

WHAT TO EXPECT WITH YOUR CRT DEVICE



IF A DOCTOR HAS TALKED ABOUT A CRT DEVICE WITH YOU OR A LOVED ONE

It is natural to want to learn more. These devices help manage your heart beat, also called heart rhythm, so you have fewer symptoms and can get back to living the life you want to live.

YOU ARE NOT ALONE

Heart Failure, or HF, is more common than you might think. It affects at least 26 million people worldwide, and it's becoming more prevalent every year.¹



WHAT IS HEART FAILURE?

When a person has heart failure, it doesn't mean the heart stops beating. It just means your heart isn't pumping blood as well as it should.

Heart failure is when the lower chambers of the heart, the ventricles, aren't able to effectively pump blood to the entire body. You may have shortness of breath, or be extremely tired.

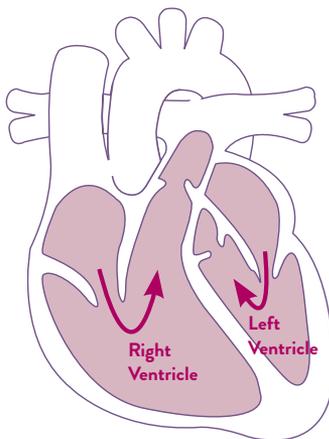
There are many possible causes: coronary artery disease, other heart-related diseases, high blood pressure, abnormal heart rhythms, diabetes, and infection.

There are also different ways to treat HF, depending on the causes and the symptoms. Your doctor may put you on medications and suggest changes to your diet, exercise and lifestyle. If your heart's "electrical" system isn't working like it should, your doctor may recommend a CRT device.

WHAT IS CRT?

COORDINATED PUMPING

Cardiac Resynchronization Therapy (CRT) involves a device that helps the bottom two chambers of your heart, the ventricles, more effectively pump blood to your entire body while you continue your normal activities.

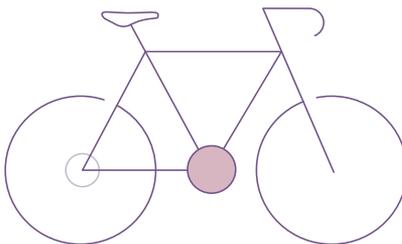


INFORMATION INSIGHTS

A CRT device will also store information about your heart rhythm. Based on this information, your doctor may adjust the settings of your CRT device to best meet your needs.

IMPROVED FUNCTIONING

Over time, your CRT device can actually help reverse some of the damage to your heart caused by Heart Failure. Studies show that CRT devices can improve one's energy and quality of life.³



TYPES OF CRT DEVICES

After a complete review of your health, your doctor may recommend one of two types of CRT devices, based on your needs.

CRT-P

A CRT-P is a pacemaker device that delivers electrical impulses to help the left and right lower chambers of the heart work together, so the heart can pump blood more effectively to the entire body.

CRT-D

A CRT-D device functions much like a CRT-P, but it also can detect a dangerously fast heart rhythm. When it does, it delivers a shock to the heart to interrupt this rhythm and restore a normal heart beat.



RECEIVING YOUR DEVICE

As with all medical procedures, talk with your doctor beforehand to review any special instructions, which may include eating and drinking limitations. Implanting your CRT device may take several hours. This is normal. Remember that your doctor is your best source of information about your procedure. Be sure to consult with your doctor before your procedure and discuss any concerns you might have afterwards, including risks.

Although implant procedures vary depending on the individual person, typical implant procedures include the following steps:

1

You will be given medicine to help with discomfort and relaxation. You will still be aware of your surroundings and be able to hear and talk with your doctor.

2

Insulated wires called leads will be placed in your heart and will be connected to your CRT device.

3

While implanting your device, the doctor may request that you take a deep breath or cough to ensure the leads are in the best position to deliver electrical pulses to the heart when needed.

4

Your doctor will then set the device in place – just under the skin, usually near the collarbone – and close the incision.*

*If you are concerned about having a small scar or bump in this location after the incision heals, ask your doctor before surgery about the possibility of placing the device where it will be less noticeable to others.

