

CorCap™ Cardiac Support Device Patient Information Booklet

What is Heart Failure?

Heart failure is a condition in which the heart is unable to pump enough blood to meet the needs of the body. To compensate for this, the heart must work harder. This can strain and damage the heart muscle, causing it to stretch. The enlarged heart is weakened and can't function as efficiently. This causes the heart to work even harder to compensate, leading to further enlargement and continuing the cycle of deterioration.

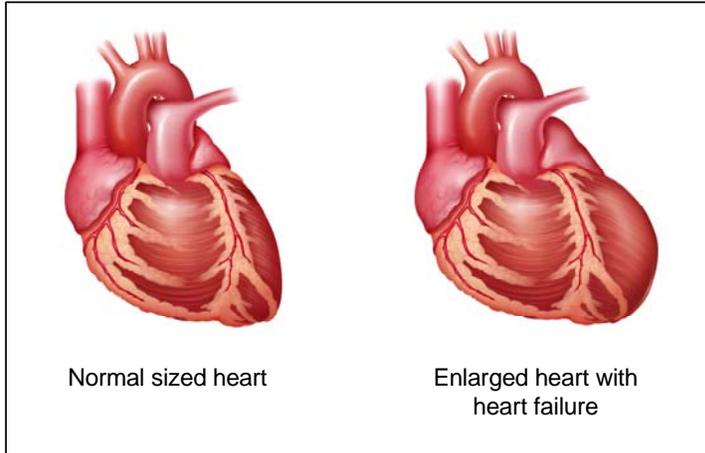


Figure 1: Normal vs. Enlarged Heart

Patients with heart failure may develop hearts that are much larger and rounder than normal (see Figure 1).

In some cases, fluid backs up in the lungs, abdomen, or ankles. This backup of fluid is often called “congestion”, which is why heart failure is sometimes referred to as congestive heart failure or

CHF.

What causes Heart Failure?

Heart failure often develops over a period of years. The cause is not always known. In some cases it is the result of other illnesses, such as long-term high blood pressure, valvular disease, or coronary artery disease that has damaged the heart tissue. You may wish to talk with a health care provider to better understand the possible reasons for development of heart failure in a specific individual.

What are common symptoms of Heart Failure?

When the heart does not pump blood well, the lungs, kidneys, and other organs may be affected. Certain symptoms may develop, including:

- Shortness of breath, especially with activity or when lying flat
- Swelling of the feet, legs, and sometimes the abdomen (belly area)
- Unexplained tiredness, lack of energy, or weakness
- Unexplained or rapid weight gain
- Inability to exercise or perform activities of daily living
- Difficulty sleeping at night due to breathing problems
- Decreased appetite

- Chest Pain

How common is Heart Failure?

It is estimated that more than 25 million people worldwide have some form of heart failure, with approximately 2 million new cases are diagnosed each year. The chance of developing heart failure tends to increase with age.

How is Heart Failure diagnosed?

Heart failure may be diagnosed following a thorough evaluation by a health care professional. He or she will ask questions about the patient's health, habits, current medications, and family history. Some tests may also be performed, such as:

- Blood tests to evaluate how different organs are functioning including the heart, kidneys, and liver
- Echocardiogram (Echo) to show the size and shape of the heart and heart valve function
- Electrocardiogram (EKG or ECG) to show the electrical pattern of the heart beat
- Cardiac Catheterization (Angiogram) or nuclear scans (Stress tests) to evaluate the health of the heart muscle and how well blood flows through blood vessels in the heart
- Exercise Tests to evaluate physical activity

Once a diagnosis of heart failure has been made, the health care provider may classify the severity of heart failure into one of four categories. These categories are based on ability to perform activities of daily living. This classification is called the New York Heart Association Functional Class (NYHA) I, II, III, or IV system.

- NYHA Class I: There is clinical evidence of heart failure or some other cardiac disease, but the patient's physician activity is not limited by symptoms.
- NYHA Class II: The patient notices some limitations to physical activities. They are comfortable when resting but have mild symptoms with ordinary activity.
- NYHA Class III: The patient has marked limitations to physical activities. They are comfortable at rest but have symptoms with light activity
- NYHA Class IV: The patient is unable to engage in physical activity without experiencing severe symptoms. They have symptoms at rest and increased symptoms with any level of activity.

How is Heart Failure treated?

