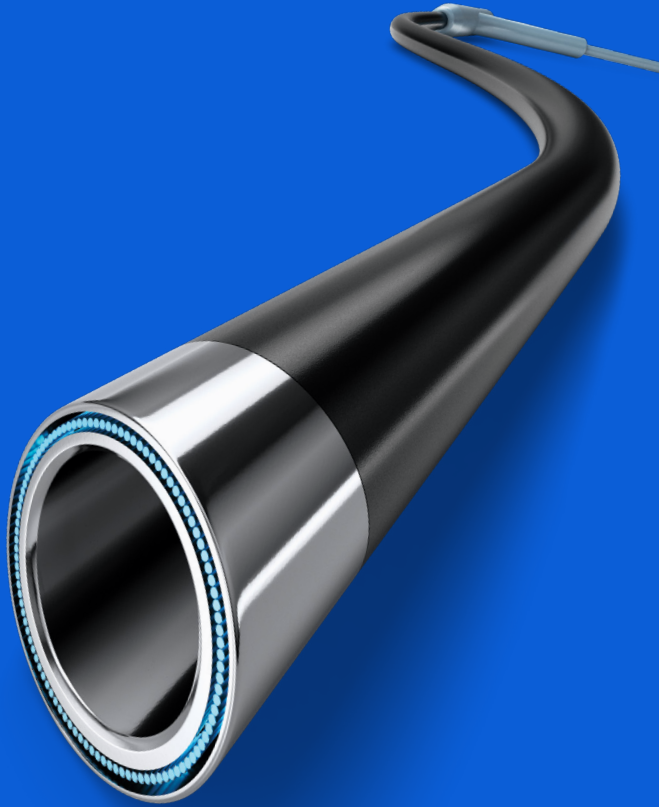


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Quick reference

CavaClear IVC Filter Removal Laser Sheath

- Equipment needed
- Step-by-step procedure
- Troubleshooting guide

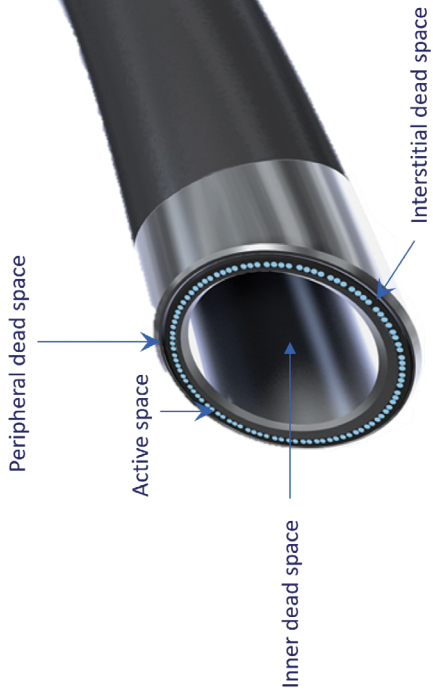
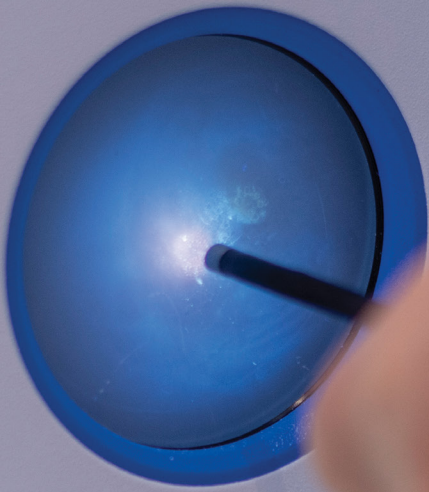


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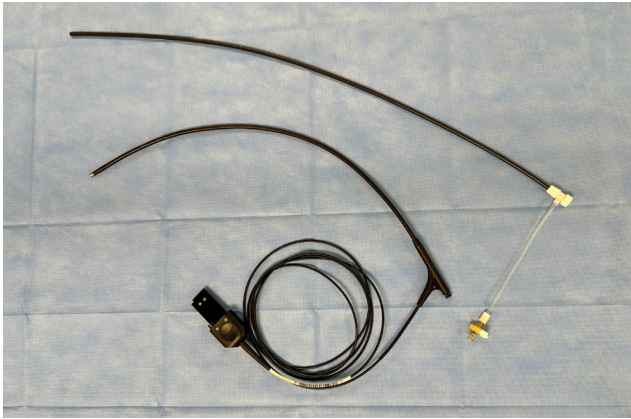


