

LIVING WITH YOUR CARDIAC RESYNCHRONIZATION THERAPY DEVICE (CRT)

Helping you lead a fuller life



Medtronic
Further. Together



HELPING YOU LEAD A FULLER LIFE

If you or someone you love has been diagnosed with heart failure, this booklet will help to understand the heart conditions and treatment. It is designed to provide you with basic information about heart failure and cardiac resynchronization therapy (CRT) devices, including what you can expect before and after you have a CRT device implanted.

Ask your doctor about your unique medical condition and therapy management.

This information is not medical advice and should not be used as an alternative to speaking with your doctor.



DURING HEART FAILURE, THE HEART ATTEMPTS TO COMPENSATE FOR LOST PUMPING POWER WHICH MAY CHANGE ITS SHAPE AND RESULT IN AN UNCOORDINATED (OR UNSYNCHRONIZED) AND INEFFICIENT HEARTBEAT

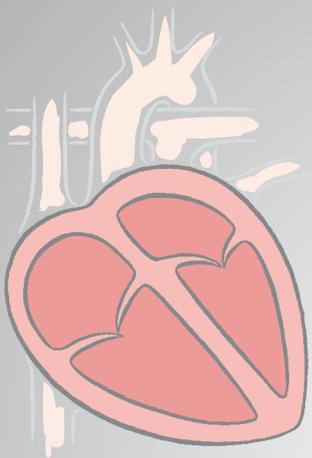
WHAT IS HEART FAILURE?

Heart failure is a condition where the heart muscle is weakened and is not able to efficiently pump blood.

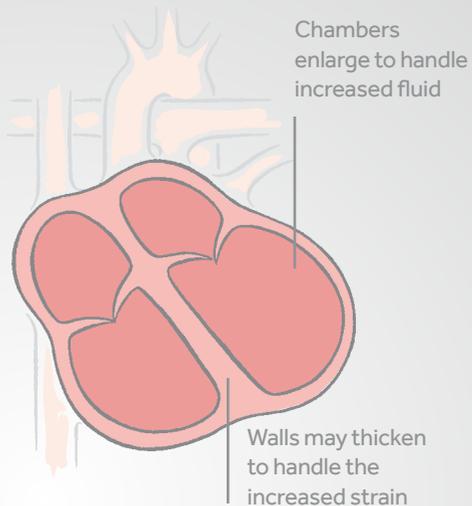
The term heart failure does not mean your heart has stopped pumping; rather, your heart muscle is not able to pump enough blood to meet your body's needs. As a result, you may feel tired, lack energy, experience shortness of breath, and notice excess fluid collecting in your body.

The heart is a fist-sized organ that acts as a pump to send oxygen-rich blood throughout the body. In a healthy heart, each chamber contracts (squeezes) in a coordinated effort; the upper chambers (atria) of the heart contract first, then the lower chambers (ventricles) contract. These coordinated contractions circulate blood between the lungs and heart and to the rest of the body. If the heart is not beating in a coordinated fashion, then the body will not receive an adequate amount of blood to function properly.

HEALTHY HEART



HEART FAILURE



SYMPTOMS OF HEART FAILURE

Heart failure is a progressive condition, meaning it will gradually worsen. At first you might not experience any symptoms, but over time your heart's pumping ability will continue to weaken and you may experience some or all of the following symptoms:

- Chronic lack of energy
- Difficulty sleeping at night due to breathing problems
- Confusion and/or impaired memory
- Increased urination at night
- Swelling of feet and legs
- Shortness of breath
- Swollen or tender abdomen with loss of appetite
- Cough with frothy sputum

CAUSES OF HEART FAILURE

Heart failure usually develops slowly after an injury to the heart. There is no single cause, and sometimes the cause is unknown. Some of the most common causes of heart failure are:

- Previous heart attack (myocardial infarction)
- Coronary artery disease
- High blood pressure (hypertension)
- Heart valve disease
- Infection of the heart (myocarditis)
- Congenital heart disease (condition you were born with)
- Endocarditis (infection of the heart's inner lining)
- Diabetes (the body does not produce or properly use insulin)

RISKS OF A POORLY PUMPING HEART

A weakened heart muscle must work harder to pump blood to the body. This may cause the heart to beat faster, which can lead to dangerously fast or irregular heart rhythms. These abnormal heart rhythms can lead to a condition called Sudden Cardiac Arrest (SCA).

