Proficient™

Sirolimus Eluting Coronary Stent System

Instructions for use - English

1. Device Description:

The Proficient™ Sirolimus Eluting Stent System comprises of following components-

- A balloon-expandable L605 Cobalt Chromium Coronary Stent
- A stent coating that consists of a blend of anti-proliferative drug and polymers
  1. Anti-proliferative drug Sirolimus (also known as Rapamycin)
  2. Bio-compatible, bio-degradable co-polymer coating which acts as drug reservoir and drug release platform
- A rapid-exchange stent delivery PTCA balloon catheter
- The stent is pre mounted on balloon catheter & placed between two platinum-iridium radio opaque markers bands.

1.1 Device Components Description:

1.1.1 Available stent lengths & diameters:

Available stent lengths & diameters (87 configurations) are shown in table-1 below

Table-1 Proficient™ Stent System Product Description

Available Stent Diameters (mm)	Available Stent Lengths (mm)										
	8	13	16	19	24	29	32	37	40	44	48
2.00	-	PRF20013	PRF20016	PRF20019	PRF20024	PRF20029	PRF20032	PRF20037	PRF20040	PRF20044	PRF20048
2.25	PRF22508	PRF22513	PRF22516	PRF22519	PRF22524	PRF22529	PRF22532	PRF22537	PRF22540	PRF22544	PRF22548
2.50	PRF25008	PRF25013	PRF25016	PRF25019	PRF25024	PRF25029	PRF25032	PRF25037	PRF25040	PRF25044	PRF25048
2.75	PRF27508	PRF27513	PRF27516	PRF27519	PRF27524	PRF27529	PRF27532	PRF27537	PRF27540	PRF27544	PRF27548
3.00	PRF30008	PRF30013	PRF30016	PRF30019	PRF30024	PRF30029	PRF30032	PRF30037	PRF30040	PRF30044	PRF30048
3.50	PRF35008	PRF35013	PRF35016	PRF35019	PRF35024	PRF35029	PRF35032	PRF35037	PRF35040	PRF35044	PRF35048
4.00	PRF40008	PRF40013	PRF40016	PRF40019	PRF40024	PRF40029	PRF40032	PRF40037	PRF40040	PRF40044	PRF40048
4.50	PRF45008	PRF45013	PRF45016	PRF45019	PRF45024	PRF45029	PRF45032	PRF45037	PRF45040	PRF45044	PRF45048

Table - 2

1.1.2	Stent Material	Electropolished L605 Cobalt Chromium alloy, laser-cut from seamless tubing in a hybrid design pattern.
1.1.3	Stent 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 than the stent length. Mounted stent length & location is defined by two platinum-iridium swaged radiopaque 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	Stent dilatation / Balloon inflation pressures	Nominal Pressure: 9 atm, Rated Burst Pressure: 14/16 atm* RBP* 14 atm for 4.50 mm diameter, all lengths. RBP* 14 atm for all diameter with length > 40mm.
1.1.9	Guide catheter compatibility	5F (Min I.D. 0.056" / 1.42 mm)
1.1.10	Guide wire compatibility	0.014" (0.36 mm)
1.1.11	Product code format PRFxxxyy	PRF = Proficient SES xxx = nominal stent diameter (mm) yy = nominal stent length (mm) For e.g. PRF30016 xxx = 300 = Diameter 3.00 mm yy = 16 = Length 16 mm

