

LOTUS *Edge*™ Aortic Valve 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 recently U.S. Food and Drug Administration (FDA) approved LOTUS *Edge*™ Aortic Valve System. The kit includes several documents with specific instructions on their use. You may also print or repurpose the press release and/or infographic for your institution's website.

- I. **Media Outreach Guide:** This guide can be used to learn how to engage with reporters to increase awareness of the availability of the LOTUS *Edge* Aortic Valve System and transcatheter aortic valve replacement (TAVR) technology at your institution and when you are training spokespeople for media interviews.
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 LOTUS *Edge* device and TAVR technology at your institution.
Audience: Spokespeople
- III. **Talking Points:** Key messages about the LOTUS *Edge* device and TAVR technology which 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 LOTUS *Edge* 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 LOTUS *Edge* device at your institution.
Audience: Reporters
- VI. **Sample Website Copy:** This sample content is intended to be used on your institution's website to drive awareness of the availability of the LOTUS *Edge* 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 sites to promote the LOTUS *Edge* device at your institution.
Audience: Consumers

We hope you find this information useful. You can also find multimedia assets, including a device image and animation, on our [Multimedia News Release](#). 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 your work in the treatment of severe aortic stenosis and use of the LOTUS *Edge*™ Aortic Valve System. Below are some tips for contacting reporters who may be interested in writing about you, your 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 LOTUS *Edge* 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 Heart Health Month.
 - 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 Contact Reporters

- Make 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.

Tools You Can Use to Contact Reporters

- Press Release
 - A press release is used to inform the media about a newsworthy topic, trend or interesting information.
 - 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 LOTUS Edge™ Aortic Valve 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 each interview:

1. **Aortic valve stenosis affects seven percent 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:³
 - i. Shortness of breath
 - ii. Chest pain, pressure, or tightness
 - iii. Fatigue
 - iv. Feeling lightheaded or dizzy
 - v. Difficulty when exercising or completing day-to-day activities
 - 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. **In April 2019, the U.S. Food and Drug Administration (FDA) approved the LOTUS Edge™ Valve System. This next-generation transcatheter aortic valve replacement (TAVR) technology is the only FDA-approved aortic valve that gives physicians the option to reposition and completely recapture the valve at full deployment.**
 - a. Delivered via a minimally invasive procedure, this TAVR technology is approved for patients with severe aortic stenosis who are considered high-risk for surgical valve replacement via open heart surgery.
 - b. The device features a braided valve frame and an adaptive seal designed to minimize paravalvular leakage by conforming to the patient’s native aortic valve.
3. **The approval of the device was based on data from the REPRISE III clinical trial, the first head-to-head pivotal study comparing two TAVR devices, the LOTUS Valve and the Evolut™R/CoreValve™. This clinical trial evaluated the safety and effectiveness of both devices in a high-risk patient population.**
 - a. Data from the study demonstrated that the LOTUS Valve showed superiority over Evolut R/CoreValve for the primary effectiveness endpoint and non-inferiority for the primary safety endpoint.
 - b. The primary effectiveness endpoint, a composite of all death, disabling stroke and moderate or greater PVL at one year, was lower with the LOTUS Valve compared to Evolut R/CoreValve (15.8% vs. 26.0%, p<0.001). The LOTUS Valve also demonstrated non-inferiority to Evolut R/CoreValve for the primary safety endpoint which was a composite of all-cause mortality, stroke, life-threatening and major bleeding events, stage two or three acute kidney injury or major vascular complications through 30 days.
 - c. The results seen in this large randomized trial, particularly the superior performance in efficacy and the continued demonstration of low PVL rates, further establish the advantages of the LOTUS Valve for the treatment of high-risk patients with severe aortic stenosis.
4. **To learn more about the LOTUS Edge device, visit: bostonscientific.com/LOTUSEdge**

1. Arora, Sameer et al. "Transcatheter Aortic Valve Replacement: Comprehensive Review and Present Status" Texas Heart Institute journal vol. 44,1 29-38. 1 Feb. 2017, doi:10.14503/THIJ-16-5852
 2. Kurtz CE, Otto CM. Aortic stenosis: clinical aspects of diagnosis and management, with 10 illustrative case reports from a 25-year experience. Medicine (Baltimore) 2010;89(6):349-79.
 3. Nishimura RA. Aortic Valve Disease, <http://circ.ahajournals.org/content/106/7/770.full> (Accessed: March 4, 2013).
 4. Ross J Jr, Braunwald E, Aortic Stenosis. Circulation 1968; 38(suppl 1):61-7.

