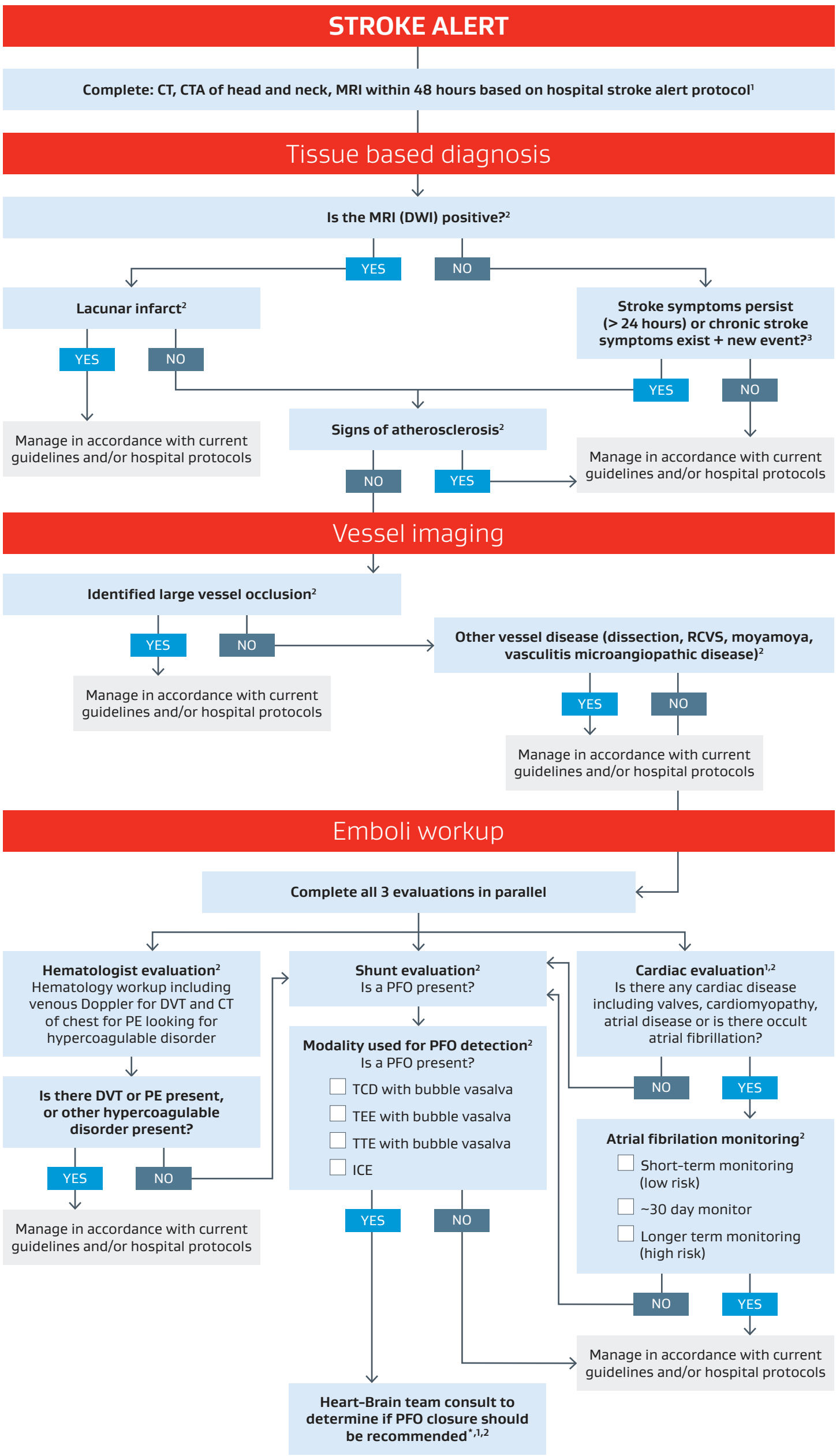


# SECONDARY STROKE PREVENTION

## PFO closure patient selection algorithm

The following algorithm may help identify patients most likely to benefit from PFO closure.



AFIB, Atrial fibrillation; CT, Computed tomography; CTA, Computed tomography angiography; DVT, Deep vein thrombosis; DWI, Diffusion-weighted imaging; FLAIR, Fluid-attenuated inversion recovery; ICE, Intracardiac echocardiography; MRI, Magnetic resonance imaging; PE, Pulmonary embolism; PFO, Patent foramen ovale; RCVS, Reversible cerebral vasoconstriction syndrome; RoPE, Risk of Paradoxical Embolism; TCD, Transcranial doppler; TEE, Transesophageal echocardiography; TIA, Transient ischemic attack; TTE, Transthoracic echocardiogram.

All content about medical diagnosis and treatment is for general information purposes only. This information is not intended or implied to be a substitute for professional medical diagnosis, treatment or care. Every medical situation is unique to the patient and requires appropriate clinical judgment from a qualified physician. This algorithm represents general clinical practice recommendations from a Heart-Brain team including Cardiologists and Neurologists during the September 2023 Stroke Team Workshop.

\* Refer to *Instructions for Use*.

- Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 Guideline for the prevention of stroke in patients with stroke and transient ischemic attack: a guideline from the American Heart Association/American Stroke Association. *Stroke* 2021;52(7):e364-e467. <https://www.ahajournals.org/doi/10.1161/STR.0000000000000375>
- Messé SR, Gronseth GS, Kent DM, et al. Practice advisory update summary: patent foramen ovale and secondary stroke prevention: Report of the Guideline Subcommittee of the American Academy of Neurology. *Neurology* 2020;94(20):876-885. <https://n.neurology.org/content/neurology/94/20/876.full.pdf>
- Søndergaard L, Kasner SE, Rhodes JF, et al; Gore REDUCE Study Investigators. Patent foramen ovale closure or antiplatelet therapy for cryptogenic stroke. *New England Journal of Medicine* 2017;377(11):1033-1042. <https://www.nejm.org/doi/full/10.1056/NEJMoa1707404>

Consult Instructions for Use  
eifu.goremedical.com

**INDICATIONS/INTENDED USE:** The GORE® CARDIOFORM 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) 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. **CONTRAINDICATIONS:** The GORE® CARDIOFORM Septal Occluder is contraindicated for use in patients: unable to take antiplatelet or anticoagulant medications such as aspirin, heparin, or warfarin; with anatomy where the GORE® CARDIOFORM Septal Occluder size or position would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins; with active endocarditis, or other infections producing bacteremia, or patients with known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement; with known intracardiac thrombi. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available.

Products listed may not be available in all markets.

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