Reducing recurrent stroke in cryptogenic stroke patients

**Patent foramen ovale (PFO) closure patient selection educational guide**

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**Step 1: Tissue diagnosis**

**Stroke-like symptoms in a patient**

**Is the MRI positive for acute ischemic stroke?**

- **YES**
  - Acute ischemic stroke
  - Are there signs of advanced atherosclerosis on FLAIR Imaging?* Not: Isolated acute infarcts without chronic associated ischemia are potentially from emboli
  - Medical management

- **NO**
  - Medical management

**Step 2: Vessel imaging**

**Vessel imaging (CTA, MRA, carotid ultrasound)**

**Is there large vessel atherosclerosis?**

- **YES**
  - Treat as appropriate

- **NO**
  - Is there other vessel disease? Dissection, RCVS, Moyamoya, Microangiopathic disease, Vasculitis
  - Refer for further evaluation

**Step 3: Emboli workup**

**Is there any major medical disease in the patient pre-disposing them to thrombosis?**

E.g. Cancer, DVT / PE history, autoimmune disease, or 1st degree relative with DVT / PE

**YES**

- Complete both the hematology and shunt workup

**NO**

**Cardiac evaluation**

Evaluate for cardiac abnormalities. Is there any cardiac disease including valvular, cardiomyopathy, atrial disease, or is there occult atrial fibrillation?

**YES**

- Conduct prolonged cardiac rhythm monitoring

**NO**

**AFIB**

- Is AFIB detected?

**YES**

- Medical management

**NO**

**Medical management**

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**INDICATIONS FOR USE outside of U.S.:** The GORE\textregistered\textsuperscript{®} CARDIOFORM\textsuperscript{®} Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of atrial septal defects (ASDs), such as ostium secundum and patent foramen ovale (PFO) closure.

**INDICATIONS FOR USE in the U.S.:** The GORE\textsuperscript{®} CARDIOFORM\textsuperscript{®} Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of the following defects of the atrial septum: ostium secundum atrial septal defects (ASDs), patent foramen ovale (PFO) closure, and the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 to 64 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke. GORE\textsuperscript{®} CARDIOFORM\textsuperscript{®} Septal Occluder is contraindicated for use in patients unable to take an antiplatelet or anticoagulant medication such as aspirin, heparin or warfarin; with anatomy where the GORE\textsuperscript{®} CARDIOFORM\textsuperscript{®} Septal Occluder size or position would interfere with other intracardiac or intravascular structures such as the right or left heart, catheters, wires, or other intracardiac shunts; with any other medical condition that pre-disposes them to thrombosis; with known intracardiac or intravascular thrombi, or any other infection that cannot be treated successfully prior to device placement; with known intracardiac thrombi, or any other infection that cannot be treated successfully prior to device placement. Patients with anticoagulant-induced gastrointestinal bleeding, uncontrolled hypertension, or medical conditions that pre-dispose them to thrombosis are also contraindicated for use. Please refer to Instructions for Use for detailed contraindications and information on contraindicated conditions.

**Medical management**

Refer to the Instructions for Use.

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The Gore REDUCE Clinical Study did not include patients on anticoagulants. The REDUCE study determined safety and efficacy of patent foramen ovale (PFO) closure with the GORE\textsuperscript{®} CARDIOFORM\textsuperscript{®} Septal Occluder or GORE\textsuperscript{®} HELIX\textsuperscript{®} Septal Occluder plus antiplatelet medical management compared to antiplatelet medical management alone in patients with a PFO and history of cryptogenic stroke. All PFO anatomies were incorporated into this study within indicated sizing parameters of the Instructions for Use.

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- Every medical situation is unique to the patient and requires a thorough examination by a qualified physician.

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