



Important safety information

RX PCTA Scoring Balloon Catheter – AngioSculpt Evo

Caution: Federal law restricts this device to sale by or on the order of a physician.

Indications for Use

The AngioSculpt Evo scoring balloon catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis and complex type C lesions, for the purpose of improving myocardial perfusion.

Contraindications

The AngioSculpt Evo catheter should not be used for the following::

- Coronary artery lesions unsuitable for treatment by percutaneous revascularization.
- Coronary artery spasm in the absence of a significant stenosis

Potential Adverse Events

Possible adverse effects include but are not limited to: death; heart attack (acute myocardial infarction); embolism, total occlusion of the treated coronary artery; coronary artery dissection, perforation, rupture, or injury; pericardial tamponade; no/slow reflow of treated vessel; emergency coronary artery bypass (CABG); emergency percutaneous coronary intervention; CVA/stroke/embolic stroke; pseudoaneurysm; restenosis of the dilated vessel; unstable angina; thromboembolism or retained device components; irregular heart rhythm (arrhythmias, including life-threatening ventricular arrhythmias); severe low (hypotension)/high (hypertension) blood pressure; coronary artery spasm; hemorrhage or hematoma; need for blood transfusion; surgical repair of vascular access site; creation of a pathway for blood flow between the artery and the vein in the groin (arteriovenous fistula); drug reactions, allergic reactions to x-ray dye (contrast medium); and infection.

Prior to using the AngioSculpt Evo scoring balloon catheter, please review the instructions for use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.