INSTRUCTIONS FOR USE

3V KROME

[Rapid Exchange Coronary Cobalt Chromium Stent System]

STERILE, SINGLE USE ONLY. Sterilized with ethylene oxide gas. Non pyrogenic. Do not re-sterilize. Do not use opened or damaged packages. Destroy product after use. Store in a dry place between 0°- 40° C, keep away from light. Refer to the accompanying Instructions for Use.

1. Description

The 3V KROME is a balloon expandable intracoronary stent premounted onto a rapid exchange delivery catheter. The 3V KROME is a L-605 alloy (cobalt chromium) stent designed to provide excellent flexibility and low profile for easy insertion, with optimal deployment characteristics for homogeneous expansion. The stent is mounted on a balloon between two radiopaque markers, which aid in the accurate placement of the balloon segment and stent.
The delivery system is a rapid exchange catheter with a balloon located at the distal tip. The distal shaft comprises two lumens, one is used for inflation of the balloon and the other permits the use of a guide wire (0.014" max.) 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 and 100 cm from the distal tip aid catheter positioning without fluoroscopy assistance.

2. Indications

The 3V KROME intracoronary stent system is intended for use in the treatment of patients with clinical symptoms of myocardial ischemia related to the pathological condition of one or more coronary arteries. Recognized use of intracoronary stents currently include but is not limited to the treatment of *de novo* or re-stenotic lesions in native coronary arteries and in de novo lesions of saphenous vein grafts. The 3V KROME is available for intracoronary implantation for inner vessel diameters of 2.25 mm to 4.50 mm.

3. Contra-indications

Related to the patient

- Patients who are judged not to be candidates for coronary artery bypass surgery,
- Patients with totally obstructed coronary arteries,
- Arterial spasm,
- Patients with allergies to procedural medications, to anticoagulation and or antiplatelet therapy or to cobalt alloy or a sensitivity to contrast media,
- Patients with an ejection fraction < 30 %,
- Patients having experienced recent acute myocardial infarction (<72 hours),
- Patients having experienced cardiogenic shock,
- Patients with bleeding diathesis or other disorder e.g. Peptic ulceration or recent cerebrovascular accident, limiting the use of antiplatelet and/or anticoagulation therapy,
- Pregnant women or women of child bearing potential

Conditions related to the lesion

- Severe stenosis of the unprotected left main coronary artery,
- Reference vessel diameter at the lesion site either < 2.25 mm or > 5.00 mm,
- Heavily calcified lesion or diffuse lesion > 40 mm in length,
- Presence of definite or probable intra-luminal thrombus in the target vessel,
- Stenosis which cannot be pre-dilated with an angioplasty balloon to a mean luminal diameter of 2.25 mm,
- Vessels where an untreated lesion of > 50% diameter would remain after the planned intervention,
- Target lesions distal to a 50% or greater stenosis, which cannot be pre-dilated or target lesions proximal to untreatable areas of significant flow compromising disease.

4. Warning

- PTCA procedures should only be performed in hospitals where emergency coronary artery bypass graft surgery can be immediately performed in the event of potentially injurious or life threatening complications.
- Only physicians trained in PTCA and stent implantations should use this device. The physician should consult current peer-reviewed publications on the interventional cardiology techniques.
- Ensure that the medical team is trained on the products and their reference system to avoid any error in choosing equipment.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during the procedure, as treatment of this patient population carries special risk.
- Persons allergic to L-605 cobalt chromium alloy may suffer an allergic reaction to this implant.
- In order to minimize the risk of stent migration, Magnetic Resonance Imaging (MRI) should not be performed until the stent has been completely endothelialised (eight weeks). The stent may cause artefacts in MRI scans due to distortion of the magnetic field.
- Appropriate anticoagulant and vasodilator therapy should be administrated before insertion of the catheter.
- When multiple stents are required, stent materials should be of similar composition.
- Re use or re sterilization may compromise the device performance.

5. Precautions for use

- The 3V KROME intracoronary stent system is designed and intended for single use. Do not re-sterilize or reuse it. Use prior to “use before” date noted on the packaging. Do not use opened or damaged packages.
- When the stent delivery system is exposed to the vasculature, it should be manipulated while under high-quality fluoroscopic observation. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Inspect the delivery system entirely prior to use for any kinks, curves or potential catheters damage, which could alter the 3V KROME intracoronary stent performances.
- Do not “roll” the mounted stent with your fingers, as this action may loosen the stent from the delivery balloon.
- Do not attempt to reposition the stent on the delivery system. Care must be taken not to handle or in any way disrupt the delicate placement of the stent on the balloon. This is most important during 3V KROME intracoronary stent system removal from the dispenser, placement over guide wires and advancement through the “Y” access system and guiding catheter hub.
- Do not remove the stent from the balloon catheter, the stent cannot be removed and placed on another balloon catheter for deployment.
- Expansion of the stent should not be undertaken if the stent is not

approximately positioned in the vessel. If the position of the stent is not optimal, it should not be expanded (See Chapter 9 of the instructions for use: removal of unexpanded stent).

