INSTRUCTIONS FOR USE

3V NEIL
[Sirolimus Drug Eluting Stent System]

STERILE. Sterilized with ethylene oxide gas. Non pyrogenic. For one procedure only. Do not re-sterilize. Do not use opened or damaged packages. Keep in a cool, dark and dry place. Use the product before expiration of the "Expiry Date" mentioned on the packing. Protect from light. Refer to accompanying Instructions for Use.

DESCRIPTION

The 3V NEIL Sirolimus Drug Eluting Stent System comprises of following components;

- A balloon expandable L605 cobalt chromium coronary stent
- A stent coating that consists of a blend of anti-proliferative drug and polymers
- Anti-proliferative drug - Sirolimus
- Biocompatible, bio-degradable co-polymer coating which acts as drug reservoir and drug release platform
- A double lumen rapid exchange stent delivery catheter
- The stent is pre-mounted on balloon catheter and placed between two platinum-iridium radio opaque markers bands, proximal and distal, to aid the balloon positioning under fluoroscopy

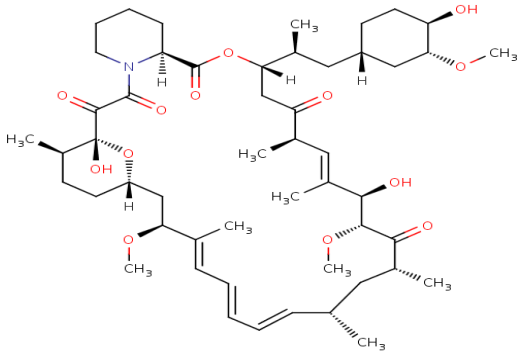
Device Components Description

Stent Material	Electropolished L605 cobalt chromium alloy, laser-cut from seamless tubing in a hybrid design pattern
Stent delivery balloon catheter system	Semi-complaint polyamide balloon, nominally 0.5mm longer than stent length. Mounted stent length & location is defined by two platinum-iridium swaged radiopaque markers under the balloon catheter. Two proximal delivery system shaft markers (90cm, 100 cm proximal to distal tip) indicate the relative position of the delivery system to the end of brachial, radial or femoral guiding catheter
Delivery system usable length	140cm
Guide wire lumen	Starts at the distal tip of the balloon catheter and ends approximately 25cm from distal tip of the balloon catheter
Guide-wire rapid exchange (Rx) port	Starts at distal tip of the balloon catheter emerges approximately 25cm from distal tip of the balloon catheter. A disposable stylet protects the distal catheter from an inadvertent kinking.
Shaft outer profile	Proximal 1.98F (0.66mm/0.026") Distal 2.4F (0.80mm/0.031") (2.00 mm diameter) Distal 2.7F (0.90mm/0.035") (2.25 to 4.00 mm diameter)
Stent dilatation/balloon inflation pressures	Nominal pressure: 8atm Rated burst pressure: 16atm except for balloon diameter 4.00mm with length higher than 20mm (14 atm)
Guide catheter compatibility	5F (Min I.D 0.058"/1.47mm)
Guide wire compatibility	0.014" (0.36mm)

Drug Component Description

- The component is coated on the stent. This coating consists of a blend of sirolimus drug (the active ingredient) and biodegradable polymers (the inactive ingredient).
- Sirolimus is also known as Rapamycin. Sirolimus is a Macrocyclic lactone produced by Streptomyces hygroscopicus.
- The chemical name of Sirolimus is (3S, 6R, 7E, 9R, 10R, 12 R, 14S, 15E, 17E, 19 E, 21S, 23S, 26R, 27R, 34aS) -9, 10, 12, 13, 14, 21, 22, 23, 24, 25, 26, 27, 32, 33, 34 ahexadecahydro 9, 27 dihydroxy - 3 - [(1R) - 2 - [(1S, 3R, 4R) - 4 - hydroxyl - 3 ethoxycyclohexyl] - 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 C51H79NO13 and M.Wt. is 914.2.

