INSTRUCTIONS FOR USE
Everolimus Eluting Coronary Stent System

1. Device Description:

The Everolimus Eluting Coronary Stent System consists of drug coated, balloon expandable, L605 cobalt-chromium alloy stent mounted on a rapid exchange PTCA balloon catheter as stent delivery system. The drug coating formulation comprises of an antiproliferative drug (derivative of Rapamycin), Everolimus and blend of Lactide and Glycoside based biodegradable polymers, which act as drug reservoir and drug release platform.

1.1 Device Components Description:

1.1.1 Available Stent Length & Diameters.

Available Stent Length & diameter are shown in below table:

Available	Available Stent Length (mm)																	
Stent Diameter (mm)	8	12	15	16	18	20	22	24	26	28	30	32	34	36	38	40	44	48
2.00	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2.25	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2.50	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2.75	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3.00	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3.50	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
4.00	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
4.50	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Table

1.1.2	Stent Material	Electropolised L605 Cobalt Chromium alloy
1.1.3	Stent Design	Laser cut from seamless tubing in a hybrid design pattern
1.1.4	Stent delivery System	Name of Delivery system: Expedient Rx SDS Balloon Dilatation catheter. Stent delivery balloon working length, nominally 1.0 mm longer then the stent length. Mounted stent length & location is defined by two gold swaged radiopaque markers under the balloon catheter. Two proximal delivery system shaft markers (90 cm & 100 cm proximal to distal tip) indicate the relative position of the delivery system to the end of brachial or femoral guiding catheter.
1.1.5	Delivery system usable length	145 cm
1.1.6	Guidewire Lumen	Start at the distal tip of the balloon catheter & end approximately 25 cm from distal tip of the balloon catheter.
1.1.7	Guidewire rapid exchange (Rx) port	Start at the distal tip of the balloon catheter emerges approximately 25 cm from distal tip of the balloon catheter
1.1.8	Shaft outer profile	*Proximal 2.1F* *Distal 2.6F*
1.1.9	Stent dilatation/ balloon inflation pressure	Nominal Pressure 08 atm, Rated Burst pressure:16 atm *RBP 16 atm for all diameter with length 48 mm
1.1.10	Guide catheter compatibility	*5F(Min I.D. 0.056"/1.42mm)*
1.1.11	Guide wire compatibility	0.014"(0.36 mm)

1.1.12	Strut Thickness	*70±10µm*
1.1.13	Entry Profile	0.018"
1.1.14	Crossing Profile	Ø 3.00mm - 0.037"
1.1.15	Balloon Material	Nylon
1.1.16	Balloon Marker Material	18K Au
1.1.17	Proximal Shaft Diameter	0.68 mm
1.1.18	Distal Shaft Diameter	0.85 mm
1.1.19	Catheter Type	Rapid Exchange
1.1.20	Drug	Everolimus
1.1.21	Drug Dose	1.00 µg/mm2
1.1.22	Polymer	blend of Lactide and Glycoside based biodegradable polymers

1.1.2 In-Vitro Information is as per the following table:

Table - Stent Compliance Chart:

Inflation Pressure (atm/bar)	Stent Diameter Ø mm							
	2.00 mm	**2.25 mm**	**2.50 mm**	**2.75 mm**	**3.00 mm**	**3.50 mm**	**4.00 mm**	**4.50 mm**
6	1.95	2.15	2.38	2.67	2.85	3.45	3.85	4.42
*8	2.04	2.25	2.52	2.77	3.06	3.55	4.08	4.52
10	2.12	2.35	2.62	2.86	3.16	3.67	4.18	4.63
12	2.20	2.42	2.70	2.97	3.24	3.78	4.30	4.73
14	2.25	2.52	2.81	3.08	3.40	3.90	4.39	4.85
**16	2.32	2.64	2.90	3.18	3.49	3.92	4 .52	4.98
18	2.36	2.67	2.93	3.22	3.55	4.13	4.56	5.05
20	2.41	2.71	2.93	3.26	3.61	4.18	4.60	5.10
22	2.43	2.75	3.00	3.30	3.64	4.23	4.64	5.14

*NP 8 atm for all diameter.
*RBP 16 atm for all diameter.

1.2 Drug Component Description:

The drug component is coated on the stent. This coating is consisting of a blend of Everolimus drug (the active ingredient), and biodegradable polymer (the inactive ingredient).