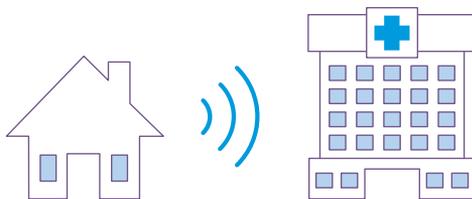
WHAT TO EXPECT IN YOUR RECOVERY

The typical hospital stay after receiving a CRT device is only a few days. This is a good time to discuss with your doctor any symptoms you may experience, especially soreness or tenderness around the incision.

A small percentage of people will develop complications because of their CRT device implant. This may include infection, a reaction to a drug used during the procedure or to the device itself, and blood loss or damage to a blood vessel, heart wall or other organs. Doctors typically discuss all of the precautions before surgery. Be sure to read all literature that comes with your CRT device paying close attention to items labeled as ‘warning’ or ‘important’ as these contain important safety information. Ask your doctor if you have any questions. Your doctor is your best source of information about complications as well as other information about your procedure and your device. You can also review information available at cardiovascular.abbott.

STAYING CLOSE, EVEN FROM A DISTANCE

Some CRT devices use wireless remote monitoring and others require a wand. Remote monitoring collects information from your device and can send it to your clinic. If your device delivers a shock, identifies a low battery or irregularities in heart rhythm being monitored by your physician, it will alert your clinic.



In order for remote monitoring to work, your transmitter should be connected and plugged in near your bed. When properly connected, the transmitter will collect information from your CRT device at night while you are sleeping and send it to your doctor as scheduled.

A RETURN TO YOUR DAILY ACTIVITIES

During recovery, your doctor may want you to cut down on physical activity. After recovery, most people are usually able to return to activities they did prior to receiving the device.



While some activities require a bit of extra planning and care, the goal of the therapy is to get you back to your daily routine. It is usually safe to travel, operate most machinery, use a cell phone and drive a car after receiving your CRT device.

It is important to avoid bumping or hitting the area around your CRT device. Contact sports are an example of an activity that could damage your CRT device or leads.

You should check with your doctor regarding any activities you are interested in resuming, especially those around strong magnetic fields, to ensure there isn't a concern about it impacting the performance of your CRT device.

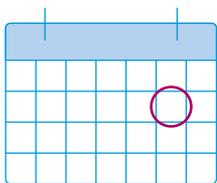




FOLLOW-UP: AN IMPORTANT PART OF YOUR JOURNEY

After your surgery, there will likely be several follow-up visits with your doctor. During these important appointments, your doctor will confirm your device is working properly. If adjustments are needed to your CRT therapy, they can be made painlessly in your clinic using technology that communicates directly with your device to update settings.

If changes are made to your CRT device at the time of your visit, a follow-up appointment may be needed. Your doctor may reduce how often you need office visits, depending on your health and remote monitoring information.



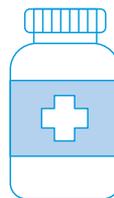
It is very important to keep your follow-up appointment schedule with your doctor. Remote monitoring does not take the place of in-person appointments.

WHAT ABOUT SHOCKS?

Shocks are part of living with a CRT-D device, but they are not something you need to be scared of receiving. If you receive a shock, your device was likely responding to a dangerous heart rhythm, and it might have just saved your life. However, there is a low possibility the device has delivered an inappropriate shock. If you receive a shock, follow up with your doctor, as he or she may want to see you.

CRT DEVICE EFFECTS ON MEDICATION AND DIET

Usually, having a CRT device does not replace medication. They work together. But your doctor may change the amount or type of medication you take. Also, depending on your overall health, your doctor may recommend changes to your diet.



WHEN DEVICE BATTERIES RUN LOW

Most CRT batteries last five to ten years, depending on the device and how often it sends electrical pulses to the heart. Since the device itself is sealed, when the battery gets too low to deliver therapy the device must be replaced. Your doctor will discuss this with you when it is needed.



OTHER MEDICAL PROCEDURES

Before any procedure, talk with your healthcare provider to let them know you have a CRT device. This includes any dental procedure.

Some CRT devices are MR Conditional, meaning it can be safe to have an MRI under specific conditions. Your doctor will need to confirm if your CRT device is one of them.

