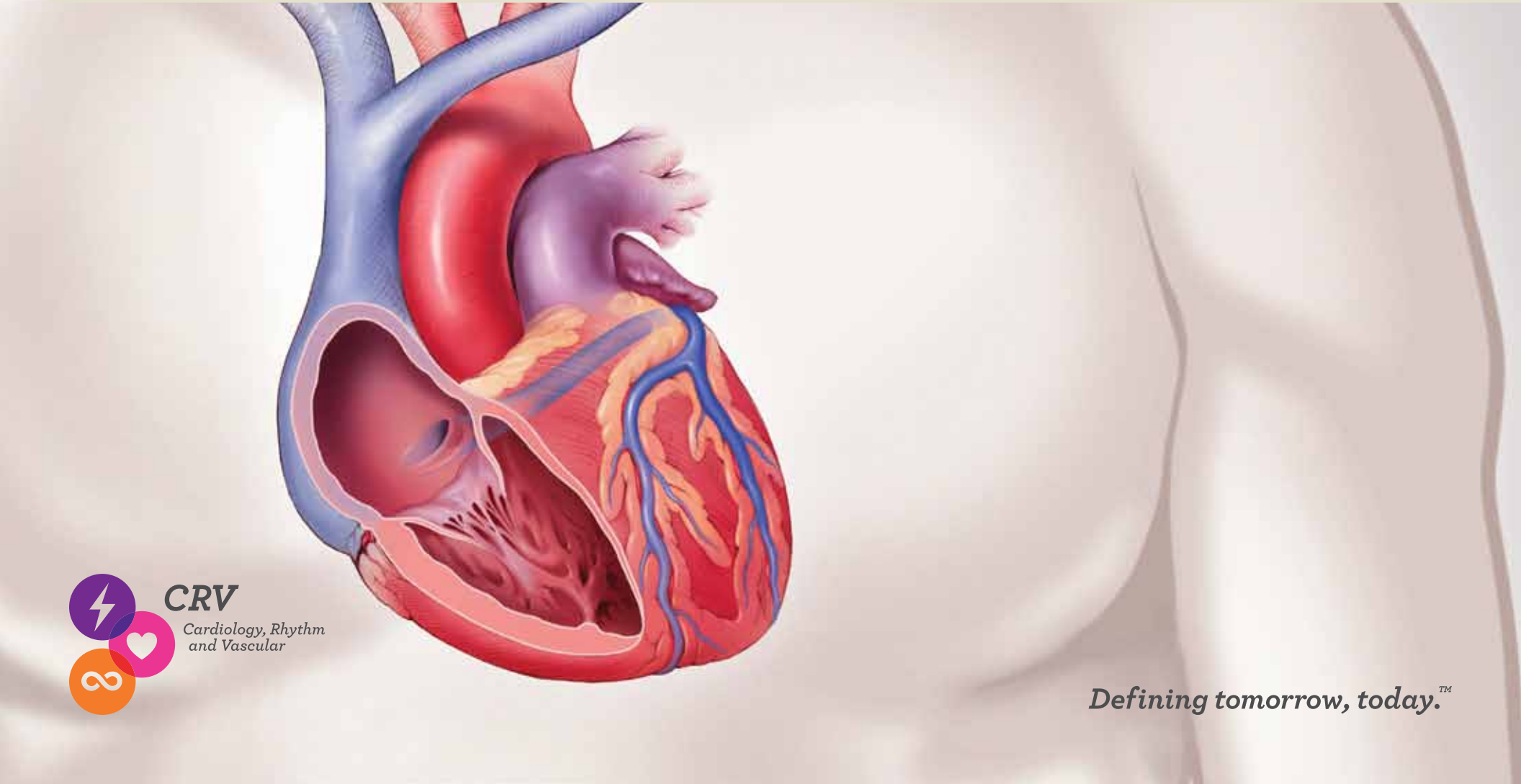
Boston Scientific

Device Therapy:

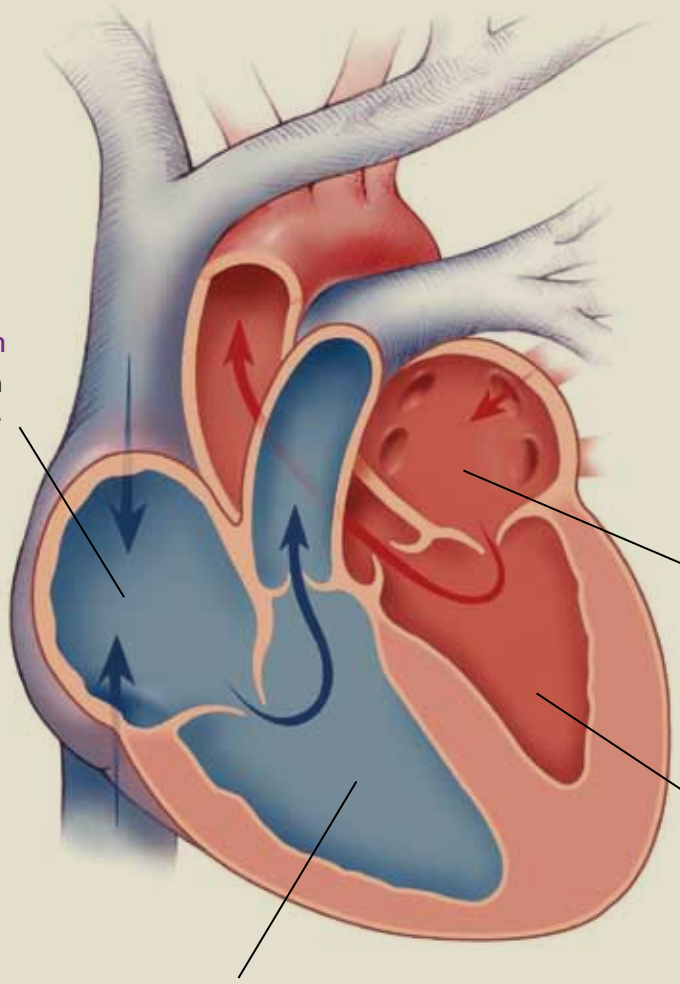
Making a Difference



CRV
Cardiology, Rhythm and Vascular

Defining tomorrow, today.™

Heart Chambers and Blood Flow



Right atrium
Blood flows in from the body

Right ventricle
Blood pumps out to the lungs

Left atrium
Blood flows in from the lungs

Left ventricle
Blood pumps out to the body

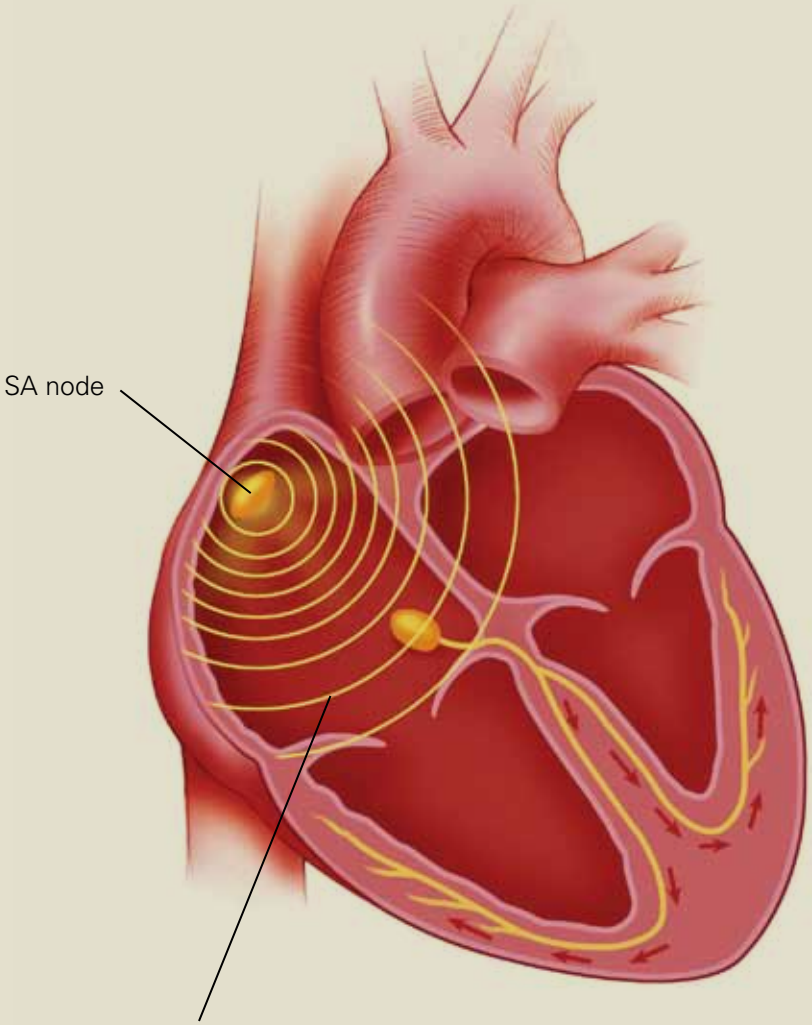
Atria

- Heart's receiving chambers
- Blood flows **into** the atria from the body and lungs

Ventricles

- Heart's pumping chambers
- Blood is pumped **out** from the ventricles

The Heart's Electrical System

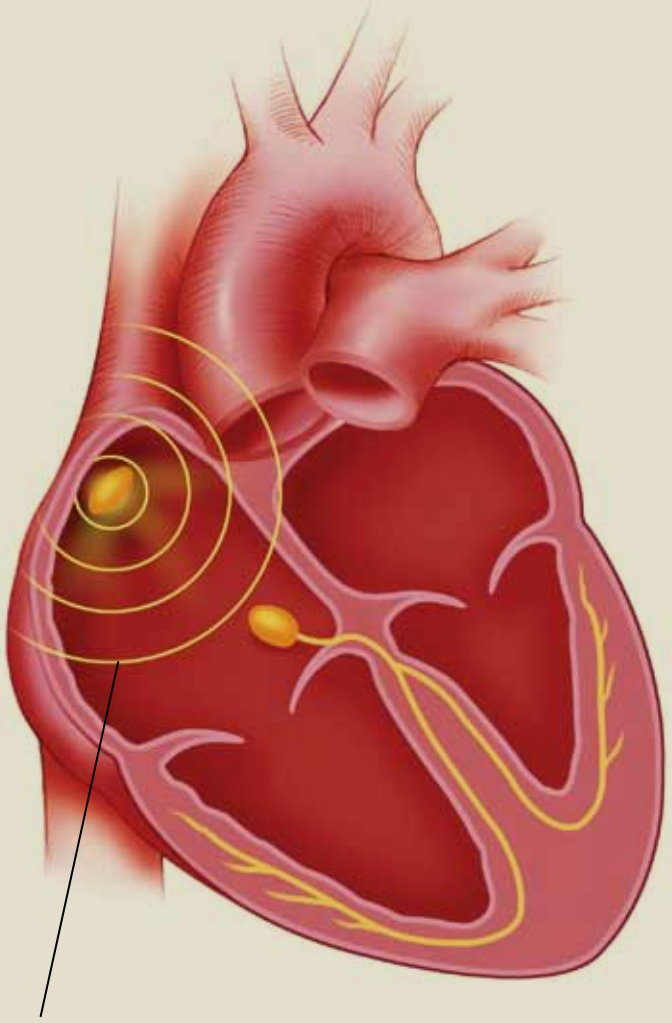


SA Node

- A bundle of specialized cells in your right atrium
- Creates the electricity that makes your heart beat
- When the electrical signals from the SA node conduct through to the ventricles, the contraction of the ventricles makes the pulse—or heartbeat
- The "natural pacemaker" of your heart; the number of heartbeats per minute is your heart rate

