Date

ULTIMASTER TANSEI SIROLIMUS ELUTING CORONARY STENT SYSTEM

INSTRUCTIONS FOR USE

REF Catalogue number

LOT Batch code

Use by date

Do not use if package is damaged

STERILE R Sterilized using irradiation

Do not resterilize

Do not reuse

30°C 1°C Temperature limitation for storage

NP Nominal Pressure

RBP Rated Burst Pressure

P Pressure

Min GC Guiding Catheter minimum inner diameter

I.D. / Ø Stent inner diameter

<L> Stent length

Consult instructions for use

Contents

Manufacturer

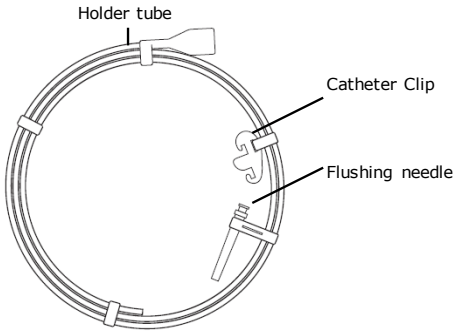
Manufacturing site

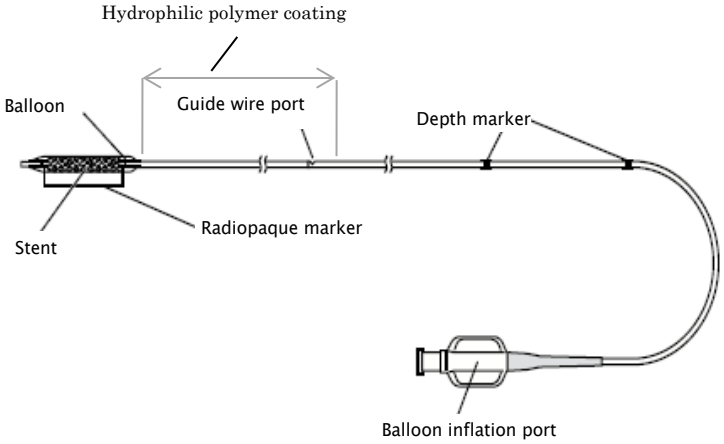
MR Conditional

PRODUCT DESCRIPTION

Ultimaster Tansei Sirolimus Eluting Coronary Stent System with Rapid Exchange Balloon Delivery System consists of a balloon expandable intra-coronary L605 cobalt chromium (CoCr) stent with abluminal drug eluting coating, that consists of a blend of Sirolimus and poly(D,L-lactide-co-caprolactone), pre-mounted onto a high pressure, semi-compliant balloon delivery catheter.

NAME OF EACH PART





DEVICE COMPONENT DESCRIPTION

STENT PLATFORM

The platform for Ultimaster Tansei Sirolimus Eluting Coronary Stent System, designed based on the Kaname® CoCr Coronary Stent, offers a flexible stent with thin struts, excellent deliverability and optimized side branch

access.

STENT COATING LAYER

SIROLIMUS – ACTIVE PHARMACEUTICAL INGREDIENT

Sirolimus is an immunosuppressive agent. Sirolimus inhibits T-lymphocyte activation and proliferation that occurs in response to antigenic and cytokine (Interleukin [IL]-2, IL-4, and IL-15) stimulation by a mechanism that is distinct from that of other immunosuppressants. In cells, sirolimus binds to the immunophilin, FK Binding Protein-12 (FKBP-12), to generate an immunosuppressive complex. This complex binds to and inhibits the activation of the mammalian Target Of Rapamycin (mTOR), a key regulatory kinase. This inhibition suppresses cytokine-driven T-cell proliferation, inhibiting the progression from the G1 to the S phase of the cell cycle. The sirolimus is intended to reduce restenosis as ancillary medicinal substance to coronary intervention using the Ultimaster Tansei Sirolimus Eluting Coronary Stent.

