SIROMOUNT®

Sirolimus Eluting Coronary Stent System

Instruction For Use

1.0 Product Description:

The SIROMOUNT Sirolimus Eluting Coronary stent System is a device/drug combination product consisting of a device (Flexia CoCr L605 coronary stent) and a drug component (a formulation of Sirolimus drug with blend of biodegradable polymer)

1.1 Device Components Description:

The SIROMOUNT Sirolimus Eluting Coronary stent System comprises of following components.

- L605 cobalt chromium (CoCr) alloy stent viz. Flexia
- A stent Coating Consist of blend of Anti proliferative drug and polymer
  Anti proliferative drug – Sirolimus (Also Known as Rapamycin)
  Biocompatible, biodegradable co polymer coating which act as drug reservoir and drug release platform
- A Rapid exchange Stent Delivery PTCA Balloon catheter (The stent is pre-mounted on balloon catheter between two platinum-iridium radiopaque markers)

The device characteristics are summarized in below Table

Table: 1 SIROMOUNT Sirolimus Eluting Coronary Stent System Product Characteristics

SIROMOUNT Sirolimus Eluting Coronary Stent System	
Available stent length (mm)	8, 12, 13, 16, 19, 20, 24, 28, 29, 32,36, 37, 40, 43, 44, 47, 48, 50, 52
Available stent diameter (mm)	2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 3.75, 4.00, 4.50
Stent Material	A medical grade L605 Cobalt Chromium alloy
Drug Component	Sirolimus Drug & Biodegradable Polymers
Rapid Exchange PTCA Balloon Delivery System	Delivery System Usable Length: 140 cm Balloon Material: Semi Compliant Polyamide Hydrophilic Coating: On the distal shaft Markers on the proximal shaft: 90 cm and 100 cm Mounted stent length & location is defined by two radio opaque markers under the balloon catheter.
Guiding Catheter Compatibility	5 F (0.056"/1.4mm) Compatible
Guide wire Rapid Exchange port	25 cm from the distal tip of the balloon catheter
Guide wire Compatibility	0.014" (0.36mm)
Balloon Inflation Pressure	Nominal Pressure (NP): 9 atm, Rated Burst Pressure (RBP): 14/16 atm* *RBP 16 atm for all the variants except the ones given below whose RBP is 14 atm: - 3.50mm & 3.75mm diameter with length ≥36mm - 4.00mm diameter with length ≥32mm - 4.50mm diameter for all stent lengths

1.2 Drug Component Description:

The Drug component is coated on the stent. This coating consist of a Sirolimus drug (the active ingredient) and biodegradable polymer (Inactive ingredient)

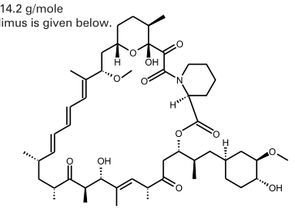
1.2.1 Active Ingredient- Sirolimus Drug:

The active ingredient in the SIROMOUNT Sirolimus-Eluting Coronary Stent System is Sirolimus. Sirolimus is macrocyclic lactone produced by a strain of Streptomyces hygroscopicus.

Nomenclature:

- **International Nonproprietary Name:** Sirolimus
- **Chemical (IUPAC) Name:** (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, 21-epoxy-3H-pyrido[2,1-c [1.4]oxaazacyclohentriacontine-1,5,11,28,29 (4H,6H,31 H)-pentone.
- **Molecular Formula:** $C_{51}H_{79}NO_{13}$
- **Molecular Weight Mass:** 914.2 g/mole

Chemical Structure of Sirolimus is given below.



Sirolimus belongs to class of therapeutics agent known as macrocyclic lactones or macrolides. It is a cytostatic and immunosuppressant. It inhibits cell mobility 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 inhibit antibody production. It demonstrate antiproliferative activities.

The active ingredient, Sirolimus content of SIROMOUNT Sirolimus Eluting Coronary stent ranges between 34 to 378 μg per stent length and vessel size.

1.2.2 Inactive Ingredients- Biodegradable Polymers:

SECS stent is coated with Sirolimus as an active substance and biodegradable polymers as inactive ingredients on the surface of the stent in the single layer. The Inactive Ingredients of coatings consist blend of Lactide and glycolide based biodegradable polymer. The polymer formulated is to provide programmed release of drug. The polymer chains are cleaved by hydrolysis to form monomeric acid and eliminate from the body through kreb's cycle, primary as carbon dioxide (CO_2) and water(H_2O) which are excreted though urine. The polymers control drug release kinetics and it degraded as the drug is released from the stent.