1.2.1 Everolimus:

Everolimus is a derivative of Rapamycin (sirolimus), and works similarly to Rapamycin as an mTOR (mammalian target of rapamycin) inhibitor. It is currently used as an immunosuppressant to prevent rejection of organ transplants. The Everolimus chemical name is 40-O-(2-hydroxyethyl)-rapamycin, and its chemical structure is provided in Figure 1. The molecular formula of everolimus is C53H83NO14 and its molecular weight is 958.22.

Everolimus, a macrolide compound derived from rapamycin, has a complex molecular structure characterized by a large cyclic lactone ring with functional groups such as hydroxyl, ethyl, and methyl side chains. This structure is essential for its activity, as it allows Everolimus to bind to FKBP12 (FK506 binding protein 12), forming a complex that inhibits the mTOR (mechanistic target of rapamycin) pathway. The inhibition of mTOR, a crucial regulator of cell proliferation and survival, leads to the suppression of smooth muscle cell proliferation and migration, making it a powerful tool in preventing restenosis, the re-narrowing of coronary arteries after stent implantation.

The drug content on Everolimus Eluting Coronary Stent range between 18µg to 254µg.

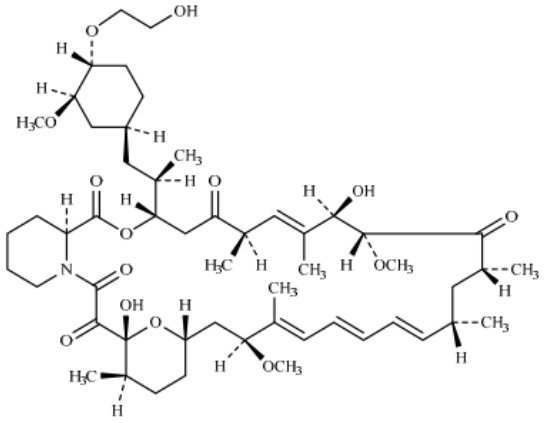

Figure: 1

1.2.2 Polymers

The inactive ingredients of the coating consists of a blend of Lactide and Glycoside based biodegradable polymers. These polymers controlled the drug release kinetic and they degrade as the drug is released from the stent.

1.2.3 Intended purpose of the Device:

Everolimus Eluting Coronary Stent System (EECS) is intended for use in the patient eligible for Percutaneous Transluminal Coronary Angioplasty (PTCA).

1.2.4 Clinical Indication:

The Everolimus Eluting Coronary Stent System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to de novo & in-stent restenosis lesions (Length *<48 mm*) in native coronary arteries with reference vessel diameter of 2.00 mm to 4.50 mm in patient eligible for percutaneous transluminal coronary Angioplasty (PTCA) and stenting procedures.

1.2.5 Principle of Operation & Mode of Action

The principle of operation in a drug-eluting stent involves coating the stent with Everolimus encapsulated in a *biodegradable polymer matrix. Once the stent is implanted, the polymer slowly degrades, releasing Everolimus at a controlled rate directly at the site of the stent. This controlled release ensures localized drug delivery, minimizing systemic side effects and maximizing the drug's effectiveness in preventing restenosis.*

The mode of action of Everolimus in the stent coating involves a sustained release of the drug, which acts directly on the arterial wall to inhibit smooth muscle cell proliferation and reduce inflammation. This targeted action ensures that the artery remains open, preventing re-narrowing due to abnormal cell growth. Everolimus also exerts immunosuppressive effects, further preventing complications such as inflammation that could contribute to restenosis. By controlling the release rate of the drug, Everolimus provides prolonged, localized treatment to maintain the patency of the treated artery, making it a critical component in drug-eluting coronary stents.

1.2.6 Intended user:

The product may only be used by Professional and Registered Interventional Cardiologist/Cardiologist/doctors trained and experienced in the PTCA (Percutaneous transluminal coronary angioplasty) procedure.

2. How to supply:

This device is sterilized with ethylene oxide (ETO) gas and non-pyrogenic. It is intended for single use only Do not Resterilize. Do not use the device if the package is opened or damaged.

Contents:

One Everolimus Eluting Coronary Stent System Housed in a protective circular Hoop tray,
One Instruction for use,

Two Stent implant cards.

2.1 Storage:

Store in between 5°C to 25°C, avoid excessive heat, protect from direct sunlight and moisture.