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

Table-3 Proficient™ Stent Compliance Chart

Inflation Pressure		Stent Diameter							
(atm)	**(kPa)**	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	608	1.90	2.10	2.36	2.60	2.80	3.25	3.78	4.35
7	709	1.95	2.19	2.41	2.65	2.90	3.30	3.82	4.40
8	811	1.98	2.23	2.46	2.71	2.94	3.40	3.90	4.45
9	**912**	**2.00**	**2.25**	**2.50**	**2.75**	**3.00**	**3.50**	**4.00**	**4.50**
10	1013	2.08	2.28	2.56	2.85	3.07	3.54	4.05	4.55
11	1115	2.10	2.30	2.60	2.89	3.10	3.58	4.10	4.60
12	1216	2.12	2.35	2.64	2.93	3.14	3.62	4.15	4.64
13	1317	2.14	2.39	2.67	2.95	3.18	3.66	4.20	4.68
14*	1419	2.16	2.42	2.70	2.97	3.20	3.70	4.24	4.72
15	1520	2.19	2.44	2.73	2.99	3.22	3.74	4.27	4.76
16	1621	2.20	2.46	2.76	3.01	3.24	3.78	4.30	4.80
17	1723	2.22	2.48	2.80	3.05	3.27	3.82	4.34	4.84
18	1824	2.24	2.51	2.85	3.11	3.29	3.86	4.38	4.88

Grey background: Nominal pressure, **Black background:** RBP (Rated Burst Pressure)

* RBP 14 atm for all diameter with length > 40 mm.

1.2 Drug Component Description:

The drug component is coated on the stent. This coating consists of a blend of Sirolimus drug (the active ingredient), and biodegradable polymers (the inactive ingredient).

1.2.1 Sirolimus:

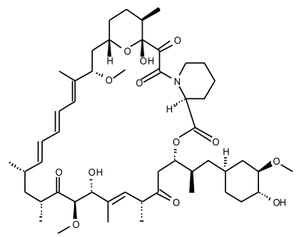
Sirolimus is also known as Rapamycin.

Sirolimus is a macrocyclic lactone produced by *Streptomyces hygroscopicus.*

The chemical name of Sirolimus (also known as rapamycin) 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-ethoxycyclohexyl]-1-methylethyl]-10,21-dimethoxy -6,8,12,14, 20,26 -hexamethyl -23,27-epoxy-3H-pyrido[2,1c][1,4]oxaazacyclohentriacontine-1,5,11,28,29(4H,6H,31H)-pentone. Its molecular formula is $C_{51}H_{79}NO_{13}$ and is molecular weight is 914.2.

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 and has a melting temperature of approximately 183-185°C. Sirolimus belongs to a class of therapeutic agents known as macrocyclic lactones or macrolides. It's a cytostatic drug and an immunosuppressant. It inhibits cell motility by suppression of m-TOR mediated 56K1 and 4E-BP1 pathways. It inhibits T-lymphocyte activation and proliferation occurring in response to antigen and cytokine. It also inhibits antibody production. It demonstrates antiproliferative activities.

The drug content on Proficient™ Sirolimus Eluting Coronary Stent ranges between 34μg to 412μg.

1.2.2 Polymer:

The inactive ingredient of the coating consists of a blend of Lactide and Glycolide based biodegradable polymers. These polymers control the drug release kinetics and they degrade as the drug is released from the stent.

2. How Supplied:

Sterile: This device is sterilized with Ethylene oxide (ETO) gas and is 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 (1) Proficient™ Sirolimus Eluting Coronary Stent System housed in a protective circular hoop tray, one (1) Instructions for Use, two (2) Stent Implant Card.

Storage: Store between 15-25°C(59-77°F) temperature in a dry, dark, cool place. Protect from light.

3. Indications:

The Proficient™ Sirolimus Eluting Coronary Stent System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to *de novo* & in-stent restenotic lesions (lengths ⩽ 44 mm) in native coronary arteries with a reference vessel diameter of 2.00 mm to 4.5 mm in patients eligible for Percutaneous Transluminal Coronary Angioplasty (PTCA) and Stenting procedures.

4. Contraindications:

Proficient™ Sirolimus Eluting Coronary Stent System is contraindicated in the following patient types:

- Patients with hypersensitivity or allergies to aspirin, heparin, clopidogrel, ticlopidine, drug such as Sirolimus (Rapamycin) or similar drugs or any analogue or derivative , cobalt, chromium, nickel, molybdenum, tungsten or 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 subacute thrombosis, vascular complications and/or bleeding events.
- Safety and effectiveness of stenting saphenous vein grafts has not been established.
- Never try to straighten a kinked hypotube. Straightening of a kinked metal may result in breakage of the shaft.

