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TZIFUWEN REV 09
15APR2022

Supraflex Cruz

Sirolimus Eluting Cobalt Chromium Coronary Stent System

Instructions for use

STERILE EO

CE 2460

Table of Contents

12.0 Patient Information

In addition to these instructions for Use booklet, the following patient specific information regarding the **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent is available:

- Evaluation Form that includes both patient and **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent specific information. All patients will be expected to keep this card in their possession at all times for procedure/stent identification.

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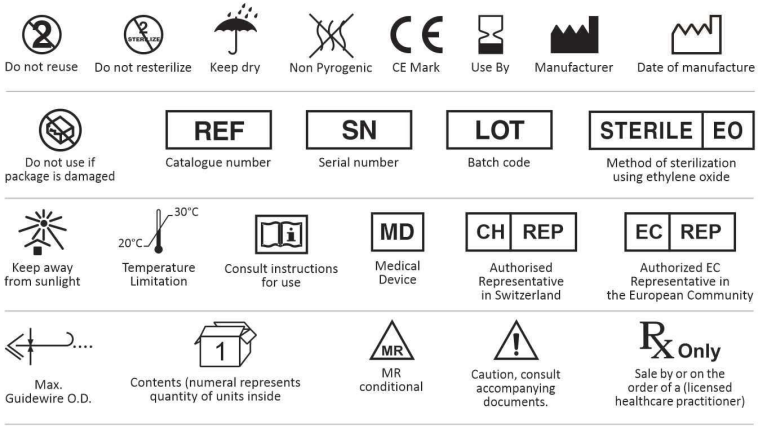
14.0 Explanation of symbols as per MDD 93/42/EEC & BS EN ISO 15223



11.5. Deployment Procedure

Step	Action
1	Inflate the delivery system expanding the stent to a nominal pressure. Higher pressure may be necessary to optimize stent apposition to the arterial wall. Balloon pressure must not exceed RBP.
2	Maintain inflation pressure for 15-30 seconds for full expansion of the stent
3	Deflate balloon by pulling negative pressure on inflation device until balloon is fully deflated.
4	Confirm stent position and deployment using standard angiographic techniques. For optimal results, the entire stenosed arterial segment should be covered by the stent. Fluoroscopic visualization during stent expansion should be used in order to properly judge the optimum expanded stent diameter as compared to the proximal and distal coronary artery diameter(s). Optimal expansion requires that the stent be in full contact with the artery wall. Stent wall contact should be verified through routine angiography or intravascular ultrasound (IVUS).
5	If stent sizing/apposition requires optimization, readvance the Stent System balloon, or another high-pressure, non-compliant balloon catheter of the appropriate size, to the stented area using standard angioplasty techniques.

11.6. Removal Procedure

Step	Action
1	Ensure that the balloon is fully deflated.
2	Fully open rotating hemostatic valve.
3	While maintaining guidewire position and negative pressure on inflation device, withdraw delivery system. NOTE. Should unusual resistance be felt at any time during either lesion access or removal of delivery system post-stent implantation, the entire system should be removed as a single unit. See Precautions 5.11 Stent/System Removal Precautions for specific delivery system removal instructions.
4	Tighten the rotating hemostatic valve.
5	Repeat angiography to assess stented area. If necessary, post-dilate within stent. Balloon inflations should utilize balloon of size closely matching vessel.
6	Final stent diameter should match reference vessel. **ASSURE THAT THE STENT IS NOT UNDERDILATED.**

11.7. *In-Vitro* Information

Pressure [atm]	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.50 mm	4.00 mm	4.50 mm
8	2.02	2.23	2.46	2.69	2.92	3.27	3.86	4.28
9	2.06	2.27	2.48	2.73	2.97	3.32	3.92	4.34
10	2.10	2.30	2.50	2.76	3.02	3.37	3.97	4.41
11	2.13	2.33	2.52	2.78	3.05	3.50	4.01	4.50
12	2.16	2.35	2.53	2.81	3.09	3.56	4.05	4.56
13	2.18	2.37	2.55	2.83	3.13	3.61	4.08	4.62
14	2.20	2.39	2.57	2.86	3.16	3.65	4.12	4.68
15	2.23	2.43	2.60	2.89	3.19	3.69	4.16	4.72
16	2.26	2.45	2.63	2.93	3.22	3.72	4.18	4.75

Nominal= 8 atm, for 2.00 mm to 2.25 mm, 10 atm for 2.50 mm to 3.00 mm, 11 atm for 3.50 to 4.50 mm
RBP=16 atm for all sizes
1atm=1.01bar=101.33kpa

1.0. Product Description

The **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent system is a combination product comprised of two regulated components: a device (Tetrinium® coronary stent system as platform) and a drug product (a formulation of Sirolimus drug with the blend of biodegradable polymers).

