

Understanding Heart Failure



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Scientific**

If you have heart failure, you are not alone. Heart failure is a common and serious medical condition that affects both men and women.

- More than 5 million people in the United States have heart failure.¹
- More than 550,000 new cases are diagnosed each year.¹
- More than 250,000 people die each year from heart failure.¹
- Heart failure can happen at any age, but is most common in people over 65.³
- Heart failure is the number one reason for hospitalization for people over age 65.³

Heart failure can also be called *congestive heart failure*, *systolic heart failure*, *diastolic heart failure*, *left-sided heart failure*, or *right-sided heart failure*.

In this brochure, we'll help you understand heart failure, its symptoms, and some of the treatments that are available. Many patients find it helpful for their family and friends to learn about their condition as well.

We encourage you to share this information with those who care about you.

Only your doctor can tell you if you have heart failure. Talk with your doctor about the treatment options that may be right for you.

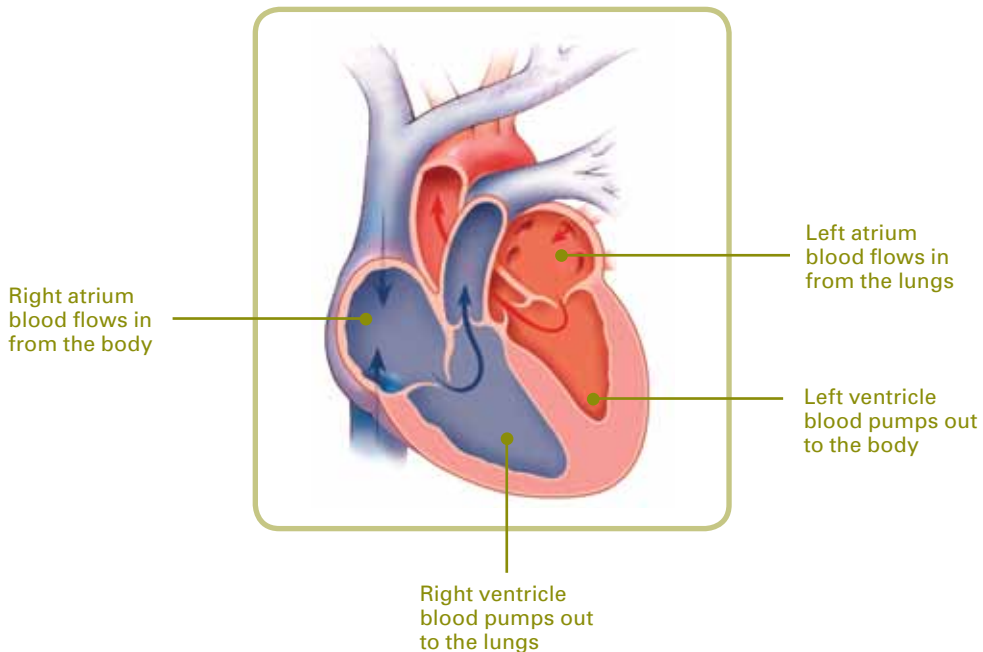
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What is heart failure?

To understand heart failure, it is helpful to be familiar with how the heart works. The heart is a hard-working muscle made up of four chambers—two upper chambers (atria) and two lower chambers (ventricles)—that pump blood and oxygen through the body.

- The atria are the receiving chambers. When blood flows into your heart from the body and lungs, it flows into the atria.*
- The ventricles are the pumping chambers. When blood leaves your heart, it is pumped out from the ventricles. The ventricles are very strong because they have to pump hard enough to push blood through your lungs and entire body. Your right ventricle pumps to your lungs, and your left ventricle pumps to your entire body.*





How does heart failure begin?

Heart failure begins when the heart is weakened or damaged. It does not mean that your heart suddenly stops working. Instead, heart failure develops slowly as your heart muscle gradually weakens.

The term *failure* means your heart cannot pump enough blood and oxygen to meet your body's needs. The heart chambers may not completely fill or empty with each beat, so less blood flows to the body. Without enough blood, important organs like your brain and kidneys cannot function properly.

