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LIMITLESS POSSIBILITIES

Yukon Choice PC

Sirolimus Eluting Coronary Stent System

Instructions for use

Manufacturing Facility

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1.0 Product Description: The **Yukon Choice PC** Sirolimus Eluting Coronary Stent System is a combination product comprised of two regulated components; a device (Stainless Steel Coronary Stent System) and a drug product (a formulation of Sirolimus in Resomer-R202S and shellac resin).

1.1 Device Component Description

The device component consists of Stainless Steel stent mounted on to a delivery system. The range of stent diameters made possible by varying the number of circumferential cells on the stent. The stent is crimped on various sizes of stent delivery system, which are sized 2.00 mm to 4.00 mm. Physical characteristics are as follows:

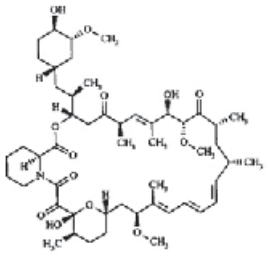
Brand Name	**Yukon Choice PC Sirolimus Eluting Coronary Stent System**
Available Stent Lengths (mm), unexpanded	8, 12, 16, 18, 21, 24, 28, 32, 36 & 40
Available Stent Diameters (mm)	2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00
Stent Material:	Stainless Steel 316 LVM Alloy
Strut Thickness (µm)	Small Vessel – 87 µm, Medium Vessel – 96 µm
Strut Width (µm)	Small Vessel – 95 µm, Medium Vessel – 120 µm
Drug Component	Sirolimus Drug (Also known as Rapamycin)
Delivery System Workable Length	143 cm (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 about 1 mm longer than stent with two platinum iridium radiopaque markers located in the catheter shaft to indicate balloon positioning and expanded stent length.
Balloon Inflation Pressure	Nominal Inflation Pressure: $9.1x10^5$ Pa or 9 ATM or 9.1 Bar
	Rated Burst Pressure: $16.2x10^5$ Pa or 16 ATM or 16.2 Bar
Guiding Catheter Inner Diameter	Minimum 5 French (Inner Lumen ≥ 0.058"/1.42mm)
Guide Wire compatibility (max)	0.014"
Catheter Shaft Outer Diameter	Proximal: 1.9 Fr Distal: 2.7 Fr

1.2 Drug Component Description

A brief description of the drug and the therapeutic class to which it belongs.

1.2.1 Sirolimus

Pharmacologic class: Macrocyclic lactone
Therapeutic class: Immunosuppressant
Pregnancy risk: Category C
Chemical name: (3S,6R,7E,9R,10R,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-methyl]-10,21-dimethoxy-6,8,12,14,20,26-hexamethyl-23,27-epoxy-3H-pyido[2,1-c][1,4] oxaazacyclohentriacontine-1,5,11,28,29(4H,6H,31H)-pentone)
International Non-proprietary name: Rapamycin (Sirolimus)
Nationally Approved Name : Sirolimus
Molecular Formula : C51H79NO13
Molecular Weight : 914.19 gm/mol
Sirolimus is off-white crystalline powder, highly lipophilic, insoluble in water, sparingly soluble in Methanol, highly soluble in dichloromethane.



1.2.2 Yukon Choice PC: Product matrix and Nominal Sirolimus content (Table)

Ref No.	Nominal unexpanded Stent Length(mm)	Nominal un-expanded Balloon OD(mm)	Nominal Sirolimus content(µg)	Ref No.	Nominal unexpanded Stent Length(mm)	Nominal un-expanded Balloon OD(mm)	Nominal Sirolimus content(µg)
YCPC-2008	8	2.00	100	YCPC-3021	21	3.00	263
YCPC-2208	8	2.25	100	YCPC-3521	21	3.50	263
YCPC-2508	8	2.50	100	YCPC-4021	21	4.00	263
YCPC-2708	8	2.75	100	YCPC-2024	24	2.00	300
YCPC-3008	8	3.00	100	YCPC-2224	24	2.25	300
YCPC-3508	8	3.50	100	YCPC-2524	24	2.50	300
YCPC-4008	8	4.00	100	YCPC-2724	24	2.75	300
YCPC-2012	12	2.00	150	YCPC-3024	24	3.00	300
YCPC-2212	12	2.25	150	YCPC-3524	24	3.50	300
YCPC-2512	12	2.50	150	YCPC-4024	24	4.00	300
YCPC-2712	12	2.75	150	YCPC-2028	28	2.00	350
YCPC-3012	12	3.00	150	YCPC-2228	28	2.25	350
YCPC-3512	12	3.50	150	YCPC-2528	28	2.50	350
YCPC-4012	12	4.00	150	YCPC-2728	28	2.75	350
YCPC-2016	16	2.00	200	YCPC-3028	28	3.00	350
YCPC-2216	16	2.25	200	YCPC-3528	28	3.50	350