Sirolimus drug chemical structure



- Sirolimus is a white to off-white powder and is insoluble in water, but freely soluble in benzyl alcohol, chloroform, acetone, and acetonitrile & has a melting temperature of approximately 183-185°C. Sirolimus belongs to a class of therapeutic agents known as macro cyclic lactones or macrolides. It is a cytostatic drug and an immunosuppressant.
- It inhibits cell motility by suppression of m-TOR mediated 56K1 and 4E-BP1 pathways.
- It inhibits T-Lymphocyte activation and proliferation occurring in response to antigen and cytokine. It also inhibits antibody production. It demonstrates anti- proliferative activities.
- The drug content on 3V NEIL sirolimus drug eluting coronary stent ranges between 34 microgram to 412 microgram.
- The coating concentration is 1.4 ± 0.2 microgram/ sq.mm

Polymer

- The inactive ingredient of the coating consists of a blend of lactide and glycolide based biodegradable polymers.
- These polymers control the drug release kinetics and they degrade as the drug is released from the stent.

INDICATIONS

The 3V NEIL Sirolimus Drug Eluting Stent System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to de novo & in-stent re-stenotic lesions (lengths ≤ 38mm) in native coronary arteries with a reference vessel diameter of 2.00mm to 4.00mm in patients eligible for Percutaneous Transluminal Coronary Angioplasty (PTCA) and stenting procedures.

CONTRA-INDICATIONS

3V NEIL Sirolimus Drug Eluting Coronary Stent System is contraindicated in the following patient types;

- Patient with hypersensitivity or allergies to aspirin, heparin, clopidogrel, ticlopidine, drugs such as Sirolimus or similar drugs or any analogue or derivative, cobalt, chromium, nickel, molybdenum, tungsten or any contrast media.
- Patient in whom anti-platelet and anti-coagulant therapy is contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon.
- Patients' undergone transplantation.

WARNING

- ***The aluminium bag is only for protection from light and humidity and is NOT sterile! Only the content of the inner Tyvek pouch placed inside the aluminium bag is sterile!***
- Judicious patient selection is necessary during use of this device since it carries the associated risks of sub-acute thrombosis, vascular complications and/ bleeding events.
- Long term permanent implantation effect of this device is unknown.
- Safety and effectiveness of direct stenting has not been studied.
- Safety and effectiveness of stenting of saphenous vein grafts has not been established.
- Never try to straighten a kinked hypotube.
- Straightening of a kinked metal may result in breakage of the shaft.
- Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of in vitro testing. Use of a pressure-monitoring device is recommended to prevent over pressurization.
- Use the device before the "Expiry date" specified on the package.
- Direct Stenting without prior dilation of the lesion has not been studied using this product (note Precaution regarding pre-dilation prior to stent implantation).
- Subsequent restenosis may require repeated dilation of the arterial segment containing the stent. The long-term outcome following repeated dilation of coronary stents is unknown at present.
- When multiple stents are required, if placement results in stent to stent contact, stent materials should be of similar composition to avoid the possibility of dissimilar metal corrosion.
- The use of Sirolimus-Eluting stents could cause the risk of a possible inflammatory and/or pro-thrombotic reaction induced by the polymer coating of the stents. The responsible physician should in each case calculate the potential risk for the patient compared to the advantages of the use of a Sirolimus Eluting stent
- The 3V NEIL Stent is not recommended for use in lesions that require stent overlapping.
- Due to the known risks of the implantation of drug eluting stents in combination with the following prolonged dual oral anti-platelet therapy the user must reconsider the alternative of a bypass surgery with the accompanying known risks.

POTENTIAL ADVERSE EVENTS

Adverse events (alphabetical order) may be associated with the implantation of a coronary stent in coronary arteries, but are not limited to the following;

- Allergic reaction
- Aneurysm
- Arrhythmias
- Death
- Dissection
- Drug reactions to antiplatelet agents /anticoagulation agents/contrast medium
- Emboli, distal (tissue, air or thrombosis emboli)Embolization, stent
- Failure to deliver the stent to intended site
- Hemorrhage
- Hypotension / Hypertension
- Infection and pain at the insertion site
- Myocardial ischemia and /or infarction
- Occlusion
- Restenosis of stented segment (greater than 50% obstruction)
- Stroke
- Thrombosis (acute, sub-acute or late)
- Ventricular fibrillation
- Vessel spasm
- Stent migration
- Stent Collapse
- Stent breakage or fracture may occur during implant
- During dual oral anti-platelet therapy no surgery in other fields is possible without a high risk of complications.

