BioMime™ branch

Sirolimus Eluting Coronary Side Branch Stent System

Instructions for use - English

1. Device Description:

The BioMime™ Branch Sirolimus Eluting Coronary Side Branch 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 outer platinum-iridium radio opaque marker bands.
- BioMime™ Branch Sirolimus Eluting Coronary Side Branch Stent is permanant implantation device.

1.1 Device Components Description:

1.1.1 Available stent lengths& diameters

Available stent lengths & diameters are shown in table-1 below

Table-1 BioMime™ Branch size matrix

Available Stent Diameters (Proximal to Distal d_1-d_2) (mm)	Available Stent Length (mm)			
	16	19	24	29
2.50 - 2.50	BBR25025016	BBR25025019	BBR25025024	BBR25025029
3.00 - 2.50	BBR30025016	BBR30025019	BBR30025024	BBR30025029
3.50 - 2.50	BBR35025016	BBR35025019	BBR35025024	BBR35025029
3.50 - 3.00	BBR35030016	BBR35030019	BBR35030024	BBR35030029
4.00 - 3.50	BBR40035016	BBR40035019	BBR40035024	BBR40035029

Table - 2 Delivery System Specification

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 Step Balloon Dilation Catheter - UNS (Lineage) Semi-compliant Polyamide balloon, nominally 0.5 mm longer on both side than the stent length. Mounted stent length & location is defined by the two most distal & most proximal platinum-iridium radiopaque marker bands and two mid platinum-iridium 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 2.70F
1.1.8	Stent dilatation / Balloon inflation pressures	Please refer product labels
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	Coating	Hydrophilic Coating
1.1.12	Product code format BBRxxxzzzyy	BBR = BioMime™ Branch xxx = nominal stent proximal diameter (d1, main branch) (mm) zzz = nominal stent distal diameter (d2, side branch) (mm) yy = nominal stent length (mm) e. g. BBR30025019 xxx = 300 = Diameter 3.00 mm zzz= 250 = Diameter 2.50 mm yy = 19 = Length 19 mm

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

Table-3 BioMime™ Branch Stent Compliance Chart

Inflation Pressure		Stent diameter (mm)									
		2.50 - 2.50		3.00 - 2.50		3.50 - 2.50		3.50 - 3.00		4.00 - 3.50	
(atm)	(kPa)	d_1	d_2	d_1	d_2	d_1	d_2	d_1	d_2	d_1	d_2
6	608	2.40	2.37	2.90	2.34	3.39	2.32	3.38	2.84	3.88	3.34
7	709	2.44	2.43	2.94	2.40	3.43	2.39	3.43	2.89	3.93	3.40
8	811	2.48	2.47	2.98	2.45	3.47	2.44	3.47	2.95	3.98	3.44
9	**912**	**2.52**	**2.50**	**3.03**	**2.50**	**3.52**	**2.50**	**3.53**	**3.00**	**4.04**	**3.50**
10	1013	2.55	2.54	3.06	2.54	3.56	2.54	3.56	3.04	4.08	3.54
11	1115	2.58	2.58	3.09	2.58	3.59	2.58	3.59	3.08	4.12	3.58
12	1216	2.61	2.61	3.12	2.61	3.62	2.62	3.62	3.12	4.16	3.62
13	1317	2.64	2.64	3.15	2.64	3.65	2.65	3.65	3.16	4.19	3.65
14	1419	2.67	2.67	3.18	2.67	3.68	2.68	3.68	3.20	4.22	3.68
15	1520	2.70	2.70	3.20	2.70	3.71	2.71	3.70	3.23	4.25	3.71
16	1621	2.73	2.73	3.22	2.73	3.73	2.74	3.72	3.26	4.28	3.74

Grey background: NP (Nominal pressure),

Black background: RBP (Rated Burst Pressure)

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-methoxycyclohexyl]-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 its molecular weight is 914.2