1.1. Device Component Description

The **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent system consists of a balloon expandable Sirolimus-eluting stent, premounted on a stent delivery system. The physical characteristics of the device component are shown in Table 1.

Table 1- Device Component Description

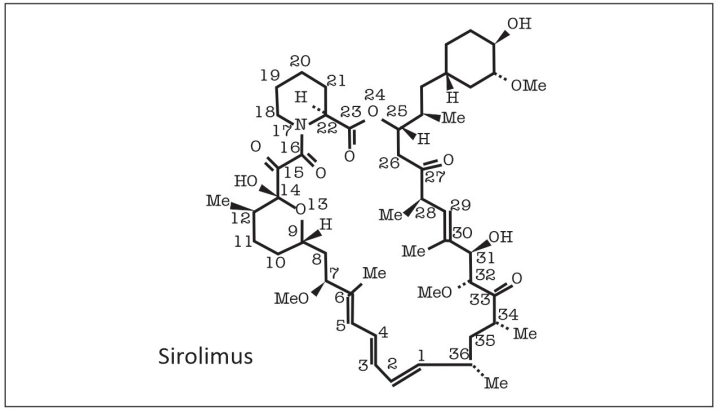
SUPRAFLEX CRUZ™ Sirolimus-eluting Coronary Stent System	
Available Stent Lengths, (mm)	8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48
Available Stent Diameters (mm)	2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50
Stent Material	L-605 Co-Cr Alloy
Stent Design	Laser cut from seamless tubing in a serpentine pattern
Stent Platform	Tetrinium™
Stent Strut Dimension	Thickness: 0.06 mm (60 µm)
Drug	Sirolimus
Polymers Type	Biodegradable Polymers
Delivery System Usable Length	1400 mm (140 cm)
Delivery System Y - Adapter Ports	Single access port to inflation/deflation lumen. A guidewire exit port is located 25 cm away from the tip. Designed for guidewire of Ø 0.014 inch.
Stent Delivery Balloon	Polyamide balloon, nominally 1 mm longer than the stent. Mounted stent length and location is defined by two radio opaque markers at proximal and distal ends of the stent.
Catheter Shaft Outer Diameter	Proximal : 0.72 mm Distal : 0.95 mm
Balloon Inflation Pressure	*NP: 8 atm for 2.00 & 2.25 mm,10 atm for 2.50 to 3.00 mm, 11 atm for 3.50 to 4.50 mm RBP: 16 atm
Guiding Catheter	5 F compatible (min.)
Guidewire Diameter	0.014 inch

*Assure full deployment of the stent (See section 11.5 Deployment Procedure). Deployment pressures should be based on lesion characteristics.
Note: 1F is equivalent to 0.33 mm. NP: Nominal Pressure, RBP: Rated Burst Pressure. 1 atm =1.01 bar

1.2. Drug Component Description

The active pharmaceutical ingredient in the **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent is Sirolimus (also known as Rapamycin).

Sirolimus is a macrocyclic lactone produced by Streptomyces hygroscopicus. The chemical name (IUPAC) of Sirolimus is [3S [3R* [S* (1R*, 3S*, 4S*)), 6S*, 7E, 9S*, 10S*, 12S*, 14R*, 15E, 17E, 19E, 21R*, 23R*, 26S*, 27S*, 34aR*]] - 9, 10, 12, 13, 14, 21, 22, 23, 24, 25, 26, 27, 32, 33, 34, 34 a - Hexadecahydro – 9, 27-dihydroxy - 3 - [2 - (4 - hydroxy - 3 methoxycyclohexyl) -1 methylethyl] - 10, 21 - dimethoxy - 6, 8, 12, 14, 20, 26 - hexamethyl - 23, 27 - epoxy 3H pyrido [2, 1 - c] [1, 4] oxaazacyclohentriacontine - 1, 5, 11, 28, 29 (4H, 6H, 31H) - pentone. Its molecular formula is $C_{51}H_{79}NO_{13}$ and its molecular weight is 914.19 g/mol. The structural formula of Sirolimus is shown below:



Sirolimus is white or off-white powder and soluble in methanol, ethanol, acetone, ethyl acetate, dichloromethane and chloroform. It is sparingly soluble in ethyl ether, hexane and petroleum ether and insoluble in water.

