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SENTRY CLINICAL TRIAL

24-Month Data[1]

Prospective Multicenter SENTRY Clinical Trial: Safety and Effectiveness of the Sentry Bioconvertible Inferior Vena Cava Filter

OBJECTIVE:

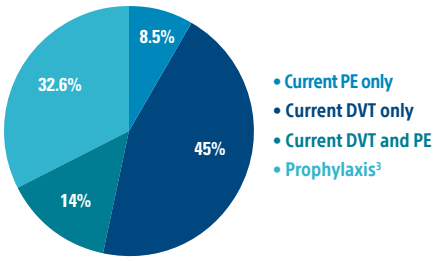
Evaluate the safety and efficacy of the Sentry Bioconvertible IVC Filter through 24 months in patients with documented deep-vein thrombosis (DVT) and/or pulmonary embolism (PE) or who were at temporary risk of developing DVT/PE.

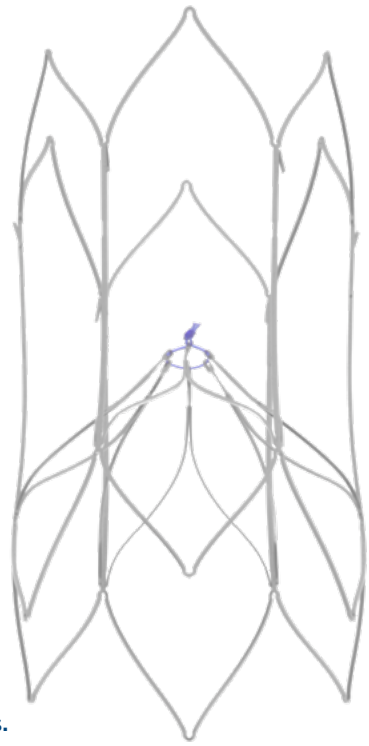
TRIAL DESIGN:

Prospective, multicenter (23 sites in the US, Belgium, and Chile), single-arm, non-randomized.

Patient Demographics	n = 129 subjects[5]
Age (Years)	62.6 ± 13.52
Male/Female	56.6% / 43.4%
BMI (kg/m2)	30.5 ± 8.38
Hypertension	58.9%
Recent Surgery (<30days)	25%
Diabetes	21.7%

Filter Placement





TRIAL METHODS:

- Sentry Bioconvertible IVC Filter placed following IFU protocol
- Imaging at baseline, 1, 2, 6, 12, and 24 months leveraging various imaging modalities
- Independent data and events monitoring and adjudication
- 100% of eligible subjects imaged at 12 months (n=111) and 24 months (n=85)

KEY RESULTS:

The composite primary 6-month endpoint of clinical success was achieved in 97.4% (111/114) of patients.

Technical success (129/130)

Freedom from new symptomatic PE at 60 days (129/129)

Freedom from IVC filter-related complications through 6 months (112/114)

	0-1 month (n=129)[4]	1-2 month (n=127)	2-6 month (n=126)	6-12 month (n=111)	12-24 month (n=85)[1,2]
New symptomatic PE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Filter-related death	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Symptomatic caval thrombosis	2 (1.6)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Stability complications	**1 month (n=122)**	**2 months (n=119)**	**6 months (n=114)**	**12 months (n=111)**	**24 months (n=85)**
Tilting	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Migration	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Fracture	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Perforation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Any complication found on imaging	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

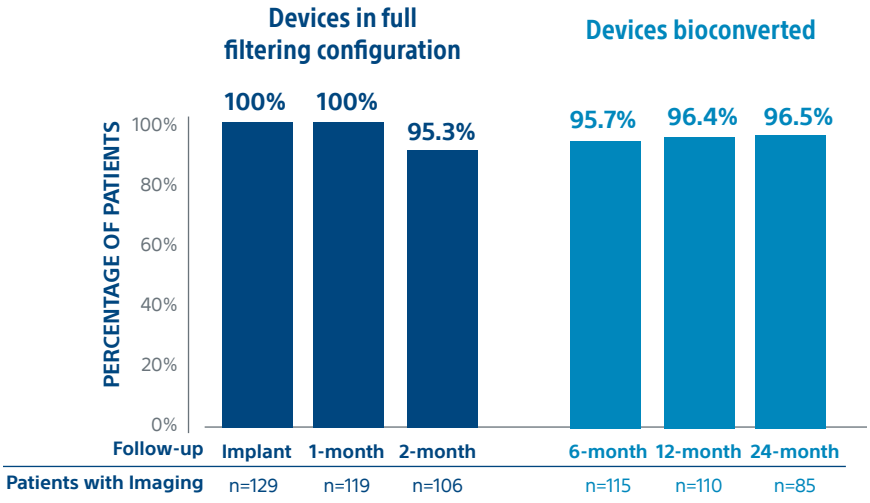
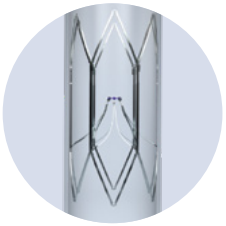
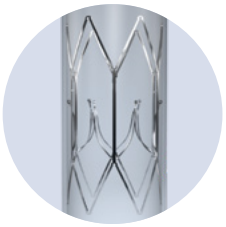


Figure 1. Filtering configuration and bioconversion status through 24 months in the Sentry clincal trial. Filtering configuration = all 6 pairs of arms held in the sentral portion of the IVC lumen. Biconverted = 1 or more pairs of filter arms separated from the central portion of the IVC lumen.