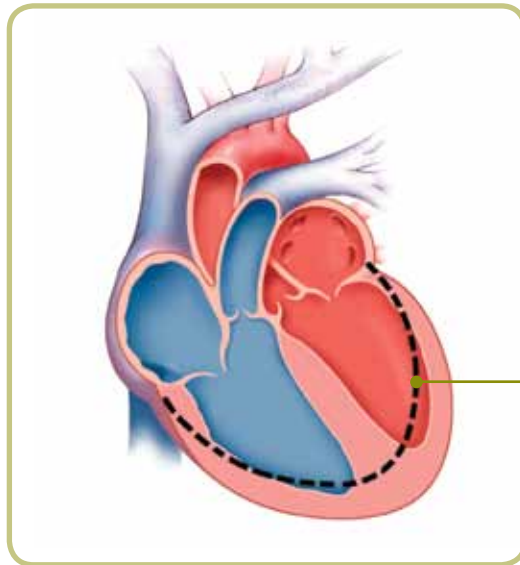
How does heart failure cause problems for the heart?

As the heart muscle weakens, other problems can result.

The heart's electrical system can become disrupted. The heart is only able to beat because the body naturally produces electricity that travels across the heart muscle and stimulates it to contract, or beat. It's normal and healthy for your heartbeat to speed up or slow down during the day as your activity level changes. But it's not normal for your heart to beat out of rhythm. A problem in your heart's electrical system can disrupt your heart's normal rhythm.

An abnormal heart rhythm is called an *arrhythmia*. Arrhythmias occur when the heart's electrical signals become interrupted or disorganized, causing the heart to beat too quickly or too slowly. When your heart beats out of rhythm, it may impair the heart's ability to pump properly. Some arrhythmias that occur in the ventricles can be life-threatening. They can lead to sudden cardiac arrest, which can lead to sudden cardiac death if not treated.

The heart can become enlarged. When the heart muscle begins to fail, the heart does not pump as strongly as it should. This means blood does not circulate as well. Your heart must work harder since it is not able to pump enough blood. Over time, the heart can grow larger, even though it is weak. The ventricles may not be able to contract or pump the blood with the same force as before.



Dotted line indicates normal-sized heart

The heart might not provide enough blood flow to the kidneys. If your kidneys do not receive enough blood, you may have water retention, swelling in the legs, feet, or abdomen, and high blood pressure. All of these problems can also cause your heart to work harder.

The heart may develop dyssynchrony. In a healthy heart, both ventricles (lower part of the heart) pump or beat at exactly the same time in a coordinated way. It's like making a fist—all of the fingers squeeze in unison. But for many people with heart failure, the ventricles do not pump at the same time. For these people, the pumping is uncoordinated. It's like making a fist just one finger at a time. This change in the rhythmic coordination, or synchrony, of the heart's contractions is called *dyssynchrony*.

How serious is heart failure?

Many people live for years with heart failure, sometimes without any symptoms. However, heart failure is a serious, chronic condition that can eventually lead to death.

The symptoms of heart failure develop because the heart muscle has suffered damage and can't keep up with the body's needs. The heart's enlargement and inability to pump tend to increase with time. Also, heart failure patients can be more prone to abnormal heart rhythms, which increases the risk of sudden cardiac arrest. People with heart failure usually die from sudden cardiac death (from untreated sudden cardiac arrest), or their heart's inability to function as a pump.

Pump failure

Pump failure develops over time as the heart muscle becomes weaker and weaker. Eventually it is too weak to continue pumping blood to vital organs, and death results.

A person with heart failure is 6 to 9 times more likely to experience sudden cardiac death than someone who does not have heart failure.²

Sudden cardiac arrest (SCA)

The usual cause of SCA is an abnormal heart rhythm known as *ventricular tachycardia* (VT) or *ventricular fibrillation* (VF). These two abnormal heart rhythms occur in the ventricles—the heart’s bottom two chambers.

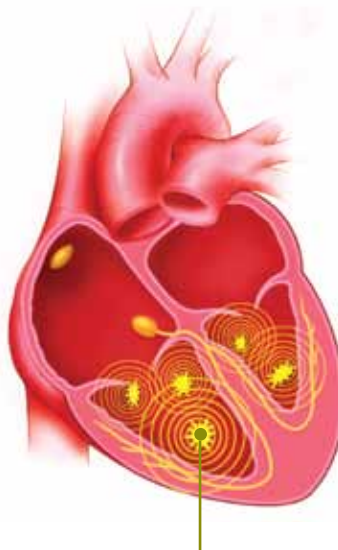
When these abnormal heart rhythms occur, the electrical impulses that cause the heart to contract are sent too quickly and erratically through the heart muscle. The heart’s contractions become so rapid and chaotic that blood cannot move through the heart’s chambers. As a result, the heart cannot pump enough blood to the body. When this happens, the person passes out and can experience sudden cardiac death if the abnormal heart rhythm is not treated.

