

How to Implant the CardioMEMS Heart Failure Sensor

A step-by-step review of the sensor implantation procedure, including pre- and postprocedural assessment.

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The CardioMEMS HF system (Abbott Vascular, formerly St. Jude Medical) includes a device sensor and patient and hospital electronics systems that allow remote transmission of pulmonary artery (PA) pressures to a secure website. Health care providers can remotely review PA pressure trends and adjust medications to achieve established pressure goals.¹ The ability to reduce PA pressures prior to the onset of heart failure (HF) symptoms improves quality of life and reduces future hospitalizations.²⁻⁵ The CardioMEMS HF device is approved for patients with New York Heart Association (NYHA) class III symptoms regardless of ejection fraction and a HF hospitalization within the previous 12 months. Device implantation involves placement of the sensor within an appropriately sized branch of the left PA using established percutaneous techniques.⁶ At present, the CardioMEMS HF system is the only US Food and Drug Administration–approved PA sensor.

HF specialists, electrophysiologists, and interventional and invasive cardiologists competent in performing right heart catheterization (RHC) via the femoral approach have the required skills for sensor implantation. Expedient and safe sensor implantation represents one essential component of the entire CardioMEMS HF system used for remote hemodynamic monitoring.⁷ This article summarizes

the basics of the sensor implantation procedure, including pre- and postprocedural assessment.

PREPROCEDURAL ASSESSMENT

Ideal patients for the CardioMEMS PA sensor implant are those receiving optimal medical therapy with continued issues in achieving appropriate volume status.⁸ Sensor implantation should not be performed in patients who are unable to take dual antiplatelet therapy or anticoagulants for 1 month after implantation. Contraindications include active infection, history of recurrent pulmonary embolism or deep vein thrombosis, inability to tolerate RHC, known coagulation disorders, and body mass index > 35 mg/kg² with

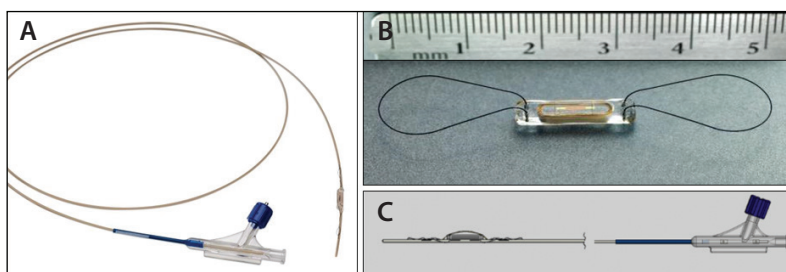


Figure 1. Components of the CardioMEMS PA sensor and delivery catheter. Over-the-wire catheter with sensor attached to the distal portion (A). The sensor measures 3.5 mm in width, 2 mm in thickness, and 15 mm in length. Two 10-mm nitinol loops are attached to the ends of the sensor and are used to maintain sensor apposition to the vessel wall (B). Profile of sensor on distal portion of catheter (C). A blue knob is connected to the tethering cord that runs the length of the delivery catheter and is used to release sensor from delivery catheter.

TABLE 1. PROCEDURAL STEPS FOR THE CARDIOMEMS PULMONARY ARTERY SENSOR IMPLANT

Steps	Components	Comments
Venous access	Femoral access with an 8-F sheath, upsized to a 12-F sheath	Internal jugular access should be considered for conditions that render placement of the catheter via the femoral approach difficult
Right heart catheterization	Measurement of right atrial, right ventricular, pulmonary artery, and pulmonary capillary wedge pressures; measurement of cardiac output by Fick principle or thermodilution method	Knowledge of cardiac filling pressures and cardiac output is essential for management of patients with NYHA class III symptoms
Engagement of left pulmonary artery	Ideal sensor placement is within a branch of the left pulmonary artery	The catheter can often be steered to the left pulmonary artery; use of an angled catheter or a guidewire may be required
Identification of appropriate sensor implant site	Ideal vessel diameter is 7–11 mm	Selective angiography is required to identify an appropriate-sized pulmonary artery branch
Placement of a 0.018-inch guidewire to the distal vessel location	The system uses a 0.018-inch over-the-wire delivery system	Various 0.018-inch guidewires can be used, including Hi-Torque Steelcore (Abbott Vascular), Platinum Plus (Boston Scientific Corporation), and CardioMEMS
Sensor preparation	The over-the-wire port of the delivery catheter is flushed with heparinized saline; the sensor and distal portion of the delivery catheter are agitated in heparinized saline	–
Advancement to the desired implant location	Continuous fluoroscopy should be used to view the sensor as it traverses through the right heart and left pulmonary artery	Use of fluoroscopic guidance ensures safe passage of the sensor to the implant location
Deployment	Counter-clockwise rotation of the hub, followed by withdrawal of the tether release system	–
Calibration	A hospital unit antenna is placed under the patient's back to calibrate the system	Use of fluoroscopy can optimize antenna location
Documentation of sensor location	Cine studies should be done to document final sensor location	–
Sheath removal	Options for hemostasis include manual or suture based	Figure-of-eight suture is an effective and safe method for hemostasis
Abbreviation: NYHA, New York Heart Association.		