- Do not attempt to reposition a fully or partially inflated balloon. Attempting repositioning may result in severe vessel damage.
- Do not use, or try to straighten bent or kinked catheters; not following these instructions could result in the shaft rupture. In case of defective product, use another 3V KROME intracoronary stent system.
- Balloon pressure should be monitored via an indeflator during inflation. Balloon inflation pressure should not exceed the rated burst pressure. To reduce the potential for damage, the inflated diameter of the balloon should approximate the diameter of the vessel proximal and distal to the stenosis.
- Use only diluted contrast medium to inflate the balloon. Do not use air or any gaseous medium.
- Do not pre-inflate the balloon prior to stent deployment. Use the balloon purging technique described in the Instructions for use chapter.
- Should any resistance be felt at any time during lesion access or delivery system removal, the entire guiding catheter and stent system should be removed as a single unit. Applying excessive force to the stent delivery system can potentially result in loss or damage to the stent and delivery system components.
- Do not attempt to pull back an unexpanded stent through the guiding catheter as dislodgement of the stent may result. The entire system guiding catheter and delivery system should be removed and replaced.
- The 3V KROME intracoronary stent delivery system is intended to perform as a unit. The stent should not be removed for use in conjunction with other dilatation devices nor should the 3V KROME intracoronary stent system be used in conjunction with other stents.
- Subsequent restenosis may require repeated dilatation of the arterial segment containing the stent. The long-term outcome following repeated dilatation of endothelialized 3V KROME intracoronary stents is unknown at present.
- 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.

Guiding catheter and Guide wire selection

- Only guiding catheters and guide wires indicated for use in coronary angioplasty should be used. Use a guiding catheter with a minimum internal diameter of 0.058'' (1.47 mm). For stents between 4.0 and 5.0, use a guiding catheter with a minimum internal diameter of 0.070" (1.80mm).
- Guide wire diameter recommended with the 3V KROME intracoronary stent system is 0.014'' (0.35 mm).

Stent selection

Careful stent sizing is important for successful stenting. In general, the stent size should match the diameter of the reference vessel, and the length of the lesion to be stented. The diameter of the expanded delivery system must not be superior to the segment diameter, proximal and distal to the lesions.

6. Individualization of treatment

The risks and benefits described in this notice should be considered for each patient before use of the 3V KROME intracoronary stent system. Patient selection factors to be assessed should include a judgement regarding risk of anti-platelet therapy. Special consideration should be given to those patients with recently active gastritis or peptic ulcer disease.
Premorbid conditions that increase the risk of poor initial results or the risks of emergency referral for bypass surgery (diabetes mellitus, renal failure and severe obesity) should be reviewed.

Thrombosis following stent implantation is affected by several baseline angiographic and procedural factors. These include vessel diameter less than 3.00 mm, intra-procedural thrombus, or poor distal runoff and/or dissection following stent implantation. In patients who have undergone coronary stenting, the persistence of a thrombus or dissection should be considered a maker for subsequent thrombotic occlusion. These patients should be monitored very carefully during the first month after stent implantation.

7. Instructions for use

A. Delivery system preparation

Check before use that the packaging has not been damaged in a way that might have rendered the product unsterile.

a. Prepare the inflation device according to the manufacturer's instructions. Prepare diluted contrast medium and sterile saline solution. Fill a 10 or 20 cc syringe with sterile saline solution.
b. Remove the 3V KROME intracoronary stent system from its dispenser.
c. Remove carefully the distal protective sleeve from the system, the stylet placed in the balloon and flush the guide wire lumen according to routine procedure. Inspect the stent to ensure that it has not been damaged. Moisten the stent with sterile saline. Carefully check the integrity of the stent attachment on the delivery system by gently pulling the stent segment through the thumb and finger. Should there be any movement of the stent, please do not use the product and return it immediately to at the address indicated on the packaging, for exchange.
d. Purge the balloon. Fill a 10 or 20 cc luer lock syringe with 1 to 3 cc of the diluted contrast medium. Connect a stopcock to the hub of the delivery system. Connect a syringe to the stopcock. Position the syringe vertically with the plunger pointing upwards. Apply strong suction with the syringe to evacuate all air from the balloon. Maintain the suction for 15-20 seconds and make sure that no more bubbles are seen passing through the diluted contrast medium. Release the suction carefully. Repeat this procedure if necessary. Once the purge is effectuated, do not apply negative pressure. Maintain neutral pressure and close the stopcock.
e. Connect the inflation system with the utmost care to avoid air bubbles entering the system.

