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Cerenovus Large Bore Catheter

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ENGLISH

IMPORTANT INFORMATION
Please read before use

Cerenovus Large Bore Catheter

STERILE | EO

℞ Only

Description
The Large Bore Catheter is a single lumen, variable stiffness catheter. The catheter has a hydrophilic coating on the distal 30 cm to reduce friction during use. The catheter includes a radiopaque marker on the distal end for angiographic visualization and a luer hub on the proximal end. A hemostasis valve and two peelable introducers are included in the package.

Indications for Use
The Cerenovus Large Bore Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the neurovascular system. The Large Bore Catheter is also indicated for use as a conduit for retrieval devices.

Contraindications
None known.

WARNINGS
- When used as a conduit for retrieval devices, the Large Bore Catheter has not been evaluated for use with more than three (3) retrieval device attempts. See labeling for the retrieval device for additional instructions for use.
- The Large Bore Catheter should only be used by physicians trained in interventional endovascular procedures at medical facilities with the proper imaging equipment.
- Limited testing has been performed with solutions such as contrast media and saline. The use of these catheters for delivery of solutions other than the types that have been tested for compatibility is not recommended.
- Do not use with Ethiodol or Lipiodol contrast media, or other such contrast media which incorporates the components of these agents.
- The appropriate anti-coagulation and anti-platelet therapy should be administered in accordance with standard medical practice.
- This device is not intended use for use with power injectors.
- If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter damage or patient injury. Remove and replace catheter.
- Do not advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the device against resistance could damage the device or cause patient injury.
- Torqueing the catheter excessively while kinked may damage the device, resulting in separation of the catheter shaft. Withdraw the entire device (the device, microcatheter, and guidewire) if the device is severely kinked.
- Dispose of all used devices in accordance with hospital policy for biohazardous materials.
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution through catheter lumen.
- This device is coated with a hydrophilic coating at the distal end of the device for a length of 30 cm. Please refer to the Preparation for Use Section for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

Precautions
Inspect the sterile package carefully. Do not use if:
- The package or seal appears damaged,
- Contents appear damaged, or
- The expiry date has passed.

- Carefully inspect all devices prior to use. Verify size, length, and condition are suitable for the specific procedure. Do not use a device that has been damaged in any way; replace with another Large Bore Catheter. A damaged device may cause complications.
- Exercise care in handling the Large Bore Catheter to reduce the chance of accidental damage.
- To control the proper introduction, movement, positioning and removal of the catheter within the vascular system, users should employ standard clinical angiographic and fluoroscopic practices and techniques throughout the interventional procedure.
- If removed from the patient, the hydrophilic coating on the Large Bore Catheter should be hydrated with heparinized saline. Do not allow the coating to dry.
- Avoid wiping the device with dry gauze as this may damage the device coating.
- Avoid excessive wiping of the coated device.
- Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance.
- Limit the exposure to X-ray radiation doses to patients and physicians by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors when possible.

Potential Adverse Events
Potential adverse events associated with the use of catheters or with the endovascular procedures include, but are not limited to:
- Access site complications
- Allergic or anaphylactic reaction
- Aneurysm perforation
- Aneurysm rupture
- Arrythmia
- Cardiac complications
- Cerebral edema
- Cerebral infarct
- Death
- Embolism (air, foreign body, plaque, thrombus)
- Hematoma
- Hemorrhage
- Hypo/hypertension
- Infection
- Inflammation or granuloma at access site
- Ischemia
- Neurological deficits
- Pseudoaneurysm
- Renal insufficiency
- Respiratory complications
- Seizure
- Stroke
- Tissue necrosis
- Transient Ischemic Attack
- Vasospasm
- Vessel dissection
- Vessel occlusion
- Vessel perforation
- Vessel rupture
- Vessel thrombosis

Use of device requires fluoroscopy which presents potential risks to physicians and patients associated with x-ray exposure. Possible risks include, but are not limited to, the following:

- Alopecia
- Burns ranging in severity from skin reddening to ulcers
- Cataracts
- Delayed neoplasia

How Supplied

The Cerenovus Large Bore Catheter is intended for SINGLE USE ONLY; DO NOT RESTERILIZE. Use aseptic technique in all phases of handling. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning. Catheters are extremely difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused.

Cerenovus will not be responsible for any product that is resterilized, nor accept for credit or exchange any product that has been opened but not used.

As long as the inner pouch is not opened or damaged, the product is sterile and nonpyrogenic.

Preparations for use

1. Set-up continuous flush through guide sheath, balloon guide, or guide catheter lumen.
2. Select an appropriately sized catheter based on intended procedure and anatomy.
3. Before removing the Large Bore Catheter from the packaging hoop dispenser, rotate the luer on the packaging hoop 90 degrees. Attach a syringe containing minimum 20 cc heparinized saline to the luer connector at the end of the hoop dispenser. Flush the dispenser to hydrate the hydrophilic coating of the catheter. Failure to do so can compromise the coating and lubricity of the catheter.
4. Gently remove the catheter and accessories from the hoop and inspect prior to use to verify that they are undamaged. Caution: Do not use a catheter that has been damaged in any way. If damage is detected, replace with another Large Bore Catheter that is not damaged.
5. Flush the catheter lumen with heparinized saline solution.
6. Attach compatible hemostasis valve with continuous flush to the catheter.

Directions for Use

1. Insert an appropriately sized guidewire or compatible microcatheter and guidewire into the Large Bore Catheter and advance until the guidewire and the catheter are aligned at the distal end.
2. Using the peel-away introducer sheath provided in the package, insert the catheter and guidewire through a hemostasis valve of the guide sheath, balloon guide, or guide catheter.
3. Remove the peel away introducer sheath from the hemostasis valve and peel the introducer from the catheter once the distal shaft of the Large Bore Catheter is placed inside the patient body.
4. Under fluoroscopic guidance, advance the catheter through the vasculature to the desired location.
   WARNING: Do not advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy.
5. Remove the microcatheter and/or guidewire prior to the introduction of other intravascular devices.
6. When using the Large Bore Catheter as a conduit for retrieval devices:
   a. Refer to the Instructions for Use supplied with the retrieval device for the associated warnings, precautions and instructions for use.
   b. Withdraw the retrieval device into the Large Bore Catheter slowly and carefully, as described in the retrieval device instructions for use.
7. When procedure is complete, remove the Large Bore device using standard technique.
8. If re-access to the vasculatures with the same device is desired, flush and clean the inner lumen of the device by infusion. Inspect the device for any damage. Caution: Do not use the device if any damage or irregularities are observed.

The physician has the discretion to modify described manipulations of the Large Bore Catheter to accommodate the complexity and variation in procedures. Any technique modification must be consistent with previously described instructions, warnings, precautions and patient safety information.

Storage

Store in a cool, dark, dry place.

Warranty

Cerenovus warrants that this medical device is free from defects in both materials and workmanship. **Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer's instructions for use. There are no warranties that extend beyond the description on the face hereof.**

Do not resterilize


Do not use if package is damaged


Manufacturer


Nonpyrogenic

QTY **Quantity**

Do not reuse

RADIOPAQUE **Radiopaque**

DO NOT AUTOCLAVE **Do not Autoclave**


Caution

Consult instructions for use