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SENTINEL™ Cerebral Protection System Media Kit Overview

Boston Scientific created this media kit as a resource to help your institution proactively discuss your work in the treatment of severe aortic stenosis and use of the SENTINEL™ Cerebral Protection System for protected transcatheter aortic valve replacement (TAVR). The kit includes several documents with specific instructions on their use. You may also print or repurpose these materials for your institution's website.

I. **Media Outreach Guide**: This guide can be used to learn how to engage with reporters to let them know about the availability of the SENTINEL Cerebral Protection System at your institution.
- Audience: Marketing and communications managers

II. **Media Interview Guide:** This guide outlines how to effectively communicate your message to engage with reporters and increase awareness of the SENTINEL Cerebral Protection System and TAVR technology at your institution.
- Audience: Reporters

III. **Talking Points**: These key messages for media spokespeople about the SENTINEL device can be used to help guide conversations with reporters during interviews.
- Audience: Spokespeople

IV. **Template Press Release**: This is a sample press release that can be customized to announce your institution's first use of the SENTINEL device.
- Audience: Reporters

V. **Template Media Pitch**: This document includes a template email that can be sent to reporters when you are reaching out to them to proactively discuss the use of the SENTINEL device at your institution.
- Audience: Reporters

VI. **Sample Website Copy**: This sample content is intended to be used on your institution's website to let visitors know about the use of the SENTINEL device at your location.
- Audience: Patients and Caregivers

VII. **Social Media Posts**: This document includes template Twitter, Facebook and LinkedIn posts that can be used on your social media channels to announce the use of the SENTINEL device at your institution.
- Audience: Patients and Caregivers

VIII. **Product Backgrounder:** This document provides background information on the SENTINEL device. Content includes clinical results of the device and information about treating aortic valve disease.
- Audience: Reporters

You can also download an image of the SENTINEL Cerebral Protection System here as well as device animation and additional resources here. If you have any questions, please contact: media@bsci.com.

I. Media Outreach Guide

Media Outreach: Getting Started

There are several steps you can take to help increase awareness of the treatment of severe aortic stenosis and use of the SENTINEL™ Cerebral Protection System at your facility. Below are some tips for contacting reporters who may be interested in writing about the hospital, patients and treatment options.

When to Reach Out to Reporters

- When your practice has news such as a new procedure or product you offer to patients, such as the SENTINEL device.
    - Reporters are often most interested in a story when you can put them in contact with local patients who can make the story come alive by providing interesting or unique perspectives. Please consult with your privacy team about obtaining patient consent before sharing the patient's name with a reporter.
- To build upon or piggy-back on national news or other trends receiving media coverage, such as the trend of transcatheter aortic valve replacement (TAVR) as a minimally-invasive option for those with severe aortic stenosis. If a story is popular in the national news, local reporters are often looking to cover how the news affects people in the local area.

How to Identify the Right Reporters

- Target a list of media contacts at your local print and online newspapers, TV and radio stations and update it periodically.
    - Include such information as the reporter's beat (i.e., topics he/she typically covers). Medical, health and science editors/reporters and feature editors/reporters are typically most interested in healthcare stories.
    - If you cannot reach the editor or reporter, call the general number and ask for the assignment editor who will direct you to the best contact for the story angle.
- The best way to identify local reporters is to follow the news. Watch local TV, listen to the radio and read the local newspaper to identify the reporters who cover the kind of medical stories most relevant to your practice and your patients.
- Do online research. Nearly all newspapers, television and radio stations have a website with general contact information.
- Twitter can also be a great resource. Many journalists will either have an e-mail listed or a link to a website where their contact information can be found.

Tools You Can Use to Contact Reporters

- Press Release
    - Press releases can be sent to local media contacts or distributed via a news service, also known as a wire, to a wider list of reporters who review them to obtain story ideas.
    - To reach a specific reporter directly, the best way to distribute a press release is via email so you can reach the reporter as quickly as possible.
- Pitch Email
    - A pitch email is targeted to a specific media contact and offers news or a story idea tailored to the reporter's interests, media outlet and its audience.

Additional Tips

- Call the reporter within a day of sending the press release or pitch email to gauge their interest level.
- If you email information to a reporter, don't send an attachment unless the reporter has requested it.
- Be persistent, but polite. If a reporter declines your story, ask them if it's okay for you to stay in touch in case anything changes.
- Consider timing media outreach until after first patient is discharged, to ensure positive clinical outcomes.