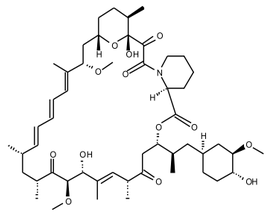

Fig.1 Sirolimus Drug Chemical Structure

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 immunosuppresessant. It inhibits cell motility by suppression of m-TOR medicated 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 BioMime™ Branch Sirolimus Eluting Coronary Side Branch Stent System ranges between 68.68 μg to 182.39 μg. The maximum number of stents with highest active drug concentration which can be used is two stents (maximum drug loading of 364.78 μg of Sirolimus drug).

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 release from the stent.

2. How Supplied:

Sterile: BioMime™ Branch 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) BioMime™ Branch Sirolimus Eluting Coronary Side Branch Stent System housed in a protective circular hoop tray, one (1) Instruction for Use, two (2) Stent Implant Cards.

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

Shelf Life: 3 years.

3. Indications:

It is intended for improving the coronary luminal diameter of the side branch of de novo bifurcated lesions in native coronary arteries with reference diameters ranging from 2.5 mm to 3.5 mm in the side branch and 2.5 mm to 4.0 mm in the main vessel. The device is intended for use in conjunction with balloon expandable coronary stents (bare metal and drug eluting) in the main branch.

4. Contraindications:

The BioMime™ Branch Sirolimus Eluting Coronary Side Branch 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.
- Angiographic evidence of thrombus.
- A significant (>50%) stenosis proximal to distal to the target lesion.
- Impaired runoff in the treatment vessel with diffuse distal disease.
- Ejection fraction ≤30%.
- Anticipated use of rotational atherectomy.
- Placement of BioMime™ Branch stent without pre-dilatation of the target lesion with an angioplasty balloon (direct stenting) is not indicated.
- Patients with moderate to severe calcification.
- Patients with totally occluded vessel.
- Target lesion has excessive tortuosity unsuitable for stent delivery & deployment BioMime™ Branch alone implantation, without a main branch stent is 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.
- Infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm or rupture.
- The stent may cause spasm, distal embolization, thrombus, or could migrate from the site of implantation down the arterial lumen. Excessive stretching of the artery may cause rupture and life-threatening bleeding.
- Stents can be partially deployed in particularly resistant lesions. Stent dislodgement from the balloon surface during deployment and/or dislodgement from the target site post-deployment can occur.
- Never try to straighten a kink 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.
- All equipment required for the implantation of this stent must be carefully examined prior to use to verify proper function.

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 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 BioMime™ Branch Sirolimus Eluting Coronary side Branch 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.
- When the delivery catheter is exposed to the vascular system, it should be manipulated while high-quality fluoroscopic observation. If resistance is met during manipulation, determine the cause of the resistance before proceeding. Excessive manipulation may cause dislodgment of the stent from the delivery catheter.
- 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.
- Do not attempt to reposition a partially deployed stent. Attempted repositioning may result in severe vessel damage.
- Guiding catheters used must have lumen sizes that are suitable to accommodate the introduction of BioMime™ Branch stent.
- 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 pseudoanerusym.
- 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.
- When recrossing a recently implanted stent care should be taken to assure the guidewire is placed within the lumen and not between the stent and the vessel wall. Otherwise, inadvertent dislodgment of the stent may occur leading to faulty positioning of the stent.

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:

BioMime™ Branch Sirolimus Eluting Coronary Side Branch has same material of construction (L605 Cobalt Chromium) as that of Meril's BioMime™ Sirolimus Eluting Stent System. BioMime is MR conditional and can be scanned safely under following condition.