2.0 Intended Use of Device/Indications:

SIROMOUNT Sirolimus Eluting Coronary Stent system (SECS) is intended for use in the patient eligible for Percutaneous Transluminal Coronary Angioplasty (PTCA).

SIROMOUNT Sirolimus Eluting Coronary Stent System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic disease due to discrete de novo lesions and in-stent restenotic lesions of length ≤ 52 mm in native coronary arteries with a reference vessel diameter of 2.00 to 4.50 mm.

3-0 Intended Users:

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

4.0 The Intended Patient Population:

- Patient who are eligible for Percutaneous Transluminal Coronary Angioplasty (PTCA).
- Patients with symptomatic ischemic disease due to discrete de novo lesions and in-stent restenotic lesions of length ≤ 52 mm in native coronary arteries with a reference vessel diameter of 2.00 to 4.50 mm.
- Patients who do not have any contraindications for using the product.
- Patients with age 18 years or above

5.0 How Supplied:

Sterile: This device is sterilized with Ethylene Oxide (ETO) gas and is Non Pyrogenic.
For single use only. Do not resterilize. Do not use if package is damaged or opened.
Contents: One (1) SIROMOUNT Sirolimus Eluting Coronary Stent System.
Storage: Store in a dry, dark and cool place.
Store at 25 °C temperature, excursion permitted 15-30 °C temperature.

6.0 Contraindication:

Use of SECS is contraindicated in the following patient types:

- Patients with hypersensitivity or allergic to aspirin, heparin, Clopidogrel, ticlopidine, drug such as Sirolimus (Rapamycin) or similar drugs on analogue or derivative, cobalt, chromium, nickel, molybdenum, tungsten or any contrast medium.
- Patients who are candidates for coronary bypass surgery.
- Transplant patients.
- Patients in whom, anti-platelet and/or anticoagulant therapy is Contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery device.

7.0 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, 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 to 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. At least 99.9 % of the balloons (with 95% confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- Device is to be used under X-rays fluoroscopy, hence standard method for using this imaging technique needs to be followed.
- Use the device before the "Expiry" date specified on the package.

8.0 Precautions:

8.1 General Precautions:

- Only interventional cardiologist 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 (CABG) 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 implant Stents of different materials in tandem overlap or contact if possible.
- The 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 be used in conjunction with other Stents.

8.2 System Handling Precautions:

- 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 haemostatic 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.
- 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 SECS 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.

8.3 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.
- 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 Removal Precautions.
- An unexpanded stent should be introduced into the coronary arteries one time only. An unexpanded stent should not be subsequently moved in and out through the distal end of the guiding catheter as stent damage or stent dislodgement from the balloon may occur.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.

8.4 Stent System Removal Precautions:

- Should unusual resistance be felt at any time during either lesion access or removal of the Delivery System post-stent implantation, the entire system should be removed as a single unit.
- Do not attempt to pull an unexpanded stent back through the guiding catheter while engaged in the coronary arteries, as stent damage or stent dislodgement from the balloon may occur.
- When removing the Delivery System as a single unit, do not retract the delivery system into the guiding catheter
- Position the proximal balloon marker just distal to the tip of the guiding catheter.
- Advance the guide wire into the coronary anatomy as far distally as safely possible.
- Tighten the rotating homeostatic 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.

8.5 Post Implantation Precautions:

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

9.0 Disposal Procedure:

SIROMOUNT Sirolimus Eluting Coronary Stent is implanted in the patient and the used delivery system must be disposed off as per local regulatory requirements and corresponding hospital disposal procedures for biohazard materials.

10.0 Potential Adverse Events:

Potential adverse events which may be associated with the use of a coronary stent include but are not limited to:

- Abrupt stent closure.
- Acute myocardial infarction.
- Allergic reactions to anti – coagulant and or antithrombotic therapy or contrast medium.
- Angina.
- Aneurysm.
- Arrhythmia, including ventricular fibrillation (VF) and ventricular tachycardia (VT).

