



## **Important safety information**

### **AngioSculpt PTA**

#### **Indications for Use**

The AngioSculpt PTA Scoring Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, infra popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neurovasculature.

#### **Contraindications**

None known for Percutaneous Transluminal Angioplasty (PTA) procedures.

#### **Potential Adverse Events**

Possible adverse effects include but are not limited to: Vessel injury such as: dissection, perforation, rupture, spasm, or arteriovenous fistula; infection/ sepsis; drug reactions, allergic reactions to contrast medium; restenosis/ occlusion of the dilated artery; embolism; thrombus; hypertension/ hypotension; hemorrhage, hematoma, pseudoaneurysm; need for blood transfusion; surgical repair of vascular access site; and no or slow reflow of the treated vessel.