

EMBLEM™ MRI S-ICD System Media Kit Overview

Boston Scientific created this media kit as a resource to help your hospital/institution proactively discuss your work in the prevention and management of sudden cardiac arrest (SCA) with the EMBLEM™ MRI Subcutaneous Implantable Defibrillator (S-ICD) System. The kit includes several documents with specific instructions on their use. You may also print or repurpose these materials for your institution's website or intranet.

- I. **Media Outreach Guide**: This guide can be used to learn how to engage with the media to let them know about the availability of the EMBLEM MRI S-ICD System at your hospital/institution.
- Audience: Marketing and communications managers
- II. **Media Interview Guide**: This guide outlines how to effectively communicate your message to engage with journalists and increase awareness of the EMBLEM MRI S-ICD System at your hospital/institution.
- Audience: Media
- III. **Talking Points**: These key messages for media spokespeople can be used to help guide conversations about the EMBLEM MRI S-ICD System with the media during interviews.
- Audience: Spokespeople
- IV. **Template Press Release**: This is a sample press release that can be customized to announce your hospital/institution's use of the EMBLEM MRI S-ICD System.
- Audience: Media
- V. **Template Media Pitch**: This document includes a template email that can be sent when you are contacting the media to proactively discuss the use of the EMBLEM MRI S-ICD System.
- Audience: Media
- VI. **Sample Website Copy**: This sample content is intended to be used on your hospital/institution's website or intranet to let people know about the use of the EMBLEM MRI S-ICD System.
- 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 EMBLEM MRI S-ICD System.
- Audience: Patients and caregivers
- VIII. **Product Backgrounder**: This document provides background information on the EMBLEM MRI S-ICD System.
- Audience: Media
- IX. **SCA Backgrounder**: This fact sheet includes statistics and information about SCA and available treatment options.
- Audience: Media

You can also download an image of the EMBLEM MRI S-ICD System [here](#) as well as access additional resources at www.SICDSYSTEM.com. If you have any questions, please contact: media@bsci.com.

I. Media Outreach Guide

There are several steps you can take to help increase awareness of the treatment and management of SCA and use of the EMBLEM MRI S-ICD System at your hospital/institution. Below are some tips for contacting media who may be interested in writing about the hospital, patients and treatment options.

When to reach out to journalists

- When you have news about a new procedure or product you can offer to patients, such as the EMBLEM MRI S-ICD System. Ensure you have a definite timing for when the product will be used and that it will be widely available.
 - It is important to ensure you have a knowledgeable physician who can speak confidently about the benefits the new technology offers their hospital and their patients.
 - Media 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 the media.
- You can also build upon national news or other trends receiving media coverage. If a story is popular in the national news, local media are often looking to cover how the news affects people in the local area, so having local statistics is very helpful, too.

How to identify the right media

- Target a list of media contacts at your local print and online newspapers, TV and radio stations and update it periodically.
 - Include information such as their beat (i.e., topics he/she typically covers). Medical, health and science journalists and features journalists are typically most interested in health care stories.
 - If you cannot reach the editor or journalist, call the general number and ask for the health 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 media

- 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 media who review them to obtain story ideas.
 - To reach a specific journalist directly, the best way to distribute a press release is via email so you can reach the journalist 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 journalist'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 interviews vary in length but 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 EMBLEM MRI S-ICD System.

Delivering your message

Take control

- a) Know what you want to accomplish in the interview and take control. Don't wait for the journalist to guide you through your story. Deliver your messages early and often. Use bridges to get back to the points you want to make (see below for more information).

Use flags

- b) 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

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

Turn negatives into POSITIVES

- d) If you are asked 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 when it comes to media interviews.

Ways to bridge

e) 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..."*

f) 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..."*

g) 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

Here is a guide to the **primary points** that can be communicated in interviews around SCA or the EMBLEM MRI S-ICD System:

- 1. Sudden cardiac arrest (SCA) is a serious, life-threatening medical emergency that happens abruptly and often without warning. It kills more than 300,000 people each year in the United States.¹**
 - a) During SCA, the heart's electrical system malfunctions, and it is no longer able to pump blood to the rest of the body.²
 - b) The first, and often only, indication of SCA is loss of consciousness due to lack of blood to the brain. At the same time, no heartbeat or pulse can be felt. While it's common not to have any warning signs before SCA occurs, some symptoms such as fatigue, shortness of breath, fainting, dizziness, lightheadedness, heart palpitations or chest pain may precede the condition.³
 - c) SCA differs from a heart attack, which occurs when a blocked artery prevents oxygen-rich blood from reaching a section of the heart, causing the cells to die.¹
 - d) If treated swiftly, SCA can be reversible through the use of emergency cardiopulmonary resuscitation (CPR) and/or an automated external defibrillator in most cases.
 - a. The chances of surviving SCA decrease by 7-10% with every minute that passes without a life-saving shock. Few attempts at resuscitation succeed after 10 minutes.⁴
 - e) Many people who experience SCA are young, active, seemingly healthy people who have no known heart disease, which is why it is so important to be educated about the potential risk factors.¹ The major risk factor for SCA is congestive heart failure and coronary heart disease. Other risk factors for SCA may include:
 - a. A personal or family history of cardiac disease or arrhythmias, diabetes, a recent heart attack and drug or alcohol abuse.¹
 - b. Intense physical stress can also trigger SCA in people who have heart problems

- 2. For those with risk factors, SCA is detectable with screening and manageable with treatment options such as the EMBLEM™ MRI Subcutaneous Implantable Defibrillator (S-ICD) System. The EMBLEM MRI S-ICD System is the only fully subcutaneous (under the skin) implantable defibrillator that provides protection without touching the heart.**
 - a) The EMBLEM MRI S-ICD System monitors a patient's heart 24 hours a day to detect irregular or dangerous heart rhythms and can deliver life-saving shocks to help return the heart rhythm to normal.
 - b) The EMBLEM MRI S-ICD System is designed to provide the same protection from SCA as traditional transvenous implantable cardioverter defibrillators (TV-ICDs). However, the entirety of the EMBLEM MRI S-ICD System sits just below the skin without the need for thin, insulated wires – known as leads – to be placed into the heart itself. This leaves the heart and blood vessels untouched, which may result in a less invasive treatment that avoids potentially serious complications associated with leads in the heart.^{5,6,7}
 - c) As the newest-generation S-ICD, the EMBLEM MRI S-ICD System provides patients with a smaller and thinner device that is projected to last close to 9 years (similar to many traditional ICD devices), and is enabled for remote patient management.^{8,9,10}
 - d) Both S-ICDs and TV-ICDs have been shown to effectively stop 95% or more of dangerously fast heart rhythms. With an ICD device, 19 out of 20 people will survive SCA.^{11,12,13}

- 3. Clinical trial results have demonstrated that the EMBLEM MRI S-ICD System is safe, effective and can be the preferred therapy choice for the majority of ICD-indicated patients without a need for pacing as it offers comparable performance while avoiding lead-related complications and serious infections associated with TV-ICDs.**
 - a) The EMBLEM MRI S-ICD System is supported by more than a decade of clinical evidence that has demonstrated its life-changing benefit and has been implanted in more than 82,000 patients, providing a safe and effective therapy while avoiding lead-related complications and serious infections associated with TV-ICDs.
 - b) Consistently, data has demonstrated excellent real-world results of the S-ICD System, including low rates of complications and high conversion efficacy.^{14,15}

- c) In May 2020, results from the first prospective, randomized, head-to-head clinical trial study of the S-ICD vs. TV-ICD demonstrated that the S-ICD offers comparable, life-saving performance to TV-ICDs in a typical ICD-indicated patient population without a pacing indication, while avoiding potential serious complication and infection associated with transvenous leads^{16,17}
- d) Data from another study, also presented in May 2020, showed that the EMBLEM MRI S-ICD System demonstrated a 97.6% inappropriate shock-free rate at one year for patients who had the SMART Pass sensing filter – an advanced feature that filters out certain signals that are the primary reason for inappropriate shocks – enabled on the newest generation EMBLEM MRI S-ICD System devices.¹⁸ This low rate of inappropriate shocks (IAS) was comparable to, or lower than, the rate of IAS observed in studies with TV-ICDs.

4. To learn more about risk factors and treatment options for SCA visit www.SICDSystem.com, a resource developed by Boston Scientific.

¹ American Heart Association. Cardiac Arrest Statistics. http://www.heart.org/HEARTORG/General/Cardiac-Arrest-Statistics_UCM_448311_Article.jsp. Accessed May 18, 2015.

² National Heart, Lung, and Blood Institute. What is Sudden Cardiac Arrest? <http://www.nhlbi.nih.gov/health/health-topics/topics/scda>. Accessed May 18, 2015.

³ National Heart, Lung, and Blood Institute. What Are the Signs and Symptoms of Sudden Cardiac Arrest? <http://www.nhlbi.nih.gov/health/health-topics/topics/scda/signs>. Accessed May 18, 2015.