The inactive ingredient in the **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent is a combination of biocompatible, biodegradable polymers formulated to provide programmed release of the drug. The polymeric chains are cleaved by hydrolysis to form monomeric acids and are eliminated from the body through Kreb's cycle, primarily as carbon dioxide (CO_2) and water (H_2O) which are excreted through urine.

The active ingredient, Sirolimus nominal content per stent ranges from 33 to 309 µg as per stent length

2.0. Indications

The **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent system is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de-novo stenotic lesions and in-stent restenotic lesions in native coronary arteries with a reference vessel diameter from 2.00 mm to 4.50 mm.

3.0. Contraindications

Use of the **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent system is contraindicated in the following patient types:

- Patients with contraindication for antiplatelet/anticoagulant therapy.
- Patients judged to have lesion that prevents complete inflation of an angioplasty balloon.
- Known hypersensitivity to Sirolimus or its derivatives.
- Known allergy to Cobalt Chromium.
- Known allergy to biodegradable polymers
- Polymers might enhance inflammatory reactions and prothrombotic response.

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 this product carries the risks associated with coronary artery stenting, including subacute thrombosis, vascular complications, and/or bleeding events.

Should there be an indication of damage to the stent delivery system, do not use.

b) Release pressure slowly allowing negative pressure to draw mixture into balloon lumen.
Do not apply negative pressure on inflation device after balloon preparation and prior to delivering the stent.

c) Detach syringe, leaving a meniscus of mixture on the hub of the balloon lumen.

11.3.3 Delivery System Preparation

- Do not attempt pre-inflation technique to purge balloon lumen.
- Do not use air or any gaseous medium to inflate the balloon.

1. Prepare an inflation device/syringe with diluted contrast medium.
2. Attach an inflation device/syringe to the stopcock; attach it to the inflation port of the product. Do not bend the product hypotube when connecting to the inflation device/syringe.
3. With the tip down, orient the delivery system vertically.
4. Open the stopcock to delivery system; pull negative for 30 seconds, release to neutral for contrast fill.
5. Close the stopcock to the delivery system; purge the inflation device/syringe of all air.
   Attach inflation device to balloon lumen directly. Apply the "meniscus to meniscus" technique to ensure that no air bubbles remain at connection.
6. Repeat steps 3 through 5 until all air is expelled. If bubbles persist, do not use the product.
7. If a syringe was used, attach a prepared inflation device to stopcock.
8. Open the stopcock to the delivery system.
9. Leave on neutral.

Do not wipe with gauze sponges as fibers may disrupt the stent.

Note: Do not pull negative pressure on inflation device before beginning the preparation step.

Note: Do not apply positive pressure to the balloon during the delivery system preparation.

Note: Do not apply negative pressure on inflation device after balloon preparation and prior to delivering the stent. This may cause dislodgement of the stent from the balloon.

Note: If air is seen in the shaft, repeat Section 11.3.3 Delivery System Preparation, steps 3 through 5, to prevent uneven stent expansion.

11.4. Delivery Procedure

Step	Action
1	Prepare the vascular access site according to standard practice.
2	Predilate the lesion with 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 guidewire while maintaining the guidewire position across 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 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 5.11 Stent/System Removal Precautions section for specific delivery system removal instructions.
6	Tighten rotating hemostatic valve. Stent is now ready to be deployed.

Note: At any time during use of device, if the stainless steel proximal shaft has been bent or kinked, do not continue to use the catheter.

5. If the integrity of the foil pouch or the sterile package has been compromised prior to the product "Use By" date (e.g., damage of the package), contact your local **SMT** representative for return information.

11.2 Materials Required (not included in stent system package)

Quantity	Material
N/A	Guiding catheter(s) ≥ 5F [(1.42 mm, 0.056 inch) inner diameter]
2-3	20 cc syringes
1,000 u /500 cc	Heparinized normal saline (HepNS)
1	<0.014 inch (0.36 mm) guidewire
1	Rotating hemostatic valve with 0.096 inch (2.44 mm) minimum inner diameter
N/A	Contrast diluted 1:1 with heparinized normal saline
1	Inflation Device (with luer fitting)
1	Three-way stopcock
1	Torque device (Optional)
1	Guidewire introducer
1	Pre-deployment dilatation catheter
N/A	Appropriate arterial sheath
N/A	Appropriately sized pre-dilatation angioplasty balloon
N/A	Appropriately sized post-dilatation noncompliant angioplasty balloon
N/A	Appropriate anticoagulation and antiplatelet drugs

11.3 Preparation

11.3.1 Packaging Removal

Note: The foil pouch is not a sterile barrier. The inner Tyvek Pouch within the foil pouch is the sterile barrier. Only the contents of the inner pouch should be considered sterile. The outside surface of the inner pouch is NOT sterile.

