a surgical or dental procedure be recommended, the risks and benefits of the procedure should be weighed against the possible risk associated with premature discontinuation of antiplatelet therapy.

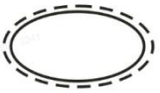
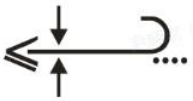
Patients who require premature discontinuation of antiplatelet therapy secondary to significant active bleeding should be monitored carefully for cardiac events and, once stabilized, have their antiplatelet therapy restarted as soon as possible per the discretion of their treating physicians.

HOW SUPPLIED

- **Sterile:** This device is sterilized with ethylene oxide gas. Non-pyrogenic. Do not use if the package is open or damaged.
- **Contents:** One Coronary Drug Eluting Stents.
- **Storage:** Any moisture, sunshine, rain, high temperature, heavy pressure and impact should be avoided in the process of transportation. Store at the temperature 10-30 °C and the relatively humidity is 50±5% with no corrosive gas and in cool, dry, well-ventilated, and clean rooms.

Definition

	**Caution**		**Keep dry**
	**Batch code**		**Non-pyrogenic**
	**Do not re-sterilize**		**Do not use if package is damaged and consult instructions for use**
	**Use by date**		**Do not re-use**
	**Manufacturer**		**Date of manufacture**
	**Catalogue number**		**Humidity limit**
	**Keep away from sunlight**	 **eIFU Indicator**	**Consult instructions for use or consult electronic instructions for use**
	**Temperature limit**		**Fragile items**
	**Medical device**		**Authorized representative in the European Community/European Union**
	**Unique device identifier**		**CE Marking**

	**MRI safety and compatibility**	2696	**Notified Body ID number**
	**Single sterile barrier system Sterilized using ethylene oxide**		**Single sterile barrier system with protective packaging outside**
	**Contains hazardous substances. (CAS7440-48-4)**		**Contains a medicinal substance. 5μg/mm Sirolimus**
	**Contain specified substance**		**Contain specified substance :Ni**
	**Guiding catheter**		**Maximum outer diameter of the guide wire**
	**Contents. Numbers represent quantity 1 unit**		**Contents. Numbers represent quantity 50 units**
	**Stent's diameter**		**Stent's length**
RX	**rapid exchange**		

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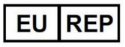

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File No.: SM-IFU-DES-001, A.4

Revision Date：2026-05-25