Ventricular tachycardia (VT)



Abnormally fast heart rhythm in the ventricles

Ventricular fibrillation (VF)



Abnormally fast and chaotic heart rhythm; ventricles quiver rather than beat

What are the causes of heart failure?

Heart failure may occur for a variety of reasons, including:

- Heart attack
- Clogged heart vessels (coronary artery disease)
- Diabetes
- High blood pressure
- Heart or blood vessel disease or problems with the heart valves
- Aging
- Lung disease
- Enlarged heart

A person can also be born with a disease that causes heart failure. Others can contract a disease or have a tremendous strain on the heart that causes it to fail. Sometimes the cause of heart failure is unknown, and this is called *idiopathic dilated cardiomyopathy*. No matter what the cause, the heart muscle is damaged and no longer pumps as well as it should.

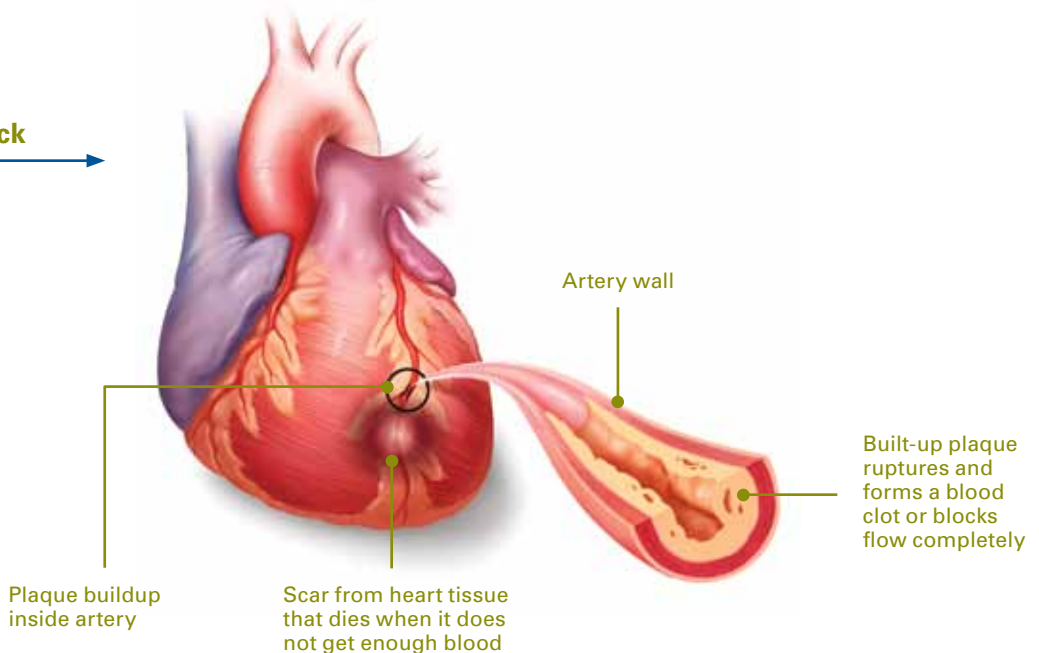
Coronary artery disease puts you at higher risk for a heart attack. If you have had a heart attack, you are 5 times more likely to develop heart failure.

An enlarged heart itself can have a number of causes:

- Alcohol or drug abuse
- High blood pressure (it makes you twice as likely to develop heart failure)
- Heart valve disease
- A viral infection in the heart
- A congenital heart problem (present from birth)
- Chemotherapy
- Family history of heart failure

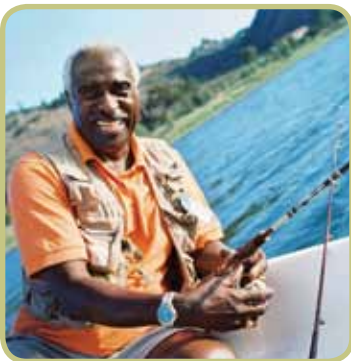
In addition, your eating habits, exercise habits, cholesterol level, and whether or not you smoke can also make a difference in how likely you are to have a heart condition, including heart failure.

