S-ICD® System

Model 1010

Details about your Boston Scientific Subcutaneous Implantable Defibrillator (S-ICD) System

What is an S-ICD System?

A completely subcutaneous implantable defibrillator (S-ICD) system is a battery-powered device that holds a tiny computer. The entire S-ICD System is implanted just under the skin to watch for and treat sudden cardiac arrest. There is nothing in or touching the heart.

Treating sudden cardiac arrest

Sudden cardiac arrest is a very serious heart condition, and if not treated within minutes, can lead to death. Only an electrical shock delivered to the heart can reset the heart’s rhythm and restore normal blood flow throughout the body.

Ventricular fibrillation (VF) is a dangerously fast heart rhythm where the heart quivers rapidly and cannot pump blood throughout the body. Most people with VF lose consciousness within a few minutes. This is called sudden cardiac arrest. If VF occurs, your S-ICD System can deliver lifesaving defibrillation therapy.

How long will my S-ICD System last?

Like anything that operates on a battery, the life of your S-ICD System will depend on how much of the battery is used. The battery is used every time your device delivers therapy. So the amount of therapy you receive affects the life of the battery. The S-ICD System is projected to last about 5 years.

How small is my S-ICD System?

<table>
<thead>
<tr>
<th>Height</th>
<th>Width</th>
<th>Thickness</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>78.2 mm</td>
<td>65.5 mm</td>
<td>15.7 mm</td>
<td>145 gm</td>
</tr>
<tr>
<td>3.08 in</td>
<td>2.58 in</td>
<td>0.6 in</td>
<td>5.1 oz</td>
</tr>
</tbody>
</table>

ACTUAL SIZE
(When printed at 100%)

World's first and only completely subcutaneous ICD
**What happens after my implant procedure?**

**Care and recovery at home**
Your doctor or nurse will give you specific instructions to follow when returning home. Full recovery from surgery can take from several days to a few months, depending on your condition. It is important that you are actively involved in your own recovery. Follow your doctor’s instructions about caring for the implant site. Let your other doctors, dentists, and emergency personnel know that you have an implanted S-ICD System.

**Follow-up visits**
Once you have an S-ICD System, it is important to follow your doctor’s guidelines for follow-up visits. These typically occur every 3 months. Your doctor uses the follow-up visits to check your device and monitor your heart condition, which can change over time. Your doctor may also adjust your device settings.

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**Important Safety Information**

**Device Quality and Reliability**
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.

(Rev. K)

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CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France.

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