1. Carefully remove the delivery system from its protective tubing for preparation of the delivery system. When using a rapid exchange (RX) system, do not bend or kink the hypotube during removal.
2. Remove the product mandrel by grasping the catheter just proximal to the stent (at the proximal balloon bond site), and with the other hand, grasp the stent protector and gently remove distally. If unusual resistance is felt during product mandrel removal, do not use this product and replace with another. Follow product returns procedure for the unused device.
3. Examine the device for any damage. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.

11.3.2 Guidewire Lumen Flush

1. Connect a syringe containing heparinized normal saline to an appropriately sized flushing needle. Carefully apply the needle to the distal tip of the delivery system and flush the guidewire lumen until fluid exits the guidewire exit port.

   Note: Use caution while flushing guidewire lumen with flushing needle to avoid damage to catheter tip.

   Note: Avoid manipulation of the stent while flushing the guidewire lumen, as this may disrupt the placement of the stent on the balloon.

   Note: Stent contact with any fluid is not recommended as there is a possibility of initiating drug release. However, if it is absolutely necessary to flush the stent with saline, contact time should be limited (1 minute maximum).
2. Prepare balloon lumen with 50/50 contrast-saline mixture as follows:

a) Using a 20 cc syringe containing 5 cc of contrast-saline mixture, apply negative pressure for 20-30 seconds, allowing air removal from the balloon. An excessive amount of air released into the syringe or no air released from the balloon may indicate damage to the stent delivery system.

- Persons allergic to L-605 cobalt chromium alloy or Sirolimus or the polymers may suffer an allergic reaction to this implant.
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

5.0. Precautions

5.1. General Precautions

5.1.1 General Precautions

- Only physicians who have received adequate training should perform implantation of the stent.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent stent blockage may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized stents is not well characterized.
- Consideration should be given to the risks and benefit of use in patients with history of severe reaction to contrast agents.
- Do not expose the delivery system to organic solvents such as alcohol or detergents.
- Care should be taken to control the position of the guide catheter tip during stent delivery, deployment and balloon withdrawal.
- The use of **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stents in patients and lesions like more tortuous anatomy, may have an increased risk of adverse event including stent thrombosis, stent embolization, myocardial infarction or death.

Overexpansion -Post-Deployment Dilatation

The stents should not be expanded to a diameter beyond the maximum labelled diameter listed on the label per IFU. Do not dilate the stent beyond the following limits:

Nominal Stent Diameter	Dilation Limit
2.00-2.25 mm	3.25 mm
2.50-3.50 mm	4.25 mm
4.00-4.50 mm	5.50 mm

5.1.2 Oral Antiplatelet Therapy

Antiplatelet drugs should be used in combination with the **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent system, per the latest guidelines [the American College of Cardiology, and the American Heart Association (ACC/AHA) or the European Society of Cardiology (ESC)].

It is very important that the patient is compliant with the post-procedural antiplatelet recommendations given by their physician. Premature discontinuation of prescribed antiplatelet medication could result in a higher risk of thrombosis, myocardial infarction or death. Prior to 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 choice. Following PCI should a surgical or dental procedure be recommended that requires suspension of antiplatelet therapy, the risks and benefits of the procedure should be weighed against the possible risk associated with premature discontinuation of antiplatelet therapy.