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Equipment needed

Equipment needed

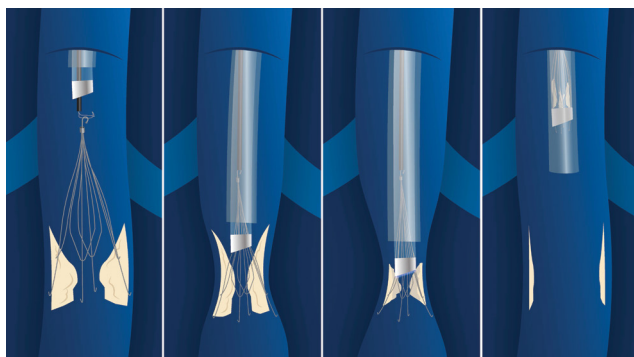


Confirm all necessary devices and equipment are in the lab before starting the procedure:

1. CavaClear laser sheath
2. Philips Laser System – Nexcimer or CVX-300
3. Fluoroscopy equipment
4. Introducer sheath (Minimum 16F for 14F laser sheath and 18F for 16F laser sheath)
5. Traction platform (i.e., a wire snare, a premade snare, or other applicable accessory equipment used to secure the IVC filter)
6. Occlusion balloons and stent grafts for emergency use

Step-by-step procedure

Step-by-step procedure



1. **Establish vascular access**
2. **Perform cavagram**
3. **Attempt traditional removal***
4. **Prep the CavaClear laser sheath**
5. **Place introducer sheath**
6. **Heparinize if not contraindicated**
7. **Establish traction platform**
(removal snare, i.e., a wire snare or a pre-made snare)
8. **Commence laser-assisted filter removal**
9. **Complete filter removal**
10. **Repeat cavagram**

***This step may be skipped if the patient has had a documented failed retrieval attempt.**

Step-by-step procedure



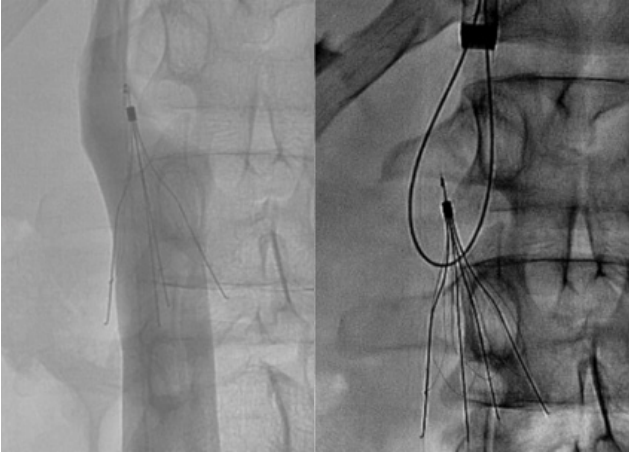
1 Establish vascular access

- Utilize ultrasound to identify and guide entry into appropriate vein – internal jugular, common femoral, or both. Patient preparation and anesthetic options should be consistent with established best practices and peer-based recommendations. Fluoroscopy will be used to monitor all transvenous maneuvers.
- Once the vessel is entered with a needle, an access wire is inserted through the needle.

Step-by-step procedure

2 Perform cavagram

- Advance a flush catheter over the wire below the filter. Perform inferior vena cavography with iodinated contrast to assess presence of thrombus and filter position in the vena cava. Additionally, assess the filters condition, i.e., presence of fractured filter components (legs).



Images courtesy of Dr. Osman Ohmed, MD

3 Attempt standard filter removal*

- Use applicable accessory equipment to attempt to capture the filter.

*This step may be skipped if the patient has had a documented failed retrieval attempt.

