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ISAR SUMMIT

Polymer Free Everolimus Eluting Coronary Stent System

Instructions for Use

Manufacturing Facility

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1.0 Product Description:

The ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent System consist of a Cobalt Chromium Coronary stent mounted on a stent delivery system. The Stent is coated with Everolimus in a polymer free drug delivery matrix of lipophilic carrier Probucol.

1.1. Device Component Description

The device components consist of Cobalt Chromium stent mounted on a delivery System. The range of stent diameters made possible by varying the number of circumferential cells on the stent. The stent is crimped on various sizes of stent delivery system, which are sizes 2.00mm to 4.00 mm. Physical characteristics areas follows:

Table 1.1: Device Component Description

Available Stent Lengths (mm)	8, 12, 16, 18, 21, 24, 28, 32, 36, 40, 44 & 48
Available Stent Diameters (mm)	2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00
Stent Material	L605 Cobalt Chromium Alloy Stent
Strut Thickness (µm)	Small Vessel - 68µm, Medium Vessel - 79µm
Strut Width (µm)	Small Vessel - 78µm, Medium Vessel - 88µm
Drug Component	Everolimus Drug
Delivery System Workable Length	143cm (1430 mm)
Stent Delivery System (SDS)	The delivery system is a rapid exchange catheter with a balloon located at the distal tip. The distal shaft comprises of two lumens, one is used for the inflation of the balloon and the other permits the use of a guide wire to enable advancement of the catheter to and through the stenosis to be stented. The balloon provides an expandable segment of known diameter at specific pressure. The proximal shaft is made of a stainless-steel hypotube. Proximal visual markers locate approximately 90 cm to 100 cm from the distal aid catheter positioning without fluoroscopy assistance.
Stent Delivery Balloon	A Semi-Compliant polyamide balloon, nominally about 1 mm longer than stent with two platinum iridium radiopaque marker located in the catheter shaft to indicate balloon positioning and expanded stent length.
Balloon Inflation Pressure	Nominal Inflation Pressure: $11/10^5$ Pa or 10.80 ATM or 11 Bar Rated Burst Pressure: $16/10^5$ Pa or 15.79 ATM or 16 Bar
Guiding Catheter Inner Diameter	5F (1.67mm) (Inner Lumen ⩾0.058")
Guide wire Compatibility (max)	0.014"
Catheter Shaft Outer Diameter	Proximal 1.9 F (0.825mm) Distal 2.7 F (0.594mm)

1.1. Drug Component Description

A brief description of the drug and the therapeutic class to which it belongs.

1.1.1 Everolimus

Active pharmaceutical ingredient (API): Everolimus Drug

Everolimus is a novel semisynthetic macrolide immunosuppressant, synthesized by chemical modification of Rapamycin Everolimus appearance: white to off-white powder.

Everolimus Solubility: Soluble in ethanol, chloroform, and Methanol

Molecular Formula: C53H83NO14

Molecular Weight: 958.224 g/mol

CAS Registry no.159351-69-6

Chemical name: 40-O-(2-hydroxyethyl)-rapamycin

The drug and hydrophobic carrier coating is adhered to the abluminal surface of the stent.

