SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (S-ICD)





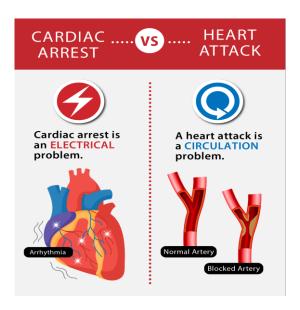
What is Sudden Cardiac Arrest (SCA)?

SCA typically occurs when an electrical problem with the heart triggers a dangerously fast heart rhythm that causes the heart to quiver rather than to pump. When the heart stops pumping blood, oxygen cannot reach the body and brain. If not treated immediately, SCA can be fatal. The most effective way to treat SCA is through "defibrillation." Defibrillation involves delivering an electrical shock to your heart to restore a normal heartbeat. To survive an SCA event, you must receive defibrillation within ten minutes, otherwise, you can die.

Who is at risk of sudden cardiac arrest?

Generally, sudden cardiac arrest strikes without warning. People who are at a higher risk for SCA include:

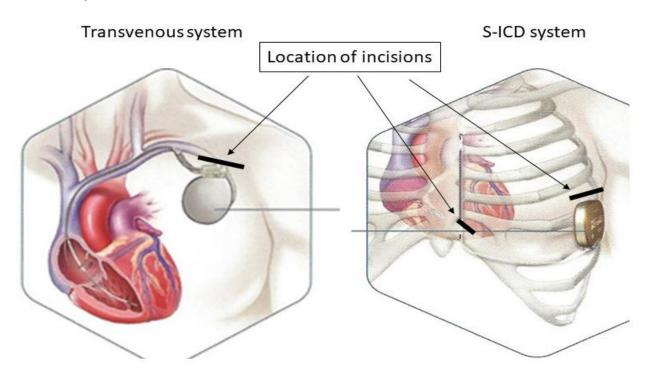
- Those who have had a heart attack
- Heart failure patients
- Survivors of a previous SCA or those who have a family member who has had an SCA event.
- People with low pumping function of their heart, otherwise known as a low ejection fraction.



What is an S-ICD?

The implantable cardioverter-defibrillator (ICD) is a device that monitors your heart rhythms. If the ICD detects any abnormalities in your heartbeat, it will decide if the detected rhythm should be treated. The type of treatment delivered by the device will depend on the settings programmed into your ICD. Remember that the ICD treats the rhythm problem when it occurs, it does not prevent it.

There are two types of ICDs being implanted today: 1) transvenous (through the veins and into the heart) ICD systems (figure on the left) and 2) the completely subcutaneous S-ICD, which does not touch the heart (figure on the right). Both types of ICDs sense when the heart rate is dangerously fast and can deliver a shock to the heart to stop the abnormal rhythm and restore a normal heartbeat.



The S-ICD system consists of a pulse generator connected to a wire (lead) that senses your heart rhythm. The pulse generator and the lead are surgically implanted. There is also a programmer that is used to communicate with your S-ICD.

a) The Pulse Generator:

The pulse generator is about the size of a cellphone, is powered by a battery, and monitors the electrical signals in your heart. It is implanted on the side of your chest under your left armpit. When an arrhythmia (irregular heartbeat) is detected in your heart, the pulse generator will determine whether the abnormal rhythm is to be treated. If so, the generator will deliver electric shock(s) to your heart via the lead (implanted wires). Depending on the programming of your S-ICD, different types of treatments are delivered, and different amounts of information can be stored.

b) The Lead System:

The lead is a wire threaded under your skin and along the breastbone ("sternum"). The tip of the lead has a sensor that "sees" your heart rhythm all the time and this information is then sent to the computer in the generator. As well, any electrical energy that the pulse generator sends to the heart travels along the lead.

c) The Programmers:

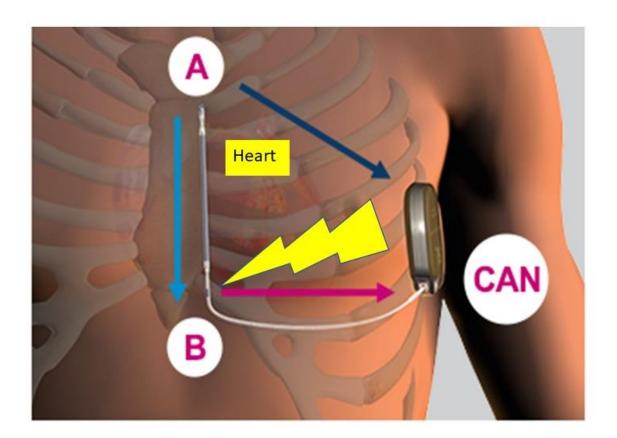
The programmer is a laptop computer-like device that communicates with your S-ICD in the same fashion that a remote control communicates with a television set. Using the programmer, the functions and settings of your S-ICD are programmed and tested after implant. Also, when you visit the ICD clinic, the programmer is used to retrieve information about your heart rhythms, stored in the pulse generator. Every time you have what your S-ICD considers to be a fast, abnormal rhythm, the S-ICD stores the:

- Date and time it occurred
- 2. An ECG (electrocardiogram) taken before, during and after the rhythm
- 3. Measurements taken during the episode

What are S-ICD Therapies?

<u>Shock:</u> If the device detects a rapid and life-threatening rhythm like ventricular tachycardia (VT) or if the rhythm is ventricular fibrillation (VF), the S-ICD will deliver a high energy shock to restore the rhythm to normal.

What a shock feels like: When your S-ICD sends a shock, you will feel a distinct "kick" in the chest. This is usually unpleasant but not dangerous and usually not extremely painful. There may be times that you do not feel a treated arrhythmia, but your S-ICD will treat any irregular rhythms it detects.



What should you do if you have an S-ICD shock?

When your S-ICD device delivers a shock, you will feel a distinct "kick" in the chest. Anyone touching you when you get a shock may feel a slight tingling sensation but will not get a shock and will not be harmed in any way. When you receive a shock:

- 1. Stop what you are doing and ask yourself how you feel.
- 2. <u>If you feel well before and after the shock</u>, call the ICD Clinic, and we can discuss your follow-up. We need to determine whether we feel your device is functioning appropriately. We also need to determine how urgently you need to see us in the office or the clinic.

OR

<u>If you feel unwell and are concerned</u>, go to your local emergency department. Inform your local hospital that you have a defibrillator. Also, inform them that you are followed at Southlake Regional Health Centre and that they should feel free to contact us at any time. Bring your list of medications and dosages with you.

3. Remember to write down the date, time, symptoms, and activities surrounding the shock in your diary.

If you receive 2 or more shocks within 24 hours, please go to your local emergency department. If your condition changes in any way and you are worried, please do not hesitate to call to discuss your concerns. If you feel symptoms of your rapid heart rhythm that fail to go away, you should contact our office or your physician.

Implanting the S-ICD

Usually, the pulse generator is implanted on the left side of your chest a few centimeters below the armpit area.

S-ICD implantation is generally considered relatively minor surgery and the operation itself usually takes about an hour.

It is performed as day surgery, meaning you arrive for the surgery and leave after the surgery on the same day. You can expect to spend a few hours at the hospital on the day of surgery.

The risks of the procedure include bleeding, infection, damaging the lung or heart which would require a drain or the lead coming out of position after surgery ("dislodgement") which would require another procedure. These complications are typically 1% or less.

PRE-OPERATIVE INSTRUCTIONS

These are general guidelines for you to follow before you have your S-ICD implanted or a replacement procedure. Be sure to follow any specific instructions from your physician and the ICD Clinic.

Some general instructions will include:

Do not eat or drink anything the night before your surgery (this includes gum, candy, and water).

Medication is usually taken as prescribed in the morning of your surgery with sips of water.