CLOSED, FILTERING CONFIGURATION



OPEN CONFIGURATION

CONCLUSION:

The Sentry Bioconvertible IVC Filter provided safe and effective protection against PE through the transient risk period, with a high rate of intended bioconversion and a low rate of device-related complications, through 24 months of imaging-intense follow-up. The SENTRY Clinical Trial represents an important paradigm shift in the prevention of PE with a next generation device.[1]

1. Dake M D et al. Final two-year outcomes for the Sentry Bioconvertible Inferior Vena Cava Filter. Journ of Vasc & Int Rad. (2019) https://doi.org/10.1016/j.jvir.2019.08.036
2. Refers to new symptomatic PEs that were determined to be "device related" by the CEC. There were 2 new symptomatic PEs between 12 and 24 months that were adjudicated by the CEC as not device or procedure related.
3. Prophylactic indication: no current PE or DVT but high risk of PE.
4. Two cases of symptomatic caval thrombosis developed and were successfully treated during the first month of follow-up
5. Inability to use anti coagulation due to contraindication, failure, complication or risk of injury from pharmacotherapy.

SENTRY INFERIOR VENA CAVA (IVC) FILTER
CAUTION: Federal (USA) law restricts this device to sale by or on order of a physician.
INTENDED USE: The Sentry IVC Filter is indicated for the prevention of recurrent Pulmonary Embolism via percutaneous placement in the inferior vena cava in patients at transient risk of PE, in the following situations: • Pulmonary thromboembolism when anticoagulants are contraindicated. • Failure of anticoagulant therapy in thromboembolic diseases. • Emergency treatment following massive PE where anticipated benefits of conventional therapy are reduced. **CONTRAINDICATIONS:** The Sentry IVC Filter should not be implanted in: • Patients with an average IVC diameter greater than 28mm • Patients with an average IVC diameter less than 16mm • Patients with an Infrarenal IVC of <9cm in length • Patients with risk of septic embolism • Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully. • Patients with uncontrolled sepsis. • Patients with demonstrated hypersensitivity to one of the components of the Filer (Nitinol; nickel and titanium, Poly p-dioxanone). **WARNINGS:** • Do not place the Filter in patients scheduled for surgery within two weeks of implantation, if the surgery is likely to involve manipulation of the IVC. • Patients with spinal or other anatomical irregularity may interfere with the successful delivery, deployment, geometry or stability of the Sentry IVC Filter. • Do not deploy the Filter unless the IVC diameter has been accurately measured; the Filter is intended for use in IVC diameters between 16mm and 28mm. If the IFC diameter is greater than 28mm or less than 16mm in diameter do not deploy the Filter. • Do not place the filter in patients with dual IVC. • The Filter is designed to be implanted using right internal jugular or right/left femoral veins. Extreme care must exercised when attempting placement via a left femoral vein insertion-tortuous venous anatomy can cause sheath kinking and make filter insertion difficult or impossible. • The Filter is a permanent implant. The Sentry IVC Filter is not a retrievable filter. Attempting to retrieve the Filter will result in damage to the Filter or the IVC. • The Sentry IVC Filter is designed to protect patients at transient risk from PE. In the SENTRY clinical study 100% of Filters were filtering at the 1-month follow-up, 95.3% of Filters were filtering at the 2-month follow-up and at the 6-month follow-up 95.7% Filters had Bioconverted. • Refer to the Clinical Summary for clinical experience wit the Sentry IVC Filter. • Procedures or activities that lead to changes in intra-abdominal pressure could affect the integrity or stability of the Filter. • Filter fractures are a known complication of IVC filters. There have been reports of serious pulmonary and cardiac complications with IVC filters requiring the retrieval of the fragment utilizing endovascular and or surgical techniques. Refer to the Clinical Summary for clinical experience with the Sentry IVC Filter. • Movement, migration and tilt are known complications of IVC filters. Migration of filters to the heart or lungs has been reported. There have also been repots of caudal filter migration. Migration may be caused by placement in IVCs with diameters exceeding the dimensions specified in the Filter IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens. Refer to Clinical Summary for clinical experience with the Sentry IVC Filter. **PRECAUTIONS:** • The Safety and effectiveness of this device has not been established for pediatric patients. • Venacavography must always be performed to select a proper implant site. Radiographs, without contrast, which do not clearly show the wall of the IVC, may be misleading. • Patients should be returned to anti-thrombotic therapy as soon as it is deemed safe. • The safety and effectiveness of this device has not been established for pregnancy, nor in suprarenal placement position. Following Filter placement, no central venous catheterization should be attempted without fluoroscopic guidance to ensure the location of the deployed Filter is known thereby reducing potential for entrapment of other devices in the Filter and subsequent sequelae. **POTENTIAL COMPLICATIONS:** Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure. Possible complications associated with IVC filter implantation include, but are not limited to, the following: • Access site complications (hemorrhage, thrombus, aneurysm, infection, intervention) • Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter or originated from superior or collateral vessels. • Arteriovenous fistula • Blood loss • Death • Edema • Embolism/Air embolism • Hematoma or nerve injury at the puncture site • Hemorrhage with or without transfusion • Extravasation of contrast material at time of vena cavogram • Infections (local or systemic) • IVC filter complications • Caval thrombosis, stenosis or occlusion **PI-719210-AA**

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