Normal ECG

The Heart's Electrical System



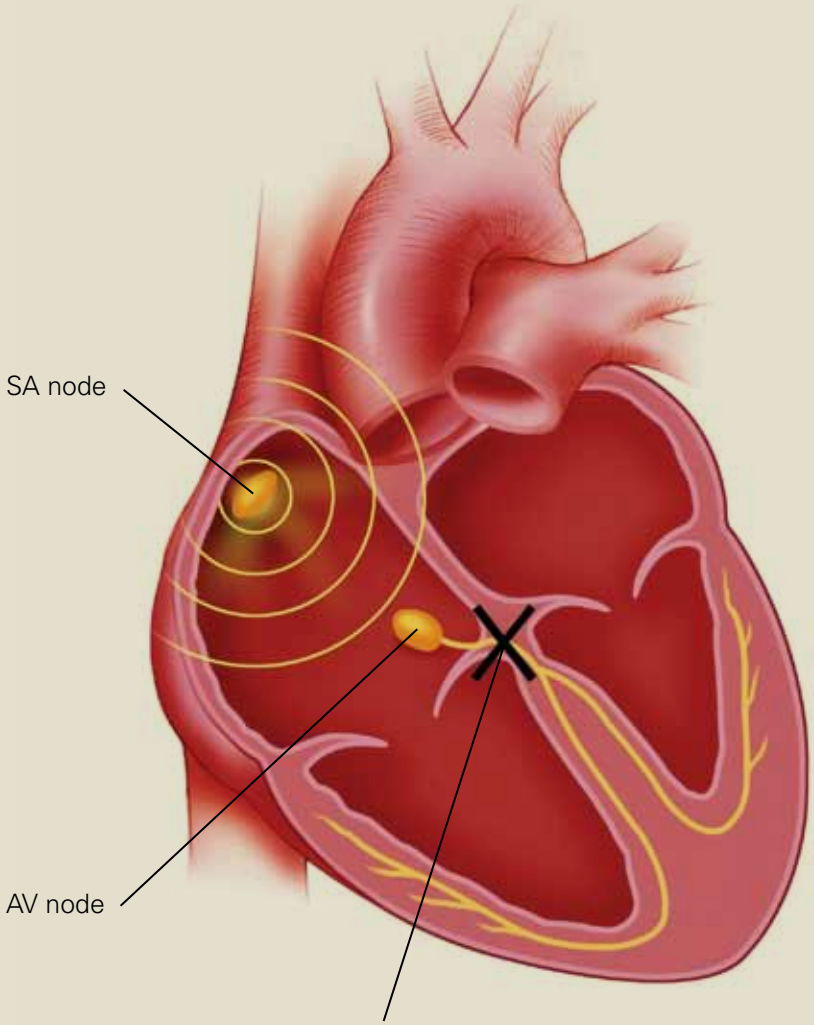
Slow heart rate or when SA node does not send out enough signals

Bradycardia

- An abnormally slow heart rate, less than 60 beats per minute
- Results from a problem in your heart's electrical system
- Heart may pump less blood and oxygen to your body

Bradycardia ECG

The Heart's Electrical System

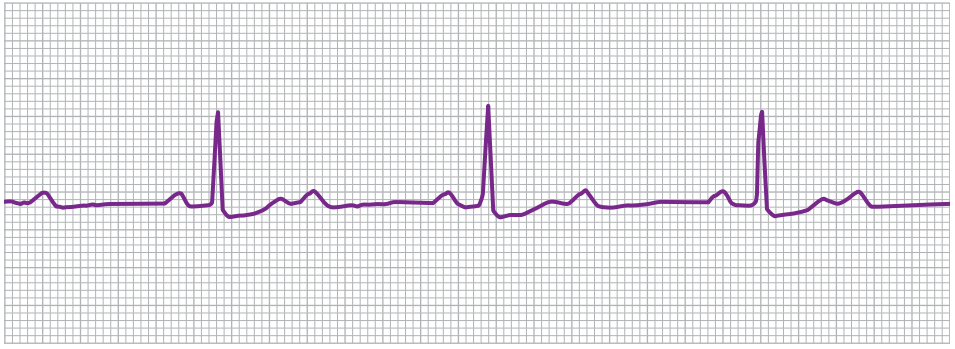


Signals from SA node are slowed or blocked and may not reach the ventricles

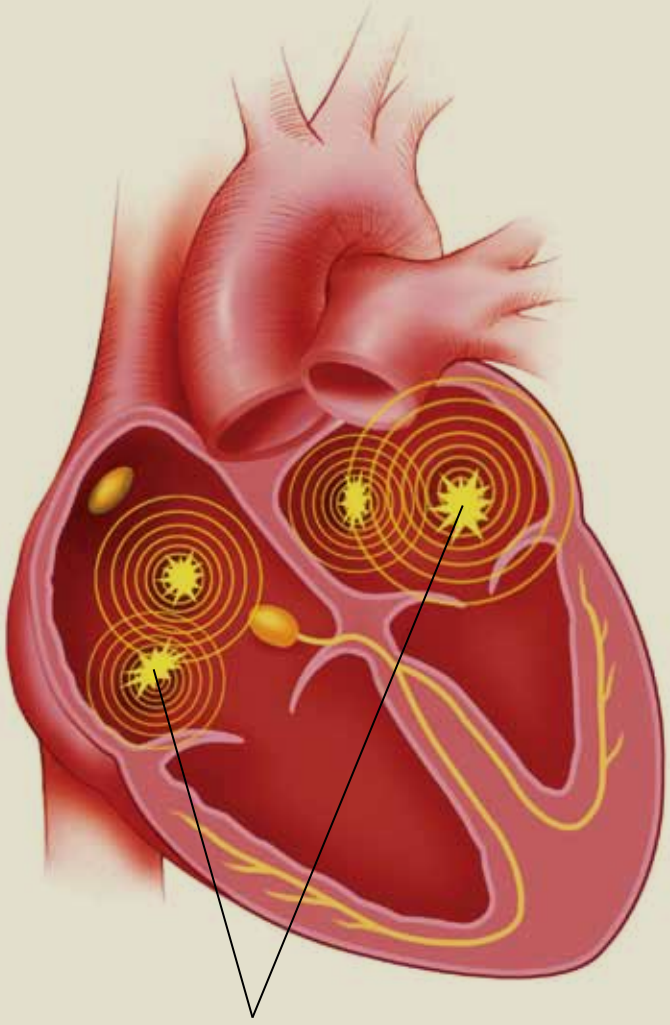
Heart Block

- A problem with the electrical pathway between the atria and the ventricles that can cause an abnormally slow heart rate
- SA node sends out natural pacemaker electrical signals to the AV node, which transmits them to the ventricles
- In heart block, these electrical signals are slowed or blocked and may not reach the ventricles

Heart Block ECG



The Heart's Electrical System

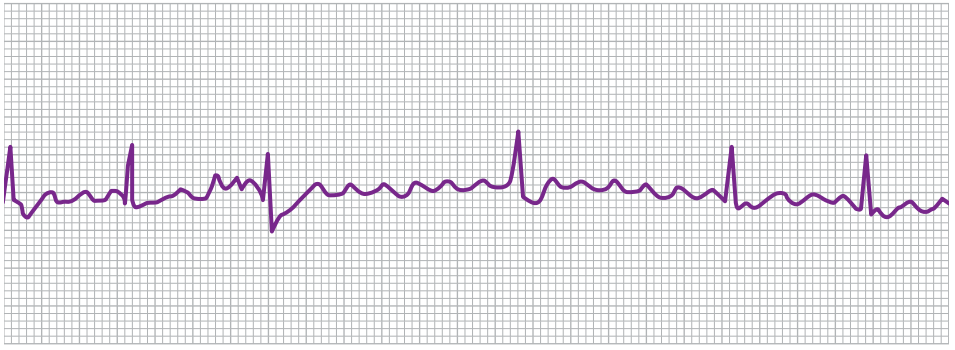


Abnormally fast and chaotic heart rate; atria quiver rather than beat

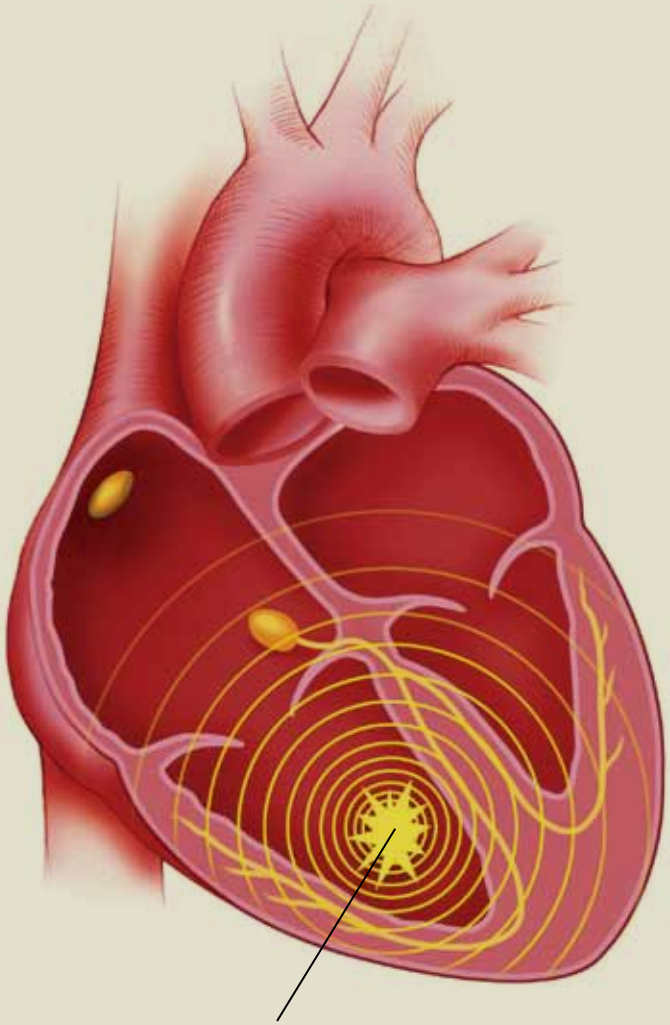
Atrial Fibrillation

- An abnormally fast and chaotic heart rate in the atria
- Electrical signals start irregularly from many areas in the atria
- Disorganized electrical signals cause the atria to quiver rather than beat; this can lessen the amount of blood that is delivered to the ventricles

