



## **Important safety information**

### **CavaClear IVC Filter Removal Laser Sheath**

The laser sheath is intended for the ablation of tissue in the removal of IVC filters that have failed a previous retrieval method.

#### **Contraindications**

- Use of the laser sheath is contraindicated:
- When IVC filter is not accessible to the operator or the IVC filter apex cannot be captured;
- When in situ thrombus is present within filter, IVC, or iliac veins;
- When IVC filter material is nonmetal;
- For use in removal of Bird's Nest IVC filters and VenaTech filters.

#### **Potential Adverse Events**

Potential adverse events include but are not limited to infection, migration of IVC filter fragments, migration of vegetation or thrombus, pulmonary embolism, venous avulsion/perforation, vena cava occlusion or torsion with subsequent thrombus, pseudoaneurysm, and hematoma formation. The following adverse events or conditions may also occur during IVC filter removal with the laser sheath but were not observed during the clinical study: bacteremia and fistula formation.