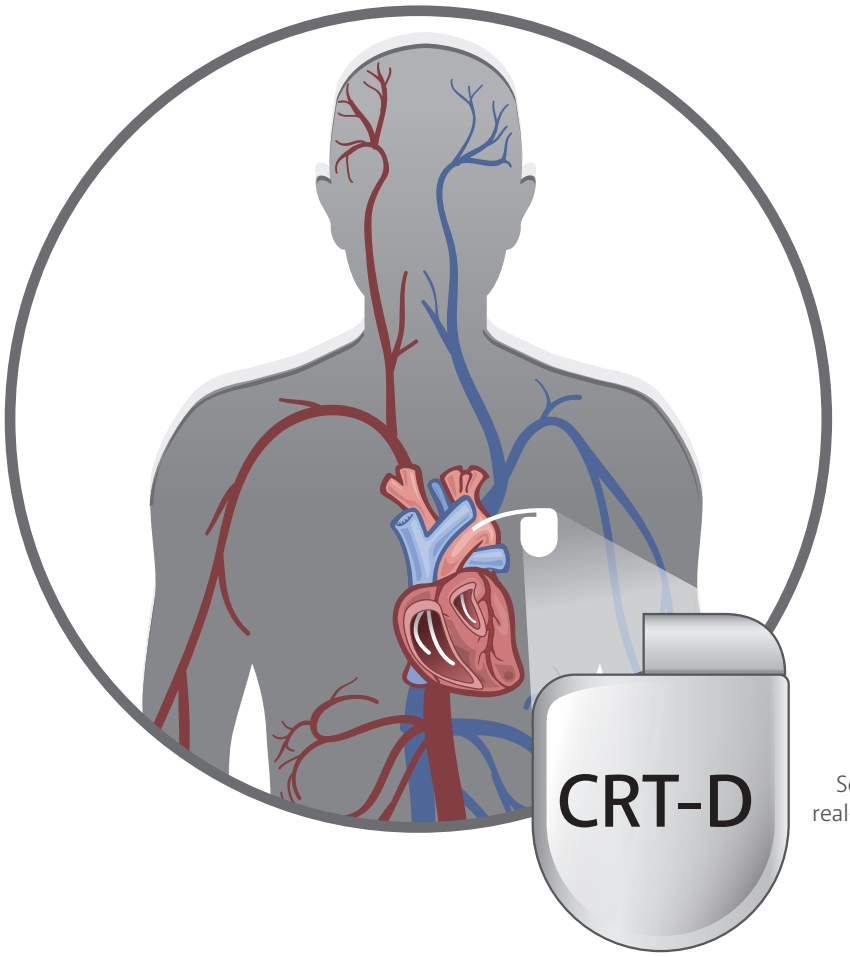
IDECIDE® CRT-D

Better conversations, better decisions

A decision aid for

Cardiac Resynchronization Therapy with Defibrillation (CRT-D)

For patients with heart failure who are getting cardiac resynchronization therapy and considering defibrillation



See the back page for real-life sizes of the device

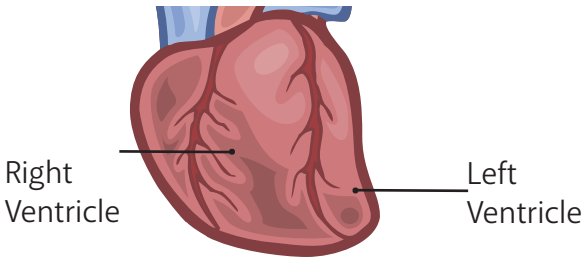
You are being offered CRT with the option of defibrillation.

This booklet will

- Explain how CRT works and why your doctor is recommending it
- Explain the option of including defibrillation to your CRT
- Help you make your decision based on your values and wishes

Section 1: What is CRT?

Sometimes patients with heart failure also have a problem with their heart beating out of sync because of damage to the electrical system of the heart. CRT is a device that helps the heart beat in sync. To do this, a special pacemaker with three wires is placed in the heart to help pace it.



Heart failure is when a heart is too weak to pump enough blood for the body. People with heart failure may become tired easily, have a hard time breathing, or have swelling in their legs. Symptoms may be minor for some people. For others, they can be pretty bad.

CRT is designed to make you feel better

CRT helps people feel better by improving the heart's ability to get blood to the body. Some people with CRT experience less:

- shortness of breath
- leg swelling
- tiredness

Some people also notice they can walk farther with CRT. Your doctor is recommending CRT to you because she or he believes this will help lessen your overall heart failure symptoms.

Does getting CRT require surgery?

You will need surgery to implant the CRT device. You would be given medication to help you sleep lightly and control pain. The CRT device is put under the skin of the chest and three wires (called "leads") are put into the heart. The surgery takes a few hours. You may stay in the hospital overnight.