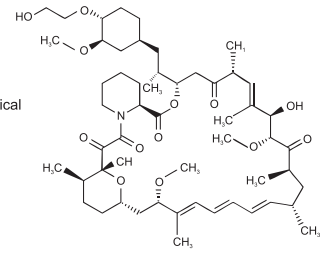

Figure 1: Structural Formula of Everolimus

1.2.2 ISAR Summit : Product Matrix and Part Numbers are mentioned as below

Length (mm)	Diameter						
	2.00 mm	**2.25 mm**	**2.50 mm**	**2.75 mm**	**3.00 mm**	**3.50 mm**	**4.00 mm**
8.00	ISIT-2008	ISIT-2208	ISIT-2508	ISIT-2708	ISIT-3008	ISIT-3508	ISIT-4008
12.00	ISIT-2012	ISIT-2212	ISIT-2512	ISIT-2712	ISIT-3012	ISIT-3512	ISIT-4012
16.00	ISIT-2016	ISIT-2216	ISIT-2516	ISIT-2716	ISIT-3016	ISIT-3516	ISIT-4016
18.00	ISIT-2018	ISIT-2218	ISIT-2518	ISIT-2718	ISIT-3018	ISIT-3518	ISIT-4018
21.00	ISIT-2021	ISIT-2221	ISIT-2521	ISIT-2721	ISIT-3021	ISIT-3521	ISIT-4021
24.00	ISIT-2024	ISIT-2224	ISIT-2524	ISIT-2724	ISIT-3024	ISIT-3524	ISIT-4024
28.00	ISIT-2028	ISIT-2228	ISIT-2528	ISIT-2728	ISIT-3028	ISIT-3528	ISIT-4028
32.00	ISIT-2032	ISIT-2232	ISIT-2532	ISIT-2732	ISIT-3032	ISIT-3532	ISIT-4032
36.00	-	-	-	ISIT-2736	ISIT-3036	ISIT-3536	ISIT-4036
40.00	-	-	-	ISIT-2740	ISIT-3040	ISIT-3540	ISIT-4040
44.00	-	-	-	ISIT-2744	ISIT-3044	ISIT-3544	ISIT-4044
48.00	-	-	-	ISIT-2748	ISIT-3048	ISIT-3548	ISIT-4048

The Nominal Drug Content is 2.60µg/mm^2

1.3 Mechanism of action

On a cellular level, everolimus inhibits, in a reversible manner, growth factor-stimulated cell proliferation. On a molecular level, everolimus forms a complex with the cytoplasmic protein FKBP-12. In the presence of everolimus, the growth factor-stimulated phosphorylation of p70 S6 kinase and 4E-BPI is inhibited. The latter proteins are key proteins involved in the initiation of protein synthesis. Since phosphorylation of both p70 S6 kinase and 4E-BPI is under the control of FRAP (FKBP-12-rapamycin associated protein, also called mTOR, mammalian target of rapamycin) this finding suggests that, the everolimus-FKBP-12 complex binds to and thus interferes with the function of FRAP, FRAP is a key regulatory protein which governs cell metabolism, growth and proliferation. Disabling FRAP function explains the cell cycle arrest at the late G1 stage caused by everolimus.

2.0 Intended uses

ISAR SUMMIT – Polymer Free Everolimus Eluting Coronary Stent System used for treatment of:

- Symptomatic coronary artery disease due to discrete de novo or restenosis lesion in native coronary artery.
- Symptomatic coronary artery disease due to culprit lesion in saphenous vein graft.
- Treatment of coronary lesion in patients undergoing primary or rescue PCI for acute ST segment elevation myocardial infraction (STEMI)
- Treatment of coronary lesion having athero thrombotic appearance in patients with non-ST-elevation acute coronary syndromes (unstable angina and non-ST-segment elevation myocardial infraction).

3.0 Indications

The **ISAR SUMMIT** Polymer Free Everolimus Eluting Coronary Stent System is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to de novo native coronary artery lesions in native coronary artery ranging from 2.00 to 4.00 mm.

4.0 Contra-Indications

The **ISAR SUMMIT** Polymer Free Everolimus Eluting Coronary Stent System is contraindicated in the following patient groups:

- Patients in whom anti-platelet and/or anticoagulation therapy is contraindicated.
- Patients with lesions that possibly cannot be treated successfully with PTCA or stent implantation.
- Patients with known sensitivity to Everolimus or structurally-related compounds, excipients & the procedural co-medication or alloying component of stent.
- Patients with known sensitivity to contrast agents.

5.0 Warning and Precaution Measures

The product should be used only by Doctors with experience of angiography, percutaneous transluminal coronary angioplasty (PTCA) and of implanting stents in coronary vessels.

ISAR SUMMIT should only be considered for implantation in lesions which do not show any signs of severe narrowing after balloon deflation.

Ensure that the inner package has not been opened or damaged as this may indicate the sterile barrier has been breached. Care needs to be taken that the stent coating does not get affected or manipulated and stent does not dislocate from the balloon. Direct touching of the stent or contact with liquids should be strictly avoided, since this can cause negatively effects on coating. Do not inflate or create a vacuum in a balloon catheter prematurely as it may lead to stent dislodgement. The recommended inflation pressure should not exceed for ISAR SUMMIT. If the balloon rupture occurs before complete stent expansion is achieved, the defective balloon should be pulled back and stent should be completely embedded in the vessel wall by the use of additional balloon catheter.