Heart Attack



What are common heart failure symptoms?

Patients can experience many symptoms from heart failure. The symptoms are most noticeable when you exert yourself, but can also be present at rest. Mowing the lawn, exercising, or even walking from one room to another can cause enough symptoms that most heart failure patients have to cut back on activities. Symptoms of heart failure may get worse over time.



Shortness of Breath

Problems with breathing is one of the most common symptoms of heart failure. Some breathing problems occur when fluid backs up in the lungs and the surrounding tissues (sometimes known as congestive heart failure). This fluid backup can cause:

- Shortness of breath after mild exercise
- Asthma-like wheezing or dry cough a few hours after lying down

If breathing problems occur when you lie flat, you may need to elevate your head or sit in a recliner to sleep. Advanced stages of heart failure can cause a feeling of suffocation.

Swelling

If too little blood reaches your kidneys, your body can retain fluid or water and begin to swell. Swelling can happen in your feet, ankles, legs, or abdomen. As the tissues retain salt and water, you might gain weight rapidly or even overnight. This can happen even if you're eating less.

Tiredness

You get tired when the muscles in your body receive too little oxygen. The more you exert yourself, the more tired you feel.

Other Symptoms

Other symptoms of heart failure may include:

- Heart palpitations
- Difficulty concentrating
- Dizziness
- Waking up at night; having to sit up to catch your breath
- Inability to lay down because of coughing or shortness of breath



How is heart failure diagnosed?

Early diagnosis is critical to early treatment, which can delay the onset of some symptoms. Your doctor may order a number of tests to determine if you have heart failure. Your test results will help doctors determine the severity of heart failure and how to best treat your condition.

An important test is the *echocardiogram*—also called an *echo*.

This relatively simple test uses ultrasound (sound waves) to create images of your heart as it is beating. It can be performed in your doctor's office and only takes a few minutes. The echo helps your doctor see:

- The shape and size of your heart
- How well your heart valves are working
- How well your heart chambers are contracting
- The percentage of blood your heart pumps with each heartbeat (your *ejection fraction*)

What is your ejection fraction?

The echo provides your doctor with a very important heart measurement: *ejection fraction* (also called EF). Your EF is the percentage of blood your heart pumps with each heartbeat. Your EF helps doctors gauge how severe your heart failure is.

- A healthy heart pumps at least one half of the blood (50%) it holds with each beat.
- If you have heart failure, your heart pumps less blood. For many people with heart failure, their EF is often less than 40%.
- A low EF (less than 35%) dramatically increases your risk for sudden cardiac death.

Other tests that your doctor may use to diagnose heart failure include:

Chest x-ray: A chest x-ray reveals the size and shape of your heart, the presence of fluid around your lungs, and the position and shape of your large arteries.

Cardiac catheterization: This test measures the blood pressure in your heart or lungs. It also measures the amount of blood flowing through your heart and blood vessels. Your doctor can also take a tiny sample (biopsy) of your heart muscle.

Stress test: This test can help show if you have coronary artery disease, which can lead to heart failure. It can also show if you might be at risk for a heart attack, or if you have irregular heart rhythms.



A patient taking a stress test

How is heart failure classified?

To help determine the treatment that will be best for you, doctors often use classification systems to indicate the degree and seriousness of heart failure. The New York Heart Association (NYHA) classification and American College of Cardiology (ACC) classification are the most commonly used systems.

The NYHA system classifies heart failure in one of four categories based on your symptoms.

Class I (the mildest form)	You can perform everyday activities and not feel out of breath or tired.
Class II	Everyday activities make you feel slightly tired and out of breath.
Class III	Even minor activity causes you to feel tired and out of breath.
Class IV (the most severe)	You're tired and short of breath even at rest.

Your NYHA classification may change as your symptoms change.

The ACC system is newer and uses letters A to D. It classifies heart failure based on how well your heart is functioning, any structural changes that have occurred, and your symptoms.

Stage A	You have several risk factors for heart failure, but do not yet have the disease.
Stage B	You have structural heart disease, but no symptoms.
Stage C	You have structural heart disease and also signs and symptoms.
Stage D	You have structural heart disease and advanced signs and symptoms.

