MeRes100™

Sirolimus Eluting BioResorbable Vascular Scaffold System

IFU45c09/30012021

Instructions for use - English

1. Device Description:

The MeRes100™ Sirolimus Eluting BioResorbable Vascular Scaffold System (MeRes100™ BRS) is a GHTF Class D Implantable Medical Device. This device consists of following components -

a. A balloon expandable scaffold made from polymer poly-L-lactide (PLLA)
b. Active component
c. Scaffold delivery system

- The scaffold is made from PLLA which is a biocompatible and bioresorbable polymer which undergoes hydrolytic degradation in the body and eventually gets eliminated as carbon dioxide and water. The active component is therapeutic agent, an anti-proliferative drug viz. Sirolimus. The drug is formulated with biocompatible bioabsorbable polymer viz. poly-DL-lactide (PDLLA) which acts as drug reservoir and controls drug release rate.
- The scaffold delivery system is a PTCA catheter
- MeRes100™ Sirolimus Eluting BioResorbable Vascular Scaffold is temporary implant which gradually resorbs over the period of 2-3 years.

1.1 Device Components Description:

1.1.1 Available Scaffold lengths & diameters:

Available scaffold lengths & diameters (56 configurations) are shown in table-1below.

Table - 1: MeRes100™ BRS Size matrix

Available Scaffold Diameters(mm)	Available Scaffold Lengths (mm)							
	13	16	19	24	29	32	37	40
2.25	MRS22513	MRS22516	MRS22519	MRS22524	MRS22529	MRS22532	MRS22537	MRS22540
2.50	MRS25013	MRS25016	MRS25019	MRS25024	MRS25029	MRS25032	MRS25037	MRS25040
2.75	MRS27513	MRS27516	MRS27519	MRS27524	MRS27529	MRS27532	MRS27537	MRS27540
3.00	MRS30013	MRS30016	MRS30019	MRS30024	MRS30029	MRS30032	MRS30037	MRS30040
3.25	MRS32513	MRS32516	MRS32519	MRS32524	MRS32529	MRS32532	MRS32537	MRS32540
3.50	MRS35013	MRS35016	MRS35019	MRS35024	MRS35029	MRS35032	MRS35037	MRS35040
4.00	MRS40013	MRS40016	MRS40019	MRS40024	MRS40029	MRS40032	MRS40037	MRS40040

Table - 2: Product Description

1.1.2	Scaffold Material	Bioresorbable Polymer laser cut from seamless PLLA tubing in a unique design pattern.
1.1.3	Scaffold delivery balloon catheter system	Name of Delivery System: Xpedient™ Rx PTCA Balloon Dilatation Catheter - UNS (Lineage) Semi-compliant Polyamide balloon, nominally 0.5 mm longer on both sides than the scaffold length. Mounted scaffold length & location is defined by two platinum-iridium swaged radio-opaque markers under the balloon catheter. Two proximal delivery system shaft markers (90 cm and 100 cm proximal to distal tip) indicate the relative position of the delivery system to the end of brachial or femoral guiding catheter.
1.1.4	Delivery system usable length	142 cm
1.1.5	Guide wire lumen	Starts at the distal tip of the balloon catheter & ends approximately 25 cm from distal tip of the balloon catheter
1.1.6	Guide-wire rapid exchange (Rx) port	Starts at the distal tip of the balloon catheter emerges approximately 25cm from distal tip of the balloon catheter. A disposable stylet protects the distal catheter from an inadvertent kinking
1.1.7	Shaft outer profile	Proximal 2.13F Distal 2.7F
1.1.8	Scaffold dilatation / Balloon inflation pressures	Nominal Pressure: Refer Product Label Rated Burst Pressure: Refer Product Label
1.1.9	Guide catheter compatibility	6F (Min I.D. 0.070" / 1.8 mm)
1.1.10	Guide wire compatibility	0.014" (0.36 mm)
1.1.11	Product code format MRSxxxyy	MRS = MeRes100 BRS xxx = nominal scaffold diameter (mm) yy = nominal scaffold length (mm) For e.g. MRS30019 xxx = 300 = Diameter 3.00 mm yy = 19= Length 19 mm
1.1.12	Drug Dose	1.25µg /mm²

