## ANSWERS TO YOUR QUESTIONS ABOUT YOUR CHILD'S HEART DEVICE



Jennifer CRT Recipient



# INTRODUCTION

Your child's doctor has prescribed an implantable heart device for your child because he or she has a heart rhythm disorder, or is at risk for a rhythm disorder that may cause the heart to beat too slow, too fast, or in a fast, unstable, and irregular manner.

This brochure provides general information about your child's heart device. More specific information on the various heart devices is provided in the following brochures:





LIFE WITH AN IMPLANTABLE DEFIRILLATOR



A CONTRACTOR OF CONTRACTOR OF

Life with a Pacemaker Life with an Living with Implantable Your Heart Defibrillator Failure (ICD) Device (CRT)

Answers to Questions about Implantable Cardiac Devices (Electromagnetic Compatibility Guide)

Ask your nurse, doctor, or contact Medtronic Patient Services for these and other additional materials.

Medtronic Patient Services is also available to answer your device questions and provide additional materials. The Medtronic Patient Services toll-free number is 1-800-551-5544, x41835. Our Patient Services Specialists are available to assist you Monday – Friday from 8 a.m. to 5 p.m. Central Time.

#### **Sisters Mary** and Emily Both ICD Recipients



### Who should I tell about my child's heart device?

It is important to inform teachers and coaches, school nurses, dentists, and others who have regular contact with your child for extended periods of time. Depending on the kinds of activities your child is involved in, this may include people at places of worship, camp counselors, trip organizers, etc.

#### How do I explain the heart device to other

adults or children? Medtronic Patient Services can provide you with additional copies of this brochure and other materials to help explain why your child has a heart device (see Resources and Contact Information at the end of this brochure). You may also find additional information provided on our website: medtronic.com, or other available websites such as parentheartwatch.org, americanheart.org, or webMD.com.

### Will my child's heart device need to be replaced?

Yes. The heart device will be replaced depending on many variables including, but not limited to, the amount of therapy provided, changes in heart condition, device technical advances, etc. Because the battery that powers the heart device is sealed, the heart device will have to be replaced when the battery power becomes low. Your child's doctor will monitor your child's health regularly and will check the device, and can give you a general idea of the replacement time.

### Will my child always need a heart device?

The heart device is not a "cure" for the heart's rhythm problems. The device does, however, help the heart to beat regularly. Sometimes the heart device simply provides backup support when the heart needs it and sometimes the heart device is the only means to provide a heartbeat. There are a few children who only need a heart device temporarily. Most children, however, who receive a heart device will need one throughout their life.

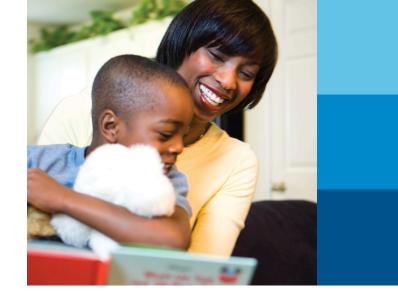
# How can I be sure that my child's heart device is providing optimal therapy?

After your child's heart device is implanted, its performance will be monitored by their physician or a nurse in a follow-up clinic (doctor's office). The follow-up schedule will be determined by your child's physician.

You may want to ask your child's doctor if remote monitoring using the Medtronic CareLink<sup>™</sup> network is appropriate for your child. This service, available by prescription only, allows your child to transmit device information to their clinic using a portable monitor. A monitor that connects using cellular only is also available, along with an app-based monitor (only for children with pacemakers, including CRT-P, at the time of printing) that connects via Wi-Fi or a cellular signal. After your child has transmitted the device data, clinic staff can review the data via the Medtronic CareLink<sup>™</sup> network.

### Are heart devices MR Conditional?

We have CRT-D, ICD, and pacing systems which are FDA-approved for use in the MRI environment. These systems have a unique design, developed so that under specific conditions, patients may safely undergo MRI scans. However, most traditional heart devices



are not considered safe in an MRI environment because the MRI could change the settings and/ or temporarily affect the normal operation of the heart device.

Talk to your child's doctor about the pacemaker, ICD, and CRT-D options available for your child and determine if their current or future cardiac system allows them safe access to an MRI scan.

What if my child's device is not FDA-approved for use in the MRI environment? We do not recommend the use of an MRI scan if your child's device is not FDA-approved for use in the MRI environment. Your child's physician should discuss all potential benefits and risks with you.

What if my child's doctor strongly recommends an MRI scan? Your child's doctor should discuss all potential benefits and risks of an MRI scan with you. Present your child's ID card to the doctor recommending the MRI scan. This card will advise them to contact your attending

heart doctor. If needed, your child's doctor can seek more information from a Medtronic representative.