DEGRADABLE POLYMERS – INACTIVE INGREDIENTS

Ultimaster Tansei Sirolimus Eluting Coronary Stent has a coating consisting of two layers: a primer layer and a drug matrix layer. The primer layer and drug carrier polymer, poly(D,L-lactide-co-caprolactone) copolymer is expected to degrade within 3-4 months. The drug coating is applied abluminal, leaving the luminal side of the stent free from drug as such enhancing endothelial coverage.

BALLOON DELIVERY CATHETER

The delivery catheter is a high pressure, semi-compliant balloon delivery catheter that has two radiopaque markers, which fluoroscopically mark the ends of the stent to facilitate proper stent placement.
The active balloon length is closely sized to the length of the stent to prevent over-expansion of the tissue proximal or distal to the stent.
At the proximal end of the system is a female luer lock connector hub. This hub connects to the balloon inflation lumen. The guide wire enters the distal tip of the catheter and exits 25 cm proximal to the tip.
The surface of catheter is partially coated with hydrophilic polymer coating which generates lubricity when wet.

Ultimaster Tansei Sirolimus Eluting Coronary Stent System – available sizes

Product Code No.	Nominal Expanded Stent Inner Diameter (mm)	Actual un-expanded stent length (mm)	Nominal Sirolimus Dose (μg)
DE-RQ2209KSM	2.25	9.2	36
DE-RQ2212KSM	2.25	12.6	49
DE-RQ2215KSM	2.25	14.9	58
DE-RQ2218KSM	2.25	18.4	72
DE-RQ2221KSM	2.25	20.7	81
DE-RQ2224KSM	2.25	24.2	94
DE-RQ2228KSM	2.25	28.8	112
DE-RQ2233KSM	2.25	33.4	130
DE-RQ2238KSM	2.25	38.0	148
DE-RQ2509KSM	2.50	9.2	36
DE-RQ2512KSM	2.50	12.6	49
DE-RQ2515KSM	2.50	14.9	58
DE-RQ2518KSM	2.50	18.4	72
DE-RQ2521KSM	2.50	20.7	81
DE-RQ2524KSM	2.50	24.2	94
DE-RQ2528KSM	2.50	28.8	112
DE-RQ2533KSM	2.50	33.4	130
DE-RQ2538KSM	2.50	38.0	148
DE-RQ2709KSM	2.75	9.2	36
DE-RQ2712KSM	2.75	12.6	49
DE-RQ2715KSM	2.75	14.9	58
DE-RQ2718KSM	2.75	18.4	72
DE-RQ2721KSM	2.75	20.7	81
DE-RQ2724KSM	2.75	24.2	94
DE-RQ2728KSM	2.75	28.8	112
DE-RQ2733KSM	2.75	33.4	130

DE-RQ2738KSM	2.75	38.0	148
DE-RQ3009KSM	3.00	9.2	36
DE-RQ3012KSM	3.00	12.6	49
DE-RQ3015KSM	3.00	14.9	58
DE-RQ3018KSM	3.00	18.4	72
DE-RQ3021KSM	3.00	20.7	81
DE-RQ3024KSM	3.00	24.2	94
DE-RQ3028KSM	3.00	28.8	112
DE-RQ3033KSM	3.00	33.4	130
DE-RQ3038KSM	3.00	38.0	148
DE-RQ3509KSM	3.50	8.9	35
DE-RQ3512KSM	3.50	11.9	46
DE-RQ3515KSM	3.50	14.9	58
DE-RQ3518KSM	3.50	17.8	69
DE-RQ3521KSM	3.50	20.8	81
DE-RQ3524KSM	3.50	23.8	93
DE-RQ3528KSM	3.50	28.2	110
DE-RQ3533KSM	3.50	34.0	133
DE-RQ3538KSM	3.50	38.6	151
DE-RQ4009KSM	4.00	8.9	35
DE-RQ4012KSM	4.00	11.9	46
DE-RQ4015KSM	4.00	14.9	58
DE-RQ4018KSM	4.00	17.8	69
DE-RQ4021KSM	4.00	20.8	81
DE-RQ4024KSM	4.00	23.8	93
DE-RQ4028KSM	4.00	28.2	110
DE-RQ4033KSM	4.00	34.0	133
DE-RQ4038KSM	4.00	38.6	151