The stages of heart failure progress in severity from A to D after structural change has occurred in your heart.

How is heart failure treated?

Early diagnosis and treatment of heart failure is very important. In most cases, heart failure cannot be cured. However, it can be effectively treated in many cases. Treatment may help to improve your quality-of-life, reduce symptoms, reduce your need for hospitalization, reduce the risk of death, and slow the disease's progression.

Many treatment options exist. The choice of heart failure treatment—and its effects—can vary from one person to another. It is very important that you follow your treatment plan by keeping doctor appointments, taking medications, and making lifestyle changes. Talk to your doctor about which treatment options may be right for you. Actively working with your doctor or nurse can help you live longer and feel better.

Lifestyle changes and self-care

As part of your treatment, your doctor might suggest ways that you can live a healthier lifestyle. For instance, eating low-fat and low-sodium foods is important for people with heart failure. Sodium can cause extra fluid to build up in your body, making heart failure worse.

Your doctor may also recommend cardiac rehabilitation as part of your treatment. In cardiac rehabilitation, you work with a team of health care experts who help you recover. They will also help you learn how to avoid future heart-related problems.

Self-care activities that you should do include:

- Weigh yourself daily and report weight gains
- Look for swelling
- Report worsening fatigue or shortness of breath
- Report if you wake at night because of shortness of breath
- Avoid alcohol
- Stop smoking
- Eat a low-sodium diet

Medications

Your doctor will probably prescribe medications for your heart failure. The type and severity of your condition will help your doctor select the right medications for you. The average person takes several different medications for heart failure. It is critical for you to take all of your medications exactly as instructed and to notify your doctor before stopping.

ACE inhibitors or angiotensin receptor blockers (ARB) are used to:

- Keep blood vessels dilated
- Block hormones that weaken the heart over time
- Lower blood pressure

Beta blockers are also commonly used to treat heart failure. These medications help to:

- Lower blood pressure
- Lower heart rate
- Block hormones that weaken the heart over time
- Improve your ejection fraction (certain types of beta blockers)

Aldosterone antagonists are commonly used in select patients with heart failure. These medications help to:

- Increase urine output
- Block hormones that weaken the heart over time

Diuretics also called water pills, help eliminate the excess fluids that build up in tissues.

These medications help to:

- Increase urine output
- Reduce coughing
- Reduce tissue swelling
- Reduce shortness of breath

Digoxin is commonly used for heart failure patients who have symptoms that persist after taking the above medications. This medication helps to:

- Reduce symptoms
- Reduce hospitalizations

How is heart failure treated?

Implantable devices

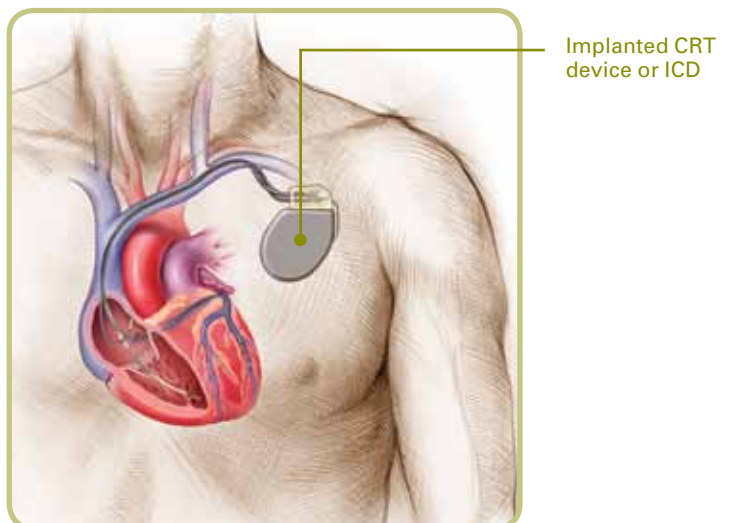
Cardiac resynchronization therapy (CRT) systems

When people with heart failure have uncoordinated contractions (*dyssynchrony*), they may benefit from cardiac resynchronization therapy, or CRT (also known as *biventricular pacing*). CRT is delivered by an implanted device. It helps restore proper timing of the heart's contractions so that the heart may improve its pumping function and work more efficiently. Doctors may prescribe this therapy in addition to medications if you continue to have symptoms. The optimum treatment may vary for each patient.