Atrial Fibrillation ECG



The Heart's Electrical System



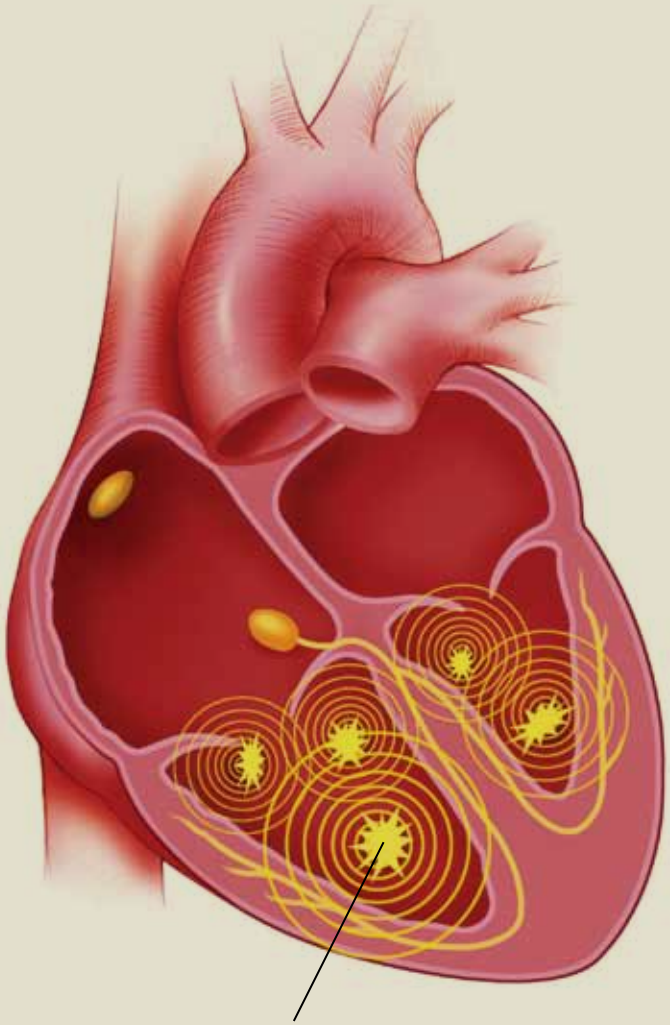
Abnormal electrical signals in the ventricles

Ventricular Tachycardia

- An abnormally fast heart rate in the ventricles
- Causes the heart to beat abnormally more than 100 times per minute
- Can resolve on its own or turn into ventricular fibrillation, an abnormally fast and chaotic rate that is more dangerous

Ventricular Tachycardia ECG

The Heart's Electrical System

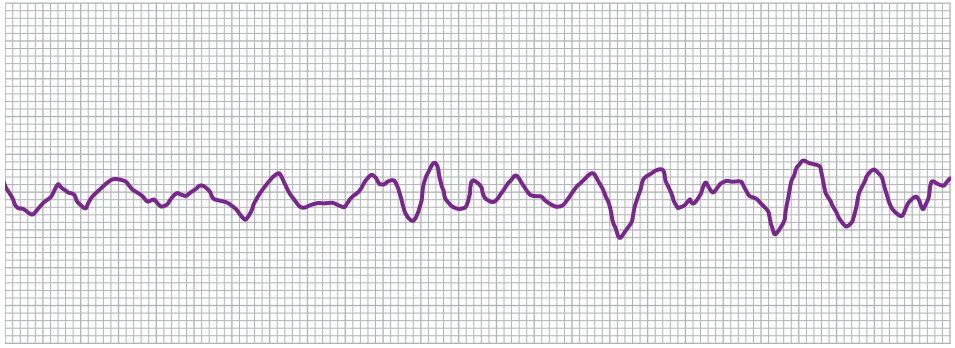


Abnormally fast and chaotic heart rate; ventricles quiver rather than beat

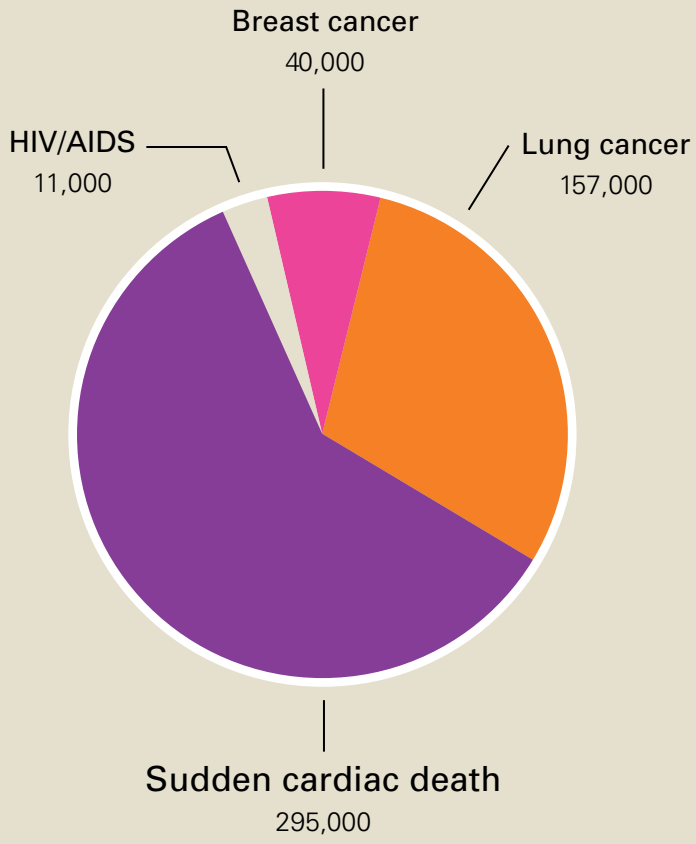
Ventricular Fibrillation

- An abnormally fast and chaotic heart rate in the ventricles
- Causes the heart to beat more than 200–300 times per minute
- Disorganized electrical signals cause ventricles to quiver rather than beat; as a result there is no circulation of blood
- The most dangerous type of abnormal heart rate—can lead to sudden cardiac arrest, and possibly death

Ventricular Fibrillation ECG



Sudden Cardiac Arrest (SCA) and Sudden Cardiac Death (SCD)



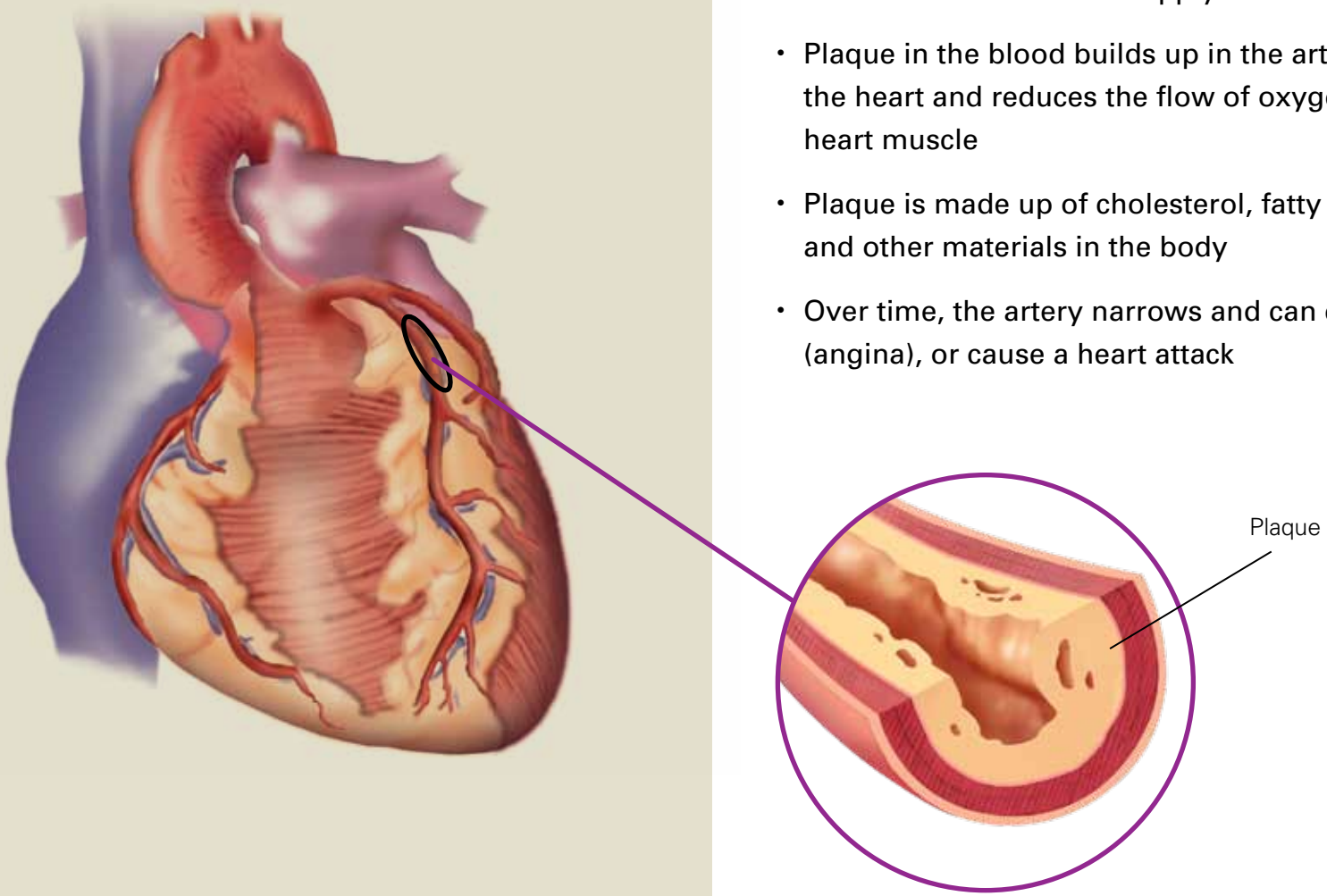
Sudden cardiac arrest (SCA) is when the heart abruptly and unexpectedly ceases to function

- Ventricular fibrillation (VF) is dangerous; can lead to SCA
- Within seconds after VF begins, a person can faint and lose consciousness
- If not treated within a few minutes with a defibrillator, SCA can lead to sudden cardiac death (SCD)
- SCD is a leading cause of death in the United States[1]
- More people die from SCD than from AIDS, breast cancer, and lung cancer combined[1,2,3,4]

Sudden cardiac arrest is not the same as a heart attack

- SCA occurs due to electrical problems in the heart, which cause a dangerously fast heart rate
- Heart attack results from heart muscle damage from blood flow blockage, rather than an electrical problem