6. Precautions:

6.1 General Precautions:

- Only physicians who have received adequate training should perform implantation of the stent.
- Stent 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 stent. The long term outcome following repeat dilatation of the endothelialized stents is not well characterized.

6.2 Stent 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.
- Remove the protective stylet from the guide wire lumen and discard.
- Do not remove the stent from the delivery system as removal may damage the stent and / or lead to stent embolization. The Proficient™ Sirolimus Eluting Coronary Stent System is intended to perform as a system.
- The stent should not be removed for use in conjunction with other dilatation catheters.
- Special care must be taken not to handle or in any way disrupt the stent 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 stent with fingers or contact with liquids prior to the preparation and delivery as this may result in coating damage, contamination or dislodgement of the stent from the delivery balloon catheter.
- Do not expose or wipe the device with organic solvents such as alcohol 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 stent.
- When backloading catheter on the guidewire, provide adequate support to shaft segments.
- Do not use if the device is found kinked.

6.3 Stent Placement Precautions:

- Do not prepare or pre-inflate the balloon prior to stent deployment, other than as directed.
- Do not induce vacuum (negative pressure) on the delivery balloon catheter before reaching the target lesion.
- Implantation of a stent 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 stents).
- Do not expand the stent if it is not properly positioned in the vessel.
- Long term outcome following repeat dilatation of endothelialized coronary stents is unknown at present.
- Placement of stents has the potential to compromise side branch patency.
- Do not exceed Rated Burst Pressure as indicated on labelling. Use of pressures higher than those specified on the product label may result in a ruptured balloon and potential intimal damage and dissection.
- Guiding catheters used must have lumen sizes that are suitable to accommodate the introduction of Proficient™ stent (see Table 2).
- Stent 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 pseudoaneurysm.
- To avoid the possibility of dissimilar metal corrosion, do not implant the stents of different material in tandem overlap or contact if possible.
- 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 changes of dislodging the proximal stent
- The safety and effectiveness of Proficient™ coronary stent in patient with prior brachytherapy of the target lesion have not been established.
- The safety and effectiveness of using mechanical artherectomy devices or laser angioplasty catheters in conjunction with Proficient™ Sirolimus Eluting Coronary Stent implantation have not been established.
- The Tyvek pouch is the sterile barrier. Therefore only the contents of the sealed Tyvek pouch should be considered sterile. Do not remove the contents from the Tyvek pouch until immediately prior to use.
- During withdrawal of the delivery system, hold saline-soaked gauze around the exposed catheter shaft and pull the catheter through the gauze to remove any excess contrast medium.
- If reinserting the catheter, flush the guide wire lumen using the flushing needle before insertion.
- Additional expansion of the deployed stent may cause a flow limiting dissection. This may be treated by implantation of another stent. When multiple stents are implanted, the ends should overlap slightly.

6.4 Stent/System Removal Precautions:

- Should any unusual resistance be felt at any time during either lesion access or removal of the stent delivery system pre-stent implantation, the entire system must be removed as a single unit.
- When removing the delivery system as a single unit, do not retract the delivery system into the guiding catheter.
- Advance the guide wire into the coronary anatomy as far distally as safely possible. Tighten the rotating haemostatic valve to secure the stent delivery system as a single unit.
- Failure to follow these steps and/or applying excessive force to the stent delivery system can potentially result in loss or damage to the stent and/or stent delivery system components.

6.5 Post Implant Precautions:

Great 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 guidewire or balloon catheter to avoid disrupting the stent geometry and stent coating.

6.6 Magnetic Resonance Imaging (MRI) Statement:

Non-clinical testing has demonstrated the "Proficient™ Sirolimus Eluting Coronary Stent Systems", single (max. 4.5 x 40 mm) and overlapped (max. 2 x 4.5 x 40 mm (max. 79 mm length)) is MR conditional.It can be scanned safely under the following conditions:

- static magnetic field of 1.5 Tesla and 3 Tesla only, with
- spatial gradient field of 33 T/m and less
- spatial gradient field product of 96 T^2/m and less
- theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of

  < 2 W/kg at 1.5 Tesla, overlapped (max. 2 x 4.5 x 40 mm (max. 79 mm length))

  < 2 W/kg at 3 Tesla, overlapped (max. 2 x 4.5 x 40 mm (max. 79 mm length))

  for 15 minutes of continuous MR scanning.