Ref No.	Nominal unexpanded Stent Length(mm)	Nominal un-expanded Balloon OD(mm)	Nominal Sirolimus content(µg)	Ref No.	Nominal unexpanded Stent Length(mm)	Nominal un-expanded Balloon OD(mm)	Nominal Sirolimus content(µg)
YCPC-2516	16	2.50	200	YCPC-4028	28	4.00	350
YCPC-2716	16	2.75	200	YCPC–2032	32	2.00	400
YCPC-3016	16	3.00	200	YCPC–2232	32	2.25	400
YCPC-3516	16	3.50	200	YCPC-2532	32	2.50	400
YCPC-4016	16	4.00	200	YCPC-2732	32	2.75	400
YCPC-2018	18	2.00	225	YCPC-3032	32	3.00	400
YCPC-2218	18	2.25	225	YCPC-3532	32	3.50	400
YCPC-2518	18	2.50	225	YCPC-4032	32	4.00	400
YCPC-2718	18	2.75	225	YCPC-2736	36	2.75	450
YCPC-3018	18	3.00	225	YCPC-3036	36	3.00	450
YCPC-3518	18	3.50	225	YCPC-3536	36	3.50	450
YCPC-4018	18	4.00	225	YCPC-4036	36	4.00	450
YCPC-2021	21	2.00	263	YCPC-2740	40	2.75	500
YCPC-2221	21	2.25	263	YCPC-3040	40	3.00	500
YCPC-2521	21	2.50	263	YCPC-3540	40	3.50	500
YCPC-2721	21	2.75	263	YCPC-4040	40	4.00	500

1.3 Mechanism of action

It is known that Sirolimus inhibits T-lymphocyte activation and smooth muscle and endothelial cell proliferation in response 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 Intended Use

Yukon Choice PC Sirolimus Eluting Coronary Stent System is used for treatment of:

- Symptomatic coronary artery disease due to discrete de novo or restenosis lesion in native coronary artery.
- Symptomatic coronary artery disease due to culprit lesion in saphenous vein graft
- Treatment of coronary lesion in patients undergoing primary or rescue PCI for acute ST segment elevation myocardial infarction (STEMI)
- Treatment of coronary lesion having athero thrombotic appearance in patients with non ST-elevation acute coronary syndromes (unstable angina and non ST-segment elevation myocardial infarction).

3.0 Indications

Yukon Choice PC Sirolimus Eluting Coronary Stent System is indicated for improving luminal diameter and reducing restenosis for treatment of coronary artery lesions in native coronary arteries ranging from 2.00 mm to 4.00 mm. Safety and efficacy of **Yukon Choice PC** in humans has been established in randomised clinical trials with 5 years follow-up.

4.0 Contra-indications

Use of **Yukon Choice PC** Sirolimus Eluting Coronary Stent System is contraindicated in the following patient types:

- Patients with a known hypersensitivity to Sirolimus or its structurally related compounds.
- Patients with a known hypersensitivity to polyolefin co-resomer.
- Patients with a known allergy to stainless steel.

Coronary artery stenting is contraindicated for use in:

- Patients who cannot receive anti-platelet and/or anti-coagulation therapy.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of stent or delivery catheter.
- Patients with a target lesion distal to previously placed stent.
- Patients with a heavily calcified lesion.
- Patients with ejection fraction <30%.
- Patients with cardiogenic shock.