⁴ American Heart Association. What Is an Automated External Defibrillator? http://www.heart.org/idc/groups/heart-public/@wcm/@hcm/documents/downloadable/ucm_300340.pdf. Accessed May 18, 2015.

⁵ Reynolds et al. The Frequency and Incremental Cost of Major Complications Among Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillator. *J Am Coll Cardiol* 2006;47:2493–7.

⁶ Peterson PN, et al. Association of single- vs dual-chamber ICDs with mortality, readmissions, and complications among patients receiving an ICD for primary prevention. *JAMA* 2013;309:2025–2034.

⁷ van Rees JB, et al. Implantation-related complications of implantable cardioverter-defibrillators and cardiac resynchronization therapy devices: a systematic

⁸ EMBLEM MRI S-ICD User's Manual 359480-004 EN US 2018-10.

⁹ MRI Technical Guide 359474-001 EN US 2015-11.

¹⁰ Data on File. Based on analysis of >2900 Emblem patients followed on LATITUDE. June 2017

¹¹ Burke, M.C. et al. *J Am Coll Cardiol*. 2015; 65(16):1605–15.

¹² Healey, J, et al. *The Lancet*. Online before print doi: 10.1016/S0140-6736(14)61903-6.

¹³ Gold MR et al. *Circulation* 2002;105:2043-2048.

¹⁴ Boersma L, Barr C, Knops R, et al. Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry: The EFFORTLESS Study. *J Am Coll Cardiol*. 2017;70(7):830-841.

¹⁵ Weiss, et al. The safety and efficacy of a totally subcutaneous implantable defibrillator. *Circulation* 2013.

¹⁶ Knops R. et al., A Randomized Trial of Subcutaneous versus Transvenous Defibrillator Therapy: The PRAETORIAN Trial. *Heart Rhythm Society Late Breaking Clinical Trials LCT-01 2020*

¹⁷ Knops R. et al. Subcutaneous versus Transvenous Defibrillator Therapy. *New England Journal of Medicine*. August 6th, 2020.

¹⁸ Gold M., et al., Understanding Outcomes with the S-ICD in Primary Prevention Patients with Low Ejection Fraction (UNTOUCHED) Trial Primary Results. *Heart Rhythm Society Late Breaking Clinical Trials LCT-02 2020*

IV. Template Press Release

HEADLINE 1: Patient Successfully Implanted with [INSERT FACILITY NAME]'s [INSERT MILESTONE # IMPLANT] EMBLEM™ MRI Subcutaneous Implantable Defibrillator System [During Sudden Cardiac Arrest Awareness Month] OR [American Heart Month]

SUBHEAD: Device is the only fully subcutaneous implantable defibrillator that provides protection without touching the heart

[INSERT CITY], [INSERT COUNTRY], [INSERT MONTH, DAY, YEAR] – [INSERT TIMING], [INSERT PHYSICIAN NAME/TITLE] performed the institution's [INSERT MILESTONE #] implant of the Boston Scientific EMBLEM™ MRI Subcutaneous Implantable Defibrillator (S-ICD) System for the treatment of patients at risk for sudden cardiac arrest (SCA). The hospital is one of the only to offer the EMBLEM MRI S-ICD System, which is the only fully subcutaneous (under the skin) implantable defibrillator (S-ICD) that provides protection without touching the heart.

[FEBRUARY IS AMERICAN HEART MONTH] OR [OCTOBER IS SUDDEN CARDIAC ARREST AWARENESS MONTH], which serves as a timely reminder of the more than 300,000 people who are killed by SCA each year in the United States¹. SCA is a serious, life-threatening medical emergency that happens abruptly and often without warning. During SCA, the heart's electrical system malfunctions, and it is no longer able to pump blood to the rest of the body. The lack of blood to the brain causes the person to lose consciousness quickly. If the person does not receive immediate treatment with defibrillation, brain damage and death can occur.²

For those at risk of SCA, one treatment option is an implantable cardioverter defibrillator (ICD), which may prevent sudden cardiac death. ICDs are implanted devices that can sense arrhythmias (irregular heartbeats) and deliver strong electrical shocks to the heart to restore a normal heartbeat.³ ICD therapy has been shown to effectively stop 95% or more of dangerously fast heart rhythms. With an ICD device, 19 out of 20 people will survive SCA.⁴

[INSERT A QUOTE ATTRIBUTED TO YOUR PHYSICIAN]

The EMBLEM MRI S-ICD System is designed to provide the same protection from SCA as traditional transvenous implantable cardioverter defibrillators (TV-ICDs). However, the entirety of the EMBLEM MRI S-ICD System sits just below the skin without the need for thin, insulated wires – known as leads – to be placed into the heart itself. This leaves the heart and blood vessels untouched, which may result in a less invasive treatment that avoids potentially serious complications associated with leads in the heart.