INDICATIONS

Ultimaster Tansei Sirolimus Eluting Coronary Stent System is indicated for improving myocardial blood flow in patients with stenotic lesions in coronary arteries, including but not limited to patients with STEMI, NSTEMI, acute coronary syndrome, diabetes mellitus, multivessel disease, bifurcation lesions, patients older than 65 years, male and female patients, patients with totally occluded lesions, long lesions, lesions residing in small coronary vessels, restenotic lesions including in-stent restenosis, ostial lesions, lesions in left main coronary artery

The Ultimaster Tansei stent system is suitable for both femoral and radial approach.

CONTRAINDICATIONS/RECOMMENDATIONS

Contraindications

- Patients in whom anti-platelet and/or anti-coagulant therapy is contraindicated.
- Patients with lesion(s) that prevents complete inflation of an angioplasty balloon.
- Patients with known allergy to L605 cobalt-chromium alloy.
- Patients with known allergy to nickel.
- Patients with known hypersensitivity to sirolimus or its structurally related compounds.
- Patients with known hypersensitivity to lactide polymers and caprolactone polymers.
- Patients with known hypersensitivity to contrast agent that cannot be controlled prophylactically prior to Ultimaster Tansei Sirolimus Eluting Coronary Stent implantation.
- Patients with extreme vessel tortuosity that may impair stent placement.

Recommendations

- It is strongly recommended not to implant stent in women who are pregnant.
- Effects of sirolimus during lactation have not been evaluated, therefore it is strongly recommended to avoid breast feeding when this stent is implanted.

WARNINGS/PRECAUTIONS

WARNINGS

• Judicious selection of patients is necessary since Percutaneous Coronary Intervention with the use of stents carries the risk of stent thrombosis, vascular complications and/or bleeding events. Hence patients should be maintained on clinically adequate post-procedural antiplatelet therapy (aspirin and thienopyridine, or appropriate antiplatelet agents).
• Only physicians who have received appropriate training should perform implantation of the stent.
• Any advancement after introduction of the delivery catheter into the vessel should be done under high resolution fluoroscopy. When resistance is felt during manipulation, determine the cause of the resistance before proceeding.
• Proper judgment is necessary to select lesion for direct stenting since insufficiently prepared lesion may lead to stent dislodgement.
• Ensure that the aluminium pack and blister pouch have not been damaged or opened as this may compromise the stability and the sterile barrier.
STORE THE DEVICE BETWEEN 1 – 30°C IN THE ALUMINIUM PACK.
The device is packed under oxygen free conditions.
Aluminium pack includes an oxygen absorber and a desiccant. Discard them without opening.
After opening the aluminium pack, use the device within 12 hours.
Do not store the device in the blister pouch.

PRECAUTIONS

Stent Handling – Precautions
• For single use only. Do not reuse. Do not resterilize. Do not reprocess. Reprocessing may compromise the sterility, biocompatibility and functional integrity of the device.
• Do not use a device that has reached or exceeded its expiry date.
• Ensure that the blister pouch has not been damaged or opened as this may compromise the sterile barrier.
• Use immediately after opening the blister pouch.
• The entire operation should be carried out aseptically.
• Do not use if the stent is exposed to abnormal rubbing or contact with objects other than the guiding catheter or opened hemostatic valve prior to implant.
• Do not rub or scrape the stent coating.
• Do not displace or remove stent on or from its delivery system as it may damage the stent and/or lead to stent embolization. Stent system is intended to perform as a system.
• Stent should not be used in conjunction with other delivery systems.
• Delivery system should not be used in conjunction with other stents.
• Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during catheter removal from packaging, catheter removal from holder, removal of protector sheath from stent, catheter placement over guide wire and advancement through rotating hemostatic valve adapter and guiding catheter hub.
• Do not "roll" the mounted stent with your fingers as this action may loosen the stent from the delivery balloon.
• Do not expose system to organic solvent. 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.
• Do not attempt to straighten the proximal shaft (hypotube) as it may cause the catheter to break if it is accidentally bent.
• Exposing the stent to fluids before implantation is not recommended. Exposure to fluids prior to implantation may result in premature release of drug.

