

PHILIPS

IVC Filter Removal
Laser Sheath

CavaClear

Laser-precise removals.
**No matter the
dwell time.**

Granted Breakthrough Device
Designation by the FDA



The growing patient need

Research has shown that IVC filters may have long-term complications, and the FDA has published multiple safety communications recommending the removal of IVC filters when no longer indicated.¹

It is estimated that 1 million patients are currently indicated to have their IVC filter removed.²

IVC filters have been shown to be effective in reducing pulmonary embolism (PE) short term; however, IVC filters have been associated with high adverse event rates the longer they remain in place.^{3,4}

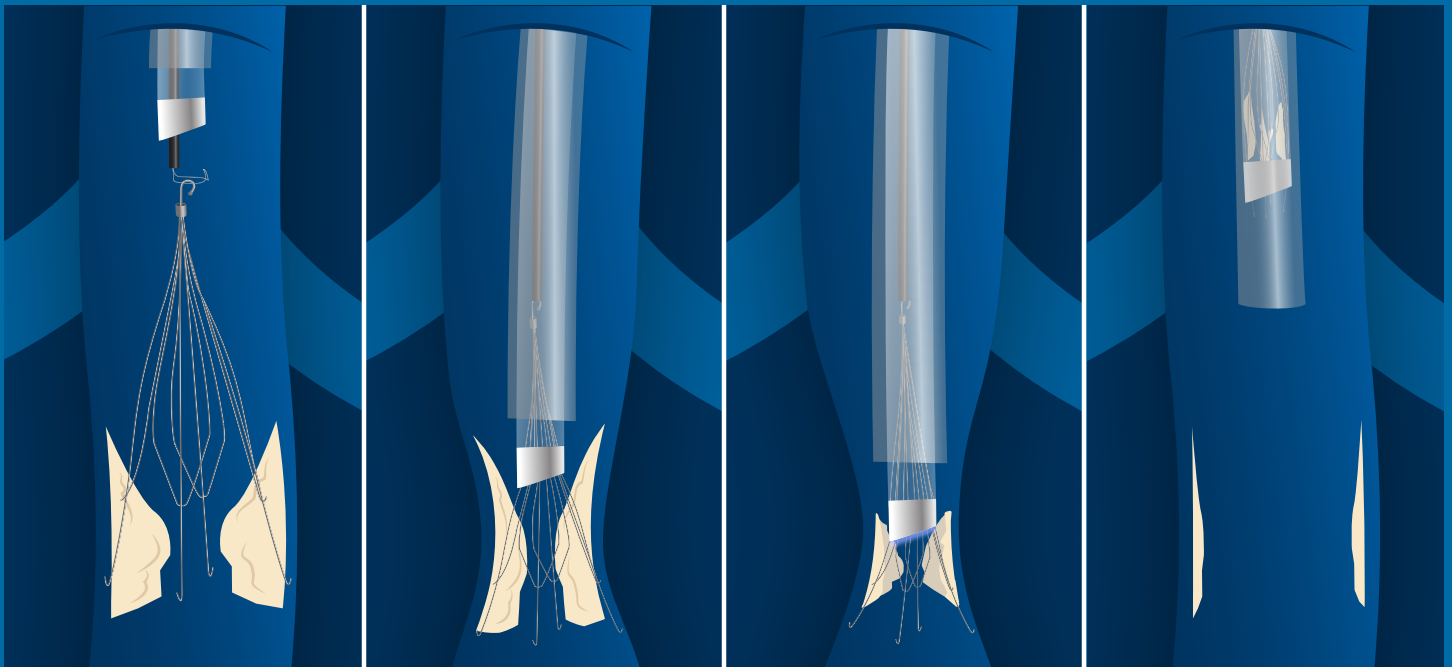
Some of these adverse events and complications include:

- Recurrent deep vein thrombosis (DVT), pulmonary embolism or caval occlusion
- Fracture of filter components, to include embolization/migration of filter components into the heart and lungs
- Perforation of the IVC and adjacent organs, resulting in pain and organ injury
- The potential need for lifelong anticoagulation

For these reasons, the FDA recommends that implanting physicians consider removing retrievable IVC filters as soon as they are no longer indicated.

