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LIMITLESS POSSIBILITIES

Racer CC Plus

Sirolimus Eluting Coronary Stent System

Instructions for Use

Manufacturing Facility

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1.0 Product Description

The Racer CC Plus Sirolimus Eluting Coronary Stent system (Racer CC Plus Stent) is a device & drug combination product consisting of two components; a device (a Sirolimus Eluting Coronary Stent System) coated with formulation containing Sirolimus drug, the active ingredient in a biodegradable Resomer matrix.

1.1 Device Component Description

The device component consists of Cobalt chromium Stent mounted on to a stent delivery System. The range of stent diameters is made possible by varying the number of circumferential cells on the stent. The stent is crimped on various sizes of stent delivery catheter, which are sized 2.00mm to 4.00mm. The device component characteristics are as follows.

Table 1.1: Device Component Description

Available Stent Lengths, Unexpanded (mm)	8, 12, 16, 18, 21, 24, 28, 32, 36, 40, 44, 48
Available Stent Diameters (mm)	2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00
Stent Material	L 605 Cobalt Chromium Alloy Stent
Strut Thickness	68µm for (SV) & 79µm for (MV)
Strut Width	78µm for (SV) & 88µm for (MV)
Drug Component	Sirolimus Drug (Also known as Rapamycin)
Delivery System Workable Length	143cm (1430 mm)
Stent Delivery System (SDS)	The delivery system is a rapid exchange catheter with a balloon located at the distal tip. The Distal shaft comprise of two lumens, one is used for inflation of the balloon and the other permits the use of a guide wire to enable advancement of the catheter to and through the stenosis to be stented. The balloon provides an expandable segment of known diameter at specific pressure. The proximal shaft is made of a stainless steel hypotube. Proximal visual markers located approximately 90 cm to 100 cm from the distal tip aid catheter positioning without fluoroscopy assistance.
Stent Delivery Balloon	A Semi-compliant Polyamide Balloon, normally 1 mm longer than stent with two platinum iridium radiopaque markers located on the catheter shaft to indicate balloon positioning and expanded stent length.
Balloon Inflation Pressure	Nominal Inflation Pressure: $11/10^5$ Pa or 10.80 ATM or 11 Bar Rated Burst Pressure: $16/ 10^5$ Pa or 15.79 ATM or 16 Bar
Guide Wire Compatibility (max)	0.014”
Guiding Catheter Inner Diameter	5F (1.67mm) (inner lumen ⩾0.058”)
Catheter Shaft Outer Diameter	Proximal 1.9 F (0.825mm) Distal 2.7 F (0.594mm)

1.2 Drug Component DescriptionFigure 1:Structural Formula of Sirolimus

1.2.1 Sirolimus

Active pharmaceutical ingredient (API): Sirolimus Drug
Sirolimus is a macrocyclic lactone produced by Streptomyces hygroscopius.
Sirolimus appearance: White to off-white powder.
Sirolimus Solubility: Frankly soluble in chloroform, acetone and acetonitrile and insoluble in water.
Molecular formula: C51H79NO13
Molecular Weight: 914.2
CAS registration no.: 53123-88-9
Chemical 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-methodycyclohexyl] -1-methylethyl] -10,21-dimethoxy 6,8,12,14,20, 26-h e x a m e t h y l-23,27-e p o x y-3H-pyridol [2,1-c] [1,4] o x a a z a c y c l o h e n t r l a c o n t i n e-1, 5,11, 28, 29 (4H, 6H, 31H) -pentone.
As inactive ingredients, we are using bio-degradable Resomer Poly L-lactide & shellac resin. A Combination of bio-degradable Resomer and shellac resin mixed with Sirolimus makes up the coatingformulation which is applied to the stent system. The drug/Resomer coating is adhered to the abluminal surface of the stent. Nominal dosages of Sirolimus onRacer CC Plus stent and stent sizes are in following table.