There may be other potential adverse events that are unforeseen at this time

PRECAUTIONS FOR USE

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 (CABG) is readily available.
- Subsequent 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.

Stent Handling Precautions

- Do not use if the package has been opened or damaged.
- Use the device before the "Expiry date" as specified on the product label
- For Single Use only. Do not resterilize or reuse
- Remove the protective stylet from the guide wire lumen and discard
- Do not remove the stent from delivery system as removal may damage the stent and/lead to stent embolization. The 3V NEIL Sirolimus Drug Eluting Coronary Stent System is intended to perform as a system.
- The stent should not be removed for use in conjunction with other dilatation catheter.
- Special care must be taken not to handle or in any way disrupt the stent position on the delivery device. This is especially important during catheter removal from packaging, placement of guidewire, advancement through the rotating haemostatic valve adaptor and guiding catheter hub.
- Do not manipulate, touch or handle the stent with fingers or

contact with liquids prior to preparation and delivery as this may result in coating damage, contamination or dislodgement of stent from the delivery balloon catheter.
- Do not expose or wipe the device with organic solvents such as alcohols or detergents.
- Use only the appropriate balloon inflation media. Do not use any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.
- When back loading catheter on the guidewire, provide adequate support to shaft segment's.

Stent placement precautions
- Do not prepare or pre-inflate the balloon prior to stent deployment, other than as directed.
- Do not include vacuum on (negative pressure) on the delivery balloon catheter before reaching the target lesion.
- Implantation of a stent may lead to dissection of the vessel distal and/ or proximal to the stented portion and may cause acute closure of the vessel requiring additional intervention (eg: CABG, further dilatation or placement of additional stents.)
- Do not expand the stent if it is not properly positioned in the vessel.
- Long term outcome following repeat dilatation of endothelialized coronary stents is unknown at present.
- Placement of stents has the potential to compromise side branch patency.
- Do not exceed rated burst pressure as indicated on labeling .use of pressures higher than those specified on product label may result in a raptured balloon and potential intimal damage and dissection.
- Guiding catheter used must have lumen sizes that are suitable to accommodate the introduction of 3V NEIL stent.
- Stent retrieval methods (use of additional wires, snares 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.
- To avoid the possibility of dissimilar metal corrosion, do not implant stents of different materials in tandem overlap or contact if possible.
- 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 changes for dislodging the proximal stent.
- The safety and effectiveness of the 3V NEIL coronary stent in patients with prior brachytherapy of the target lesion have not been established.
- The safety and effectiveness of using mechanical artherectomy devices or laser angioplasty catheters in conjunction with 3V NEIL Sirolimus Eluting coronary stent implantation have not been established.
- The Tyvek pouch is the sterile barrier. Therefore only the contents of the sealed Tyvek pouch should be considered sterile. Do not remove the contents from Tyvek pouch until immediately prior to use.
- During withdrawal of the delivery system, hold saline- soaked gauze around the exposed catheter shaft and pull the catheter through the gauze to remove any excess contrast medium.
- If reinserting the catheter, flush the guidewire lumen using flushing needle before insertion.
- Additional expansion of a deployed stent may cause a flow limiting dissection.
- This may be treated by implantation of another stent. When multiple stents are implanted, the ends should overlap slightly.

Stent/ system removal precautions
- Should any unusual resistance be felt at any time during either lesion access or removal of stent delivery system, pre-stent implantation, the entire system must be removed as a single unit.
- When removing the delivery system as a single unit, do not retract the delivery system into 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 stent delivery system as a single unit.
- Failure to follow these steps and /or applying excessive force to the stent delivery system can potentially result in loss or damage to the stent and /or stent delivery system components.