Blood thinners may be stopped one or two doses in advance of the surgery. Check with the ICD Clinic or your physician beforehand for clarification.

You will usually be given antibiotics just before the procedure. Be sure you notify the ICD Clinic if you have any allergies to medications like penicillin.

POST-OPERATIVE INSTRUCTIONS

A nurse will give you post-operative instructions after your surgery. You must follow these post-operative instructions in addition to other instructions from the ICD clinic or your physician. These precautions are necessary for a healthy recovery from surgery.

WOUND CARE

Your incisions will usually be closed with dissolvable stitches. If not, the stitches will need to be removed in 7 - 10 days by your family doctor or ICD clinic nurse our first follow-up appointment. Invisible stitches will dissolve on their own and will not need removal.

If you notice any signs of redness, swelling, localized pain, or oozing from the incisions or openings of the incision, **YOU MUST REPORT IT TO US IMMEDIATELY**. If you are unsure, call us anyway.

Try not to get the wounds wet for the first 4 days. You may take a shower after the first 4 days. For the first 4 days, we recommend taking a sponge bath and avoiding wetting the wounds.

Keep the wounds covered (fresh dressing daily) for about 4 days, then leave it open to the air.

Do not allow a doctor or nurse to place a needle into your device pockets at any time, even if it appears infected.

EXERCISE AND ACTIVITY

Do not raise the arm on the side with the incisions above the level of your shoulder for approximately 1 month. Remember that activities like brushing your hair, or reaching for a high cabinet, or golfing can all stretch that arm.

Do not lift heavy objects (more than 5-10 pounds) with your affected arm for 6 weeks.

But you must continue to move that arm a little. If you do not, the shoulder will give you problems that may require up to 6 months of physiotherapy.

We suggest the following shoulder exercise: hold your arms outstretched at your sides and make small circles in the air. Do this exercise for 10 - 15 rotations, 4 times per day.

PAIN MANAGEMENT

You should be able to manage the pain with either plain Tylenol or Extra Strength Tylenol for a few days. If you find that your pain is still unmanageable, please call us.

RESUMING ACTIVITIES AND RETURNING TO WORK

You and your physician will decide when you may resume your regular activities and return to work. If you have been hospitalized for some time, try to increase your activity slowly.

Usually, you can return to light work within a few days. But heavier work may require 2-4 weeks off work.

MEDIC ALERT BRACELET

A Medic Alert bracelet/necklace identification should always be worn. Should you fall unconscious, the Medic Alert identification will let people know that you have an S-ICD and give information about any other health problems you have.

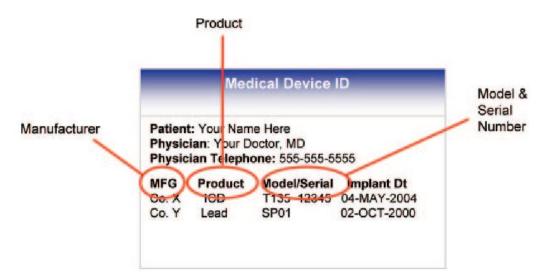
You should receive a Medic Alert application before leaving the hospital at the time of your implant. If you already have a Medic Alert, you must contact them so the information in their files can be updated.



S-ICD IDENTIFICATION CARD

You will be given a temporary S-ICD identification card on the day of your surgery. You should receive your permanent card within 4-8 weeks after the operation.

<u>You should always carry your S-ICD Identification card.</u> The card contains important information about your device and will need to be seen at some medical appointments, by airport security officers, and in case of a medical emergency.



DIARY AND MEDICATION LIST

Please keep a diary with the following information and bring it to all your ICD clinic visits:

- 1. Your current medications including the dosage (the amount)
- 2. Doctor appointments and tests performed
- 3. Any treatment given by the S-ICD device. Include the time and date and what you were doing when you received the shock.

How do I Follow-up with my S-ICD?