After surgery, there will be a bump the size of a small bar of soap under your skin and a visible scar.

CRT is an important therapy that can help some patients feel better. If you are not interested in getting CRT, talk to your doctor.
In the next section we are going to discuss the option of whether or not to get a CRT device that can also provide defibrillation.

Section 2: Your decision - whether or not to add defibrillation

People with heart failure may be at risk for sudden dangerous heart rhythms.
- may be life-threatening
- can cause a cardiac arrest

Cardiac arrest is when the heart suddenly stops working. The best treatment for these dangerous heart rhythms is a "defibrillator." CRT combined with a defibrillator is called a "CRT-D."

CRT-D = CRT with defibrillator = CRT with defibrillation

How does a CRT-D work?

CRT-Ds sense dangerous rhythms and treat them right away. It does this by using pacing or an electrical shock to stop a dangerous heart rhythm and change it to a normal heart rhythm. This happens much faster than a person could get to the hospital for treatment.

Hearing about dangerous heart rhythms and sudden cardiac death can be scary. It can be difficult to think about the end of our lives. You may be thinking "I've never had a dangerous heart rhythm, so why should I get a CRT-D?" This is a great question. Other people like you facing this decision have wanted more information.

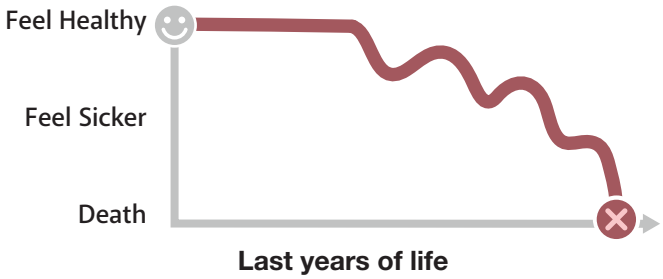
Learn more about your options

Is CRT with defibrillation right for me?

There is an important trade-off to consider when deciding whether to get a CRT-D. Consider two possible paths:

Path 1

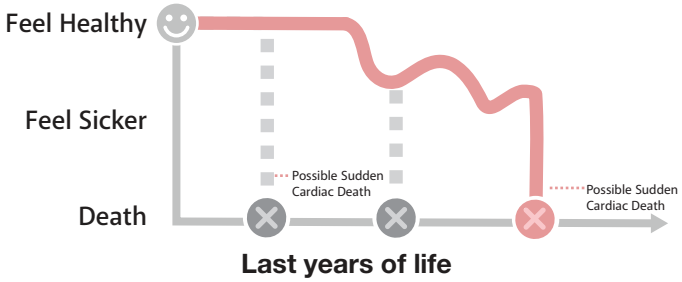
You may choose to get a CRT-D. You may be feeling like you usually do, then a dangerous heart rhythm could happen. The CRT-D may help you live longer by treating a dangerous heart rhythm. You will continue to live with heart failure that may get worse over time.



"I'm not ready to die. I have so much to live for. Even if it means getting shocked, I'm willing to do anything that can help me live longer."

Path 2

You may choose to NOT get an ICD. You may be feeling like you usually do, and then a dangerous heart rhythm could happen. You may die quickly from the dangerous heart rhythm. This can happen at any time.



"I've lived a good life. The idea of dying quickly sounds like a painless way to go. I've always said I hope to die in my sleep. Going through surgery and getting shocked is not the kind of thing I want."

Over 5 years, about 20 out of every 100 patients get shocked by their CRT-Ds. About 80 out of every 100 will not get shocked. Most shocks happen because of dangerous heart rhythms but some happen when they are not needed.

How does it feel to receive a shock?

Patients say that getting shocked is like "being kicked in the chest." Some patients pass out before they are shocked and do not remember being shocked. Before a shock is delivered, the CRT-D will try to correct your dangerous heart rhythm.

What are the risks of getting a CRT-D?

Problems do occur:

- 4 out of every 100 patients will experience some bleeding after surgery.
- 2 out of every 100 patients will have a serious problem like damage to the lung or heart.
- About 1 out of every 100 patients will develop an infection.
- Some patients develop anxiety or depression from being shocked.

Considering CRT with defibrillation

Lifestyle Considerations

Whether or not you add defibrillation, consider these:

People with a CRT & CRT-D should avoid strong magnetic fields and some industrial equipment. If you work with industrial equipment, discuss this with your doctor. Normal appliances like a microwave are okay.

You should be careful about metal detectors at the airport. Some metal detectors do not work with a CRT & CRT-D. You should talk with airport security and your doctor. It is okay to walk through security systems at department stores.

