cardiac resynchronization therapy

for moderate to severe

heart failure
This pamphlet provides general information about a new heart failure (HF) treatment option called **cardiac resynchronization therapy**. This therapy is intended for a select group of heart failure patients and involves the use of a pacemaker-like device. This device should help the heart pump blood more efficiently. Cardiac resynchronization therapy is not a replacement for medications. It is recommended that anyone choosing to receive cardiac resynchronization therapy should continue to follow his or her physician’s advice regarding their medications.

Before describing cardiac resynchronization therapy, let’s first discuss general information about how the heart works, heart failure and the treatment options available.

**How does the heart work in normal rhythm?**

The human heart is an amazing pump. It has four chambers: two smaller, upper chambers called the right and left atria, and two larger, lower chambers called the right and left ventricles. These four chambers work together to produce powerful contractions (heartbeats) to pump blood to your entire body every minute.

This coordinated pumping action is controlled by the heart’s electrical system. Normally the electrical signal to start a heartbeat (contraction) begins in the sinoatrial node (SA node), called the heart’s natural pacemaker. From the SA node, the signal travels through specialized tissues through the upper chambers of the heart (atria), and causes them to contract. The signal then travels to the lower chambers (ventricles) through a special “electrical bridge” called the AV node, which separates the atria from the ventricles. Once the electrical impulse leaves the AV node, it travels to the ventricles and stimulates them to contract.
What is meant by heart failure?
The term “heart failure” may sound frightening, but it does not mean that the heart has stopped working. Heart failure is a treatable disease. When someone has heart failure, it means that the heart is weakened and doesn’t work (or pump blood) as well as it should. This may cause some of the following symptoms:

Symptoms that may occur with heart failure
- Shortness of breath
- Swelling of the feet and legs
- Lack of energy, feeling tired
- Difficulty sleeping at night due to breathing problems
- Cough with “frothy” sputum
- Swollen or tender abdomen, loss of appetite
- Increased urination at night
- Confusion, impaired memory

Most physicians will classify the severity of heart failure as belonging to one of four categories: New York Heart Association (NYHA) Functional Class I, II, III or IV. These classes are a way of measuring a person’s heart failure based upon his or her activity limitations. Class I heart failure patients may not even know they have heart failure. They typically have no physical limitations as to what they can do, and typically do not feel any of the symptoms noted above. Class II heart failure patients have mild symptoms and usually only experience them while doing light activities such as walking, mowing the yard or doing household chores.

Moderate to severe heart failure patients typically fall into either Class III or Class IV. They may have trouble breathing when doing simple activities of daily living such as walking to the mailbox or climbing stairs. Class IV heart failure patients also may be bedridden for the majority of their day because they feel too weak to do simple activities such as walking from room to room.
How common is heart failure?

More than 22 million people worldwide are estimated to have some form of heart failure. Nearly two million new cases are diagnosed each year. The risk of developing heart failure increases with age, and it is estimated that 1,000 out of every 100,000 people who are over the age of 65 develop heart failure.¹

What can be done to treat heart failure?

In most cases, heart failure can be treated and managed. A number of medications are typically used to increase the heart’s pumping ability, manage swelling (fluid retention) and treat other symptoms associated with heart failure.

Lifestyle changes, such as eating less salt, getting enough rest and exercising in moderation, are also important in the treatment of heart failure. In some cases, surgery may help. A new treatment option is cardiac resynchronization therapy. The remainder of this pamphlet will provide details about this therapy.

What is cardiac resynchronization therapy?

Cardiac resynchronization (CR) therapy is an option for patients with moderate to severe (Class III or IV) heart failure and ventricular dysynchrony (definition follows). The therapy is delivered through a specially designed pacemaker called a cardiac resynchronization device.

It’s estimated that 15% of all heart failure patients have ventricular dysynchrony.² As we discussed earlier, normally the two lower chambers of the heart (the ventricles) beat at the same time and are “synchronized.” When a heart failure patient has ventricular dysynchrony, the two lower chambers beat separately, and the heart is not able to pump blood efficiently to the body.
Cardiac resynchronization therapy sends tiny electrical pulses to both the right and left ventricles to make them beat at the same time. The pulses are delivered from a small, implanted device that is about the size of a stack of 2-3 silver dollars. The device is placed under the skin in the chest and connected to three leads (soft insulated wires) that are inserted through the veins into the heart.