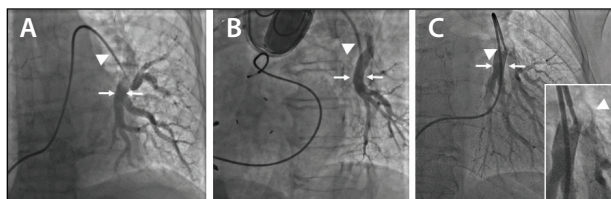


Figure 2. Selective pulmonary angiography is used to estimate vessel size. The size of the vessel at the implant location (arrows) is approximately 9 to 10 mm in diameter, estimated by comparing the size of the vessel to the adjacent tip of the balloon wedge catheter (arrowhead, 2.3 mm, 7 F) (A). The size of the vessel at the implant location (arrows) is approximately 7 to 8 mm in diameter, estimated by comparing the size of the vessel to the adjacent tip of the balloon wedge catheter (arrowhead, 2.3 mm, 7 F) (B). The size of the vessel is approximately 9 to 10 mm in diameter, estimated by comparing the size of the vessel to the inflated balloon of the balloon wedge catheter (arrowhead, 10 mm) (C). The inset shows a magnified view of the inflated balloon wedge catheter (arrowhead) (C).

chest circumference > 165 cm. Patients being evaluated for the sensor implant should be comfortable with the concept of pressure-guided therapy and have the motivation and a knowledge base sufficient such that health care providers can reliably provide medication adjustments via brief phone communications. Interruption of anticoagulation therapy (warfarin, novel oral anticoagulants) prior to the procedure is not required.

DEVICE IMPLANTATION

The delivery catheter used to deploy the CardioMEMS PA sensor utilizes an 0.018-inch over-the-wire system with the sensor attached to the distal portion of the catheter via a tethering release cord (Figure 1). The sensor measures 3.5 mm in width, 2 mm in thickness, and 15 mm in length. Two 10-mm-diameter polytetrafluoroethylene-coated nitinol loops maintain sensor apposition to the vessel wall after release. The implantation procedure should take approximately 15 to 20 minutes and should always include a complete RHC with accurate measurement of cardiac filling pressures and cardiac output. Procedural steps are listed in Table 1.

Venous Access

Femoral access is achieved using standard techniques with the initial sheath upsized to a standard 12-F sheath. A 7-F Arrow balloon wedge catheter (Teleflex) is favored over the traditional 7-F Swan-Ganz catheter (Edwards Lifesciences), as it is easier to manipulate from the femoral approach into the left PA and allows improved imaging for pulmonary angiography, given the balloon wedge catheter's 0.035-inch lumen com-

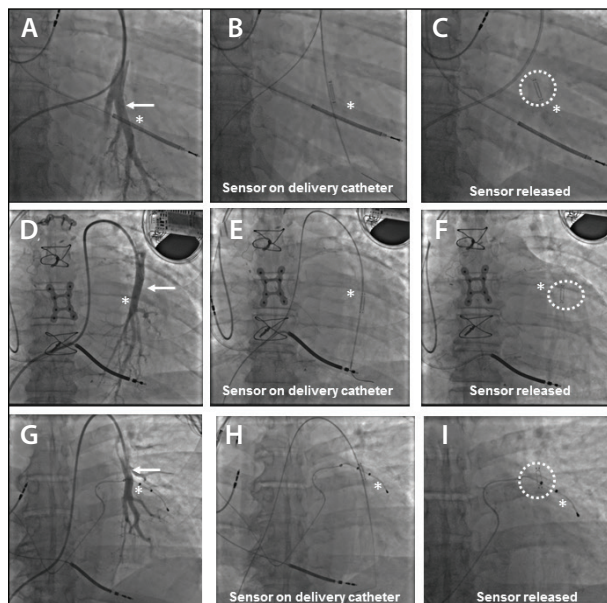


Figure 3. Fluoroscopic markers are used to identify the planned implant location. Implant site (arrow) with asterisk indicating that the implant site is superior to the rib (A). Sensor on the delivery catheter prior to release (asterisk) (B). Sensor (dotted circle) released to the desired location (asterisk) (C). Implant site (arrow) with asterisk indicating that the site is adjacent to the rib (D). Sensor on the delivery catheter prior to release (asterisk) (E). Sensor (dotted circle) released to the desired location (asterisk) (F). Implant site (arrow) and asterisk indicating that the implant site is adjacent to the left ventricular lead (G). Sensor on the delivery catheter prior to release (asterisk) (H). Sensor (dotted circle) released to the desired location (asterisk) (I).

pared to the 0.025-inch lumen of the Swan-Ganz catheter. Accurate measurement of cardiac filling pressures and cardiac output allows assessment of cardiovascular status and provides a prescription for adjustment of HF medications. Selective pulmonary angiography is performed using an automated injection system or via hand injection to define an appropriate implant location.