1.2 Drug Component Description:

1.2.1 Coating:

- MeRes100™ BRS is coated with a blend of active drug component and an excipient component in a 1:1 ratio. The excipient component (carrier) controls the drug release kinetics.
- The coating in MeRes100™ BRS has two components.
  a. Active component (Drug) – Sirolimus
  b. Excipient component (Carrier) – poly-DL-lactide (PDLLA)

1.2.2 Drug (Sirolimus):

Sirolimus (ATC Code L04AA10) is a widely used drug which belongs to a class of therapeutic agents known as macrocyclic lactones or macrolides. It's a cytostatic drug and an immunosuppressant. Sirolimus drug is the active ingredient of the device that controls growth of neo-intimal inflammatory cells and reduces its volume.

Synonyms: Rapamycin, Rapamune.

The IUPAC name of Sirolimus is (3S,6R,7E,9R,10R,12R,14S,15E,17E,19E,21S,23S,26R,27R,34aS)-9,10,12,13,14,21,22,23,24,25,26,27,32,33,34,34a-hexadecahydro-9,27-dihydroxy -3-[(1R)-2-[(1S,3R,4R)-4-hydroxy-3-methoxycyclohexyl]-1-methylethyl]-10,21-dimethoxy-6,8,12,14,20,26-hexamethyl-23,27-epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclohentriacontine-1,5,11,28,29(4H,6H,31H)-pentone.

Its molecular formula is $C_{51}H_{79}NO_{13}$ and its molecular weight is 914.2 AMU

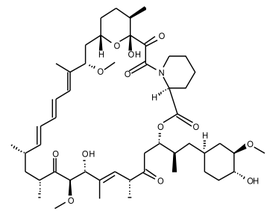


Fig.1 Sirolimus Drug Chemical Structure

Sirolimus is a white to off-white powder and is insoluble in water, but freely soluble in benzyl alcohol, chloroform, acetone, and acetonitrile. It has a melting temperature of approximately 183-185°C. Sirolimus belongs to a class of therapeutic agents known as macrocyclic lactones or macrolides.The drug content on MeRes100™ BRS ranges 107.1 µg to 552.2 µg.

1.2.3 Excipient:

The excipient or carrier component of the coating consists of a biodegradable polymer viz. poly-DL-lactide (PDLLA). The polymer acts as drug carrier and controls the drug release kinetics. PDLLA degrades with time from the scaffold.

2. How Supplied:

Sterile: This device is sterilized with E-beam radiation. It is intended for single use only. Do not resterilize. Do not use the device if the package is opened or damaged.

Contents: One (1) MeRes100™ BRS housed in a protective circular hoop tray, one (1) Instructions for Use, two (2) Scaffold Implant Cards.

Storage: Store at dry and well ventilated place at a temperature 25°C ± 2°C; excursions permitted to 5°C lower side and 40°C higher side. Protect from light.

Note: Based on in vitro testing, MeRes100™ BRS is demonstrated to be compatible for excursion temperatures of 5°C lower side and 40°C higher side upto 3 months.

Shelf Life: 2 years.

3. Indications:

The MeRes100™ BRS is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to de novo lesion in native coronary arteries in patients eligible for Percutaneous Transluminal Coronary Angioplasty (PTCA) and Scaffolding procedures.

The scaffold will eventually resorb and potentially facilitate normalization of vessel function in patients.

Covering of minimum 2 mm of non-diseased tissue on either side of the target lesion is recommended. For example, the lesion length may not be more than 15 mm for the scaffold with 19 mm length.

4. Contraindications:

MeRes100™ BRS is contraindicated in the following patient types.

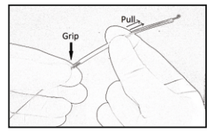
- Patients with hypersensitivity or allergies to aspirin, heparin, clopidogrel, bivalirudin, ticlopidine, prasugrel, ticagrelor and drug such as Sirolimus (Rapamycin) or similar drugs or any analogue or derivative, poly-L-lactide (PLLA), poly-DL-lactide (PDLLA), platinum, or with any contrast media.
- Patients in whom anti-platelet and/or anti-coagulant therapy are contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon.
- Transplant patients.