Note: Do not apply positive or negative pressure before insertion of the balloon at the lesion site.

B. Implantation procedure

Standard techniques for placement of an approximately sized introducer sheath, guiding catheter and guide wire should be employed during use with the 3V-KROME.
A guiding catheter with a minimum lumen diameter of 0.058".
Insert the guide wire (0.014'' max) into the guiding catheter with a minimum lumen diameter of 0.058'' and advance it through to the target lesion site. To avoid movement of the guide wire, tighten the "Y" access

system, so that the guide wire is firmly rounded in the "Y" access system.

1. Pre-dilatation

Pre-dilate using a catheter approved for coronary dilatation selecting a length and diameter corresponding to the lesion to be stented. For pre-dilatation, please follow the manufacturer's instructions for use for preparation and utilization of the pre-dilatation catheter. Withdraw the catheter after pre-dilatation.

Note: A non-pre-dilatation (Direct Stenting) technique may be considered in the patients who present the following criteria:

- Age ≥ 18 and ≤ 75 years,
- Reference vessel diameter 3.00 – 5.00 mm,
- De novo and re-stenotic lesions ≤ 40 mm,
- Recent (≤ 6 months) history of angina,
- Myocardial infarction ≥ 72 hours,
- TIMI 3 Flow in target vessel,
- No angiographic evidence of calcium, severe tortuosity, ≥ 90° angulation at lesion.

2. Stent placement

a. Attach the "Y" access system to the guiding catheter, which has been previously placed in the vasculature. The choice of the guide wire and the "Y" access system remains the responsibility of the physician within a compatibility limit of 0.014" for the guide wire. Insert the guide wire (0.014" max.) into the guiding catheter and advance it to through the tip. To avoid any movement of the guide wire, tighten the "Y" access system, so that it closes firmly around the guide wire. Back-load the guide wire into the distal tip of the 3V KROME ensuring that it exits through the notch located approximately 25 cm proximal to the dilatation catheter tip. Open the "Y" access system and advance the 3V KROME to the distal end of the guiding catheter.

Note: The two markers located on the proximal part of the shaft may be used to estimate when the 3V KROME intracoronary stent system has reached the distal end of the guiding catheter (depending on whether the approach is brachial or femoral).

Caution: *If resistance is felt, use fluoroscopy to determine the cause of resistance before proceeding.*

b. Confirm stent position using standard angiographic techniques. For optimal results the entire stenosed arterial segment should be covered by the stent.

Caution: *Expansion of the stent should not be undertaken if the stent is not properly positioned in the stenotic segment of the vessel. If the position of the stent is not optimal, it should be repositioned or removed. (See Chapter 9 of the instructions for use: Removal of an unexpanded stent).*

c. Inflate the balloon to a minimum pressure of 8 bars in order to deploy the stent. The inflation pressure should not exceed the Rated Burst Pressure. (See Chapter 8 of the instructions for use: Compliance chart for the 3V KROME delivery system). All efforts should be taken to ensure that the stent is not under dilated, and that the stent is in full contact with the arterial wall upon deflation of the delivery balloon.

d. After stent deployment, deflate the balloon. When the balloon is completely deflated withdraw the catheter leaving the guide wire in place across the stenosis. Visual observation should be used to determine proper stent deployment. The final stent internal diameter should match the size of the reference vessel diameter.

3. Post dilatation

a. If the stent expansion requires optimization, re-advance the 3V KROME delivery balloon or another balloon catheter of the appropriate size to the stented area using standard angioplasty techniques.

b. Inflate the balloon to the desired pressure while observing under fluoroscopy. Deflate the balloon.

c. Reconfirm stent deployment and angiographic result. Repeat inflations until the desired result is achieved.

d. After deflation, slowly withdraw the balloon catheter, guide wire and guiding catheter.

4. Recommended drug regimen

The following drug regimen is provided only as a guide. Patients should receive adequate anti-platelet and anti-coagulation therapy as determined by their physician.

The anti-platelet and anti-coagulation regimen utilized in numerous trials and registries cite the use of Aspirin (Acetylsalicylic acid, ASA) 325 mg daily and Ticlopidine 250 mg twice daily. Aspirin should be continued for at least one year and Ticlopidine for a maximum of thirty days. The patient's primary care physician should institute appropriate biweekly safety monitoring.

8. Inflation pressure

We recommend a deployment pressure for the 3V KROME intracoronary stent system of minimum 8 bars.