II. **Media Interview Guide**

Media Outreach: Preparing for a Media Interview

Media interviews are usually quick, which means there is a short window of time to deliver information. Below you will find helpful ideas to ensure your spokesperson gets your message across when speaking with the media about the SENTINEL™ Cerebral Protection System.

Delivering Your Message

Take Control

- Know what you want to accomplish in the interview and take control. Don't wait for the reporter to guide you through your story. Deliver your messages early and often. Use bridges to get back to the points you want to make.

Use Flags

- Phrases such as "What's most important…" and "The key thing is…" and "There are three critical factors…" signal to the audience that you're about to say something important.

Build Bridges

- Building bridges is one of the most important interview techniques. Often a reporter will ask you a question that may not allow you to dive right into your message. Don't just answer his or her question; find a way to go beyond the answer to your message.

Turn negatives into POSITIVES

- If the reporter asks you a negative question, don't be defensive and don't repeat the negative question as part of your response. Address the negative with your perspective – and then bridge to a message. Always end on a positive note.

*Please note – NOTHING is off the record

Ways to Bridge

- **ADDRESS the Immediate Question**
  (Without echoing negative language)
  - *"Not at all…"*
  - *"On the contrary…"*
  - *"I wouldn't phrase it that way…"*
  - *"That hasn't been my/our experience…"*

- **BRIDGE to a Key Message**
  - *"…but what I can tell you is…"*
  - *"…the important issue here is…"*
  - *"…the point I want to get across is…"*
  - *"…the most important thing to note is…"*
  - *"…the answer to the question I think you're asking is…"*

- **DELIVER the Key Message**
  - Bridging can also be used to provide additional information
    - *"You're absolutely right to say that, but there's another aspect to this that people may not realize…*

III. Talking Points

Talking Points

The **primary points** that should be communicated in interviews around TAVR or the SENTINEL™ Device:

1. **Aortic valve stenosis affects 7% of all people over the age of 65.**[1]
    a) Severe aortic stenosis is the significant narrowing of the aortic valve opening. Over time, the valve leaflets can become stiff, reducing their ability to fully open and close. When this happens, your heart needs to work harder to move blood throughout the body.[2]
    b) The symptoms most frequently associated with severe aortic stenosis include: shortness of breath; chest pain, pressure, or tightness; fatigue; feeling lightheaded or dizzy; difficulty when exercising or completing day-to-day activities. [3]
    c) The only effective treatment is to replace the aortic valve. Left untreated, severe aortic stenosis can eventually lead to heart failure, severe infection and even death.[3]

2. **The SENTINEL device is the first and only commercially available device in the U.S. offering protected TAVR – proven embolic protection against the risk of TAVR-related stroke.**
    a. Stroke is a devastating and unpredictable occurrence, and one of the biggest concerns of any patient and physician.
    b. While transcatheter aortic valve replacement (TAVR) – a minimally invasive procedure to replace the diseased aortic valve – is now comparable with surgical alternatives in terms of effectiveness and safety, there is still a risk that embolic debris can dislodge during the procedure and potentially cause a stroke.
        i. Stroke rates ranging from 1-9% have been reported across all contemporary TAVR procedures, with an average of 3%.[4-17]
    c. The SENTINEL Cerebral Protection System (CPS) provides protection against stroke by capturing embolic debris dislodged during TAVR before it can reach the brain.
        i. Clinical evidence shows that cerebral embolic debris is generated in the vast majority of patients undergoing TAVR, regardless of patient risk profile or valve type.[18-20]
        ii. The SENTINEL IDE showed that 1 in 4 TAVR patients had an average of 25 pieces of debris captured and removed by the SENTINEL device that were visible to the naked eye.[20]

3. **Clinical trials involving more than 3,500* patients have demonstrated that the SENTINEL device is safe and effective.**[18,21-22]
    a. The SENTINEL device captures and removes cerebral embolic debris in 99% of TAVR patients.[20]
    b. Studies show a 63% reduction in TAVR-related strokes when SENTINEL Cerebral Protection was used.[20]
    c. SENTINEL technology has been used to protect thousands of patients worldwide and is the most-studied embolic protection device in its field.
    d. SENTINEL does not impact cath lab workflow or procedural timing.[20]
        i. One size accommodates 90% of anatomies
        ii. 4 minutes median deployment time to place both filters

    * Clinical studies including 3,500 patients, with 2,600 receiving the SENTINEL device

4. **To learn more about the SENTINEL device, visit: www.bostonscientific.com/sentinel** or **www.treattheheart.com**.