If any resistance become apparent at any point of time during the stent system insertion procedure, highest care has to be taken as this resistance can indicate damage to the stent. Before taking any further step the cause has to be found immediately. If resistance occurs while advancing through the guiding catheter, the entire delivery system should be pulled back.If resistance occurs after the stent has left the guiding catheter, or if the stent cannot be advanced to corresponding target lesion, there is an increased risk of stent dislodgement. This may lead to vascular embolization. The stent system should be then pulled back as follows:

1. Using fluoroscopy, navigate the stent back into the distal end if guiding catheter.
2. Pull the guiding catheter together with the stent back into ascending aorta, without changing the position of guide wire.
3. If necessary, fill the balloon slightly, in order to reduce likelihood of the stent slipping off or being pulled off the balloon.
4. Pull the guiding catheter and the stent together back through the introducer.

When placing more than one stent, it is recommended that the distal stent placed first. If a further stent has to be placed distally, care must be taken to ensure that the guide wire is not positioned between vascular wall & the stent.

5.1 Brachytherapy

The safety and effectiveness of the ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent System in patients with prior brachytherapy of the target lesion have not been established. The safety and effectiveness of use of brachytherapy to treat in-stent restenosis in ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent System have not been established.

5.2 Use in conjunction with other procedures

The safety and effectiveness of using mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters) or laser angioplasty catheters in conjunction with ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent System implantation have not been established.

5.3 Use in Special Population

5.3.1 Pregnancy

There are no adequate and well-controlled studies in pregnant women or men intending to father children. Systemic levels of everolimus have not been demonstrated in any pre-clinical or clinical trials with the ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent System. Effective contraception should be initiated before implanting an ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent System and for 12 weeks after implantation. The ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent System should be used during pregnancy only if the potential benefit outweighs the potential risk to the embryo or foetus.

5.3.2 Use during Lactation

It is not known whether Everolimus is excreted in human milk. The pharmacokinetic and safety profiles of Everolimus in infants are not known. Because many drugs are excreted in human milk and because of the potential for adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to implant the stent, taking into account the importance of the stent to the mother.

5.3.3 Pediatric Use

The safety and efficacy of the ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent System in pediatric patients have not been established.

5.3.4 Geriatric Use

Clinical studies of the ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent System did not find that patients age 65 Years and over differed with regard to safety and efficacy compared to younger patients.

5.3.5 Gender

Clinical studies of Everolimus based stent are generalizable in safety and effectiveness for both male and Female patients.

5.3.6 Non-Coronary Use

The safety and effectiveness of this product has not been established in the cerebral, carotid or peripheral vasculature.

5.4 Lesion/Vessel Characteristics

The safety and effectiveness of the ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent system have not been established in the following patient populations:

- Patients with unresolved vessel thrombus at the lesion site.
- Patients with coronary artery reference vessel diameter < 2.0 mm or >4.0 mm.
- Patients with lesions located in the in saphenous vein grafts, in the unprotected left main coronary artery system, ostial lesions, or lesions located at a bifurcation.
- Patients with diffuse disease or poor overflow distal to the identified lesions.
- Patients with tortuous vessels in the region of the obstruction or proximal to the lesion.
- Patients with a recent acute myocardial infarction where there is evidence of thrombus or poor flow.
- Patients with multi vessel disease.
- Patients with lesions longer than 48 mm and requiring more than one ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent system.
- Patients with chronic total occlusions
- Patients with in-stent restenotic lesions.

5.5 Drug Interaction

A complete study of possible interactions of Everolimus in association with treatment accompanying has not been established. It is rather improbable that interactions with other drugs will occur due to significant lower dosage compared to oncologically indicated Everolimus therapy. For possible interactions within the scope of Everolimus administrated for oncological indications the relevant instructions for use should be consulted.

The metabolism of Everolimus is mainly driven by CYP3A4-isoenzyme. If the patient intakes strong inhibitors or inductors of CY3P4A or further implantation of additional Stents is indicated, local or systemic effect must be taken into consideration.

