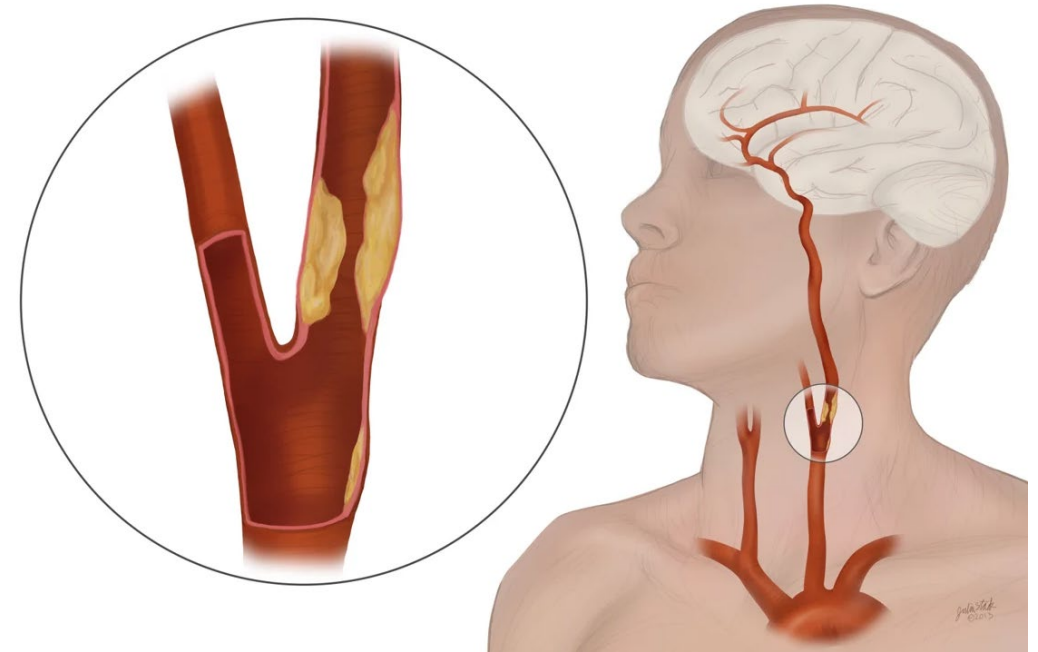


Fragmentation of Carotid Arteries

SkyRunner Carotid Intravascular Lithotripsy (IVL) System

Overview of Disease State

- Carotid artery disease results in narrowing of the carotid arteries, most often caused by atherosclerotic plaque buildup, which reduces cerebral blood flow
- Carotid plaque may embolize, resulting in a transient ischemic attack (TIA) or an ischemic stroke