In May 2020, results from the first head-to-head clinical trial study of the S-ICD vs. TV-ICD demonstrated that the S-ICD System offers comparable, life-saving performance to TV-ICDs in a typical ICD-indicated patient population without a pacing indication. Thus, demonstrating that the S-ICD System can be the preferred therapy choice for this population as it offers comparable performance while avoiding lead-related complications and serious infections associated with TV-ICDs.

The U.S. Food and Drug Administration (FDA) granted regulatory approval for the EMBLEM MRI S-ICD System in 2016.^{5,6}

For more information on the EMBLEM MRI S-ICD System, visit www.SICDSystem.com.

[INSERT INSTITUTION BOILERPLATE DESCRIPTION HERE]

CONTACT:

[HOSPITAL PR CONTACT NAME]

[TITLE], [HOSPITAL NAME]

[PHONE NUMBER]

[EMAIL ADDRESS]

Boston Scientific Corporation

¹ American Heart Association. Cardiac Arrest Statistics. http://www.heart.org/HEARTORG/General/Cardiac-Arrest-Statistics_UCM_448311_Article.jsp. Accessed May 18, 2015.

² National Heart, Lung, and Blood Institute. What is Sudden Cardiac Arrest? <http://www.nhlbi.nih.gov/health/health-topics/topics/scda>. Accessed May 18, 2015.

³ Huikuri H, et al. Sudden death due to cardiac arrhythmias. *NEJM*. 2001;345:1473.

⁴ Himmrich E, et al. Is ICD programming for double intraoperative defibrillation threshold energy safe and effective during long-time follow-up? Results of a prospective randomized multicenter study (Low-Energy ENDOTAK Trial - LEFT). *Z Kardiol*. 1999;88:103-12 [German language edition].

⁵ EMBLEM MRI S-ICD User's Manual 359480-004 EN US 2018-10.

⁶ MRI Technical Guide 359474-001 EN US 2015-11.

V. Template Media Pitch

SUBJECT LINE OPTION 1: [INSERT FACILITY] Implants [INSERT MILESTONE # IMPLANT] Defibrillator to Help Prevent SCA, Leaving the Heart Untouched [During Sudden Cardiac Arrest Awareness Month] OR [American Heart Month]

SUBJECT LINE OPTION 2: Patient Successfully Implanted with Only Defibrillator that Leaves Heart Untouched

[INSERT JOURNALIST NAME],

[INSERT TIMING/ DURING AMERICAN HEART MONTH OR SUDDEN CARDIAC ARREST AWARENESS MONTH] [INSERT PHYSICIAN NAME & TITLE], implanted the facility's [INSERT MILESTONE # IMPLANT] Boston Scientific EMBLEM MRI S-ICD System. The device sits just below the patient's skin without the need for thin, insulated wires – known as leads – to be placed into the heart itself. By leaving the heart and blood vessels untouched, the EMBLEM MRI S-ICD System results in a less invasive treatment that avoids potentially serious complications associated with leads in the heart.

[INSERT PATIENT NAME, IF HAVE PATIENT CONSENT], who received the S-ICD at [INSERT FACILITY] this week, is one of 850,000 people in the U.S. who are at risk of SCA and are indicated for an ICD device, yet many remain unprotected. In fact, SCA kills more than 300,000 people each year in the United States. [INSERT MORE DETAILS OF PATIENT STORY IF AVAILABLE/OF INTEREST, IF HAVE PATIENT CONSENT].

The press release is included below. Please let me know of any questions, and I can facilitate an interview with [INSERT NAME/TITLE OF ANY AVAILABLE SPOKESPEOPLE].

Best,

[INSERT NAME & CONTACT INFORMATION]

[INSERT FULL TEXT OF PRESS RELEASE]

VI. Sample Website Copy

[INSTITUTION] is proud to offer the EMBLEM™ MRI Subcutaneous Implantable Defibrillator (S-ICD) System, the only subcutaneous implantable defibrillator that provides protection from both sudden cardiac death and the risks and complications associated with transvenous leads.