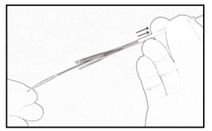
5. Warnings:

- Judicious patient selection is necessary during use of this device since it carries the associated risks of thrombosis, vascular complications and/or bleeding events.
- It is not recommended to treat patients having a lesion with excessive tortuosity proximal to or within the lesion.
- Excessive Balloon dilatation of any cells of a deployed MeRes100™ BRS will cause scaffold damage.
- Device (i.e. Guide sheaths) that decrease the inner diameter of the guide catheter through which the MeRes100™ BRS system is tracked will affect minimum guide catheter compatibility and hence must not be used with the MeRes100™ BRS system. For example do not insert a 5-in-6, or 6-in-7 guide sheath into a 6F or 7F guiding catheter, as doing so will result in an inner diameter that is too small for use with the MeRes100™ BRS System.
- Careful selection of the scaffold diameter with respect to target lesion reference vessel diameter is recommended to minimize the potential damage to the scaffold during placement.
- Adequate lesion preparation prior to scaffold implantation is recommended. It is not recommended to treat patients with a lesion that prevents complete inflation of an angioplasty balloon (e.g. a severely calcified lesion that has not had adequate lesion preparation), or a lesion with greater than 40% residual stenosis after pre-dilatation by visual estimation.
- Do not intentionally torque the device.
- Persons allergic to poly-L-lactide (PLLA), poly-DL-lactide (PDLLA),sirolimus or platinum may suffer an allergic reaction to this implant.
- Never try to straighten a kinked hypotube. This may result in breakage of the shaft.
- Effect of multiple Stenting is not evaluated independently. Decision of multiple Stenting is at the physician's discretion.

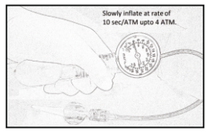
6. Device Handling Instructions:

- Pre-dilate the lesion prior to Scaffold deployment.
- Grip the proximal end of inner transparent *banana-peel-away-sheath* and gently prise away the outer blue-sheath. Along with stainless steel stylet, discard both the protective sheaths (See below Figures).

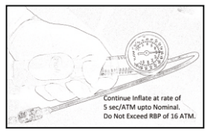




- Scaffold is now ready for use.
- Backload the device on to the guidewire without touching the Scaffold.
- Do not apply negative pressure to the inflation device.
- Keep the rotating hemostatic valve fully open to allow smooth passage of Scaffold and its delivery system.
- Keep a Timer Device handy.
- Once the Scaffold is in the guiding catheter and is correctly positioned across the lesion, allow at least 60 seconds for the Scaffold to be conditioned at body temperature.
- Prepare the device by applying negative pressure on the inflation device.
- Under fluoroscopic guidance, slowly inflate the Scaffold at the rate of 10 seconds/atm upto 4 atm (see below Figure).



- Thereafter, continue to inflate at the rate of 5 seconds/atm upto nominal pressure or higher till desired Scaffold expansion is obtained.
- Do not exceed the rated burst pressure (RBP) as indicated on labeling (see below Figure.



- Do not expand the Scaffold beyond 0.5 mm over its stated diameter.
- Maintain Scaffold deployment pressure for 30 additional seconds before balloon deflation.
- Post dilate only using a new non-compliant (NC) balloon.
- NC balloon should be shorter than the Scaffold length and sized to remain within the Scaffold diameter and boundaries taking care that the Scaffold expansion is never beyond 0.5 mm over its stated diameter.

7. Precautions:

7.1 General Precautions:

- Only physicians who have received adequate training should perform implantation of the scaffold.
- Scaffold placements should only be performed at hospitals where emergency coronary artery bypass graft surgery (CABG) is readily available.
- Subsequent blockage may require repeat dilatation of the arterial segment containing the scaffold. The long term outcome following repeat dilatation of the endothelialized Scaffolds is not well characterized.