**After receiving cardiac resynchronization therapy, what can be expected?**

Within weeks of receiving the implanted device, a heart failure patient may begin to feel more energetic. A doctor or nurse will provide guidelines before starting any new activities. It is important to follow their advice. Two different doctors may be used to manage the patient following implant. A heart failure doctor will probably continue to monitor the patient on a weekly, or sometimes daily, basis. A different cardiologist may assist with managing the device’s operation and the leads. These doctors are specialists in the care of people who have received implanted devices such as pacemakers. They will consult with the heart failure physician to ensure that optimal care is provided. Talk to a doctor or nurse about any questions regarding support.

**What benefits does this therapy provide?**

The safety and effectiveness of cardiac resynchronization therapy has been evaluated and proven in several FDA and worldwide clinical trials. In fact, cardiac resynchronization therapy has been commercially available in Europe since 1998. The clinical trials found that patients had an improved quality of life and reduced, or fewer, symptoms associated with their heart failure when they were treated with cardiac resynchronization therapy in combination with drugs, versus drugs alone.
In particular, cardiac resynchronization has been shown to:

- Improve the NYHA Functional Class of some patients (the way a physician classifies the severity of heart failure)
- Improve the patient’s ability to exercise and perform other physical activities
- Improve a patient’s quality of life

Who is a good candidate for this therapy?
Symptomatic heart failure patients with the following characteristics appear to benefit the most:

- Patients whose ventricles do not beat together (ventricular dysynchrony)
- Patients whose medications do not adequately treat their symptoms and who continue to have a poor quality of life (NYHA Class III or IV)
- Patients whose heart is not able to pump blood effectively

The Medtronic InSync® System was studied in the United States in patients with moderate to severe heart failure (NYHA Functional Class III and IV), limited functional capacity, systolic ventricular dysfunction, and ventricular dysynchrony. Please consult with your physician to determine if you are a candidate.

As with any active implantable device, there are potential risks associated with the InSync System.

In the U.S. clinical study investigating the InSync System, some patients reported worsening heart failure that required additional treatment. Some patients experienced loss of cardiac resynchronization because of lead dislodgement or other lead related events. Other patients reported irregular heartbeats (arrhythmias), which were treated by implanting a cardioverter defibrillator (ICD) or drug therapy. Your physician should discuss these and other potential risks with you.
Who is Medtronic?
Medtronic, Inc. is the world’s leading medical technology company, providing lifelong solutions for people with chronic disease. For patients with advanced heart failure, Medtronic provides cardiac resynchronization devices and lead systems that offer therapies to enhance their quality of life.

Visit us at www.medtronic.com

Note: This pamphlet was designed for general educational purposes to help answer your questions about cardiac resynchronization therapy for treating moderate to severe heart failure. It should not be considered the exclusive source for this type of information. Please talk to your doctor about your questions and concerns.

References:
Disclosure for Medtronic InSync® System

Indications: The InSync System is comprised of the InSync Model 8040 generator and left ventricular leads. The InSync Model 8040 device is indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy, and have a left ventricular ejection fraction ≤35% and a QRS duration ≥130 ms. The left ventricular leads have application as part of a Medtronic biventricular pacing system.

Contraindications: If a patient has an implanted defibrillator or cardioverter defibrillator (ICD), unipolar pacing with the InSync System is contraindicated because it may cause unwanted delivery or inhibition of the defibrillator or ICD therapy. The left ventricular leads are contraindicated for those patients with coronary venous vascular that is inadequate for lead placement.

Warnings and Precautions: Patients implanted with an InSync System should avoid magnetic resonance imaging (MRI), diathermy, high sources of radiation, electro surgical cautery, external defibrillation, lithotripsy, and radiofrequency ablation. These may result in electrical reset of the device and may result in inappropriate sensing and/or therapy. An implantable defibrillator may be implanted concomitantly with the InSync System, provided implant protocols are followed for device and defibrillator lead placement and device configuration.

See your physician for more information on the uses, contraindications, warnings, precautions, and potential complications of the InSync System.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.