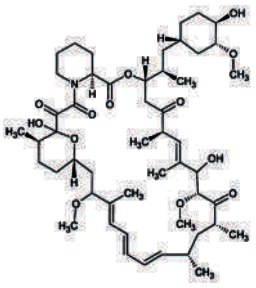

Figure 1: Structural Formula of Sirolimus

1.2.2 Racer CC Plus: Product Matrix and Nominal Sirolimus Content (Table)

Ref No.	Stent Length (mm)	Stent Diameter (mm)	Nominal Sirolimus content (µg)	Ref No.	Stent Length (mm)	Stent Diameter (mm)	Nominal Sirolimus content (µg)
RRPP-2008	8	2.00	100	RRPP-2224	24	2.25	300
RRPP-2208	8	2.25	100	RRPP-2524	24	2.50	300
RRPP-2508	8	2.50	100	RRPP-2724	24	2.75	300
RRPP-2708	8	2.75	100	RRPP-3024	24	3.00	300
RRPP-3008	8	3.00	100	RRPP-3524	24	3.50	300
RRPP-3508	8	3.50	100	RRPP-4024	24	4.00	300
RRPP-4008	8	4.00	100	RRPP-2028	28	2.00	350
RRPP-2012	12	2.00	150	RRPP-2228	28	2.25	350
RRPP-2212	12	2.25	150	RRPP-2528	28	2.50	350

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Ref No.	Stent Length (mm)	Stent Diameter (mm)	Nominal Sirolimus content (µg)	Ref No.	Stent Length (mm)	Stent Diameter (mm)	Nominal Sirolimus content (µg)
RRPP-2512	12	2.50	150	RRPP-2728	28	2.75	350
RRPP-2712	12	2.75	150	RRPP-3028	28	3.00	350
RRPP-3012	12	3.00	150	RRPP-3528	28	3.50	350
RRPP-3512	12	3.50	150	RRPP-4028	28	4.00	350
RRPP-4012	12	4.00	150	RRPP -2032	32	2.00	400
RRPP-2016	16	2.00	200	RRPP-2232	32	2.25	400
RRPP-2216	16	2.25	200	RRPP-2532	32	2.50	400
RRPP-2516	16	2.50	200	RRPP-2732	32	2.75	400
RRPP-2716	16	2.75	200	RRPP-3032	32	3.00	400
RRPP-3016	16	3.00	200	RRPP-3532	32	3.50	400
RRPP-3516	16	3.50	200	RRPP-4032	32	4.00	400
RRPP-4016	16	4.00	200	RRPP-2736	36	2.75	450
RRPP-2018	18	2.00	225	RRPP-3036	36	3.00	450
RRPP-2218	18	2.25	225	RRPP-3536	36	3.50	450
RRPP-2518	18	2.50	225	RRPP-4036	36	4.00	450
RRPP-2718	18	2.75	225	RRPP-2740	40	2.75	500
RRPP-3018	18	3.00	225	RRPP-3040	40	3.00	500
RRPP-3518	18	3.50	225	RRPP-3540	40	3.50	500
RRPP-4018	18	4.00	225	RRPP-4040	40	4.00	500
RRPP-2021	21	2.00	263	RRPP-2744	44	2.75	550
RRPP-2221	21	2.25	263	RRPP-3044	44	3.00	550
RRPP-2521	21	2.50	263	RRPP-3544	44	3.50	550
RRPP-2721	21	2.75	263	RRPP-4044	44	4.00	550
RRPP-3021	21	3.00	263	RRPP-2748	48	2.75	600
RRPP-3521	21	3.50	263	RRPP-3048	48	3.00	600
RRPP-4021	21	4.00	263	RRPP-3548	48	3.50	600
RRPP-2024	24	2.00	300	RRPP-4048	48	4.00	600

Note:Sirolimus Drug to Polymer in the ratio of 36.5:63.5 in all sizes

1.3 Mechanism of Action

The mechanism (or mechanisms) by which a RRPP Stent affects neointima production as seen in clinical studies has not been established. It is known that sirolimus inhibits T-lymphocyte activation and smooth muscle and endothelial cell proliferation inresponse to cytokine and growth factor stimulation. In cells, sirolimus binds to the immunophilin, FK Binding Protein-12 (FKBP-12).The sirolimus-FKBP-12 complex binds to and inhibits the activation of the mammalian Target of Rapamycin (mTOR), leading to inhibition of cell cycle progression from the G1 to the S phase.