You will follow-up in the ICD clinic. Your first clinic appointment will be approximately 2-4 weeks after your S-ICD device is implanted. We will check if the device and lead are operating properly and check your wounds.

Follow-ups after that will be at 6 months and then every 6-12 months after that unless there is a problem. Some of your follow-ups may be in person, but others may be done by remote monitoring (see image and description later).

What to bring to each clinic visit:

- 1. Ontario Health Card
- 2. A current and complete list of all your medications (including the dosages), or all your pills in their original containers
- 3. Your diary (see earlier)

At the clinics, the information stored in your S-ICD will be read through the programmer by placing a wand over the device.

Your device and lead will also be checked to ensure that they are functioning properly, and the battery voltage is good. Your wounds will be examined and any symptoms you are having will be discussed.

Feel free to ask us any questions at that time.

Please note that the clinic is not meant to replace the care you receive from your family doctor and your cardiologist in your community. A letter will be sent to your doctor after each clinic visit.

What is Remote Monitoring?

A remote monitor is a portable device that you either take home or it is delivered to you. It usually sits at your bedside and allows you to send information stored in your device to your ICD clinic. It may be connected to a telephone landline or a cellular or Wifi Accessory.

Your S-ICD device information is then transmitted to a secure Internet website where your clinic can access and review information about how your heart and device are working.

The remote monitor provides the same device information to your doctor that an in-clinic office visit provides. Information in your device may also be sent automatically, using wireless communication. This process is silent and usually happens at night while you are asleep.

Automatic, wireless monitoring can also notify your clinic of irregular heart activity or conditions with your device, such as a low battery. Your clinic may program your device to send such notifications to help manage your care.

Remember, remote monitoring is not meant to be an emergency service and will only be read during regular clinic hours.



How long will the battery last? Does it need to be replaced?

On average, your device's battery will last 5-10 years. The average is about 6-7 years. It depends on how much the device is used. When we interrogate your device, we will find out how much battery is remaining. We always replace the battery when there is still more than 3 months of battery life remaining.



When your battery needs replacing, we replace the entire generator (see above). The wires will remain in place and will not be routinely changed.

For the battery replacement procedure, you will come in for a day surgery, just like your original implant. However, battery replacement usually takes less time.

Living with your S-ICD

The idea of having an S-ICD is so that you can live your life as normally as possible. Your device is meant to be an "ambulance in your chest" so that you can be protected wherever you go.

But you should be aware of some practical items you will encounter in everyday life.

a) Other Surgery

Before you undergo any surgical procedure, you must contact the ICD clinic since reprogramming may be necessary. Certain equipment may interfere with the functioning of your S-ICD device. If you are unsure about any other treatment you may undergo, don't hesitate to call us to discuss your concerns.

b) Travel

Your S-ICD will not prevent you from traveling to most countries in the world. If you need emergency care, just go to the nearest hospital and show them your S-ICD wallet ID card and they will be able to contact someone to come and read your defibrillator.

Remember to show your S-ICD identification card to airport security to avoid being searched with a handheld wand. Please request a manual search. Plan to add an extra 5 - 10 minutes to your pre-boarding time to get through security.

c) Dental Work

You should let your dentist know that you have an implanted device before any dental work. Your dentist may prescribe antibiotics before dental work to prevent any infection from getting into the bloodstream.





What is electromagnetic interference (EMI)?

Your S-ICD device is sensitive to strong electrical and magnetic fields/currents. Strong electrical and magnetic currents will interfere with the proper functioning of your S-ICD. This is called "electromagnetic interference" or EMI.

General household appliances are safe to use, provided they are properly grounded, and are in good condition. Examples of appliances and other household objects that will not interfere with your device include microwaves, cordless phones, TV/DVD players, TV remotes, AM/FM radios, computers, photocopiers, fax machines, Wifi internet, toasters, hairdryers, electric razors and toothbrushes, sewing machines, heating pads, lawnmowers, and leaf-blowers.

