Cordella™ Pulmonary Artery Sensor System

Patient Implant Leaflet

IMPORTANT

PLEASE READ THIS MANUAL LEAFLET BEFORE USING THE CORDELLA™ PULMONARY ARTERY SENSOR SYSTEM

Exclusively for Clinical Investigations

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Information for Patients

The Cordella™ Pulmonary Artery (PA) Sensor System is intended to connect healthcare professionals and patients with tools designed to improve comprehensive heart failure management. This guide provides basic information about instructions for use of the Cordella™ Pulmonary Artery Sensor System in the home.

NOTE: The information provided in this patient manual leaflet does not attempt to define any intervention, health care policy, or procedures. Clinical procedures and policies are the responsibility of your doctor.

Device Description

The Cordella™ Pulmonary Artery Sensor (Cordella Sensor) is a small implant that resides permanently in the pulmonary artery. The Cordella Sensor will enable PA pressure measurements with the myCordella Patient Reader while at home. The Reader will collect and securely transmit PA pressure readings to the clinician. Measurements from this device are equivalent to those obtained by trained clinical personnel using invasive, fluid-filled catheter-based products.

Intended Use and Patient Population

The Cordella PA Sensor System is intended to measure, record, and transmit PA pressure data from NYHA Class III heart failure patients at home to clinicians for assessment and patient-centered heart failure management.

Operating Instructions

Please reference the Reader Patient Manual.

Safety Information

To prevent personal injury or damage to any equipment, please read and observe all safety information.

Warnings	**This symbol indicates "the possibility of system damage or malfunction, delay in receipt of information to a doctor, inaccurate readings, or injury."**
Precautions/Cautions	**This symbol indicates "the possibility of system damage, malfunction, or the delay in treatment."**

Warnings

- The Reader is suitable for home healthcare environments and professional healthcare facilities except for near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbance is high.
- The Reader and Docking Station should not be used adjacent to or stacked with other equipment. If it is necessary to operate the components adjacent to or stacked with other equipment, verify that the system is operating normally in the configuration in which it will be used. If necessary, contact customer service to help re-locate the system.
- DO NOT expose any power accessories to water or other liquids.
- DO NOT disassemble or modify any component of the Cordella™ PA Sensor System.
- DO NOT use myCordella™ in the presence of explosive or flammable anesthetic agents.
- The Cordella™ PA Sensor System is not intended for emergency use or real-time monitoring.
- The Cordella™ PA Sensor System is not intended to be an emergency response device. In case of a medical emergency, call the local Emergency Medical Services and/or your healthcare provider.
- After the implantation procedure, it is critical to adhere to prescribed anticoagulation and other medications from the physician.
- Power cables may pose a tripping hazard. Be mindful of cords crossing walkways.
- myCordella™ Patient Reader may be interfered with by other equipment generating electromagnetic interference (EMI). Avoid using the system simultaneously within ~1.5 meters of possible EMI sources such as: laptop computers, tablets, e-readers, cell phones, cordless phones, wireless routers, hair dryers, electric shavers, refrigerators, metal furniture, home stereos, alarm-clock radios, air conditioners, electric ovens, washers, dryers, dishwashers, televisions and microwaves. When possible, turn off and unplug possible EMI sources within your home during myCordella™ use.
- The Reader requires special precautions regarding electromagnetic compatibility (EMC) and needs to be placed into service according to the EMC information provided. If interference is noted, remove or stop using the interfering equipment.
- Use only the cables and accessories provided. The use of accessories, transducers or cables other than those specified or provided as replacement parts, may result in decreased immunity of the system, inaccurate readings, damage to the system, injury to user, or improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than ~1.5 meters to any part of the Reader. Otherwise, degradation of the performance of the Reader could result.
- Under certain conditions, the Reader's surface may exceed 41°C. If the Reader becomes too warm to hold comfortably, place it back in the Docking Station and wait for several hours for it to cool. If the Reader remains too warm to hold comfortably for more than a day, contact customer service.
- If the skin becomes red, warm, or irritated, immediately stop using the Reader and contact customer service.

- Contact Endotronix customer service if more than 1 Cordella user resides in the same home. DO NOT use more than one Reader in the same general vicinity at one time, as use of multiple Readers at once may cause them to interfere with each other.
- The Reader contains Lithium Ion batteries. DO NOT place the Reader on a hot surface.