7.2 Scaffold Handling Precautions:

- Do not use if the package has been opened or damaged.
- Use the device before the "Use By" date as specified on the product label.
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.
- Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Carefully slide the blue outer sheath towards the distal flare, opening the transparent Banana peel on the inner sheath.
- Remove the Banana peel sheath and stylet along with the blue outer sheath from the guide wire lumen and discard.
- Do not remove the scaffold from the delivery system, as the removal may damage the scaffold and / or lead to scaffold embolization. The scaffold system is intended to perform together with all components as a system.
- The scaffold should not be removed and used with other dilatation catheters. The delivery system should not be used with other scaffolds/stents.
- Special care must be taken not to handle or in any way disrupt the scaffold position on the delivery device. This is especially important during catheter removal from the packaging, placement of the guide wire, advancement through the rotating haemostatic valve adaptor and guiding catheter hub.
- Do not manipulate, touch or handle the scaffold with fingers or contact with liquids prior to the preparation and delivery as this may result in coating damage, contamination and dislodgement of the scaffold from the delivery balloon catheter.
- Do not expose or wipe the device with any liquid, organic solvents or detergents.
- Use only the appropriate balloon inflation media. Do not use any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the scaffold.
- When back loading catheter on the guide wire, provide adequate support to shaft segments.
- Do not use if the device is found kinked.

7.3 Scaffold Placement Precautions:

- Do not prepare or pre-inflate the balloon prior to scaffold deployment, other than as directed. Use balloon purging technique described in Delivery System Preparation.
- Do not over expand the scaffold. This may cause scaffold damage. Size the reference target lesion diameter appropriately to ensure adequate scaffold apposition.
- Do not induce vacuum (negative pressure) on the delivery system before deployment of the scaffold. This may cause dislodgement of the scaffold from the balloon.
- Multiple attempts in advancing the MeRes100™ BRS to cross a lesion may lead to scaffold damage or dislodgement.
- Implantation of a scaffold may lead to dissection of the vessel distal and / or proximal to the stented portion and may cause acute closure of the vessel requiring additional intervention (e.g. CABG, further dilatation or placement of additional scaffold/s).
- Do not expand the scaffold if it is not properly positioned in the vessel.
- Long term outcome following repeat dilatation of endothelialized coronary scaffolds is unknown.
- Do not exceed Rated Burst Pressure (RBP) as indicated on labeling. Use of pressures higher than those specified on the product label may result in a ruptured balloon and potential intimal damage and dissection.
- If necessary, post dilatation can be performed with a non compliant balloon. Ensure not to exceed allowable expansion limits of the scaffold.
- Scaffold retrieval methods (use of additional wires, snares or forceps) may result in additional trauma to the coronary vasculature and / or the vascular access site. Complications may include bleeding, hematoma or pseudo aneurysm.
- Potential interaction with other drug eluting scaffolds/stents has not been evaluated and should be avoided.
- The extent of the patient's exposure to drug and polymer is directly related to the number and size of scaffolds implanted.
- If the unexpanded scaffold is retracted into the guiding catheter, it should not be reintroduced in the artery as this may damage or dislodge the scaffold. In case any resistance is felt while retracting MeRes100™ BRS System in guiding catheter, the system as a whole should be removed as a single unit.
- It is recommended not to use the MeRes100™ BRS in the patients with prior brachytherapy of the target lesion or the use of brachytherapy for the treated site restenosis.
- In the event of acute occlusion following scaffold placement, a bailout implant may be deployed within the scaffold ensuring that the bailout implant covers the MeRes100™ BRS completely. All abrupt closure cases must be treated as an emergency as per the hospital standard of care. It is recommended that the bailouts to be done with a metallic sirolimus eluting scaffold/stent of appropriate size.

7.4 Scaffold / System Removal Precautions:

- In case any resistance is felt at any time during lesion access or withdrawal of the MeRes100™ BRS system before scaffold 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 entirely into the guiding catheter.
- Pull back the scaffold delivery system and position the proximal balloon marker just distal to the tip of guiding catheter.
- Advance the guide wire into the coronary anatomy as far distally as safely possible.
- Tighten the rotating haemostatic valve to secure the delivery system to the guiding catheter.
- Remove the guiding catheter and delivery system as a single unit.

Failure to follow these steps and/or applying excessive force to the scaffold delivery system can potentially damage the scaffold and/or scaffold 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.

7.5 Post Implant Precautions:

Great care must be exercised when crossing a newly deployed scaffold with other devices such as another scaffold delivery system, an Intravascular Ultrasound (IVUS) catheter, OCT catheter, a coronary guidewire or balloon catheter to avoid disrupting the scaffold geometry and scaffold coating.