5.0 Warning

- Please ensure that the inner package has not been opened or damaged as this may indicate the sterile barrier has been breached.
- 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.
- Persons allergic to SS 316 LVM or Sirolimus may suffer an allergic reaction to this implant.
- Do not use Drug eluting Balloon before Drug Eluting Stent implantation.
- Polymers might enhance inflammatory reactions and prothrombic response.

6.0 Precautions

6.1 General Precautions

- The **Yukon Choice PC** Sirolimus Eluting Coronary Stent System should not be exposed to any direct handling or contact with liquids prior to preparation and delivery as the coating may be susceptible to damage or premature drug elution.
- 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 characterised.
- 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.

6.2 Use of Multiple Stents

The extent of the patient's exposure to drug and polymer is directly related to the number of stents implanted. Use of more than two **Yukon Choice PC** Sirolimus Eluting Coronary Stent System has not been fully evaluated. Use of more than two **Yukon Choice PC** Sirolimus Eluting Coronary Stent System will result in the patient receiving larger amounts of drug. When multiple stents are required, resulting in stent-to-stent contact, stent materials should be of similar composition to avoid the possibility of dissimilar metal corrosion.

6.3 Brachytherapy

The safety and effectiveness of the **Yukon Choice PC** Sirolimus Eluting Coronary Stent System 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 **Yukon Choice PC** Sirolimus Eluting Coronary Stent System **have not been established.**

6.4 Use 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 **Yukon Choice PC** Sirolimus Eluting Coronary Stent System implantation have not been established.

6.5 Use in Special Populations

6.5.1 Pregnancy: There are no adequate and well-controlled studies in pregnant women or men intending to father children. Systemic levels of Sirolimus have not been demonstrated in any pre-clinical or clinical trials with the **Yukon Choice PC** Sirolimus Eluting Coronary Stent System . Effective contraception should be initiated before implanting an **Yukon Choice PC** Sirolimus Eluting Coronary Stent System and for 12 weeks after implantation. The**Yukon Choice PC** Sirolimus Eluting Coronary Stent System should be used during pregnancy only if the potential benefit outweighs the potential risk to the embryo or foetus.

6.5.2 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, 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.

6.5.3 Paediatric Use:

The safety and efficacy of the **Yukon Choice PC** Sirolimus Eluting Coronary Stent System in paediatric patients have not been established.

6.5.4 Geriatric Use: Clinical studies of the **Yukon Choice PC** Sirolimus Eluting Coronary Stent System did not find that patients age 65 Years and over differed with regard to safety and efficacy compared to younger patients.

6.5.5 Gender

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

6.5.6 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.

6.5.7 Non Coronary Use

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

6.6 Lesion/Vessel Characteristics

The safety and effectiveness of the **Yukon Choice PC** 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 < 2.0 mm or >4.0 mm.
- Patients with lesions located in the in saphenous vein grafts, in the unprotected left main coronary artery system, 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.
- Patients with multi vessel disease.
- Patients with lesions longer than 40 mm and requiring more than on **Yukon Choice PC** Sirolimus Eluting Coronary Stent System .
- Patients with chronic total occlusions.
- Patients with in-stent restenotic lesions.

6.7 Drug Interactions

Consideration should be given to the potential for drug interaction when deciding to place the **Yukon Choice PC** Sirolimus Eluting Coronary Stent System in a patient who is taking a drug that could interact with Sirolimus, or when deciding to initiate therapy with such a drug in a patient who had recently received the **Yukon Choice PC** Sirolimus Eluting Coronary Stent System. The drug interactions are unlikely to be detectable. 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.

6.8 Magnetic Resonance Imaging (MRI) – Stent Migration

An MRI scan should not be performed on a patient after stent implantation until there is adequate neointimal investment of the stent because of a potential for stent migration. For a conventional drug coated SS 316 LVM Stent this period is usually considered to be eight weeks. Because of the reduced neointimal formation associated with the **Yukon Choice PC** Stent, the period of vulnerability may be longer, but there is currently insufficient information to provide a specific recommendation.