MR image quality is compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant.

6.7 Drug Interaction:

While no specific clinical data are available, drugs, like Tacrolimus, that act through the same binding protein (FKBP) may interfere with the efficacy of Sirolimus.

- Drug interaction studies have not been performed. Sirolimus is metabolized by CYP3A4. Strong inhibitors of CYP3A4 (e.g. ketoconazol) might cause increased Sirolimus exposure to levels associated with systemic effects, especially if multiple stents are deployed. Systemic exposure of Sirolimus should also be taken into consideration if the patient is treated concomitantly with systemic immunosuppressive therapy.

7. Adverse Effects:

Undesirable effects/adverse events (in alphabetical order) that may be associated with the implantation of a coronary stent in native coronary arteries include but are not limited to:

- Abrupt stent closure
- Acute myocardial infarction
- Allergic reactions
- Aneurysm

- Angina
- Arrhythmias, including ventricular fibrillation (VF) and ventricular tachycardia (VT)
- Arteriovenous fistula
- Cardio tamponade
- Coronary Artery Occlusion
- Cardiogenic shock
- Death
- Dissection
- Drug reactions to antiplatelet agents / anticoagulation agents / contrast media
- 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
- Hemorrhage
- Hypotension / Hypertension
- Incomplete Stent Apposition
- Infection, including infection and/or pain at the access site
- Myocardial Infarction
- Myocardial Ischemia
- Perforation or rupture
- Pericardial effusion
- Prolong Angina
- Pseudoaneurysm
- Renal failure
- Respiratory failure
- Restenosis of stented segment
- Rupture of native and bypass graft
- Shock / Pulmonary edema
- Spasm
- Stent compression
- Stent migration
- Stroke / cerebrovascular accident / TIA
- Stent thrombosis (acute, subacute, or late)/occlusion
- Ventricular fibrillation
- Vessel perforation
- Vessel spasm
- Vessel trauma requiring surgical repair or reintervention

Potential adverse events, not captured above, that may be related to Sirolimus following oral administration:

- Abnormal liver function tests
- Anemia
- Arthralgias
- Diarrhea
- Hypercholesterolemia
- Hypersensitivity, including anaphylactic/anaphylactoid type reactions
- Hypertriglyceridemia
- Hypokalemia
- Infections
- Interstitial lung disease
- Leukopenia
- Lymphoma and other malignancies
- Thrombocytopenia

There may be other potential adverse events that are unforeseen at this time.

8. Recommended Drug Regimen:

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

9. Individualization of Treatment:

- The risk and benefits should be considered for each patient before use of Proficient™ Sirolimus Eluting Coronary Stent. Patient selection factors should include a judgement regarding risk of antiplatelet therapy. Special consideration should be given to those 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 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 patients who have undergone coronary stenting, 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 stent implantation.

10. Use in Special Populations:

The safety and effectiveness of the Proficient™ Sirolimus Eluting Coronary Stent has not been established in the following patient populations:

- Patient with unresolved vessel thrombus at the lesion site
- Patient with coronary artery reference vessel diameter < 2.00 mm
- Patients with unprotected lesions located in the left main coronary artery
- Patients with brachytherapy treatment of the target lesion
- **Pregnant Patients:** There are no adequate and well controlled studies in pregnant women or men intending to father children. Effective contraception should be initiated before implanting Proficient™ Sirolimus Eluting Coronary Stent and for 12 weeks after implantation. The Proficient™ Sirolimus Eluting Coronary Stent should be used during pregnancy only if the potential benefit outweighs the potential risk to the embryo or fetus.
- **Lactation:** It is not known whether Sirolimus is distributed in human breast milk. Because similar drugs are known to be excreted in human milk, and because of the risk of adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or implant the stent, taking into account the importance of the stent to the mother.
- The safety and effectiveness of using brachytherapy treatment, mechanical artherectomy devices (directional artherectomy catheters, rotational artherectomy catheters) or laser angioplasty catheters to treat in stent stenosis of a Proficient™ Sirolimus Eluting Coronary Stent + Sirolimus Eluting Coronary Stent has not yet been established.