Step-by-step procedure

Some standard filter removal techniques include:

- Manufacturer retrieval tool
 - Some filters have a manufacturer retrieval device that may be used if appropriate. These cannot be utilized with CavaClear Laser Sheath.
- Loop or tulip snare technique
 - Use an opened snare, such as the 15 or 20mm goose neck or 12-20 mm tulip shaped snare to capture the filter hook.
- In-situ loop snare technique
 - Use a reverse curve catheter and an exchange length wire (260 cm or greater). Loop the catheter and wire under the apex of the filter. Both caudal and cranial ends may need to be looped with biconical filters. Ensure the wire is under only the apex and not the secondary struts. In the context of a uni-conical filter, ensure the wire is positioned beneath enough filter legs to provide adequate support. Capture the free end of the wire with a snare and pull through the introducer sheath.

Tip:

The in-situ loop snare technique may be preferred to primary snaring of the filter hook as the hook can straighten out.

- Dual access
 - Dual access combines any traction platform in both the IJ and femoral vessels, often to capture a “cage”/biconical type filter on both ends.

Step-by-step procedure

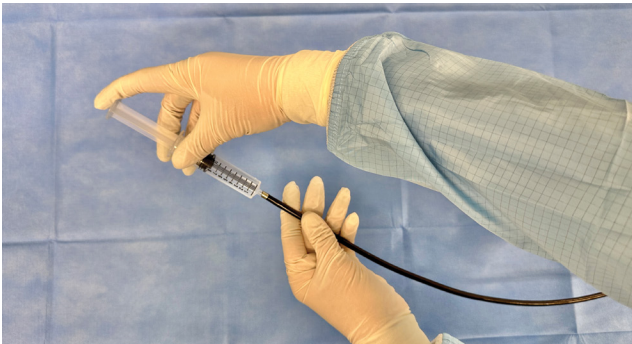


4 Prep the CavaClear laser sheath

- Confirm the patient has a documented retrieval attempt before using the CavaClear laser sheath. CavaClear is an advanced retrieval technique.
- Select appropriately sized laser sheath. Operator experience and preference are the determining factors.
- Using sterile technique, open the sterile package. Remove the packaging wedges from the tray and gently lift the device from the tray while supporting the proximal coupler.
- Visually inspect the device for bends, kinks, or other damage. Do not use if it is damaged.
- Plug in and turn on Philips Laser System—warm-up takes 5 min.
- Follow proper laser safety, including safety glasses and signage.

Step-by-step procedure

- Connect foot pedal.
- Connect the laser coupler to the connector of the CVX-300 Excimer Laser or Philips Laser System (PLS).
- Calibrate the laser sheath.
- Fill a sterile syringe with 10 mL of saline solution. Inject the saline into the inner lumen of the laser sheath. Using another 10 mL of saline, wet the outer jacket of the laser sheath.

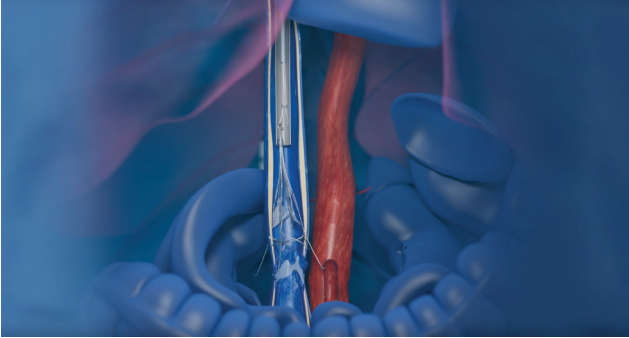


5 Place introducer sheath

- Deliver the introducer sheath (minimum 16F for 14F laser sheath and 18F for 16F laser sheath) into the vein – dilation may be needed at the operator's discretion.
- Introduce tip of filter into introducer sheath and apply pressure to the back of the introducer sheath to maintain the location of the distal end over the apex of the filter.

6 Heparinize if not contraindicated

Step-by-step procedure



7 Establish traction platform (e.g., snare)

- Re-insert the traction platform through the CavaClear laser sheath and the introducer sheath.
- Recapture the filter.
- Advance the laser sheath into the introducer sheath utilizing the traction platform (snare) as a rail.



