Echo Intracranial Base Catheter

RX ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Warning

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization 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 resterilization 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. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy. Used product and any associated used materials should be handled and processed as biohazardous material.

Device description

The Echo Intracranial Base Catheter is a single lumen, flexible, variable stiffness catheter with an 0.100 inch inner diameter, designed for use in facilitating the insertion and guidance of appropriately sized interventional devices into the neurovascular system. It has a radiopaque marker band on the distal end and a Luer hub at the proximal end. The distal catheter shaft has a 14 cm lubricious coating to reduce friction during use. It is packaged with a dilator and two Rotating Hemostatic Valves. The Echo Intracranial Base Catheter is compatible with introducer sheaths with an inner diameter of 9F or greater. The device's shaft contains polymers with tallow-derived additives of bovine and porcine origin.

Contents

One (1) Echo Intracranial Base Catheter

One (1) Vascular Dilator

Two (2) Rotating Hemostatic Valves

Dimensions of the Echo Intracranial Base Catheter are included on the individual device label. The Echo Intracranial Base Catheters are available in 2 different lengths, the device configurations are presented in Table 1 below. Compatibility information for the Echo Intracranial Base Catheter is presented in Table 2.

Table 1.0 specifications

Catheter REF	Catheter Inner Diameter in (mm)	Catheter Outer Diameter in (mm) [F]	Effective length (cm)	Overall length (cm)
ECHO100100	0.100 (2.54)	0.118 (3.00) [9]	100	103
ECHO100105	0.100 (2.54)	0.118 (3.00) [9]	105	108

Accessory	Length (cm)
Dilator (ECHO100100)	116
Dilator (ECHO100105)	121
Rotating Hemostatic Valve (RHV) with Lock Feature	8
Rotating Hemostatic Valve (RHV)	7

Table 2.0 compatibility information

Recommended Maximum Guidewire Diameter in (mm)	Recommended Maximum Catheter Outer Diameter in (mm)
0.035 (0.89)	0.098 (2.49)

Intended user

The Echo Intracranial Base Catheter should be used only by physicians trained in percutaneous procedures and/or interventional techniques.

Intended use/Indications for use

The Echo Intracranial Base Catheter is indicated for the introduction of interventional devices into the neurovasculature.

Contraindications

Patients with a known allergy or intolerance to tallow derivative device materials of bovine and porcine origin.

Warnings

- When the Echo Intracranial Base Catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the Echo Intracranial Base Catheter if resistance is met during manipulation; determine the cause of the resistance before proceeding.
- The device is coated with a hydrophilic coating at the distal end of the device for a length of 14 cm. Please refer to the Instructions 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.
- If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.
- Do not use the Echo Intracranial Base Catheter with power injectors.

Precautions

- Do not use a device that has been damaged in any way. Damaged device may cause complications.
- Use the device prior to the "Use By" date specified on the package.
- Exposure to temperatures above 50°C (122°F) may damage device. Do not autoclave.
- Torquing or moving the device against resistance may result in damage to the vessel or device.
- Maintain a constant infusion of appropriate flush solution. To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution through catheter lumen.
- Examine the device to verify functionality and to ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- Operators should take all necessary precautions to limit X-ray radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors whenever possible.
- 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.

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 (Hematoma or Hemorrhage at the puncture site)
- Acute Vessel Occlusion
- Air Embolism
- Allergic reaction and anaphylaxis from contrast media
- Allergic reaction to bovine and porcine tallow-derived materials
- Death
- Distal Embolization
- Emboli
- False Aneurysm Formation
- Infection
- Intracranial Hemorrhage
- Ischemia
- Kidney damage from contrast media
- Neurological Deficit including Stroke, TIA
- Vessel Spasm, Thrombosis, Dissection or Perforation

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