Micro-Access Elite HV®
Hemostasis Valve Introducer Kits
Instructions for Use

Package Contents: •One-Sheath •One-Dilator •One-Guidewire (Stainless/Stainless or Nitinol/Gold) •One-Echo Needle (4cm or 7cm)

Do not reuse

Do not resterilize

Consult instructions for use

Store at room temperature

Manufacturer

Date of manufacture

Non-pyrogenic Fluid path

STERILE EO
Sterilized using ethylene oxide

Do not use if the product sterilization barrier or its packaging is compromised

DEHP
DEHP free

LATEX
Components and packaging do not contain natural rubber latex

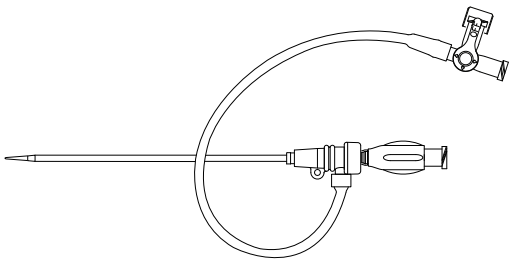
LOT
Batch code

REF
Catalog number

MODEL NUMBER
Model number

Use by

Rx only



Picture for reference only.

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Refer to Micro-Access Elite HV® Hemostasis Valve Assembly for French Size Color Identification:

4F	5F	6F	7F
Red	*Lt. Grey*	*Green*	*Orange*

Instructions for Use:

Contents of unopened, undamaged package are:
STERILE • NONPYROGENIC*
Disposable - This device is intended for one use only.
Do not reuse or resterilize.
Sterilized with Ethylene Oxide.

Device Description:

The Micro-Access Elite HV® Hemostasis Valve Introducer System consists of a dilator, echo-needle, guidewire, and sheath with a hemostasis valve and a sideport on the most proximal end of the sheath assembly.
The Micro-Access Elite HV® Introducer System is designed to facilitate percutaneous introduction of catheters into the vascular system while minimizing blood loss.

Indications for Use:

The Micro-Access Elite HV® Introducer Sytem is indicated for use in percutaneous procedures to introduce catheters and other intravascular devices into the vasculature.

Contraindications:

Use of the introducer is contraindicated if the patient has a known or suspected obstruction in the vessel. There is increased risk of pneumothorax for the patient who has severe 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, perforation of the vessel wall, pneumothorax and subclavian vein thrombosis.

Precautions:

Do not use if package is open or damaged. Inspect all components prior to use. Store at room temperature.

*Nonpyrogenic refers to fluid pathway only.

Cautions:

This procedure should only be performed by physicians thoroughly trained in this procedure. If resistance is met when advancing or withdrawing the guidewire or the introducer sheath, determine the cause by fluoroscopy and correct before continuing with the procedure.

Because of the delicate and fragile nature of guidewires, extra care in handling must be taken.

Do not expose to organic solvents, eg. alcohol.

Do not attempt to use a guidewire larger then the maximum diameter specified on the package label.

Individual patient anatomy and physician technique may require procedural variations.

Insertion into artery may cause excessive bleeding and/or other complications.

Do not leave a catheter introducer sheath in place for extended periods of time without a catheter or an obturator to support the cannula wall.

Damage to the valve assembly may occur under the following circumstances:

- Obturator or catheter in valve assembly for extended periods.
- Inner catheter is withdrawn too rapidly.

Warnings:

Do not alter this device in any way. Do not reuse this device.
Do not withdraw guidewire through metal needles; guidewire may shear or unravel. Do not resterilize.

USE STERILE TECHNIQUE, A Suggested Procedure:

1. Peel open package and place contents on sterile field. Inspect catheter introducer sheath and accessories for defects. Do not use any defective devices.
2. To remove air, flush the dilator, catheter introducer sheath 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 patient's 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 the 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 system by carefully inserting the dilator completely into the 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 system 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 hemostat 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.

OBTURATOR Insertion And Withdrawal:

1. For occlusion of sheath, use obturator of same size as sheath.
2. For flushing and infusion, use an obturator (supplied separately) one french size smaller than the designated sheath size.
3. While holding the sheath in place, slide the obturator through the sheath valve and firmly push the snap fit ring into the sheath valve cap.
4. Attach a flushing line to the sheath sideport extension and flush.
5. Establish an infusion drip via the sideport extension per hospital protocol.
6. While holding the sheath in place, place thumb and index finger between the sheath and obturator hubs, squeeze firmly and withdraw.

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

Manufactured for:
B. Braun Interventional Systems Inc.
824 Twelfth Avenue
Bethlehem, PA 18018
www.bisusa.org
Made in U.S.A.

Customer Service, ordering:
TEL: (877) VENA-CAV (836-2228)
FAX: (610) 849-1334

Technical Support:
TEL: (800) 443-VENA (8362)

Manufacturer:
GALT MEDICAL CORP.
2220 Merritt Drive
Garland, TX 75041