



assure[®]
Cardiac Recovery System



**Recover
with
Confidence**

The State of Your Heart

Discovering that you have a heart condition can be stressful. With the ASSURE® wearable defibrillator, or ASSURE system, you're not alone.

Your healthcare team prescribed a wearable defibrillator because your condition may put you at risk for irregular heart rhythms. These rhythms, ventricular tachycardia (VT) and ventricular fibrillation (VF), can be life-threatening and result in sudden cardiac death (SCD) if not treated quickly. The ASSURE system is a temporary solution to help protect you as your healthcare team evaluates your heart recovery, and:

- Your Ejection Fraction (EF), a measure of how well your heart pumps blood, improves.
- You are assessed for an implantable cardiac defibrillator (ICD).
- Your medications are adjusted.
- Or, your risk for SCD is lowered and long-term solutions are assessed.

The ASSURE system can monitor your heart continuously and, if VT or VF is detected, it is designed to automatically deliver an electrical shock to help restore your heart to a normal rhythm.



Heart Protection Designed for You

The ASSURE system is a modern approach to sudden cardiac death protection.

It fits into your everyday routine and allows you to feel confident while protected.

The ASSURE system is designed to be simple to use, comfortable to wear, and easily hidden under clothing.

Its unique features provide information about your heart to your doctors, so you can focus on your recovery.





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1. HeartPoint™ Alert Button
Provides a simple way of interacting with the system—by hearing, feeling, and touching—all from an intuitive location on your body.

2. SensorFit™ Garments
Designed to be worn at all times, except for bathing or swimming, the SensorFit Garment is breathable and lightweight. It is tailored in two styles and a wide range of sizes. It features nonadhesive, cushioned electrocardiogram sensors and holds the defibrillation therapy pads.

3. Monitor
Continuously analyzes your heart rhythm when worn using the ASSURE Detection Algorithm, stores information about your heart rhythms, and provides a defibrillation shock if needed.

4. Carry Pack
Worn easily clipped to a belt, around the waist, or over the shoulder.

Connected and Protected

The ASSURE patient app can automatically transmit your ASSURE system data to the Kestra CareStation® remote patient data platform, available to your doctors and care teams. The app also empowers you to participate in your recovery by tracking a daily step count and hours worn.

Keep your mobile device with the app charged and nearby to stay connected and protected. For your privacy and protection, all the data is encrypted. The ASSURE patient app is not a substitute for appropriate medical attention.



Assurance When You Need It

If a shock occurs while wearing the ASSURE system, the ASSURE Assist® service attempts to contact you and your emergency contact, then emergency services, via the ASSURE patient app to determine if additional support is needed.*

* The ASSURE Assist service requires a smartphone with the ASSURE patient app to be connected to the Internet and or Wi-Fi®, powered on, location services enabled with location permissions granted and within 30 feet of the ASSURE system for proper operation. In the event of an emergency, the ASSURE patient app is not a substitute for appropriate medical attention and should not be relied on to contact emergency services. Kestra Medical Technologies Inc. (KMT) does not represent or warrant that the ASSURE Assist service prevents death, bodily or personal injury, or damage to you. KMT makes no representation of warranty as to the promptness of the ASSURE Assist service or emergency services. See important information about your ASSURE system in the Patient Handbook and important information about the ASSURE Assist service in the Patient Application User Manual for a full explanation of service conditions and requirements.

Your Care Champions

An ASSURE patient specialist will meet you in the hospital, clinic, or at home to deliver your ASSURE system. They will help ensure proper fit of your Garment and train you how to use the system. They will help you understand daily use of the wearable defibrillator, how to respond to alerts, and how to return the system when your prescription ends.

When you return home, it is important to always wear your ASSURE system. Take care to change the Battery daily and clean your Garments as needed. Check in with your system by pressing the HeartPoint Alert Button at any time.



Follow Up and Support

The Kestra Care™ team is accessible 24/7 by calling the ASSURE Helpline at (833) 692-7787 (toll free). You can also use the Patient Handbook or the ASSURE patient application to find information about topics like responding to alerts or general care.

Your ASSURE System is a rental and must be returned when your doctor tells you it is no longer needed. Follow return instructions on the box.

Important Information About Your ASSURE System

Indications for Use: The ASSURE system is indicated for adult patients who are at risk for sudden cardiac arrest and are not candidates for, or refuse, an implantable defibrillator.

Contraindications: The ASSURE system is contraindicated for use on patients with an active implantable defibrillator.

Intended Use: The ASSURE system is intended for patients who have been prescribed this device by their physician.

Warnings:

Do not place the Monitor, Therapy Cable, Charger, or Battery in water or other liquids. Avoid spilling any liquids on these devices. Exposure to liquids may cause devices to malfunction or fail. Follow the instructions provided with the devices to properly clean these devices.

If you will be away from home for longer than 24 hours, take the spare, fully charged Battery and Charger with you.

During use, do not stack or place the ASSURE system near other electronic equipment. Doing so may cause the system to malfunction or fail due to electromagnetic interference exposure from the other equipment. If such use is necessary, the ASSURE system and the other equipment should be observed to verify that they are operating normally.

Only use portable radio frequency (RF) communications equipment that is included with or intended for use with the ASSURE system. Do not use any other portable RF communications equipment (including antenna cables and external antennas) any closer than 12 inches (30 cm) to any part of the system. Otherwise, equipment performance may suffer.

When washing the Garment, do not use chlorine bleach, bleach alternatives, fabric softeners, or anti-static sprays. In addition, do not use detergents or detergent "pods" that include bleach or fabric softener additives.

Do not connect line voltages, power banks, or other devices that may attempt to use the USB port on the Charger as an input port. The Charger's USB port is a dedicated charging port that is Output Only and must be used solely to charge connected devices. Always remove the Therapy Cable before washing the Garment.

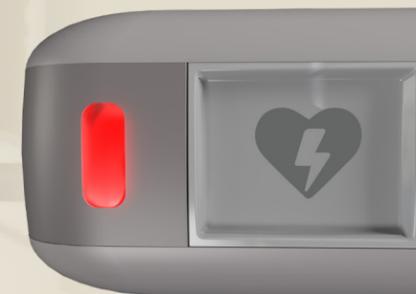
If the Plug is removed from the Monitor and then reinserted while the ASSURE system is operational, the system may issue the Connect Plug to Monitor alert repeatedly. This alert will continue to play even if the Plug is removed and re-inserted into the Monitor. If this occurs, remove the Battery from the Monitor, and then re-insert it to restart the ASSURE system.



What to Expect During and After a Shock

If the ASSURE system determines you need a shock to correct your heart rhythm, it will first vibrate and give an audio alert. Pressing the Alert Button will cancel the shock. If you do not press the Alert Button, the Therapy Pads will release gel onto your back and chest and a shock will be delivered. The ASSURE system will continue to analyze your heart rhythm and administer shocks, if needed.

Call 911 after a shock and continue to wear the ASSURE system until medical professionals direct you to remove it.



Shock Alert Icon



HeartPoint Alert Button



Kestra Medical Technologies, Inc. is a wearable medical device and digital healthcare company that helps protect cardiac patients with diagnostic monitoring and therapeutic products that are intuitive, intelligent, and mobile. Kestra innovations empower providers and patients to collaborate toward better care and improved outcomes.

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