Table 8 - Discreate analysis from TALENT randomized controlled trial (total patients=1435)[3]

Group of Patients	% of patients from TALENT trial	Supraflex DOCE%	Xience DOCE%	HR (95%CI)	p value
Diabetic Mellitus	23.3%	5.8%	8.5%	0.66 (0.29–1.52)	0.331
Multivessel Disease	21.7%	10.0%	5.7%	1.81 (0.79–4.14)	0.159
Long Lesion[#]	56.4%	5.7%	7.0%	0.81 (0.47–1.41)	0.465
Small Vessels[@]	44.9%	8.0%	5.8%	1.41 (0.77–2.57)	0.266
STEMI	16.4%	2.5%	3.4%	0.73 (0.16–3.25)	0.678
Left Main	2.1%	13.3%	26.7%	0.49 (0.09–2.67)	0.408

[#]>18 mm, [@]≤ 2.75 mm
Device Oriented Composite Endpoints (DOCE), ST-elevation Myocardial Infarction (STEMI), DOCE includes cardiac death, target-vessel myocardial infarction, or clinically indicated target lesion revascularization

Table 9 - Discreate analysis from FLEX Registry (total patients=995)[6]

Group of Patients	% of patients from FLEX registry	MACE%	Cardiac death (%)	MI (%)	TLR (%)	ST (%)
Multivessel Disease	22.7%	5.5%	2.7%	2.7%	1.4%	1.8%
Long Lesion[#]	58.0%	4.4%	1.6%	1.9%	0.9%	0.9%
Small Vessels[@]	18.7%	5.9%	1.1%	2.7%	2.2%	0.5%
ACS	40.0%	5.9%	2.3%	2.3%	1.3%	1.0%
STEMI	19.9%	6.6%	2.5%	2.5%	1.5%	1.5%
Total Occlusion	18.6%	6.6%	1.6%	2.7%	2.2%	1.6%
Left Main	1.1%	9.1%	9.1%	0.0%	0.0%	0.0%
Female Patients	20%	6.2%	2.1%	2.6%	1.5%	1.5%

[#]≥28 mm, [@]≤2.5 mm
Major Adverse Cardiac Events (MACE), Myocardial Infarction (MI), Target Lesion Revascularization (TLR), Stent Thrombosis (ST), Acute Coronary Syndrome (ACS), ST-elevation Myocardial Infarction (STEMI), MACE includes cardiac death, myocardial infarction, target lesion revascularization and non-target lesion target vessel revascularization
Reference: [1]Abhyankar A et al. Catheter Cardiovasc Interv. 2020 Nov 28. doi: 10.1002/ccd.29371. [2]Abhyankar A et al. Catheter Cardiovasc Interv. 2021 Feb 15;97(3):423-430. [3]Pothineni R et al. J Am Coll Cardiol. 2019 Oct, 74 (13 Supplement) B300. [4]Data on file [5]Zaman A et al. Lancet. 2019 Mar 9;393(10175):987-997. [6]Lemos PA et al. BMJ Open. 2016 Feb 17;6(2):e010028.

5.6. Lesion/Vessel Characteristics

The safety and effectiveness of the **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent have not been established in patients with coronary artery reference vessel diameter < 2.00 mm and > 4.50 mm

5.7. 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 (P-gp).

Consideration should be given to the potential for drug interaction when deciding to place a **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent 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 a **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent. The effect of drug interactions on the safety or efficacy of the **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent has not been determined.

5.8. Magnetic Resonance Imaging (MRI) – Safety Information

Non-clinical testing and MRI simulations were performed to evaluate the entire family, including single and two-overlapped versions of the **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent. Non-clinical testing demonstrated that the entire family of this product (i.e., including all single and two or more overlapped versions up to 120 mm in length) is MR Conditional. The **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent has been shown in non-clinical testing to be MRI safe immediately following implantation. A patient with an implant from this family can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla
- Maximum spatial gradient magnetic field of 1,500-gauss/cm (15-T/m)
- Maximum MR System reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e. per pulse sequence) in normal operating mode

Under the scan condition defined, an implant from the **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent is expected to produce a maximum temperature rise of 3.5°C after 15 minutes of continuous scanning (i.e. per pulse sequence).

In non-clinical testing, the image artifact caused by an implant from the **SUPRAFLEX CRUZ™** Sirolimus-eluting coronary stent extends approximately 4 mm from this device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

5.9. Stent Handling Precautions

- For single use only. Do not resterilize or reuse this device. Note the "Use By" date on the product label.
- Do not remove the stent from the delivery balloon – removal may damage the stent and/or lead to stent embolization. The stent system is intended to perform as a system.
- Do not induce a vacuum on the delivery system prior to reaching the target lesion.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important while removing the catheter from the packaging, placing it over the guidewire, and advancing it through the large- bore rotating hemostatic valve and guiding catheter hub.
- Stent manipulation (e.g., rolling the mounted stent with your fingers) may loosen the stent from the delivery system balloon and cause dislodgment as well as it 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.