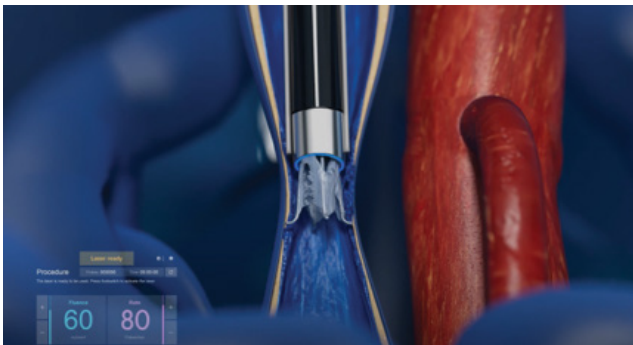
8 Commence filter removal

Tip:

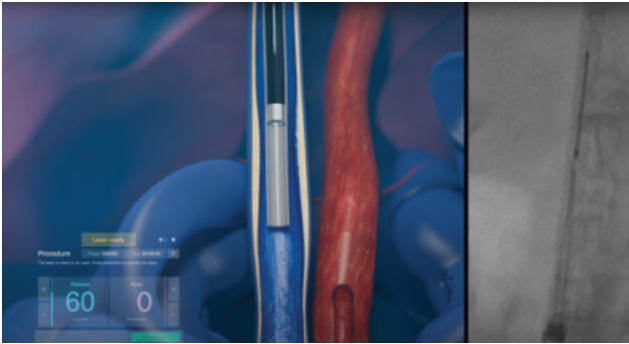
With uniconical filters, the net force should be in the cephalad direction. Be particularly mindful of the traction platform. Keep coaxial alignment of the laser sheath with the traction platform and avoid pushing the filter caudally.

Step-by-step procedure

- Advance the CavaClear Laser Sheath through the introducer and advance over the filter. The legs of the filter will collapse inward.
- When resistance is met, press the laser sheath gently into the obstruction tissue. Do not activate the laser when the distal tip of the laser sheath is inside the introducer sheath. Pull back the introducer sheath while maintaining the laser sheath in position at the obstruction tissue. Verify that the introducer sheath is retracted so that its distal end does not overlap the distal tip of the laser sheath.
- The laser should only be activated when the laser sheath is oriented parallel to the center axis of the filter. Activate the laser to ablate the fibrosis. Advancement rate should be 1-2mm/sec.
- Additional pullback and advancement may be necessary until the filter releases from the IVC.



Step-by-step procedure



9 Complete filter removal

- Once the filter is contained in the laser sheath remove the CavaClear laser sheath and IVC filter simultaneously through the introducer sheath.
- Deactivate the laser (place in "Standby" mode).
- Slowly withdraw laser sheath from IJ and/or femoral access.

Tip:

As a complement to the perioperative protocols, a robust, stress-tested rescue plan is critical for a safe, predictable, and responsible IVC filter removal program. During IVC filter retrieval, have occlusion balloons and stent grafts available for the rare case in which a rescue plan is necessary.

10 Repeat cavagram

- Perform inferior vena cavography with iodinated contrast to re-assess vena cava and ensure completion of procedure.

Troubleshooting guide

Troubleshooting CavaClear

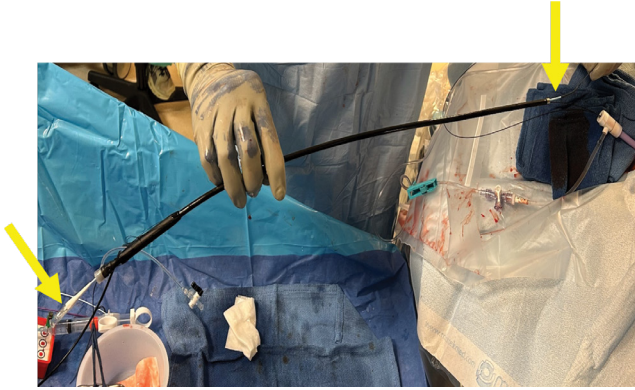
1. If an obstruction or resistance is met during filter removal and the laser sheath cannot be advanced further over filter apex or hook:

- Use orthogonal fluoroscopic views to ensure that the tip of the laser sheath is aligned and coaxial with the filter.
- Verify that the introducer sheath is retracted so that its distal end does not overlap the distal tip of the laser sheath. Press the laser sheath gently into the obstruction tissue. Do not activate the laser when the distal tip of the laser sheath is inside the introducer sheath. Pull back the introducer sheath while maintaining the laser sheath in position at the obstruction tissue.
- Place the laser in READY mode. Depress the foot switch, activating the laser. While the laser is activated, use gentle pressure on the laser sheath to advance the device while applying equal and opposite traction to the traction device. When the laser sheath breaks through the obstruction, release the foot switch.

2. If the laser sheath becomes kinked or damaged during use as evidenced by fluoroscopy:

- It is recommended to discontinue use of the device. Weigh the relative risks and benefits of device removal versus continued use.

Troubleshooting CavaClear



3. If the operator experiences back bleeding through the sheath, though the laser sheath is performing safely and as expected:

- Consider use of a hemostatic sheath or assembly to improve operator experience.
- One technique that has been used by prior operators requires the insertion of a 9F hemostatic sheath through the traction platform exit of the CavaClear laser sheath and secured using sutures.
- If used in combination with the in-situ loop snare technique, a catheter may be inserted through the hemostatic sheath attached to the traction platform exit of the laser sheath. The externalized wires of the established in-situ loop snare may be delivered through the laser sheath and hemostatic sheath via the inserted catheter. The catheter is then removed. The externalized wires are now running through both the CavaClear laser sheath and the hemostatic sheath, allowing for the delivery of the CavaClear laser sheath over the traction platform.

Image courtesy of Dr. Mark Lessne

For informational purposes only: Philips is not providing technique recommendations.

Indications

The laser sheath is intended for the ablation of tissue in the removal of IVC filters that have failed a previous retrieval method.

Contraindications

Use of the laser sheath is contraindicated:

- When IVC filter is not accessible to the operator or the IVC filter apex cannot be captured;
- When in situ thrombus is present within filter, IVC, or iliac veins;
- When IVC Filter material is nonmetal;
- For use in removal of Bird's Nest IVC filters and VenaTech filters

Warnings

Do not attempt to remove an Inferior Vena Cava (IVC) Filter using the laser sheath if fluoroscopy is not available.

Do not attempt to remove an Inferior Vena Cava (IVC) Filter using the laser sheath when the filter will not fit into the inner lumen of the laser sheath. Do not attempt to operate the laser sheath without the availability of conventional endovascular access and foreign body retrieval tools.

The laser sheath should be used only by physicians who are experienced in endovascular IVC Filter removal techniques.

Warnings (cont.)

The CVX-300® Excimer Laser or Philips Laser System (PLS) should be used only by physicians who have received adequate training (See Section 10.3).

Protective glasses are required when the laser is in use. Avoid eye or skin exposure to direct or scattered radiation. Refer to exposure label on the CVX-300® Excimer Laser or Philips Laser System (PLS).

Maintain appropriate traction on the IVC Filter with applicable accessory devices while appropriate counter-traction with the laser sheath is maintained during the removal process.

This device is designated for use with only the CVX-300® Excimer Laser or Philips Laser System (PLS).

Adequate instructions for the safe installation of the CVX-300® Excimer Laser or Philips Laser System (PLS) are provided in servicing information provided by Philips and should be followed.

Adverse events

Potential adverse events include but are not limited to: infection, migration of IVC filter fragments, migration of vegetation or thrombus, pulmonary embolism, venous avulsion/perforation, vena cava occlusion or torsion with subsequent thrombus, pseudoaneurysm, and hematoma formation.

For reference use only. For complete instructions, please refer to IFU.

Caution

Federal (USA) law restricts this device to sale by or on the order of a physician. For further information, please call Philips at 1-888-744-5477 or consult the Philips website at **www.philips.com**.



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MAT-5378-v1 072025