WHAT IS 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 contract or 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.¹ 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.² Only about 5% of people survive SCA, because defibrillation was not delivered within this critical time frame.²

WHO IS AT RISK OF SUDDEN CARDIAC ARREST?

Generally, sudden cardiac arrest strikes without warning. People who are at a higher risk for SCA include²:

- 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 a low ejection fraction

EF NUMBER: A NUMBER YOU SHOULD KNOW

EF stands for "ejection fraction." It is the percentage of blood that is pumped out of the heart with each heartbeat. Your doctor determines how well your heart is pumping based on your EF number.

Your EF number can change over time. It is important for you and your doctor to check your EF regularly.



50-75%
HEART'S
PUMPING
ABILITY IS
NORMAL

CHART OF TYPICAL EF RANGES²:

People with a low EF – 35% or below – are at an increased risk for SCA.³

A healthy heart has an EF between 50% and 75%. This indicates the heart is pumping well and able to deliver enough blood to the body and brain. Even a healthy heart does not pump 100% of blood out of the heart during each beat, some blood always remains in the heart.

HOW IS EF MEASURED?

The most common way to measure EF is with an echocardiogram. This test is usually performed in a doctor's office or hospital's diagnostic area.

TREATING HEART FAILURE

Heart failure is a progressive condition. Your doctor may prescribe a variety of treatment options that may slow the progression of the disease, strengthen your heart, and improve your quality of life. Some of these treatments may include medications, lifestyle changes, exercise, and device therapy, or a combination of these. Only your doctor can determine which option is right for you.

36-49%
HEART'S
PUMPING
ABILITY
IS BELOW
NORMAL

**35%
& BELOW**
HEART'S
PUMPING
ABILITY IS LOW



WHEN PEOPLE REFER TO AN IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY (CRT) DEVICE, THEY ARE ACTUALLY DISCUSSING THE SYSTEM – THE CRT DEVICE AND THE LEADS

WHAT IS A CARDIAC RESYNCHRONIZATION THERAPY DEVICE?

- A **CRT device** is a device implanted under the skin, typically just below the collarbone. The device delivers therapies to coordinate the heart's pumping action and treats fast, irregular, or slow heart rhythms depending on the type of CRT device. This device may also be referred to as a heart failure device, biventricular device, three-lead CRT device, CRT-P (pacemaker), or a CRT-D (defibrillator).
- **Leads** are thin, soft insulated wires about the size of a spaghetti noodle. The leads carry the electrical impulse from the CRT device to your heart and relay information about the heart's activity back to the CRT device.

HOW DOES A CARDIAC RESYNCHRONIZATION THERAPY DEVICE WORK?

A cardiac resynchronization therapy device is designed to monitor your heart rhythm 24 hours a day. It sends electrical pulses to pace the lower chambers of your heart to help them beat in a more coordinated rhythm. This coordinating or "resynchronization" therapy improves the heart's ability to pump blood and oxygen more efficiently to the body. Your doctor will program the CRT device to deliver the most effective therapies for your specific heart condition.

IN RESPONSE TO ABNORMAL HEART RHYTHMS, A CRT DEVICE MAY ALSO PROVIDE THE FOLLOWING THERAPIES:

- Pacing therapy for slow heart rhythms – electrical impulses are delivered to the heart when the heart's own rhythm is too slow or irregular
- Defibrillation therapies for fast or irregular heart rhythms – a shock therapy is delivered to the heart to interrupt fast heart rhythms and restore a normal heart rate

There are two types of CRT devices: a CRT pacemaker (CRT-P) and a CRT defibrillator (CRT-D). CRT-D devices, like all defibrillators, have a pacemaker function in them. Both devices help to coordinate the heart's pumping action and deliver pacing therapy for a slow heart rate. However, the CRT-D can also treat fast heart rhythms.

All cardiac resynchronization devices are designed to use three leads. One lead is placed inside the right atrium, another lead is placed inside the right ventricle, and the third lead is placed inside a vein on the outside of the left ventricle.