6.9 Stent Handling Precautions

- For single use only. Do not resterilize or reuse this device. Note the “Use Before” date on the product label.
- Avoid exposure of device to fluids before implantation, this can affect the Drug coating on the Device.
- 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 vaccum 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 **Yukon Choice PC** Sirolimus Eluting Coronary Stent System is not deployed, follow product return procedures and avoid handling of the stent with hands.

6.10 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 10- Operator's Manual.
- Use balloon purging technique described in section Operator's Manual.
- The vessel should be pre-dilated with an appropriate 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 6.11 Stent/System Removal Precautions.)
- 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 in (*Precautions – 6.11 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.
- Ensure full coverage of the entire lesion/dissection site so that there are no gaps between stents.

6.11 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 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.

6.12 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 endothelialised to minimize the potential for migration. The stent may cause artifacts in MRI scans due to distortion of the magnetic field.
- Administration of appropriate anticoagulant, antiplatelet and coronary vasodilator therapy is critical for a successful long term result. Clopidogrel or Ticlopidine is required for a minimum of 6 months and strongly recommended for 12 months in patients who are not at high risk of bleeding per the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. Acetylsalicylic acid is to be administered indefinitely to reduce the risk of thrombosis. It is recommended to follow the latest clinical guidelines from European Society of Cardiologists (ESC guidelines) for antithrombotics.

7.0 Adverse Events

7.1 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 reaction to anti-coagulant and/or antithrombotic therapy or contrast medium
- Angina
- Aneurysm
- Arrhythmias, 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
- Drug reactions to antiplatelet agents / anticoagulation agents / contrast medium
- 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
- 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

8. Patient Counselling Information

Cardiologist 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 term.
- Discuss risks of early discontinuation of the antiplatelet therapy.

9. Packaging (Contents: One (1) The **Yukon Choice PC** Sirolimus Eluting Coronary Stent System **:**

Sterile: This device is sterilized with ETO, Non-pyrogenic.

- Do not use if the package is opened or damaged.
- **Storage:** Store in cool and dry place at temperature from 8°C to 25°C.

10. Operator's Manual

10.1 Access to Package Holding Sterile Stent Delivery System

- Tear open outer foil pouch to reveal second inner pouch.
- 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.

10.2 Inspection Prior to Use

Prior to using the **Yukon Choice PC** Sirolimus Eluting Coronary Stent System, carefully 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.

10.3 Materials Required for use with the system

- Appropriate Guiding Catheter(s) (Minimum size 5F),
- 2-3 Nos. 10-20 cc Syringes
- 1,000 µ / 500 cc Sterile Heparinised Normal Saline (HepNS)
- 0.014" x 175 cm (minimum length) Guidewire,
- Rotating Haemostatic valve with minimum 0.096" inner diameter,
- Contrast medium diluted 1:1 with sterile saline solution,
- Inflation Device
- Three way stopcock,
- Torque Device
- Guidewire Introducer

10.4 Preparation

10.4.1 Guide wire Lumen Flush

Step	Action
1	Remove protective cover from tip.
2	Flush guide wire lumen with HepNS until fluid exits guide wire exit notch.
3	AVOID manipulation of stent during flushing of the guidewire lumen, as this may disrupt the placement of the stent on the balloon.
4	DO NOT apply negative or positive pressure to the balloon during the delivery system preparation.
5	Rinse the catheter with sterile heparinized normal saline solution.

10.4.2 Delivery System Preparation

Step	Action
1.	Prepare the inflation device or syringe with diluted contrast medium.
2.	Attach the inflation device/syringe to the stopcock; attach to inflation port.
3.	With tip down, orient Delivery System vertically.
4.	Open stopcock to Delivery System; pull negative for 30 seconds; release to neutral for contrast fill.
5.	Close stopcock to Delivery System; purge inflation device/syringe of all air.
6.	Repeat steps 3 to 5 until all air is expelled. Note: If air is seen in shaft, repeat Balloon Preparation steps 3 to 5 to prevent uneven stent expansion.
7.	If a syringe was used, attach a prepared inflation device to stopcock.
8.	Open stopcock to Delivery System.
9.	Leave on neutral.