Post Implant Precautions
- Care must be exercised when crossing a newly deployed stent with an intravascular ultrasound (IVUS) catheter, a coronary guidewire, or a balloon catheter to avoid disrupting the stent geometry or coating.
- Do not perform Magnetic Resonance Imaging (MRI) scan on patient's post-stent implantation until the stent has been completely endothelialized (90 days) 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 (i.e., clopidogrel or ticlopidine) for a period of 6 months to reduce the risk of stent thrombosis.

Magnetic Resonance Imaging (MRI) statement
- Non-clinical testing of coronary stents of similar metal configurations as 3V NEIL stents available in the market are shown to be MRI safe at filed strengths of 3 tesla or less, spatial gradient field of 720 gauss/ cm or less and a maximum whole body averaged specific absorbtion rate (SAR) of 2.0 W/kg for 15 min of MRI.
- The effect of heating in the MRI environment for stents with fractured struts is not known.
- MRI image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

Drug Interaction
- While no specific clinical data are available drugs like tacrolimus that act through the same binding protein (FKBP) may interfere with the efficacy of Sirolimus.
- Drug interaction studies have not been performed. Sirolimus is metabolized by CYP3A4. Strong inhibitors of CYP3A4 (eg: 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.

Pregnancy and Lactation
- This product has not been tested in pregnant women, women who wants to be pregnant, nursing mothers or in men intending to

father children, effects on the developing foetus have not been studied.
- While there is no contraindication, the risks and reproductive effects remain unknown.

Pregnancy
- In animals, Sirolimus was embryo- and foetotoxic at clinically relevant exposures.
- Teratogenic effects have not been observed. The potential risk for humans is unknown.
- The 3V NEIL Stent should not be used in pregnant women, unless the clinical condition of the mother requires treatment with the stent.

Lactation

It is not known whether Sirolimus is excreted in human breast milk. Sirolimus is excreted in milk of lactating rats. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to implant the stent taking into account the importance of the stent to the mother.

Antiplatelet Regimen

Patients receiving the 3V NEIL should receive Clopidogrel or Ticlopidine for at least 6 months post procedure and aspirin indefinitely. Since the relative risk of stent thrombosis with the 3V NEIL Stent is equivalent to that of a bare metal stent, the physician should use best clinical judgment in determining the need for a more extended duration of antiplatelet therapy in high risk groups, as they would when using a bare metal stent.

Materials required (not included in Stent System package)
- Select guiding catheter(s) min. ID 0.058"/1.47mm with the appropriate configuration for the coronary artery to be treated.
- 10 or 20 ml syringe
- Rotating hemostatic valve(s) with a minimum diameter of 0.096"/ 2.44mm
- Guide wire 0.014"/ 0.36mm
- Contrast medium diluted 1:1 with heparinized normal saline
- Sterile physiological saline solution
- Inflation device and a three-way stopcock for balloon inflation

INSTRUCTIONS FOR USE

Inspection Prior to use
- Carefully inspect the sterile package before opening.
- Do not use if the package has been damaged or opened.
- Do not use after the "Expiry date".
- ***The aluminium bag is only for protection from light and humidity and is NOT sterile! Only the content of the inner***
- ***Tyvek pouch placed inside the aluminium bag is sterile!***
- If the sterile package appears intact, carefully remove the system from the package and inspect for bends, kinks and other damage.
- Tear open the sterile pouch to carefully remove the product and pass on or drop the contents into the sterile field using aseptic technique.
- Verify that the stent is located between the radiopaque markers.
- Do not use if any defects are noted.

Materials Required
- Appropriate guiding catheter(s)
- 2-3 syringes (10-20cc)
- 1000 micro/500 cc Normal heparinized saline (Hep NS)
- 0.014" (0.36mm) diameter guidewire, 175cm minimum length
- Rotating hemostatic valve with an appropriate internal diameter
- Contrast medium diluted 1:1 with heparinized normal saline
- Inflation device
- Three-way stopcock
- Torque device
- Guidewire introducer

Preparation

Packaging Removal
- Carefully remove the delivery system from its protective tubing for preparation of the delivery system. Do not bend or kink hypotube during removal.
- Remove the product mandrel and stent protector by grasping the catheter just proximal to the stent (at the proximal balloon bond site), and with the other hand, grasp the stent protector on the distal end and remove gently.