Sudden cardiac arrest (SCA) is a serious, life-threatening medical emergency that happens abruptly and often without warning. It kills more than 300,000 people each year in the United States.¹ During SCA, the heart's electrical system malfunctions, and it is no longer able to pump blood to the rest of the body. The lack of blood to the brain causes the person to lose consciousness quickly. If the person does not receive immediate treatment with defibrillation, brain damage and death can occur.²

If treated swiftly, SCA can be reversible through the use of emergency cardiopulmonary resuscitation (CPR) and/or an automated external defibrillator in most cases.^{3,4} For those with risk factors, SCA is detectable with screening and manageable with treatment options such as the EMBLEM MRI S-ICD System. The EMBLEM MRI S-ICD System continuously monitors a patient's heart rhythm, 24 hours a day and is able to send out an electric shock to correct any abnormal rhythm. It is designed to provide the same protection from SCA as traditional transvenous implantable cardioverter defibrillators (TV-ICDs). However, the entirety of the EMBLEM MRI S-ICD System sits just below the skin without the need for thin, insulated wires – known as leads – to be placed into the heart itself. This leaves the heart and blood vessels untouched, which may result in a less invasive treatment that avoids potentially serious complications associated with leads in the heart.

In May 2020, results from the first head-to-head clinical trial study of the S-ICD vs. TV-ICD demonstrated that the S-ICD System offers comparable, life-saving performance to TV-ICDs in a typical ICD-indicated patient population without a pacing indication.^{5,6} Thus, demonstrating that the S-ICD System can be the preferred therapy choice for this population as it offers comparable performance while avoiding lead-related complications and serious infections associated with TV-ICDs.

To learn more about the EMBLEM MRI S-ICD System, please visit www.SICDSystem.com.

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

¹ American Heart Association. Cardiac Arrest Statistics. http://www.heart.org/HEARTORG/General/Cardiac-Arrest-Statistics_UCM_448311_Article.jsp. Accessed May 18, 2015.

² National Heart, Lung, and Blood Institute. What is Sudden Cardiac Arrest? <http://www.nhlbi.nih.gov/health/health-topics/topics/scda>. Accessed May 18, 2015.

³ American Heart Association. What Is an Automated External Defibrillator? http://www.heart.org/idc/groups/heart-public/@wcm/@hcm/documents/downloadable/ucm_300340.pdf. Accessed May 18, 2015.

⁴ Huikuri H, et al. Sudden death due to cardiac arrhythmias. *NEJM*. 2001;345:1473.

⁵ Knops R. et al. Subcutaneous versus Transvenous Defibrillator Therapy. *New England Journal of Medicine*. August 6th 2020.

⁶ Knops R. et al., A Randomized Trial of Subcutaneous versus Transvenous Defibrillator Therapy: The PRAETORIAN Trial. *Heart Rhythm Society Late Breaking Clinical Trials LBCT-01* 2020.

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 EMBLEM MRI S-ICD System throughout the year. Keep in mind:

- For added engagement with your followers:
 - Consider using an image of the S-ICD System in relevant posts, pending country regulations.
 - Develop an infographic or quote card that highlights a key statistic.
 - Incorporate the #SuddenCardiacArrest or #CardiacArrest hashtag.
 - Tag your local patient association or the physician involved in the procedure.
- 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:

- Dr. [INSERT PHYSICIAN NAME AND TITLE] performed the [INSERT MILESTONE IMPLANT] EMBLEM MRI™ S-ICD System implant at [INSERT INSTITUTION NAME]! The S-ICD is the only implantable cardiac defibrillator that leaves the heart and vasculature untouched. [INSERT LINK TO MILESTONE PRESS RELEASE]
- This Sudden Cardiac Arrest Awareness Month, we're excited to share that Dr. [INSERT NAME] has performed the [INSERT MILESTONE IMPLANT] EMBLEM MRI™ S-ICD System implant at [INSTITUTION NAME], protecting patients from #SCA without touching the heart and vasculature. [INSERT LINK TO MILESTONE PRESS RELEASE]

LinkedIn post:

- We are pleased to share that the EMBLEM™ MRI S-ICD System has been implanted in more than [INSERT MILESTONE NUMBER] patients at risk of sudden cardiac arrest (SCA) at [INSERT INSTITUTION NAME]. SCA is a serious, life-threatening medical emergency in which the heart's electrical system malfunctions, and it is no longer able to pump blood to the rest of the body. The chances of surviving SCA decrease by 7-10% with every minute that passes without a life-saving shock. To learn more about the S-ICD System, visit: <http://www.sicdsystem.com> #Cardiovascular #HospitalNews

Facebook posts:

- Sudden cardiac arrest (SCA) is a serious, life-threatening medical emergency that happens abruptly and without warning. During SCA, the heart's electrical system malfunctions, and it is no longer able to pump blood to the rest of the body. [INSERT INSTITUTION NAME] is proud to offer the only leadless technology to treat SCA. Learn more: [INSERT LINK TO MILESTONE PRESS RELEASE]
- Dr. [INSERT PHYSICIAN NAME AND TITLE] implanted the [INSERT MILESTONE NUMBER] EMBLEM™ MRI S-ICD System in a patient at risk for sudden cardiac arrest at [INSERT INSTITUTION NAME]. Learn more: [INSERT LINK TO MILESTONE PRESS RELEASE]
- Did you know an implantable cardioverter defibrillator (ICD) may help prevent sudden cardiac death? We are proud to offer our patients the EMBLEM MRI™ S-ICD System — the only approved implantable cardiac defibrillator that leaves that heart and vasculature untouched while including MRI compatibility. Learn more: <http://www.sicdsystem.com>

EMBLEM™ MRI S-ICD System Background Information

About the EMBLEM™ MRI Subcutaneous Implantable Defibrillator (S-ICD) System

The EMBLEM MRI S-ICD System is the only fully subcutaneous (under the skin) implantable defibrillator (S-ICD) that provides protection without touching the heart. Unlike traditional ICDs that require placement of at least one lead in or on the heart, the S-ICD System is implanted just under the skin and provides the patient protection from SCA without invading the heart and blood vessels. Leads in the heart may be associated with infrequent but serious complications, including lead displacement, fracture and systemic blood infections, or the need for lead extraction, which may lead to hospital readmission, increased mortality and associated costs.^{1, 2, 3}

The EMBLEM MRI S-ICD System is MRI compatible in 1.5 tesla MR-environments when conditions of use are met and is equipped with an Atrial Fibrillation Monitor.^{4, 5} These improvements allow physicians to more fully manage their patient's heart condition while continuing to eliminate the risks caused by leads in the heart and vasculature. The EMBLEM MRI S-ICD System is also enabled for remote patient management for increased convenience.

How the S-ICD System works

Like other ICDs, the S-ICD System continuously monitors a patient's heart rhythm, 24 hours a day. If the S-ICD System detects a heart arrhythmia (abnormal rhythm) problem, it sends out an electrical shock to correct it.

The experience of receiving a shock can differ for each person. Because many patients faint or become unconscious shortly after a very fast heart rhythm starts, they do not feel these high-energy shocks. Those who are conscious sometimes describe the shock as a "kick in the chest." The sensation lasts for only a second. If shock is felt, a patient should notify their physician immediately.

How the S-ICD System is different from a traditional ICD

ICD therapy is a trustworthy therapy that has prolonged thousands of lives. When ICD devices were first introduced in the 1980s, they were implanted in the abdomen. Later came the transvenous ICD, which is implanted in the shoulder area. The less invasive S-ICD System is the newest type of ICD device, which delivers protection without touching the heart.

Transvenous ICD

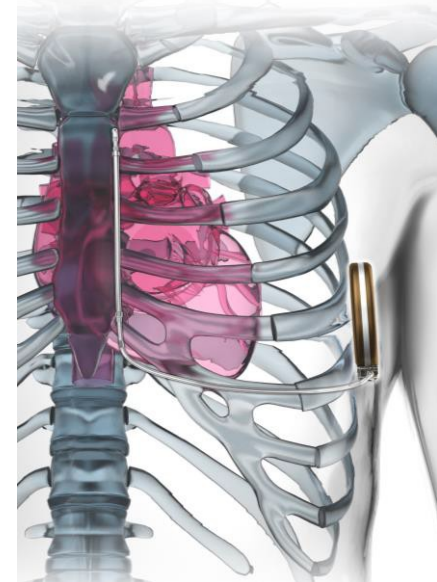
- Typically implanted in the left shoulder area, near the collarbone.
- Using X-ray imaging, the leads are fed through a vein into the heart and across the heart valve.
- Depending on the patient's heart condition, 1 or 2 leads will be placed in the heart, and then they are attached to the heart wall for optimal connectivity.

S-ICD System

- Typically implanted on the left side of the chest next to the rib cage, with the lead implanted just under the skin above the breastbone.
- The electrode is placed under the skin and delivers therapy without wires implanted in the heart.
- S-ICD leaves the heart and blood vessels untouched and intact.