5.6 Magnetic Resonance Imaging (MRI) - Stent Migration

An MRI scan should not be performed on a patient after stent implantation until there is adequate neointimal investment of the stent because of a potential for stent migration. For a conventional drug coated stent this period is usually considered to be eight weeks. Because of the reduced neointimal formation associated with the ISAR SUMMIT Polymer free Everolimus eluting coronary stent system, the period of vulnerability may be longer, but there is currently insufficient information to provide a specific recommendation.

5.7 Stent Handling Precautions

- For single use only. Do not re-sterilize or reuse this device. Note the “Use Before” date on the product label.
- Avoid exposure of device to fluids before implantation, this can affect the Drug coating on the Device.
- Do not remove the stent from the delivery balloon as removal may damage the stent and/or lead to stent embolization. The stent system is intended to perform as a system.
- Do not induce a vacuum on the delivery system prior to reaching the target lesion.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during stent system removal from packaging, placement over guide wire, and advancement through rotating haemostatic valve adaptor and guiding catheter hub.
- Do not “roll” the mounted stent with your fingers as this action may loosen the stent from the delivery balloon and may damage the coating.
- 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.
- In the event the ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent system is not deployed, follow product return procedures and avoid handling of the stent with hands.

5.8 Stent Placement Precautions

- Do not prepare or pre-inflate balloon prior to stent deployment other than as directed. Use balloon purging technique described in section 9 operators manual.
- Use balloon purging technique described in section Operator's Manual
- The vessel should be pre-dilated with an appropriate sized balloon.
- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent and reduces the chances for dislodging the proximal stent. Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (CABG, further dilatation, placement of additional stents, or other).Do not expand the stent if it is not properly positioned in the vessel. (See 5.9 Stent/System Removal Precautions.)
- Placement of a stent has the potential to compromise side branch patency. The vessel should be pre- dilated with an appropriate sized balloon.
- Balloon pressures should be monitored during inflation. Do not exceed rated burst pressure as indicated on the product label, use of pressures higher than those specified on the product label may result in a ruptured balloon with possible intimal damage and dissection.
- Do not attempt to pull an unexpanded stent back through the guiding catheter, as dislodgement of the stent from the balloon may occur. Remove as a single unit per instructions in (*Precautions – 5.9 Stent/System Removal Precautions).
- An unexpanded stent should be introduced into the coronary arteries one time only. An unexpanded stent should not be subsequently moved in and out through the distal end of the guiding catheter as stent damage or stent dislodgement from the balloon may occur.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications may include bleeding, hematoma or Pseudoaneurysm.
- Ensure full coverage of the entire lesion/dissection site so that there are no gaps between stents.

5.9 Stent/System Removal Precautions

- Should unusual 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.
- Do not attempt to pull an unexpanded stent back through the guiding catheter while engaged in the coronary arteries, as stent damage or stent dislodgement from the balloon may occur.

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 haemostatic valve to secure the Delivery System to the guiding catheter; then remove the guiding catheter, guiding wire 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.

5.10 Post Implantation Precautions

- Great care must be exercised when crossing a newly deployed stent with a coronary guide wire or balloon catheter to avoid disrupting the stent geometry and stent coating.
- Do not perform a Magnetic resonance imaging (MRI) scan on patient's post-stent implantation until the stent has completely endothelialised to minimize the potential for migration. The stent may cause artifacts in MRI scan due to distortion of the magnetic field.
- Prescribe an antiplatelet therapy for a period of 6 months to reduce the risk of stent thrombosis.

6.0 Adverse Events

Potential Adverse Event

Potential adverse events which may be associated with a PTCA procedure and/or stent implantation are but are not limited to:

- Acute/subacute occlusion of treated vessel
- Acute myocardial infraction, cardiogenic shock
- Vascular complications which make a surgical operation necessary, e.g. coronary artery bypass graft surgery (CABG)
- Intraluminal thrombus formation
- Stent dislocation, respectively failed stent placed at target lesion site
- Restenosis of stented vessel segment
- Haematoma at the access point
- Pseudoaneurysm
- Pulse arrhythmia, ventricular fibrillation
- Cerebral circulatory disorders
- General bleeding and infection
- Distal embolism
- Hypotension
- Palpitations
- Angina pectoris, ischemia
- Arterial perforation, arterial rupture
- Vascular Spasm
- Death

7.0 Patient Counselling Information

Cardiologist should consider the following in counselling patient about this product:

- Discuss the risks associated with stent placement
- Discuss the risks associated with an Everolimus eluting stent.
- Discuss the risks/benefits issues for this particular patient
- Discuss alteration to current lifestyle immediately following the procedure and over the long terms.
- Discuss the risks of early discontinuation of the antiplatelet therapy.