7.6 Magnetic Resonance Imaging (MRI) Statement:
The MeRes100™ Sirolimus Eluting BioResorbable Vascular Scaffold System has not been tested for safety in the Magnetic Resonance Imaging (MRI) environment. Therefore, MRI scans should not be performed on patient's post-scaffold implantation until the scaffold has been completely endothelialized to minimize the potential for migration. This device has not been evaluated for heating in the MRI environment. The effect of heating in the MRI environment on the drug and polymer coating is not known. If the area of interest is in the exact same area or relatively close to the position of the scaffold, MR image quality may be compromised.

7.7 Drug Interaction:
While no specific clinical data are available, the drugs that act through the same binding protein FKBP (for example, other drugs of limus family), may interfere with the efficacy of Sirolimus.

8. Adverse Effects:
Undesirable effects/adverse events that may be associated with the implantation of a coronary scaffold in native coronary arteries include but are not limited to:

- Abrupt closure
- Access site complications
- Acute myocardial infarction
- Allergic reactions or hypersensitivity to poly-L-lactide (PLLA), poly-DL-lactide (PDLLA), and reactions to antiplatelet drugs or contrast agent or platinum.
- Aneurysm
- Angina
- Arterial perforation
- Arterial rupture
- Arrhythmias, including ventricular fibrillation (VF) and ventricular tachycardia (VT)
- Arteriovenous fistula
- Bleeding complications, which may require transfusion
- Cardiac arrest
- Cardiac ,pulmonary or renal failure
- Cardio tamponade
- Coronary artery spasms
- Cardiogenic shock
- Coronary or scaffold embolism
- Coronary or scaffold thrombosis
- Death
- Dissection
- Drug reactions to antiplatelet agents / anticoagulation agents / contrast media.
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergent or non-emergent coronary artery bypass graft surgery
- Failure to deliver the scaffold at the intended site
- Fever
- Hypotension / Hypertension
- Infection, including infection and/or pain at the access site
- Injury to the coronary artery
- Ischemia, myocardial
- Nausea and vomiting
- Palpitations
- Pericardial effusion
- Peripheral ischemia (due to vascular or nerve injury)
- Pulmonary edema
- Pseudo aneurys
- Renal insufficiency/failure
- Restenosis of scaffolded segment
- Shock
- Stroke/ cerebrovascular accident and TIA
- 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

Potential adverse events associated with daily oral administration of sirolimus include the following, but are not limited to:

- Abdominal pain
- Acne
- Anemia
- Angioneurotic edema
- Coagulopathy
- Diarrhea
- Edema
- Hemolysis
- Hemolytic uremic syndrome
- Hepatic disorders
- Hepatitis
- Hypercholesterolemia
- Hyperlipidemia
- Hypertension
- Hypertriglyceridemia
- Hypogonadism male
- Infections
- Interstitial lung diseases
- Jaundice
- Leukopenia
- Liver function test abnormal
- Lymphocele
- Myalgia
- Nausea
- Pain
- Pancreatitis
- Pericardial effusion
- Pneumonia/Pneumonitis
- Pulmonary alveolar proteinosis
- Pyelonephritis
- Rash
- Renal tubular necrosis
- Sepsis
- Surgical wound complication
- Thrombocytopenia
- Thrombotic thrombocytopenic purpura
- Urinary tract infection
- Venous thromboembolism
- Viral, bacterial and fungal infection
- Vomiting
- Wound infection

9. Recommended Drug Regimen:
Antiplatelet or anticoagulant therapy is recommended as per institutional practices for coronary scaffolding.

10. Individualization of Treatment:

- The risk and benefits should be considered for each patient before use of MeRes100™ BRS system. Patient selection factors should include a judgment regarding risk of anti-platelet therapy. Special consideration should be given to the patients with recently active gastritis or peptic ulcers disease.
- Pre-morbid conditions that increase the risk of a poor initial result or the risks of emergency referral for bypass surgery (diabetes mellitus, renal failure and severe obesity), should be reviewed.
- A review of the vessel location, reference vessel size, lesion length, qualitative target lesion characteristics, and the amount of myocardium in jeopardy from acute or subacute thrombosis must also be considered.
- Thrombosis following scaffold implantation is affected by several baseline angiographic and procedural factors. These include vessel diameter less than 3 mm, intra-procedural thrombus and dissection following scaffold implantation. In patients who have undergone coronary scaffolding, the persistence of a thrombus or dissection should be considered a marker for subsequent thrombotic occlusion. These patients should be monitored very carefully during the first month after scaffold implantation.