3. Contraindications:

Everolimus Eluting stent system is contraindicated in following patient types:

- *Patient with hypersensitive of allergic to aspirin, heprin, clopidogrel, ticklopidine, Drug or any analogue or derivative, cobalt, chromium, nickle, molybdenum, tungsten or any contrast media.*
- *Patients in whom anti-platelet and/or anti-coagulant therapy are contraindicated.*
- *Patient judge to have a lesion that prevents complete inflation of an angioplasty balloon.*
- *Transplant patients*.

4. Warnings:

- *Please ensure that the inner package has not been opened or damaged as this may indicate the sterile barrier has been breached.*
- *Do not Re-sterilize and/or reuse this device. Reuse or Re-sterilization may 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 and it may also compromise the structural integrity of the device. The device is intended for single use only.*
- *Should unusual resistance be felt at any time during lesion access or delivery system removal, the entire guiding catheter and stent system should be removed as a single unit.*
- *Applying excessive force to the stent delivery system can potentially result in loss or damage to the stent and delivery system components.*
- *Since the use of this device carries the associated risk of sub-acute thrombosis, vascular complications and / or bleeding events, and judicious selection of patients is necessary.*
- *Patients with known allergy to Cobalt alloy (L605) may suffer an allergic reaction to this implant, and the risk benefit ratio should be carefully assessed.*
- *The device should be manipulated while under high – quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of resistance before proceeding.*
- *Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of in vitro testing. Use of a pressure monitoring device is recommended to prevent over pressurization.*
- *The device is to be used under X-rays fluoroscopy, hence the standard method for using this imaging technique needs to be followed.*
- *Use the device before the "Product Used by date" specified on the package.*
- *Poly Medicure Limited will not be responsible for any direct or indirect incidental or consequential damages if product not used as per instructions for use.*

5. Risks Associated with Re-use:

Cross contamination/infection/ device malfunction

6. *Information on medical device intended to be used with other devices*:

The Everolimus Eluting Coronary Stent System is designed for use with guidewires (guidewire OD < ID of stent delivery system), Guiding Catheter (OD of PTCA catheter < ID of guiding catheter), Rotating hemostatic valve, syringes, inflation devices, three-way stopcocks (must comply with ISO 80369-7), torque devices (guidewire OD ≤ ID of torque device's gripping mechanism), ensuring compatibility and safe operation as per specified dimensions and standards.

7. Material of construction

Everolimus-eluting stents manufactured with different materials such as L605 cobalt chromium alloy, Everolimus, Resomer® R 202 S/Resomer L206S, PC, Pebax, LLDPE, HDPE, SS, NYLON and AU.

8. Use Environment:

These stents are typically implanted in hospitals equipped with catheterization laboratories where PCI procedures are performed. The environment must be sterile and equipped with appropriate imaging technologies like angiography systems.

9. Shelf life of the device:

2 years from date of manufacturing.

10. Target Patient population:

Everolimus-eluting coronary stents are designed for patients with coronary artery disease (CAD) who require percutaneous coronary intervention (PCI).

11. Precaution:

11.1 General Precautions:

- *Only physicians who have received adequate training should perform implantation of the stent.*
- *Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.*
- *Subsequent blockage may require repeat dilatation of the arterial segment containing the stent.*
- *To avoid the possibility of dissimilar metal corrosion, do not implants Stents of different materials in tandem overlap or contact is possible.*
- *The DES and Coronary Stent system is intended to perform as a system. The stent should not be removed for use in conjunction with other dilatation catheters, nor should the DES be used in conjunction with other Stents*.

11.2 Stent Handling Precautions:

- *The stent is intended for single use only. Do not re-sterilize or reuse this device.*
- *Verify the visual integrity of the stent device.*
- *Note the "Expiry" date on the product label.*
- *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 hemostatic valve adaptor and guiding catheter hub.*
- *Stent manipulation (e.g., rolling the mounted stent with your fingers) may loosen the stent from the delivery system balloon and cause dislodgement.*
- *Do not "roll" the mounted stent with your fingers as this action may loosen 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.*
- *In the event the Coronary Stent is not deployed, follow product return procedures and avoid handling of the stent with hands.*
- *Avoid any fluid contact with the stent before introducing the guiding catheter*.

11.3 Stent Placement Precautions:

- *Do not prepare or pre-inflate balloon prior to stent deployment other than as directed. Use balloon purging technique described in Operator's Manual.*
- Do not induced vacuum (negative pressure) on the deliver balloon catheter before reaching the target lesion.
- *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.*
- *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 of Stent/System*.
- Guiding catheter used must have lumen sizes that are suitable to accommodate the introduction of Polymed stent.
- *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.*
- *To avoid the possibility of dissimilar metal corrosion, do not implant the stent of different material in tandem overlap or contact if possible*.