Heart failure is managed in a variety of ways. Often, patients are prescribed medications along with a diet and exercise program. Changes in symptoms and weight should be closely monitored, with any noted changes promptly communicated to a health care provider. Close follow up with a health care provider may help patient to manage symptoms and limit heart failure progression.

Medications: Often, a combination of medication is prescribed by a health care provider, to improve heart function and minimize symptoms. It may take several months to adjust heart medications to the optimal dosage. It is very important that medications are taken as directed and that names, dosages and dosage frequency is tracked and monitored. Patients may choose to write this information down and carry it with them. Any noted side effects should be reported to a health care provider. Heart failure medications may include:

- **Beta Blocker:** Blocks substances in the blood that can damage and weaken heart muscle. Also slows the heart rate, which lessens the work the heart has to do. Over time this helps the heart beat stronger and work better
- **ACE Inhibitor/ARB:** Keeps blood vessels open making it easier for the heart to pump and helps limit the build up of extra fluid in your body (This drug may also be used to lower your blood pressure if it is too high.)
- **Diuretic (Water Pill):** Helps your kidneys remove extra fluid and salt from your body
- **Aldosterone Inhibitor:** Helps with removal of excess fluid but retains Potassium

Diet: Heart failure may lead to storage of excess sodium (salt) in your body. This can lead to shortness of breath due to a back-up of fluid in the lungs. Swelling due to excess fluid may also be noted in the legs and feet. Adhering to a low-sodium diet can help to minimize excess salt and fluid in the body. Weight loss may also be advised in order to decrease stress to the heart, since excess weight may cause the heart to work harder in order to pump the blood through your body.

Exercise: An exercise program can keep muscles in shape and facilitate better heart function. Suggested activities may include walking, slow biking and relaxed swimming. Exercise programs should always be discussed with a health care provider who is familiar with an individual patient's needs and abilities, and exercise limits should be followed.

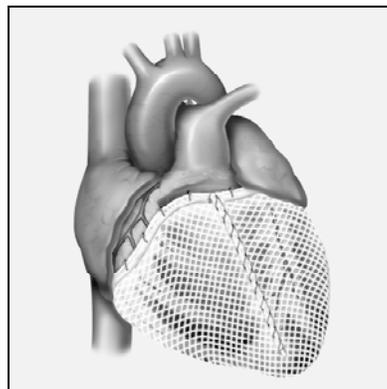
Why might a physician consider treatment with the CorCap CSD?

If a patient continues to experience progressive symptoms, despite treatment with diet, exercise, and optimal heart failure medication, alternative treatment options may be considered. Patients with an abnormally large heart with a decreased ability to pump (ejection fraction) may be candidates for CorCap CSD therapy.

This treatment has been shown to help the heart return to a more normal size and shape, and improve patient quality of life. Implant requires surgery, and should be discussed with a health care provider familiar with the patient's unique medical history and a cardiac surgeon familiar with the implant technique.

What is the CorCap Cardiac Support Device (CSD) and how is it implanted?

The CorCap Cardiac Support Device (CSD) is a latex-free polyester mesh wrap designed to support that heart to halt or reverse heart failure progression. This material used in its construction has a history of use in implantable medical devices. The device has been designed for biocompatibility and does not necessitate anti-rejection medication.



During surgery, the CorCap CSD is placed around the lower chambers of the heart, then secured and adjusted to provide a custom fit. The CorCap CSD is designed to allow for normal heart function, while alleviating the stress to the muscle which otherwise may lead to damage to the muscle tissue. This is intended to prevent the heart from becoming larger. The CorCap CSD may be implanted as an independent procedure, or along with other cardiac procedures.

How long does the surgery take?

The total length of surgery will vary depending on the requirements of the surgery, and whether additional procedures will be performed. Once the chest is opened it usually takes about 30 minutes to implant the CorCap CSD.

What are the risks of CorCap CSD surgery?

The risks of CorCap CSD implant are similar to those for heart surgery. These risks may include bleeding, abnormal heart rhythms, a blood coagulation abnormality that could cause small blood clots to be released into the blood circulation and possibly clogging blood vessels or causing a stroke or heart attack, a (usually temporary) deterioration in heart function, infection, pneumonia, problems with lung, kidney or liver function, accidental injury during surgery or need for reoperation, an allergic reaction to anesthesia or medications, or death. A health care professional should discuss these risks in greater detail with patients considering the procedure.

What happens after the operation?