1. Arora, et al. Transcatheter Aortic Valve Replacement: Comprehensive Review and Present Status. Tex Heart Inst J. 2017 Feb 1;44(1):29-38. doi: 10.14503/THIJ-16-5852.
2. Kurtz, et al. Aortic stenosis: clinical aspects of diagnosis and management, with 10 illustrative case reports from a 25-year experience. Medicine (Baltimore). 2010 Nov;89(6):349-79. doi: 10.1097/MD.0b013e3181fe5648.
3. Nishimura RA. Aortic Valve Disease. Circulation. 2002;106:770–772. https://doi.org/10.1161/01.CIR.0000027621.26167.5E.
4. Kapadia, et al. Cerebral Embolic Protection During Transcatheter Aortic Valve Replacement. J Am Coll Cardiol. 2017 Jan 31;69(4):367-377. doi: 10.1016/j.jacc.2016.10.023.
5. Popma, et al. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. N Engl J Med. 2019 May 2;380(18):1706-1715. doi: 10.1056/NEJMoa1816885.
6. Mack, et al. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. N Engl J Med. 2019 May 2;380(18):1695-1705. doi: 10.1056/NEJMoa1814052.
7. Linke, et al. Treatment of Aortic Stenosis With a Self-Expanding, Resheathable Transcatheter Valve. Circ Cardiovasc Interv. 2018 Feb;11(2):e005206. doi: 10.1161/CIRCINTERVENTIONS.117.005206. (SUPPLEMENT)
8. Sondergaard, et al. One-Year Outcomes with a Self-Expanding, Repositionable Transcatheter Heart Valve in Severe Aortic Stenosis Patients: PORTICO-I. J Am Coll Cardiol. 2018 Dec 11;72(23 Pt A):2859-2867. doi: 10.1016/j.jacc.2018.09.014.
9. Grube, et al. J Am Coll Cardiol. Clinical Outcomes With a Repositionable Self-Expanding Transcatheter Aortic Valve Prosthesis: The International FORWARD Study. Aug 15;70(7):845-853. doi: 10.1016/j.jacc.2017.06.045.
10. Grube E. presented at Euro PCR 2019.
11. Thourani, et al.Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. Lancet. 2016 May 28;387(10034):2218-25. doi: 10.1016/S0140-6736(16)30073-3.
12. Kodali, et al. Early clinical and echocardiographic outcomes after SAPIEN 3 transcatheter aortic valve replacement in inoperable, high-risk and intermediate-risk patients with aortic stenosis. Eur Heart J. 2016 Jul 21;37(28):2252-62. doi: 10.1093/eurheartj/ehw112.
13. Meredith, et al. Repositionable percutaneous aortic valve implantation with the LOTUS valve: 30-day and 1-year outcomes in 250 high-risk surgical patients. EuroIntervention. 2017 Sep 20;13(7):788-795. doi: 10.4244/EIJ-D-16-01024.
14. Feldman, et al. Effect of Mechanically Expanded vs Self-Expanding Transcatheter Aortic Valve Replacement on Mortality and Major Adverse Clinical Events in High-Risk Patients With Aortic Stenosis: The REPRISE III Randomized Clinical Trial. JAMA. 2018 Jan 2;319(1):27-37. doi: 10.1001/jama.2017.19132.
15. Van Mieghem, et al. Use of a Repositionable and Fully Retrievable Aortic Valve in Routine Clinical Practice: The RESPOND Study and RESPOND Extension Cohort. JACC Cardiovasc Interv. 2019 Jan 14;12(1):38-49. doi: 10.1016/j.jcin.2018.10.052.
16. Tchétché, et al. 1-Year Outcomes of the CENTERA-EU Trial Assessing a Novel Self-Expanding Transcatheter Heart Valve. JACC Cardiovasc Interv. 2019 Apr 8;12(7):673-680. doi: 10.1016/j.jcin.2019.01.231.
17. Thyregod, et al. Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis: 1-Year Results From the All-Comers NOTION Randomized Clinical Trial. J Am Coll Cardiol. 2015 May 26;65(20):2184-94. doi: 10.1016/j.jacc.2015.03.014.
18. Van Mieghem, et al. Histopathology of embolic debris captured during transcatheter aortic valve replacement. Circulation 2013;127:2194–201.
19. Schäfer U. Safety and Efficacy of Protected Cardiac Intervention: Clinical Evidence for Sentinel Cerebral Embolic Protection. Interv Cardio Review. 2017;12(2):128–32.
20. SENTINEL IDE Trial. Data presented at SENTINEL FDA Advisory Panel, February 23, 2017.
21. Seeger J. Snapshots from Real World High Volume Single Center Experiences with Sentinel Cerebral Embolic Protection During TAVR, University of Ulm, presented at TVT 2018.
22. Chakravarty T. Snapshots from Real World High Volume Single Center Experiences with Sentinel Cerebral Embolic Protection During TAVR, Cedars Sinai Medical Center, presented at TVT 2018.

