

Epi-Ease™ Epicardial Access Device

Set-Up Guide

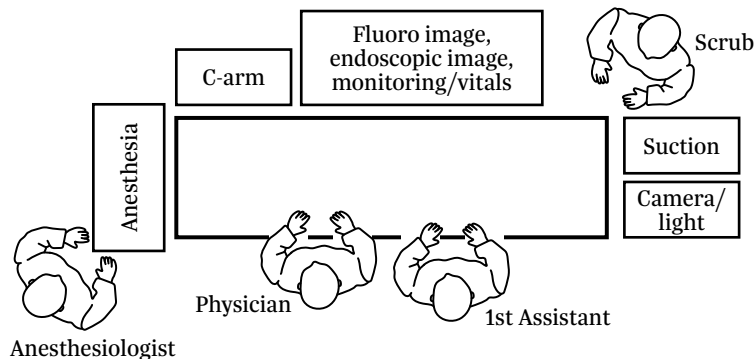


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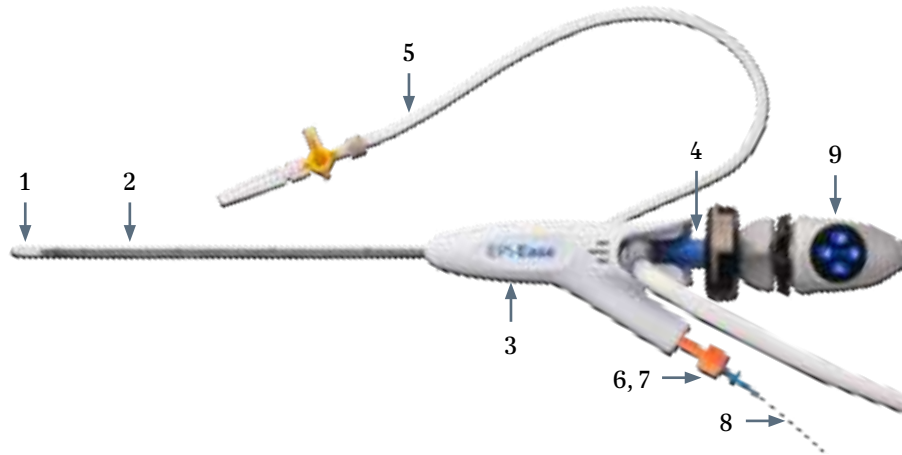
Equipment and Supplies

- ☐ Epi-Ease epicardial access device
- ☐ Fiberoptic light source
- ☐ Fiberoptic light cable
- ☐ Endoscope
(2.9 mm x 315 mm – 330 mm – 30 degree)
- ☐ Endoscopic camera/integrated coupler
- ☐ Camera control unit
- ☐ Fluoroscopy C-arm
- ☐ Vacuum source (minimum-400 mmHg) with tubing
- ☐ Video monitor
- ☐ Guidewire 0.014 inch/minimum 130 cm length/3-12 gram tip load

EPi-Ease Epicardial Access Procedure: Room Setup



Epi-Ease Device Product Description



1) Distal tip

2) Outer shaft

3) Handle

4) Endoscope/fiberoptic light cable*

5) Vacuum tubing with stopcock

6) Needle actuator

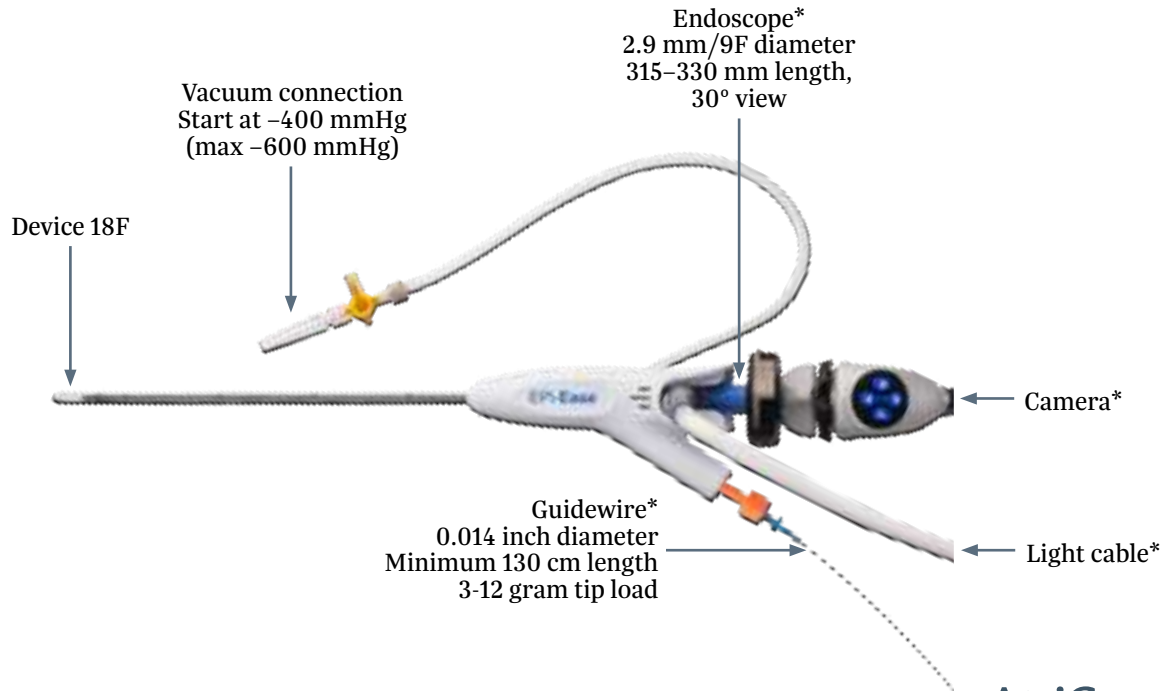
7) Guidewire port

8) Guidewire*

9) Camera unit*

*commercially available

Epi-Ease Device Set-Up

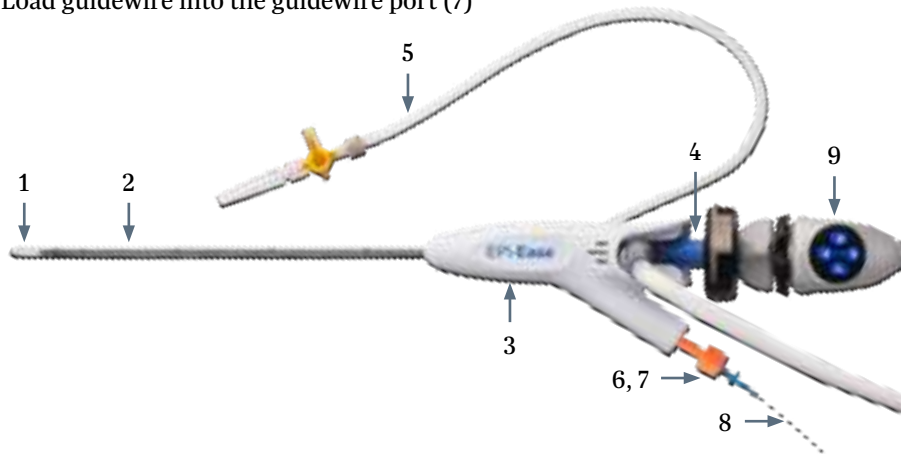


*commercially available

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EPI-Ease Device Set-Up

- ❑ Prepare scope/camera/fiberoptic light cable assembly (4, 9)
- ❑ Load endoscope/fiberoptic light cable (4) and camera unit (9) into the EPI-Ease device
- ❑ Connect the vacuum tubing with stopcock (5) to the vacuum source
- ❑ Load guidewire into the guidewire port (7)



Camera/Scope Preparation

- ❑ Attach the camera and fiberoptic light cable prior to insertion into the EPi-Ease device



Attach camera to endoscope



**Attach fiberoptic light
cable to endoscope**

Camera, Scope and Guidewire Preparation

- ☐ Attach the endoscope and camera to the EPI-Ease device
- ☐ See image below to insure full insertion



Posterior view



Superior view



Lateral view



Bottomed out view

- ☐ Insert 0.014 inch guidewire into the guidewire port on the EPI-Ease device



**Guidewire inserted into
guidewire port**

Device Preparation

- ☐ Connect the vacuum tubing to the vacuum source
- ☐ Ensure the stopcock is set to the “OFF” position during device insertion
- ☐ Recommended starting vacuum pressure is -400 mmHg
- ☐ DO NOT exceed -600 mmHg vacuum pressure



Epi-Ease suction tubing and stopcock (OFF position)



Epi-Ease suction tubing and stopcock (ON position)

Ancillary Equipment



Fiberoptic light source and camera control unit*



Fiberoptic light cable*



Endoscope*
2.9 mm/9F diameter: 315-330 mm length, 30 degree view



Endoscopic camera*



Guidewire*
Diameter: 0.014 inch,
minimum 130 cm length
3-12 gram tip load



Vacuum equipment*
Capable of -600 mmHg minimum

*commercially available

Epi-Ease: Procedural Steps

- ❑ Epi-Ease device and ancillary equipment are prepared (vacuum, light source, fiberoptic light cable, camera, endoscope, camera control unit, guidewire).
- ❑ Physician makes small subxiphoid incision. Incision should be at least 0.5 cm below the xiphoid or between 0.5 to 3 cm below the inferior aspect of the xiphoid depending on body habitus and/or anterior or posterior approach to obtain pericardial access.
- ❑ Epi-Ease device is inserted into the incision.
- ❑ Epi-Ease device is advanced to target epicardial site of interest. A location free of cardiac vessels and pericardial fat should be selected.
- ❑ Epi-Ease device is placed onto the pericardium, stopcock is opened to retract the pericardium and create a bleb.

Epi-Ease: Procedural Steps *continued*

- ❑ If device needs to be rotated to accommodate the chosen access site, always maintain camera orientation.



**Posterior approach:
camera orientation facing up**



**Anterior approach:
camera orientation facing up**

EPI-Ease: Procedural Steps *continued*

- ☐ Needle is advanced through the device to contact the pericardium. Ensure the needle actuator is pointing away from the pericardium (*needle bevel is pointed away from the pericardium*).
- ☐ Needle is carefully advanced further to puncture the pericardium.
- ☐ Guidewire is advanced through the needle until roughly 2-4 cm of guidewire has been introduced to the epicardial space. Check on fluoroscopy that the guidewire is outside of the distal tip.
- ☐ Vacuum is deactivated and needle is retracted, leaving only the guidewire in the epicardial space.
- ☐ Needle actuator is rotated 180 degrees allowing for further delivery of the guidewire (*needle bevel points toward pericardium*).
- ☐ Ensure guidewire is in epicardial space via fluoroscopy.
- ☐ EPI-Ease device is removed. Hold the guidewire in place to avoid losing access during device removal.

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

Rx Only

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