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 96T2/m and less
- Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of

  < 2 W/kg at 1.5 Tesla, overlapped (max. 2x4.5x40 mm (max. 79 mm length))

  < 2 W/kg at 3 Tesla, overlapped (max. 2x4.5x40mm (max. 79mm 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
- Acute or subacute closure of the coronary artery
- 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 / cerebovascular 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 BioMime™ Brach Sirolimus Eluting Coronary Side Branch Stent System. 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 BioMime™ Branch Sirolimus Eluting Coronary side Branch Stent System 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 < 2.50mm.
- 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 BioMime™ Branch Sirolimus Eluting Coronary Side Branch Stent System and for 12 weeks after implantation. The BioMime™ Branch Sirolimus Eluting Coronary Side Branch Stent System 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 BioMime™ Branch Sirolimus Eluting Coronary Side Branch Stent System has not been evaluated in cases of in-stent restenosis or previously stented lesions.
- The safety and effectiveness of BioMime™ Branch has not been evaluated in pediatric subjects below 18 years.

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
- Balloon Expandable Coronary Stent (main vessel)

11.3. Preparation

- Use of this coronary stent and delivery system requires advanced angioplasty skills. The following instructions provide technical guidance but do not obviate formal training for the physician in the use of coronary stents and delivery systems.
- Choose the appropriate stent/balloon size using the results of diagnostic angioplasty and stent matrix in Table -1.
- Remove the stent delivery system from the packaging and place in a sterile area using sterile technique.
- Prior to using this device, all equipment, including the entire BioMime™ Branch Sirolimus Eluting Coronary Side Branch Stent System should be visually examined carefully for defects. Specially, examine the distal balloon region for kinks or bends in the catheter and damage to the stent. Do not use any defective equipment.
- Utilize standard techniques and the manufacturer's instructions to place the vascular sheath, guiding catheter, coronary stent (main vessel), and guidewire.
- Stent Delivery system preparation:
  a. Utilize standard techniques for preparation of the BioMime™ Branch Sirolimus Eluting Coronary Side Branch Stent System.
  b. Visually inspect the balloon/stent assembly to assure proper placement of the stent between the most distal and most proximal marker bands. Do not use any defective equipment.
  Note: You may not be able to see the two middle marker bands as they are located under the stent.
  Do not wipe the balloon / stent assembly as this may cause damage or dislodgement of the stent.
  c. Remove the stylet from the guidewire lumen.

11.4. Stent Deployment Procedure

- Place the guidewire across the lesion into the side branch and a second guidewire across the lesion into the distal main vessel.
- Pre-dilate the lesion with an appropriately sized balloon in order to facilitate the tracking of the stent across the lesion.
- Advance the BioMime™ Branch Sirolimus Eluting Coronary Side Branch Stent System prepared in the point 11.3 over the side branch guidewire to the treatment site.
- Pay special attention to ensure that the side branch origin is straddled by mid markers on BioMime™ Branch Sirolimus Eluting Coronary Side Branch Stent System.

Caution: Do not apply excessive force to advance the BioMime™ Branch Sirolimus Eluting Coronary Side Branch Stent System. If the advancement of the system is not possible in spite of adequate guide catheter support, consider removing the BioMime™ Branch – Sirolimus Eluting Coronary Side Branch Stent System to perform additional pre-dilatation.