Stent Placement – Precautions
• Do not introduce negative pressure, or pre-inflate delivery system prior to stent deployment other than as directed.
• Always select an appropriate size of the stent as an undersized stent may result in inadequate expansion of the lesion while an oversized stent may lead to inadequate expansion of the stent or damage to the vessel wall.
• Always verify whether the stent is well apposed against vessel wall because incomplete stent apposition may lead to stent thrombosis.
• When treating multiple lesions in the same vessel, stent the distal lesion prior to stenting the proximal lesion. Stenting in this order avoids crossing the proximal stent with the distal stent and reduces the chances for

dislodgement.
• Do not expand the stent if it is not properly positioned in the vessel. (See Stent System Removal – Precautions)
• Placement of a stent has the potential to compromise side branch patency.
• Do not exceed rated burst pressure as indicated on the device label. Use of pressure higher than specified may result in balloon rupture with possible intimal damage and dissection.
• An unexpanded stent may be retracted into the guiding catheter one time only. Subsequent movement in and out through the distal end of the guiding catheter should not be performed as the stent may be damaged or dislocated. In case of stent dislodgement, 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. Complication may include bleeding, hematoma or pseudoaneurysm.

Stent / System Removal-Precautions

Stent introduction into the coronary artery is limited to one time only as dislodgement may occur.
Should unusual resistance be felt at any time during either lesion access or removal of the stent delivery system pre-stent implantation, carefully attempt to pull the stent delivery system back through the guiding catheter. If resistance is felt in doing so, or if resistance is felt during the removal of the stent delivery system post-stent deployment, the delivery system and guiding catheter must be removed as a single unit.

When removing the delivery system and guiding catheter as a single unit:
• Do not attempt to retract an unexpanded stent into the guiding catheter while engaged in the coronary arteries. Stent damage or dislodgement may occur.
• Position the proximal balloon marker just distal to the tip of the guiding catheter.
• Advance the guide wire into the coronary anatomy as far distally as safely possible.
• Tighten the rotating hemostatic valve to secure the delivery system to the guiding catheter, then remove the guiding catheter 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 stent dislodgement or damage to the stent and/or delivery system components.
• 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.

Post Implant-Precautions
• Care must be exercised when crossing a newly deployed stent with a coronary guide wire, IVUS catheter, OCT catheter, balloon or other stent delivery system to avoid disruption of the stent geometry.

• Patients should be maintained on clinically adequate post-procedural antiplatelet therapy (aspirine, thienopyridine or other appropriate antiplatelet agents) according to the current guidelines. In case of need, dual antiplatelet therapy can be discontinued earlier, but not before one month.

•Magnetic Resonance Imaging (MRI)
Non-clinical testing has demonstrated the Ultimaster Sirolimus Eluting Coronary Stent, overlapped configuration (max. 2 stents ×max. OD4mm × 38mm = 73.6mm total 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 36 T/m and less
- spatial gradient field product of 99 T^2/m and less
- theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of
  < 2 W/kg at 1.5 Tesla, (related to 3.6°C temperature increase; allowable level in accordance with CEM43 concept), 73.6 x 4.0 mm, overlapped configuration
  < 2 W/kg at 3 Tesla, (related to 3.6°C temperature increase; allowable level in accordance with CEM43 concept), 73.6 x 4.0 mm, overlapped configuration
  for 15minutes of continuous MR scanning.
  Temperatures and SAR have been derived from computer modeling with human realistic anatomy (no cooling effects considered).