11. Clinical Use Information:

11.1 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, carefully remove the system from the package and inspect for bends, 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

11.2 Materials Required:

- Appropriate guiding catheter(s)
- 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 haemostatic valve with an appropriate internal diameter
- Contrast diluted 1:1 with normal saline
- Inflation device
- Three-way stopcock
- Torque device
- Guide wire introducer

11.3 Preparation:

11.3.1 Guidewire Lumen Flush:

- Remove the protective stylet from the guide wire lumen and discard.
- Flush the guide wire with HepNS until the fluid exits the guide wire exit port approximately 25 cm distal to catheter distal tip.

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

11.3.2 Delivery system Preparation:

- Prepare an inflation device with diluted contrast medium
- Attach inflation device to stopcock; attach to hub (balloon inflation port)

Caution: Do not apply negative or positive pressure to balloon at this time.

- Open stopcock to stent delivery system
- Leave inflation device on neutral
- Purge the inflation device of all air

11.3.3 Delivery Procedure:

- Prepare vascular access site according to standard practice.
- Prepare lesion site according to standard practice. Predilate the lesion with a PTCA catheter.
- Maintain neutral pressure on inflation device. Open rotating haemostatic valve as widely as possible.
- Backload delivery system onto proximal portion of guide wire while maintaining guide wire position across target lesion.
- Advance the stent delivery system over guide wire 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 Precautions, section 6.4 for specific stent delivery removal instructions.

- Tighten the rotating haemostatic valve. The stent is now ready to be deployed.

11.3.4 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 the 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.

11.3.5 Further Dilatation of the Stented Segments:

All efforts should be taken to assure 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 results 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 - 2.50 mm	3.00 mm
2.75 mm - 3.50 mm	4.00 mm
4.00 mm - 4.50 mm	5.00 mm

11.3.6 Removal Procedure:

- Ensure that the balloon is fully deflated
- While maintaining guide wire position and negative pressure on the inflation device, withdraw the stent delivery system.

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 Precautions, section 6.4 for specific stent delivery system removal instructions.

- Repeat angiography to assess the stented area. If an adequate expansion as not been obtained, exchange back to the original delivery catheter or achieve proper stent apposition to the vessel wall.
- Final internal stent diameter should match reference vessel. **ASSURE THAT THE STENT IS NOT UNDERDILATED.**

12. Antiplatelet Regimen:

Physician should use the information from the current Drug Eluting Stent literature, guideline and specific needs of individual patients to determine the specific antiplatelet/anticoagulation regime to be used for their patients in general practice.

Current guidelines for the 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 patient's condition. In case an unanticipated interruption or discontinuation of DAPT is required any time after one month following DES coronary stent implantation, data from published literature show low stent thrombosis rates and no observed 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 requires early discontinuation of antiplatelet therapy, the interventionalist and patient should carefully consider whether a Drug Eluting Stent and its associated recommended antiplatelet therapy is the appropriate PCI 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

Stent inner diameter

Stent length

Temperature Limitation

Contains one unit

MGCID
Min guide catheter I.D.

Keep dry

Do not use if box open or damaged

SN
Serial number

REF
Reference number

LOT
Lot number

Consult instruction for use

Max. guide wire diameter

For single use only do not reuse

Non-Pyrogenic

STERILE EO
Sterilized using ethylene oxide

Use by

Manufacturer

Manufacturing date

Do not resterilize

MR Conditional

EC REP
Authorized representative in the European community

IFU9202/21092020

Meril

CE 1434

An ISO 13485 & GMP Certified Company

Manufactured by:
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