Patients are typically taken to a recovery area or intensive care area (ICU) to as the anesthetic wears off and consciousness is regained. Family members may be permitted to visit in the recovery room or the ICU within an hour or two following surgery. Tubes and wires are typically attached to the patient's body in order to facilitate a safe and efficient recovery from surgery. Patients are monitored closely for any complications during the hospital stay. Typically time in the ICU ranges from 1-2 days and hospital stay often ranges from 5-7 days, but this is patient dependant.

Will there be pain following the operation?

There is likely to be some discomfort at the site of the incision(s). Patients experiencing severe pain ma be provided medication to relieve the pain.

What can be done to facilitate recovery?

- Deep breathing exercises and coughing are important to help speed recovery. Frequent deep breathing and coughing reduces the chance of pneumonia and fever and shouldn't harm incisions. Following a sternotomy procedure, it may be easier to cough or deep breathe by supporting the chest with a pillow.
- Changing position in bed every few hours can also aid recovery. Lying prone for an extended period of time may be detrimental to the lungs.
- Patients are encourages to get out of bed and sit in a chair or walk around the room as soon and as often as possible. Assistance may be required at first, but as a patient progresses, frequent short walks in the hall may be helpful to regain strength and mobility.
- Incisions should be kept clean, dry and open to the air. This lets the wound dry and begin to heal. Depending upon the surgery performed, a health care provider will determine when patients are able to shower and wash incisions with soap and water.

- Once the digestive system is functioning normally, patients will typically be encouraged to eat a varied diet as prescribed. Appetite may be reduced following surgery, but it is important to take in adequate nutrition as it aids healing. Small frequent meals may be best during the first days after surgery.

What can patients expect after they are sent home?

- It is common for patient's to feel weak and tired even after being released to go home. It may take 6-8 weeks for a chest incision to heal completely following a sternotomy procedure. Patients are typically advised to avoid lifting objects heavier than 5-10 pounds during this time. The incision color usually changes from purple to red to pink, but will not return to a normal color for several months.
- Mild to moderate daily exercise is the best way to regain strength. Follow the recommendations of a health care provider. Although patients may start slowly, some physical activity several times a day is often beneficial.
- Depression is common in patients when they first return home. Recovery from surgery may not seem fast enough, and time may seem to stand still. The best way to work through depression is to be physically active and to discuss feelings openly.

Does implant of a CorCap CSD eliminate the need for medications?

The CorCap CSD is not intended to take the place of medications, dietary or exercise recommendations. CorCap CSD therapy is intended to prevent and possibly reverse the worsening of heart failure, but is not a cure for heart failure. Patient will need to continue to manage their heart failure as they did prior to having the CorCap CSD implanted.

Is there anything special required following implant of the CorCap CSD?

Specific antibiotics or anti-coagulation medications are not required due to CorCap CSD implant, but may be necessitated if additional procedures are performed. A health care provider should be consulted to discuss medications need for a particular patient.

This booklet also contains a CorCap Patient Identification card. Following implant of the CorCap CSD, patients should complete the information on this card and carry it with them in case of an emergency or in the event that questions arise regarding the CorCap CSD.

Are there any tests that can no longer be performed following CorCap CSD implant?

The CorCap CSD is constructed from a polyester mesh which is MRI compatible and latex free. The CorCap CSD is also safe to go through any security clearance screening. Patients may wish to talk with their health care provider to determine whether additional procedures were performed, or devices implanted, which may impact MRI compatibility.

When should patients contact their health care provider?

Following cardiac surgery, patients should contact their health care provider immediately if any of the following symptoms are noted:

- Signs or symptoms of infection such as redness, drainage at incision sites, fever >100° F or >37.7°C, or chills
- A weight gain of 3 pounds in a day or 5 pounds in a week
- Shortness of breath or fatigue that
 - is worse than usual lasting 2 or more days in a row, or
 - is gradually worsening over a period of a week, or
 - causes a decrease in your normal activity level, or
 - breathlessness that wakes you up at night.
- Any new symptoms such as heart palpitations, swollen ankles and feet, abdominal swelling, or any other sign or symptom that seems unusual
- Unexplained bleeding or bruising

Where might I obtain additional information about heart failure and CorCap CSD therapy?

It is important that all your questions regarding heart failure and treatment options are answered. You may wish to write down questions as a reference when talking with health care providers. The space below is provided for you to note any questions you may have regarding the information provided.
