BOSS SUPPORT CATHETER
INSTRUCTIONS FOR USE

PLEASE READ ALL INSTRUCTIONS PRIOR TO USE

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

Device Description

The Boss Crossing Support Catheter (Boss CSC) is intended to guide and support a guidewire during access of the peripheral vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or other diagnostic devices. The proposed device is intended for single use and is provided sterile using Ethylene Oxide gas. The device is available as two low profile catheters, 2.4F and 3.9F, in the lengths of 90cm to 150cm which are compatible with 0.018" and 0.035" guidewires, respectively. Both catheter shafts are composed of a high performance thermoplastic material in a monolithic single layer construction. The proximal end of each catheter includes a standard catheter hub with luer fitting and a strain relief. The distal end of both catheters are equipped with a single platinum/iridium RO marker which enables visibility under fluoroscopy. There is a hydrophilic coating on the distal portion of each catheter shaft to enhance lubricity. The device is provided either as a kit containing one of each size catheter, or as a single pack containing only one catheter.
Each catheter is packaged in an individual spiral HPDE hoop that is secured to a HDPE card and placed inside a Tyvek Mylar pouch.

There are six versions of the device offered:

1. 3.9F/90cm length catheter packaged with a 2.4F/150 cm length catheter
2. 3.9F/90cm length catheter packaged with a 2.4F/135 cm length catheter
3. 3.9F/90cm length catheter packaged individually
4. 2.4F/150cm length catheter packaged individually
5. 2.4F/135cm length catheter packaged individually
6. 2.4F/90cm length catheter packaged individually

Figure 1. BOSS Support Catheter

Indication for Use

The Boss Crossing Support Catheter (Boss CSC) is Indicated to guide and support a guidewire during access of the peripheral vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or diagnostic contrast agents.

Contraindications

- Patients with a contraindication to anti-platelet and/or anti-coagulation therapy
- Women who are pregnant or supposed to be pregnant
- Do not use in the cerebral vasculature or the coronary arteries.

Potential Complications/Adverse Events

Bleeding Complications	Intra-vessel Thrombosis
Allergic Reaction to Drugs	Femoral Pseudoaneurysm / Pseudoaneurysm Formation / Vessel spasm
Distal Embolization	Vessel Injury / Perforation / Dissection
Hypotension	Vessel Embolism / Occlusion
Infection / Pain at Puncture Site	Arrhythmia
Arteriovenous Fistula	Hemorrhage and Hemorrhagic Shock
Hematoma	Fever/chill
Bradycardia and Palpitation	Nausea and Vomiting
Death	

Warnings and Precautions

Warnings:

- Do not exceed the maximum infusion pressure of 300psi.
- **Do not** heat or bend the catheter tip. Abrasion of the hydrophilic coating or damage to the catheter may result.
- Avoid introducing air or any other gas through the catheter into the vascular system.
- The catheter should not be advanced into a vessel having a reference vessel diameter smaller than the OD of the catheter.
- The catheter should not be advanced through an area of resistance unless the source of resistance is identified by fluoroscopy and appropriate steps are taken to remove or reduce the obstruction.
- Carefully handle the product under fluoroscopy. If any resistance is felt while handling the product, immediately stop the manipulation and find out the cause to avoid damage to blood vessels and separation or breakage of the product.
- **Do not** torque the product excessively while the distal part of the product is positioned across a stenosis or within a stent
- Take extra care when exchanging a guide wire while leaving the product in the vessel. Carefully insert a guide wire into the product. If any resistance is felt, stop the manipulation and remove the product with the guide wire to avoid separation or breakage of the product.
- Perform appropriate anticoagulant or antiplatelet therapy according to the patient's condition to avoid complications, such as thrombotic embolization.

Precautions:

- This product must only be used by physicians who are qualified to perform percutaneous endovascular interventions using over the wire devices.
- Catheter manipulation should only be performed under fluoroscopic guidance
- This product has been sterilized by ethylene oxide gas. For single use only. Do not reuse. Do not re-sterilize. Do not reprocess. Reprocessing may compromise the sterility, biocompatibility and functional integrity of the device.
- Sterile and non-pyrogenic in an unopened and undamaged unit packaging. Do not use if the unit package or the product has been damaged or soiled.
- Use immediately after opening the package. Dispose of safely after single use to avoid risk of infection.
- Use the product prior to the expiry date indicated on the package.
- The catheter should be examined to verify functionality and to ensure that its size and shape are suitable for the specific procedure for which it is to be used.