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1.0 Product Description:

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1.1 Device Components Description:

The SIROMOUNT Sirolimus Eluting Coronary stent System comprises of following components.

- L605 cobalt chromium (CoCr) alloy stent viz. Flexia
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  Biocompatible, biodegradable co polymer coating which act as drug reservoir and drug release platform
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Available stent diameter (mm)	2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 3.75, 4.00, 4.50
Stent Material	A medical grade L605 Cobalt Chromium alloy
Drug Component	Sirolimus Drug & Biodegradable Polymers
Rapid Exchange PTCA Balloon Delivery System	Delivery System Usable Length: 140 cm Balloon Material: Semi Compliant Polyamide Hydrophilic Coating: On the distal shaft Markers on the proximal shaft: 90 cm and 100 cm Mounted stent length & location is defined by two radio opaque markers under the balloon catheter.
Guiding Catheter Compatibility	5 F (0.056"/1.4mm) Compatible
Guide wire Rapid Exchange port	25 cm from the distal tip of the balloon catheter
Guide wire Compatibility	0.014" (0.36mm)
Balloon Inflation Pressure	Nominal Pressure (NP): 9 atm, Rated Burst Pressure (RBP): 14/16 atm* *RBP 16 atm for all the variants except the ones given below whose RBP is 14 atm: - 3.50mm & 3.75mm diameter with length ≥36mm - 4.00mm diameter with length ≥32mm - 4.50mm diameter for all stent lengths

1.2 Drug Component Description:

The Drug component is coated on the stent. This coating consist of a Sirolimus drug (the active ingredient) and biodegradable polymer (Inactive ingredient)

1.2.1 Active Ingredient- Sirolimus Drug:

The active ingredient in the SIROMOUNT Sirolimus-Eluting Coronary Stent System is Sirolimus. Sirolimus is macrocyclic lactone produced by a strain of Streptomyces hygroscopicus.

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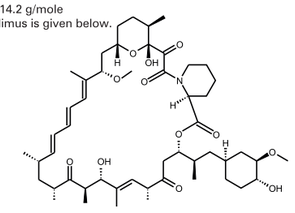

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1.2.2 Inactive Ingredients- Biodegradable Polymers:

SECS stent is coated with Sirolimus as an active substance and biodegradable polymers as inactive ingredients on the surface of the stent in the single layer. The Inactive Ingredients of coatings consist blend of Lactide and glycolide based biodegradable polymer. The polymer formulated is to provide programmed release of drug. The polymer chains are cleaved by hydrolysis to form monomeric acid and eliminate from the body through kreb's cycle, primary as carbon dioxide (CO_2) and water(H_2O) which are excreted though urine. The polymers control drug release kinetics and it degraded as the drug is released from the stent.

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3-0 Intended Users:

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

4.0 The Intended Patient Population:

- Patient who are eligible for Percutaneous Transluminal Coronary Angioplasty (PTCA).
- Patients with symptomatic ischemic disease due to discrete de novo lesions and in-stent restenotic lesions of length ≤ 52 mm in native coronary arteries with a reference vessel diameter of 2.00 to 4.50 mm.
- Patients who do not have any contraindications for using the product.
- Patients with age 18 years or above

5.0 How Supplied:

Sterile: This device is sterilized with Ethylene Oxide (ETO) gas and is Non Pyrogenic.
For single use only. Do not resterilize. Do not use if package is damaged or opened.
Contents: One (1) SIROMOUNT Sirolimus Eluting Coronary Stent System.
Storage: Store in a dry, dark and cool place.
Store at 25 °C temperature, excursion permitted 15-30 °C temperature.

6.0 Contraindication:

Use of SECS is contraindicated in the following patient types:

- Patients with hypersensitivity or allergic to aspirin, heparin, Clopidogrel, ticlopidine, drug such as Sirolimus (Rapamycin) or similar drugs on analogue or derivative, cobalt, chromium, nickel, molybdenum, tungsten or any contrast medium.
- Patients who are candidates for coronary bypass surgery.
- Transplant patients.
- Patients in whom, anti-platelet and/or anticoagulant therapy is Contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery device.

7.0 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, 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 to 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. At least 99.9 % of the balloons (with 95% confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- Device is to be used under X-rays fluoroscopy, hence standard method for using this imaging technique needs to be followed.
- Use the device before the "Expiry" date specified on the package.