NOTE: Care should be taken not to kink or bend the shaft upon application.

Guide wire Lumen flush
- Remove the protective stylet from the guide wire lumen and discard
- Flush the guide wire lumen with HepNS until the fluid exists, the guide wire exit port approximately 25cms distal to catheter distal tip.

  Caution: Avoid manipulation of stent during flushing of guide wire lumen, as this may disrupt the placement of the stent on the balloon.

Balloon Preparation
1. Stent contact with any fluid is not recommended, as there is a possibility of drug release. However, if it is absolutely necessary to flush the stent with saline, contact time should be limited (1 minute maximum).
2. Prepare inflation device/syringe with diluted contrast medium.
3. Attach inflation device/syringe to stopcock; attach to inflation port. Do not bend the hypotube when connecting to inflation device/syringe.
4. With tip down, orient Stent System vertically.
5. Open stopcock to Stent System; pull negative for 15 seconds; release to neutral for contrast fill.
6. Close stopcock to Stent System; purge inflation device/syringe of all air.
7. Repeat steps 4 through 6 until all air is expelled. If bubbles persist, do not use device.
8. If a syringe was used, attach a prepared inflation device to stopcock.
9. Open stopcock to Stent System.
10. Leave on neutral.

Delivery Procedure
1. Prepare the vascular access site according to standard PTCA practice.
2. Pre-dilate the lesion/vessel with appropriate diameter balloon having a ratio of 1:1 with the diameter of the vessel.
3. Maintain neutral pressure on inflation device attached to Stent

System.

4. Backload Stent System onto proximal portion of guidewire while maintaining guidewire position across target lesion.
5. Fully open rotating hemostatic valve to allow for easy passage of the stent and prevent damage to the stent.
6. Ensure guiding catheter stability before advancing the Stent System into the coronary artery. Carefully advance the Stent System into the hub of the guiding catheter, keeping the hypotube straight.

NOTE: If unusual resistance is felt before the stent exits the guiding catheter, do not force passage. Resistance may indicate a problem and use of excessive force may result in stent damage or stent dislodgement from the balloon. Maintain guidewire placement across the lesion and remove the Stent System and guiding catheter as a single unit.

7. Advance the Stent System over the guidewire to target lesion under direct fluoroscopic visualization. Utilize the proximal and distal radiopaque balloon markers as a reference point. If the position of the stent is not optimal, it should be carefully repositioned or removed (see Section "Stent System Removal Precautions"). The inside edges of the marker bands indicate both the stent edges and balloon shoulders inflated. Expansion of the stent should not be undertaken if the stent is not properly positioned in the target lesion segment of the vessel.

NOTE: If unusual resistance is felt at any time during lesion access before stent implantation, the Stent System and the guiding catheter should be removed as a single unit (see section "Stent System Removal Precautions").

8. Sufficiently tighten the rotating hemostatic valve. Stent is now ready to be deployed.

Deployment Procedure

1. Inflate the Stent System expanding the stent to a minimum pressure of the nominal pressure. Higher pressures may be necessary to expand the stent to optimize stent apposition against the arterial wall. Balloon pressure must not exceed rated burst pressure.
2. Maintain inflation pressure for 15-30 seconds for full expansion of the stent.
3. Deflate balloon by pulling negative 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. All efforts should be taken to assure that the stent is not under dilated.
5. If stent sizing/apposition requires optimization, re-advance the Stent System balloon, or another balloon catheter of the appropriate size, to the stented area using standard angioplasty techniques.
6. Inflate the balloon to the desired pressure while observing under fluoroscopy. Deflate the balloon (see Balloon Compliance Chart supplied with device).
7. Reconfirm stent position and angiographic result. Repeat inflations until the desired result is achieved.

Removal Procedure

1. Ensure balloon is fully deflated.
2. Fully open rotating hemostatic valve.
3. While maintaining guidewire position and negative pressure on inflation device, withdraw Delivery System.

In Vitro Information

Refer to Compliance Chart supplied with device for stent inner diameter at nominal to rated burst pressure.