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10.5 Delivery Procedure

Step	Action
1.	Prepare the vascular access site according to standard practice.
2.	Predilate the lesion with a PTCA catheter.
3.	Maintain neutral pressure on the inflation device. Open the rotating hemostatic valve as widely as possible.
4.	Backload the delivery system onto the proximal portion of the guidewire while maintaining the guide wire 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. 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 Precautions – 6.11 Stent/System Removal Precautions for specific Delivery System removal instructions.
6.	Tighten rotating hemostatic valve. Stent is now ready to be deployed.

10.6 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.	Turn 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 routine angiography or intravascular ultrasound.
5.	Fully cover the entire lesion and balloon treated area (including disections) with the **Yukon Choice PC** Sirolimus Eluting Coronary Stent System, allowing for adequate stent coverage into healthy tissue proximal and distal to the lesion.
6.	If more than one **Yukon Choice PC** Sirolimus Eluting Coronary Stent System is needed to cover the lesion and balloon treated area, adequately overlap the stents, taking into account stent foreshortening. Ensure no gaps between to stents by positioning the balloon marker bands of the second **Yukon Choice PC** Sirolimus Eluting Coronary Stent System 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 stent is adequately expanded by angiographic injection through the guiding catheter.

10.7 Removal Procedure

Step	Action
1.	Ensure that the balloon is fully deflated.
2.	Fully open rotating haemostatic valve
3.	While maintaining guide wire position and negative pressure on inflation device, withdraw the Delivery System.
4.	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. See Precautions – 6.11 Stent/System Removal Precautions for specific Delivery System removal instructions.
5.	Tighten rotating haemostatic valve.
6.	Repeat angiography to assess stented area. If necessary, post dilate within stent. Balloon inflations should incorporate balloon size closely matching vessel.
7.	Final stent diameter should match reference vessel. ENSURE STENT IS NOT UNDERDILATED

10.8 Disposal Procedure

Discard the used mounting and delivery system as biomedical waste (Bio-Hazard), and handover to the biomedical waste handling department/subcontractors for incineration. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

11. Compliance Chart, Inflation Pressure

Balloon Ø [mm]	Inflation Pressure [ATM / bar / 10^5 Pa]														
				NP							RBP				
	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Ø 2,00	1,90	1,94	1,97	2,00	2,03	2,07	2,10	2,13	2,17	2,20	2,23	2,27	2,35	2,38	2,41
Ø 2,25	2,15	2,18	2,21	2,25	2,28	2,32	2,35	2,38	2,42	2,45	2,49	2,52	2,55	2,59	2,62
Ø 2,50	2,40	2,43	2,47	2,50	2,54	2,57	2,60	2,64	2,67	2,71	2,74	2,77	2,81	2,84	2,88
Ø 2,75	2,65	2,68	2,72	2,75	2,78	2,82	2,85	2,88	2,92	2,95	2,98	3,01	3,28	3,31	3,34
Ø 3,00	2,89	2,93	2,97	3,00	3,04	3,08	3,12	3,15	3,19	3,23	3,26	3,30	3,34	3,37	3,41
Ø 3,50	3,37	3,42	3,46	3,50	3,54	3,58	3,63	3,67	3,71	3,75	3,79	3,84	3,88	3,92	3,96
Ø 4,00	3,85	3,90	3,95	4,00	4,05	4,10	4,16	4,21	4,26	4,31	4,36	4,41	4,46	4,51	4,56

Nominal Pressure — Rated Burst Pressure

12. Sterilisation And Storage Conditions

- Single use device do not re-sterilize
- Store the device package at temperature from 8°C to 25° C

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LIMITLESS POSSIBILITIES

13. 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

14. 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
	Pyrogen Free
MD	Medical Device
	Contains a medicinal substance

Symbol	Description
RBP	Rated Burst Pressure
	Manufacturer
EC REP	European Authorized Representative
CE xxxx	CE Mark
	Consult Instruction for Use.
	Do not use if package open or damaged
	Keep Away from Sun Light
	Keep dry.
NP	Nominal Pressure
	Warning / Caution
#	Content of the package
	Single sterile barrier system with protective packaging outside

15. Disclaimer of Warranty and Limitation of Remedy

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