2.0 INDICATIONS

The Racer CC Plus Stent is indicated for treatment of patients with stenosis in Coronary Arteries. It is indicated for improving the coronary lumina! diameter in patients with symptomatic ischemic disease due to lesions of length ⩽ 48 mm in native coronary arteries with a reference diameter from 2.0mm to 4.00mm.

3.0 CONTRAINDICATIONS

Use of Racer CC Plus Stent is contraindicated in the following types of patients:

- Patients with a hypersensitivity to Sirolimus drug or its structurally related compounds.
- Patients with a known hypersensitivity to polyolefin co-Resomer.

Coronary artery stenting is contraindicated for use in:

- Patients who cannot receive recommended antiplatelet and/or anticoagulation therapy.
- Patients who have lesion that prevents complete inflation of an angioplasty balloon or proper placement of stent or delivery catheter.
- Patients with heavily calcified lesion.
- Patient with Ejection Fraction < 30%.
- Patient with cardiogenic shock.

4.0 WARNINGS

- Please ensure that the inner package has not been opened or damaged as this may indicate the sterile barrier has been breached.
- The use of product carries the risks associated with coronary artery stenting, including sub thrombosis, vascular complications, and/or bleeding events.
- Patients with known hypersensitivity to L605 cobalt chromium alloy may suffer allergic reaction to this implant.
- Patients who are unlikely to comply with recommended antiplatelet therapy should not receive this product (see information regarding antiplatelet therapy).

5.0 PRECAUTIONS

5.1 General Precautions

- Stent implantation should only be performed by Cardiologists who have received appropriate training.
- Stent placement should be performed at hospitals where emergency coronary artery bypass graft surgery is possible.
- Subsequent restenosis may require repeat dilation of the arterial segment containing the stent. Long-term outcomes following repeat dilation of the stent is not well characterized.
- Risks and benefits should be considered in patients with severe contrast allergies.
- Do not expose the delivery system to organic solvents, such as alcohol or detergents.
- When drug eluting stents are used outside the specific indications for Use, patient outcome may differ from the result of considered clinical trial.
- Care should be taken to control the guiding catheter tip during stent delivery, deployment and balloon withdrawal. Before withdrawing the stent delivery system, visually confirm complete balloon deflation by fluoroscopy to avoid guiding catheter movement in the vessel and subsequent arterial damage.

- Stent thrombosis is a low-frequency event that current drug eluting stent (DES) clinical trials are not adequately powered to fully characterize. Stent thrombosis is frequently associated with myocardial infarction (MI) or death. Analysis of DES related thrombosis from various trials are expected and should be considered in making treatment decisions as data becomes available.
- Compared to use within the specified Indications for Use, the use of drug eluting stents in patients and lesions outside the labelled indications may have an increased risk of adverse events, including stent thrombosis, stent embolization, myocardial infarction or death.

5.2 Pre and Post Procedure Antiplatelet Regimen

- The optimal duration of dual antiplatelet therapy, specifically clopidogrel or ticlopidine is unknown and DES thrombosis may still occur despite continued therapy. The use ofAspirin together with clopidogrel or ticlopidine is referred to as "dual anti platelet therapy".
- Data from several studies suggest that a longer duration of Clopidogrel than was recommended post procedurally in drug-eluting stent pivotal trials may be beneficial. Based upon consensus opinion, practice guidelines recommend that patients receive aspirin indefinitely plus a minimum of 3 months of Clopidogrel, with Clopidogrel therapy extended to 12 months in patients at low risk of bleeding.
- It is very important that patients are compliant with the post-procedural antiplatelet recommendations. Early discontinuation of prescribed antiplatelet medication could result in a higher risk of thrombosis, myocardial infarction or death. Prior to Percutaneous Coronary Intervention (PCI), if a surgical or dental procedure is anticipated that requires early discontinuation of antiplatelet therapy, the interventional cardiologist and patient should carefully consider whether a drug-eluting stent and its associated recommended antiplatelet therapy is the appropriate PCI treatment choice. Following PCI, should a surgical or dental procedure should be weighed against the possible risk associated with early discontinuation of antiplatelet therapy.
- Patients who require early discontinuation of anti-platelet therapy should be monitored carefully for cardiac events. At the discretion of the patient's treating Cardiologist, the antiplatelet therapy should be restarted as soon as possible.

