CardioMEMS™ AAA Pressure Sensor System

Instructions for Use

CAUTION: Investigational Device. Limited by United States law to investigational use.

CardioMEMS™ AAA Pressure Sensor
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I. Device Description

The CardioMEMS AAA Pressure Sensor System is designed to monitor pressure within the sac of a repaired aneurysm during endovascular stent-graft placement. When placed in the aneurysm sac during the stent-graft procedure, it provides acute verification that the stent graft repair has been successful. The goal of the procedure is to exclude the aneurysm sac from blood flow and resultant pressure.

The CardioMEMS AAA Pressure Sensor System includes:

- The CardioMEMS AAA Pressure Sensor with radiopaque markings
- A sterile Delivery System (pre-loaded with the Pressure Sensor)
- Electronics (supplied separately)

The CardioMEMS AAA Pressure Sensor operates by wirelessly conveying changes in AAA sac pressure to the electronic monitor. The outer layer of the sensor is completely encapsulated in medical grade silicone. There is a Nitinol basket made from PTFE coated nitinol wire surrounding the sensor.

The CardioMEMS AAA Pressure Sensor is pre-loaded in a sterile Delivery System. The Delivery System is designed to aid proper positioning of the Pressure Sensor between the wall of the aneurysm sac and the exterior surface of the stent graft.

The CardioMEMS AAA Electronics provides the user with a digital display. The display relays information about the pressure sensor including signal strength and pressure tracings. The Electronics can also display a summary of the data gathered over a specified period of time.

II. Indications

The CardioMEMS AAA Pressure Sensor System is indicated for the measurement of pressure within the aneurysm sac during and upon completion of the AAA endovascular stent graft procedure to confirm aneurysm sac exclusion from the systemic circulation.

III. Contraindications

Patients who are pregnant, patients presenting with a ruptured aortic aneurysm and patients weighing more than 350 pounds (138kg) should not receive the CardioMEMS AAA Pressure Sensor. Patients who are not indicated to receive a stent graft should not receive the CardioMEMS AAA Pressure Sensor.

IV. Warnings and Precautions

- Do not attempt to use the CardioMEMS AAA Pressure Sensor System before completely reading and understanding the information contained within this booklet as well as the Sensor System Study Procedure Manual.
- This device should only be used by physicians and medical personnel trained in vascular intervention techniques.

- Always inspect the device and packaging prior to use to verify that no damage has occurred during shipping and/or handling and that the sterility of the product has not been compromised. If any damage is evident, do not use and return the product to CardioMEMS.
- The CardioMEMS AAA Pressure Sensor and Delivery System is single use only. Do not attempt to resterilize the Sensor and/or Delivery System.
- Delivery of the CardioMEMS Pressure Sensor should be performed under visual guidance (e.g., fluoroscopy). Bending or kinking the Delivery System might result in the inability to correctly place the sensor within the repaired aneurysm sac. If the Delivery System becomes bent or kinked during delivery, do not attempt to deploy the CardioMEMS Pressure Sensor. Remove and insert a new Delivery System with Sensor.
- The CardioMEMS AAA Pressure Sensor System should be utilized only in patients that are candidates for endovascular stent graft repair surgery.
- All electronics, including components and accessories, supplied by CardioMEMS are to be used only for this sensor and not other products, appliance or devices.
- Accuracy of the sensor may be affected by a change in body temperature (-2mm Hg/1°C).

V. Adverse Events

To be determined

VI. Clinical Studies

To be determined

VII. Patient Selection and Treatment

To be determined

VIII. Patient Counseling Information

To be determined

IX. How Supplied

Both the Pressure Sensor and the Delivery System are supplied sterile. EtO has been used to achieve sterilization Do not attempt to resterilize. Do not use if package is open or damaged. All electronic components should be stored at room temperature.

X. Clinician Use Information

A. Specifications

CardioMEMS AAA Pressure Sensor

Deployed Length – 30.0 mm

Deployed width – 5.0 mm

Deployed thickness-1.5 mm

Nitinol Basket Expanded Diameter – 15mm

CardioMEMS AAA Pressure Sensor Delivery System

Delivery System OD – 16Fr

Delivery System ID – 14Fr

Delivery System usable length – 30cm

Delivery System total length-61cm

The antenna cover can be cleaned with gentle soap solution if soiled.

B. Additional Required Supplies

In addition to the CardioMEMS AAA Pressure Sensor System, the following equipment is required to successfully deploy the CardioMEMS AAA Pressure Sensor into the correct location:

- Fluoroscope with digital angiography capabilities (C-arm or fixed)
- Fluoroscope with the ability to record and recall images

C. Recommended Materials

- Sterile introducer sheaths of 8 or 10 French for introduction into femoral arteries during road mapping or further diagnostic imaging
- Power injector for angiographic contrast studies
- Radiopaque ruler with centimeter increments
- Assorted angiographic and guiding catheters as well as angioplasty catheters to potentially dilate blood vessels prior to or following insertion of the Delivery System and Pressure sensor
- Assorted Guidewires such as Amplatz SuperStiff™, Lunderquist™, and Glidewires™ in 0.038" size
- Cook 14 French Check-Flo® Plus ™ Introducer Set
  Reorder # RCF-14.0-38-30-J-RB
- Heparinized Saline Solution
- Radiopaque contrast media

D. MRI Information

To be determined

Refer to Sensor System Study Procedure Manual for complete instructions for implanting the CardioMEMS AAA Pressure Sensor.

Xl. Patient Information

A Patient Implant Card implant will be given to the patient after implantation of the sensor. All patients should be instructed to keep this card in their possession at all times for procedure identification.

This device is approved for wireless transmission under FCC ID:XXXCS-A-000051. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

X11. Disclaimer of Warranty

DISCLAIMER OF WARRANTY FOR THE U.S.

ALTHOUGH THE CARDIOMEMS AAA PRESSURE SENSOR AND CATHETER, HEREAFTER REFERRED TO AS THE CARDIOMEMS PRESSURE SENSOR SYSTEM, HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, CARDIOMEMS HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. CARDIOMEMS, THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESSED AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. CARDIOMEMS SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND CARDIOMEMS TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

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Patents Pending
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