Convergent Bibliography

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EPi-Sense® Guided Coagulation System Indications for Use

The EPi-Sense® Guided Coagulation System with VisiTrax® is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery for the treatment of arrhythmias including Atrial Fibrillation (AFIB) or Atrial Flutter (AFL). Contraindications include patients with Barrett's Esophagitis, left atrial thrombus, a systemic infection, active endocarditis, or a localized infection at the surgical site at the time of surgery. Reported adverse events associated with epicardial ablation procedure may include, but are not limited to, the following: pericardial effusion, excessive bleeding, Pericarditis, phrenic nerve injury, stroke/TIA/neurologic complication. Please review the Instructions for Use for a complete listing of contraindications, warnings, precautions and potential adverse events located at the following AtriCure web address: https://www.atricure.com/instructions-for-use/international. Individual results may vary. Please consult with your physician regarding your condition and appropriate medical treatment. The devices are used to form scars in the heart tissue. Possible problems during the procedure may result in the formation of unwanted scar tissue, damage to nerve and blood vessels, heart rhythm disorder, blood clots, pooling of fluid in the sac around the heart and tissue tearing or puncture.