5.3 Use of Multiple Stents

The patient's risk factors are directly related to his exposure to drug and Resomer and are directly related to the number of stents implanted. Use of more than two stents has not received adequate clinical evaluation. With use of more than two stents, the patient will receive larger amounts of drug and Resomer than the experience and is reflected in the product testing.

To avoid the possibility of dissimilar metal corrosion, do not implant stents of different materials in tandem where overlap or contact is possible. The possible interactions of Racer CC Plus Stent with other drug-eluting or coated stents have not been evaluated and should be avoided whenever possible.

5.4 Brachytherapy

The safety and effectiveness of Racer CC Plus Stent in patients with prior brachytherapy of the target lesion have not been established. The safety and effectiveness of use of brachytherapy to treat in-stent restenosis in Racer CC Plus Stent have not been established. Both vascular brachytherapy and the Racer CC Plus Stent alter arterial biology, and the combined vascular responses of these two treatments have not been determined.

5.5 Uses In Conjunction With Other Procedures

The safety and effectiveness of using mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters) or laser angioplasty catheters in conjunction with Racer CC Plus Stent have not been established.

5.6 Uses In Special Population

5.6.1 Pregnancy

Pregnancy Category C: There are no adequate and well controlled studies in pregnant women or men intending to father children. Effective contraception should be initiated before implanting a Racer CC Plus Stent and for 12 weeks after implantation. The Racer CC Plus Stent should be used during pregnancy only if the potential benefit outweighs the potential risk to the embryo or foetus.

5.6.2 Use During Lactation

A decision should be made whether to discontinue nursing or to implant the stent, taking into account the importance of the stent to the mother.

Sirolimus is excreted in trace amounts in milk of lactating rats. It is not known whether Sirolimus is excreted in human milk, the pharmacokinetic and safety profiles of Sirolimus in infants are not known, because many drugs are excreted in human milk and because of the potential for adverse reactions in nursing infants from Sirolimus.

5.6.3 Gender

Clinical studies of Sirolimus based stents did not find any significant differences in safety and effectiveness for male and female patients.

5.6.4 Ethnicity

Clinical studies have not been completed to study any differences in safety and effectiveness due to ethnicity, either by individual category or when grouped.

5.6.5 Paediatric Use

The safety and effectiveness of Racer CC Plus Stent below the age of 18 years have not been established.

5.6.6 Geriatric Use

Clinical studies of the Racer CC Plus Sirolimus Eluting Coronary Stent System did not find that patients aged 65 Years and over differed with regard to safety and efficacy compared to younger patients.

5.6.7 Non-Coronary Use

The safety and effectiveness of this product has not been established in the cerebral, carotid or peripheral vasculature.

5.7 Lesion /Vessel Characteristics

The safety and effectiveness of the Racer CC Plus Stent have not been established in these noted patient groups:

- Patients with vessel thrombus at lesion site.
- Patients with coronary artery reference vessel diameter < 2.0 mm or > 4.00 mm.
- Patients with lesions located in saphenous vein grafts, in the unprotected left main coronary artery system, ostial lesions or lesions located at Bifurcations.
- Patients with diffuse disease or poor flow distal to the identified lesions.
- Patients with multi vessel disease.
- Patients with tortuous vessels in the region of the obstruction or proximal to the lesion.
- Patients with a recent acute myocardial infarct.
- Patients with lesions longer than 48 mm and requiring more than one Racer CC Plus Stent.
- Patients with chronic total occlusions.
- Patients with in-stent restenotic lesions.

The safety and effectiveness of Racer CC Plus Stent have not been established in the cerebral, carotid, or peripheral vasculature.

5.8 Drug Interactions

Several drugs are known to affect the metabolism of Sirolimus, and other drug interactions may be inferred from known metabolic effects. Sirolimus is known to be a substrate for both cytochrome P450 IIIA4 (CYP3A4) and P-glycoprotein. For more information refer to Rapamune®EU SPC date 1.09.2016.