⚠ Precautions

- Avoid exposing any components of myCordella™ to water or liquids. Contact customer service for a replacement if any components are exposed to liquids.
- DO NOT drop the Reader. Handle with care.
- If dropped, the Reader battery may be exposed. If the battery is exposed, contact Endotronix™ immediately for a replacement Reader. Any damage to the Reader may result in an inaccurate reading.
- DO NOT use the Reader if the plastic casing has been damaged, cracked or any component becomes dislodged.
- If the Reader label becomes compromised, contact Endotronix customer service.
- Accuracy of the Cordella™ PA Sensor System is affected by a change in body temperature (<-3mmHg/Δ°C).
- Accuracy of the Cordella™ PA Sensor System is slightly affected by large changes in elevation between the initial baseline calibration and subsequent measurements. Readings may lose accuracy when taken >2000m of elevation.
- The Cordella Sensor is a permanent implant. Removing the implant after implantation is not recommended.
- The Cordella Sensor may be affected by a change in elevation above or below sea level. If you plan to travel below sea level or SCUBA dive or extremely high altitudes without pressurization, please contact customer service.
- DO NOT attempt to pair the Reader to any devices except the myCordella™ Tablet.

⚠ CAUTION

- All right heart catheterizations must be performed under fluoroscopic guidance to prevent contact with, or dislodging of the sensor.

Appointment with your clinician

After you get your Cordella PA Sensor System, your clinician will schedule appointments to see you. During your appointments, your clinician will examine you to see how you feel and make sure that your Cordella PA Sensor System is working well for you.

How long Cordella Sensor System should last

Expected service life (of Sensor): 10-year useful life with calibration at implant and every three (3) years or when deemed necessary by a medical professional
Expected service life (of Reader): Four years
Expected service life (of Docking Station): Four years

Materials to which you can be exposed

Your Cordella Pulmonary Artery Sensor System is made from many materials including Borofloat, nitinol, epoxy and silicone. There are many other materials that are inside of your Sensor or Reader, so they will never come into contact with your body. However, your body comes into contact with the materials that are outside of your Sensor such as Borofloat, nitinol, epoxy and silicone. Similarly, the material outside of your Reader that may touch your body is ABS and Polycarbonate (PC/ABS alloy). Talk to your clinician if you have any questions or concern about these materials.

Surface area of the permanent implantable in contact with blood is 5.08 cm^2.

See the glossary at the end of this booklet. It will explain these materials.

Glossary of Materials Used

Borofloat – Glass material that is highly inert as an implantable material. Most of the surface of the Sensor is made up of Borofloat glass.

Nitinol – Metal mixture of nickel and titanium that has unique properties such as shape memory.

Epoxy – A type of plastic. It is used as an adhesive to bond certain parts together.

Silicone – A flexible plastic rubber. It is used on the surface of your Sensor as a protective coating.

ABS – A type of plastic used as a cover for the Reader housing known for durability and impact resistance.

Polycarbonate - A type of plastic used as a cover for the Reader housing.

Definition of Symbols

The following symbols are used on the labels of the Cordella™ Pulmonary Artery Sensor System.

REF	Manufacturer's catalogue or part number so that the medical device can be identified.
LOT	Manufacturer's batch code so that the batch or lot can be identified.
SN	Manufacturer's serial number so that a specific medical device can be identified.
EC REP	Authorized representative in the European Community.
	Need for the user to consult the instructions for use.
	Temperature limits to which the medical device can be safely exposed.
	Range of atmospheric pressure to which the device can be safely exposed.
	Device that needs to be protected from moisture.
	Device manufacturer.
	Device has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use.
	General warning.
	Possibility of system damage, malfunction, or the delay in treatment.
	The myCordella™ Patient Reader operates using lithium-ion batteries. Lithium-ion batteries should not be crushed or burned.

	On/Standby button.
	Electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE). All electrical and electronic products, batteries, and accumulators must be taken to separate collection at the end of their working life. This requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste.

Contact Us

Questions or concerns regarding setup, use, unexpected operation or events, and general inquiries can be directed to the contact information below:

Endotronix™ Customer Service

1800 814 282 (IE)

Support@endotronix.com

Patents: www.endotronix.com/patents