IV. Template Press Release

HEADLINE 1: [INSERT FACILITY NAME] Is First in [INSERT CITY/REGION] To Use Device Designed to Reduce Risk of Stroke During Heart Valve Replacement Procedures

OR

HEADLINE 2: [INSERT FACILITY NAME] Now Offers Device Designed to Reduce Risk of Stroke during Valve Replacement Procedures

[INSERT CITY], [INSERT STATE], [INSERT MONTH, DAY, YEAR] – [INSERT TIMING], [INSERT PHYSICIAN NAME] completed a procedure using the SENTINEL™ Cerebral Protection System, a new technology shown to help protect patients from the risk of stroke during a minimally invasive heart valve procedure known as transcatheter aortic valve replacement (TAVR). This is the first time this protected TAVR device was used in [INSERT STATE, CITY OR REGION].

As a non-surgical alternative to replace the aortic valve in patients with aortic stenosis, TAVR can help save lives and significantly improve quality of life. However, like all medical procedures, it may involve risk. During TAVR procedures, embolic debris such as calcium or tissue can break loose, travel through the bloodstream towards the brain and potentially cause neurological and neurocognitive damage. Recent studies have estimated approximately 3%* of patients experience a clinically-apparent stroke within 30 days of a TAVR procedure.[1-14]

The SENTINEL™ Cerebral Protection System filters, captures and removes such debris, and is the only FDA-cleared device to protect the brain against the risk of stroke during TAVR. It has been shown to capture debris flowing toward the brain in 99% of TAVR cases, and to reduce the incidence of strokes by 63% within the first 72 hours of the procedure.[15]

OPTIONAL TEXT:
[INSTITUTION NAME] is also among the first institutions to offer this protected TAVR technology in conjunction with the new LOTUS *Edge*™ Aortic Valve System for patients with severe aortic stenosis. This technology is the only aortic valve approved by the FDA that is 100 percent repositionable, and its design also minimizes leaking by conforming to the patient's native aortic valve.

[INSERT A QUOTE ATTRIBUTED TO YOUR PHYSICIAN. POTENTIAL, SAMPLE QUOTE IS INCLUDED BELOW OR YOU CAN INSERT YOUR OWN QUOTE.]

"The risk of stroke is a reality of the TAVR procedure and the SENTINEL System has been shown to help reduce that risk," said [INSERT PHYSICIAN NAME, TITLE]. "I am proud to have performed the first procedure in [INSERT CITY/REGION] using this device which advances our mission of offering patients the latest medical technologies."

About Aortic Valve Disease
Aortic valve disease results in dysfunction of the aortic valve, one of the four valves that control the flow of blood in and out of the heart. Aortic valve stenosis is the process of thickening and stiffening in the valve, which can result in an abnormal narrowing of the aortic valve opening and reduction in blood flow. Aortic stenosis is a common problem affecting approximately 7% of all people over age 65.[16] From the onset of severe aortic stenosis symptoms, the average survival rate is 50% at two years and 20% at five years.[17-19]

For more information on the SENTINEL CPS, please visit [INSERT INSTITUTION WEBSITE].

*Stroke rates ranging from 1-9% have been reported across all contemporary TAVR procedures.

[INSERT CLINIC BOILERPLATE DESCRIPTION HERE]

CONTACT:

[HOSPITAL PR CONTACT NAME]
[TITLE], [HOSPITAL NAME]
[PHONE NUMBER]
[EMAIL ADDRESS]