11.4 Stent/Systems 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 hemostatic 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*.

11.5 Post implant 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 endothelialized to minimize the potential for migration. The stent may cause artifacts in MRI scans due to distortion of the magnetic field.*
- *Prescribe an anti-platelet therapy (ASA and Thienopyridines) for a period of minimum 1 month to reduce the risk of stent thrombosis.*
- *Care must be exercised when crossing a newly deployed stent with other devices such as another stent delivery system, an intravascular ultrasound (IVUS) catheter, a coronary Guide wire or balloon catheter to avoid disrupting the stent geometry*.

11.6 Drug interaction:

While no specific clinical data are available, drug, like, tacrolimus, that act through the same binding protein (FKBP) may interfere with the efficiency of Everolimus. Drug interaction studied have not been performed. Everolimus is metabolized by CYP3A4 (strong inhibitors of CYP3A4Iketoconazol) might cause increased Everolimus exposure to levels associated with systemic effects, especially if multiply stents are deployed. Systematic exposure of Everolimus should also be taken into consideration if the patient is treated concomitantly with systemic immunosuppressive therapy.

12. Possible Adverse effects:

Possible Adverse effects which may be associated with the use of a stent in native coronary arteries include but are not limited to:

• Abrupt stent closure • Acute myocardial infraction • Allergic reaction • Aneurysm • Angina • Arrhythmias, including ventricular fibrillation (VF) and ventricular tachycardia (VT) • Arteriovenous fistula • Cardiac tamponade • Coronary Artery occlusion • Cardiogenic shock • Death • Dissection • Drug reaction to antiplatelets agents • Emboli, distal (air, tissue or thrombotic emboli) • Embolization, stent • Emergency coronary Artery bypass graft surgery (CABG) • Failure to deliver the stent at the intended site • Fever • Fistulization • Heart failure • Hematoma • Haemorrhage • Hypotension/hypertension • Incomplete stent apposition • Infection • Myocardial infraction	• Myocardial ischemia • Perforation or rupture • Pericardial effusion • Prolong angina • Renal failure • Respiratory failure • Restenosis of stented segment • Rupture of native and bypass graft • Shock/pulmonary edema • Spasm • Stent compression • Stent migration • Stroke/cerebrovascular/TIA • Stent thrombosis • Ventricular fibrillation • Vessel perforation • Vessel spasm • Vessel trauma requiring surgical repair • Potential adverse events • Abnormal liver function test • Anemia • Arthralgias • Diarrhea • Hypercholesterolemia • Hypersensitivity, including anaphylactic type reaction • Hypertriglyceridemia • Hypokalaemia • Interstitial lung disease • Leukopenia

	• Lymphoma and other malignancies • Thrombocytopenia

13. Recommended Drug Regimen:

Antiplatelet or anticoagulant therapy is recommended as per institutional practices for coronary stenting.

14. Individualization of treatment:

- The risk and benefits should be considered for each patient before use of everolimus eluting coronary stent. Patient selection factor should include a judgment regarding risk of antiplatelet therapy. Special consideration should be given to those patients with recently active gastritis or peptic ulcers disease.
- Pre-morbid condition that increase the risk of a poor initial result or the risk 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 stent implantation is affected by several baseline angiographic and procedural factors. These include vessel diameter less than 3 mm, intra procedural thrombus and dissection following stent implantation. In patient's undergone stenting the persistence of thrombus or dissection should be considered a marker for subsequent thrombotic occlusion. These patients should be monitored very carefully during the first month after stent implantation.

15. Used *in* special population:

The safety and effectiveness of the Everolimus eluting coronary stent has not been established in the following patient's population:

- *Pregnancy: There are no adequate and well-controlled studies in pregnant women. Systemic levels of Everolimus have not been demonstrated in any pre-clinical or clinical trials with the Everolimus Eluting Coronary Stent System. Effective contraception should be initiated before implanting Everolimus Eluting Coronary Stent and for 12 weeks after implantation. The Everolimus Eluting Coronary 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 or to implant the stent, taking into account the importance of the stent to the mother.*
- *Pediatric Use: The safety and efficacy of the Everolimus Eluting Coronary Stent in pediatric patients have not been established.*
- *Geriatric Use: Clinical studies of the Everolimus- Biodegradable polymer based Stent did not find that patients aged 65 years and over differed with regard to safety and performance compared to younger patients*.