**Ryan** Pacemaker Recipient

## If my child had an MRI scan, did this affect their heart device? Your child's doctor can determine

if there is an effect on your child's heart device. If your child did not see their doctor after an MRI scan, contact the doctor.

### What concerns should I have about playing, diet,

**colds**, **etc.?** Your child, after consultation with his or her physician, will be able to engage in most activities, including: swimming, riding tricycles or bikes, jumping rope, and running.

Your child should be careful, however, to avoid activities that may involve a direct blow to the heart device, such as football, wrestling, and other heavy contact sports.

Food, diet, normal immunizations, emotional changes, and colds will not affect pacemaker function. Be sure, however, to consult with your child's physician regarding any special restrictions or concerns.

#### Can my child use a cell phone?

Yes. When talking on a cell phone keep the phone's antenna six inches away from the heart device, and use the phone on the ear opposite the heart device. We also recommend you avoid placing the cell phone in a pocket near the heart device.

## Are electronic items in the home safe for my child to use and be around?

Yes. Most household electronic items are safe for your child to use and be around as long as they are properly maintained and in good working order. This includes microwave ovens, MP3 players, computers (desktop, laptop, and tablets such as an iPad®\*), and other household appliances. As a general precaution, we do recommend keeping electronic items, items that transmit wireless signals, and items with electric motors at least six inches away from your child's heart device.

#### Will magnets affect my child's heart device?

Items such as magnetic therapy products, stereo speakers, and toys containing magnets may temporarily affect the normal operation of your child's heart device if the magnet is close enough and strong enough. We recommend keeping items with magnets at least six inches away from your child's heart device. A magnet will not damage your child's heart device and the heart device resumes normal operation once the magnet is moved away.

Please refer to the Answers to Questions about Implantable Cardiac Devices (Electromagnetic Compatibility Guide) for further information.

### What is the Patient Identification Card?

Approximately four to six weeks after surgery, your child will receive an identification card. You and/or your child should carry the card at all times. It will be useful in managing your child's follow-up care or in case of a medical emergency. Use this card to inform your child's doctors, dentists, and other healthcare providers that your child has a heart device.

It is important that we have current and accurate contact information so we can provide you with necessary information about your child's heart device. Therefore, please notify Patient Services by telephone, email, or letter of any changes to your child's address, telephone number, area code, or information regarding the doctor, so our information is current. The Patient Services telephone number can be found near the bottom of your Patient Identification card.

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John Doe 3850 Victoria St I Shoreview MN 5	•		
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Ple	ase contact us with changes	at 1-800-551-5544	
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### Are there other forms of Patient

**Identification?** Medical jewelry, such as medical bracelets or pendants, helps alert caregivers that your child has a heart device and provides the doctor's name and telephone number, as does the Medtronic ID card.

### Will my child be able to travel?

Given the short duration of security screening, it is unlikely that your child's heart device will be affected by metal detectors (walk-through archways and hand-held wands) or full body imaging scanners (also called millimeter wave scanners and 3D imaging scanners) such as those found in airports and other secure buildings.

To minimize the risk of temporary interference with your child's heart device while going through the security screening process, your child should avoid touching metal surfaces around any screening equipment. Your child should not stop or linger in a walk-through archway, but simply walk through the archway at a normal pace. If a hand-held wand is used, ask the security operator not to hold it over your child's heart device and not to wave it back and forth over the heart device. You may also request a hand search as an alternative.

If you or your child have concerns about these security screening methods, show your child's device ID card, request alternative screening, and then follow the instructions of the security personnel.

Medtronic also offers a multi-language travel card for patients that you can request online or by calling Patient Services.

## RESOURCES & CONTACT INFORMATION

#### **AskthelCD**

At AsktheICD.com you can start an anything goes Q&A about living with your implantable cardiac device.

### MyPacemaker.com

Find in-depth bradycardia information, or use our step-by-step interactive guide to answer some of your common pacemaker questions.

#### How can I learn more about heart devices?

Your child's doctor or cardiology nurse can answer any medical questions you have about your child's medical condition and about the particular device he or she has implanted.

Additionally, you can ask your child's doctor or nurse if there is a heart device support group in your community or online. These groups provide ongoing support and education to patients and their families.

We also encourage you to visit our website at medtronic.com where you can access information 24 hours a day.