1. Kapadia, et al. Cerebral Embolic Protection During Transcatheter Aortic Valve Replacement. J Am Coll Cardiol. 2017 Jan 31;69(4):367-377. doi: 10.1016/j.jacc.2016.10.023.
2. Popma, et al. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. N Engl J Med. 2019 May 2;380(18):1706-1715. doi: 10.1056/NEJMoa1816885.
3. Mack, et al. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. N Engl J Med. 2019 May 2;380(18):1695-1705. doi: 10.1056/NEJMoa1814052.
4. Linke, et al. Treatment of Aortic Stenosis With a Self-Expanding, Resheathable Transcatheter Valve. Circ Cardiovasc Interv. 2018 Feb;11(2):e005206. doi: 10.1161/CIRCINTERVENTIONS.117.005206. (SUPPLEMENT)
5. Sondergaard, et al. One-Year Outcomes with a Self-Expanding, Repositionable Transcatheter Heart Valve in Severe Aortic Stenosis Patients: PORTICO-I. J Am Coll Cardiol. 2018 Dec 11;72(23 Pt A):2859-2867. doi: 10.1016/j.jacc.2018.09.014.
6. Grube, et al. J Am Coll Cardiol. Clinical Outcomes With a Repositionable Self-Expanding Transcatheter Aortic Valve Prosthesis: The International FORWARD Study. Aug 15;70(7):845-853. doi: 10.1016/j.jacc.2017.06.045.
7. Grube E. presented at Euro PCR 2019.
8. Thourani, et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. Lancet. 2016 May 28;387(10034):2218-25. doi: 10.1016/S0140-6736(16)30073-3.
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10. Meredith, et al. Repositionable percutaneous aortic valve implantation with the LOTUS valve: 30-day and 1-year outcomes in 250 high-risk surgical patients. EuroIntervention. 2017 Sep 20;13(7):788-795. doi: 10.4244/EIJ-D-16-01024.
11. Feldman, et al. Effect of Mechanically Expanded vs Self-Expanding Transcatheter Aortic Valve Replacement on Mortality and Major Adverse Clinical Events in High-Risk Patients With Aortic Stenosis: The REPRISE III Randomized Clinical Trial. JAMA. 2018 Jan 2;319(1):27-37. doi: 10.1001/jama.2017.19132.
12. Van Mieghem, et al. Use of a Repositionable and Fully Retrievable Aortic Valve in Routine Clinical Practice: The RESPOND Study and RESPOND Extension Cohort. JACC Cardiovasc Interv. 2019 Jan 14;12(1):38-49. doi: 10.1016/j.jcin.2018.10.052.
13. Tchétché, et al. 1-Year Outcomes of the CENTERA-EU Trial Assessing a Novel Self-Expanding Transcatheter Heart Valve. JACC Cardiovasc Interv. 2019 Apr 8;12(7):673-680. doi: 10.1016/j.jcin.2019.01.231.
14. Thyregod, et al. Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis: 1-Year Results From the All-Comers NOTION Randomized Clinical Trial. J Am Coll Cardiol. 2015 May 26;65(20):2184-94. doi: 10.1016/j.jacc.2015.03.014.
15. SENTINEL trial. Data presented at SENTINEL FDA Advisory Panel, February 23, 2017.
16. Arora, et al. Transcatheter Aortic Valve Replacement: Comprehensive Review and Present Status. Tex Heart Inst J. 2017 Feb 1;44(1):29-38. doi: 10.14503/THIJ-16-5852.
17. Grimard, et al. Aortic Stenosis: Diagnosis and Treatment. Am Family Physician. 2008; 78(6):717-725.
18. Ramaraj, et al. Degenerative Aortic Stenosis. BMJ. 2008; 336(7643):550-555.
19. Lester, et al. CHEST 1998; 113:1109-14.

V. Template Media Pitch

SUBJECT LINE: [INSERT FACILITY NAME] Is [First/Among First] in [INSERT CITY/REGION] to use Device Designed to Reduce Risk of Stroke during Heart Valve Replacement Procedures

[INSERT REPORTER NAME],

[INSERT TIMING], Dr. [INSERT NAME] of [INSERT INSTITUTION NAME] is one of the first cardiologists in [INSERT CITY/REGION] to use a device shown to protect patients with aortic stenosis from stroke during a minimally-invasive transcatheter aortic valve replacement (TAVR) procedure to restore proper blood to the diseased valve.

OR

[*ALTERNATIVE INTRO/PATIENT STORY DETAILS IF AVAILABLE/OF INTEREST AND HAVE PATIENT CONSENT; PLEASE CONSULT WITH YOUR LEGAL COUNSEL TO ENSURE PROPER CONSENT FORM*].

[INSERT TIMING], a [INSERT CITY, REGION] man/woman has become the first patient in the area to undergo a minimally-invasive transcatheter aortic valve replacement (TAVR) procedure while using a new technology to protect his/her brain from the risk of stroke. The procedure was performed at [INSERT FACILITY NAME].