16. Patient Information

In addition to these instructions for use, the following patient specific information regarding the Everolimus Eluting Coronary Stent is available:

- Stent implant card that includes both patient and Everolimus Eluting Coronary Stent specific information. All patients will be expected to keep this card in their possession at all times for procedure/stent identification.

17. Clinical use information:

17.1 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 be used before the use by date.
- If the sterile package appears intact, carefully remove the system from the package and inspect for bend, kinks and other damage.
- Tear open the sterile pouch to carefully remove the product and pass on or drop the contents into the sterile field using aseptic technique.
- Verify that the stent is located between the radiopaque markers.
- Do not use if any defects are noted.

17.2 Material Required (not included in stent system package):

- Appropriate guiding catheter(S)
- 2-3 syringe (10-20 cc)
- 1000µ/500cc, normal heparinized saline (HepNS)
- 0.014" (0.36mm) diameter guidewire, 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
- Guidewire introducer

17.3 Direction for use (Preparation):

These directions are general guidelines intended for use by qualified healthcare professionals. Any instructions, indications and contraindications given are not exhaustive and it is the clinician's responsibility to ensure safe, correct use of this product considering medical conditions of the patient.

17.3.1 Guidewire lumen flush

Remove the protective stylet from the guidewire lumen and discard. Flush the guidewire with HepNS until the flush exit the guidewire exit port approximately 25 cm distal to catheter distal tip. Caution: Avoid manipulation of stent during flushing of guidewire lumen, as this may disrupt the placement of the stent on the balloon.

17.3.2 Delivery system preparation

- Prepare an inflation device with diluted contrast medium. Attach inflation device to stopcock; Attached to hub (balloon inflation port).
  Caution: Do not apply negative or positive pressure to balloon at this time. Open the stopcock to stent delivery system. Leave inflation device on neutral.
- Ensure that all air is purged from the inflation device before use.

17.3.3 Delivery Procedure

- Prepare vascular access site according to standard practice.
- Prepare lesion site according to standard practice.
- Predilate the lesion with the PTCA catheter. Maintain neutral pressure on inflation device.
- Open rotating hemostatic valve as widely as possible. Backload delivery system onto proximal portion of guidewire while maintaining guidewire position across target lesion.
- Advance the stent delivery system over guidewire to target lesion use radiopaque balloon markers to position stent across lesion. Perform angiography to confirm stent position.

Note: should unusual resistance be felt at any time during the either lesion access or removal of the stent delivery system before stent implantation, the entire system should be removed. See stent system removal precaution, section 11.4 for specific stent delivery removal instruction.

17.3.4 Deployment procedure

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

- Before deployment reconfirm the correct position of the stent relative to target lesion via radiopaque balloon markers.
- Attach the inflation device (only partially filled with contrast media) to a stopcock (three way minimum) and

apply negative pressure to purge the balloon of air.

- Turn the stopcock to the off position to the catheter and purge the inflation device of air. Close the side port of the stopcock.
- Under fluoroscopic visualization, inflate the balloon to deploy the stent but do not exceed the labelled rated burst pressure. 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.
- Deflate the balloon by pulling a vacuum with the inflation device. Make sure the balloon is fully deflated before any attempted movement of the catheter.
- Confirm adequate stent expansion by angiographic injection through the guiding catheter.

17.3.5 Further dilatation of the stented segments

All effort should be taken to ensure that the stent is not under dilated.

If the deployed stent size is still inadequate with respect to vessel diameter, or if full contact with the vessel wall is not achieved, a larger balloon may be used to expand the stent further.

If the initial angiographic result are suboptimal, the stent may be further expanded using a low profile, high pressure, and non-compliant balloon catheter. If this is required, the stented segment should be recrossed carefully with a prolapsed guidewire to avoid dislodging the stent.

Note: Post dilatation is recommended for stent length >40 mm **Caution**: do not dilate the stent beyond the following limits.

