SECONDARY STROKE PREVENTION

PFO closure patient selection algorithm

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. $\mathrm{R}_{\mathrm{x\ Only}}$

Products listed may not be available in all markets.

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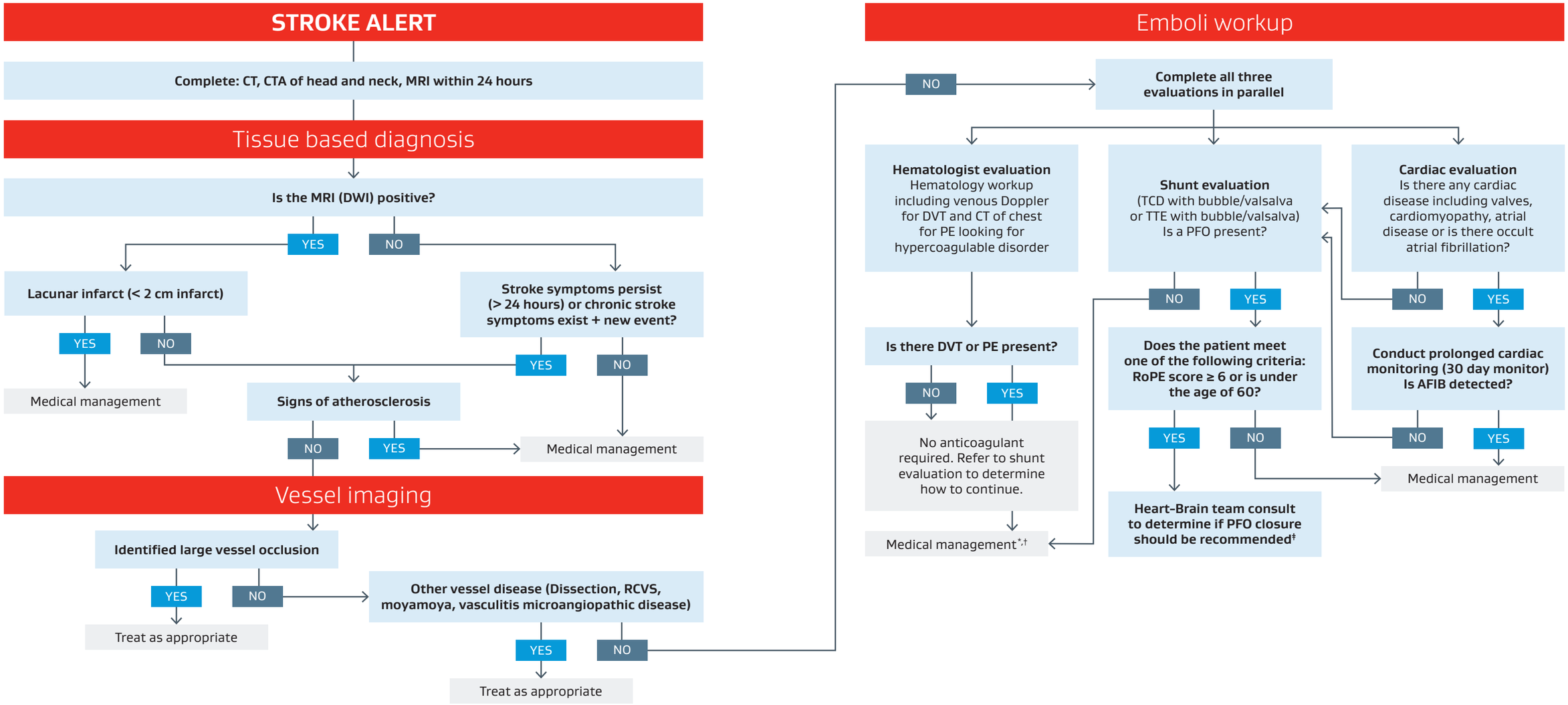
Together, improving life

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



* Duration of anticoagulant use varies by case, and the decision to maintain its use in conjunction with PFO closure should be at the physician's discretion.

† The Gore REDUCE Clinical Study did not include patients on anticoagulents. The REDUCE study determined safety and efficacy of patent foramen ovale (PFO) closure with the GORE® CARDIOFORM Septal Occluder or GORE® HELEX® 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*.

‡ Refer to *Instructions for Use*.

AFIB, Atrial fibrillation; CT, Computed tomography; CTA, Computed tomography angiography; DVT, Deep vein thrombosis; DWI, Diffusion-weighted imaging; FLAIR, Fluid-attenuated inversion recovery; 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 May 2022 Stroke Team Workshop.