A CRT device is a special kind of pacemaker—sometimes called a *biventricular pacemaker*. While functioning like a normal pacemaker to treat slow heart rhythms, a CRT device also delivers small electrical impulses to the left and right ventricles to help them contract at the same time. This will help your heart pump more efficiently.

CRT benefits

- Reduce symptoms
- Improve quality-of-life
- Improve exercise capacity



Implantable cardioverter defibrillator (ICD) systems

Dangerously fast abnormal heart rhythms can cause sudden cardiac arrest. This can lead to sudden cardiac death within a few minutes if not treated. ICDs prevent sudden cardiac death by treating the dangerously fast abnormal rhythms. A person with heart failure is 6 to 9 times more likely to experience sudden cardiac death than someone who does not have heart failure.² An ICD may be used for people with heart failure who are at high risk for sudden cardiac death.

The ICD has two functions—it treats slow heart rhythms as a normal pacemaker and also treats dangerously fast abnormal rhythms. If the device senses a heart rate that is abnormal and dangerously fast, it delivers small amounts of electrical energy or a shock (defibrillation) to return the heart to a normal rhythm. Some CRT devices also have a built-in ICD.

ICD benefits

- Treat sudden cardiac arrest to prevent sudden cardiac death
- Provide normal pacemaker therapy if needed
- Identify other heart rhythms

Not everyone with heart failure will benefit from an implantable device. Some people may not need a device if they respond favorably to other treatments, such as lifestyle changes and medication. Patients may have other medical conditions that could prevent a device from being beneficial. Your doctor will review your personal health condition to determine whether an implantable device may be right for you.

There are risks associated with the implantation of a device or lead(s). It is important that you talk with your doctor about the risks as well as the benefits. For more information regarding some of the potential risks, see page 23 in this brochure.

How is heart failure treated?

Surgeries

Doctors can use one of several surgical options to treat heart failure. Angioplasty is the least invasive because there is no need to cut open the chest. Assist devices, bypass, valve, and heart transplant surgeries are more invasive because a surgeon must cut open the chest to perform the surgeries. Talk to your doctor if you have questions about the surgeries described below.

Angioplasty: If a blocked vessel is a primary cause of a patient's heart failure, angioplasty might be used to open the vessel. The goals of angioplasty are to:

- Reduce blood vessel blockages
- Allow blood to flow more easily through blood vessels
- Reduce chest pain or angina

The angioplasty procedure involves:

- Passing a balloon-tipped catheter to the blocked area of a blood vessel
- Inflating the balloon to press the blockage of fatty deposits (plaque) against the blood vessel wall

Often, angioplasty is followed by placing a stent in the blood vessel. A stent is a small mesh tube that helps keep the blood vessel from becoming blocked again.

Bypass surgery: Bypass surgery reroutes blood around blocked vessels. Bypass surgery involves:

- Removing parts of blood vessels from another part of the body, usually the leg
- Sewing or grafting these vessels on to the blood vessel past the clogged area to bypass them

Valve surgery: Sometimes heart failure stems from a faulty valve. (A valve is one of the “doors” that opens and closes between the heart’s chambers, allowing blood to pass from one chamber to another.) A faulty heart valve may be repaired or replaced with either a transplanted valve or a manufactured valve.

Assist devices: On occasion, patients with very advanced heart failure receive a heart assist device. This mechanical pump is able to:

- Perform the job of the left ventricle
- Pump blood to the body

Some assist devices are fully implanted in the body, while others are not. For people on the heart transplant waiting list, an assist device can be used until a donor heart becomes available.

Heart transplant: This option is reserved for the most advanced cases of heart failure. Not only is transplant surgery very complex, but there is always the risk that the body’s immune system will reject the new heart. There are criteria that must be met to be a transplant candidate. Your doctor will determine if you are a candidate.

Every person with heart failure has different needs. If you’ve been diagnosed with heart failure, talk with your doctor about the treatment options available to you. Your doctor will help you understand the risks associated with each option, and together you can choose the treatment that is right for you.

Heart failure research continues

Many advances in treatment for heart failure have been made over the past few decades, but heart failure is still very common. Scientists are trying to determine the best ways to prevent and treat heart failure.

