Indications, Safety, and Warnings

Abre™ venous self-expanding stent system

Indications for use

The Abre™ venous self-expanding stent system is intended for use in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction.

Cautions

- This device was designed for single use only. Do not reuse, reprocess, or resterilize this device. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device or create a risk of contamination, which could result in patient injury, illness, or death.
- If unusually high resistance is encountered when advancing the Abre™ delivery system over the guidewire, assess the cause of the resistance before proceeding.
- If high resistance is felt when initially rotating the thumbwheel, do not force deployment. Carefully withdraw the system and do not use it.
- Do not use in patients with a total venous occlusion that cannot be dilated to allow passage of the guidewire.
- Do not use the device with contralateral access.
- Stenting across a major branch could cause difficulties during future diagnostic or therapeutic procedures.

Contraindications

- Do not use the Abre™ system with patients with known hypersensitivity to nickel titanium (nitinol).
- Do not use the Abre™ system with patients who are judged to have a lesion that prevents complete inflation of a balloon dilatation catheter or proper placement of the stent or the stent delivery system.
- Do not use the Abre™ system with patients in whom anticoagulant or antiplatelet therapy is contraindicated.

Potential complications

The potential adverse events (or complications) that may occur or require intervention with the use of this device include, but are not limited to, the following:

- Access failure
- Access site infection
- Allergic reaction to contrast medium or procedure medications
- Allergic reaction to nitinol or other device materials
- Aneurysm
- AV fistula
- Bleeding
- Bruising
- Death
- Device breakage
- Device maldeployment
- Edema
- Embolization
- Fever
- Hematoma
- Hypertension
- Hypotension, nausea, or other vasovagal response
- Infection
- Myocardial infarction, arrhythmia, or other cardiovascular insufficiency
- Open surgical repair
- Pain

- Pseudoaneurysm
- Renal insufficiency or renal failure (new or worsening)
- Respiratory distress or pulmonary embolism
- Sepsis
- Stent fracture
- Stent malapposition
- Stent malposition
- Stent migration
- Stroke, paradoxical embolism, transient ischemic attack, or intracerebral hemorrhage
- Tissue necrosis
- Venous occlusion, restenosis, or thrombosis, within or outside of stented segment
- Vessel damage, including intimal injury, dissection, perforation, or rupture

MRI safety information

MRI conditional

Nonclinical testing demonstrated that the Abre™ stent in single and overlapped conditions is MR Conditional for stents up to 150 mm.

A patient with this device can be scanned safely, immediately after stent placement, under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Maximum spatial gradient magnetic field of 4000 Gauss/cm or less (40 T/m)
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode)

MR image quality may be compromised if the area of interest is in the exact location or close to the position of the Abre™ stent.

MRI-related temperature rise

Under the scan conditions as defined in the previous section, "MR Conditional," the Abre™ stent is expected to produce a maximum temperature rise less than or equal to 5.2 C after 15 minutes of continuous scanning (per pulse sequence). The effect of temperature rise in the MRI environment for stents with fractured struts is not known.

It is recommended that patients register conditions under which the implant can be scanned safely with the MedicAlert Foundation (medicalert.org) or equivalent organization.

Artifact information

In nonclinical testing, the maximum artifact size as seen on the gradient echo pulse sequence at 3.0 Tesla extends approximately 5 mm, relative to the size and shape of the Abre™ stent. The lumen of the stent can be visualized using the T1-weighted spin echo pulse sequence and the T1-weighted gradient echo pulse sequence at 3.0 Tesla.