8.0 Packaging & Storage: One (1) ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent system:

Sterile: This device is sterilized with ETO, Non-pyrogenic, the contents inside the sterile barrier system are sterile.

- Do not use if the package is opened or damaged.
- Storage: Store in cool and dry place at 25°C, Do not freeze
  Excursion limit 15°C to 30°C

9.0 Operator's manual

9.1 Access to Package Holding Sterile Stent Delivery System

- Tear open outer foil pouch to reveal second inner pouch.
- Note: DO NOT drop or hand inner pouch into sterile field.
- Remove inner pouch from outer foil pouch.
- Peel open inner pouch using aseptic technique to reveal sterile package.

9.2 Inspection Prior to Use

Prior to using the ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent system, carefully remove the system from the package and inspect for bends, kinks, and other damage. Verify that the stent is located between the radiopaque balloon markers. Do not use if there is any damage to the packaging.

9.3 Materials Required

Quantity	Material
N/A	Appropriate Guiding catheter(s) minimum Size 5F
2-3	10-20 cc syringes
1000µ/500cc	Sterile Heparinised Normal Saline (Hep NS)
1	0.014" x 175 cm (minimum length) Guidewire
1	Rotating Haemostatic valve with minimum 0.096" inner diameter
	Contrast medium diluted 1:1 with sterile saline solution
1	Inflation Device with three-way stopcock
1	Torque Device
1	Guidewire Introducer

9.4 Preparation

9.4.1. Guide wire Lumen Flush

Step	Action
1	Remove protective cover from tip.
2	Flush guide wire lumen with HepNS until fluid exits guide wire exit notch.
3	Avoid manipulation of stent during flushing of the guidewire lumen, as this may disrupt the placement of the stent on balloon.
4	DO NOT apply negative or positive pressure to the balloon during the delivery system preparation.
5	Rinse the catheter with sterile heparinized normal saline solution

9.4.2 Delivery System Preparation

Step	Action
1.	Prepare the inflation device or syringe with diluted contrast medium.
2.	Attach the inflation device/syringe to the stopcock; attach to inflation port.
3.	With tip down, orient Delivery System vertically.
4.	Open stopcock to Delivery System; pull negative for 30 seconds; release to neutral for contrast fill.
5.	Close stopcock to Delivery System; purge inflation device/syringe of all air.
6.	Repeat steps 3 to 5 until all air is expelled.
7.	Note: If air is seen in shaft, repeat Balloon Preparation steps 3 to 5 to prevent uneven stent expansion.
8.	If a syringe was used, attach a prepared inflation device to stopcock.
9.	Open stopcock to Delivery System.
10.	Leave on neutral.

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9.5 Delivery Procedure

Step	Action
1.	Prepare the vascular access site according to standard practice.
2.	Predilate the lesion with a PTCA catheter.
3.	Maintain neutral pressure on the inflation device. Open the rotating hemostatic valve as widely as possible.
4.	Backload the delivery system onto the proximal portion of the guidewire while maintaining the guide wire position across the target lesion.
5.	Advance the stent delivery system over the guidewire to the target lesion. Use the radiopaque balloon markers to position the stent across the lesion; perform angiography to confirm the position of the stent. NOTE. If during the process of moving the Delivery System into position you notice the stent has moved on the balloon, do not deploy the stent. The entire system should be removed as a single unit. See Precautions – 5.9 Stent/System Removal Precautions for specific Delivery System removal instructions.
6.	Tighten rotating hemostatic valve. Stent is now ready to be deployed.