In non-clinical worst-case phantom testing the Ultimaster Sirolimus Eluting Coronary Stent, overlapped

configuration (max. 73.6 x 4.0 mm) produced a temperature rise of less than 5.2°C (with a background temperature increase of ≈1.1°C) at a maximum whole body averaged specific absorption rate (SAR) of ≈ 2.3 W/kg assessed by calorimetry for 15 min. of continuous MR scanning with whole body coil in a 1.5 Tesla Intera, Philips Medical Systems (Software: Release 12.6.1.4, 2012-11-05) MR Scanner.

In non-clinical worst-case phantom testing the Ultimaster Sirolimus Eluting Coronary Stent, overlapped configuration (max. 73.6 x 4.0 mm) produced a temperature rise of less than 10.1°C (with a background temperature increase of ≈2.4°C) at a maximum whole body averaged specific absorption rate (SAR) of ≈ 2.1 W/kg assessed by calorimetry for 15 min. of continuous MR scanning with whole body coil in a 3 Tesla Magnetom Trio, Siemens Medical Solutions (Software: Numaris/4, syngo MR A30) MR Scanner.

The Ultimaster Sirolimus Eluting Coronary Stents have not been tested in simultaneous combination with other devices.

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.

The results referenced above are obtained from Ultimaster Sirolimus Eluting Coronary Stent evaluation tests. The stent of Ultimaster Tansei
Sirolimus Eluting Coronary Stent System is identical to the Ultimaster Sirolimus Eluting Coronary Stent

INDIVIDUALIZATION OF TREATMENT

The risks and benefits of Sirolimus-eluting stent should be considered for each patient before (using) implanting Ultimaster Tansei Sirolimus Eluting Coronary Stent. Physicians are responsible for assessing patient appropriateness for undergoing stent implantation prior to procedure.

OPERATOR'S MANUAL

Inspection Prior to Use

• Carefully inspect the stent delivery system package for damage to the sterile barrier. Prior to using the Stent System, carefully remove the system from the package and inspect for bends, kinks, and other damage.

Materials Required / Quantity Material.

• Appropriate guiding catheter (minimum inner diameter of guiding catheter is 1.42mm (0.056").
• 2 – 3 syringes (10 – 20 ml)
• 1,000 u/500 ml Heparinized Normal Saline (HepNS)
• 0.36 mm (0.014") x 175 cm (minimum length) guide wire
• Rotating hemostatic valve with appropriate minimum inner diameter [2.44 mm (0.096")]
• Diluted contrast medium 1:1 with heparinized normal saline (HepNS)
• Inflation device
• Pre-deployment dilatation catheter
• Three-way stopcock
• Torque device
• Guide wire introducer
• Appropriate arterial sheath
• Appropriate anticoagulation and antiplatelet drugs.

Preparation
Guide wire Lumen Flush
Step Action

1. Carefully remove the stent system from its holder, then remove the stent protector sheath from over the stent.

CAUTION Carefully slide off the protector sheath from the stent by fixing the sheath at the distal end between the thumb and finger while gently pulling sheath and attached stylet.

2. Verify that the stent is centered on the balloon and located between the radiopaque balloon markers.

CAUTION Do not use if any defects are noted.

3. Flush the guide wire lumen with HepNS using the flushing needle supplied with Ultimaster Tansei stent system. Insert the flushing needle into the tip of the catheter and flush until solution exits the guide wire port.

CAUTION Avoid manipulating the stent while flushing the guide wire lumen as this may dislocate the stent on the balloon.

