Broadway 8 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.

Device description

The Broadway 8 Catheter is a single lumen, flexible, variable stiffness catheter. It has a radiopaque marker band on the distal end and a luer hub at the proximal end. The Broadway 8 Catheter shaft has a lubricious hydrophilic coating at the distal end (distal 34cm) to reduce friction during use. It is packaged with two Rotating Hemostatic Valves, two peel-away introducer sheaths, and one FastPassTM Delivery Assist Catheter. The FastPass Delivery Assist Catheter has a radiopaque marker band on the distal end, a luer hub at the proximal end, and a lubricious hydrophilic coating at the distal end (distal 45cm) to reduce friction during use. The shaft of the Broadway 8 Catheter and the FastPass Delivery Assist Catheter contain polymers with tallow-derived additives of bovine and porcine origin.

Contents

One (1) Broadway 8 Catheter
One (1) FastPass Delivery Assist Catheter
Two (2) rotating hemostatic valves
Two (2) peel-away introducer sheaths

Dimensions of the Broadway 8 Catheter and the FastPass Delivery Assist Catheter are included on the individual device label and presented in Table 1.0 below. Compatibility information for Broadway 8 Catheter and FastPass Delivery Assist Catheter are presented in Table 2.0.

Table 1.0 specifications

Broadway 8 Catheter inner diameter in (mm) [F]	Broadway 8 Catheter inner diameter in (mm) [F]	Broadway 8 Catheter outer diameter in (mm) [F]	Broadway 8 Catheter working length (cm)	FastPass Delivery Assist Catheter inner diameter in (mm) [F]	FastPass Delivery Assist Catheter distal outer diameter in (mm) [F]	FastPass Delivery Assist Catheter bulb outer diameter in (mm) [F]	FastPass Delivery Assist Catheter working length (cm)
BRW084132-01	0.084 (2.13)	0.098 (2.49) [7.5]	132	0.016 (0.41)	0.033 (0.84) [2.5]	0.075 (1.91) [5.7]	156

Table 2.0 compatibility information

Recommended minimum inner diameter of sheath or guide catheter for Broadway 8 in (mm)	Recommended maximum guidewire diameter for FastPass Delivery Assist Catheter in (mm)
0.100 (2.54)	0.014 (0.36)

Intended user

The Broadway 8 Catheter should only be used by physicians trained in interventional endovascular procedures.

Intended use/Indications for use

The Broadway 8 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.

Contraindications

Patients with a known allergy or intolerance to tallow derivative device materials of bovine and porcine origin. The Broadway 8 Catheter has not been evaluated for use in the coronary vasculature. Do not use automated high-pressure contrast injection equipment with the Broadway 8 Catheter because it may damage the device.

Warnings

- Exposure to temperatures above 50°C (122°F) may damage device. Do not autoclave.
- Torqueing or moving the device against resistance may result in damage to the vessel or device.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter if resistance is met during manipulation; determine the cause of the resistance before proceeding.
- This device is coated with a hydrophilic coating at the distal end of the device for a length of 34 cm. Please refer to the Operational Instructions 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.
- Limit the usage of the Broadway 8 Catheter to arteries greater than the catheter's outer diameter.
- Do not use a device that has been damaged in any way. Damaged device may cause complications.

Precautions

- Use the device prior to the "Use By" date specified on the package.
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution through catheter lumen.
- There is an inherent risk with the use of angiography and fluoroscopy.
- Operators should take all the necessary precautions to limit X-radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible.
- Do not insert or advance the Broadway 8 Catheter if resistance is encountered. If resistance is encountered, remove device and replace.
- 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.
- If resistance is experienced during the procedure while removing Broadway 8 Catheter, stop retracting Broadway 8 Catheter and remove as a full system including the guide catheter.

Precautions (cont.)

- Avoid taking the proximal markerband on the FastPass Delivery Assist Catheter into the proximal face of the clot to minimize clot disruption. The proximal markerband of FastPass Delivery Assist Catheter indicates the start of the bulb outer diameter (0.075 in).

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 (including hematoma or hemorrhage at the puncture site, sterile inflammation or granulomas at the access site, tissue necrosis) •
- Acute vessel occlusion
- Air embolism
- Allergic reaction and anaphylaxis from contrast media
- Allergic reaction to bovine and porcine tallow-derived materials
- Arteriovenous fistula
- Death
- Distal embolization
- Emboli
- False aneurysm formation
- Infection
- Intracranial hemorrhage
- Ischemia
- Kidney damage from contrast media
- Neurological deficit including stroke, transient ischemic attack
- Vessel spasm, thrombosis, dissection or perforation

Use of device requires fluoroscopy which presents potential risk 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

This document is intended solely for the use of healthcare professionals.

A physician must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that physicians be trained in the use of any particular product before using it in a procedure. The information presented is intended to demonstrate the breadth of Stryker product offerings. A physician must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.