As a non-surgical alternative to replace the aortic valve in patients with aortic stenosis, TAVR can help save lives and significantly improve quality of life. However, like all medical procedures, it may involve risk. Embolic debris such as calcium or tissue can break loose during the procedure, travel through the bloodstream towards the brain and potentially cause neurological and neurocognitive damage. Recent studies have estimated that approximately 3%* of patients who are undergoing a TAVR procedure experience a clinically-apparent stroke within 30 days.[1-14]

The SENTINEL™ Cerebral Protection System filters, captures and removes debris, and is the only FDA-cleared device to protect patients against the risk of stroke during TAVR. It has been shown to capture debris flowing toward the brain in 99% of TAVR cases, and to reduce the incidence of strokes by 63% within the first 72 hours of the procedure.[15]

OPTIONAL TEXT:
[INSTITUTION NAME] is also among the first institutions to offer this protected TAVR technology in conjunction with the newly FDA-approved LOTUS *Edge*™ Aortic Valve System for patients with severe aortic stenosis.

A news release with more information about the SENTINEL device is included below. Please let me know if I can help facilitate an interview with the patient or [PHYSICIAN NAME].

*Stroke rates ranging from 1-9% have been reported across all contemporary TAVR procedures.

Best,

[INSERT NAME & CONTACT INFORMATION]

[INSERT FULL TEXT OF PRESS RELEASE]

1. Kapadia, et al. Cerebral Embolic Protection During Transcatheter Aortic Valve Replacement. J Am Coll Cardiol. 2017 Jan 31;69(4):367-377. doi: 10.1016/j.jacc.2016.10.023.
2. Popma, et al. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. N Engl J Med. 2019 May 2;380(18):1706-1715. doi: 10.1056/NEJMoa1816885.
3. Mack, et al. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. N Engl J Med. 2019 May 2;380(18):1695-1705. doi: 10.1056/NEJMoa1814052.
4. Linke, et al. Treatment of Aortic Stenosis With a Self-Expanding, Resheathable Transcatheter Valve. Circ Cardiovasc Interv. 2018 Feb;11(2):e005206. doi: 10.1161/CIRCINTERVENTIONS.117.005206. (SUPPLEMENT)
5. Sondergaard, et al. One-Year Outcomes with a Self-Expanding, Repositionable Transcatheter Heart Valve in Severe Aortic Stenosis Patients: PORTICO-I. J Am Coll Cardiol. 2018 Dec 11;72(23 Pt A):2859-2867. doi: 10.1016/j.jacc.2018.09.014.
6. Grube, et al. J Am Coll Cardiol. Clinical Outcomes With a Repositionable Self-Expanding Transcatheter Aortic Valve Prosthesis: The International FORWARD Study. Aug 15;70(7):845-853. doi: 10.1016/j.jacc.2017.06.045.
7. Grube E. presented at Euro PCR 2019.
8. Thourani, et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. Lancet. 2016 May 28;387(10034):2218-25. doi: 10.1016/S0140-6736(16)30073-3.
9. Kodali, et al. Early clinical and echocardiographic outcomes after SAPIEN 3 transcatheter aortic valve replacement in inoperable, high-risk and intermediate-risk patients with aortic stenosis. Eur Heart J. 2016 Jul 21;37(28):2252-62. doi: 10.1093/eurheartj/ehw112.
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11. Feldman, et al. Effect of Mechanically Expanded vs Self-Expanding Transcatheter Aortic Valve Replacement on Mortality and Major Adverse Clinical Events in High-Risk Patients With Aortic Stenosis: The REPRISE III Randomized Clinical Trial. JAMA. 2018 Jan 2;319(1):27-37. doi: 10.1001/jama.2017.19132.
12. Van Mieghem, et al. Use of a Repositionable and Fully Retrievable Aortic Valve in Routine Clinical Practice: The RESPOND Study and RESPOND Extension Cohort. JACC Cardiovasc Interv. 2019 Jan 14;12(1):38-49. doi: 10.1016/j.jcin.2018.10.052.
13. Tchétché, et al. 1-Year Outcomes of the CENTERA-EU Trial Assessing a Novel Self-Expanding Transcatheter Heart Valve. JACC Cardiovasc Interv. 2019 Apr 8;12(7):673-680. doi: 10.1016/j.jcin.2019.01.231.
14. Thyregod, et al. Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis: 1-Year Results From the All-Comers NOTION Randomized Clinical Trial. J Am Coll Cardiol. 2015 May 26;65(20):2184-94. doi: 10.1016/j.jacc.2015.03.014.
15. SENTINEL trial. Data presented at SENTINEL FDA Advisory Panel, February 23, 2017.