5.9 Magnetic Resonance (MR) Imaging

Non clinical testing has demonstrated that the metallic platform of Racer CC Plus Stent is MR-conditional. They can be scanned safely, post implantation under following conditions:

- Magnetic field of 3 Tesla
- Gradient Field of 500 Gauss/cm

5.10 Stent Handling Precautions

- For single use only. Do not re-sterilize or reuse the product. Note the "Expiry Date" on the product label.
- Do not remove the stent from the delivery balloon — removal may damage the stent and coating and/or lead to stent embolization. The stent system is intended to perform as a system.
- Do not induce 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.
- Do not "roll" the mounted stent with your fingers as this action may loosen the stent from the delivery balloon and may damage the coating.
- 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 Racer CC Plus Stent is not deployed, follow product return procedures and avoid handling of the stent with hands.
- Avoid exposure of device to fluids before implantation, this can affect the Drug coating on the Device.

5.11 Stent Placement Precautions

- Do not prepare or pre-inflate balloon prior to stent deployment other than as directed.
- Use balloon purging technique described in section Operator's Manual.
- The vessel should be pre-dilated with an appropriately sized balloon.
- 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. (See section: Precautions Stent/System Removal Precautions.)
- Placement of a stent has the potential to compromise side branch patency. The vessel should be pre-dilated with an appropriately sized balloon.
- Balloon pressures should be monitored during inflation. Do not exceed rated burst pressure as indicated on the product label. (See section: Inflation Pressure Recommendations) 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. (See section: 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 Pseudo aneurysm.
- Ensure full coverage of the entire lesion/dissection site so that there are no gaps between stents.

5.12 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. When removing the Delivery System 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.
- DO NOT retract the Delivery System into the guiding catheter.
- Position the proximal balloon markerjust 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 haemostatic 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.

5.13 Post Procedure 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 endothelialzed to minimize the potential for migration. The stent may cause artefacts in MRI scans due to distortion of the magnetic field.
- Prescribe an antiplatelet therapy fora period of 6 months to reduce the risk of stent thrombosis.
- Patients who require early discontinuation of antiplatelet therapy should be monitored carefully for cardiac events. At the discretion of patient's treating Cardiologist, the anti-platelet therapy should be restarted as soon as possible.

6.0 Potential Adverse Events

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

- Abrupt stent closure
- Acute myocardial infarction
- Allergic reaction to anti-coagulant and/or antithrombotic therapy or contrast medium
- Angina
- Aneurysm
- Arrhythmias, including ventricular fibrillation (VF) andventricular 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
- Drug reactions to antiplatelet agents / anticoagulation agents/ contrastmedium
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergency or non-emergent Coronary Artery Bypass Graft Surgery
- Entry site complications
- Heart Failure
- Hematoma
- Haemorrhage, 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
- Pseudoaneurysm, femoral
- Renal Failure
- Respiratory Failure
- Restenosis of the stented segment
- Rhythmical disturbances
- Shock/Pulmonary edema
- Spasm
- Stroke/cerebrovascular accident/TIA
- Total occlusion of the coronary artery
- Unstable angina pectoris
- Vascular complications, which may require vessel repair
- Ventricular fibrillation

Potential adverse events not captured above, that may be unique to the Sirolimus drug coating:

- Allergic/immunologic reaction to drug or stent coating
- Allopecia
- Anemia
- Blood product transfusion
- Gastrointestinal symptoms
- Hepatic enzyme changes
- Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia)
- Histologic changes in vessel wall, including inflammation, cellular damage or necrosis
- Myalgia/Arthralgia
- Peripheral neuropathy

7.0 Patient Counselling Information

Cardiologists should consider the following in counselling patient about this product:

- Discuss the risks associated with stent placement
- Discuss the risks associated with a Sirolimus Eluting implant
- Discuss the risks/benefits issues for this particular patient
- Discuss alteration to current lifestyle immediately following the procedure and over the long terms.
- Discuss risks of early discontinuation of the antiplatelet therapy

The following stent implantation, the patients are expected to keep the Patient Implant Card that includes product details at all times for procedure/stent identification.

8.0 Packaging

Sterile: This device is sterilized with ETO gas and is non-pyrogenic. Do not use if the package is opened or damaged. Do not re-sterilize. Do not reuse.