Delivery Procedure
Step Action
1. Prepare vascular access site according to standard practice.
2. Predilate lesion with PTCA catheter.
3. Remove the PTCA catheter
4. Open rotating hemostatic valve on the guiding catheter as widely as possible.
5. Backload Delivery System onto proximal portion of guide wire while maintaining guide wire position across target lesion.
   CAUTION Confirm that the guide wire OD does not exceed 0.36 mm (0.014”). If a large size guide wire has been used, exchange the wire in the standard manner.
6. Advance stent Delivery System over guide wire to target lesion. Utilize radiopaque balloon markers to position stent across lesion: perform angiography to confirm stent position.
   CAUTION Take care not to damage the delivery catheter and stent when advancing the delivery catheter over the guide wire.

Deployment Procedure
Step Action
1. Before deployment reconfirm the correct position of the stent relative to the target lesion via the catheter markers.
2. Attach the inflation device to the delivery catheter hub and apply negative pressure to purge the balloon of air.
3. Under fluoroscopic visualization, inflate the balloon to at least 912 kPa (9 atm) for 15-30 seconds to deploy the stent but do not exceed the labeled rated burst pressure (see label on packaging or below table).
4. Optimal expansion requires the stent to be in full contact with the artery wall, and with the stent internal diameter matching the size of the reference vessel diameter.
5. Stent wall contact should be verified through routine angiography or intravascular ultrasound.
6. 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.
7. Confirm adequate stent expansion by angiographic injection through the guiding catheter.

In vitro Information: Inflation Pressure Recommendation for Ultimaster Tansei Sirolimus Eluting Coronary Stent System

Ultimaster™ Tansei™

Sirolimus eluting coronary stent system

Pressure **P**	(kPa)	709	811	912	1013	1115	1216	1317	1419	1520	1621	1723	1824
	(atm)	7	8	9	10	11	12	13	14	15	16	17	18
Stent **I.D.**	2.25mm	2.17	2.21	2.25	2.29	2.32	2.34	2.37	2.40	2.43	**2.45**	2.48	2.51
	2.5mm	2.42	2.46	2.50	2.53	2.56	2.59	2.61	2.64	2.66	**2.68**	2.71	2.73
	2.75mm	2.66	2.71	2.75	2.79	2.82	2.84	2.87	2.89	2.92	**2.94**	2.97	3.00
	3.0mm	2.89	2.95	3.00	3.04	3.07	3.10	3.13	3.16	3.18	**3.20**	3.23	3.25
	3.5mm	3.39	3.45	3.50	3.55	3.58	3.62	3.64	**3.67**	3.70	3.73	3.75	3.78
	4.0mm	3.86	3.94	4.00	4.06	4.10	4.15	4.19	**4.23**	4.27	4.31	4.35	4.40

NP Nominal Pressure

RBP Rated Burst Pressure(Do not exceed)

Note: These nominal, in vitro device specifications do not take into account lesion resistance. The stent sizing should be confirmed angiographically. Do not exceed the RBP.

Removal Procedure
Step Action

1. Ensure balloon is fully deflated.
2. Fully open rotating hemostatic valve.
3. While maintaining guidewire position, withdraw 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 for specific stent delivery system removal instructions.
4. Tighten rotating hemostatic valve.
5. Repeat angiography to assess stented area. If an adequate expansion has not been obtained, exchange to a balloon catheter of appropriate balloon diameter to achieve proper stent apposition to the vessel wall. Do not dilate the stent beyond the limit tabulated below.

Nominal stent diameter (ID)	Post-Dilatation limits (ID)
Φ2.25mm, 2.5mm, 2.75mm, 3.0mm	4.5mm
Φ3.5mm, 4.0mm	5.5mm

6. Final stent diameter should match reference vessel diameter.

INSTRUCTION FOR SIMULTANEOUS USE OF TWO DEVICES IN GUIDING CATHETER (KISSING BALLOON TECHNIQUE)

6Fr Compatibility – Any combination of one Ultimaster Tansei Sirolimus Eluting Coronary Stent System (I.D. 2.25mm – 4.0mm) and one Hiryu™ (2.25mm-4.00mm) or one Accuforce™ (2.00mm-4.00mm) PTCA balloon catheter can be used simultaneously within a 6Fr (I.D:1.8mm) guiding catheter.