Laser-precise removals. No matter the dwell time.

Philips IVC Filter Removal Laser Sheath – CavaClear – is the first and only FDA-cleared solution for advanced IVC filter removal. The state-of-the-art laser sheath is designed to safely and predictably ablate scar tissue 360 degrees around an embedded IVC filter to potentially reduce or minimize the risks of complications often seen with chronically implanted filters. The device is designed as an advanced solution to help relieve patients' anxiety⁵ by providing an effective, minimally invasive solution for embedded IVC filters.



Safe

Philips CavaClear can help deliver relief to patients who have embedded filters—with a low risk of complications. CavaClear demonstrated 96-99.4% clinical success and 0.7-2%^{6,7} major adverse event rate.

By using cool ultraviolet laser energy around the embedded IVC filter, it can assist in fast filter capture with low required force.

CavaClear has a penetration depth of just 50 microns, less than the width of a human hair.⁸

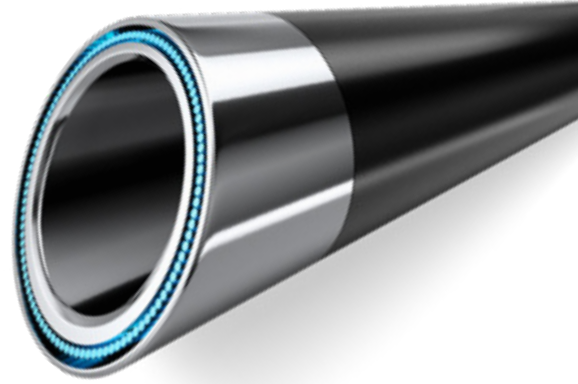
Efficient

Philips CavaClear requires 43% less force than basic removal techniques⁹, with a success rate of up to 99.4%.⁶ Circumferential tissue ablation around the embedded IVC filter can easily capture the filter within seconds of laser activation.¹⁰

CavaClear is a reliable, proven solution to potentially reduce anxiety related to prolonged filter dwell times and give hope to patients with embedded IVC filters.

