HV, HVRO & MicroAccess Sheath Introducer Kits: Instructions for Use

Description

A Kimal Micro HV Sheath Introducer Kit is comprised of two parts. The Introducer assembly consists of a dilator and an outer Sheath body that permits entry of a catheter/guidewire once the inner dilator is removed. The sheath body and dilator have a proximal female luer attachment to allow syringe connection and guidewire entry. The Introducer valve is haemostatic and includes a sidearm with stopcock for fluid administration and a suture ring for securement.

In HV Sheath Introducer kits the 0.035-38" spring-coil guidewire is constructed of stainless steel with one 3mm J tip end and a straight flexible end

In HVRO MicroAccess sheath Introducer kits the 0.018" spring-coil tip guidewire is constructed either of a nitinol core with platinum tip or a stainless steel core with stainless steel tip.

Indications for Use

The Kimal HV Sheath Introducer Kits are intended to facilitate introduction of catheters and guidewires into the vascular system following a successful Seldinger needle puncture and introducer placement.

Relative Contraindications

Use of the Introducer is contraindicated if the patient has known or suspected obstruction in the vessel. There is an increased risk of pneumothorax in patients with chronic lung disease.

Potential Complications

The potential complications related to the use of the introducer include, but are not limited to the following: air embolism, wound infection, intimal tear, subclavian artery puncture, pneumothorax, subclavian vein thrombosis, bleeding, cardiac arrhythmia, haematoma formation, haemothorax, hydrothorax, thoracic duct injury, vessel erosion.

When using an introducer, potential exists for thrombus formation or emboli and plaque dislodgement.

Precautions Prior to Use

Store in a dry, dark, cool place. Do not use if package is open or damaged. Inspect all components prior to use.

It is recommended that all components be flushed with a heparinised saline solution prior to use. The device should only be used by a physician trained in the technique of percutaneous vessel entry and familiar with the complications of angiographic or percutaneous procedures.

Precautions

Withdrawal of the guidewire back through a metal needle may damage the guidewire and/or its coating.

Caution should be exercised if resistance is encountered when advancing the guidewire or sheath introducer into the vessel. Use fluoroscopy to determine the cause before continuing.

Do not expose the product to organic solvents e.g. alcohol.

Damage to the valve assembly may occur if the dilator or a catheter is left in the valve for extended periods or if the inner catheter is withdrawn too rapidly.

Never manipulate a guidewire if resistance is encountered. If resistance is felt, discontinue the procedure and remove the guidewire or the guidewire and device as a single unit

Disclaimer

The condition of the device must be verified prior to use. Kimal is not responsible for any damage to person, property, etc. from any inappropriate or unrecommended use of the device(s), including reuse.

For single use only. Do not re-sterilize, reprocess, or reuse. 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. Reuse, 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(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Use sterile technique, a suggested procedure:

1. Peel open package and place contents on sterile field. Inspect catheter introducer and accessories for defects. Do not use any defective devices.
2. Flush the Introducer needle (if supplied), dilator, catheter introducer and sideport with normal saline solution.
3. Prep skin and drape in area of anticipated puncture site as desired.
4. Insert needle cannula into vessel. The needle position should be verified by observing blood return.
5. The angle of the needle should be adjusted depending on the patients build: shallow in a thin person, deeper in a heavyset person.

6. Aspirate the puncture needle using a syringe.
7. Remove the syringe and insert soft tip of the guidewire through the introducer needle into the vessel. Advance guidewire to required depth. Leave an appropriate amount of guidewire exposed. At no time should the guidewire be advanced or withdrawn when resistance is met. Determine the cause of resistance before proceeding. Fluoroscopic verification of the guidewire location is suggested.
8. Hold guidewire in place and remove introducer needle. Do not withdraw the guidewire back into the cannula as this may result in separation of the guidewire. The cannula should be removed first.

CAUTION: Do not allow Guidewire to advance totally into patient.

9. Assemble the introducer set by carefully inserting the dilator completely into sheath introducer. Firmly push the snap fit ring on the dilator into the sheath valve cap.
10. When using an introducer with a sideport, follow standard hospital practice for using a continuous drip of normal saline solution through the sideport while the hemostasis introducer is in the vessel.
11. While holding the catheter introducer set close to the skin, advance the dilator and sheath together with a twisting motion over the guidewire and into the vessel. Fluoroscopic observation may be advisable. Attaching a clamp or haemostat to the proximal end of the guidewire will prevent inadvertently advancing the guidewire entirely into the patient.
12. To detach the dilator from the sheath cap, push the dilator hub to one side until it becomes detached. Remove the vessel dilator and guidewire, leaving the sheath as a conduit into the vessel.
13. Introduce the selected catheter or other device into the sheath using the instructions provided by the manufacturer of the catheter or other device, and standard hospital practice.
14. To change catheters, slowly withdraw the catheter from the vessel and repeat the insertion procedure.

CAUTION: When removing the catheter, aspirate via the sideport extension to collect fibrin that may have been deposited at the tip of the sheath.

Dilator, insertion and withdrawal:

- For occlusion of sheath, use dilator of same size as sheath.
- For flushing and infusion, use a dialtor one French size smaller than the designated sheath size.
- While holding the sheath in place, slide the dilator through the sheath valve and firmly push the snap fit ring into the sheath valve cap.
- Attach a flushing line to the sheath sideport extension and flush.
- Establish an infusion drip via the sideport extension per hospital protocol.
- While holding the sheath in place, place thumb and index finger between the sheath and dilator hubs, squeeze firmly and withdraw.

CAUTION: When removing the dilator, aspirate via the sideport extension to collect any fibrin that may have deposited at the tip of the sheath.

Summary safety and clinical performance (SSCP)

The Summary of Safety and Clinical Performance (SSCP) can be referenced on the Eudamed public website (https://ec.europa.eu/tools/eudamed) or can be requested directly from Kimal (regulatory_department@kimal.co.uk)

Serious adverse events

If a serious adverse event occurs, please report it to Kimal at vigilance@kimal.co.uk and to your national competent authority.


Manufacture

Sterilised by ethylene oxide

Product does not contain latex

Do not re-sterilise


Do not re-use


Do not use if package is damaged


Keep out of sunlight


Keep dry

Medical device


Consult instructions for use

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