8.0 Precautions:

8.1 General Precautions:

- Only interventional cardiologist 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 (CABG) 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 implant Stents of different materials in tandem overlap or contact if possible.
- The 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 be used in conjunction with other Stents.

8.2 System Handling Precautions:

- 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 haemostatic 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.
- 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 SECS 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.

8.3 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.
- 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 Removal Precautions.
- An unexpanded stent should be introduced into the coronary arteries one time only. An unexpanded stent should not be subsequently moved in and out through the distal end of the guiding catheter as stent damage or stent dislodgement from the balloon may occur.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.

8.4 Stent System Removal Precautions:

- Should unusual resistance be felt at any time during either lesion access or removal of the Delivery System post-stent implantation, the entire system should be removed as a single unit.
- Do not attempt to pull an unexpanded stent back through the guiding catheter while engaged in the coronary arteries, as stent damage or stent dislodgement from the balloon may occur.
- When removing the Delivery System as a single unit, do not retract the delivery system into the guiding catheter
- Position the proximal balloon marker just distal to the tip of the guiding catheter.
- Advance the guide wire into the coronary anatomy as far distally as safely possible.
- Tighten the rotating homeostatic 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.

8.5 Post Implantation Precautions:

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

9.0 Disposal Procedure:

SIROMOUNT Sirolimus Eluting Coronary Stent is implanted in the patient and the used delivery system must be disposed off as per local regulatory requirements and corresponding hospital disposal procedures for biohazard materials.

10.0 Potential Adverse Events:

Potential adverse events which may be associated with the use of a coronary stent include but are not limited to:

- Abrupt stent closure.
- Acute myocardial infarction.
- Allergic reactions to anti – coagulant and or antithrombotic therapy or contrast medium.
- Angina.
- Aneurysm.
- Arrhythmia, including ventricular fibrillation (VF) and ventricular tachycardia (VT).

- Arterial perforation.
- Arterial rupture.
- Arteriovenous fistula.
- Bleeding complications.
- Bradycardia.
- Cardio tamponade.
- Cardiogenic shock.
- Coronary spasm
- Coronary or stent embolism.
- Coronary or stent thrombosis.
- Death.
- Dissection of the coronary artery.
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergency or non – emergent Coronary Artery Bypass Graft Surgery.
- Entry site complications.
- Heart Failure.
- Hematoma.
- Hemorrhage, requiring transfusion.
- Hypotension / Hypertension.
- Infection.
- Infection and / or pain at the access site.
- Injury to the coronary artery.
- Ischemia.
- Nausea and vomiting.
- Palpitations.
- Perforation or rupture.
- Pericardial effusion.
- Pseudoanerusym.
- Renal failure.
- Respiratory failure.
- Restenosis of stented segment.
- Rhythmical disturbances.
- Shock / Pulmonary edema.
- Spasm.
- Stroke / cerebovascular accident / TIA.
- Stent embolization.
- Stent compression.
- Stent migration.
- Total occlusion of coronary artery.
- Unstable angina pectoris.
- Vascular complications, which may require vessel repair.
- Ventricular fibrillation.

11.0 Use in Special Population:

11.1 Pregnancy:

There are no adequate and well-controlled studies in pregnant women. Effective contraception should be initiated before implanting SIROMOUNT Sirolimus eluting coronary stent and 12month after implantation. The SIROMOUNT stent should be used during pregnancy only if the potential benefit outweighs the potential risk to the embryo or fetus.

11.2 Use during Lactation:

It is not known whether the Sirolimus is distributed in human breast milk. Because the similar drug are known to be excreted in human milk, and because of the risk of adverse reaction in nursing the Infants, a decision should be made whether to discontinue nursing or to implant the stent, taking into account the importance of the stent to the mother.

11.3 Pediatric Use:

The safety and efficacy of the SECS in pediatric patients have not been established.

11.4 Geriatric Use:

Clinical studies of the (Sirolimus Eluting) Stent did not find that patients age 65 years and over differed with regard to safety and performance compared to younger patients.