Compliance Chart for the 3V KROME Delivery System

Pressure (atm)	Balloon Diameter (mm)						
	2.25	**2.50**	**2.75**	**3.00**	**3.50**	**4.00**	**4.50**
2	1.98	2.20	2.42	2.64	3.08	3.52	3.96
3	2.03	2.25	2.48	2.70	3.15	3.60	4.05
4	2.07	2.30	2.53	2.76	3.22	3.68	4.14
5	2.12	2.35	2.59	2.82	3.29	3.76	4.23
6	2.16	2.40	2.64	2.88	3.36	3.84	4.32
7	2.21	2.45	2.70	2.94	3.43	3.92	4.41
8*	2.25	2.50	2.75	3.00	3.50	4.00	4.50
9	2.28	2.54	2.79	3.05	3.55	4.06	4.57
10	2.32	2.58	2.83	3.09	3.61	4.12	4.64
11	2.35	2.61	2.87	3.14	3.66	4.18	4.70
12	2.39	2.65	2.92	3.18	3.71	4.24	4.77
13	2.42	2.69	2.96	3.23	3.77	4.31	4.85
14	2.46	2.74	3.01	3.29	3.83	4.38	4.93
15	2.50	2.78	3.06	3.34	3.89	4.45	5.01
16**	2.54	2.83	3.11	3.39	3.96	4.52	5.09
17	2.58	2.86	3.15	3.44	4.01	4.58	5.15
18	2.61	2.90	3.19	3.48	4.06	4.64	5.22

** Nominal Pressure*

*** Rated burst pressure except for balloon diameters superior to 4.00mm and for balloon diameter 4.00mm with length higher than 20mm (14bars)*

9. Removal of an unexpanded stent

- **Precautions**

Expansion of the stent should not be undertaken if the stent is not approximately positioned in the vessel. If the position of the stent is not optimal, it should not be expanded. In the case when an unexpanded stent must be withdrawn, ensure that the stent is not damaged or displaced and that the guiding catheter is coaxially positioned relative to the stent system and cautiously withdraw the stent into the guiding catheter. If unusual resistance is encountered when withdrawing the stent towards the guiding catheter, the entire system (guiding catheter and delivery system) should be removed and replaced (Refer paragraph 9b).

- **Removal in case of resistance**

Subsequent movement in and out through the distal end of the guiding catheter should

not be performed as the stent may be damaged when retracting the un-deployed stent back into the guiding catheter. If unusual resistance is felt at any time during either the lesion access or removal of the delivery system post-stent implantation, the entire system should be removed as a single unit.
When removing the 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 to the coronary artery into the coronary anatomy as far distally as safely possible
- Tighten the "Y" access system valve to secure the delivery system to the guiding catheter, and then remove the guiding catheter, the guide wire and the delivery system as a single unit.

Failure to follow these steps and/or applying excessive push or pull force to the 3V KROME intracoronary stent 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.
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.

10. Known potential complications

a. Short and medium term

- Nausea and vomiting
- Arterial fistula
- Dissection or perforation of the coronary artery
- Injury or rupture of the coronary artery
- Total occlusion
- Thrombosis
- Arterial spasm
- Ventricular fibrillation
- Disturbance of cardiac conductibility
- Bradycardia
- Embolism
- Side branch occlusion
- Entry site complications

➔ These complications can directly result in the patient's death.

b. Long term

- Emergency or non-emergent Coronary Artery Bypass Graft Surgery
- Restenosis of the dilated artery
- Unstable angina
- Ischemia
- Acute myocardial infarction
- Disturbance of cardiac conductibility
- Bleeding complications

➔ These complications can directly result in the patient's death.

11. 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.

12. Storage requirements

Use before the expiry date clearly indicated on the label.
Store at room temperature 0°C - 40° C, in a dry place, protected from light.

13. Packaging and product range

One unit per box. Sterile packaging.
Sterilized by Ethylene Oxide. Non pyrogenic.

Lengths and diameters available

Stent Length (mm)	Balloon Diameter (mm)						
8	2.25	2.50	2.75	3.00	3.50	4.00	4.50
12	2.25	2.50	2.75	3.00	3.50	4.00	4.50
16	2.25	2.50	2.75	3.00	3.50	4.00	4.50
20	2.25	2.50	2.75	3.00	3.50	4.00	4.50
24	2.25	2.50	2.75	3.00	3.50	4.00	4.50
28	2.25	2.50	2.75	3.00	3.50	4.00	4.50
32	2.25	2.50	2.75	3.00	3.50	4.00	4.50
36	2.25	2.50	2.75	3.00	3.50	4.00	4.50
40	2.25	2.50	2.75	3.00	3.50	4.00	4.50

14. Conversion Chart

1cc	1 mL.		
1 French	0.0131"	0.33 mm	
1 bar	0.98 atm	14.5 PSI	10^5 Pa

15. Symbols meaning

Qty	Quantity per box
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

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