#### Important Safety Information

An implantable pacemaker, defibrillation, or cardiac resynchronization therapy (CRT) system relieves symptoms of heart rhythm disturbances. It does this by restoring normal heart rates. A normal heart rate provides your body with the proper amount of blood circulation. The pacemaker system is intended for patients who need rate-adaptive pacing or chronic pacing or for patients who may benefit from synchronizing the pumping of the heart chambers. In addition to these functions, an implantable cardioverter-defibrillator (ICD) system delivers therapies to treat patients with heart rhythm disorders or who are at significant risk of developing heart rhythm disorders. A cardiac resynchronization therapy (CRT) implantable cardioverter-defibrillator (ICD) system delivers therapies to treat patients who may benefit from synchronizing the pumping of the heart chambers. A CRT ICD (also referred to as CRT-D) also delivers therapies to treat patients with heart rhythm disorders or who are at significant risk of developing heart rhythm disorders. Risks associated with these implantable device systems include, but are not limited to, infection at the surgical site and/or sensitivity to the device material, failure to deliver therapy when it is needed, or receiving extra therapy when it is not needed. After receiving an implantable device system, you will have limitations with magnetic and electromagnetic radiation, electric or gas-powered appliances, and tools with which you are allowed to be in contact. Your physician may prescribe an MRI scan for you. A magnetic resonance imaging (MRI) scan is a type of medical imaging that uses magnetic fields to create an internal view of the body, which doctors use for diagnostic purposes. Unlike previous generations of heart devices, your SureScan™ heart device system was designed and tested to be used safely with MRI scanners. The electromagnetic fields present during MRI scans have the potential to cause hazardous effects on heart devices, which can result in cardiac tissue heating, inappropriate therapy, and dangerous arrhythmias. Due to the unique design of the SureScan™ heart device systems, these risks are reduced to a very low level so that under specified conditions, patients may safely undergo MRI scans. You can undergo an MRI scan as long as you meet the patient eligibility requirements that Medtronic provides to your heart doctor and the scan is conducted according to Medtronic directions. For example, your heart device system must consist only of a Medtronic SureScan™ model heart device and the appropriate number of SureScan<sup>™</sup> labeled leads (visit http://www.mrisurescan.com). Any other combination may result in a hazard to the patient during an MRI scan. The Revo MRI™ SureScan<sup>™</sup> and Advisa MRI<sup>™</sup> SureScan<sup>™</sup> pacing systems; the Evera MRI<sup>™</sup> SureScan<sup>™</sup> and Visia AF MRI<sup>™</sup> defibrillation systems; and the Amplia MRI<sup>™</sup> SureScan<sup>™</sup> and Compia MRI<sup>™</sup> SureScan<sup>™</sup> CRT ICD systems are MR Conditional. This means the system is designed to allow patients to undergo MRI when your doctor determines you meet patient eligibility requirements and the scan is conducted according to Medtronic directions. This treatment is prescribed by your physician. This treatment is not for everyone. Please talk to your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this treatment, results may vary. For further questions, contact patient services at 1-800-551-5544.

#### Medtronic MyCareLink Smart™ Monitor Reader, MyCareLink™ Patient Monitor, CareLink™ Monitor and MyCareLink Connect™ Patient Website

The Medtronic MyCareLink Smart<sup>™</sup> Monitor Reader, MyCareLink<sup>™</sup> Patient Monitor and the CareLink<sup>™</sup> Monitor are prescription devices indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices based on physician instructions and as described in the product manuals. The MyCareLink Connect<sup>™</sup> Patient Website is intended to provide patients, their friends/family and caregivers messages regarding transmission status of patient device diagnostic data to the CareLink<sup>™</sup> Network. Transmissions to the CareLink<sup>™</sup> Network sent via cellular or Wi-Fi connectivity are subject to cellular and/or Wi-Fi service availability. The Monitor or Monitor Reader must be on and in range of the implanted device. Web browsers currently supported by the MyCareLink Connect<sup>™</sup> Patient Website are: Microsoft<sup>®\*</sup> Internet Explorer<sup>®\*</sup> for Windows<sup>®\*</sup> Version 8.x and Version 9.x, Mozilla Firefox<sup>®\*</sup> for Windows Version 13.x, Google Chrome<sup>™\*</sup> for Windows Version 20.x. MyCareLink Connect<sup>™</sup> Patient Website availability may be unavailable at times due to maintenance or updates, or due to coverage being unavailable in your area. These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician.

The Medtronic CareLink<sup>™</sup> Service is prescribed by your physician. This service is not for everyone. Please talk to your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this service, results may vary. For further information, please call CareLink<sup>™</sup> Patient Services at 1-800-929-4043 (8:00 a.m. to 5:00 p.m., Monday–Friday, Central Time) or see the Medtronic website at www.medtronic.com.

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#### Patient Services

Medtronic 8200 Coral Sea St. NE MVS14 Mounds View, MN 55112 Patient toll-free line: 1.800.551.5544 Fax: 763.367.5809 8:00 a.m. to 5:00 p.m. CT Mon.-Fri.

#### Medtronic

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#### medtronic.com

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