9.6. Deployment Procedure

Step	Action
1.	Before deployment, reconfirm the correct position of the stent relative to the target lesion via radiopaque balloon markers
2.	Attach the inflation device (only partially filled with contrast media) to a three-way stopcock and apply negative pressure to purge the air bubble if any
3.	Turn the stopcock on the catheter to the off position and purge the inflation device of air. Close the side port of the stopcock.
4.	Under fluoroscopic visualization, inflate the balloon to at least the nominal pressure to deploy the stent, but do not exceed the labelled rated burst pressure of 16 bar. Maintain inflation pressure for 15-30 seconds for full expansion of the stent. Optimal expansion requires the stent to be in full contact with the artery wall, with the stent internal diameter matching the size of the reference vessel diameter. Stent wall contact should be verified through routine angiography or intravascular ultrasound.
5.	Fully cover by entire lesion and balloon treated area (including dissection) with the ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent system, allowing for adequate stent coverage into healthy tissue proximal and distal to lesion.
6.	If more than one ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent system is needed to cover the lesion and balloon treated area, adequately overlap the stents, taking into account stent foreshortening. Ensure no gaps between to stents by positioning the balloon marker bands of the second ISAR SUMMIT Polymer Free Everolimus Eluting Coronary Stent system inside the deployed stent prior to expansion.
7.	Deflate the balloon by pulling a vacuum with the inflation device. Make certain that the balloon is fully deflated stent prior to move the catheter. Confirm that the stent is adequately expanded by angiographic injection through the guiding catheter.

9.7 Removal Procedure

Step	Action
1.	Ensure that the balloon is fully deflated.
2.	Fully open rotating haemostatic valve
3.	While maintaining guide wire position and negative pressure on inflation device, withdraw Delivery System.
4.	NOTE. Should unusual 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 Precautions – 5.9 Stent/System Removal Precautions for specific Delivery System removal instructions.
5.	Tighten rotating haemostatic valve.
6.	Repeat angiography to assess stented area. If necessary, post dilates within stent. Balloon inflations should incorporate balloon size closely matching vessel.
7.	Final stent diameter should match reference vessel. ENSURE STENT IS NOT UNDERDILATED

9.8 Disposal Procedure

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

10.0 Compliance Chart, Inflation Pressure

Balloon Ø [mm]	Inflation Pressure (atm/bar/10^5Pa)															
						NP						RBP				
	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Ø 2.00	1.83	1.87	1.90	1.93	1.96	2.00	2.03	2.06	2.10	2.13	2.16	2.20	2.23	2.26	2.29
Ø 2.25	2.08	2.11	2.14	2.18	2.21	2.25	2.28	2.31	2.35	2.38	2.42	2.45	2.48	2.52	2.55
Ø 2.50	2.33	2.36	2.40	2.43	2.47	2.50	2.53	2.57	2.60	2.64	2.67	2.70	2.74	2.77	2.81
Ø 2.75	2.58	2.61	2.65	2.68	2.71	2.75	2.78	2.81	2.85	2.88	2.91	2.94	2.98	3.01	3.04
Ø 3.00	2.81	2.85	2.89	2.92	2.96	3.00	3.04	3.07	3.11	3.15	3.18	3.22	3.26	3.29	3.33
Ø 3.50	3.29	3.34	3.38	3.42	3.46	3.50	3.55	3.59	3.63	3.67	3.71	3.76	3.80	3.84	3.88
Ø 4.00	3.75	3.80	3.85	3.90	3.95	4.00	4.06	4.11	4.16	4.21	4.26	4.31	4.36	4.41	4.46
						"Nominal Pressure"					"Rated Burst Pressure"				

11.0 Conversion Chart

1 cc	1 ml		
1 French	0.0131 inch	0.33 mm	
1 bar	0.99 atm	14.5 PSI	10^5 Pa

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12.0 Symbols Meaning

Symbol	Description
Stent	Stent Length
⌀	Stent Diameter
LOT	Batch No.
SN	Serial No.
YYYY MM	Manufacturing Date
YYYY MM	Use by Date (Expiry Date)
STERILE EO	Sterile and method of sterilization using Ethylene Oxide
2 / 2 STERILIZE	Single use only & Do not Re-sterile
REF	Reference No.
	Pyrogen Free
MD	Medical Device
	Contains a medicinal substance

Symbol	Description
	Storage Temperature
RBP	Rated Burst Pressure
	Manufacturer
	Consult Instruction for Use.
	Do not Use if package open or damaged
	Keep Away from Sun Light
	Keep dry.
NP	Nominal Pressure
	Attention : See instruction for use
#	Content of the package
	Single sterile barrier system with protective packaging outside

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