Contents: One Racer CC Plus Sirolimus Eluting stent mounted on Rapid exchange delivery system

Storage: Temperature limitation: 8 to 25°C, store at dry place. Keep away from direct sunlight.

9.0 Operator's Manual

9.1 Access To Package Holding Sterile Stent Delivery System

Tear open outer foil pouch to reveal second inner pouch of Tyvek. Note: Do not drop or hand inner pouch into sterile field. Remove inner pouch from outer foil pouch. Peel open inner pouch using aseptic technique to reveal sterile package. Pass or drop the product into the sterile filed using an aseptic technique.

9.2 Inspection Prior To Use

Prior to using the Racer CC Plus Stent, carefully inspect the stent delivery system package. Remove the system from the package and inspect for bends, kinks, and other damage. Verify that the stent is located between the radiopaque balloon markers. Do not use if there is any damage to the packaging noted.

9.3 Materials Required

Quantity	Material
N/A	Appropriate guiding catheter(s)
2-3	10-20 cc syringes
1000µ /500cc	Sterile Heparinised Normal Saline
1	0.014 inch x 175 cm (minimum length) guide wire
1	Rotating haemostatic valve with 0.096inch minimum inner diameter
N/A	Contrast diluted 1:1 with normal saline
1	Inflation device
1	Torque device
1	Guide wire Introducer
1	3-way Stopcock

9.4 Preparation

- AVOID manipulation of stent during flushing of the guidewire lumen, as this may disrupt the placement of the stent on the balloon.
- DO NOT apply negative or positive pressure to the balloon during the delivery system preparation.
- Rinse the catheter with sterile heparinized normal saline solution.
- Flush the guide wire lumen with HepNS.

9.5 Delivery System Preparation

STEP	ACTION
1.	Prepare the inflation device or syringe with diluted contrast medium.
2.	Attach the inflation device or syringe to the stopcock; attach to balloon inflation port hub.
3.	Open the stopcock to stent delivery system.
4.	Leave the inflation device or syringe on neutral.

9.6 Delivery Procedure

STEP	ACTION
1.	Prepare the vascular access site according to standard practice.
2.	Pre-dilate the lesion with a PTCA catheter. Limit the longitudinal length of pre-dilatation by the PTCA balloon to avoid creating a region of vessel injury that is outside the boundaries of the Racer CC Plus Stent.
3.	Maintain neutral pressure on the inflation device. Open the rotating haemostatic valve as widely as possible.
4.	Backload the delivery system onto the proximal portion of the guidewire while maintaining the guidewire position across the target lesion.
5.	Advance the stent delivery system over the guidewire 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: Should unusual resistance be felt at any time during lesion access or removal of the stent delivery system before stent implantation, the entire system should be removed as a single unit.

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9.7 Deployment Procedure

STEP	ACTION
1.	Before deployment, reconfirm the correct position of the stent relative to the target lesion via the radiopaque balloon markers
2.	Attach the inflation device (only partially filled with contrast media) to a three-way stopcock and apply negative pressure to purge the balloon of air.
3.	Tum the stopcock on the catheter to the off position and purge the inflation device of air. Close the side port of the Stopcock.
4.	Under fluoroscopic visualization, inflate the balloon to at least the nominal pressure to deploy the stent, but do not exceed the labelled rated burst pressure of 16 bar. Maintain inflation pressure for 15-30 seconds for full expansion of the stent. Optimal expansion requires the stent to be in full contact with the artery wall, with the stent internal diameter matching the size of the reference vessel diameter. Stent wall contact should be verified through routing angiography or intravascular ultrasound.
5.	Fully cover the entire lesion and balloon treated area (including dissections) with the Racer CC Plus Stent, allowing for adequate stent coverage into healthy tissue proximal and distal to the lesion.
6.	If more than one Racer CC Plus Stent is needed to cover the lesion and balloon treated area, adequately overlap the stents, taking into account stent foreshortening. Ensure no gaps between stents by positioning the balloon marker bands of the second Racer CC Plus Stent inside the deployed stent prior to expansion.
7.	Deflate the balloon by pulling a vacuum with the inflation device. Make certain that the balloon is fully deflated before attempting to move the catheter.
8.	Confirm that the sterile is adequately expanded by angiographic injection through the guiding catheter.

