



LifeVest® Questions and Answers

Q: What is LifeVest?

A: LifeVest is a wearable cardioverter defibrillator (WCD) that is worn by patients at risk for sudden cardiac death (SCD). A defibrillator is a device that is used to treat dangerously fast heart rhythms by applying an electrical shock to the heart. While some defibrillator devices are implanted under the skin, the LifeVest WCD is worn directly against the patient's skin.

LifeVest is designed to detect certain rapid life-threatening heart rhythms and automatically deliver a treatment shock to save a patient's life. LifeVest allows patients to return to most common activities of daily living with peace of mind that they have protection from SCD.

Q. What is sudden cardiac death?

A: The heart's electrical system controls the heartbeat. When this system fails, it may trigger a dangerously fast heartbeat. This fast heartbeat causes the heart to quiver or shake instead of pumping blood to the body and brain. When this happens, a person can suddenly pass out. This is sudden cardiac arrest (SCA). It occurs without warning, and without treatment, death occurs in minutes. This is sudden cardiac death (SCD).

Timely defibrillation is the single most important factor to save an SCA victim's life. A treatment shock must be delivered within a few minutes after an event to be effective; with each passing minute, a patient's chances of survival drops 10 percent.

LifeVest is designed to detect certain life-threatening rapid heart rhythms and automatically deliver a treatment shock to restore a normal rhythm. In a typical situation, the entire event, from detecting a life-threatening rapid heart rhythm to automatically delivering a shock, occurs in about one minute.

Q. What types of patients are prescribed LifeVest?

A: A patient's doctor may prescribe LifeVest if he or she believes that the patient's current condition puts them at risk for developing a life-threatening rapid heart rhythm, which could cause them to become unconscious and unable to call for help. LifeVest is prescribed for protection from SCD.

LifeVest is used for a wide range of patients, including those who have a reduced heart function following a heart attack, before or after bypass surgery or stent placement, or for those with cardiomyopathy or heart failure that places them at particular risk.





Most patients will wear the device temporarily, until their heart gets stronger or until a long-term treatment is decided. LifeVest allows a patient's physician time to assess their long-term risk for SCD and make appropriate plans.

Q: How does LifeVest work?

A: LifeVest is designed to detect certain rapid life-threatening heart rhythms and automatically deliver a treatment shock to save a patient's life. LifeVest consists of a garment, an electrode belt, and a monitor. The garment, worn under the clothing, contains the electrode belt, which is designed to detect certain rapid heart rhythms and deliver treatment shocks. The monitor is worn around the waist or from a shoulder strap and is designed to continuously monitor the patient's heart.

Q: Does LifeVest require bystander intervention? Does it protect patients when they are alone?

A: LifeVest is designed to detect certain life-threatening rapid heart rhythms and automatically deliver a treatment shock to save a patient's life. The device does not require the assistance of another person or emergency personnel for it to work.

Q: How long are patients required to wear the LifeVest WCD? When can patients remove the LifeVest WCD?

A: The length of time a patient needs to wear the LifeVest WCD is specific to their condition and should be discussed with their doctor.

It is critical for patients to wear the LifeVest WCD at all times, including while sleeping. The LifeVest WCD should only be removed when a patient is taking a short shower or bath, and if possible, this should only be done when someone is home with the patient.

LifeVest is intended to be worn while a patient is at high risk of SCD. Most patients wear the device temporarily, until their heart gets stronger or until a long-term treatment is decided.

Q: Can a patient maintain a normal lifestyle while wearing the LifeVest WCD?

A: LifeVest allows patients to return to most common activities of daily living with peace of mind that they have protection from SCD. With the LifeVest WCD, patients can continue to do most things they enjoy, like spending time with family and friends, going to restaurants, attending services at a place of worship, when doing chores around the house, even to doctor's appointments.





Q: Is wearing the LifeVest WCD noticeable to others?

A: The LifeVest WCD is fit to a patient's body and is worn under regular clothes. Other than the monitor, which is worn in a holster around the waist or on a shoulder strap, most people will not know that a person is wearing the device.

Q: How is the LifeVest WCD different from an automatic external defibrillator (AED)?

A: Use of an AED requires bystander assistance. The bystander operates the AED by applying the electrodes to the patient and following instructions.

By contrast, the LifeVest WCD requires no bystander intervention. LifeVest can protect patients when they are alone or sleeping. LifeVest is designed to continuously monitor a patient's heart, detect certain life-threatening rapid heart rhythms and automatically deliver a treatment shock to restore a normal heart rhythm. In addition, LifeVest can offer peace of mind for family members who may worry about awaiting EMS personnel arrival or having to resuscitate a loved one themselves.

Q: Is LifeVest covered by insurance?

A: The LifeVest WCD is covered by most health plans in the United States, including commercial, state, and federal plans. This list summarizes the types of patient conditions and situations that are covered.

- Primary prevention (EF ≤ 35% and MI, NICM, or other DCM), including:
 - After recent MI (Coverage during the 40-day ICD waiting period)
 - Before and after CABG or PTCA (Coverage during the 90-day ICD waiting period)
 - Listed for cardiac transplant
 - Recently diagnosed nonischemic cardiomyopathy (Coverage during the 3- to 9-month ICD waiting period)
 - NYHA class IV heart failure
 - Terminal disease with life expectancy of less than 1 year
- ICD indications when patient condition delays or prohibits ICD implantation
- ICD explantation

Patients should contact their medical insurance provider with any questions about specific coverage, or call ZOLL at 1-800-543-3267 with any questions.

Q: How many patients are wearing LifeVest?

A: On any given day, tens of thousands of people around the world have protection from sudden cardiac death by wearing LifeVest.





Q: Where is LifeVest available?

A: LifeVest is available in the United States, Europe, Japan, and several other countries worldwide.

Q: Who manufactures the LifeVest WCD?

A: The LifeVest WCD is manufactured by ZOLL in its Pittsburgh, PA facility.

Q: Is the LifeVest WCD FDA approved?

A: The LifeVest WCD was approved by the FDA in 2001.

Q: Where can a patient or physician learn more about the LifeVest?

A: ZOLL offers 24-hour technical support and can be reached at 1-800-543-3267. The LifeVest team is here to answer questions and provide assistance. Questions can also be sent by email to <u>LifeVest.Info@zoll.com</u>.

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