It is possible to exercise with a CRT-D. Talk to your doctor to learn which exercises are safe for you.

It is okay to have sex when you have a CRT-D.

You may use a cell phone but you should keep the phone at least 6 inches away from the CRT-D.

<u>For CRT-Ds only:</u> Doctors recommend that a patient not drive for up to 6 months after getting a shock from their CRT-D. Some states and countries have even stricter laws. Talk to your doctor about the driving laws in your area.

Will a CRT-D make me feel better?

The defibrillator will not make you feel better. However, the CRT may make you feel better. Refer back to page 2 for more information.

Can the CRT-D be taken out?

It is best not to remove the CRT-D unless you have an infection or are having the CRT-D replaced.

Can the CRT-D be turned off?

Yes. It is possible to turn off the defibrillator of the CRT-D without surgery. You may keep the resynchronization therapy turned on. In patients who are close to death, the defibrillator is often turned off so that it will not shock them. Some patients may choose to have it turned off because they no longer want to prevent sudden death.

CRT-Ds have to be replaced every 5 to 10 years, when the battery wears down. This requires another surgery. Replacing CRT-D wires is rare but is sometimes required.

How good are CRT-Ds at preventing death?

Survival

Would I survive a dangerous heart rhythm without the defibrillator (CRT-D)?

You may survive a dangerous heart rhythm only if you are treated within a few minutes with an external shock. However, many patients die before emergency help can reach them.

Will I live longer with a CRT-D?*

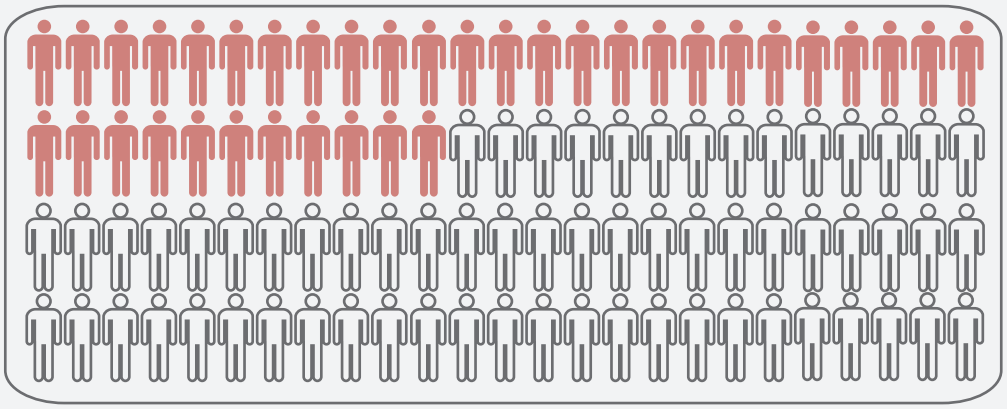
Without a CRT-D: Patients without a CRT-D are more likely to die suddenly from a dangerous heart rhythm. Without a CRT-D, over 5 years, 36 out of every 100 patients with heart failure will die over a 5-year period.

With a CRT-D: Patients with a CRT-D are less likely to die suddenly of a dangerous heart rhythm. With a CRT-D, 29 out of every 100 patients with heart failure will die over a 5-year period. This means 7 more patients would live with a CRT-D over a 5-year period.

The numbers below are from recent medical studies. However, no one can know what will happen to any one person.

What are the benefits of getting a CRT with defibrillation (CRT-D)

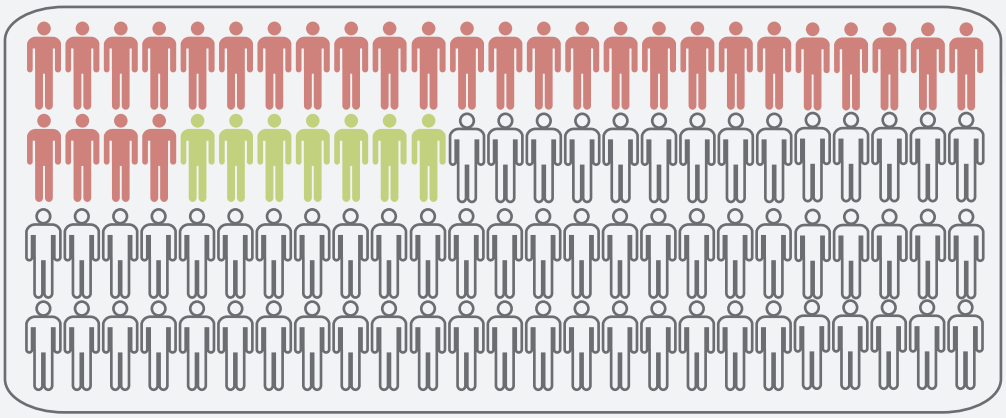
Results from a 5-year study*



No CRT-D

36 die

64 live



Yes CRT-D

29 die

71 live

7 saved

Number of people who live because of the CRT-D

Number of people who die for any reason

Number of people not affected

*SCD-HeFT. Bardy, GH , et al. NEJM 2005;352:225-237.

