Evident™ 35 Peripheral Imaging Catheter

Instructions for Use
Model: EV35P

℞ ONLY **CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

Device Description

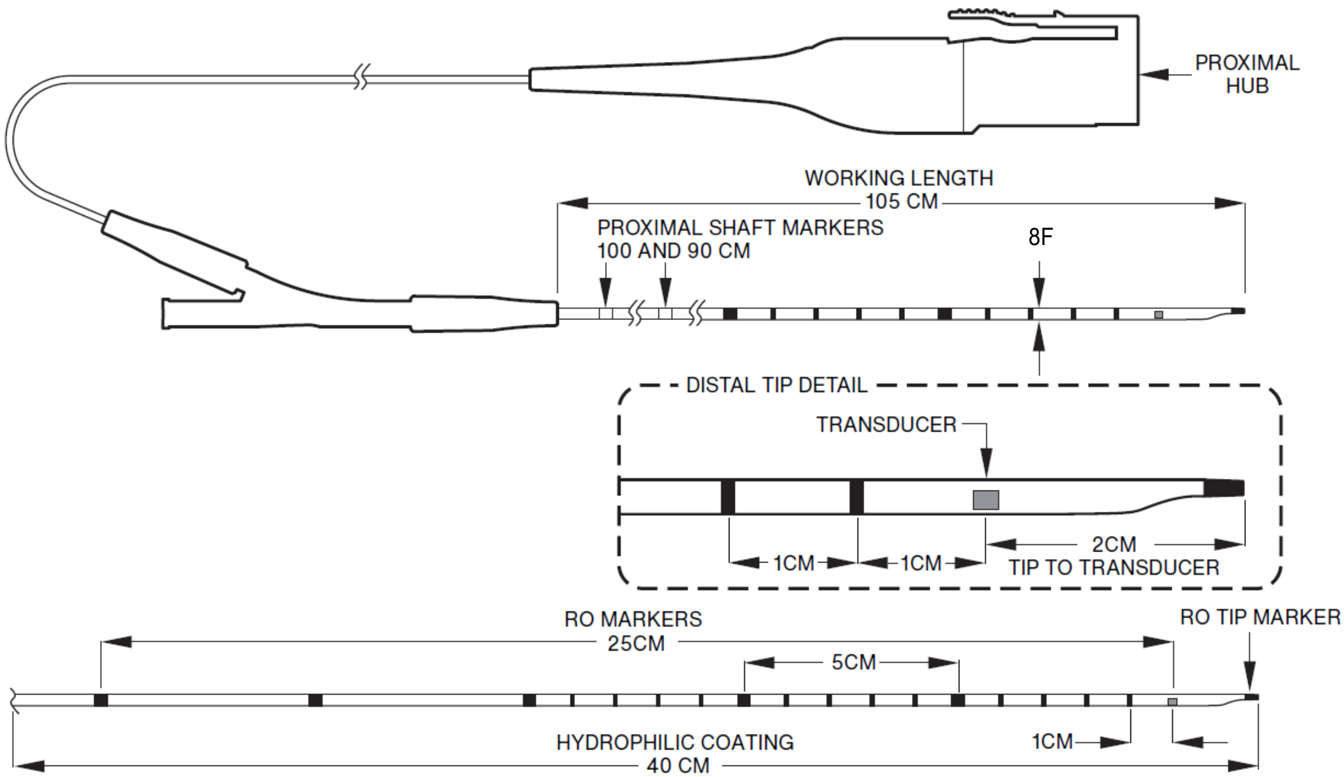
The Evident 35 Peripheral Imaging Catheter is a sterile, over-the-wire catheter for intravascular ultrasound imaging of peripheral vessels. The catheter includes an ultrasound transducer located at the distal end of a rotating imaging core inside the catheter body. A proximal extension extends beyond the working length of the catheter. A proximal hub at the end of the proximal extension connects the catheter to a Catheter Interface Module (CIM), part of the Evident Vascular™ Guidance System, allowing for communication with the workstation.

The Evident 35 catheter has a working length of 105 cm. The distal 40 cm has a lubricious, hydrophilic coating.. The catheter is pre-filled and sealed with an acoustic coupling fluid and requires no flushing of the internal imaging lumen prior to use. The guidewire lumen extends the entire working length and exits at a mid-shaft Y-hub.