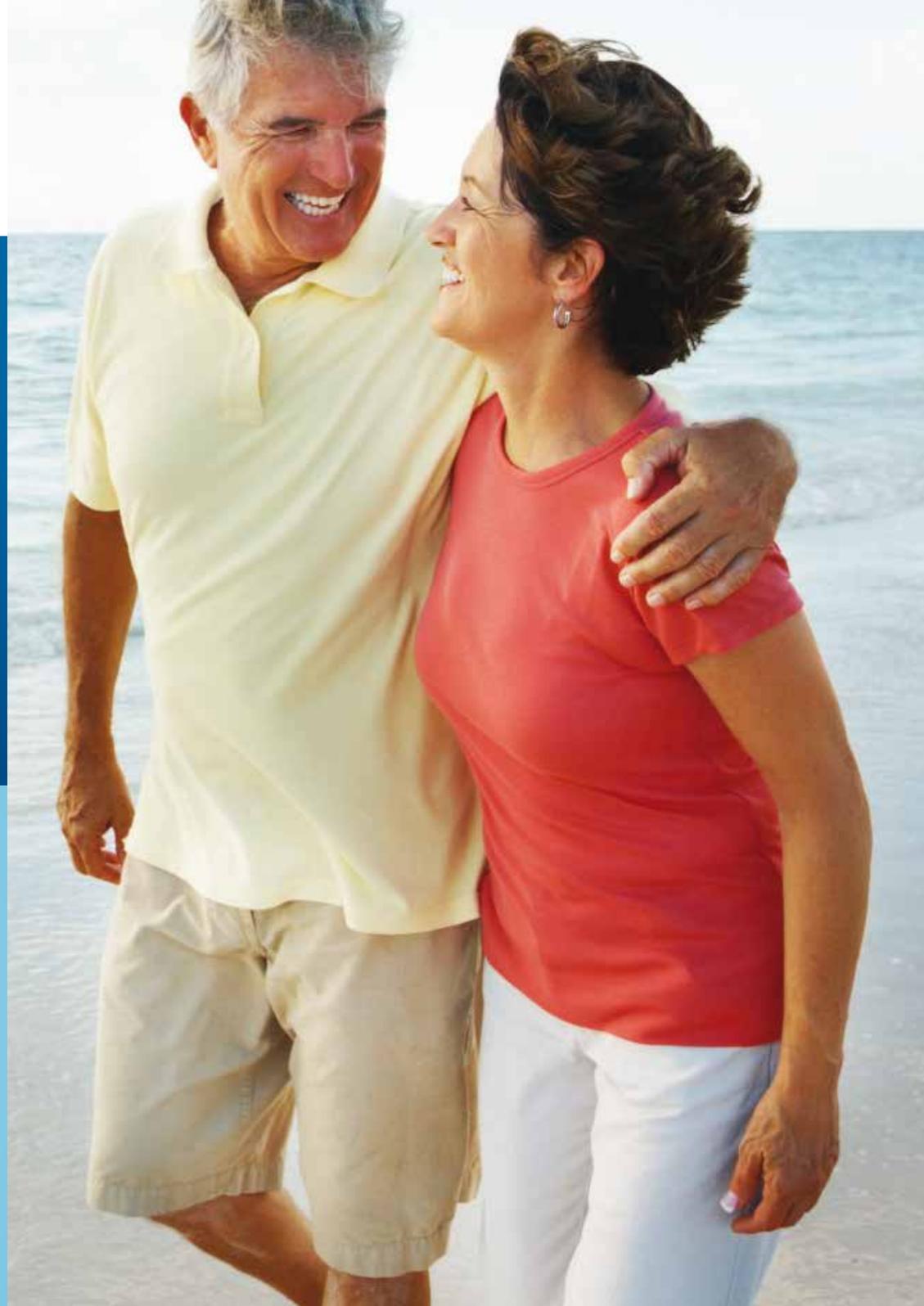
CARDIAC
RESYNCHRONIZATION
THERAPY



CRT Defibrillator (CRT-D) and Leads



CRT Pacing (CRT-P) and Leads



GETTING A CRT DEVICE IMPLANTED

THE GENERAL STEPS OF AN IMPLANT PROCEDURE INCLUDE:

- A small incision, approximately two to four inches long, will be made in the upper chest area, just below your collarbone
- Three leads will be guided through a vein into your heart, and the leads will be connected to the CRT device
- The CRT device settings will be programmed, and the device will be tested to ensure it is working properly to meet your medical needs
- The CRT device will be inserted beneath your skin, and the incision in your chest will be closed

FOLLOW-UP CARE AND MONITORING

Follow-up appointments allow the implanted CRT device to be thoroughly checked. During these check-ups, your doctor may:

- Monitor the battery status of the CRT device
- Check the leads to determine how they are working with the CRT device and your heart
- Review your CRT device settings to ensure they are programmed appropriately to your medical needs
- Make programming adjustments to your CRT device

In addition to these check-ups with your doctor, your clinic or practice may choose to have your CRT device checked through remote monitoring.

This remote monitoring can replace some visits, but not all. Your doctor may still need to perform a physical examination or to adjust your CRT device settings or medications.

REMOTE MONITORING VIA THE MEDTRONIC CARELINK® NETWORK

The CareLink® Network allows you to send information stored in your implanted CRT device to your clinic, as instructed by your doctor, using a portable monitor. Your CRT device information is then transmitted to a secure Internet website where your clinic can access and review information about how your heart and CRT device are working. The CareLink Network provides the same CRT device information to your doctor that an in-clinic office visit provides.

Information in your CRT device may be sent automatically, using wireless communication. This process will be silent and usually happens during the night while you're asleep. CRT devices with automatic, wireless monitoring can also notify your clinic of irregular heart activity or conditions with your CRT device, such as a low battery. Your clinic may program your CRT device to send such notifications to help manage your care.

THE CARDIAC RESYNCHRO- NIZATION THERAPY (CRT)

MRI-CONDITIONAL TECHNOLOGY

Currently, most CRT are not considered safe in an MRI environment because the MRI could change the settings, temporarily affect the normal operation of, or potentially damage the heart device.

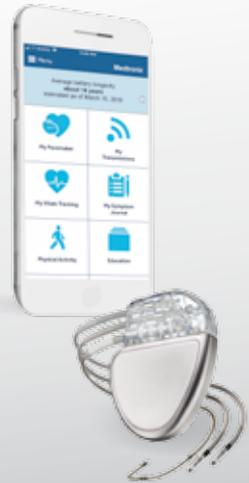
Medtronic has a CRT Systems which is CE Marked for use in the MRI environment. This CRT system has a unique design, developed so that under specific conditions, patients may safely undergo MRI scans (3T and 1.5T)

This information is designed to help you learn more about CRT options. It is intended to provide you with helpful information, but is for information purposes only, is not medical advice and should not be used as an alternative to speaking with your doctor. Speak to your doctor for more information and any questions specific to your health and treatment options appropriate for you.

**THE PROCEDURE
TO IMPLANT A
CRT DEVICE
DOES NOT
REQUIRE
OPEN HEART
SURGERY
AND MOST
PEOPLE GO HOME
WITHIN 24 HOURS**



**BEFORE THE
SURGERY
MEDICATION MAY
BE GIVEN TO MAKE
YOU SLEEPY AND
COMFORTABLE
GENERALLY, THE
PROCEDURE IS
PERFORMED UNDER
LOCAL ANESTHESIA**



A SMARTPHONE CONNECTED CARDIAC RESYNCHRONIZATION THERAPY DEVICE (CRT) OPTION

The most advanced CRT device can communicate directly and securely with an App on your smartphone or tablet. This App allows you to stay connected to your clinic, providing peace of mind and freedom, so you can continue living your life – uninterrupted.

FREEDOM

Continue with your daily life – wherever you go – knowing your CRT device can connect to your clinic through your smartphone or tablet via the App.

PEACE OF MIND

- Feel confident that your clinic receives your CRT device data because you can see the status of your transmission in the app.
- Access information about your CRT device – including battery life, implant date, device name, model number, serial number, and clinic information – so you are comfortable answering questions when asked.
- Motivate yourself to engage in health behaviors
 - Track your physical activity level with data the app gets from your CRT device.
 - Record your weight, blood pressure, and heart rate – and track these measurements over time to help you better understand your health status.
- Keep a record of your symptoms to share with your doctor at in office visit.
- Easily access answers to frequently asked questions about living with a CRT device.