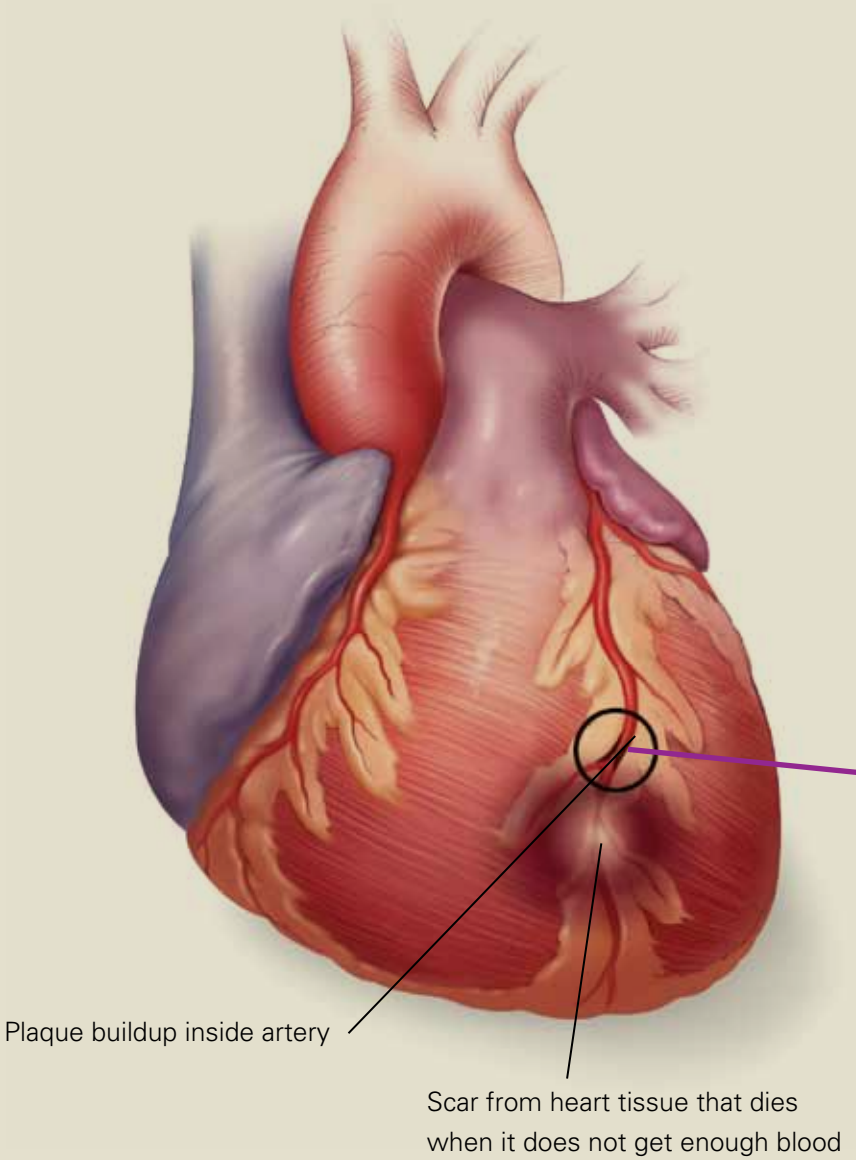
Coronary Artery Disease



Coronary Artery Disease

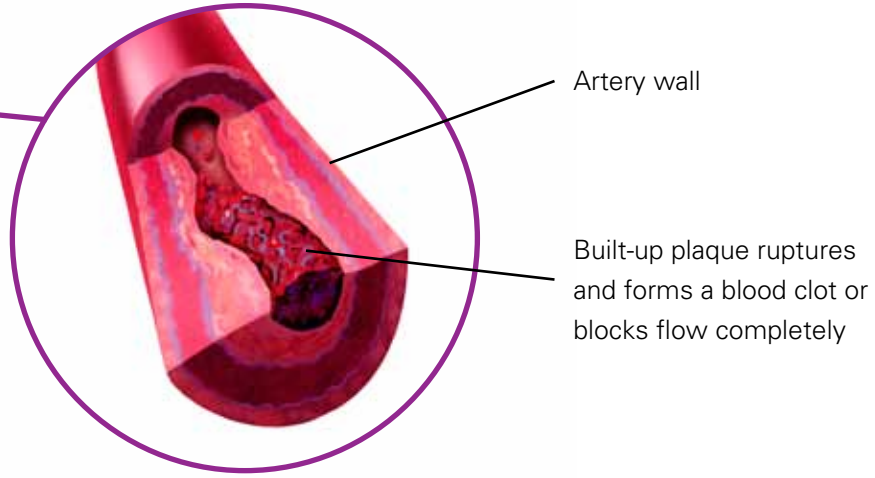
- Affects the arteries that supply blood to the heart
- Plaque in the blood builds up in the arteries and walls of the heart and reduces the flow of oxygen-rich blood to the heart muscle
- Plaque is made up of cholesterol, fatty deposits, calcium, and other materials in the body
- Over time, the artery narrows and can cause chest pain (angina), or cause a heart attack

Heart Attack



Heart Attack

- A heart attack occurs when plaque buildup ruptures and forms a blood clot, or when the plaque buildup completely blocks blood flow
- The blood clot keeps blood and oxygen from reaching heart muscle, causing it to die and scar
- Some heart attack survivors are at increased risk for sudden cardiac arrest due to the scar:
  - Scar lessens the heart's ability to pump blood
  - Scar can affect the heart's electrical system without warning or symptoms and cause sudden cardiac death



Heart Failure

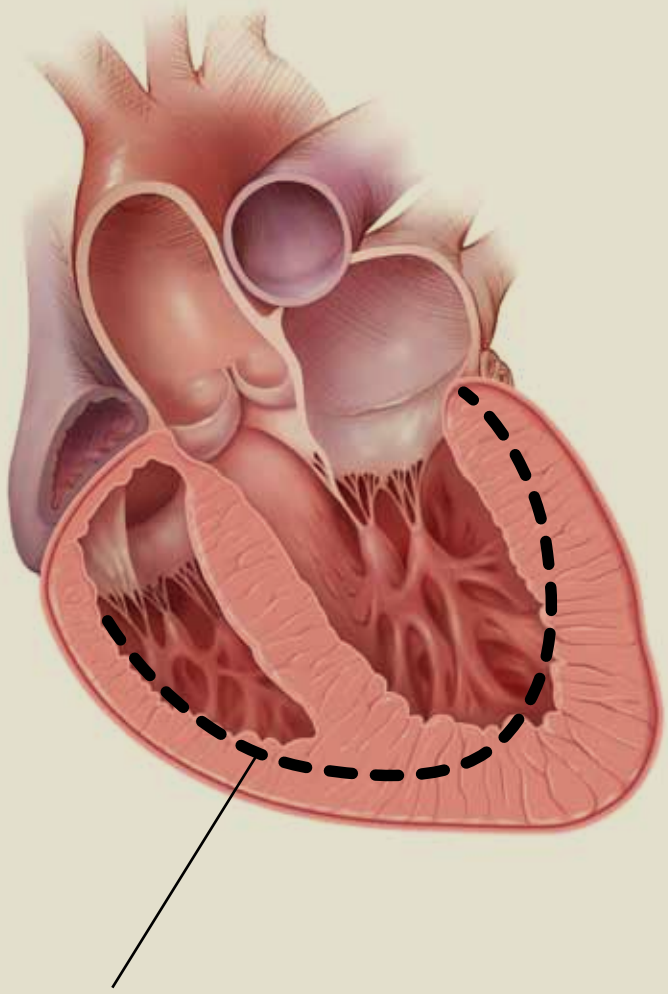
Heart Failure

- Does not mean the heart suddenly stops working; happens slowly as your heart muscle gradually weakens
- Usually begins when the heart is weakened or damaged
- "Failure" means the heart is not able to pump enough blood and oxygen to meet your body's needs
- Important organs like your brain and kidneys cannot function properly without enough blood

U.S. Heart Failure Facts

- More than 5 million people 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 affects both men and women and can happen at any age
- Heart failure is most common in people over 65, and is the number one reason for hospitalization for people over age 65[4]

Heart Failure



Dotted line indicates normally-sized heart

As heart failure progresses, you may experience:

Enlarged heart:

- Heart must work harder since it is not able to pump enough blood
- Over time, heart can grow larger, even though it is weak
- Ventricles may not be able to contract or pump blood with the same force
- May result in dyssynchrony, which means the ventricles don't squeeze blood out at the same time

Disruption of the heart's electrical system:

- Can lead to sudden cardiac arrest and sudden cardiac death
- A person with heart failure is six to nine times more likely to experience sudden death than someone who does not have heart failure[4]

Common Symptoms

- Shortness of breath
- Swelling in feet, ankles or stomach
- Tiredness
- Other:
  - Heart palpitations or fluttering feeling
  - Difficulty concentrating
  - Dizziness
  - Waking up at night; having to sit up to catch your breath
  - Inability to lay down because of cough or shortness of breath

Classification Systems

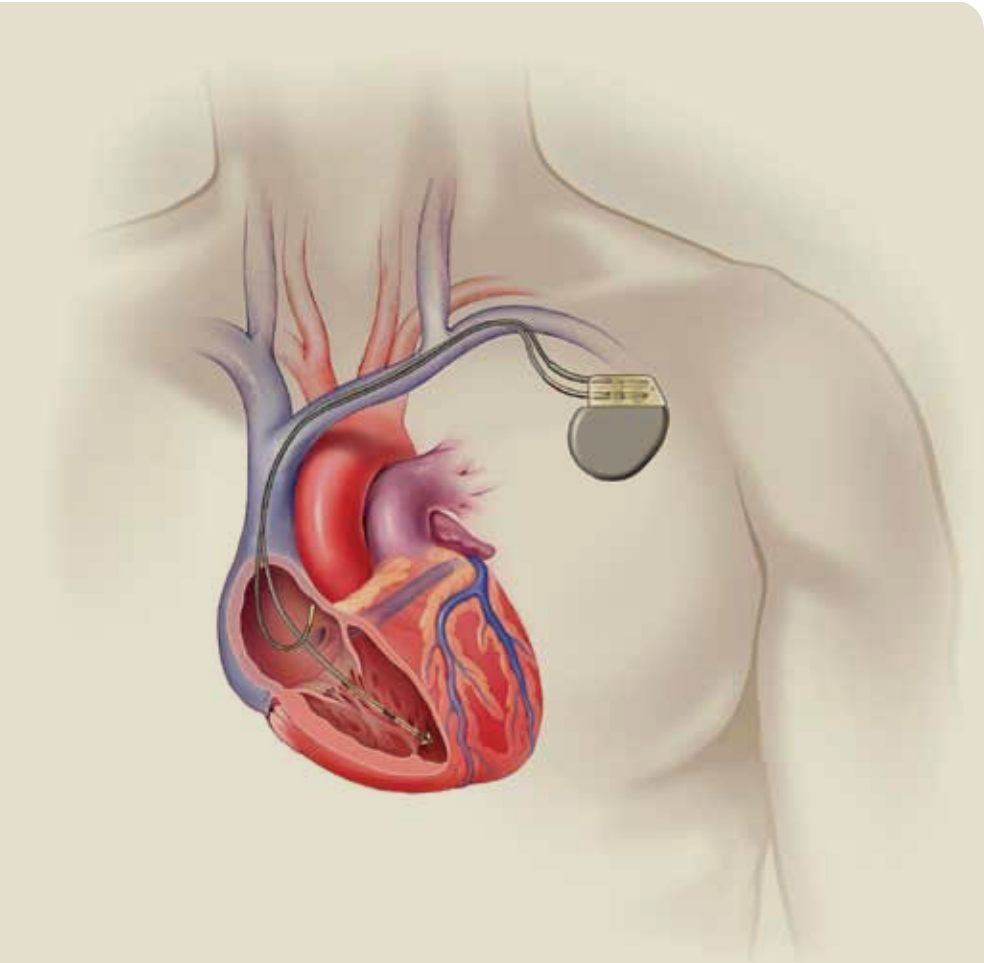
New York Heart Association classification:

Class I	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	You're tired and short of breath even at rest

American College of Cardiology system:

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

How a Pacemaker Works



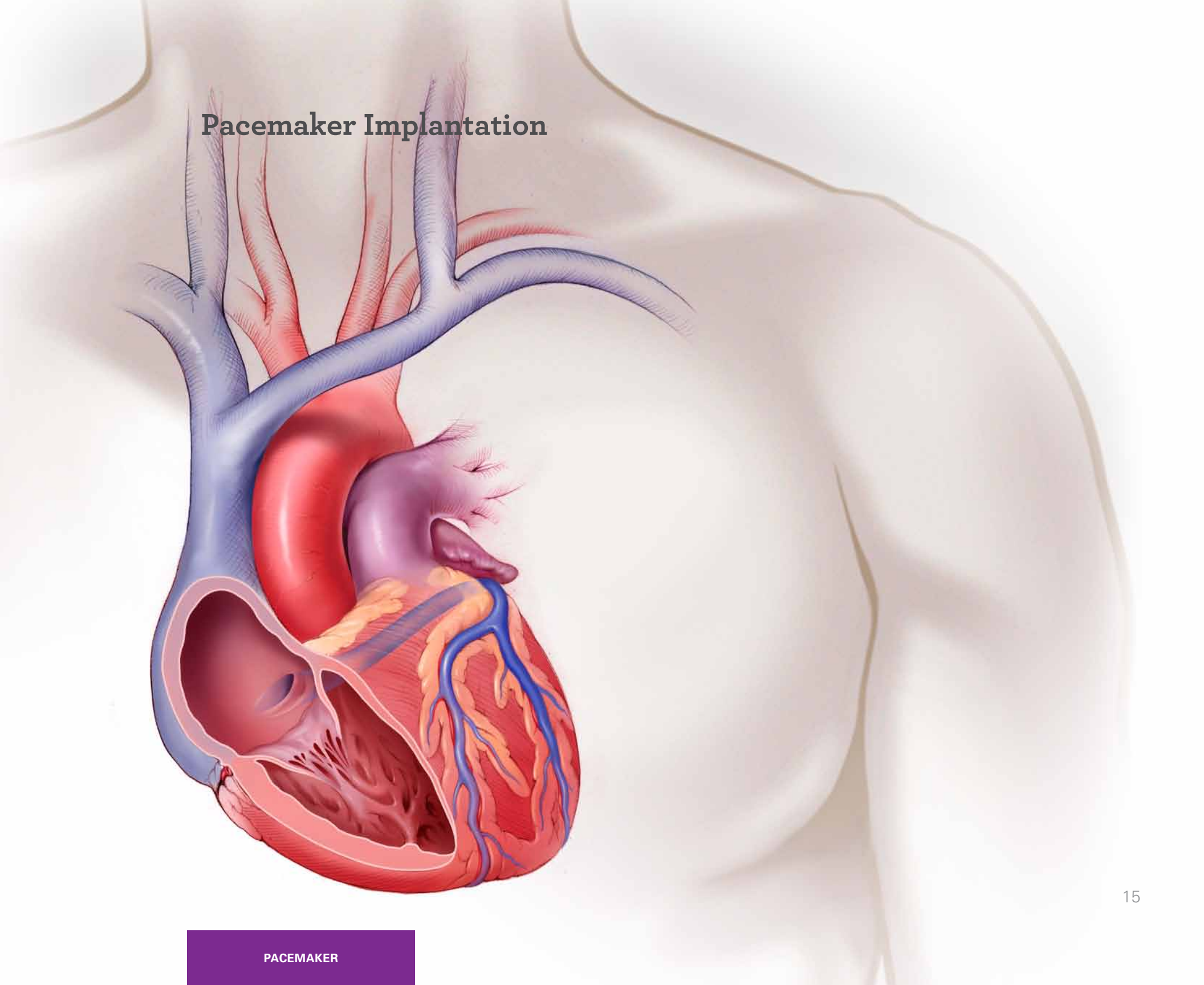
PACEMAKER

A Pacemaker:

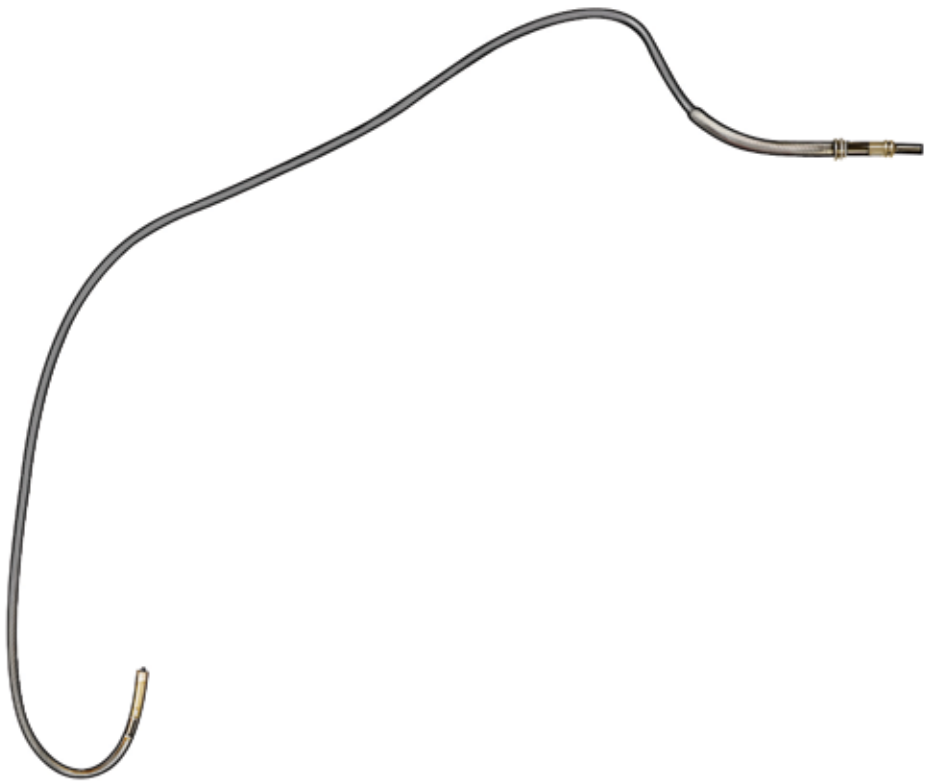
- Is a small implanted device that treats bradycardia, a slow heart rate
- Can have one or two leads
- Sends small, painless electrical signals to your heart to restore a normal rate
- Uses sensors to detect when you rest and need a slow heart rate, or when you exercise and need a faster heart rate

Note: There are risks associated with the implantation of a device or lead(s).
See pages 26–27 for more information on these risks.

Pacemaker Implantation



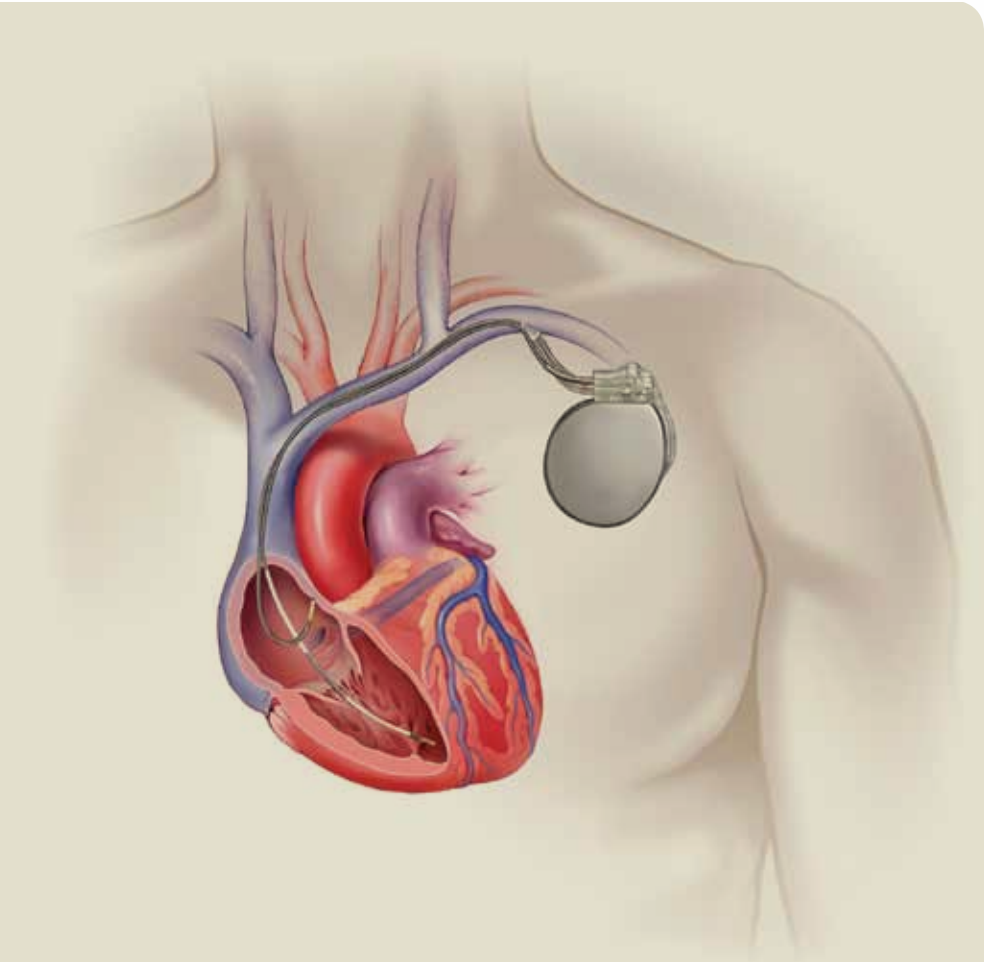
PACEMAKER



PACEMAKER

PACEMAKER

How an Implantable Cardioverter Defibrillator (ICD) Works



An ICD:

- Is a small implanted device that treats tachycardia, an abnormally fast heart rate (usually ventricular tachycardia or ventricular fibrillation)
- Can have one or two leads
- Monitors your heart rate at all times and treats abnormal heart rates when needed
- Sends small electrical signals to your heart to restore a normal rate or may send a higher-energy shock to slow down the heart rate if it is dangerously fast
- Can also act like a pacemaker to treat a slow heart rate
- Can help you survive a sudden cardiac arrest episode

Note: There are risks associated with the implantation of a device or lead(s).
See pages 26–27 for more information on these risks.

More than 600,000 people worldwide have received an ICD[5]

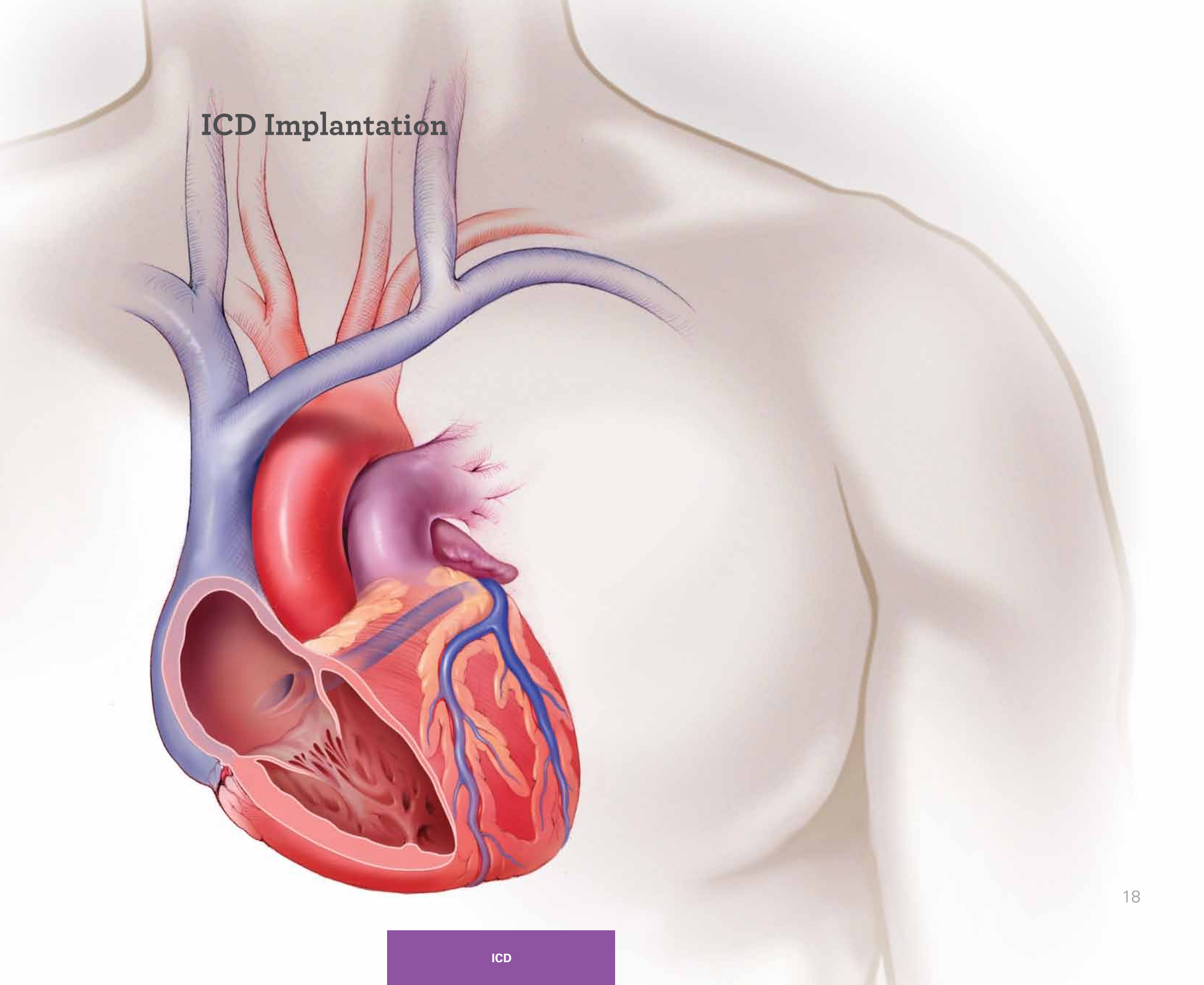
Why Consider an Implantable Cardioverter Defibrillator (ICD)?

