ElectroWire
Better Transseptal for All

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LightningWire Transseptal Puncture System (TPS) Brief Statement

Indications

The LightningWire TPS is used to create an atrial septal defect in the heart, whereby various cardiovascular catheters are introduced.

Contraindications

The LightningWire TPS is not recommended for use with:

- Any conditions that do not require the creation of an atrial septal defect
- Known or suspected atrial thrombus
- Known or suspected atrial myxoma
- Cerebrovascular accident (CVA) within one week
- Any indication of increased risk of life-threatening bleeding with anticoagulation
- Any inability to tolerate anticoagulation for any reason
- History of inter-atrial septal patch repair
- History of device closure of atrial septal defect or patent foramen ovale

Warnings & Precautions

The LightningWire TPS:

- should only be used by physicians experienced in RF powered transseptal procedures.
- is not intended for use in children or in pregnant or nursing women.
- is intended for use only with compatible transseptal introducer sets and ESGs.

Physicians should assess and communicate patient-specific risks and benefits. Certain patient conditions require special consideration. Such conditions include, but aren't limited to, an enlarged aortic root, a small left atrium, a dilated right atrium, fibrotic or calcified inter-atrial septal tissues, the presence of atrial septal defect or patent foramen ovale closure devices, the presence of intra-cardiac devices such as pacemaker/defibrillator leads, distortion of normal thoracic anatomy, and congenital malformations of the heart.

Potential Complications

Adverse events that may occur while creating an atrial septal defect include:

Allergic reaction	Sepsis/Infection	Thromboembolic events	Vessel perforation
Atrial Flutter or Fibrillation	Myocardial Infarction	Vessel spasm	Ventricular arrhythmias
Stroke	Hemorrhage	Vascular thrombosis	Perforation of the myocardium
Hematoma	Arteriovenous fistula	Ventricular Tachycardia	Pain and/or Tenderness
Vascular Trauma	Pericardial effusion	Tachycardia	Foreign body/wire fracture
Pericardial tamponade	Wire entrapment/entanglement	Thermal injury	Additional Surgical Procedure

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact an ElectroWire representative at (800) 654-8238 and/or visit the company website at www.electrowiremedical.com.

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

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