References: *The physician should consult recent literature on current medical procedures involving balloon dilatation, such as that published by international cardiologists' associations.*

STORAGE REQUIREMENTS

- Use before the expiry date clearly indicated on the label.
- Store between 15°C - 25°C temperatures in a dry, cool place.
- Protect from light.

Compliance Chart for
3V NEIL Sirolimus Drug Eluting Stent System

Pressure (atm)	Balloon Diameter (mm)					
	2.25	**2.50**	**2.75**	**3.00**	**3.50**	**4.00**
2	1.98	2.20	2.42	2.64	3.08	3.52
3	2.03	2.25	2.48	2.70	3.15	3.60
4	2.07	2.30	2.53	2.76	3.22	3.68
5	2.12	2.35	2.59	2.82	3.29	3.76
6	2.16	2.40	2.64	2.88	3.36	3.84
7	2.21	2.45	2.70	2.94	3.43	3.92
8*	**2.25**	**2.50**	**2.75**	**3.00**	**3.50**	**4.00**
9	2.28	2.54	2.79	3.05	3.55	4.06
10	2.32	2.58	2.83	3.09	3.61	4.12
11	2.35	2.61	2.87	3.14	3.66	4.18
12	2.39	2.65	2.92	3.18	3.71	4.24
13	2.42	2.69	2.96	3.23	3.77	4.31
14	2.46	2.74	3.01	3.29	3.83	**4.38**
15	2.50	2.78	3.06	3.34	3.89	4.45
16**	**2.54**	**2.83**	**3.11**	**3.39**	**3.96**	**4.52**
17	2.58	2.86	3.15	3.44	4.01	4.58
18	2.61	2.90	3.19	3.48	4.06	4.64

Nominal Pressure

****Rated burst pressure (RBP) recommendation*** except for balloon diameter 4.00mm with length higher than 20mm (14atm)

NOTE: Tolerance of Balloon diameter: ±10%

- Available stent lengths and diameters

Available Sizes						
Stent Lengths (mm)	**Balloon Diameter (mm)**					
	2.25	**2.50**	**2.75**	**3.00**	**3.50**	**4.00**
8	○	○	○	○	○	○
12	○	○	○	○	○	○
16	○	○	○	○	○	○
20	○	○	○	○	○	○
24	○	○	○	○	○	○
28	○	○	○	○	○	○
32	○	○	○	○	○	○
36	○	○	○	○	○	○
40	○	○	○	○	○	○

LIABILITY

It has endeavored to ensure that the products comply with all relevant standards and regulations currently in force and to ensure that the quality of the products meets the requirements of the above mentioned standards and regulations for a period ending upon the indicated expiry date. The above statement does not apply when the products are used for a purpose other than its intended purpose. Where any loss or damage is caused (other than death or personal injury) due to a defective product shall not be liable for such loss or damage.

PACKAGING AND PRODUCT RANGE

- Delivered in a peelable tyvek pouch, covered by an aluminium pouch placed in an outer cardboard carton box
- One unit per box
- Device is sterilized by Ethylene Oxide
- Non-Pyrogenic

DISPOSAL INSTRUCTIONS

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

RE-USE PRECAUTION STATEMENT

- Contents are supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile seal is damaged. If damage is found call S3V Vascular Technologies' representative.
- For single patient use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization 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. Re-use, reprocessing or re-sterilization 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 from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

CONVERSION CHART

1 cc	1 ml		
1 French	0.013"	0.33 mm	
1 bar	0.99atm	14.5 PSI	10^5Pa

SYMBOLS MEANING

Qty	Quantity per box
SN	Serial Number
REF	Reference Number
Ø	Diameter
↔	Length
	Single use
	Store protected from sun
	Store in a dry place
Ø	Min. guiding catheter internal diameter
Ø	Maximum guide wire diameter
	Temperature limitation
	Manufacturer
	Manufacturing Date
LOT	Lot Number
	Expiry Date
	Do not use if Package is Damaged
i	Consult Instructions For Use
	Do Not Re-sterilize
!	Caution

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