The Procedure

The S-ICD System is surgically inserted during a 6-step procedure that generally takes about one hour:



S-ICD vs. Pacemaker

Both devices are implanted in people and both use electrical impulses to stimulate the heart, but there are differences:

- **A pacemaker** helps control an abnormally slow heart rhythm by sending small electrical pulses to the heart if it is beating too slowly.
- **An ICD device**, such as the **S-ICD System**, sends an electric shock to the heart if it detects a dangerously fast heartbeat in order to restore the heart to its normal rhythm. It is designed to prevent SCA.

1. An incision is made on the left side of the chest, next to the rib cage.
2. A pocket or pouch is formed under the skin, where the S-ICD pulse generator will be inserted.
3. Two small incisions are made slightly to the left of the breastbone to allow the electrode to be placed under the skin.
4. The electrode is then attached to the S-ICD pulse generator.
5. Once the S-ICD System is implanted, most doctors will test the device. Patients will be asleep during this part of the procedure, during which the doctor induces an arrhythmia (irregular heartbeat) and the S-ICD is allowed to detect and stop the abnormal heart rhythm automatically. Some settings will be adjusted to work best for each patient's heart using a separate programmer tablet.
6. Finally, the doctor will close the incisions to complete the procedure.

More than a decade of clinical research supports the S-ICD System

The EMBLEM MRI S-ICD System is supported by more than a decade of clinical evidence that has demonstrated its life-changing benefit for patients and has been implanted in more than 82,000 patients, providing a safe and effective therapy while avoiding lead-related complications and serious infections associated with TV-ICDs.

- Consistently, data has demonstrated excellent real-world results of the S-ICD System, including low rates of complications and high conversion efficacy.⁶⁻⁸
- In May 2020, results from the first prospective, randomized, head-to-head clinical trial study of the S-ICD vs. TV-ICD demonstrated that the S-ICD offers comparable, life-saving performance to TV-ICDs in a typical ICD-indicated patient population without a pacing indication.
- Data from another study, also presented in May 2020, showed that the EMBLEM MRI S-ICD System demonstrated a 97.6% inappropriate shock-free rate at one year for patients who had the SMART Pass sensing filter – an advanced feature that filters out certain signals that are the primary reason for inappropriate shocks – enabled on the newest generation EMBLEM MRI S-ICD System devices.

Indications, contraindications, warnings and complete implant instructions for use can be found in the product labeling supplied with each device (www.bostonscientific.com/sicd).

Additional Resources

- Learn more about the EMBLEM MRI S-ICD System at www.SICDSystem.com

¹ Reynolds et al. The Frequency and Incremental Cost of Major Complications Among Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillator. *J Am Coll Cardiol* 2006;47:2493–7.

² Peterson PN, et al. Association of single- vs dual-chamber ICDs with mortality, readmissions, and complications among patients receiving an ICD for primary prevention. *JAMA* 2013;309:2025-2034.

³ van Rees JB, et al. Implantation-related complications of implantable cardioverter-defibrillators and cardiac resynchronization therapy devices: a systematic

⁴ EMBLEM MRI S-ICD User's Manual 359480-004 EN US 2018-10.

⁵ MRI Technical Guide 359474-001 EN US 2015-11.

⁶ Boersma L, Barr C, Knops R, et al. Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry: The EFFORTLESS Study. *J Am Coll Cardiol*. 2017;70(7):830-841.

⁷ Weiss, et al. The safety and efficacy of a totally subcutaneous implantable defibrillator. *Circulation* 2013.

⁸ Burke, M.C. et al. *J Am Coll Cardiol*. 2015; 65(16):1605–15.

Facts About Sudden Cardiac Arrest (SCA)

What is sudden cardiac arrest (SCA)?

SCA is a serious, life-threatening medical emergency that happens abruptly and without warning. During SCA, the heart's electrical system malfunctions, and it is no longer able to pump blood to the rest of the body. The lack of blood to the brain causes the person to lose consciousness quickly. If the person does not receive immediate treatment with defibrillation, brain damage and death can occur.¹ The chances of surviving SCA decrease by 7-10% with every minute that passes without a life-saving shock. Few attempts at resuscitation succeed after 10 minutes.² In more than 90% of victims, death occurs.³

What causes SCA?

SCA is usually caused by a problem with the heart's electrical system, resulting from coronary artery disease, a heart attack or other heart problems.

When the electrical signals in a heart are abnormal, this can cause an irregular heart rhythm called an arrhythmia. An arrhythmia may cause the heart to beat too fast, too slow or with an irregular rhythm. If the heart rate becomes very fast, unstable and irregular, it may become a dangerous rhythm called ventricular fibrillation (VF). With VF, the heart quivers rapidly and cannot pump blood throughout the body. This causes most SCAs.^{1, 4}

What are the risk factors of SCA?