9.8 Further Dilatation of Stented Segments

PRECAUTIONS: Do not dilate the stent beyond the following limits.

Nominal Stent Diameters	Dilatation Limits
2.0 mm – 2.50 mm	3.00 mm
2.75 mm – 3.50 mm	4.00 mm
4.00 mm	4.50 mm

All efforts should be taken to assure that the stent is not under dilated. If the deployed stent size is still inadequate with respect to vessel diameter or if full contact with the vessel wall is not achieved, a larger balloon may be used to expand the stent further. The stent may be further expanded using a low profile, and non-compliant balloon catheter. If this is required, the stented segment should be recrossed carefully with a prolapsed guidewire to avoid dislodging the stent. The balloon should be centered within the stent and should not extend outside of the stented region.

9.9 Removal Procedure

STEP	ACTION
1.	Ensure that the balloon is fully deflated.
2.	While maintaining the guidewire position and negative pressure on the inflation device, withdraw the stent delivery system.
3.	Note: Should unusual resistance be felt at any time during either lesion access or removal of stent delivery system before stent implantation, the entire system should be removed as a single unit.
4.	Repeat angiography to assess the stented area. If adequate expansion has not been obtained, exchange back to original stent delivery catheter or exchange to another balloon of appropriate balloon diameter to achieve proper stent apposition to the vessel wall.
5.	The final stent diameter should match the reference vessel. ASSURE THAT THE STENT IS NOT UNDERDILATED.

9.10 Disposal Procedure

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

10.0 Compliance Chart/ Inflation Pressure

Balloon Ø [mm]	Inflation Pressure (ATM/bar/10^5Pa)														
						NP					RBP				
	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Ø 2.00	1.83	1.87	1.90	1.93	1.96	2.00	2.03	2.06	2.10	2.13	2.16	2.20	2.23	2.26	2.29
Ø 2.25	2.08	2.11	2.14	2.18	2.21	2.25	2.28	2.31	2.35	2.38	2.42	2.45	2.48	2.52	2.55
Ø 2.50	2.33	2.36	2.40	2.43	2.47	2.50	2.53	2.57	2.60	2.64	2.67	2.70	2.74	2.77	2.81
Ø 2.75	2.58	2.61	2.65	2.68	2.71	2.75	2.78	2.81	2.85	2.88	2.91	2.94	2.98	3.01	3.04
Ø 3.00	2.81	2.85	2.89	2.92	2.96	3.00	3.04	3.07	3.11	3.15	3.18	3.22	3.26	3.29	3.33
Ø 3.50	3.29	3.34	3.38	3.42	3.46	3.50	3.55	3.59	3.63	3.67	3.71	3.76	3.80	3.84	3.88
Ø 4.00	3.75	3.80	3.85	3.90	3.95	4.00	4.06	4.11	4.16	4.21	4.26	4.31	4.36	4.41	4.46
						"Nominal Pressure"					"Rated Burst Pressure"				

11.0 Sterilization And Storage Conditions

- Single use device only, do not re-sterilize
- Storage Temperature- 8°C-25°C

12.0 Conversion Chart

1 cc	1 ml		
1 French	0.0131 inch	0.33 mm	
1 bar	0.99 atm	14.5 PSI	10^5 Pa

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LIMITLESS POSSIBILITIES

13.0 Symbols Meaning

Symbol	Description
Stent	Stent Length
⌀	Stent Diameter
LOT	Batch No.
SN	Serial No.
YYYY MM	Manufacturing Date
YYYY MM	Use by Date (Expiry Date)
STERILE EO	Sterile and method of sterilization using Ethylene Oxide
2 / 2 STERILIZE	Single use only & Do not Re-sterile
REF	Reference No.
	Storage Temperature
MD	Medical Device
	Contains a medicinal substance

Symbol	Description
RBP	Rated Burst Pressure
	Manufacturer
	Consult Instruction for Use.
	Do not Use if package open or damaged
	Keep Away from Sun Light
	Keep dry.
NP	Nominal Pressure
	Attention : See instruction for use
	Pyrogen Free
#	Content of the package
	Single sterile barrier system with protective packaging outside

14.0 Disclaimer Of Warranty And Limitation Of Remedy

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