11.5 Lesion/Vessel Characteristics:

The safety and effectiveness of the SIROMOUNT Sirolimus Eluting Coronary Stent System have not been established in the following patient populations:

- Patients with unresolved vessel thrombus at the lesion site.
- Patients with coronary artery reference vessel diameter < 2.00 mm or > 4.50 mm.
- Patients with lesions located in the left main coronary artery, Ostial lesions, or lesions located at a bifurcation.
- Patients with diffuse disease or poor overflow distal to the identified lesions.
- Patients with tortuous vessels in the region of the obstruction or proximal to the lesion.
- Patients with a recent acute myocardial infarction where there is evidence of thrombus or poor flow.

12.0 Individualization of Treatment:

- The risks and benefits should be considered for each patient before use of the SIROMOUNT Sirolimus Eluting Coronary Stent. Patient selection factors to be assessed should include a judgment regarding risk of anti-platelet therapy. Stenting is generally avoided in those patients at heightened risk of bleeding.
- Premorbid conditions that increase the risk of a poor initial result and the risk of emergency referral for bypass surgery (diabetes mellitus, renal failure, and severe obesity) should be reviewed.
- Thrombosis following stent implantation is affected by several baseline angiographic and procedural factors. These include vessel diameter less than 3.0mm, intra procedural thrombus, poor distal runoff, dissection and/or early discontinuation of anti-platelet therapy following stent implantation. In patients, who have undergone coronary stenting, the persistence of a thrombus or dissection should be considered a maker for subsequent thrombotic occlusion. These patients should be monitored very carefully during the first month after stent implantation.
- A review of the vessel location, reference vessel size, lesion length, qualitative target lesion characteristics, and the amount of the myocardium in jeopardy from acute or sub-acute thrombosis must also be considered.

13.0 Clinical Use Information:

13.1 Access to Package Holding Sterile Stent Delivery System

Carefully inspect the stent delivery system package, and check for damage to the sterile barrier. Tear open the sterile pouch using aseptic technique to reveal sterile stent system. Do not use device if any damage to packaging is noted.

13.2 Inspection Prior to Use:

Prior to using the SIROMOUNT Sirolimus Eluting Coronary Stent System, carefully remove the system from the package and inspect for bends, kinks, and other damage. Verify that the stent does not extend beyond the radiopaque balloon markers. Do not use if any defects are noted.

13.3 Materials Required:

- Appropriate guiding catheter(s)
- 10 to 20cc syringes (2 to 3 No.)
- 1,000 u / 500 cc Heparinized Normal Saline (HepNS)
- 0.014 inch (maximum) x 175 cm (minimum length) guide wire
- Rotating haemostatic valve with 0.096 inch minimum inner diameter
- contrast diluted 1:1 with normal saline
- Inflation device
- Three-way stopcock
- Torque device
- Guide wire introducer

13.4 Preparation:

13.4.1 Guide wire Lumen Flush:

- Remove the protective cover from the tip.
- Flush Guide wire lumen with HepNS until fluid exits Guide wire exit notch.

13.4.2 Delivery System Preparation:

- Prepare the inflation device or syringe with diluted contrast medium.
- Attach the inflation device/syringe to the stopcock; attach it to the inflation port.
- With tip down, orient Delivery System vertically.
- Open stopcock to Delivery System; pull negative for 30 seconds; release to neutral for contrast filling.
- Repeat above two steps until all air is expelled.
  Note: If air is seen in shaft, repeat above mentioned steps to prevent uneven stent expansion.
- If a syringe was used, attach a prepared inflation device to stopcock.
- Open stopcock to Delivery System.
- Leave on neutral.

13.5 Delivery Procedure:

- Prepare the vascular access site according to standard practice.
- Pre-dilate the lesion with a PTCA catheter.
- Maintain neutral pressure on the inflation device. Open the rotating haemostatic valve as widely as possible.
- Backload the delivery system onto the proximal portion of the Guide wire while maintaining the Guide wire position across the target lesion.
- Advance the stent delivery system over the Guide wire to the target lesion. Use the radiopaque balloon markers to position the stent across the lesion; perform angiography to confirm the position of the stent.
  NOTE: If during the process of moving the Delivery System into position you notice the stent has moved on the balloon, do not deploy the stent. The entire system should be removed as a single unit.
- See section 8.4 Stent System Removal Precautions in section 8.0 Precautions.
- Tighten rotating haemostatic valve. Stent is now ready to be deployed.