Implant Location

The ideal location for the implant is a left-sided, posteriorly directed PA branch measuring 7 to 11 mm in diameter with an appropriate distal vessel length to allow a stable and safe position for the 0.018-inch guidewire (Figure 2). Left anterior oblique or lateral projection imaging can confirm that the chosen branch travels in a posterior direction. Vessel size can be estimated by visual assessment using an adjacent catheter or inflated balloon (Figure 2). Quantitative vessel angi-

ography is not required. Multiple selective angiograms may be required to identify an optimal implant site. In the absence of an appropriately sized left-sided PA branch, the sensor can be implanted into a right-sided PA branch. Fluoroscopic landmarks such as ribs, coronary calcium, coronary stents, and pacer/implantable defibrillator wires can be used to establish the desired implant location (Figure 3). Additional supplies that may be required for the implantation procedure include an angled catheter (JR4 or KMP) or 0.035-inch angled standard Glidewire (Terumo Interventional Systems), which can be used to engage the left PA when catheter rotation fails to enter the left PA.

Alternate Access

Although current instructions for use specify femoral access, the right internal jugular (IJ) approach can be useful for those with morbid obesity, severe tricuspid regurgitation, pulmonary hypertension, or other conditions making placement of the balloon wedge catheter difficult via the femoral approach. Ultrasound imaging to assess the size and optimal puncture location of the IJ vein should be considered. A retrospective study of 48 patients at two implantation centers found that deployment time and procedural complications were similar between femoral and IJ approaches.⁹

Catheterization and Implant Delivery

Once an appropriate implant location is identified, the delivery system is prepared by flushing the over-the-wire port with heparinized saline. The sensor and distal portion of the delivery catheter are agitated in heparinized saline for 20 to 30 seconds. A 0.018-inch wire is placed into the distal portion of the desired PA branch. Care should be taken to avoid creating a distal wire loop (Figure 4).

When advancing the sensor through the delivery sheath, the sensor should be held with the thumb and index finger to prevent movement of the sensor relative to the delivery catheter as it enters the sheath. Mild resis-

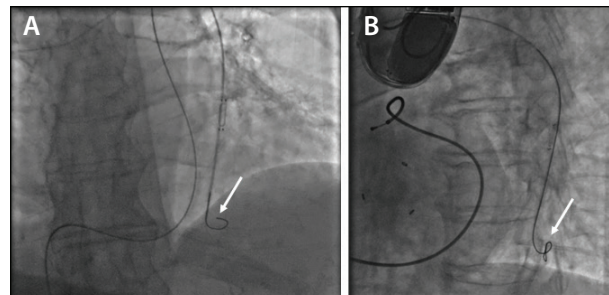


Figure 4. Sensor on the delivery catheter with fluoroscopic appearance of a distal wire loop. Removal of the wire with a distal wire loop may cause dislodgement of the sensor to a more proximal location. Distal wire loop (arrow) (A). Distal wire loop (arrow) (B).

tance is encountered as the sensor traverses the sheath. Continuous fluoroscopic imaging is performed as the sensor travels through the right heart to the desired implant location. To release the sensor, the cap of the tether release cord is rotated in a counter-clockwise direction, and the tether release cord is withdrawn through the length of the delivery catheter. The wire is maintained in a distal position and the delivery catheter is withdrawn past the sensor under fluoroscopic imaging to ensure the sensor has not moved. The delivery catheter is removed, and the balloon wedge catheter is readvanced over the guidewire to the main PA. Care should be taken to avoid advancing the balloon wedge catheter into the newly placed sensor. The hospital electronics antenna is placed behind the patient and the sensor is calibrated. Use of fluoroscopy can assist in positioning the antenna adjacent to the sensor. The 12-F sheath is removed with manual hemostasis or use of figure-of-eight sutures.¹⁰

Troubleshooting Difficult Procedures

The majority of sensor implant procedures are straightforward. Difficult implant procedures occur in the setting of severe tricuspid regurgitation, dilated right atrium or right ventricle, pulmonary hypertension,