The catheter has a distal tip radiopaque marker, as well as shaft markers extending over a length of 25 cm with the transducer at the 0-cm position. The first 15 cm of markers occur every 1 cm, with the remainder occurring every 5 cm.

The Evident 35 catheter is designed for use with the Evident Vascular Guidance System. The catheter is compatible with a 0.035" (0.89 mm) interventional guidewire, and a 8F or larger introducer sheath.

The catheter is supplied in a single, sterile package and limited to single use.



Intended Use

The Evident 35 Peripheral Imaging Catheter is intended for ultrasound examination of peripheral vascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.

Contraindications

This product is contraindicated in the presence of conditions that create unacceptable risk during catheterization. It is not to be used in the coronary arteries.

Adverse Events

The following potential risks or discomforts may be associated with vascular imaging procedures. These risks include those associated with all catheterization procedures. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

The physician should communicate all foreseeable risks to the patient.

- Myocardial infarction
- Vessel occlusion
- Vessel dissection
- Perforation, rupture, or injury
- Restenosis
- Hemorrhage or hematoma
- Drug reactions
- Allergic reaction to contrast medium
- Hypotension/hypertension
- Infection/sepsis
- Vessel spasm
- Arteriovenous fistula
- Embolism
- Entry puncture site bleeding
- Vascular wall injury
- Vessel thrombosis
- Pseudoaneurysm (at site of catheter insertion)
- Renal insufficiency/failure
- Vessel aneurysm
- Vessel trauma requiring surgical repair or intervention
- Additional surgical intervention
- Death

Warnings

- The EV35P imaging catheter should be used only by physicians who are familiar with and properly trained to perform the techniques, as well as the specific approach to be used, in a fully equipped catheterization lab.
- The catheter is supplied sterile. If the package is opened or damaged, compromising the sterility, discard the product.
- The catheter is for single-use only. Do not reuse or resterilize.
- Do not use the catheter for purposes other than those indicated.
- Use the catheter with the introducer sheath size and guidewire size as indicated on the product label. Failure to do so may result in inability to advance the catheter and/or damage to the catheter.
- The catheter may not be safe for patients who cannot be properly anticoagulated or who cannot receive anti-platelet or anti- coagulation therapies.
- The catheter has no user-serviceable parts. Do not attempt to repair or modify any component of the catheter assembly as provided. Modifying the catheter could result in poor image quality or patient complications.
- The safety and effectiveness of the coated device has not been established, or is unknown, in vascular regions other than those specifically indicated.
- Failure to abide by the warnings in this labeling might result in damage to the device, which may necessitate intervention or result in serious adverse events.
- Never advance or withdraw the catheter without direct fluoroscopic visualization, as it might cause vessel injury or patient complications.
- Do not forcibly advance the catheter if resistance is encountered. The catheter should never be forcibly inserted into lumens narrower than the catheter body or forced through a tight stenosis. A catheter that is forcibly advanced might cause vessel injury or patient complications. Determine the source of resistance, exercise caution when removing the device and/or other components as a unit, and exchange the device for a new one to complete the procedure when there is resistance or the device does not move freely.
- Do not advance the catheter along a guidewire that may be passing between one or more stent struts. This could result in stent dislocation, the entrapment of the catheter/guidewire, or separation of the catheter distal tip from the catheter hub.
- If resistance is met upon withdrawal of the catheter, assess the cause of resistance using fluoroscopy. If necessary, remove both the catheter and guidewire together. If additional imaging is needed, exchange the device for a new one to complete the procedure.
- Use caution when removing the catheter over the guidewire from a stented vessel to minimize patient risk.