CavaClear has proven clinical success rates of 96-99.4%.^{6,7}

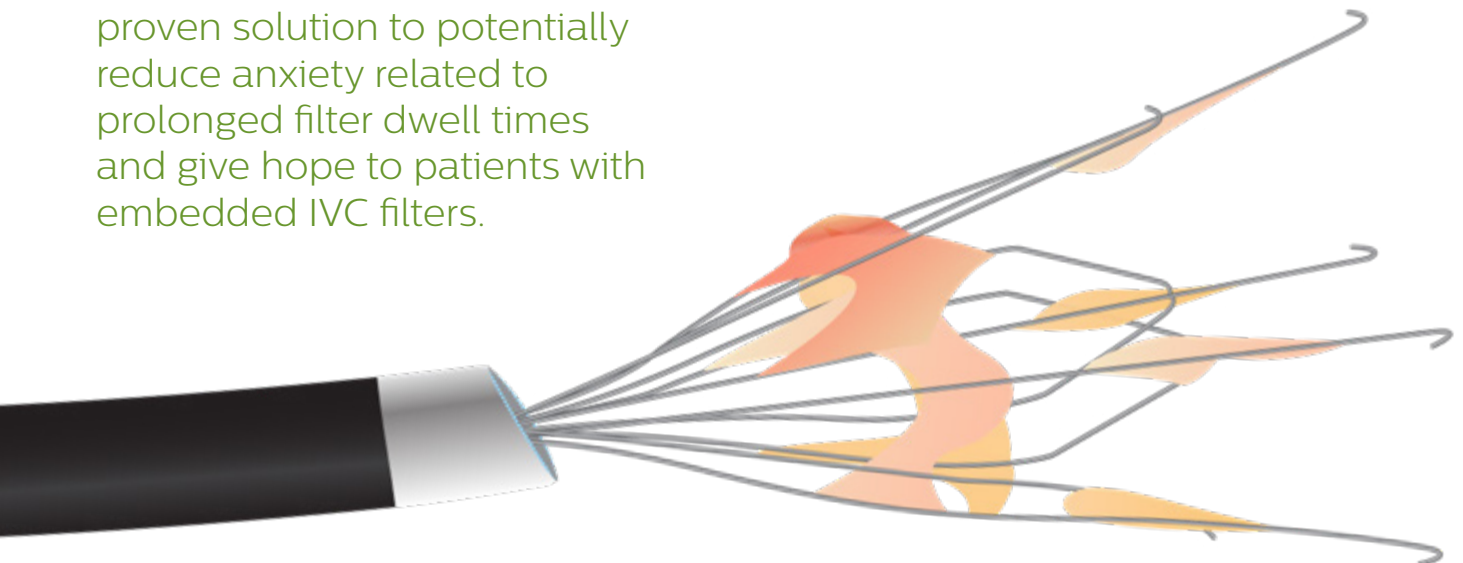
360-degree precise tissue ablation



Controlled

With a beveled tip and laser mechanism of action that does not damage the IVC filter⁸, Philips CavaClear can enhance your control in removal procedures. It's a simple, safe design that's easy to learn and integrate into your workflow.

CavaClear requires 43% less force than standard retrieval techniques.⁹



Philips IVC Filter Removal Laser Sheath – CavaClear

Components



Compatible with
Philips Laser Systems –
Nexcimer and CVX-300



CavaClear plugs into the Philips Laser
Systems – Nexcimer and CVX-300 –
and is available in 14Fr and 16Fr sizes

Ordering information

Model number	500-514	500-516
Sheath size	14Fr	16Fr
Minimum tip inner diameter (Fr/inches/mm)	10.2/0.134/3.40	12.5/0.164/4.17
Maximum tip outer diameter (Fr/inches/mm)	14.7/0.192/4.88	17.2/0.225/5.72
Working length (cm)	50	50
Repetition rate (Hz)	25-80	25-80
Clinical energy setting (mJ/mm)	30-60	30-60

Important safety information

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

Contraindications

When fluoroscopy is not available. When IVC filter is not accessible to the operator or the IVC Filter apex cannot be captured with a compatible endovascular snare or looped wire. When the IVC Filter will not fit into the inner lumen of the Laser Sheath. 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 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. The CVX-300 Excimer Laser or Philips Laser System (PLS) should be used only by physicians who have received adequate training. 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 device 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.

See IFU for complete safety information.

*2021 DRG data calculation

References

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5. Kuo, W. et al. Laser-Assisted Removal of Embedded Vena Cava Filters: A First-In-Human Escalation Trial in 500 Patients Refractory to High-Force Retrieval. Journal of the American Heart Association 9:24, 1-9 (2020).
6. Kuo, W. et al. Laser-Assisted Removal of Embedded Vena Cava Filters: A First-In-Human Escalation Trial in 500 Patients Refractory to High-Force Retrieval. Journal of the American Heart Association 9:24, 1-9 (2020).
7. Desai, K. et al. Excimer Laser Sheath-Assisted Retrieval of “Closed-Cell” Design Inferior Vena Cava Filters. J Am Heart Assoc; 9: e017240 (2020).
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9. Kuo WT, Odegaard JI, Rosenberg JK, Hofmann LV. Laser-assisted removal of embedded vena cava filters: a 5-year first-in-human study. Chest 2017; 151:417–424.
10. Kuo, W. et al. The Excimer Laser Sheath Technique for Embedded Inferior Vena Cava Filter Removal. J Vasc Interv Radiol 2010; 21:1896-1899.

For more information about CavaClear,
contact your Philips representative

