D'VILL™ Introducer

INSTRUCTIONS FOR USE

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Read all instructions prior to use

Interventional Systems
B BRAUN

Distributed by:
B. Braun Interventional Systems Inc.
824 Twelfth Avenue
Bethlehem, PA 18018
Customer Service:
TEL: (877) 836-2228
FAX: (610) 849-1334
Technical Support
TEL: (800) 443-8362
www.bisusa.org
Made in U.S.A.

IFU-700B Rev:01
28 June 2019

Manufactured by:
NuMED, Inc.
2880 Main Street
Hopkinton, NY 12965

Instructions for Use:

INDICATION: Recommended for introduction of balloons, catheters and other diagnostic and interventional devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.

DESCRIPTION

The NuMED D'VILL Introducer consists of a dilator and sheath, with a hemostasis valve and side port on the proximal end of the sheath assembly. There is a single image band embedded in the distal end of the sheath tubing for imaging purposes.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas. Sterile and non-pyrogenic if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

CONTRAINDICATIONS

None known.

WARNINGS

- Administer appropriate anticoagulation therapy to reduce potential thrombosis. If the patient is not appropriately anticoagulated, thrombus formation may occur.
- Contrast should not be injected through the side port with an auto-injector device.
- The maximum diameter of the device to be introduced should be determined to ensure passage through the sheath. All devices used with this product should move freely through the valve and sheath. Damage to the sheath may result when the fit is tight.
- If vessel size if smaller than the introducer sheath outer diameter, major bleeding, vessel damage, or serious injury to the patient, including death, may result.
- Always keep the sheath in position when inserting, manipulating or withdrawing a device through the sheath.
- Aspirate through the side-arm of the valve to clear the sheath, then flush with heparinized solution before removing or inserting devices through the sheath.
- Always make sure the balloon has cleared the tip of the sheath before inflating.
- Use caution to avoid damage to the sheath when puncturing, suturing or incising tissue near the sheath.
- Do not advance the sheath or any other component if resistance is met, without first determining the cause and taking remedial action.
- This device is intended for single use only. Do not resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of cross-contamination.
- The device should be used prior to the 'Use By' date noted on the package label.

PRECAUTIONS

- Only physicians who have received appropriate training and are familiar with the principles, clinical applications, side effects and hazards commonly associated with vascular interventional procedures should use this device.
- Proper functioning of the device depends on its integrity. Care should be used when handling the device. Damage may result from kinking, stretching, or forceful wiping of the device.
- Guidewires are delicate instruments. Care should be exercised while handling to help prevent the possibility of breakage.
- Careful attention must be paid to the maintenance of tight connections and aspiration before proceeding to avoid air introduction into the system.
- Under no circumstances should any portion of the introducer be advanced against resistance. The cause of the resistance should be identified with fluoroscopy and action taken to remedy the problem.
- If resistance is felt upon removal, all components should be removed together as a unit, using a gentle twisting motion combined with traction.
- Before removing a catheter from the introducer, it is very important that the balloon is completely deflated.

POTENTIAL COMPLICATIONS

- Potential complications related to the use of an introducer include, but are not limited to, the following: infection, air embolism, hematoma formation and perforation of vessel.

INSPECTION AND PREPARATION

1. Upon removal from package, inspect device for defects.
2. Ensure the inner diameter (ID) of the sheath is appropriate for the maximum diameter of the device being introduced.
3. Using the side-arm of the valve, flush the sheath by completely filling with heparinized solution.
4. Flush the dilator with heparinized solution.
5. Carefully insert the dilator completely into the sheath.

INTRODUCTION

1. Using standard Seldinger technique, access the target vessel with the appropriate needle.
2. Insert guidewire into vessel through the needle. Remove needle, leaving guidewire in place.
3. Advance dilator/sheath combination over guidewire.
4. Remove dilator. Aspirate and flush side-arm.
5. Insert selected device using instructions provided by the manufacturer of the device.

REMOVAL

1. Withdraw the sheath.
2. Remove the guidewire.
3. Apply pressure to the insertion site according to standard practice or hospital protocol for percutaneous vascular procedures.

WARNING

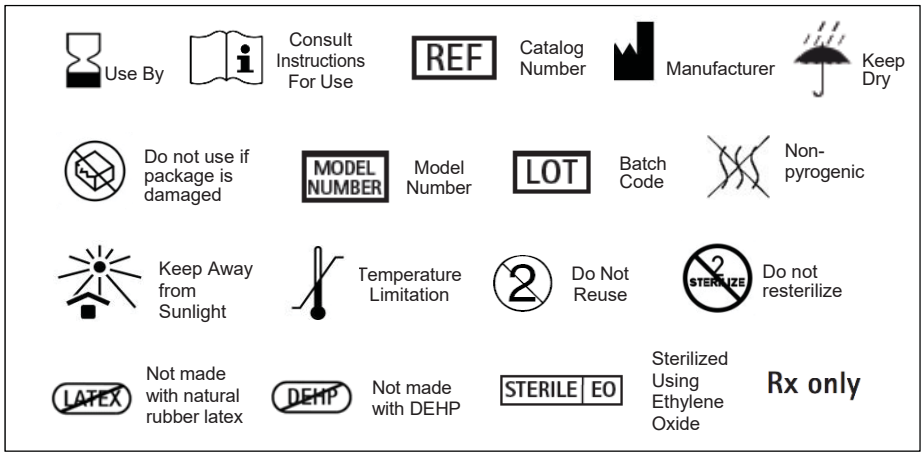
NuMED devices are placed in the extremely hostile environment of the human body. Devices may fail to function for a variety of causes including, but not limited to, medical complications or failure of devices by breakage. In addition, despite the exercise of all due care in design, component selection, manufacture and testing prior to sale, devices may be easily damaged before, during, or after insertion by improper handling or other intervening acts. Consequently, no representation or warranty is made that failure or cessation of function of devices will not occur or that the body will not react adversely to the placement of devices or that medical complications will not follow the use of devices.

NuMED cannot warrant or guarantee NuMED accessories because the structure of the accessories may be damaged by improper handling before or during use. Therefore, no representations or warranties are made concerning them.

Warranty and Limitations

Devices and accessories are sold in an 'as is' condition. The entire risk as to the quality and performance of the device is with the buyer. NuMED disclaims all warranties, expressed or implied, with respect to devices and accessories, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose. NuMED shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from the use of any device or accessory or caused by any defect, failure, or malfunction of any device or accessory, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind NuMED to any representation or warranty with respect to devices and accessories.

Description of Graphical Symbols



D'VILL is a trademark of NuMED, Inc.