

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

Michael D. Dake, MD et al. J Vasc Interv Radiol. 2018; 29: 1350-1361.e4
and SENTRY Trial 2-year Update, VIVA Symposium, Nov 2018.

Objectives

Evaluate the safety and efficacy of the BTG Sentry IVC filter.

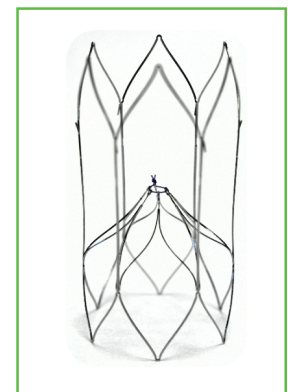
- **Primary Endpoint:** Composite endpoint encompassing -
 - Technical success in deployment without acute events;
 - Freedom from new symptomatic Pulmonary Embolism at 60 days
 - Freedom from IVC filter related complications at 6 months
- **Secondary Endpoints Include:** Freedom from IVC filter complications and new symptomatic PEs at 12 months

Patients

- ≥ 18 years of age
- Requirement of transient PE protection of < 60 days
- Documented or high risk of PE or DVT
- Inability to use anti-coagulation due to contraindication, failure, complication or risk of injury from pharmacotherapy
- n= 129; 23 centers

Methods

- BTG Sentry IVC filter placed following IFU protocol
- Imaging at baseline, 1, 2, 6, 12, and 24 months leveraging various imaging modalities
- Independent CEC, DSMB, and core lab
- External monitoring with 100% source data verification
- 100% of eligible subjects imaged at 12 months (n=111) and 24 months (n=85)



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Key Results

- **97.4% met the primary composite endpoint:**
 - 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) including:
 - No tilting, migration, embolization, fracture, or perforation
 - Two symptomatic caval thrombosis (one at day 8 & day 32)
 - No other symptomatic filter related complication requiring invasive intervention, or filter-related death
- **No new symptomatic PEs or IVC filter-related stability complications through 12 months**
- **Zero additional instances of IVC filter tilt, migration, embolization, fracture or IVC perforation through 24-months³**
- **96.4% of BTG Sentry filters bioconverted at 12 months (106/110) and 96.5% at 24 months (82/85)**
 - No need to place a second filter at any time during the original PE protection period

BTG Sentry IVC Filter Trial Secondary Endpoints

	0-1 month (n=129)	1-2 months (n=127)	2-6 months (n=126)	6-12 months (n=117)	12-24 months (n=85) ^{3,4}	SIR reported rates ¹
New symptomatic PE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.5-6%
Stability complications	1 month (n=129)	2 months (n=119)	6 months (n=114)	12 months (n=111)	24 months (n=85)³	Published rates²
Tilt	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0-55%
Migration	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0-25%
Fracture	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0-50%
IVC perforation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1-100%
Any complication found on imaging	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	

Conclusion

The BTG Sentry Bioconvertible IVC filter provided safe and effective protection against PE through transient risk period, with a high rate of bioconversion and a low rate of device-related complications, through 24 months of imaging-intense follow-up. The SENTRY Study represents an important paradigm shift in the prevention of PE with a next generation device.³

1 - Caplin. *J. Vasc. Interv. Radiol.* 2011; 22, 1499-1506; reporting periods vary for cited rates.

2 - Deso. *Semin Intervent Radio* 2016; 33:93-100; reporting periods vary for cited rates.

3 - Dake, M., *SENTRY Trial 2-year Update, VIVA Symposium*, Nov 2018

4 - 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 related.

Product availability varies by country. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Prior to use, please refer to the applicable Instructions for Use (IFU) for complete product indications, contraindications, warnings, and precautions.

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