VI. Sample Website Copy about SENTINEL™ Cerebral Protection System

[INSTITUTION] is proud to offer the SENTINEL™ Cerebral Protection System shown to help protect patients from risk of stroke during a transcatheter aortic valve replacement (TAVR) procedure.

As a non-surgical alternative for these patients, TAVR can save lives and significantly improve quality of life, but like all medical procedures, it may involve risk.

During the TAVR procedure, pieces of the calcified heart valve or other embolic debris can break loose and travel through the arteries toward the brain. This may block blood flow to the brain, which can cause long-term damage. Unfortunately, the damage is difficult to predict.

The SENTINEL Cerebral Protection System is the first and only device in the U.S. to offer protection from the risk of stroke during TAVR. It works by capturing embolic debris dislodged during TAVR before it can reach the brain.

Clinical trials involving more than 3,500* patients have demonstrated that the SENTINEL device is safe and effective. The SENTINEL Cerebral Protection technology has been used to protect thousands of patients worldwide and is the most-studied embolic protection device in its field. Studies show more than a 60% reduction in TAVR-related strokes when the SENTINEL Cerebral Protection was used. [1-3]

To learn more about the SENTINEL device, please visit http://www.bostonscientific.com/sentinel

[To learn more about (*insert link to any info about TAVR or valve disease you may have on your website*), click here.]

1. Van Mieghem N. Snapshots from Real World High Volume Single Center Experiences with Sentinel Cerebral Embolic Protection During TAVR, Erasmus Medical Center, presented at TVT 2018.
2. Seeger J. Snapshots from Real World High Volume Single Center Experiences with Sentinel Cerebral Embolic Protection During TAVR, University of Ulm, presented at TVT 2018.
3. Chakravarty T. Snapshots from Real World High Volume Single Center Experiences with Sentinel Cerebral Embolic Protection During TAVR, Cedars Sinai Medical Center, presented at TVT 2018.

* Clinical studies including 3,500 patients, with 2,600 receiving the SENTINEL device

VII. Social Media Posts

Below are template Twitter, Facebook and LinkedIn posts that you can use to announce the first procedure at your facility and generate interest in your use of the SENTINEL™ device throughout the year. Keep in mind:

- For added engagement with your followers:
  - Include a photo of the physician who performed the first procedure or a photo of the patient with any of the messages. *[Make sure to obtain appropriate permissions to publish the images.]*
  - Consider using an image of the device in relevant posts.
  - Develop an infographic or quote card that highlights a key statistic.
  - Incorporate the #TAVR hashtag.
- You can create a shortened web link – also known as a bit.ly – by copying and pasting the web address of your desired page destination into https://bitly.com/. It will produce a shorter web link that can be tracked.

Sample Posts

Tweets:

- Proud to be first in [INSERT STATE/REGION] to offer #TAVR patients with an extra layer of protection from #stroke risk – the SENTINEL System. #ProtectedTAVR
- Patient safety is our #1 priority. See how the SENTINEL System reduces #stroke risk in #TAVR procedures. #ProtectedTAVR https://bit.ly/2zJQ1HR (links to whiteboard video) OR https://bit.ly/2WYxTb2 (links to patient brochure)
- Excited to offer the new SENTINEL System that captures/removes debris during #TAVR before it can reach the brain. #ProtectedTAVR bit.ly/2tzh6Jj (link to YouTube animation video or hospital release)

LinkedIn post:

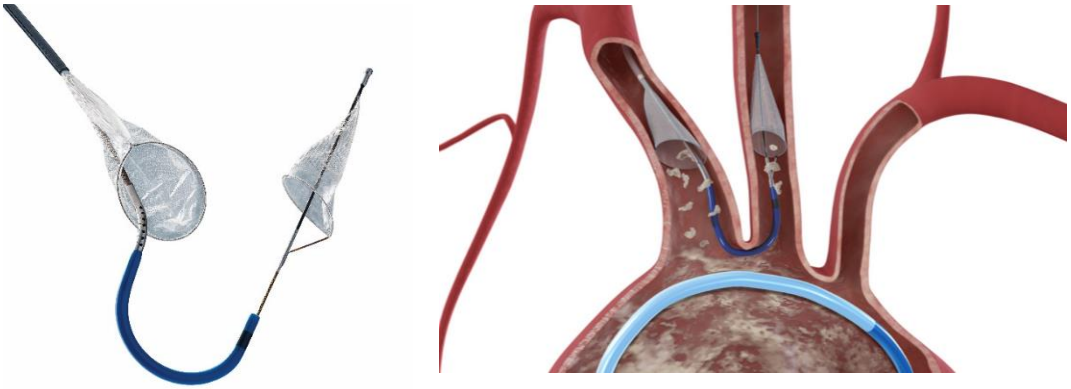
- We are excited to offer advanced technology to help protect patients from the risk of #stroke during #TAVR. The SENTINEL™ Cerebral Protection System filters, captures, and removes potentially dangerous debris before it can reach the brain, and has been shown to reduce the incidence of strokes by 63% within the first 72 hours of the procedure. Read our announcement (link to hospital announcement) and see how it works here: https://bit.ly/2zJQ1HR (links to whiteboard video) OR https://bit.ly/2WYxTb2 (links to patient brochure)