IV. Template Press Release

HEADLINE 1: [INSERT FACILITY NAME] Among First Hospitals in [INSERT STATE, REGION OR CITY] to Use New Minimally-Invasive Valve Replacement Technology for Patients with Aortic Valve Disease

HEADLINE 2: [INSERT FACILITY NAME] Now Offers New Minimally-Invasive Valve Replacement Technology for Patients with Aortic Valve Disease

Newly FDA-Approved LOTUS Edge™ Valve System Offers Safe and Effective Alternative to Open Heart Surgery

[CITY, STATE], [DATE] – [INSERT FACILITY NAME] is among the first hospitals in [INSERT STATE, REGION OR CITY] to offer the LOTUS Edge™ Valve System to high-risk patients with severe aortic stenosis.

As a non-surgical alternative for these patients, often with complex anatomical challenges, the transcatheter aortic valve replacement (TAVR) device is delivered via a minimally-invasive procedure to restore proper valve function.

The Boston Scientific LOTUS Edge device is the only aortic valve approved by the U.S. Food and Drug Administration (FDA) that is 100 percent repositionable, which enables physicians to precisely place the new valve into an optimal position in the heart; thereby helping to improve outcomes for the patient. And because not everyone’s valve is the same size, the device also features a braided valve frame and an adaptive seal that minimizes paravalvular regurgitation or leaking (PVL) by conforming to the patient’s native aortic valve.

Aortic valve stenosis affects seven percent of all people over the age of 65.¹ 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 sudden death.²

[Insert a quote attributed to your implanting physician. Potential, sample quote is included below or you can insert your own quote.]

“With the approval of the LOTUS Edge valve, we now have access to a safe and effective technology to treat severe aortic stenosis for our patients who cannot withstand traditional surgery. I have confidence in the level of control unique to this valve system, from precise delivery and deployment, to surgical-like PVL results, ensuring the best outcomes for our patients,” said [PHYSICIAN NAME], [HOSPITAL NAME].

To learn more, please visit [INSTITUTION WEBSITE].

[INSERT CLINIC BOILERPLATE DESCRIPTION HERE]

CONTACT:

[Hospital PR Contact Name]
[Title], [Hospital Name]
[Phone number]
[Email address]

1. Arora, Sameer et al. "Transcatheter Aortic Valve Replacement: Comprehensive Review and Present Status" *Texas Heart Institute journal* vol. 44,1 29-38. 1 Feb. 2017, doi:10.14503/THIJ-16-5852
2. Nishimura RA. Aortic Valve Disease, <http://circ.ahajournals.org/content/106/7/770.full> (Accessed: March 4, 2013).

V. *Template Media Pitch*

SUBJECT LINE: [INSERT FACILITY NAME] Among First Hospitals in [INSERT STATE, REGION OR CITY] to Use New Minimally-Invasive Valve Replacement Technology to Treat Severe Aortic Stenosis

[Reporter name],

[INSERT TIMING], Dr. [NAME] in [INSERT CITY/REGION] at [INSTITUTION NAME] is among the first cardiologists using the newly FDA-approved LOTUS *Edge*™ Valve System for patients with severe aortic stenosis who are considered high-risk for open heart surgery.

As a non-surgical alternative for these patients, often with complex anatomical challenges, the transcatheter aortic valve replacement (TAVR) device is delivered via a minimally-invasive procedure to restore proper blood flow to the diseased valve.

The Boston Scientific LOTUS *Edge* device is the only FDA-approved aortic valve that is 100 percent repositionable at full deployment, which enables physicians to precisely place the new valve into an optimal position in the heart; thereby helping to improve outcomes for the patient. And because not everyone's valve is the same size, the device also features a braided valve frame and an adaptive seal that minimizes leakage of blood around the valve, or paravalvular leakage (PVL), which can lead to future complications.

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

A press release with more information about the LOTUS *Edge* device is included below. Please let me know if I can help facilitate an interview with [PATIENT NAME] and [Dr. NAME].

Best,

[INSERT NAME & CONTACT INFORMATION]

[INSERT FULL TEXT OF PRESS RELEASE]

VI. Sample Website Copy about LOTUS Edge™ Valve System

[INSTITUTION] is proud to offer the LOTUS Edge™ Valve System for patients with severe aortic stenosis who are considered high-risk for open heart surgery.

As a non-surgical alternative for these patients, often with complex anatomical challenges, this transcatheter aortic valve replacement (TAVR) device is delivered via a minimally-invasive procedure to restore proper blood flow to the diseased valve.