13.6 Deployment Procedure:

- CAUTION: Refer to the product label and the compliance chart in 13.7 below for in vitro stent inner diameter, nominal pressure and RBP. Deploy stent slowly by pressurizing delivery system in 1 atm increments, every 5 seconds, until stent is completely expanded. Maintain pressure for 30 seconds. If necessary, the delivery system can be re-pressurized or further pressurized to assure complete apposition of the stent to the artery wall. Do not exceed RBP.
- Deflate balloon by pulling negative on inflation device for 30 seconds.

13.7 In Vitro Information:

- SIROMOUNT Stent and Balloon Compliance:

Compliance Chart of SIROMOUNT Sirolimus Eluting Coronary Stent System

Pressure (atm)	2.00	2.25	2.50	2.75	3.00	3.50	3.75	4.00	4.50
6	1.85	2.06	2.26	2.58	2.80	3.25	3.49	3.72	4.35
7	1.92	2.14	2.33	2.64	2.90	3.30	3.58	3.79	4.40
8	1.96	2.18	2.40	2.71	2.95	3.40	3.66	3.88	4.45
9	2.00	2.25	2.50	2.75	3.00	3.50	3.75	4.00	4.50
10	2.05	2.30	2.55	2.81	3.07	3.54	3.79	4.05	4.55
11	2.09	2.34	2.59	2.86	3.10	3.58	3.83	4.12	4.60
12	2.12	2.37	2.62	2.91	3.14	3.62	3.87	4.17	4.64
13	2.15	2.40	2.65	2.95	3.18	3.66	3.91	4.22	4.68
14	2.19	2.44	2.68	2.98	3.20	3.70	3.95	4.26	4.72
15	2.22	2.47	2.71	3.01	3.22	3.74	3.99	4.30	4.76
16	2.25	2.50	2.74	3.04	3.24	3.78	4.02	4.34	4.80
17	2.29	2.54	2.77	3.07	3.27	3.82	4.05	4.37	4.84
18	2.33	2.57	2.80	3.10	3.29	3.86	4.08	4.40	4.88

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

RBP 16 atm except sizes of
3.50 x 36, 37, 40, 43, 44, 47, 48, 50 & 52 mm
3.75 x 36, 37, 40, 43, 44, 47, 48, 50 & 52 mm and
4.00 x 32, 36, 37, 40, 43, 44, 47, 48, 50 & 52 mm stents and
4.50 mm diameter stents for all stent lengths.
*RBP 14 atm for
3.50 x 36, 37, 40, 43, 44, 47, 48, 50 & 52 mm
3.75 x 36, 37, 40, 43, 44, 47, 48, 50 & 52 mm and
4.00 x 32, 36, 37, 40, 43, 44, 47, 48, 50 & 52 mm stents
*RBP 14 atm for 4.50 mm diameter stents for all stent lengths.

13.8 Removal Procedure:

- Ensure that the balloon is fully deflated.
- Fully open rotating haemostatic valve.
- While maintaining Guide wire position and negative pressure on inflation device, withdraw Delivery System.
  NOTE: Should unusual resistance be felt at any time during either lesion access or removal of Delivery System post-stent implantation, the entire system should be removed as a single unit.
- Tighten rotating haemostatic valve.
- Repeat angiography to assess stented area. If necessary, post dilate within stent. Balloon inflations should incorporate balloon size closely matching vessel.
- Final stent diameter should match reference diameter. Assure stent is not under-dilated.

14.0 Patient Information:

In addition to these Instructions, the following patient specific information regarding the SECS Coronary Stent is available:

- A Stent Implant Card that includes both patient and Coronary Stent specific information. This stent implant card will be expected to forward to the company along with patient information and stent identification.

15.0 Compatibility with other Medical Devices

SIROMOUNT Sirolimus Eluting Coronary Stent System may be used with the other medical devices given below but not limited to the following:

- Guiding Catheter
- Guide Wire
- Inflation Device

16.0 Disclaimer of Warranty and Limitation of Remedy:

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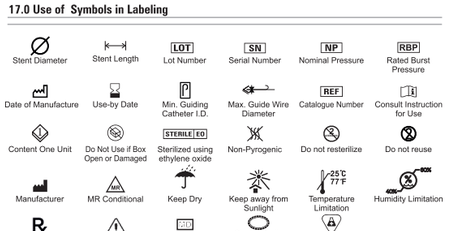
17.0 Use of Symbols in Labeling



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