Learn more about the benefits of remote monitoring via an App on your smartphone or tablet on: www.mclheart.com

LIVING WITH A CRT DEVICE

Many people with a CRT device resume their normal daily activities after recovering from the implant procedure. There may be certain situations your doctor will ask you to avoid. Discuss your activity and lifestyle goals with your doctor and develop a plan that works best for you.

FREQUENTLY ASKED QUESTIONS

CAN I USE A MOBILE PHONE?

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

ARE HOUSEHOLD APPLIANCES SAFE TO USE?

Yes. Most household appliances are safe to use as long as they are properly maintained and in good working order. This includes microwave ovens, major appliances, electric blankets, and heating pads.

WILL MAGNETS AFFECT MY DEVICE?

Items that contain magnets, such as magnetic therapy products, stereo speakers, and hand-held massagers can temporarily affect the operation of your CRT device. Therefore, it is recommended you keep items containing magnets at least six inches away from your implanted CRT device. We do not recommend the use of magnetic mattress pads and pillows because it is difficult to maintain a six-inch distance when using these items.

WILL I BE ABLE TO TRAVEL?

Given the short duration of security screening, it is unlikely that your Medtronic CRT 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, courthouses, and jails.

To minimize the risk of temporary interference with your CRT device while going through the security screening process, avoid touching metal surfaces around any screening equipment. Do not stop or linger in a walk-through archway; 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 CRT device and not to wave it back and forth over your CRT device. You may also request a hand search as an alternative.

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

ARE CRT-DS AND CRT-PS MRI-COMPATIBLE?

Currently, the latest CRT devices are 1.5T and 3T MRI Conditional. Present your device identification card to your physician to determine if your heart device is MRI-conditional, which may allow you access to MRI scan.

EDUCATIONAL SERVICES FOR PATIENTS

MEDTRONIC PATIENT SERVICES

If you have a Medtronic cardiac device and want to learn more or have questions about living with an implanted CRT device, please contact your clinics and physicians.

The Medtronic website includes in-depth information on heart conditions and treatment options for patients and their caregivers. Our interactive website allows you to take assessments, view video, read patient stories, and link to other resources. Visit us online at www.medtronic.eu

A CLOSER LOOK AT AN INTERNATIONAL COMPANY

Medtronic was founded in 1949 in Minnesota, U.S.A.

Today, we are the global leader in medical technology. Every second, the lives of two people are improved by a Medtronic product or therapy. With deep roots in the treatment of heart disease, Medtronic provides a wide range of products and therapies. The company mission is to alleviate pain, restore health and extend life for millions of people around the world. These are the demands we make of ourselves and of our products for the patients, relatives and doctors who trust our technology.

REFERENCES

- 1 Zipes DP, Roberts D. Results of the international study of the implantable pacemaker cardioverter-defibrillator. A comparison of epicardial and endocardial lead systems. The Pacemaker-Cardioverter-Defibrillator Investigators. *Circulation*. July 1, 1995;92(1):59-65.
- 2 American Heart Association. Statistical fact sheet. Sudden death from cardiac arrest. www.americanheart.org.
- 3 Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for device-based therapy of cardiac rhythm abnormalities [corrections appear at *J Am Coll Cardiol*. April 21, 2009;53(16):1473. *J Am Coll Cardiol*. January 6, 2009;53(1):147.]. *J Am Coll Cardiol*. May 27, 2008;51(21):e1-62

Indications, Safety, and Warnings

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan® device, see the MRI SureScan® Technical manual before performing an MRI. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.com.



www.medtronic.com/manuals

Consult instructions for use at this website. Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat Reader® with the browser.

Important Reminder: This information is intended only for users in markets where Medtronic products and therapies are approved or available for use as indicated within the respective product manuals. Content on specific Medtronic products and therapies is not intended for users in markets that do not have authorization for use.

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PATIENT INFORMATION WEBSITES

www.suddencardiacarrest.co.uk
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Videos are available on
YouTube - Medtronic Europe

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