Neuroform EZ® Stent System

See package insert for complete indications, contraindications, warnings and instructions for use.

Humanitarian Device: Authorized by Federal law for use with embolic coils for the treatment of wide neck, intracranial, saccular aneurysms arising from a parent vessel with a diameter of ≥ 2 mm and ≤ 4.5 mm that are not amenable to treatment with surgical clipping. Wide neck aneurysms are defined as having a neck ≥ 4 mm or a dome-to-neck ratio
< 2. The effectiveness of this device for this use has not been demonstrated.

INTENDED USE / INDICATIONS FOR USE

The Neuroform EZ Stent System is intended for use with embolic coils for the treatment of wide neck, intracranial, saccular aneurysms arising from a parent vessel with a diameter of ≥ 2 mm and ≤ 4.5 mm that are not amenable to treatment with surgical clipping. Wide neck aneurysms are defined as having a neck ≥ 4 mm or a dome-to-neck ratio of < 2.

CONTRAINDICATIONS

Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.

POTENTIAL ADVERSE EVENTS

Potential complications include, but are not limited to: allergic reaction, aneurysm perforation/rupture, coil herniation through stent into parent vessel, death, embolus, hemorrhage, in-stent stenosis, infection, ischemia, neurological/intracranial sequelae, pseudoaneurysm, stent fracture, stent migration/embolization, stent misplacement, stent thrombosis, stroke, transient ischemic attack, vasospasm, vessel occlusion or closure, vessel thrombosis, vessel perforation/rupture, dissection, trauma or damage, other procedural complications including but not limited to anesthetic and contrast media risks, hypotension, hypertension, access site complications.

Refer to the appropriate embolic coil DFU for other complications that may occur due to coil embolization.

WARNINGS

- 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.
- This device should only be used by physicians who have received appropriate training in interventional neuroradiology or interventional radiology and preclinical training on the use of this device as established by Stryker Neurovascular.
- Select a stent size (length and diameter) to maintain a minimum of 4 mm on each side of the aneurysm neck along the parent vessel. An incorrectly sized stent may result in damage to the vessel or stent migration. Therefore, the stent is not designed to treat an aneurysm with a neck greater than 22 mm in length.
- If excessive resistance is encountered during the use of the Neuroform EZ Stent System or any of its components at any time during the procedure, discontinue use of the stent system. Continuing to move the stent system against resistance may result in damage to the vessel or a system component.
- Persons allergic to nickel titanium (Nitinol) may suffer an allergic response to this stent implant.

CAUTIONS / PRECAUTIONS

- The Neuroform EZ® Stent System is provided STERILE for single use only.
- Use the Neuroform EZ Stent System prior to the "Use By" date printed on the package.
- Carefully inspect the sterile package and Neuroform EZ Stent System prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components.
- For MRI information, please refer to the "MRI Information" section.
- The Neuroform EZ Stent System should not be used for recapturing the stent.
- Exercise caution when crossing the deployed stent with adjunct devices.
- After deployment, the stent may foreshorten up to 1.8% in 2.5 mm stents and up to 5.4% in 4.5 mm stents.
- The safety of the Neuroform EZ Stent System in patients below the age of 18 has not been established.
- In cases where multiple aneurysms are to be treated, start at the most distal aneurysm first.
- The safety of "Y" stenting or techniques of passing a guidewire through stent interstices to access other vessels for the purpose of stenting has not been clinically established.

MRI INFORMATION

Magnetic Resonance Conditional

Non-clinical testing and analysis have demonstrated that Neuroform™ Stent is MR Conditional alone, or when overlapped with a second stent, and adjacent to a Stryker Neurovascular coil mass. A patient with Neuroform Stent can be safely scanned immediately after placement of this implant, under the following conditions:

- static magnetic field of 1.5 and 3.0 Tesla
- spatial gradient field up to 2500 Gauss/cm (25 Tesla/m)
- normal operational mode for gradients and SAR (maximum whole body averaged specific absorption rate (SAR) of lower than 2.0 W/kg and maximum head SAR of lower than 3.2 W/kg) for a total active MR scan time (with RF exposure) of 15 minutes or less per scan sequence.

In an analysis based on the temperature rises in non-clinical testing of stents and the calculated SAR in the patient during an MR scan, Neuroform Stents were determined to produce an in-vivo temperature rise of 4°C or lower for 15 minutes of MR scanning in normal operational mode in 1.5 T and 3 T MR systems. The Neuroform Stent should not migrate in this MRI environment.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. In Spin Echo and Gradient Echo sequence evaluations Neuroform stent image artifact extended approximately 2 mm from the device. Lumen of the stent was partially obscured by the artifact. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant.

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