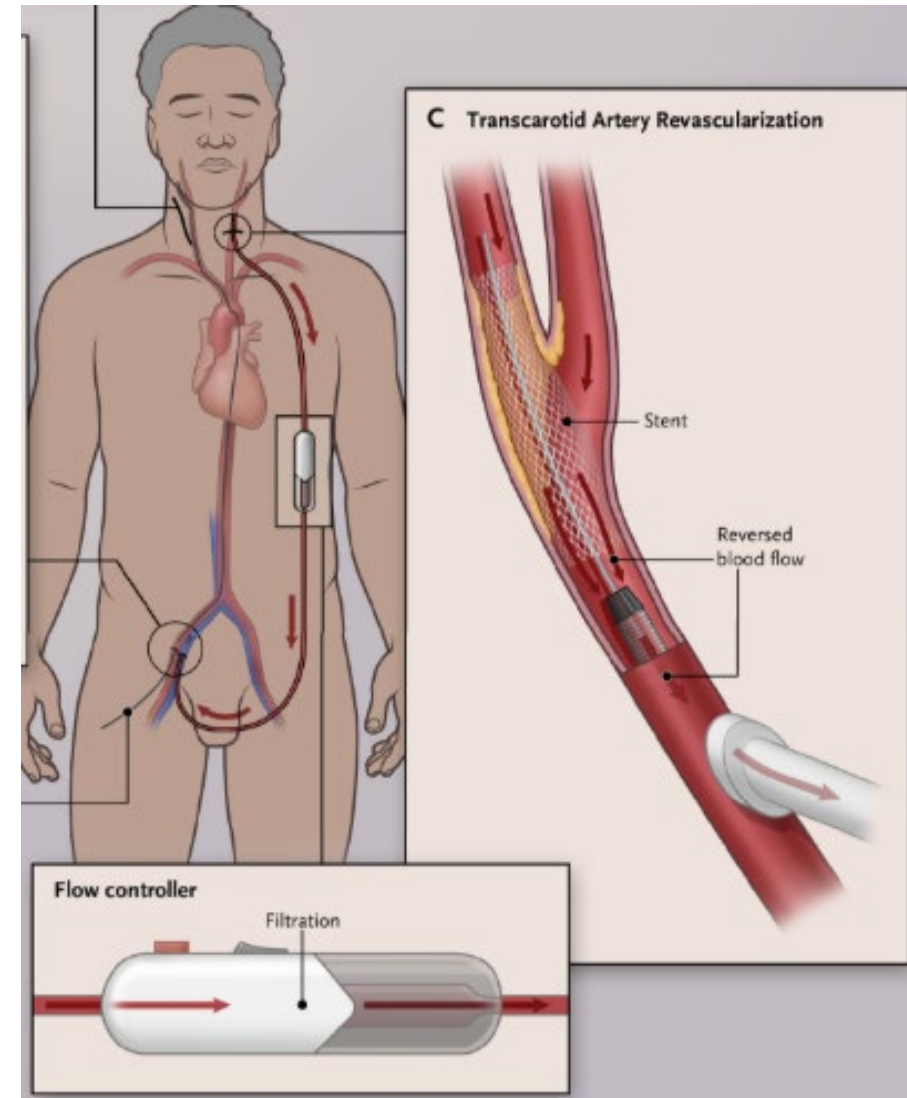


Current Treatments

- Optimal Medical Therapy (OMT)
 - Combination of pharmacotherapy and lifestyle modifications
 - Typically recommended for all patients and may be combined with surgical or endovascular options
- Surgical Intervention—Carotid Endarterectomy (CEA)
 - Incision is made directly in the carotid artery, plaque is removed, and the artery is repaired
 - Typically considered in symptomatic patients with stenosis $\geq 50\%$ or asymptomatic patients with stenosis $\geq 70\%$
 - Physiological abnormalities, comorbidities, or anatomic abnormalities may make a patient a poor candidate for CEA

Current Treatments

- Transcarotid Arterial Revascularization (TCAR)
 - A less invasive alternative to CEA where a stent is placed utilizing direct carotid access via an incision near the clavicle
 - The procedure utilizes a neuroprotection system that performs reverse flow to filter emboli during the procedure to minimize intraprocedural stroke risk
 - Significant calcification can make patients not suitable for stenting due to the risk of inadequate stent expansion



Current Treatments

- Transfemoral Carotid Artery Stenting
 - A less invasive alternative to CEA where a stent is used to restore blood flow to the narrowed artery. It is deployed through a catheter inserted in the femoral artery
 - Embolic protection is placed proximal or distal to the lesion to minimize intraprocedural stroke risk from embolization
 - Significant calcification can make patients not suitable for stenting due to the risk of inadequate stent expansion

Impacts of Calcification on Carotid Stenting

- Calcification increases the risk of stent under-expansion and restenosis in TCAR or Transfemoral
- Pre-dilation with conventional balloons has limited efficacy and requires higher inflation pressures, increasing the risk of dissection, embolization, and/or perforation
- Severe calcification can currently exclude patients from being candidates for an endovascular procedure
- SkyRunner IVL may offer an endovascular treatment option to patients who are currently poor candidates for carotid stenting due to vascular calcification

