AtriCure

MD

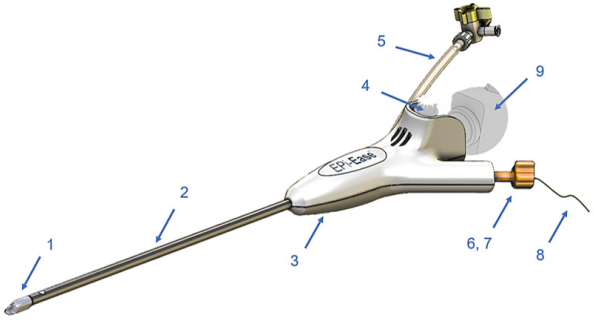
Instructions for Use

EPi-Ease™ Epicardial Access System- (EAS)

Rx ONLY

⚠ **Caution:** Federal Law (US) restricts this device to sale by or on the order of a physician

FIGURE 1



EPi-Ease™ with feature callouts. The endoscope camera unit and the guidewire are also shown.

INDICATION FOR USE

The EPi-Ease™ Epicardial Access System (EAS) is intended to access the epicardial surface of the heart via a subxiphoid approach.

INTENDED USE

The EPi-Ease™ EAS is intended to be used during percutaneous procedures to access the epicardial surface of the heart via a subxiphoid approach.

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.

SYSTEM DESCRIPTION

The EPi-Ease™ EAS system is comprised of the EPi-Ease™ device and the following commercially available components:

1. 30º 3mm rigid endoscope
2. 0.014" guidewire
3. Vacuum source capable of administering a minimum of -400mmHg

PRODUCT DESCRIPTION

The EPi-Ease™ EAS is a sterile, single-use device designed to facilitate visualization of the pericardial surface and delivery of a guidewire to the epicardial space for percutaneous epicardial procedures. The device consists of a clear distal tip with integrated suction aperture, a stainless-steel shaft, and proximal handle that encases a 22Ga Tuohy needle, and has interfaces to facilitate guide-wire delivery, vacuum application, and endoscope insertion.

PACKAGE CONTENTS

One (1) EPi-Ease™ Epicardial Access Device, supplied STERILE and NON-PYROGENIC in an unopened, undamaged package. For single use only. Do not re-sterilize. Do not re-use.

NOMENCLATURE

This instruction refers to features of the EPi-Ease™ (Figure 1) as follows:

[1] Distal tip
[2] Outer Shaft (needle housed inside)
[3] Handle
[4] 3mm Rigid Endoscope (commercially available)
[5] Vacuum Tubing with Stopcock
[6] Needle Actuator
[7] Guidewire Port
[8] 0.014" Guidewire (commercially available)
[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 (AF)
- 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),

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 >5mm
- 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

⚠ WARNINGS ⚠

Read all instructions carefully prior to using the device. Failure to properly follow instructions may lead to injury and/or improper device function.

The use of EPi-Ease™ should be limited to properly trained and licensed medical personnel. The use of EPi-Ease™ from non-trained or nonlicensed personnel could potentially result in death or serious injury.

Abort the procedure, or find a new location, if any conditions from 'recommended patient screening' section are detected during the procedure. Using the device in a patient with pre-existing conditions may inhibit access to areas of the epicardium due to pericardial fibrosis.

If the device malfunctions discontinue any use of the device to prevent unintended harm.

Always store the device in accordance with specifications identified per labeling/IFU. This is to prevent damage to the device or sterile packaging.

Never use the device after it has exceeded its shelf life. This will prevent infection and potential malfunction or breakage of the device.

Do not re-sterilize or reuse the device as this could damage the device or result in infection.

Ensure the settings of the fluoroscopic machine are correct before the procedure. The guidewire may be difficult to see with incorrect settings leading to incorrect use.

⚠ WARNING ⚠

This device contains small amounts of Nickel (CAS# 7440-02-0) and Cobalt (CAS# 7440-48-4). Do not use the device if the patient has sensitivity to Nickel or Cobalt as this may result in an adverse patient reaction.

⚠ CAUTIONS:

- Inspect all components before use. Do not use if the package or device appear to be damaged or defective.
- Do not attempt to use a guidewire larger than 0.014".

INSTRUCTIONS FOR USE

1. Inspect the product packaging prior to opening to ensure there is no obvious damage or sterility barrier breach. If there is damage or the sterility barrier is breached do not use the device to avoid risk of malfunction or patient infection.

DEVICE PREPARATION

2. Load the endoscope into the device until it bottoms out at the distal tip.

⚠ WARNINGS ⚠

Do not exceed -400mmHg of vacuum as this may lead to unintended tissue damage.

3. Attach the device to a vacuum source using standard suction tubing and set the stopcock to 'Off'.
   a) Vacuum source should be on and set to a suggested beginning level of -100mmHg.

⚠ WARNINGS ⚠

Ensure an appropriate guidewire, suitable for percutaneous epicardial access, is used to avoid unintended tissue trauma.

4. Load the guidewire into the guidewire port (Figure 1, item 6/7).

SKIN INCISION

⚠ WARNINGS ⚠

Do not make skin incision too deep as this may result in damage to unintended tissue.

5. Create a subxiphoid incision that allows access to the pericardial space.

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DEVICE DISSECTION

> **⚠WARNINGS⚠**
> Do not apply excessive force during blunt dissection to prevent damage to unintended tissue.
> Do not proceed with blunt dissection if the distal tip aperture is not visible in the endoscopic image as this may result in damage to unintended tissue.
> Always ascertain the trajectory of blunt dissection to avoid damage to unintended tissue.

6. Insert the distal tip of the device into the incision site to gain access to the pericardial space.
7. If flushing is desired at any point during the procedure, connect a syringe to the 'vent' port on the stopcock. Remove syringe prior to venting.
8. Use fluoroscopy to maintain gross position and trajectory of approach; use endoscopic visualization to navigate locally while blunt dissecting through the connective tissues and to help avoid critical structures (diaphragm, major vessels, etc.).

> **⚠WARNINGS⚠**
> Confirm the target tissue using endoscopic visualization, prior to puncture, to avoid damage to unintended tissue.

9. Use endoscopic guidance to locate a suitable pericardial puncture site.

PERICARDIAL RETRACTION (BLEB FORMATION)

> **⚠WARNINGS⚠**
> Do not apply excessive downward pressure on the pericardium.

10. Confirm the suction aperture is oriented toward the pericardium and is in full contact to facilitate a seal.
11. Turn the stopcock to the OPEN position.
12. Observe the bleb form within the distal window of the device in the endoscopic view.

NEEDLE INSERTION AND GUIDEWIRE ADVANCEMENT

13. Keep position of device stable with one hand.
14. Use free hand to operate needle actuation mechanism (Figure 1, item 6/7) to advance the needle into the bleb.
15. Use endoscopic visualization to confirm successful puncture.

    a) If the needle does not successfully puncture the pericardium, retract the needle, increase the vacuum by -50mmHg increments and repeat all steps in the Needle Insertion section, or consider an alternative puncture site. Do not exceed -400mmHg.

> **⚠WARNINGS⚠**
> Never try to insert the guidewire against resistance. This may cause unintended tissue damage.

16. While stabilizing the position of the device with one hand, use the other hand to carefully advance the guidewire.

> **⚠WARNINGS⚠**
> The needle should be retracted immediately after puncture and initial wire delivery to avoid damage to unintended tissue.

⚠ **CAUTION:** Verify the position of the guidewire using fluoroscopy.

NOTE: It is recommended not to exceed six needle puncture/wire delivery attempts at any singular pericardial access location.

17. After confirming initial wire delivery is in the epicardial space, disengage the vacuum by turning the stopcock to the OFF position, and withdraw the needle.
18. Rotate the needle so that the tip faces towards the pericardium and continue advancing the guidewire into the epicardial space.

> **⚠WARNINGS⚠**
> Always use fluoroscopy to confirm proper wire placement to avoid unintended tissue trauma from the guidewire itself or subsequent device delivery.

19. Use fluoroscopic visualization to confirm the wire is within the epicardial space.

REMOVING AND DISPOSING OF THE DEVICE

20. Withdraw the device over the guidewire until the distal tip is out of the patient.
21. Stabilize the guidewire at the incision site and remove the device completely off the guidewire.

> **⚠WARNINGS⚠**
> Always dispose of the device as instructed by the IFU to avoid exposure to the non-sterile product.

22. After use, this device should be treated as medical waste and disposed of following hospital protocol.

RETURN OF USED PRODUCT

If for any reason this product must be returned to AtriCure, Inc., a return goods authorization (RGA) number is required from AtriCure, Inc., prior to shipping. If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment; and it should be properly labeled with an RGA number and an indication of the biohazardous nature of the contents of shipment. Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from AtriCure, Inc.

DISCLAIMER STATEMENTS

Users assume responsibility for approving the acceptable condition of this product before it is used, and for ensuring that the product is only used in the manner described in these instructions for use, including, but not limited to, ensuring that the product is not re-used.

UNDER NO CIRCUMSTANCES WILL ATRICURE, INC. BE RESPONSIBLE FOR ANY INCIDENTAL, SPECIAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, WHICH IS THE RESULT OF THE DELIBERATE MISUSE OR RE-USE OF THIS PRODUCT, INCLUDING ANY LOSS, DAMAGE, OR EXPENSE WHICH IS RELATED TO PERSONAL INJURY OR DAMAGE TO PROPERTY.

SYMBOLS GLOSSARY

	Manufacturer		Caution
US	Country and Date of manufacture	#	Model number
	Do not use if package damaged		Single Sterile Barrier system with protective packaging inside
	Keep dry		Single Sterile Barrier System with protective packaging outside
MD	Medical device	UDI	UDI
	Fluid path	REF	Catalogue Number
LOT	Lot Number		Use-by date
	Consult instructions for use		Non-pyrogenic
LATEX	Not Made with natural Rubber Latex	PHT	Does not contain phthalates
	Contains Hazardous Materials	STERILIZE	Do not re-sterilize
	Do not re-use	STERILE R	Sterilized by Gamma Radiation
Rx ONLY		Caution: Federal Law (US) restricts this device to sale by or on the order of a physician	
60°C (140°F) / -29°C (-20°F)	Transit Temperature limit	85% / % / 30%	Transit Humidity limit

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