

CLINICAL DOCUMENTATION CHECK LIST

Diagnosis of cryptogenic ischemic stroke

It is recommended that the comprehensive evaluation follow the latest professional society guidelines for diagnosing a cryptogenic ischemic stroke, and should include at a minimum the following assessments:

- MRI or CT scanning of the head to rule out small vessel disease or lacunar infarct¹
- TEE to rule out non-PFO intra-cardioembolic sources or conditions or aortic arch atheroma¹
- ECG and prolonged cardiac rhythm monitoring (~ 30 days) to rule out atrial fibrillation and other heart rhythm disturbances that may be associated with stroke¹
- Intra and extracranial artery imaging: MRA, CT angiography, or contrast angiography to rule out an ischemic stroke associated with atherosclerotic plaque, arterial dissection or other vascular diseases¹
- Hematological evaluation to rule out underlying hypercoagulable state¹

This list is not an exhaustive list of all conditions to consider. It is the responsibility of the provider to determine the proper assessments to determine the diagnosis of a cryptogenic stroke.

1. AMPLATZER™ PFO Occluder Instructions for Use.

The AMPLATZER™ PFO Occluder is indicated for percutaneous transcatheter closure of a patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 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.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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3200 Lakeside Dr., Santa Clara, CA. 95054 USA, Tel: 1.800.227.9902
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