Skyrunner Carotid IVL Meets the Unmet Need in Calcified Carotid Artery Disease

- Patients who would benefit from revascularization but are high risk for CEA and poor candidates for stenting due to heavy calcification.
- Typically, these patients are excluded from surgical or endovascular treatments for Carotid Artery Disease due to:
 - Heavy circumferential calcium
 - Inadequate vessel compliance
 - Severe medical/surgical comorbidities
 - Hostile carotid anatomy
 - Prior carotid surgical intervention
 - Limited life expectancy

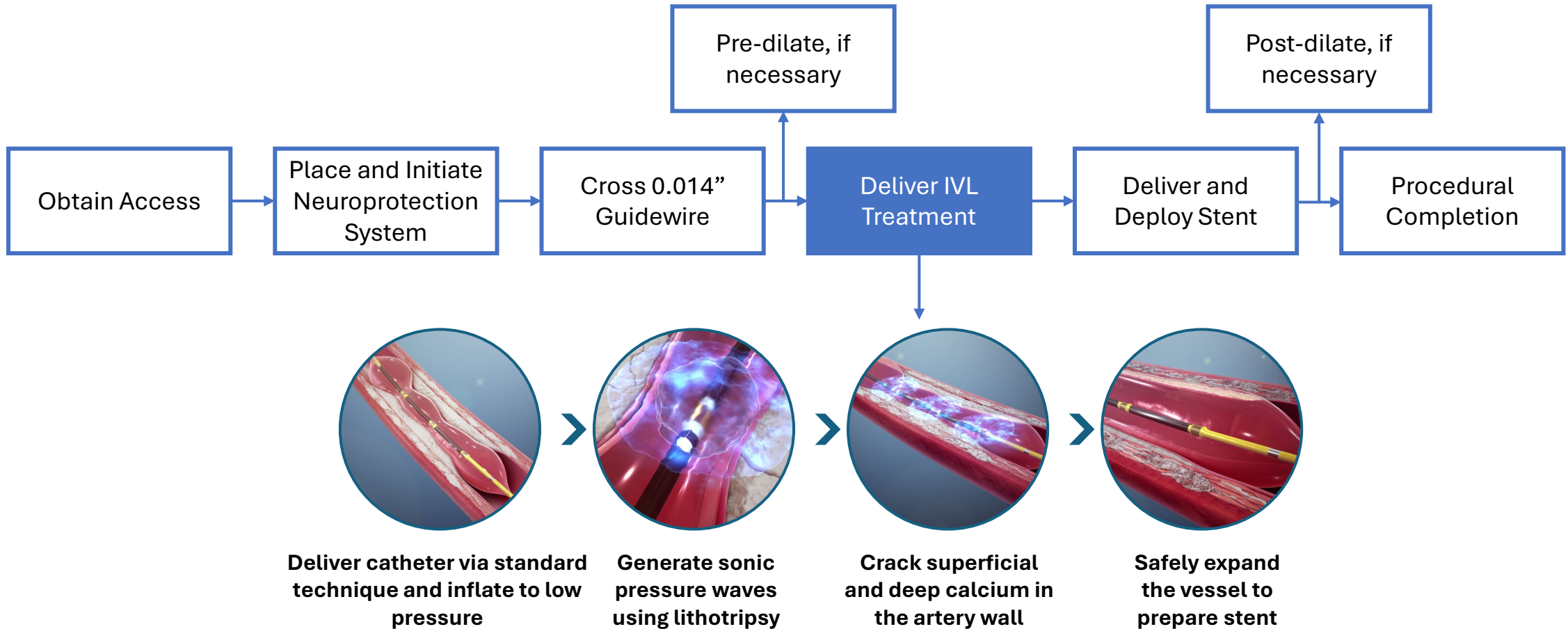
SkyRunner IVL System

Components:

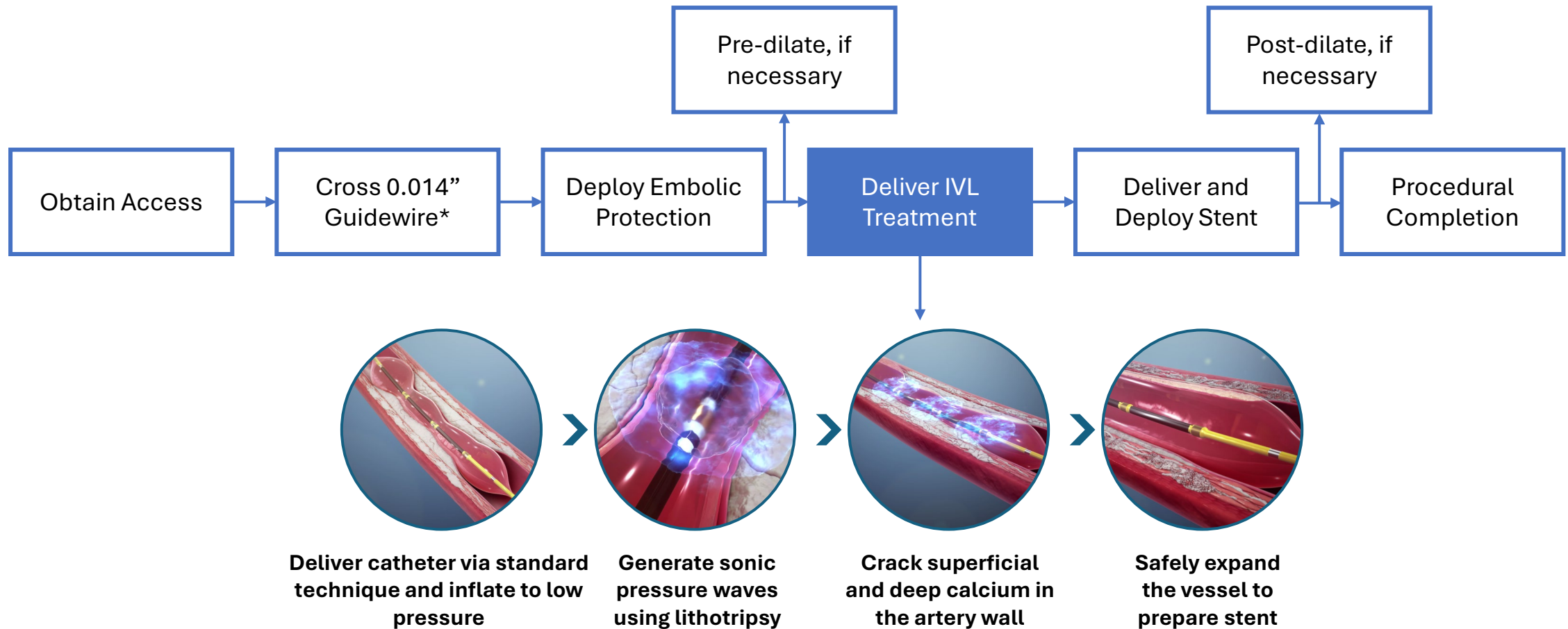
- Generator – portable, rechargeable, non-sterile, reusable
- Connector Cable – non-sterile, reusable
- Cable Sleeve – single-use sterile sleeve to be placed over the connector cable
- IVL Catheter – single-use sterile catheter that delivers intravascular lithotripsy



Transcarotid Artery Revascularizations (TCAR) Procedure with IVL



Transfemoral Carotid Artery Stenting Procedure with IVL



*Note: If a proximal protection device is used, the device is deployed prior to crossing the lesion with a 0.014" guidewire

How will SkyRunner be recognized

Documentation of the use of the SkyRunner Carotid Intravascular Lithotripsy (IVL) System will be included in the operative report

- Shockwave IVL Catheter
- SkyRunner IVL Catheter
- SkyRunner Catheter
- IVL Catheter
- Carotid IVL Catheter
- Lithotripsy Catheter
- Carotid Lithotripsy