11. Use in Special Populations:
The MeRes100™ BRS is not recommended in the following patient populations.

- Patient with unresolved vessel thrombus at the lesion site.
- Patients with unprotected lesions located in the left main coronary artery.
- Patients with torturous vessel that may impair scaffold placement in the region of the obstruction or proximal to the lesion.
- Patients under high risk of primary Percutaneous Coronary Intervention (PCI) for acute myocardial infarction characterized by presence of cardiogenic shock or evidence of massive thrombus in the infarct-related artery.
- Patients with chronic total occlusions.
- Patients with brachytherapy treatment, mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters) or laser angioplasty catheters of the target lesion.
- Pregnant or nursing women or men intending to father children. Effective contraception should be initiated before implanting MeRes100™ BRS and for 12 weeks after implantation.
- The safety and effectiveness of MeRes100™ BRS has not been evaluated in pediatric subjects below 18 years.

12 Clinical Use Information:

12.1 Inspection prior to use:

- Carefully inspect the sterile package before opening.
- Do not use if the package has been damaged or opened.
- The product should not be used after the "Use By" date.
- If the sterile package appears intact, tear open the sterile pouch and carefully remove the product in the sterile field using aseptic technique.
- Remove the system carefully from hoop tray packing.
- Inspect the delivery system for bends, kinks and other damage.
- Verify that the scaffold is located between the radiopaque marker bands.
- Do not use if any of the above defects is noted.

12.2 Dual Layer sheath Removal:

- Prior to removal of the packaging mandrel (inserted into the distal tip of the catheter), carefully slide the blue outer sheath towards the distal flare, opening the transparent banana peel on the inner sheath.
- Remove banana peel sheath and stylet along with the blue outer sheath from the guide wire lumen and discard. Special care should be taken to avoid handling the scaffold (see scaffold handling Precautions).
- Do not use if sheath cannot be removed as indicated.
- Verify that the scaffold does not extend beyond the radiopaque balloon markers and no scaffold struts are lifted. Do not use if any defects are noted.

12.3 Materials Required:

- Appropriate guiding catheter(s) of 6F/0.070"/1.8mm minimum inner diameter.
- 2-3 syringes (10-20 cc).
- 1000 u/500 cc, normal heparinised saline (HepNS).
- 0.014" (0.36 mm) diameter guide wire, 175 cm minimum length.
- Rotating hemostatic valve with an appropriate internal diameter.
- Contrast diluted 1:1 with normal saline.
- Inflation device.
- Three-way stopcock.
- Torque device.
- Guide wire introducer.

12.4 Device Preparation:

12.4.1 Guide wire Lumen Flush:

- Flush the guide wire lumen with HepNS until the fluid exits the guide wire exit port approximately 25 cm distal to catheter distal tip.

Caution: Avoid manipulation of scaffold during flushing of guide wire lumen, as this may disrupt the placement of the scaffold on the balloon.

12.4.2 Delivery system Preparation:

a. Prepare an inflation device with diluted contrast medium.
b. Attach inflation device hub to the stopcock.
c. With the tip down, orient the delivery system vertically.
d. Open stopcock to scaffold delivery system; pull negative for 30 seconds; release to neutral for contrast fill.
e. Close the stopcock to the delivery system, purge all the air from the inflation device / syringe.
f. Repeat steps c through e until all air is expelled.
It is important to expel all the air from the shaft to prevent uneven expansion of the scaffold.
g. If a syringe is used, attach a prepared inflation device to the stopcock.
h. Open the stopcock to the delivery system.
I. Leave inflation device on neutral.

12.4.3 Delivery Procedure:

a. Prepare vascular access site according to standard practice.
b. Predilate the lesion with a PTCA catheter.
c. Maintain neutral pressure on inflation device.
d. Open rotating haemostatic valve as widely as possible.
e. Backload delivery system onto proximal portion of guide wire while maintaining guide wire position across target lesion.
f. Advance the scaffold delivery system over guide wire to target lesion. Use radiopaque balloon markers to position scaffold across lesion; perform angiography to confirm scaffold position.
g. Tighten the rotating haemostatic valve.
The scaffold is now ready to be deployed.
If any resistance is experienced during lesion access, remove the entire system together as single unit.

