



EMBLEM™

S-ICD System Model 209

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S-ICD System Model 219

Details about your Boston Scientific EMBLEM or EMBLEM MRI Subcutaneous Implantable Cardioverter Defibrillator System

What is the EMBLEM or EMBLEM MRI S-ICD System?

The EMBLEM or EMBLEM MRI S-ICD is a completely subcutaneous implantable cardioverter defibrillator (S-ICD). Like other implantable cardioverter defibrillators (ICDs) your EMBLEM or EMBLEM MRI S-ICD System continuously monitors your heart rhythm 24 hours a day. It's designed to deliver lifesaving defibrillation therapy (an electric shock to the heart) when it senses that your heart rate is dangerously fast. The EMBLEM or EMBLEM MRI S-ICD Systems differ from traditional ICD devices. Placed just under the skin with no wires touching the heart, it eliminates potentially serious short- and long-term risks associated with placing electrical wires inside the heart or blood vessels.

The EMBLEM or EMBLEM MRI S-ICD Systems allow you to undergo MRI screenings. Your heart doctor or radiologist will advise you on additional steps necessary for MRI screenings.

What is sudden cardiac arrest?

Sudden cardiac arrest is a serious and life-threatening medical emergency. Most cases of sudden cardiac arrest are caused by a type of irregular heartbeat (or arrhythmia) known as ventricular fibrillation. Ventricles are the lower chambers of your heart. During ventricular fibrillation, these chambers beat very fast and irregularly. This causes little or no blood to be pumped through the body. If not treated within a few minutes, death can occur.

If ventricular fibrillation or sudden cardiac arrest occurs, your EMBLEM or EMBLEM MRI S-ICD System can deliver lifesaving defibrillation therapy.

How long will my EMBLEM or EMBLEM MRI S-ICD System last?

Like anything that operates on a battery, the life of your EMBLEM or EMBLEM MRI S-ICD System will depend on how much of the battery is used. The battery is used every time your device delivers therapy (shock), so the amount of therapy you receive affects the life of the battery. The EMBLEM or EMBLEM MRI S-ICD System are projected to last nearly 9 years¹.

What size is my EMBLEM or EMBLEM MRI S-ICD System?

Width	Height	Thickness	Weight
83.1 mm 3.27 in	69.1 mm 2.72 in	12.7 mm 0.5 in	130 gm 4.6 oz



(Actual size not shown)

What happens after my implant procedure?

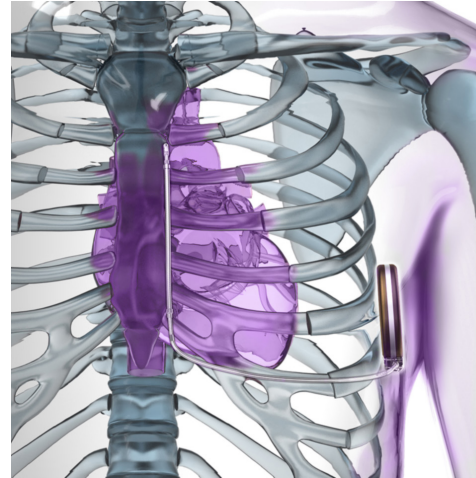
Because every EMBLEM or EMBLEM MRI S-ICD System patient is different, it's hard to say with certainty what your recovery time will be. In general, you will likely be able to return home the day after your implant procedure. Full recovery from the procedure normally takes about 4 to 6 weeks.

Care and recovery at home

Your doctor will provide you with a complete set of instructions to follow once your procedure is completed. Always consult your doctor for specific information or to ask any additional questions you might have. You'll also receive a patient identification card, which alerts medical and security professionals that you have an implanted medical device. Let your other doctors, dentists, and emergency personnel know that you have an implanted EMBLEM or EMBLEM MRI S-ICD System.

Follow-up visits

Your doctor will schedule regular visits with you every 3 to 6 months to see how you are doing and to check your EMBLEM or EMBLEM MRI S-ICD System. During these routine check-ups, your doctor may adjust the settings of your system using a wireless programmer. If you are enrolled in the LATITUDE™ NXT Patient Management System, your doctor can check your EMBLEM or EMBLEM MRI S-ICD remotely between visits.



The EMBLEM or EMBLEM MRI S-ICD System is implanted under the skin and provides protection from sudden cardiac arrest while leaving your heart untouched.

For more information on the EMBLEM or EMBLEM MRI S-ICD System and to see other patients' stories, visit www.sicdsystem.com.

Boston Scientific provides a support line to patients who are implanted with its products. Please call us if you have questions about your implanted EMBLEM or EMBLEM MRI S-ICD device.

Boston Scientific Patient Services 1-866-484-3268

1. Van der Stuijt, W, Williams, JL, Brisben, AJ, et al. Real world battery longevity of the subcutaneous implantable cardioverter-defibrillator (S-ICD). Presented at European Society of Cardiology (ESC) 28 August 2023, Amsterdam

Device Quality and Reliability

It is Boston Scientific's intent to provide implantable devices of high quality and reliability. However, these devices may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. Refer to Boston Scientific's CRM product performance report on www.bostonscientific.com for more information about device performance, including the types and rates of malfunctions that these devices have experienced historically. While historical data may not be predictive of future device performance, such data can provide important context for understanding the overall reliability of these types of products. Also, it is important that you talk with your doctor about the risks and benefits associated with the implantation of a device.

S-ICD™ System

Important Safety Information

An implantable cardioverter defibrillator is designed to monitor and treat heart rhythm problems, greatly reducing the risks associated with them. There are risks associated with this device including, but not limited to, allergic reactions, bleeding, death, fever, infection, kidney failure, need for surgical replacement, nerve damage, stroke and tissue damage. Electrical or magnetic fields can affect the device. In some cases, the device may not respond to irregular heartbeats or may deliver inappropriate shocks and in rare cases severe complications or device failures can occur. Your physician should discuss all potential benefits and risks with you and describe the appropriate medical care.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. 92481216 (Rev. A)

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Cardiology

300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
Customer Service:
1.866.484.3268

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