



Phoenix Atherectomy System

Indications for Use

The Phoenix Atherectomy System is intended for use in atherectomy of the peripheral vasculature. The system is not intended for use in the coronary, carotid, iliac or renal vasculature.

Contraindications

The use of the Phoenix Atherectomy System is contraindicated where introduction of any catheter would constitute an unacceptable risk to the patient. Contraindications include but are not limited to:

- Recent history of myocardial infarction or thrombotic or hemorrhagic stroke
- Any evidence or history of intracranial bleeding or aneurysm
- Known hypercoagulable state or coagulopathy
- Bleeding diathesis, platelet dysfunction, thrombocytopenia, or thrombocytosis
- Patients in whom antiplatelet, anticoagulant, or thrombolytic therapy is contraindicated
- Allergy or intolerance to contrast agents or medications used to perform endovascular procedures
- Do NOT operate the Phoenix Atherectomy System in vessels smaller than the indicated size as perforation, dissection or injury may occur.

Potential Adverse Events

Potential adverse effects (e.g., complications) associated with the use of this device and other interventional catheters include but are not limited to the following (alphabetical order): Access site injury, including pain; Arterial dissection; Arterial occlusion; Arterial perforation or pseudoaneurysm; Arterial restenosis; Arterial rupture; Arterial spasm or abrupt or sub-acute closure; Bleeding complications which may require transfusion; Death; Embolism, including thrombus, plaque, air, device, etc.; Emergency or non-emergency arterial bypass surgery; Fracture of any component of the device that may or may not lead to serious injury or surgical intervention; Hematoma; Hypotension; Infection or fever; Ischemia; Reaction to contrast media, procedure medications or Catheter materials, including allergic reaction; Vascular injury which may require surgical repair.

See complete IFU for more information before attempting use of Phoenix.