<u>Cellular phones</u> rarely interfere with your S-ICD. You are in no danger if others near you are using cell phones or if you use a cell phone and hold it to your ear. Cell phone antennae should be kept at least 6 inches (15 cm) away from your S-ICD device. Do not put the cell phone in the breast pocket of your shirt or jacket on the side where your S-ICD is implanted. If your S-ICD is in your abdomen, do not clip the phone to your belt near the device. When using a cell phone, place the phone on the ear that is opposite to the side where your device is implanted. In other words, if your S-ICD device is on the left side of your chest or abdomen, use the phone on the right side of your head.



When should you worry about EMI?

Before undergoing any of the following procedures, please contact the ICD clinic:

<u>Diathermy</u> - This test employs electrical currents to body tissue. The electrical fields could potentially interfere with device functioning.

<u>Electrocautery</u> - This is a medical instrument used during surgery to stop bleeding. Electrocautery should only be used if your device is turned off.

<u>Lithotripsy</u> - This is the procedure by which stones (e.g. kidney stones) are broken up. Your device may require re-programming.

<u>Radiation therapy</u> – Radiation is sometimes used in the treatment of cancer. If the radiation will be aimed directly over the device, it could disrupt the device. Radiation aimed away from the device is usually acceptable. The device may require re-programming.

The following items may be used, but **you should exercise caution**:

<u>Car engine repair:</u> use caution when near the coil, distributor, or spark plug cables of a running engine. Turn off the engine before making any adjustments to the distributor. DO NOT LEAN on running electrical engines.

<u>Large stereo speakers:</u> do not lift them close to your device.

Soldering guns, demagnetizers: 6 inches away from your device. Metal detectors 24 inches.

CB, Amateur HAM radios: you should keep a distance between the radio antenna and your device. It depends on the location/power. Portable (1 foot), car (3 feet), home (10 feet).

<u>Retail and library security systems:</u> to prevent the effects of these systems on your device, just walk normally through them. Do not linger near or lean against these detectors. It is unlikely that your device will set off retail or library security systems. However, always carry your device ID card.

Is there anything I cannot do with my device?

Heavy electrical or industrial equipment often produces EMI. This equipment may affect how your device works. Check with your doctor before working with the following equipment:

Dielectric heaters - used in industry to bend plastics.

Electric arc welding equipment

Electric steel furnaces used in factories

Induction furnaces such as kilns (induction stoves may be used observing some cautions)

Industrial magnets

Power plants - large generators, transmission lines, transmission buildings, and turbines

Gas-powered chain saws

Can I have an MRI?

Most devices implanted today are "compatible" with magnetic resonance imaging (MRI). The device may require some programming before and after your MRI. You should always have your device checked before and after an MRI.

Certain types of MRI protocols or MRI aimed directly at the device may not be allowed by your device manufacturer. Older devices and leads may not ever be "compatible" with MRI.

Some centers will perform an MRI on any type of device (whether compatible or not) but you need to consult with the MRI department doing your test.

If you have abandoned leads, or broken leads, or certain types of adapters, you may not be able to have an MRI at all.

Can I drive with my device?

Initially, you may not be allowed to drive a car right after your surgery (usually 7 days). Further restrictions on driving will depend on your condition.

Remember that the S-ICD does not prevent your rhythm problem. Rhythm problems can still occur and if they do, the device will treat them.

But if you have a rhythm problem requiring treatment from your device, your driving may be restricted for 1-6 months depending on the condition. Your driving would likely be restricted for longer or forever if you did not have the device.

Commercial driving (large trucks, commercial vehicles, large passenger vehicles like buses) may be restricted by your condition whether you have the device or not.

Where should I contact you?

You can contact us at the ICD clinic:

Southlake Regional Health Centre Medical Arts Building Suite 602, 581 Davis Drive Newmarket, Ontario, L3Y 2P6

Phone: 905-895-4521 ext 2860