The American Heart Association and the American College of Cardiology's latest guidelines include the highest recommendation that implantable defibrillators can help you survive an episode of sudden cardiac arrest.[6]

Only 1 person in 20 usually survives an episode of sudden cardiac arrest. The other 19 people die before reaching the hospital.[4]

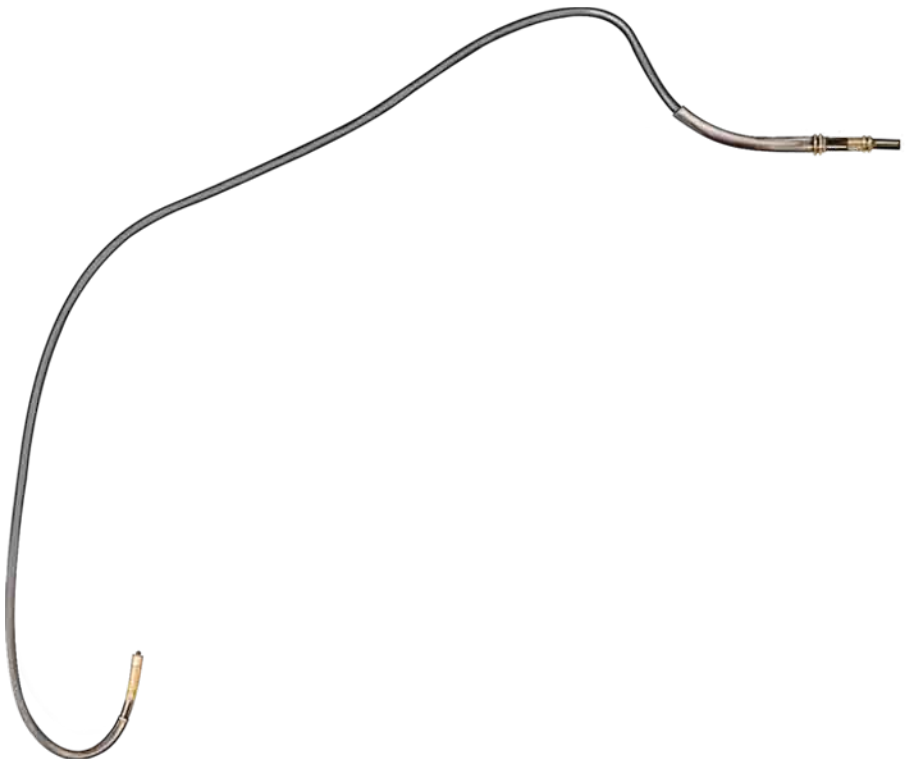
With an implantable defibrillator, 19 out of 20 people will survive. Implantable defibrillators have been shown to effectively terminate the majority of dangerously fast heart rates that can lead to sudden cardiac arrest.[7]

ICD Implantation



ICD

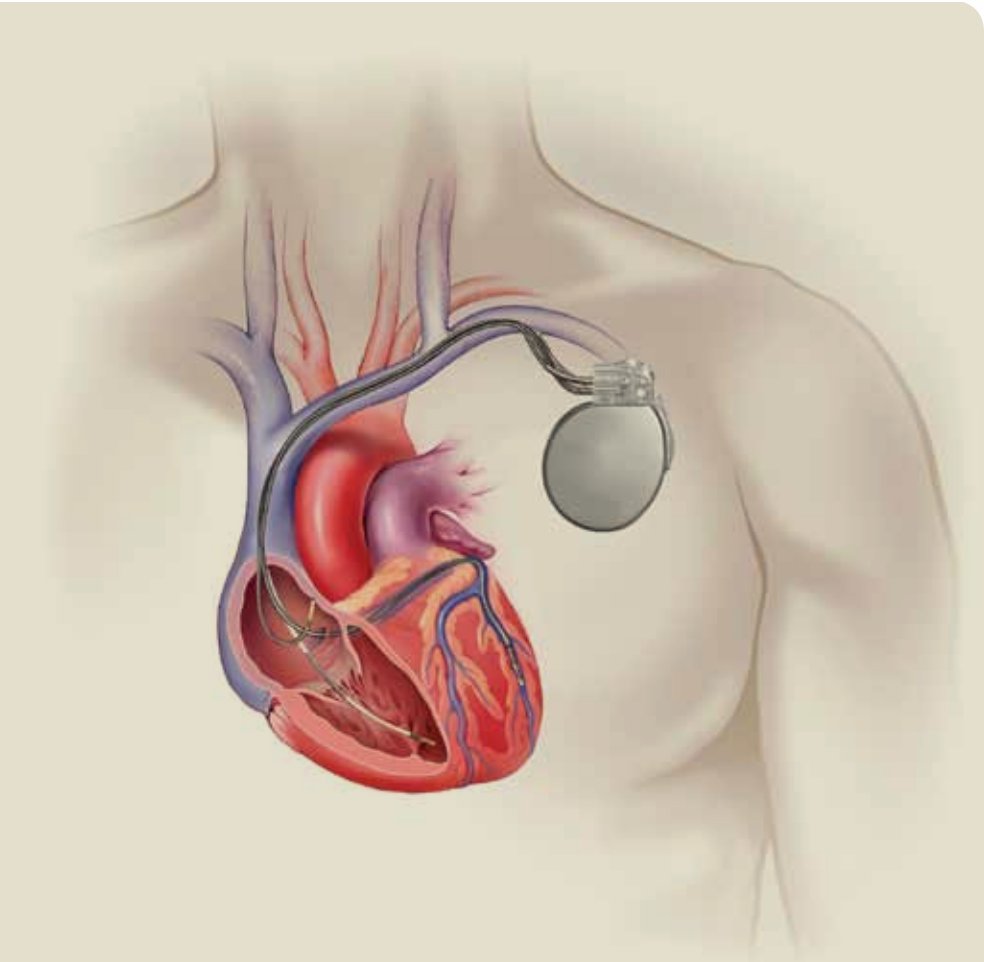
ICD



ICD

ICD

How a Cardiac Resynchronization Therapy (CRT) Device Works

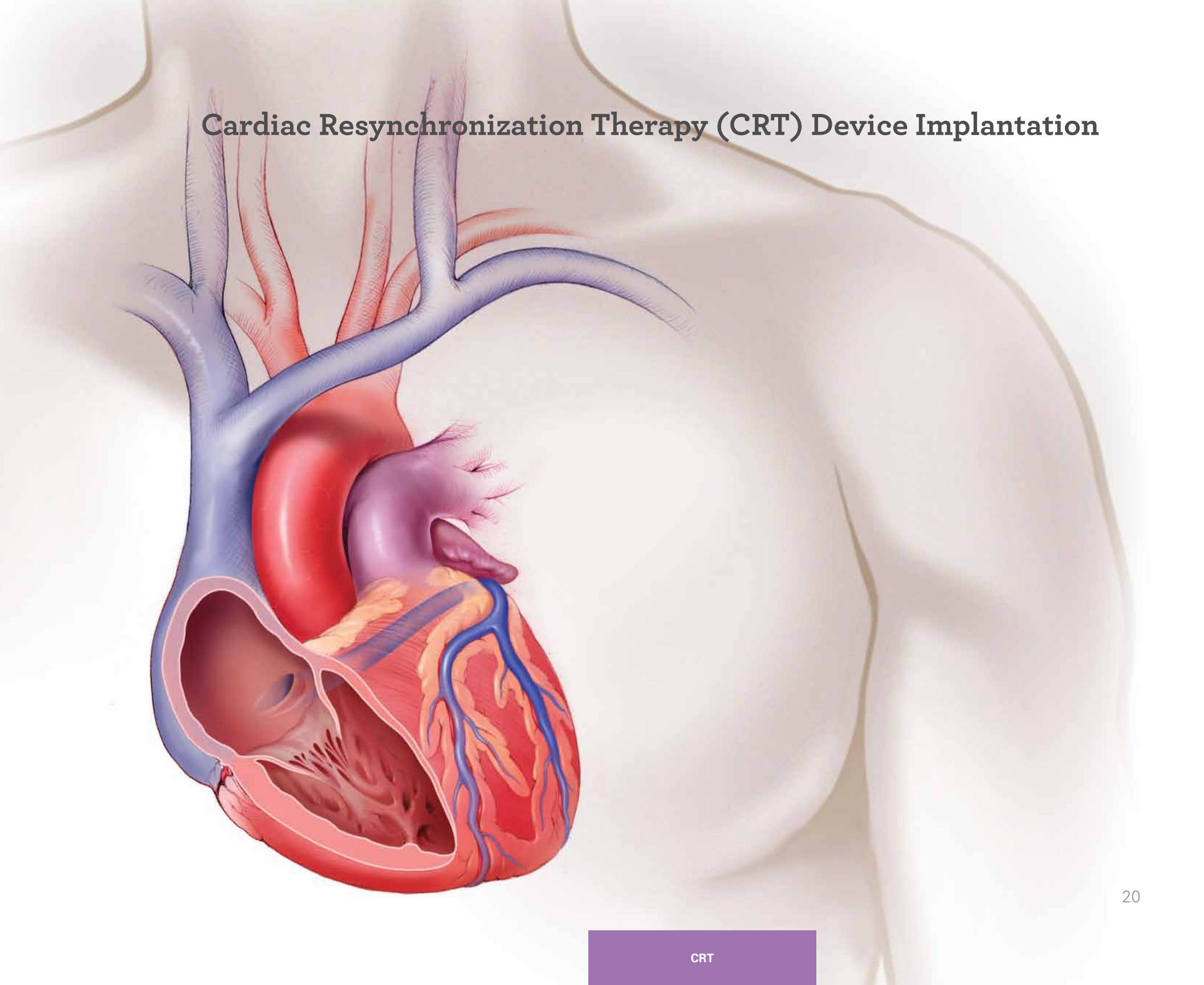


A CRT Device:

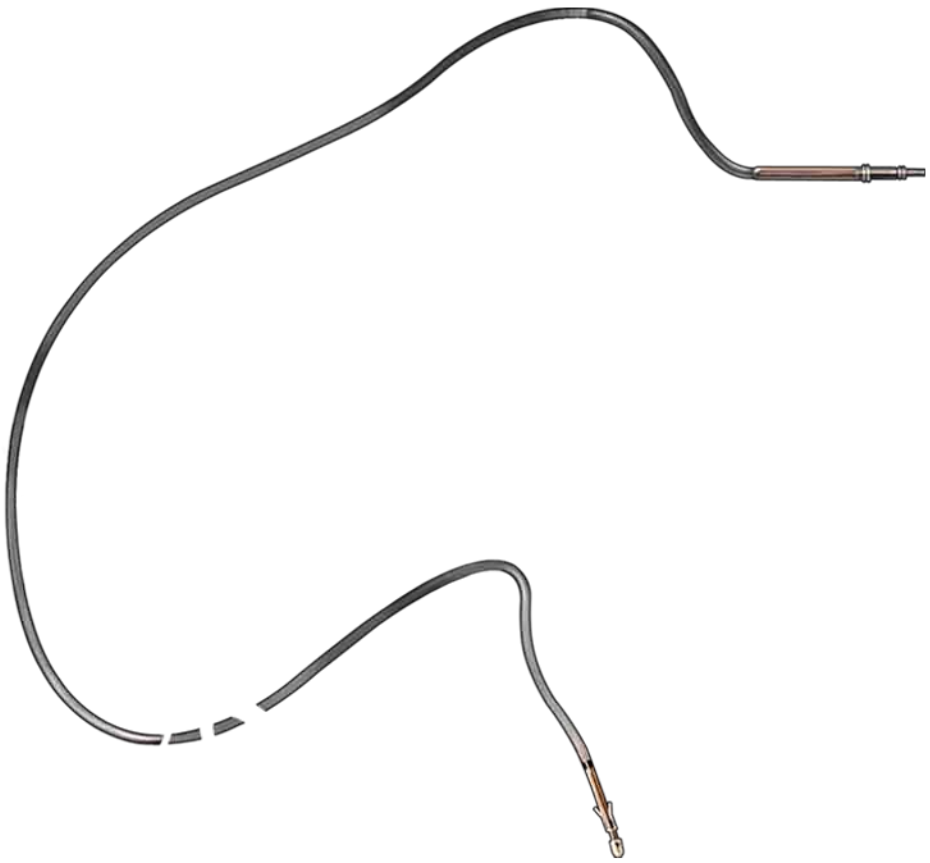
- Is a small, implanted special pacemaker that treats heart failure; is also known as a biventricular pacemaker
- Has three leads
- Is used in addition to medication
- **CRT device with pacemaker (CRT-P):** Works as a pacemaker; sends a small electrical signal to your heart to restore a normal heart rate when needed
- Sends small electrical signals to the left and right ventricles to help them contract at the same time and help your heart pump more efficiently
- **CRT device with defibrillator (CRT-D):** Functions like a CRT-P device, but can also help people who are at risk for sudden cardiac arrest; a defibrillator sends a higher-energy shock to slow down a dangerously fast heart rate

Note: There are risks associated with the implantation of a device or lead(s).
See pages 26–27 for more information on these risks.

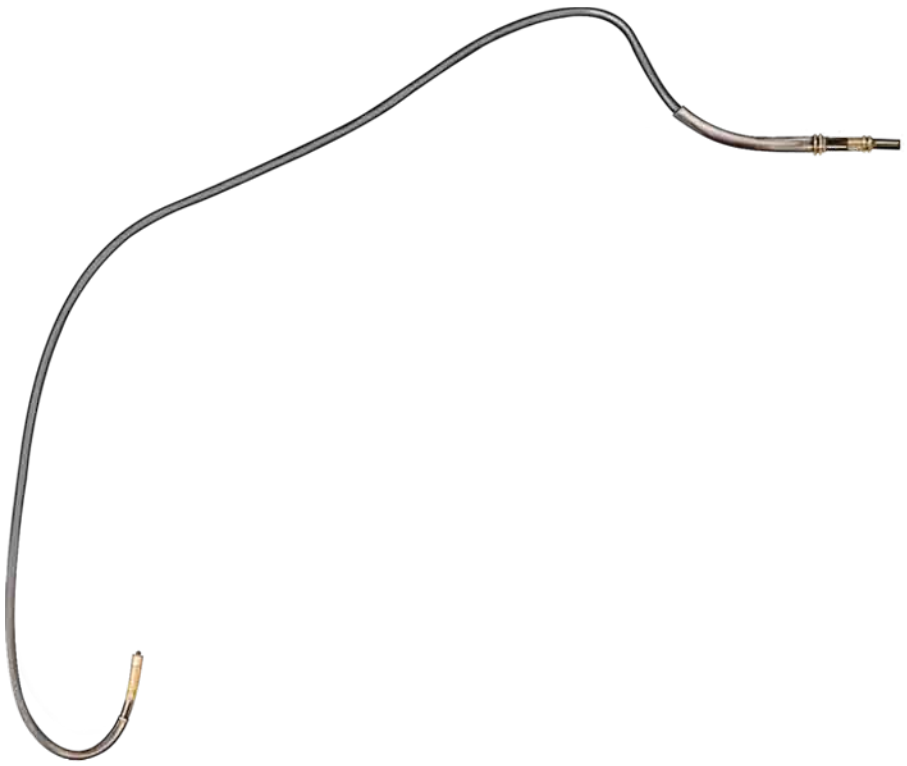
Cardiac Resynchronization Therapy (CRT) Device Implantation



CRT



CRT



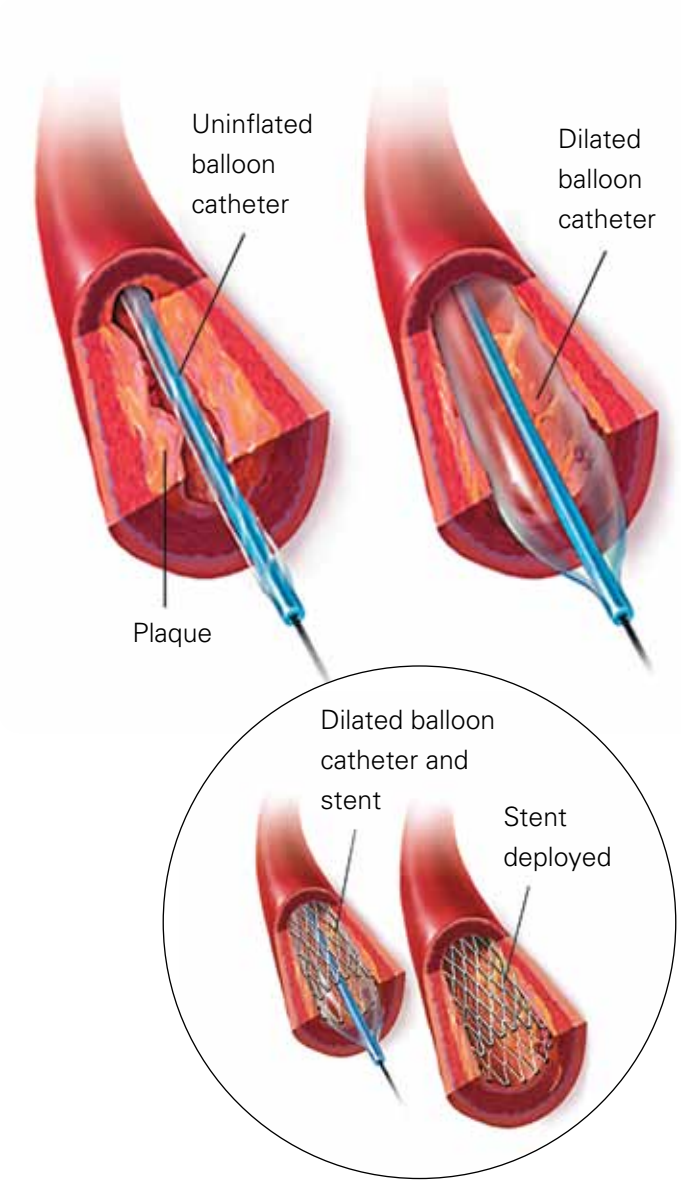
20c

CRT

20d

CRT

Angioplasty and Stenting

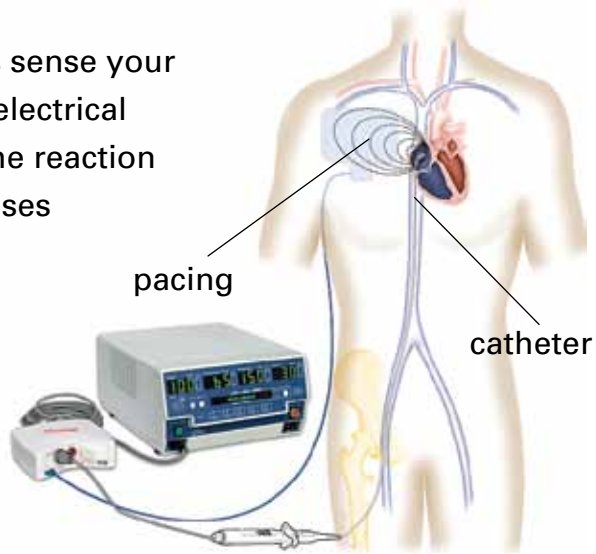


Angioplasty with Stenting

- Is performed when coronary arteries become narrowed or blocked
- A thin tube called a catheter is placed through the groin or arm up to the heart artery that is blocked
- A small balloon located on the tip of the catheter is inflated slowly to push the plaque back against the walls of the artery
- When a stent is used, the balloon catheter is inflated and the stent expands to the size of the artery

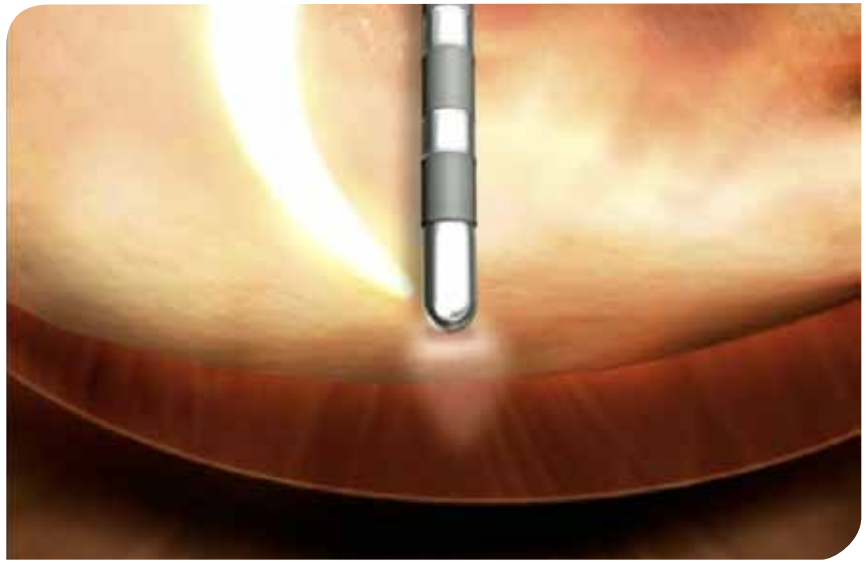
Electrophysiology Study

- Is a test used to identify and measure arrhythmias
- It can also show how well medications work
- During the EP study, thin tubes called catheters are inserted into your heart
- Some of the catheter wires deliver tiny electrical impulses to your heart. This is called “pacing” your heart
- The other wires sense your heart’s normal electrical impulses and the reaction to pacing impulses