Precautions

- Before use, carefully inspect the catheter for physical damage. Do not use a damaged catheter.
- Protect the catheter distal tip from impact and excessive force.
- Protect the electrical connections from exposure to fluid.
- During use, ensure that the placement of the catheter does not preclude blood flow through the vessel.
- While inserting the catheter through a hemostasis valve into a guide or sheath, do not turn on imaging until after the catheter distal end is in the sheath or guide lumen.
- If inserting the catheter through a rotating hemostasis valve, tighten the valve around the catheter just enough to prevent fluid or blood leakage. Excessive tightening of the valve may cause image distortion and/or catheter damage.
- Do not advance the catheter without guidewire support, as it can cause difficulty in reaching the intended region or may cause the catheter distal tip to kink.
- Do not advance the catheter around a tight bend without sheath or guide catheter support, as it can cause difficulty in reaching the intended region or may cause the catheter distal tip to kink.
- When inserting the guidewire, both the catheter and the guidewire must be straight with no bends or kinks. Bends or kinks might damage the guidewire lumen.
- During the procedure, provide appropriate anticoagulation to the patient, as needed.
- After use, dispose of the catheter and packaging according to institutional, local, and state policies.

Storage and Handling

Store the catheter at room temperature in a cool, dry place. Do not expose to extreme heat or cold.

Equipment and Accessories

The following equipment and accessories are required for using the Evident EV35P Peripheral Imaging Catheter:

- Evident Vascular Guidance System including the Catheter Interface Module (CIM).
- Interventional guidewire, 0.035” (0.89 mm)
- Introducer sheath, 8F

Instructions for Use

Evident Vascular System Setup

Refer to the Evident Vascular Guidance System User Manual for information on setting up the system and starting a new case.

NOTE: Use sterile technique during all catheter preparation and usage steps.

Catheter Preparation

Prior to use, inspect the pouch for damage to the sterile barrier. Do not use the catheter if the packaging is compromised. Do not use a catheter past the Use by date.

1. Using sterile technique, remove the catheter from the sterile pouch.
2. Inspect the catheter for damage. Do not use a potentially contaminated or damaged catheter.
3. Flush the guidewire lumen at the guidewire exit port with sterile heparinized saline.
4. Connect the catheter to the CIM. Orient the catheter hub with the CIM connector for proper connection. The catheter hub clicks into the CIM connector.
5. Once the catheter is connected to the CIM, verify proper catheter function on the tablet.
6. The tablet screen displays Catheter Connected and a concentric ring.
7. Wipe down the working length with sterile heparinized saline to activate the hydrophilic coating.

Vessel Access and Catheter Placement

Before inserting the catheter, ensure the patient has been prepped using standard protocols for interventional treatment.

8. Using standard procedures, gain access to the vasculature with an introducer sheath and/or guide catheter.
9. Introduce the guidewire and advance it to the region of interest. **NOTE:** Guidewires with extra support or stiffness in the distal section are recommended.
10. Backload the guidewire into the distal guidewire lumen of the catheter until the guidewire exits from the guidewire lumen. Advance the catheter over the guidewire and into the sheath or guide.
11. Continue to advance catheter in the patient vasculature. Using fluoroscopy and the radiopaque tip marker for guidance, advance the catheter over the guidewire to the target area of interest using standard endovascular techniques.
12. Using fluoroscopy and the image of the transducer, position the catheter at the target site for imaging (see below)

NOTE: Radiopaque shaft markers on the distal working length can be used as an aid in measuring patient morphology or lesion length while under fluoroscopy.

Imaging

13. Once the catheter is at the desired site, begin imaging the vasculature. Refer to the Evident Vascular Guidance System User Guide for information on using the user interface during imaging, measuring, and recording.
14. If necessary, navigate the catheter over the guidewire to image additional segments of vasculature.

Catheter Removal

15. Once imaging is complete, remove the catheter from the patient. NOTE: If the catheter might be used for additional imaging during the procedure, to preserve the sterile field the catheter can remain connected to the CIM between uses.
16. When the procedure is complete, disconnect the catheter from the CIM by pressing the release latch on the catheter hub and pulling the hub from the CIM connector.
17. After use, dispose of the catheter and packaging according to institutional, local, and state policies.

Specifications

Model	EV35P
Working length	105 cm
Introducer sheath compatibility	8F
Maximum guidewire	0.035" (0.89 mm)
Acoustic Output–Compliance to FDA Guidelines and IEC 60601-2-37: Refer to the Evident Vascular Guidance System User Manual for Acoustic Output Parameters	

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Symbols

The following symbols can be found on the catheter packaging: