Hybrid AF™ Therapy
EPi-Ease™ Access Device

For Subxiphoid Pericardial Access

AtriCure

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Overview

The pericardium can be reached via subxiphoid approach, which allows the physician to access the epicardial space to perform epicardial cardiovascular procedures, including those for ventricular arrhythmias. However, epicardial access through current techniques, carries significant risk of complications or adverse events which may be reduced with direct visualization.

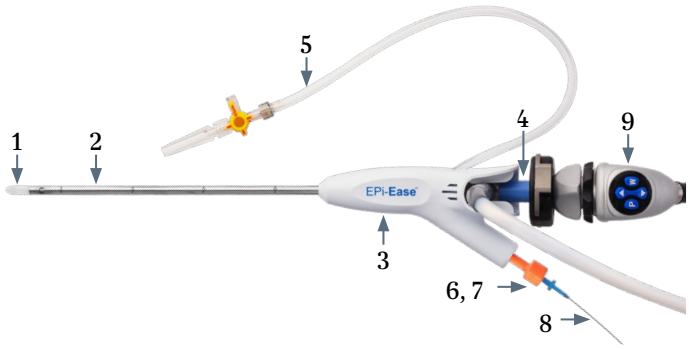
The EPi-Ease device is an epicardial access system (EAS), which is designed to access the epicardial surface of the heart via a subxiphoid approach, utilizing fluoroscopy and direct visualization. It is intended to be used during percutaneous procedures for access of the epicardial surface of the heart.

Equipment Required

As with most epicardial access procedures an OR Hybrid room or catheterization laboratory capable of C-Arm/fluoroscopy is paramount to safely proceed with the EPi-Ease device. The physician should also have commercially available 30 degree ~300 mm rigid endoscope with light cable, a 0.014 inch guidewire and a vacuum source capable of administering -600mmHg.

Product Description

The EPi-Ease is a sterile, single-use device designed to facilitate visualization of the pericardial surface, guided entry into the pericardial space and delivery of a guidewire to the epicardial space for percutaneous epicardial procedures. The device consists of a radiopaque distal tip with integrated suction aperture, an 18F outer-diameter stainless-steel shaft with a working length of 22 cm and proximal handle that encases a 22Ga Tuohy needle, which interfaces to facilitate 0.014 inch guidewire delivery, vacuum application and 3 mm endoscope insertion for direct visualization.



1) Distal tip
2) Outer shaft
3) Handle
4) Endoscope/fiberoptic light cable*
5) Vacuum tubing with stopcock*
6) Needle actuator
7) Guidewire port
8) Guidewire*
9) Camera unit*

**commercially available*

Potential Complications

Possible complications include but are not limited to:

- Thromboembolism
- Air embolism
- Local and systemic infection
- Bleeding or hematoma at puncture site
- Perforation (e.g., diaphragm, liver, lung, and vessels)
- Thrombus formation
- Epicardial irritation
- Perforation of the heart chambers leading to cardiac tamponade
- Pericarditis
- Hemopericardium
- Esophageal injury
- Coronary artery injury
- Abdominal bleeding
- Pneumopericardium
- Atrial fibrillation (Afib)
- Ventricular tachycardia (VT) requiring cardioversion
- Ventricular fibrillation (VF)
- Myocardial infection
- Death
- Excessive bleeding related to the procedure (defined as bleeding which requires > 3 units of blood products and/or surgical)
- Any serious incident that has occurred in relation to this device should be reported to AtriCure and the competent authority of the Member State in which the user and/or patient is located

Recommended Patient Screening

Patients with the following pre-existing conditions may not be suitable for this procedure:

- Congenital absence of the pericardium
- Epicardial surface fat pad on the epicardium surface > 5 mm
- Constrictive and adhesive pericarditis (large percentage of adhesion)
- Active infection
- Previous cardiac surgery
- Myocardial infarction
- Hemodynamic instability
- Unstable angina
- Recent cerebral vascular accident (CVA)
- Presence of acute cardiac thrombus
- Acute conditions, such as electrolyte abnormality, acute ischemia, and drug toxicity
- Cardiac defibrillator epicardial patch

Contraindications

The EPi-Ease epicardial access system is contraindicated for use in the following conditions:

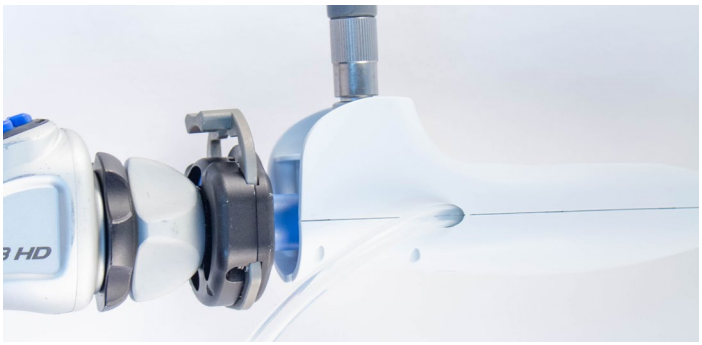
- Congenital absence of the pericardium
- Absence of free pericardial space

Device Set-Up

The EPi-Ease device should be aseptically transferred to the surgical field and prepared in a sterile fashion. The 3 mm 30 degree rigid endoscope should be connected to the camera and light source and inserted (or "seated") snugly into the camera port.

Superior view

Lateral view



Bottomed out view

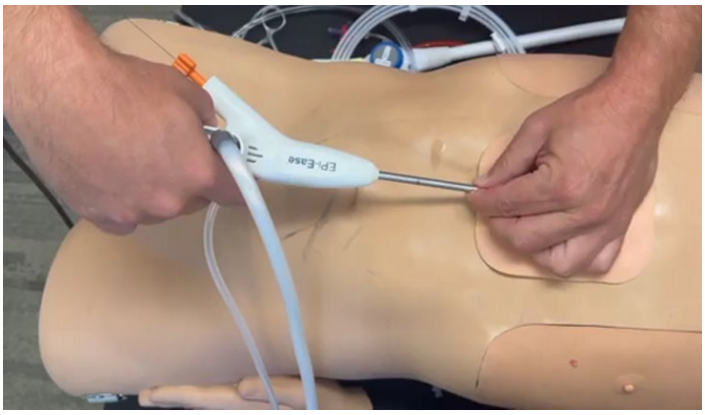
The device's vacuum tubing and stopcock will need to be connected to a vacuum source at the foot of the bed. Insert 0.014 inch guidewire into the guidewire port and insert until 2 mm proximal to the Tuohy needle bevel, so it won't impair needle puncture effectiveness.

Subxiphoid Access

The skin incision should be subxiphoid and approximately 1-2 cm in length. Use an instrument (hemostat, mosquito, etc.) to perform the initial blunt dissection using full left lateral fluoroscopy up to the diaphragmatic ligament. Do not dissect past the diaphragmatic ligament as this may cause a defect in the pericardium that may lead to early entry of the device tip into the epicardial space. The EPi-Ease device will be inserted into the incision at a steep angle, initially, to get beneath the subxiphoid process. Then shallow out angle while using 90 degree left lateral fluoroscopic view to stay above the diaphragm and avoid critical abdominal structures. Begin bluntly dissecting the subcutaneous tissue by gently rocking the device on its axis (right-to-left). Use visualization via the endoscope to assist in measured advancement of the device.

Tissue dissection should be slowly performed while advancing the device superior to the diaphragm with a trajectory towards the patient's left shoulder, following the groove of the infrasternal subcostal angle. A helpful tip during insertion is to pull back the device and let the channel you are creating fill with air. Also, remember to utilize your fluoroscopic and endoscopic views to confirm your positioning. Make sure you are driving the device with the suction 'OFF' to prevent pulling any unintended fat/tissue into the aperture.

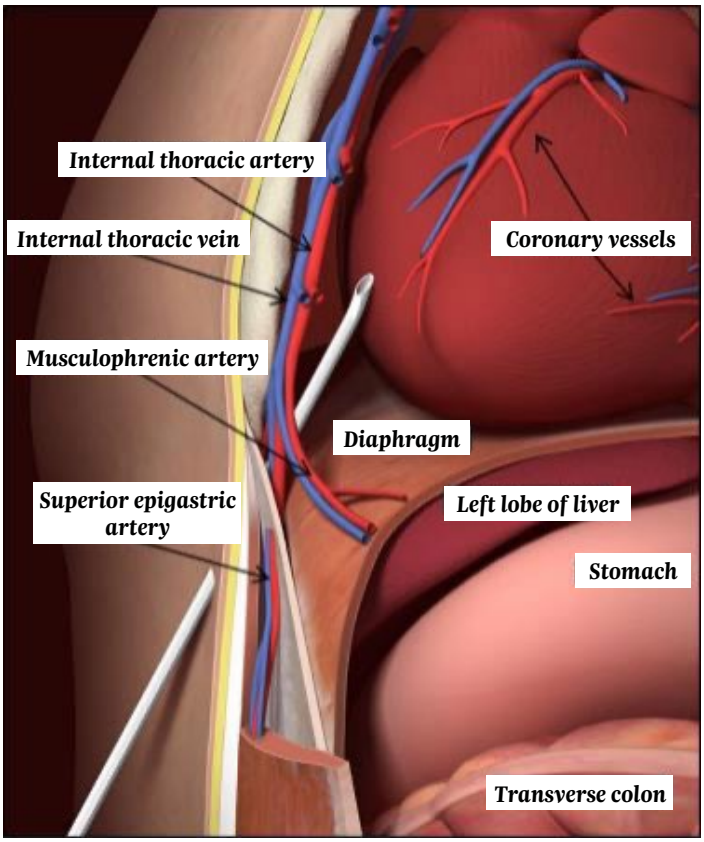
The physician's left hand should be guiding/feeding entrance of the shaft, while the right hand is being utilized for stability, similar to femoral sheath insertion. This will prevent any accidental over advancing of the device into adjacent tissue. Do not apply excessive force or advance if you encounter significant resistance. Attain a fluoroscopic shot to determine positioning. Do not advance if the distal tip of the aperture is not visible in the endoscopic and or fluoroscopic image.

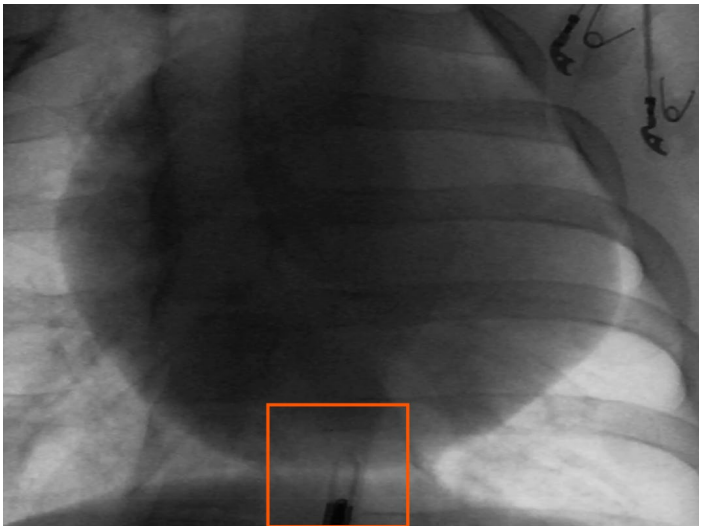


Relevant Anatomy

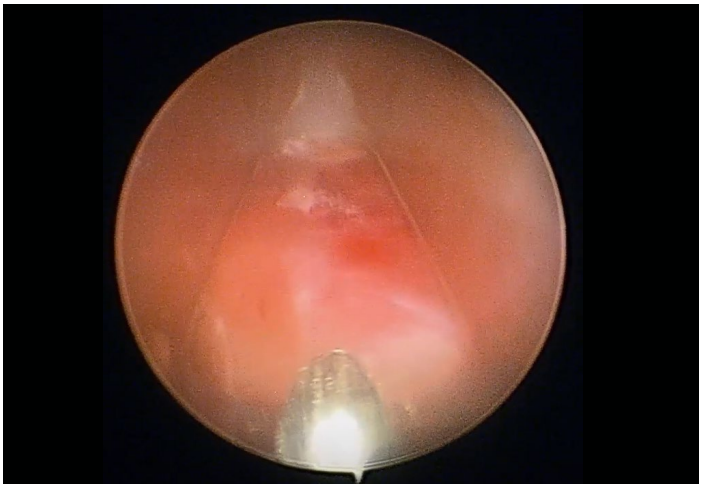
After incision, the device will be inserted into the subcutaneous tissue, through the linea alba and into the cardiophrenic space/fat. The physician will need to identify the diaphragm and visualize the glistening fibers of the pericardium. Your positioning can be confirmed via fluoroscopy to check your location and trajectory.

When looking for a location to suction onto the pericardium, the interventricular groove should be avoided, as well as any visible coronary arteries. Pericardial fat is another barrier to success, and should be avoided, as it can be sucked up into the suction aperture – obstructing your view. If this occurs, fat can be cleared by either irrigating with saline through the suction channel or by removing the device and manually removing the tissue.





Flouro – Left lateral when over diaphragm just coming onto pericardium

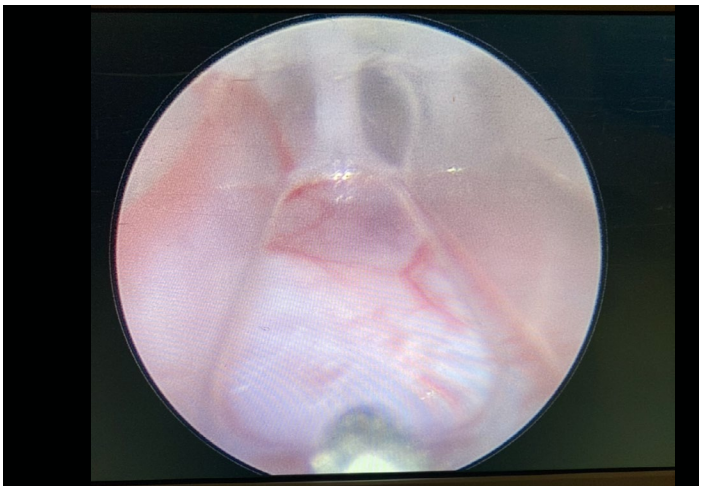


Endo – Left lateral when over diaphragm just coming onto pericardium

Endoscopic Visualization

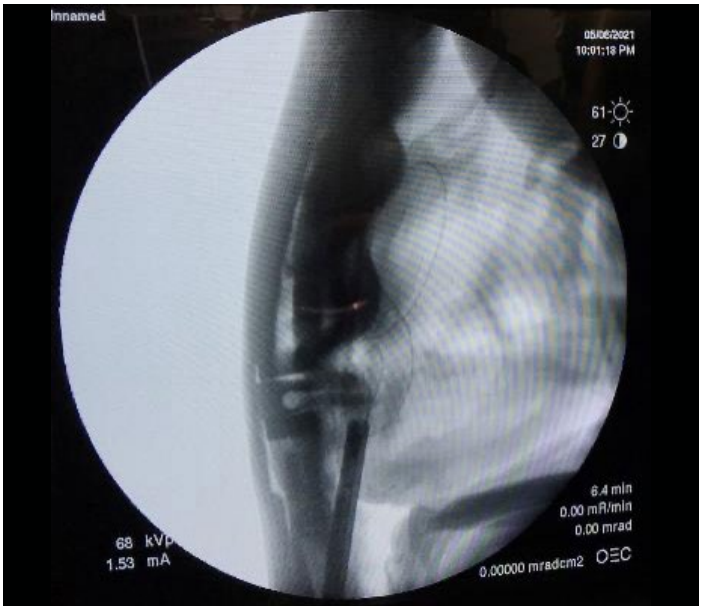
The endoscopic view allows for direct visualization of the pericardium and can help delineate anatomy and optimize safety of needle insertion. Correlate the endoscopic view with the fluoroscopic view to ensure location and efficacy of the device. Your endoscopic view will help you navigate locally, while bluntly dissecting through connective tissues and help avoid critical anatomical structures.

Typical Endoscopic view of the pericardium



Fluoroscopic Visualization

When coupled with direct visualization, fluoroscopy can help the physician determine trajectory of the device, as well as depth and gross anatomical positioning. The radiopaque tip allows the user to identify where the distal end is in relation to relevant anatomy and can help facilitate guidewire placement/insertion after the pericardium has been penetrated.

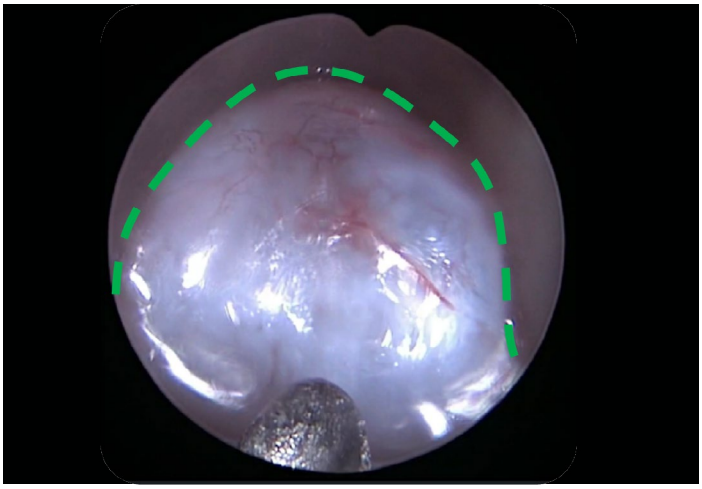


Epicardial Access and Guidewire Insertion

Once the pericardial surface has been reached, and the user has found a location that is ideal for device placement (area without fat pad or coronary artery beneath it), prepare for pericardial retraction.

Confirm the suction aperture is oriented toward the pericardium and is in full contact to facilitate a seal. Turn the stopcock to the 'ON' position, starting at -400 mmHg.

Observe the bleb form within the distal window of the device in the endoscopic view. Do not apply excessive downward pressure on the pericardium as this can limit the ability of the device to retract the pericardium, resulting in a smaller bleb. If a sizable bleb is not formed, first try to oscillate the device to sweep left and right and collect more pericardium in the distal aperture. If this does not help, the user can couple this maneuver with increasing suction in increments of 50 mmHg until -600 mmHg is reached. Do not exceed -600 mmHg. Alternately, you can move locations and try and find a location that gives better pericardial retraction performance.



Once an acceptable bleb is formed, employ the needle actuator, which should be facing the bevel of the needle 'upward' (or bevel away from pericardium, or bevel at 12 o'clock for an anterior stick). Keep the device stable with your left hand and use your right hand to operate the needle actuator. Utilize the sensitivity and feedback of the needle actuator to make a safe and controlled

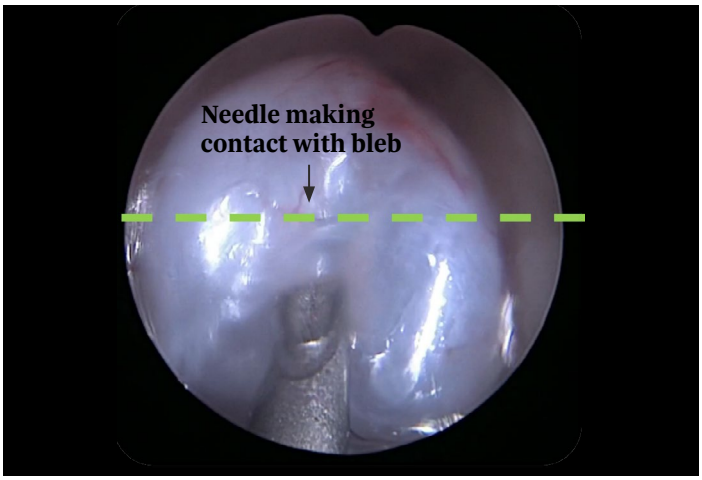
insertion into the pericardium.

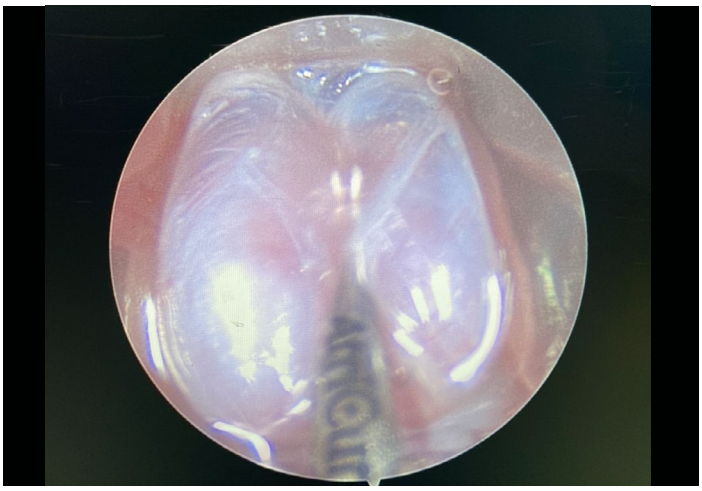
If the needle does not successfully puncture the pericardium, initially, retract the needle and increase vacuum incrementally by -50 mmHg, until needle insertion is successful.

During insertion, if you notice clear fluid and/or bubbles coming from the pericardium, that is a good sign, as this likely represents pericardial fluid. Feed guidewire into the pericardium and utilize fluoroscopy and direct visualization to see if the guidewire appears to be within the pericardial space. Never advance the guidewire if you encounter resistance or visualize the guidewire is not freely advancing into the pericardial space. After ~4 cm of wire is advanced, use fluoroscopy to confirm initial wire delivery. After confirmation of initial wire delivery, retract the needle, turn off suction to the device, and rotate the needle actuator 180 degrees to reduce friction between the needle and the wire during wire advancement. After final wire delivery, use fluoroscopy to confirm that the wire crosses over the ventricular septum and does not extend outside of the cardiac silhouette.

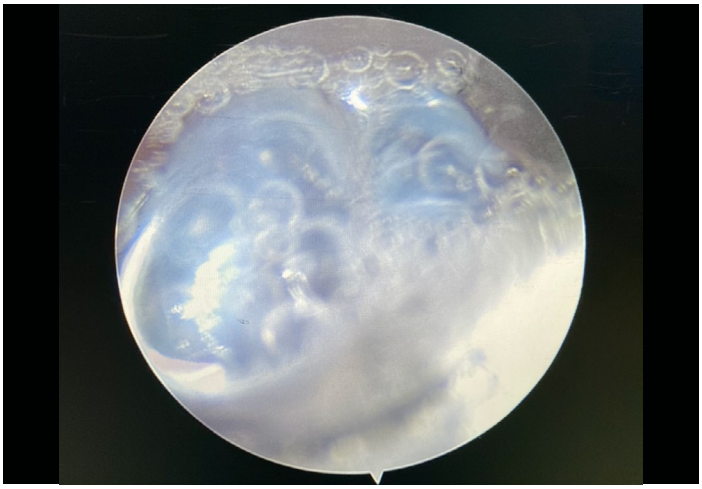
After you have successfully inserted the guidewire within the epicardial space, then hemostat or hold the guidewire in place and withdraw the device outward over the guidewire until the distal tip is completely off the guidewire. Dispose of the device in accordance with the IFU and hospital protocols. Now you can begin your interventional procedure, knowing you have utilized direct visualization for a more reproducible epicardial access.

Ideally, you want to see the needle make contact with the bleb about 15-20 percent into the endoscopic view. If this does not happen, your chances of making a fully trans pericardial stick may be compromised.

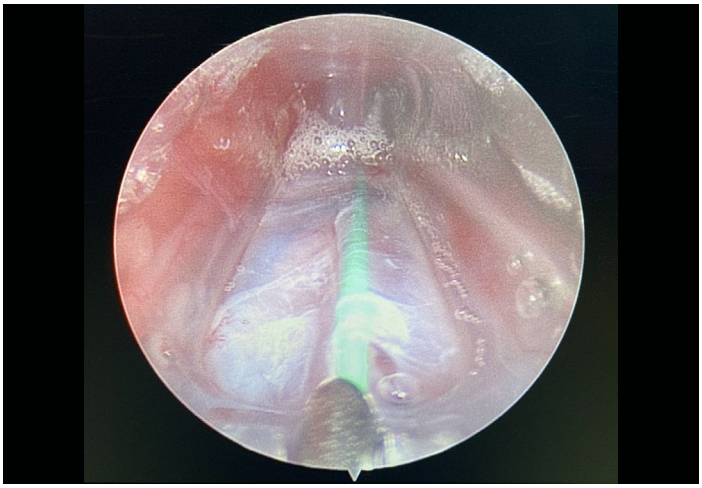




Pericardial fluid/bubbling is confirmation that you have successfully breached the pericardium.



Successful delivery of guidewire with needle appropriately retracted and bevel down to facilitate continued insertion.



***U.S. Indications**: The EPi-Ease Epicardial Access System is intended to access the epicardial surface of the heart via a subxiphoid approach.*

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