Nominal stent diameter	Dilatation limits
2.00 mm - 2.25 mm	3.00 mm
2.50 mm - 3.00 mm	4.00 mm
3.50 mm - 4.50 mm	5.00 mm

17.3.6 *Stent Delivery System* Removal procedure

If removal of the stent delivery system is required prior to stent deployment, follow these steps:

- *Ensure coaxial alignment of the guiding catheter relative to the stent delivery system.*
- *Cautiously withdraw the stent delivery system into the guiding catheter.*
- *If unusual resistance is encountered during withdrawal, do not force the system. Instead, remove the stent delivery system and guiding catheter as a single unit under direct fluoroscopic visualization.*

If removing the stent delivery system after stent deployment, proceed as follows:

- *Deflate the balloon by applying negative pressure using the inflation device. Note: Larger and longer balloons may require (up to 30 seconds) to deflate than smaller and shorter balloon. Confirm complete balloon deflation under fluoroscopy.*
- *Set the inflation device to negative or neutral pressure.*
- *Stabilize the guiding catheter just outside the coronary ostium and anchor it in place.*
- *Maintain guide wire position across the stented segment throughout the procedure.*
- *Gently withdraw the stent delivery system using slow and steady pressure, ensuring continuous fluoroscopic monitoring*.

Note: should unusual resistance be felt at any time during either lesion access or removal of the stent delivery system before stent implantation the entire system should be removed. See stent system removal precaution section 11.4 for specific stent delivery system removal instruction.

18. Antiplatelet regimen:

Interventional cardiologist should use the information from the current drug eluting stent literature, guidelines and specific needs of individual patients to determine the specific antiplatelet/and anticoagulation regime to be used for their patients in general practice.

Current guidelines for DAPT discontinuation should be followed and are recommended. The decision to interrupt or discontinue DAPT is the responsibility of the treating physician, taking into consideration the individual patients condition. In case an unanticipated interruption or discontinuation of DAPT is required any time after 1 month following

Drug eluting coronary stent implantation, data from published literature show low stent thrombosis rates and not observed the increased risk for stent thrombosis.

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 require early discontinuation of antiplatelet therapy, the intervention list and patient should carefully consider whether a drug eluting stent and its associated recommended antiplatelet therapy is the appropriate PCI choice. Following PCI should a surgical or dental procedure be recommended, risk and benefits of the procedure should be weighed against the possible risk associated with premature discontinuation of antiplatelet therapy.
Patients who required 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 physician.

19. Disclaimer of warranty and limitation of remedy:

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20. Reporting of Incident to Manufacturer & Competent Authority:

For providing feedback on this product write to customercare@polymedicure.com

21. Disposal of device:

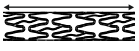
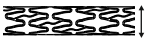
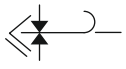
POLYMED recommend handling and disposing of Everolimus Eluting Coronary Stent System in accordance with accepted medical practice/ CDC guidelines/ and applicable local, state and country laws and regulations.

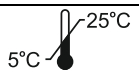
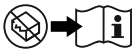
Product identification and model:

Trade Name	***Basic UDI***	***Size ranges***		***Product Codes***
POLYMED	*890209520500E2*	***Length:*** *08-48mm*	***Diameter:*** *2.00mm*	*60145-60162, 20500-20517*
			Diameter: *2.25mm*	*20518-20535, 60163-60180*
			Diameter: *2.50mm*	*20536-20553, 60181-60198*
			Diameter: *2.75mm*	*20554-20571,60199-60216*
			Diameter: *3.00mm*	*20572-20589, 60217-60234*

			Diameter: *3.50mm*	*20590-20607, 60235-60252*
			Diameter: *4.00mm*	*20608-20625, 60253-60270*
			Diameter: *4.50mm*	*20626-20643, 60271-60288*

Details of symbols used in Labels

S. No.	Title	Symbols
1.	Indicates Batch Code or Batch Number or Lot number	
2.	Indicates Date of Manufacturing of Medical Devices (Mfg. Date)	
3.	Indicates "INDIA" as Country of Manufacture	
4.	Indicates the date after which the Medical Devices not to be used (Exp. Date)	
5.	Indicates the medical device manufacturer / manufactured by	
6.	Product Ref. No./Catalogue No.	
7.	Symbol for sterilized using Ethylene Oxide	
8.	Single sterile barrier system with protective packaging inside	
9.	Keep Dry	
10.	Non-Pyrogenic	
11.	Keep away from Sunlight	
12.	Consult Instructions For Use	
13.	Symbol for Caution	
14.	For single use only	
15.	Do not Resterilize	
16.	Stent length	
17.	Stent diameter	
18.	Maximum Guidewire O.D.	

21.	Do not use if product package is opened/damaged	
22.	Storage Condition	
23.	Symbol indicating "Medical Device"	MD
24.	Symbol indicating "Unique Device Identifier"	UDI
25.	Do not use If package (Sterile barrier system) is damaged and check IFU.	

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