Update on the Sentry Bioconvertible Non-Retrieval IVC Filter

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CAUTION: Investigational device, Contraindicated for use in pregnant women. Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Financial Relationship Disclosures

• Novate Medical Ltd. shareholder

Retrievable VC Filters Meta-analyses (n=9419)

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<th>Author</th>
<th>Journal</th>
<th>No. VCF's</th>
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<td>Sarosiek</td>
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<td>J Hosp Med 2009</td>
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Sentry VC Filter

• Represents next generation filter
• "Bioconvertible" device with a cylindrical, stabilizing frame
• Needs no retrieval
• Intended to provide PE protection for no less than 60 days
• Unique design should reduce filter related complications: tilting, fracture, perforation, and embolization

Filter configuration

Bioconverted configuration
**Filtering @ 60 days**

**Bioconverts after 60 days**

**CT**

**CTV**

**Pathology**

**Histology**

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**What Happens After Filter Bioconverts?**

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**Is 60 Days Long Enough To Protect Patient From PE?**

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**Sentry Filter IDE Study (n=135)**

- PI: Michael Dake MD, Stanford, CA
- PURPOSE: Evaluate safety, efficacy and results for 510(k)
- DESIGN: Prospective, single arm, multi-center study
- SITES: Include up to 25 US and OUS
- PRIMARY ENDPOINTS: Composite rate of clinical success at 6 months defined as
  - Technical success
  - Freedom from symptomatic PE during 60 day protection period
  - Freedom from filter related complications

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**Conclusion**

The Sentry VC Filter is a bioconvertible device which remains in the filtering configuration for a minimum of 60 days, offering temporary protection from PE

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**Conclusion**

The device then bioconverts:

- Filter cone apex separates
- Filter arms retract and embed in VC wall
- Resulting in a widely patent lumen
- Thereby, avoiding the necessity of a second invasive retrieval procedure to remove the filter.