12.4.4 Deployment Procedure:

Caution: Refer to product label for in-vitro scaffold inner diameter and RBP.

a. Before deployment, reconfirm the correct position of the scaffold relative to target lesion via the radiopaque balloon markers.
b. Deploy the Scaffold slowly, at the rate of 10 seconds/atm upto 4 atm. Thereafter, continue to inflate at the rate of 5 seconds/atm upto nominal pressure or higher till desired Scaffold expansion is obtained.
c. Maintain Scaffold deployment pressure for 30 seconds before balloon deflation.
d. If necessary, further pressurize the delivery system to ensure complete apposition of the scaffold to the artery wall. Do not exceed the RBP of the balloon or maximum deployment diameter of the scaffold.

12.4.5 Further Dilatation of the Scaffolded Segments:
All efforts should be made to assure that the scaffold is not underdilated. If the deployed scaffold size is still inadequate with respect to vessel diameter or if full contact with the vessel wall is not achieved (i.e. the initial angiographic results are suboptimal), a larger balloon may be used to expand the scaffold further. The scaffold may be further expanded using a low profile, high pressure and non-compliant balloon catheter. If this is required, the scaffold segment should be crossed carefully with a prolapsed guide-wire to avoid dislodging the scaffold.
Caution: Do not dilate the scaffold beyond the following dilatation limits. Expansion beyond the dilatation limits may result in scaffold damage. To ensure not to cross the maximum dilatation limits, use non compliant balloon of diameters as stared below.

Table - 3: Maximum Dilatation Limits for Nominal Scaffold Diameters

Nominal Scaffold Diameter	Dilatation Limits	Non-compliant Balloon Diameter
2.25 mm	2.75 mm	2.50 mm
2.50 mm	3.00 mm	2.75 mm
2.75 mm	3.25 mm	3.00 mm
3.00 mm	3.50 mm	3.25 mm
3.25 mm	3.75 mm	3.50 mm
3.50 mm	4.00 mm	3.75 mm
4.00 mm	4.50 mm	4.25 mm

12.4.6 Removal Procedure:

a. Deflate the balloon by pulling negative on the inflation device for 30 seconds. Ensure that the balloon is fully deflated.
b. Fully open the rotating hemostatic valve.
c. While maintaining guide wire position and negative pressure on the inflation device, withdraw the scaffold delivery system.
Note: If resistance be felt at any time during removal of the scaffold delivery system, the entire system should be removed together. See Scaffold/System Removal Precautions.
d. Tighten the rotating hemostatic valve.
e. Repeat angiography to assess the treated.
f. Final internal scaffold diameter should match reference vessel diameter to ensure that the scaffold is not underdilated.

12.4.7 Disposal:
After usage, dispose the system as per accepted regulations for medical waste management.
Note: Updated guidelines for the procedure have to be consulted through new publications.

13. Anti platelet Regimen:
Physician should use the information from the current Drug Eluting Scaffold literature, guideline and specific needs of individual patients to determine the specific antiplatelet/anticoagulation regime to be used for their patients in general practice. It is very important that the patient is compliant with the post procedure antiplatelet recommendation. Premature discontinuation of prescribed antiplatelet medication could result in a higher risk of thrombosis, myocardial infraction 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 Scaffold and its associated recommended antiplatelet therapy is the appropriate PCI choice. Following PCI, should a surgical or dental procedure be recommended, the risk 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 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.

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Symbols used in labeling


Scaffold inner diameter


Scaffold length

MGCID
Min guide catheter I.D.


Contains one unit

Max. guide wire diameter

SN
Serial number

REF
Reference number

Keep dry


Consult instructions for use

LOT
Lot number


Do not re-use


Non-pyrogenic

STERILE R
Sterilized using Irradiation


Do not resterilize


Manufacturer


Date of manufacture


Do not use if package is damaged


Use-by date


Keep away from sunlight


Caution

EC REP
Authorized representative in the European community


Temperature limit

IFU45c09/30012021

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WARNING:
To be sold by retail on the prescription of a cardiac surgeon / interventional cardiologist only.

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