Medications					
Drug	Class	Adjustment	Date	Dose	Frequency
Warfarin (Coumadin®)	Anticoagulant	Start	04-27-2017	3 mg 0.0 Tablet	Use as Directed
Carvedilol (Coreg®)	Beta-Blocker	Start	04-27-2017	25 mg 0.0 Tablet	Use as Directed
Levothyroxine (Synthroid®)	Hormone Replace	Start	04-27-2017	0.125 mg 0.0 Tablet	Use as Directed
Allopurinol		Start	04-27-2017	100 mg 0.0 Tablet	Use as Directed
Bumetanide (Bumex®)	Loop Diuretic	Start	04-27-2017	0.5 mg 0.0 Tablet	Use as Directed
Atorvastatin (Lipitor®)	Statin	Start	04-27-2017	40 mg 0.0 Tablet	Use as Directed
Aspirin	Antiplatelet	Start	04-27-2017	81 mg 0.0 Tablet	Use as Directed
Benazepril (Lotensin®)	ACE-Inhibitor	Start	04-27-2017	10 mg 0.0 Tablet	Use as Directed

Right Heart Cath Implant Values	
Please enter values obtained during PA Sensor implant procedure.	
RA Mean: 8 mmHg	PA Mean: 27 mmHg
RV Systolic: 38 mmHg	PA Systolic: 37 mmHg
RV Diastolic: 9 mmHg	PA Diastolic: 19 mmHg
PCWP: 11 mmHg	Cardiac Output: 4.2 L/min
Cancel Save	

Figure 5. Current medications and RHC implant values are entered into a secure website.

the presence of devices within the right heart (mechanical valves, pacer/defibrillator leads), or engaging the delivery catheter as it traverses the tricuspid valve. If resistance is encountered as the sensor traverses the tricuspid valve plane, the sensor is likely interacting with chordae tendineae or being caught at the union of the chordae tendineae and a papillary muscle. Rotation of the sensor and/or “bouncing” the guidewire usually resolves this. If resistance continues, the delivery catheter and guidewire should be removed and the balloon wedge catheter readvanced through the tricuspid valve, ensuring the balloon is completely inflated and “floats” freely through tricuspid valve structures. An inferior vena cava filter is not a contraindication to sensor implantation. Continuous fluoroscopic imaging is required to view the sensor as it traverses the filter.

In the unlikely occurrence that the sensor is unable to traverse the inferior vena cava filter, a long 12-F sheath can be placed through the filter. Movement of the sensor to a more proximal location during deployment can be addressed by (1) maintaining distal wire position, (2) readvancing the inflated balloon wedge catheter to contact the sensor, (3) pushing the sensor forward using the inflated balloon wedge catheter, and (4) repeating this process until the sensor is advanced to the desired implant location. Snaring the sensor is not advised. Occasionally, a wire loop can form distal to the sensor (Figure 4), which could potentially engage the sensor during wire removal and potentially “pull” the sensor to a more proximal location. The most effective method to resolve a distal wire loop is to (1) release the sensor, (2) advance the delivery catheter past the sensor, (3) withdraw the distal portion of the wire with the wire loop into the delivery catheter, and (4) remove the delivery catheter and wire together to a location proximal to the sensor.

POSTPROCEDURAL ASSESSMENT

The implantation procedure represents only one component of the entire CardioMEMS HF system.⁷ After sensor placement, it is essential to establish initial pressure goals, ensure patient compliance with pressure transmission, and coordinate health care provider involvement for pressure review and adjustment of medications to achieve the desired pressure goals. Over time, because of changes in renal function (ie, rise in creatinine), changes in blood pressure (ie, persistent hypotension), and impairment in quality of life (ie, orthostatic hypotension), the initially established pressure goals may require adjustment.

All patients should demonstrate the ability to transmit PA pressures prior to hospital discharge. A chest

radiograph should be obtained to document sensor location. Medications and RHC pressures and cardiac output at the time of sensor implantation should be entered into a secure website (Figure 5). Contacting patients on the day after sensor implantation to inform them of successful pressure transmission establishes a cadence for future communications and encourages compliance with pressure transmission.

Recalibration of the sensor may be required in < 3% of patients and can be identified by gradual dampening and/or loss of fidelity of the PA pressure waveform. Recalibration is done by either repeat RHC to directly measure PA pressure or use of transthoracic echocardiography (tricuspid regurgitant jet velocity) to estimate PA pressure.

CONCLUSION

The CardioMEMS HF sensor represents a major advance in the care of patients with NYHA class III HF. Implantation can be safely performed using standard percutaneous techniques in approximately 15 to 20 minutes and should always include complete RHC with accurate measurement of pressures and cardiac output. ■

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