Facebook posts:

- We are proud to be the first in [INSERT STATE/REGION] to offer an extra layer of protection to our patients undergoing minimally invasive heart valve procedure known as transcatheter aortic valve replacement (TAVR). Learn more about the SENTINEL™ Cerebral Protection System here: (link to hospital press release)
- Patient safety is our #1 priority. Our TAVR (transcatheter aortic valve replacement) patients now have the option to help protect themselves from the risk of stroke using the SENTINEL™ Cerebral Protection System, a device that filters, captures, and removes potentially dangerous debris before it can reach the brain. See how it works here: https://bit.ly/2zJQ1HR (links to whiteboard video) OR https://bit.ly/2WYxTb2 (links to patient brochure)

SENTINEL™ Cerebral Protection System

Background Information



What is the SENTINEL Cerebral Protection System (CPS)?

- The SENTINEL CPS is an FDA-cleared and CE-Marked device predominately used during transcatheter aortic valve replacement (TAVR) procedures for patients with aortic valve stenosis, a thickening and stiffening in the valve which can result in abnormal narrowing of the aortic valve opening and reduction in blood flow.
- The SENTINEL CPS is used to filter, capture and remove debris such as calcium or tissue that can break loose during TAVR procedures and travel through the bloodstream towards the brain and potentially cause neurological damage (e.g., stroke).
- The system is percutaneously delivered with an embolic filter delivered to the brachiocephalic artery, and a second embolic filter delivered to the left common carotid artery. At the completion of the procedure, the filters and debris are recaptured into the catheter and removed from the patient.
- The SENTINEL CPS received CE Mark in 2014 and was cleared for use by the U.S. FDA in 2017. The system is commercially available in Europe, the U.S. and select countries in Asia.

SENTINEL Cerebral Protection System Clinical Results

- The SENTINEL CPS has been used in more than 20,000 procedures globally to-date.[1]
- 3,500* patients have been studied in randomized controlled trials and registries.
- The pivotal US SENTINEL IDE trial demonstrated:
    - 63% reduction in peri-procedural “all stroke” to day 3 (3.0% vs 8.2%)[2]
    - 99% debris capture and retrieval verified by independent core-lab[2]
- Post market studies with over 2,000 patients combined prospective/retrospective registries validated a 60-80% peri-procedural relative reduction in neurologist-adjudicated TAVR all-stroke with an average absolute reduction of 3-4% at 72 hours and 7 days post TAVR.[3-5]

Treating Aortic Valve Disease

- Aortic valve disease results in dysfunction of the aortic valve, one of the four valves that control the flow of blood in and out of the heart.
- Aortic valve stenosis, the thickening and stiffening of the valve, is the most common valvular heart disease in the world, affecting approximately 7% of all people over age 65.[6]
- TAVR is a minimally-invasive procedure to replace the aortic valve in patients with aortic stenosis. In fact, an estimated 82,000 TAVR cases will be performed in the U.S. in 2019, and that number is expected to grow to 164,000 by 2025.[7]
- Embolic debris such as calcium or tissue can break loose during the procedure, travel through the bloodstream towards the brain and potentially cause neurological and neurocognitive damage.
- Recent studies have estimated approximately 3%* of patients experience a clinically-apparent stroke within 30 days of a TAVR procedure.[8-21]

Additional Resources:

- Learn more about the SENTINEL Cerebral Protection System at www.bostonscientific.com/sentinel or www.treattheheart.com.
- Download a product image here as well as device animation and additional resources here.

*Stroke rates ranging from 1-9% have been reported across all contemporary TAVR procedures.

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* Clinical studies including 3,500 patients, with 2,600 receiving the SENTINEL device