Electrolytic eCLIPs™ Bifurcation System

Lifetime of the device

The expected lifetime of the device is the life of the patient.

Indications for Use

The eCLIPs™ Bifurcation System is indicated for the treatment of intracranial bifurcation aneurysms.

Contraindications

Use of the System is only eligible to patients whom the following contraindications do not apply:

- Patients in whom antiplatelet/anticoagulation therapy is contraindicated.
- Patients in whom the angiography demonstrates the anatomy is not appropriate for endovascular treatment, due to severe intracranial vessel tortuosity or stenosis or inadequate iliac/femoral access, or intracranial vasospasm, or not responsive to medical therapy.
- Patients who have sensitivities or allergies to nickel or nickel titanium (Nitinol).
- Patients with hypersensitivity to 316LVM stainless steel may suffer an allergic reaction to this implant.
- Patients with a history of coagulation disorders.
- Patients in whom necessary medication administered during and/or after the procedure is contraindicated.
- Patients with lesions that cannot be crossed with a guidewire and/or a catheter is contraindicated.
- Patients with accessories and/or previously implanted devices that cannot be crossed with a guidewire and/or a catheter.

Potential Complications and Adverse Events

Potential adverse events are similar for any interventional arterial implant procedure and include but may not be limited to the following:

- Allergic reaction including, but not limited to, contrast, Nitinol metal, and medications
- Arterial Dissection
- Arteriovenous fistula
- Arrhythmia
- Cerebral Ischemic Stroke or Ischemia
- Coil Migration
- Coma
- Death
- Implant fracture
- Implant migration or misplacement
- Implant thrombosis or occlusion
- Embolism (air, tissue or thrombotic)
- Incomplete aneurysm occlusion
- Infection
- Hemorrhage or Hematoma at entry site
- Hypertension
- Hypotension
- Hydrocephalus
- Headache
- Intracerebral/intracranial Hemorrhage
- Mass effect
- Neurological deficits
- Parent artery stenosis
- Perforator occlusion
- Perforated aneurysm or aneurysm rupture
- Seizure
- Stroke
- Thromboembolism
- Transient ischemic attack (TIA)
- Vasospasm
- Vessel occlusion
- Vessel perforation
- Vision impairment

Note: Any serious incident that has occurred in relation to the System should be reported to the manufacturer and the regulatory authorities in the country to which the System was distributed.

MR Information

Non-clinical testing demonstrated that the eCLIPs™ Implant is MR Conditional. A patient with this Implant can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5T) or 3.0-Tesla (3.0T) only
- Maximum spatial gradient field of up 1,900-Gauss/cm (19-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode
- The RF heating results indicate the maximum temperature rise under these conditions is approximately 4.1°C. The presence of this implant is not expected to produce a measureable image artifact.

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