The technique can be performed as per the instructions listed below:

1. Insert Ultimaster Tansei Sirolimus Eluting Coronary Stent System using the instructions provided.
2. Insert one Hiryu or one Accuforce balloon catheter, track to the target site and inflate the balloon.
3. Removing the catheters: Remove one catheter and its associated guide wire completely prior to removing the other catheter and its associated guide wire.

CAUTION Care should be taken when introducing, torquing and removing one or both devices to avoid entanglement.

DRUG INTERACTION

Drugs that act through the same binding protein (FKBP) may interfere with the efficacy of sirolimus.

Sirolimus is metabolized by CYP3A4. Strong inhibitors of CYP3A4 (e.g. ketoconazole) 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.

Based on the results of the human pharmacokinetic study, the systemic effect of sirolimus after single stent implantation is considered negligible.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with coronary stent placement include but are not limited to:

- Abrupt vessel closure
- Acute myocardial infarction
- Allergic reaction to anti-coagulation and/or anti-thrombotic therapy, contrast material, or stent and/or delivery system materials or any other PCI mandatory medication
- Aneurysm
- Arrhythmias, including ventricular fibrillation and ventricular tachycardia
- Arteriovenous fistula
- Cardiac tamponade
- Cardiogenic shock
- Death

- Emboli, distal (air, tissue or thrombotic emboli)
- Emergent Coronary Artery Bypass Surgery
- Failure to deliver the stent to the intended site
- Fever
- Hematoma
- Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and pain at insertion site
- Ischemia, myocardial
- Myocardial infarction
- Nausea and vomiting
- Prolonged angina
- Pseudoaneurysm
- Renal failure
- Restenosis of stented segment
- Rupture of native and bypass graft
- Stent compression
- Stent embolization
- Stent migration
- Stent thrombosis/occlusion
- Stroke/cerebrovascular accident
- Thrombosis (acute, subacute, or late)
- Total occlusion of coronary artery
- Unstable or stable angina pectoris
- Vessel dissection
- Vessel perforation
- Vessel spasm

Potential adverse events that may be associated with sirolimus drug and polymer coating. Sirolimus administration is limited to intra-coronary stent delivery. Therefore adverse events are not fully characterized but are considered to be consistent to those noted in sirolimus oral administration including:

- Abnormal liver function tests
- Anemia
- Arthralgias
- Changes in lipid metabolism which may include hypertriglyceridemia or hypercholesterolemia
- Diarrhea
- Hypersensitivity to the drug (sirolimus or its excipients) or to the polymer (or individual components) including anaphylactic/anaphylactoid type of reactions
- Hypokalemia
- Immune suppression, especially in patients with hepatic insufficiency or who are taking medications that inhibit CYP3A4 or P-glycoprotein
- Infections
- Interstitial lung disease
- Leukopenia
- Lymphoma and other malignancies
- Myalgia
- Thrombocytopenia

Because of the low systemic exposure to sirolimus after stent implantation, it is very unlikely that any of the adverse events (apart from hypersensitivity reaction) associated with oral administration of sirolimus will occur.

HOW SUPPLIED

STERILE AND NON PYROGENIC in undamaged and unopened blister pouch. This device is sterilized by e-beam.

CONTENTS: One balloon expandable Sirolimus Eluting coronary stent mounted on a rapid exchange delivery system. One Flushing needle.

STORAGE: Store between 1 and 30°C.

DISPOSAL: After use dispose of delivery system in accordance with local regulations.

Storage – precautions

Warning/stent handling – precautions

Inner surface of the Aluminium pack and outer surface of the Blister pouch are NON STERILE.
The CONTENTS of the Blister pouch are STERILE.