- Do not attempt to pull on an unexpected stent back into the guiding catheter, as stent damage or stent dislodgement may occur. Movement in and out through the distal end of the guiding catheter should not be performed as the stent may be damaged when retracting the undelpoyed stent back into the guiding catheter. To withdraw the BioMime™ Branch – Sirolimus Eluting Coronary Side Branch Stent System, the entire system with the guiding catheter should be removed as single unit.
- When removing the system as the single unit:
  a. Do not retract the delivery system in to the guiding catheter.
  b. Position the proximal balloon marker just distal to the tip of the guiding catheter.
  c. Advance the guide wire into the coronary anatomy as far distally as safely possible.
  d. Tighten the rotating hemostatic valve secure delivery system to the guiding catheter, then remove the guiding catheter and delivery system as a single unit.
- Failure to follow these steps and/or applying eccessive force to the delivery system can potentially result in loss or damage to the stent and/or delivery system components.
- Inflate the BioMime™ Branch Sirolimus Eluting Coronary Side Branch Stent System, expanding the stent to optimize strut apposition against the arterial wall. Do not exceed the rated burst pressure of the balloon provided in the compliance chart included with device.
- After stent deployment, deflate the balloon catheter and withdraw it while maintaining the guide wire position.
- **Caution:** Do not begin withdrawal of the delivery catheter until the balloon is fully deflated. Using Fluoroscopic guidance, observe the withdrawal of BioMime™ Branch Sirolimus Eluting Coronary Side Branch Stent System to ensure that the catheter does not catch onto the stent. If resistance is encountered, carefully advance the BioMime™ Branch Sirolimus Eluting Coronary Side Branch Stent System and gently withdraw.
- Select an angioplasty balloon catheter using the proximal main branch vessel diameter as a guide. Position the catheter with the distal marker at the side branch origin and dilate the balloon to the 1:1 balloon to artery ratio.
- Perform post BioMime™ Branch Side Branch Stent deployment angiography following administration of intra coronary nitroglycerin unless contraindicated. Confirm the position of the BioMime™ Branch Side Branch Stent within the artery and its proper apposition against the arterial wall.
- Retract the post dilatation balloon while maintaining both guidewires.
- With the assistance of fluoroscopy, reposition guide wire previously inside branch into main vessel distal to the side branch origin.
  - Use special attention to avoid guide wire retraction proximal to BioMime™ Branch stent.
- Remove initially placed 'trapped' main vessel guide wire.
- Select and appropriate balloon expandable coronary stent to treat the main vessel.
  - Select stent with sufficient length to cover the entire lesion as well as to cover proximal portion of the BioMime™ Branch Side Branch Stent.
- Prepare the balloon expandable coronary stent to treat main vessel according to its instruction for use.
- Track balloon expandable coronary stent to lesion site within the main vessel such that the distal portion of the main vessel stent extends through the BioMime™ Branch Side Branch Stent. In addition, the proximal portion of the main vessel stent should cover the main vessel region of the BioMime™ Branch Side Branch Stent.
  a. If resistance is encountered when tracking the balloon expandable coronary stent. Across the proximal portion of the BioMime™ Branch Side Branch Stent, do not use excessive force.

  Note: Consider removal of balloon expandable coronary stent (main vessel) and perform 'post dilatation' of the main vessel portion of the BioMime™ Branch Side Branch Stent.
- Deploy balloon expandable coronary (main vessel) stent.
- Retract stent delivery balloon catheter while maintaining guide wire portion.
- Select and additional guidewire and prepare according to instruction for use.
- Under fluoroscopy guidance, advance the guide wire through proximal portion to the main vessel stent and into the side branch.
  - Use special attention to ensure that the guide wire enters the proximal portion of the main vessel stent via the lumen.
- Utilizing appropriately sized balloon catheter, perform simultaneous balloon inflation in both the side branch and main vessel stent.
  a. Use special attention to ensure that both balloons are position within the stented arterial segments.
  b. Do not exceed the rated burst pressure for each balloon as specified in the instruction for use.
- Remove both angioplasty balloon catheters.
- Repeat angiography to confirm adequate stent expansion. Remove the guide wire.
- Repeat angiography to reconfirm angiographic result.
- Remove guide catheter, using standard technique.
- Discard all disposable devices used during this procedure per local requirements for medical device waste disposal.

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 limit


Contains one unit


Min guide catheter I.D.


Keep dry


Do not use if package is damaged


Serial number


Reference number


Lot number


Consult instructions for use


Max. guide wire diameter


Do not re-use


Non-pyrogenic


Sterilized using ethylene oxide


Use-by date


Manufacturer

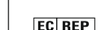

Date of manufacture


Do not resterilize


MR Conditional


Keep away from sunlight


Caution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