ALERTING PEOPLE WHO NEED TO KNOW

It is important to make sure your health care team and others – such as airport security people – are aware that you have a CRT device. To help with this, you will receive an ID card you should carry with you at all times. This card will indicate whether you have an MR conditional device and will allow you to inform people that you have an implanted device that may set off a metal detector.

For more information, please visit [cardiovascular.abbott](https://www.cardiovascular.abbott) and search “Living with Your Device”.

References

1. Gianluigi Savarese, Lars H Lund. Global Public Health Burden of Heart Failure. *Card Fail Rev.* 2017 Apr; 3(1): 7-11.
2. <https://my.clevelandclinic.org/health/diseases/17078-heart-failure-in-women>
3. Leeor M. Jaffe, Daniel P. Morin. Cardiac Resynchronization Therapy: History, Present Status, and Future Directions. *Ochsner J.* 2014 Winter; 14(4): 596-607.

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Rx Only

CRT-D Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are also intended to resynchronize the right and left ventricles in patients with congestive heart failure. **Contraindications:** Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance or acute myocardial infarction. **Adverse Events:** Implantation of the pulse generator system, like that of any other device, involves risks, some possibly life-threatening. These include but are not limited to the following: acute hemorrhage/bleeding, air emboli, allergic reaction, arrhythmia acceleration, cardiac or venous perforation, cardiac tamponade, cardiogenic shock, cyst formation, death, erosion, exacerbation of heart failure, extracardiac stimulation, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation, histotoxic reactions, inappropriate shocks, infection, keloid formation, myocardial irritability/damage, nerve damage, pneumothorax, thromboemboli, venous occlusion. Other possible adverse effects include mortality due to: component failure, device-programmer communication failure, lead abrasion, lead dislodgment or poor lead placement, lead fracture, inability to defibrillate, inhibited therapy for a ventricular tachycardia, interruption of function due to electrical or magnetic interference, shunting of energy from defibrillation paddles, system failure due to ionizing radiation. Other possible adverse effects include mortality due to inappropriate delivery of therapy caused by: multiple counting of cardiac events including T waves, P waves or supplemental pacemaker stimuli. Among the psychological effects of device implantation are imagined pulsing, dependency, depression, fear of inappropriate pulsing and fear of losing pulse capability.

CRT-P Indications: The devices are indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of those symptoms. Cardiac Resynchronization Therapy Pacemakers (CRT-Ps) are indicated for patients who would benefit from resynchronization of the right and left ventricles and have one or more conventional indications for the implantation of a pacemaker. Rate-Modulated Pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Dual Chamber Pacing is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. Atrial Pacing is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular Pacing is indicated for patients with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability. AF Suppression™ pacing is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications. **Contraindications:** Devices are contraindicated in patients with an implanted cardioverter-defibrillator. Rate-Adaptive Pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. AF Suppression stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. Dual-Chamber Pacing, though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation, or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients. Single-Chamber Ventricular Demand Pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing. Single-Chamber Atrial Pacing is relatively contraindicated in patients who have demonstrated compromise of AV conduction. Atrial Fibrillation. Allure™ devices are contraindicated in patients having chronic atrial fibrillation or intermittent atrial fibrillation that does not terminate. For specific contraindications associated with individual modes, refer to the programmer's on-screen help. **Potential Adverse Events:** The following are potential complications associated with the use of any pacing system: air embolism, allergic reaction, body rejection phenomena, cardiac tamponade or perforation, hematoma, bleeding hematoma, seroma, formation of fibrotic tissue, local tissue reaction, inability to interrogate or program due to programmer or device malfunction, infection/erosion, interruption of desired pulse generator function due to electrical interference, either electromyogenic or electromagnetic, lead malfunction due to conductor fracture or insulation degradation, loss of capture or sensing due to lead dislodgement or reaction at the electrode/tissue interface, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, pacemaker migration or pocket erosion, pectoral muscle or diaphragmatic stimulation, phrenic nerve stimulation, pneumothorax/hemothorax, device migration and pocket erosion, endocarditis, excessive bleeding, induced atrial or ventricular arrhythmias, myocardial irritability, pericardial effusion, pericardial rub, pulmonary edema, rise in threshold and exit block, valve damage, cardiac/coronary sinus dissection, cardiac/coronary sinus perforation, coronary sinus or cardiac vein thrombosis, death.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

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