Catheter Flow Rates*

- Maximum infusion pressure is 300psi. Minimum infusion flow rates at 300 psi for the BOSS 2.4F and 3.9F catheters at 37C are provided below:

BOSS Catheter	Sterile Saline @ 300psi	Contrast Media** @ 300psi
2.4F	1.3 mL/Sec	0.4 mL/Sec
3.9F	9.1 mL/Sec	6.8 mL/Sec

***Catheter Flow Rates are approximate values**
**** 100% Omnipaque (Omnipaque is a Registered Trademark of Amersham Heath, Princeton NJ, USA)**

Directions For Use

1. Remove the device in its packaging card from the pouch
2. Leaving the catheter in its hoop, flush the lumen by injecting at least 3.0 cc heparinised saline through the catheter hub
    a. Note: Flushing the catheter within the hoop will activate the hydrophilic coating and keep it activated until it is removed from the hoop prior to use.
    b. Once removed from the hoop, the catheter surface may become dry if not used immediately. Soak the catheter prior to use in heparinized saline to lubricate the surface. Additional wetting with heparinised saline solution will reactivate the hydrophilic coating

CAUTIONS

- **Do not** bend the product at the edge of the holder. The product may break or separate,
- **Do not** use if the catheter has been damaged or any other anomaly is observed.

3. Insert the product over the wire into a hemostatis valve attached to the guiding catheter or sheath.

CAUTIONS

- Take care not to damage the product when a guide wire is inserted from its distal end.
- Use a guide wire of an appropriate diameter.
- Use a guiding catheter or sheath with an appropriate inner diameter.
- Make sure the that the hemostasis valve is open enough for insertion of the product. If not, the product damage may occur.

Do not advance the guidewire briskly and/or force it into the catheter when the catheter is bent or twisted. This may cause breakage/separation of the catheter, resulting in damage to the vessel.

4. Under fluoroscopic guidance, introduce the catheter into the vascular system using standard endovascular techniques.
5. Advance the catheter over the guidewire to the target vessel under fluoroscopy using standard endovascular techniques
6. Advance the guide wire and the product to the target under fluoroscopy.

CAUTIONS

-Manipulate the product slowly and carefully in the vessel to avoid product damage or patient injury.
-**Do not** insert the product into a vessel with a smaller diameter than the outer diameter of the product to avoid product damage or patient injury.
-**Do not** torque the product if it is or seems stuck in order to avoid Product damage or patient injury

7. If injection of contrast media is required, withdraw the guidewire and inject the contrast media from the catheter hub.

CAUTIONS

- Before starting infusion, verify that the catheter has not been kinked or blocked. Ignoring this warning may cause the catheter to break/ rupture/separate, resulting in damage to the vessel.
- When injecting contrast media, do not exceed the maximum permissible infusion pressure of 300 psi (2,068kPa).

8. Open the hemostasis valve. Withdraw the product along the guide wire leaving the guide wire inside the vessel. Close the hemostasis valve after removing the product.

CAUTIONS

- Confirm position of the guide wire under fluoroscopy when the product is removed.
- Remove the product, the guide wire and the guiding catheter or sheath together if any resistance is felt while withdrawing the product.
- After removal, the catheter should be rinsed with heparinized saline solution to remove blood residues from the catheter's surface.
- If blood residues do not come off, wipe gently once with a gauze soaked with heparinized saline solution. Do not use disinfectants, which can compromise the integrity of the hydrophilic coating. If necessary, flush the lumen of the catheter with heparinized saline solution to remove blood residues.

How Supplied

The device is supplied sterilized by ethylene oxide gas in peel-open packaging. This product is intended for one-time use. Sterile if the packaging is presented unopened or undamaged. Do not use the product if there is doubt to sterility of the device.

Storage Conditions

Avoid exposure to water, direct sunlight. Extreme temperature or high humidity storage.
Store in a dark, dry and cool place. Upon removal from package, inspect the product to ensure no damage has occurred.

Symbols Glossary

Catalogue number

Contents

Sterilized using ethylene oxide

Do not reuse

Batch code

Use by date

Stacking limit by #

Consult instructions for use

Keep dry

Fragile

Keep away from sunlight

Do not use if package is damaged

Manufacturer

Max guide wire outer diameter

Maximum injection pressure

Non-pyrogenic

Prescription Device

Legal Manufacturer

Marvao Medical Devices Ltd
Unit 1 Galway Business Park,
Dangan, H91 A3EF
Galway, Ireland
Email: info@marvaomedical.com
Phone: + 353 91 759 301