Cardiac Ablation

- Is a procedure used to treat many types of arrhythmias
- The EP doctor sends energy through catheters in your heart to the specific cells in your heart that are causing your arrhythmia
- This restores the normal electrical pathways of your heart and allows it to beat normally again



Surgery and Recovery

Surgery

- Over the years, advances in medical technology have made the surgery to implant a device much simpler
- 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 (see pages 26–27 for more information on risks)
- Today's devices rely on sophisticated computer technology; your doctor will program your device to deliver the right type of therapy for your heart condition

Surgery and Recovery

Recovery

- After surgery, you may stay in the hospital for a day or two; this allows the doctors and nurses to watch and record your heart rate and your overall health
- Full recovery from surgery can take from several days or weeks to a few months
- While you recover, your doctor may ask you to avoid strenuous activity (especially lifting and other activities that use your upper body), so the leads have time to firmly attach to your heart tissue and your incision can heal

Insurance Coverage

Insurance Coverage

- Most health insurance companies, including Medicare, view device therapy as medically necessary for appropriately selected patients
- If your doctor has determined that an implantable cardiac device is right for you, your insurance will usually pay
- Provide your doctor's office with your insurance information; ask them to check your coverage before scheduling your implant procedure

Important Safety Information to Discuss with Your Doctor

Cardiac Resynchronization Therapy Devices

Cardiac resynchronization therapy pacemakers (CRT-P) and defibrillators (CRT-D) are designed to treat heart failure patients who may or may not have symptoms (CRT-D), or who may have symptoms despite the best available drug therapy (CRT-P and CRT-D). 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. Your physician should discuss all potential benefits and risks with you. For further safety information, refer to the Physicians Instructions for Use or call 1/866-484-3268. (Rev. F)

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. Your physician should discuss all potential benefits and risks with you. For further safety information, refer to the Physicians Instructions for Use or call 1/866-484-3268. (Rev. F)

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 haveadditional 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. Your physician should discuss all potential benefits and risks with you. For further safety information, refer to the Physicians Instructions for Use or call 1/866-484-3268. (Rev. F)

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 <file://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. F)

Important Safety Information to Discuss with Your Doctor

As with any surgical procedure, it is important to understand that there are risks associated with the implantation of a cardiac device and/or lead(s). Complications do not happen very often. However, it is important that you talk with your doctor about the risks of having a cardiac device implant, as well as the benefits.

The potential risks include, but are not limited to:

- Discomfort from the incision
- Bleeding
- Formation of a blood clot (hematoma)
- Damage to adjacent structures (tendons, muscles, nerves)
- Puncturing of a lung (pneumothorax)
- Damage to the heart (perforation or tissue damage)
- Puncturing of the heart or a vein on the outside of the heart (tamponade)
- Dangerous arrhythmias (abnormal heart rhythms)
- Heart attack
- Stroke
- Death

After your doctor implants your cardiac device, you may experience certain complications. These may include, but are not limited to, the following:

- You may develop an infection.
- You may experience erosion of the skin near the device.
- The lead(s) may move out of place in the heart.
- The electrodes on the lead or the pacing pulses may cause an irritation or damaging effect on the surrounding tissues. This includes heart tissue and nerves.
- The device may move from the original implant site (migration).
- You may not feel or function the same psychologically.
- The device may deliver inappropriate therapy (shocks or pacing).
- The device might not be able to detect or appropriately treat your heart rhythms.
- The device may exhibit malfunctions at a very low rate of occurrence. These malfunctions may result in lost or compromised ability to deliver therapy.

Your Lifestyle

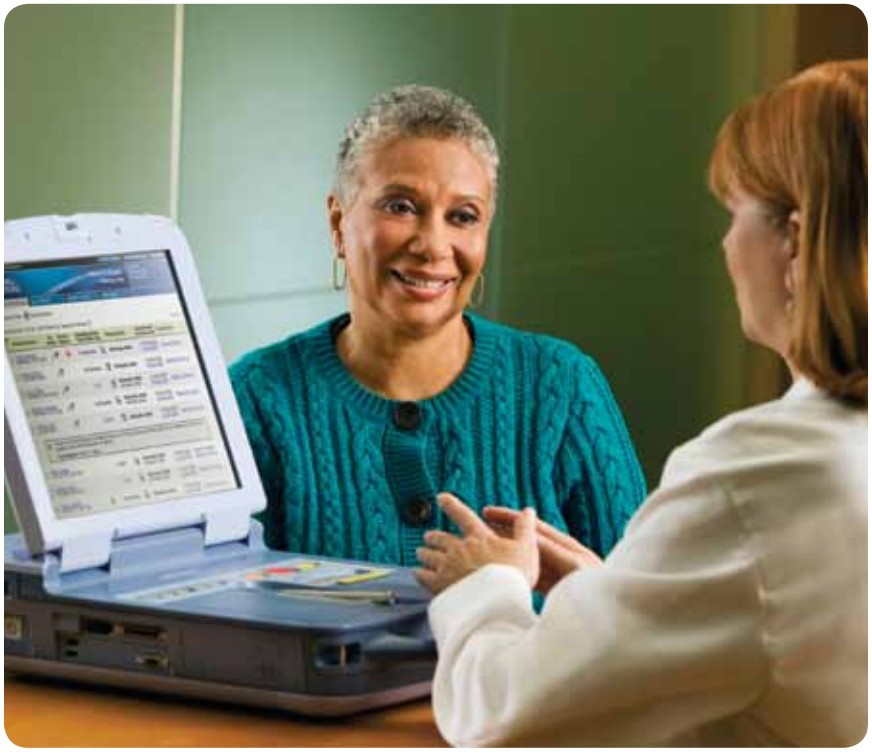
Your Lifestyle

- With an implanted heart device, most patients are able to work and enjoy hobbies, sexual activity, and travel
- Devices help most patients enjoy active and productive lifestyles as their overall health permits
- **Driving:** Whether you are able to drive once you have a device will depend on your specific symptoms and the driving laws where you live; your doctor or nurse will discuss any restrictions with you
- **Traveling:** You can feel confident and safe when traveling; the Medical Device ID card that you may receive with your device helps you alert medical and security personnel that you have an implanted device
- **Sexual intimacy:** For most people with a device, sexual intimacy is not a medical risk; the natural heart rate increase that occurs during sex is the same as the heart rate increase when you exercise

Using Household Items, Appliances and Tools

- Under normal use, it is safe for someone with a device to use most household items, including hair dryers, heating pads, electric razors, remote controls, vacuums, microwaves, TVs, radios, mp3 players, computers, and many other appliances and tools
- People with a device do need to be aware that it can be affected by electromagnetic interference (EMI); certain tools and household items should be used with caution or not used
- Talk with your doctor about a specific appliance, tool, or piece of equipment

Follow-up Office Visits



Follow-up Office Visits

- Your doctor will want to check your device and overall heart health on a regular basis
- Your follow-up plan will include visits to your doctor's office
- It is important to attend these visits, even if you are feeling well
- A device called a programmer will be used to ensure your device is working properly to provide the best treatment for your heart condition

Remote Monitoring with the LATITUDE® Patient Management System

If you receive a device from Boston Scientific, you may be able to use a remote device monitoring system:

- LATITUDE® Patient Management system allows your doctor to check certain types of devices remotely—you do not have to leave the comfort of your home
- System is easy to set up, and uses a regular phone line to transmit data securely to your doctor
- Your doctor receives regular updates on your heart health and device status, such as whether you are experiencing abnormal heart rates or how much energy is left in the device's battery
- If your device delivered therapy, its computer memory will store information about what your heart was doing before, during and after the abnormal heart rate
- You may not need to visit your doctor's office as often; your heart and device are actually monitored more closely for more comprehensive care

Remote Monitoring with the LATITUDE® Patient Management System

Wireless Communicator:
Sends information automatically to your doctor weekly or even daily

Wanded Communicator:
Hold the special wand over your device for 15 seconds to send information to your doctor weekly

The Communicator

- Two versions: wireless and wanded
- Sits on your nightstand or near where you sleep or rest
- Gathers and sends your device information on a date scheduled by your doctor or nurse
- Device information is transmitted over your phone line to a secure, Web-based server
- Your doctor can look at the information and assess your device function
- You can travel with your Communicator in all 50 states
- Support for the system is available to patients 24 hours a day, 7 days a week

Remote Monitoring with the LATITUDE® Patient Management System

Heart Failure Management

If you are a heart failure patient, your doctor may prescribe an in-home wireless weight scale and blood pressure cuff to provide daily weight and blood pressure readings

Other Helpful Resources

Resources:

- Brochures, videos, DVDs
- www.bostonscientific.com
- www.lifebeatonline.com
- *LifeBeat*℠ newsletter—available online and in print
- HEARTISTRY℠ CD available from your doctor

Patient Services: 1-866-484-3268

- **LATITUDE® Customer Service:** For questions about your LATITUDE remote monitoring system
- **Technical Patient Support Services:** For technical questions about living with your implanted device
- **Medical Records:** For questions about your ID card, traveling with your device, or to update your mailing address or doctor's contact information

Important Safety Information to Discuss with Your Doctor

The LATITUDE Patient Management system is used to remotely communicate with a compatible pulse generator device from Boston Scientific CRM and send data to a central database. The LATITUDE system is contraindicated for use with any pulse generator other than a device from Boston Scientific CRM.

The LATITUDE system is designed to tell your doctor within 24 hours if alert conditions are detected by the Communicator. Alert notifications are based on clinician configured alert settings. However, alert notification cannot occur if:

- The Communicator is unplugged or is not able to connect to the LATITUDE system through an active phone line.
- Your device and the Communicator cannot establish and complete a communication session. This session must be initiated by you if you have a device that uses inductive telemetry (Communicator that has a wand).
- The Communicator becomes damaged or it malfunctions.
- The patient is not compliant with prescribed use or is not using the LATITUDE system as described in the patient manual.

Up to two weeks may go by before the LATITUDE system detects the events mentioned above, and additional time may be required for clinic notification and resolution of the condition.

Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care. Alerts can be verified by reviewing supporting diagnostic information stored in the implanted device and viewing information on the LATITUDE clinician website.

The wanded and wireless Communicator uses a radio frequency (RF) communication system to communicate with an optional weight scale and blood pressure monitor. This communication can be disrupted by electromagnetic interference. Avoid placing your Communicator next to or in the immediate vicinity of other wireless products and sources of electromagnetic energy. The wireless Communicator uses RF to also send and receive signals from the implanted device (RF enabled devices only). Using the blue Interrogate button more than as prompted by your Communicator or as instructed by your physician may lead to a decrease in the battery life of your implanted device. Your communicator is designed to be used in the continental US, Alaska, Hawaii, and Puerto Rico. These devices are available by prescription only. (Rev. L)

Endnotes

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4 Stevenson, WG, Stevenson, LW. Prevention of sudden death in heart failure. *J Cardiovascular Electrophysiology.* 2001:12;113–114.

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6 Epstein AE, DiMarco, JP, Ellenbogen, KA, et al. ACC/AHA/HRS Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. *J. Am. Coll. Cardiol.* 2008;51:e1–e62.

7 Himmerich, E, Liebrich, MA, Michel, U, et al. Is ICD programming for double intraoperative defibrillation threshold energy safe and effective during long-time follow-up? Results from a prospective randomized multicenter study (Low Energy ENDOTAK Trial-LEFT). *Z Kardiol.* 1999;99:103–112 (German language edition).