Two studies have shown that implantable devices may help heart failure patients:

- The COMPANION study, sponsored by Boston Scientific CRM (formerly Guidant), found that people treated with a CRT-D device (CRT device with a built-in defibrillator) and medication lived longer than those treated with medications alone. It also found that people who received a CRT device had fewer symptoms and reported a better quality-of-life.⁴
- The SCD-HeFT study of heart failure patients, sponsored by the National Heart, Lung, and Blood Institute, found that patients who had an ICD in addition to medication had a 23% lower risk of death than patients treated with only medication and a placebo.⁵

Other research has studied drugs called statins, which can reduce cholesterol levels, to see whether they also improve survival in heart failure patients.^{6,7}

Researchers are also looking at genetics in relation to heart failure treatments. One study is investigating whether patients who have certain genetic markers may respond better to beta blockers than those who do not.

Important safety information

Cardiac Resynchronization Therapy Devices

Cardiac resynchronization therapy pacemakers (CRT-P) and defibrillators (CRT-D) are designed to treat heart failure patients who have symptoms despite the best available drug therapy. They are also designed to help your heart pump more effectively and meet your body's need for blood flow. CRT-P and CRT-D systems are not for everyone, including people with separate implantable cardioverter-defibrillators (CRT-P only) or certain steroid allergies. Procedure risks include infection, tissue damage, and kidney failure. Patients who should not receive this device include: patients who have additional medical conditions that may not allow the pacemaker to function appropriately (CRT-P only) and patients whose ventricular rhythm disturbances or heart failure have a reversible or temporary cause. In some cases, the device may be unable to detect or appropriately respond to your heart rhythm (CRT-P and CRT-D) or may deliver inappropriate shocks (CRT-D only). In rare cases severe complications or device failures can occur. Electrical or magnetic fields can affect the device. Only your doctor knows what is right for you. These devices are available by prescription only. Individual results may vary. For further safety information, refer to the Physicians Instructions for Use or call 1/866-484-3268.

Implantable Cardioverter Defibrillators

An implantable cardioverter defibrillator is designed to monitor and treat heart rhythm problems, greatly reducing the risks associated with them. But it is not for everyone, including people with certain steroid allergies. Procedure risks include infection, tissue damage, and kidney failure. Patients who should not receive this device include: patients whose ventricular rhythm disturbances have a reversible or temporary cause and patients with certain types of atrial rhythm disturbances. Procedure risks include infection and tissue damage. In some cases, the device may not respond to irregular heartbeats or may deliver inappropriate shocks. In rare cases severe complications or device failures can occur. Electrical or magnetic fields can affect the device. Only your doctor knows what is right for you. This device is available by prescription only. Individual results may vary. For further safety information, refer to the Physicians Instructions for Use or call 1/866-484-3268.

Pacemakers

A pacemaker system is designed to monitor and treat your heart rhythm problems, greatly reducing the risks associated with them. But it is not for everyone, including patients with certain steroid allergies. Procedure risks include infection, tissue damage, and kidney failure. Patients who have additional medical conditions that may not allow the pacemaker to function appropriately should not receive a device. In rare cases severe complications or device failures can occur. Electrical or magnetic fields can affect the device. Only your doctor knows what is right for you. This device is available by prescription only. Individual results may vary. For further safety information, refer to the Physicians Instructions for Use or call 1/866-484-3268.

Device Quality and Reliability

It is Boston Scientific's intent to provide implantable devices of high quality and reliability. However, these devices may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. Refer to Boston Scientific's CRM product performance report on www.bostonscientific.com <<http://www.bostonscientific.com/>> for more information about device performance, including the types and rates of malfunctions that these devices have experienced historically. While historical data may not be predictive of future device performance, such data can provide important context for understanding the overall reliability of these types of products. Also, it is important that you talk with your doctor about the risks and benefits associated with the implantation of a device.

(Rev. D)

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The logo for Boston Scientific, featuring the words "Boston" and "Scientific" stacked vertically in a serif font. The "B" in "Boston" is significantly larger than the other letters.

Delivering what's next.™

Cardiac Rhythm Management

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FOOTNOTES:

1. American Heart Association. Heart Disease and Stroke Statistics—2009 update. Available at www.americanheart.org.
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5. Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med* 2005; 352:225–237.
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