The Boston Scientific LOTUS Edge device is the only aortic valve approved by the U.S. Food and Drug Administration (FDA) that gives physicians the option to reposition and completely recapture the valve at full deployment, thereby helping to improve outcomes for the patient. And because not everyone's valve is the same size, the device also features a braided valve frame and an adaptive seal that minimizes paravalvular regurgitation or leaking (PVL) by conforming to the patient's native aortic valve.

Aortic valve stenosis affects seven percent of all people over the age of 65.¹ 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 sudden death.²

To learn more about the LOTUS Edge valve, please visit bostonscientific.com/LOTUSEdge.

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

1. Arora, Sameer et al. "Transcatheter Aortic Valve Replacement: Comprehensive Review and Present Status" *Texas Heart Institute journal* vol. 44,1 29-38. 1 Feb. 2017, doi:10.14503/THIJ-16-5852
2. Nishimura RA. Aortic Valve Disease, <http://circ.ahajournals.org/content/106/7/770.full> (Accessed: March 4, 2013).
- 3.

VII. Social Media Posts

Below are template Twitter, Facebook and LinkedIn posts that you can use to announce the first implant at your facility and generate interest in your use of the LOTUS *Edge*™ technology throughout the year. Keep in mind:

- For added engagement with your followers:
 - Include a photo of the physician who performed the first implant 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 the 7 percent 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

Timed Milestone Posts
<i>First use by facility/doctor</i>
Proud to now offer the new LOTUS <i>Edge</i> ™ Aortic Valve System to help treat more high-risk patients with severe #AorticStenosis [bit.ly link to facility press release if issued] #AorticValve #TAVR
Dr. [NAME] recently used the new LOTUS <i>Edge</i> ™ #TAVR system to help restore proper aortic valve function in a patient with severe #AorticStenosis [bit.ly link to facility press release if issued]
<i>Heart Health Month (February)</i>
This #HeartMonth learn more about a non-surgical option to treat severe #AorticStenosis, and why [insert facility or Dr. name] uses the LOTUS <i>Edge</i> ™ #TAVR system: [bit.ly link to BSC website or facility product web page]. #HeartHealth
Evergreen Posts
#DYK #AorticStenosis is the most common valvular heart disease and affects 7 percent of people over 65? Learn more about a minimally-invasive treatment technology: [bit.ly link to BSC website] #TAVR
Learn why [insert facility or Dr. name] uses the LOTUS <i>Edge</i> ™ #TAVR system as an alternative to open heart surgery for high-risk patients with severe #AorticStenosis: [bit.ly link to BSC website or facility product web page].

Sample Facebook and LinkedIn Posts

Timed Milestone Posts
<i>First use by facility/doctor</i>

Did you know that #AorticStenosis affects 7 percent of people over the age of 65? This condition occurs when the leaflets in the aortic valve in the heart stiffen and narrow, restricting blood flow to the rest of your body.

While some people with severe aortic stenosis may not be candidates for open heart surgery to replace the diseased valve, we are proud to now offer the LOTUS *Edge*™ Aortic Valve System, which replaces the valve via a minimally invasive procedure called transcatheter aortic valve replacement (#TAVR)

Learn more about our first LOTUS *Edge* procedure performed by Dr. [NAME]: [\[bit.ly link to facility press release if issued\]](#)

We are proud to now offer our patients the recently FDA-approved LOTUS *Edge*™ Aortic Valve System, a #TAVR technology for people with severe #AorticStenosis who are considered high-risk for open heart surgery. Learn more about what makes this device such an exciting offering for our patients: [\[bit.ly link to BSC website or facility product web page\]](#).

Heart Health Month (February)

This #HeartMonth we're proud to offer high-risk patients with severe #AorticStenosis an alternative, minimally-invasive option to open heart surgery. Learn why [\[insert facility or Dr. name\]](#) uses the LOTUS *Edge*™ #TAVR system: [\[bit.ly link to BSC website or facility product web page\]](#).

Evergreen Posts

The LOTUS *Edge*™ Aortic Valve System – a #TAVR technology – is the only FDA-approved aortic valve that allows physicians to reposition and completely recapture the valve at full deployment. Its flexible design also accommodates different patient anatomies to minimize leaking around the valve. Learn more about this minimally invasive procedure for the treatment of high-risk patients with severe #AorticStenosis: [\[bit.ly link to BSC website or facility product web page\]](#).

Sometimes, patients with severe #AorticStenosis aren't good candidates to go through open heart surgery to replace their diseased valve. Learn why [\[insert facility or Dr. name\]](#) uses the LOTUS *Edge*™ #TAVR system as a non-surgical option to address this common valve disease: [\[bit.ly link to BSC website or facility product web page\]](#).