In Summary

FAQ	Implant an CRT-D	Implant CRT Only
What does a CRT-D do?	A CRT-D may stop a dangerous heart rhythm that could cause sudden death by giving an electrical shock to the heart.	Without defibrillation, you will have a higher risk of dying suddenly if a dangerous heart rhythm happens.
What is involved?	A CRT-D is put under the skin of your chest and wires ("leads") go into your heart. You will probably stay one night in the hospital. In about 5-10 years, when the battery runs out, the CRT-D will need to be replaced	The procedure to place a CRT is the same as a CRT-D.
Will I live longer with a CRT-D?	Patients with a CRT-D are less likely to die suddenly of a dangerous heart rhythm. With a CRT-D, 29 out of 100 patients with heart failure will die over a 5-year period. This is 7 fewer deaths than if they did not have a CRT-D.	Patients without a CRT-D are more likely to die suddenly from a dangerous heart rhythm. Without a CRT-D, 36 out of 100 patients with heart failure will die over a 5-year period.
Will I get shocked by the CRT-D? What will that feel like?	Over 5 years, 20 out of every 100 patients who have a CRT-D will get a shock. 80 out of 100 patients will not get shocked. Patients say that getting shocked is like "being kicked in the chest."	You will not get a shock from a CRT if you do not get a CRT-D.
What are the risks of getting a CRT-D?	4 out of every 100 patients will have some bleeding. 2 out of every 100 patients will have a serious problem, such as damage to the lung, a heart attack, or a stroke. 1 out of every 100 patients will get an infection, which may require removing the CRT-D.	The procedure to place a CRT is the same as a CRT-D. The risks are the same.
Will a CRT-D improve my symptoms?	The defibrillator itself will not improve your heart failure symptoms.	CRT has been shown to reduce shortness of breath, leg swelling, and tiredness.
Are there things I cannot do?	This depends on your heart problem. Talk to your doctor about driving limitations and other activities.	Even without a CRT-D, talk with your doctor about driving limitations and other activities.
Can the CRT-D be taken out?	It is best not to remove the CRT-D unless it gets infected or it is time to have it replaced when the battery runs out.	It is best not to remove the CRT unless it gets infected or it is time to have it replaced when the battery runs out.
Can the CRT-D be turned off?	Yes, the CRT-D can be turned off without surgery. This is recommended if a person is likely to die from another illness.	It is generally not recommended to turn off CRT pacemaker since the device will not prolong your life and has no ability to shock your heart.

Your values and wishes

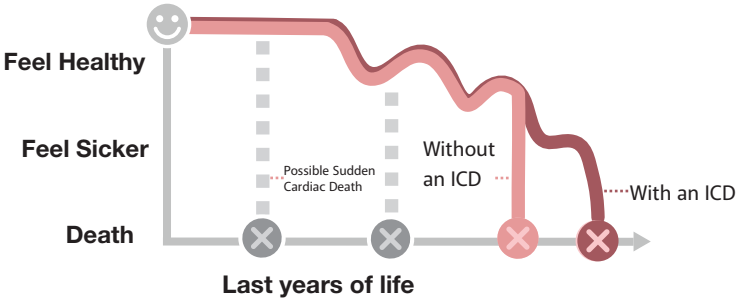
It may be helpful for you to talk with your family and friends. You may want to share the information in this decision aid with them. You should also share with your doctor your questions and concerns before making a final decision. It is important that you have all of the information you need to make a decision that is right for you. You have the right to make your own choices!

Questions...

Concerns...

You know what is important to you better than anyone else. Any decision about your treatment should be based on your goals and values!

Consider the "two paths" of your options:



Patients' thoughts:

Jim: "The whole thing is just getting all the information from any source that you can. And take it all in and the final decision is up to you. You have to make that decision, not your doctor. And too many patients think the doctor is God, but the doctor doesn't know your body the way you do. So the final decision is yours."

Caroline: "First of all, I think it's a very personal choice. I think everybody needs to make their own decision. But, I think it needs to be an informed decision."

On a Scale...

While no-one can predict the future, if you were able to choose, how would you like to live out the rest of your life? (check one box)

Die quickly (for example, dying suddenly in your sleep) and not live as long. ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ Live as long as possible even with an illness like heart failure that may get

Life-size CRT-D images

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