SCA can strike people of any age, gender, race, and even those who seem in good health. Factors increasing the risk for SCA include:^{5, 6}

- Personal or family history of coronary heart disease, arrhythmias, or SCA
- Previous heart attack, heart failure or heart defect
- High blood pressure
- High cholesterol
- Obesity
- Diabetes
- Sedentary lifestyle
- Smoking
- Drug or alcohol abuse
- Age

Sudden Cardiac Arrest vs. Heart Attack

- SCA is an **electrical problem**, caused by an arrhythmia that prevents the heart from pumping blood to the brain and vital organs. The patient is unconscious and not breathing.^{1, 4}
- A heart attack is a plumbing problem caused by one or more blockages in the heart's blood vessels, preventing proper flow. Part of the heart muscle dies. The patient is awake and breathing.^{1, 4}

What are the symptoms of SCA?

The first sign of SCA is loss of consciousness, with no heartbeat. While there are often no warning signs, some of these symptoms may occur before SCA:⁷

- Fatigue or weakness
- Shortness of breath
- Fainting
- Dizziness or lightheadedness
- Heart palpitations
- Chest pain

How is SCA diagnosed?

SCA is diagnosed after the event and may appear as ventricular fibrillation on an electrocardiogram (ECG). For those who may be at risk for SCA, a doctor may suggest one or more of the following tests, which will help determine the best treatment plan:⁸

- **Electrocardiogram (EKG):** The EKG senses and records heartbeats to show how a heart's electrical system is working.

- **Echocardiogram (Echo):** The echo uses ultrasound to create images of a heart as it beats, to help a doctor learn about the shape and size of the heart, how well the heart valves are working, and the amount of blood pumped with each heart beat (called the ejection fraction).
- **Electrophysiology (EP) study:** The EP study involves checking how electrical impulses travel through the heart muscle to help find out about abnormal heart rhythms.

How is SCA treated?

Those at risk for SCA might be treated with medications. However, medications alone have not proven to be very effective in reducing the risk of SCA.⁹ Another treatment option is a pacemaker-like device called an implantable cardioverter defibrillator (ICD), which may prevent sudden cardiac death.⁹ ICD therapy has been shown to effectively stop 95% or more of dangerously fast heart rhythms.¹⁰

Once SCA occurs, cardiopulmonary resuscitation (CPR) and defibrillation are required within the first several minutes to restore electrical activity to the heart and revive the heart's pumping function.^{11, 12}

- **Cardiopulmonary Resuscitation (CPR):** CPR involves chest compressions with assisted breathing (30:2 ratio). This is an important step to allow external defibrillation therapy to be effective.¹³
- **Defibrillation:** This is a strong electrical shock to the heart to stop the arrhythmia and restore a normal heartbeat. There are two types – automated external defibrillators (AEDs) use paddles to deliver a shock to the outside of the body, and ICDs are implanted pacemaker-like devices that can sense arrhythmias and deliver life-saving shocks.⁹

Sudden Cardiac Arrest Survival

- SCA kills more than **300,000 people** each year in the United States.³
- Only **1 in 11** people usually survives SCA; the other 10 die before reaching the hospital.³
- With an ICD device, **19 out of 20** people will survive SCA.¹⁰

¹ National Heart, Lung, and Blood Institute. What is Sudden Cardiac Arrest? <http://www.nhlbi.nih.gov/health/health-topics/topics/scda>. Accessed May 18, 2015

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⁷ National Heart, Lung, and Blood Institute. What Are the Signs and Symptoms of Sudden Cardiac Arrest? <http://www.nhlbi.nih.gov/health/health-topics/topics/scda/signs>. Accessed May 18, 2015.

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¹¹ National Heart, Lung, and Blood Institute. How Is Sudden Cardiac Arrest Treated? <http://www.nhlbi.nih.gov/health/health-topics/topics/scda/treatment>. Accessed May 18, 2015.

¹² National Heart, Lung, and Blood Institute. How Can Death Due to Sudden Cardiac Arrest Be Prevented? <http://www.nhlbi.nih.gov/health/health-topics/topics/scda/prevention>. Accessed May 18, 2015.

¹³ National Institute of Health – Medline Plus. CPR – adult. <http://www.nlm.nih.gov/medlineplus/ency/article/000013.htm>. Accessed May 18, 2015.