**Disclosure**

Speaker name:
Erin H. Murphy, MD, FACS

- I have the following potential conflicts of interest to report:
  - Receipt of grants/research support
  - Receipt of honoraria and travel support
  - Participation in a company sponsored speakers’ bureau
  - Employment in industry
  - Shareholder in a healthcare company
  - Owner of a healthcare company
  - Consultant: Medtronic, Boston Scientific, Philips Volcano, Vesper, Cook

- I do not have any potential conflict of interest

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**Abre™ Venous Self-Expanding Stent System**

- First generation dedicated venous stent from Medtronic
- CE mark in April 2017
- First implant in US and Europe in December 2017
- This marked the start of the US IDE Trial as well as commercialization in Europe

**Disclaimer:** The Abre™ self-expanding venous stent received CE Mark in 2017 and is available for commercial use in Europe. Abre™ is not commercially available in the United States.

**Abre™ Venous Self-Expanding Stent System**

- **Indications for Use:**
  - The Abre™ Venous Self-Expanding Stent System is intended for use in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction

- **Contraindications:**
  - Do not use the Abre™ system with patient with known hypersensitivity to nickel titanium (nitinol)
  - Do not use the Abre™ system with patients in whom anticoagulant or antiplatelet therapy is contraindicated

- **ABRE – Stent Sizing**

  
<table>
<thead>
<tr>
<th>Size Matrix</th>
<th>Lengths</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 mm</td>
<td>18 mm</td>
</tr>
<tr>
<td>16 mm</td>
<td>14 mm</td>
</tr>
<tr>
<td>12 mm</td>
<td>10 mm</td>
</tr>
<tr>
<td>8 mm</td>
<td>6 mm</td>
</tr>
</tbody>
</table>

  - Selection of stent length: Cover lesions & land in healthy vessel, avoid skip areas between stents, avoid overlapping stents under il, prevent stent migration

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**Abre™ Venous Self-Expanding Stent System**

The Abre system consists of:

- **Stent:**
  - Flexible
  - Self-expanding
  - Nickel-titanium alloy (nitinol)

- **Stent Delivery System:**
  - Over-the-wire
  - 0.018" guidewire compatible
  - Triaxial catheter (inner shaft, retractable sheath, and an isolation sheath)

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**Abre™ Venous Self-Expanding Stent System**

- **Selection of stent length:** Cover lesions & land in healthy vessel, avoid skip areas between stents, avoid overlapping stents under il, prevent stent migration
**ABRE – Strength across diameters**

*The Abre™ Stent*

- **Challenge in venous stent design:** Maintaining strength uniformly across larger stent diameters.
- **Addressed with customized design for each stent size:** Each diameter has customized strut dimensions, achieved by altering wall thickness, length of struts and width of struts, designed to deliver uniform radial strength and compression resistance.

**Test data on file at Medtronic. Bench test results may not be indicative of clinical performance.**

**ABRE – Flexibility**

*The Abre™ Stent*

- Open-cell design with 3 connection points between the struts to optimize flexibility and stable deployment.
- More connection points – prone to breakage.
- Less – prone to hinge points.
- Connection points are offset and spiral to allow more flexibility than a straight line would.

**ABRE – Durability**

*The Abre™ Stent*

- Key Factor driving durability: Strut radii at corners of compacted stent.
- Reduce breakage and maintain 9F: Radii opened selectively and varied.
- Unique strut radii design, optimized to stent durability.

**ABRE – Precise Deployment**

*The Abre™ Stent*

- Tri-axial shaft design removes friction and stabilizes stent position.
- Rotating thumb wheel offers predictable placement cranially and caudally with tactile & auditory feedback.

*Test data on file at Medtronic. Bench test results may not be indicative of clinical performance.*

**ABRE Investigational Device**

- **Purpose**: Evaluate the safety and effectiveness of the Abre venous self-expanding stent system.
- **Study design**: Prospective, multi-center, single-arm, non-randomized study in the US and EU.
- **Sample size**: 200 subjects (minimum of 100 subjects from the US) included from up to 35 sites.
- **Indication**: Intended for treatment of symptomatic iliofemoral venous outflow obstruction.
- **Patient Populations**: Acute deep vein thrombosis (ADVT), Post-thrombotic syndrome (PTS), Non-thrombotic iliac vein lesion (NIVL).
- **Follow-up**: 1-, 6-, 12-, 24- and 36-months post-index procedure.
- **Primary endpoints**: Primary effectiveness: Primary patency at 12 months, defined as freedom from target lesion occlusion and restenosis ≥50% and freedom from clinically driven target lesion revascularization.
- **Primary safety**: Major adverse events at 30 days.

**ABRE US Sites - 16**

- [Dr. Ross](#)
  - Piedmont Atlanta Hos
  - Atlanta, GA
- [Dr. Kolluri](#)
  - OHR Methodist Hosp
  - Columbus, OH
- [Dr. Gagne](#)
  - The Vascular Experts
  - Darien, CT
- [Dr. Dexter](#)
  - Sentara Vascular
  - Norfolk, VA
- [Dr. Rundback](#)
  - Holy Name Med Ctr
  - Teaneck, NJ
- [Dr. Bjarnason](#)
  - Mayo Clinic
  - Rochester, MN
- [Dr. Berland](#)
  - NYU Langone MC
  - New York, NY
- [Dr. Razavi](#)
  - Saint Joseph Hospital
  - Orange, CA
- [Dr. Hnath](#)
  - Albany Med Center
  - Albany, NY
- [Dr. Williams](#)
  - UM Health System
  - Ann Arbor, MI
- [Dr. DeFreitas](#)
  - NC Heart and Vascular
  - Raleigh, NC
- [Dr. Ting](#)
  - Mount Sinai Hospital
  - New York, NY
- [Dr. Gibson](#)
  - Lake Washington Vasc
  - Bellevue, WA
- [Dr. R.](#)
  - Atrium Health Orange
  - Charlotte, NC
- [Dr. McAllister](#)
  -心脏中心 北卡罗来纳州 诺曼，NC
- [Dr. Neeraj](#)
  - Cardiac Center Texas
  - McAllen, TX
- [Dr. Driscoll](#)
  - Cardioworld Heart Center
  - Columbus, OH
- [Dr. Thompson](#)
  - Virginia Med Center
  - Richmond, VA
- [Dr. Panos](#)
  - Carolina Orthopaedic
  - Charlotte, NC
- [Dr. Williams](#)
  - UAB Health System
  - Birmingham, AL
- [Dr. Khan](#)
  - Cardiac Center Texas
  - McKinney, TX
- [Dr. Gasparis](#)
  - SB Univ Hospital
  - Stony Brook, NY