

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



Scan this QR code for additional product details and ordering information.

References

1. Kuo WT, Odegaard JJ, Rosenberg JK, Hofmann LV. Laser-assisted removal of embedded vena cava filters: a 5-year first-in-human study. *Chest* 2017; 151:417–424.
2. Philips data on file - 7030-0619 - Mechanism and Implementation of Catheter-Based Ultraviolet Photoablation.
3. Philips data on file – D052155-00 DVR for Laser Energy Effects on IVC Filters Project 1349
4. Desai, K. et al. Excimer Laser Sheath-Assisted Retrieval of “Closed-Cell” Design Inferior Vena Cava Filters. *J Am Heart Assoc*; 9: e017240 (2020)
5. Desai, K. et al. Safety and Success Rates of Excimer Laser Sheath-Assisted Retrieval of Embedded Inferior Vena Cava Filters. *JAMA Netw Open*. 2022 Dec 1;5(12):e2248159.
6. Health, C. for D. and R. Safety Communications - Removing Retrievable Inferior Vena Cava Filters: FDA Safety Communication. (2014)

Important safety information

Indications for use

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. The CVX-300 Excimer Laser or Philips Laser Shvvsystem (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.

PHILIPS

Laser-precise removals. No matter the dwell time.

- Less force, more control
- Efficiency meets certainty
- Proven for complex removals

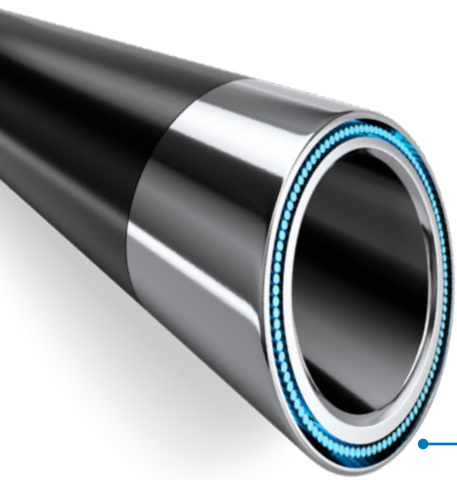


CavaClear IVC Filter Removal Laser Sheath

Less force, more control

Take on complex retrievals with confidence. By requiring 43% less force than standard techniques¹ and penetrating only 50 microns, less than the width of a human hair,² CavaClear delivers precision without compromising safety.

- Promotes patient safety by reducing the mechanical forces needed
- Avoids vessel trauma or filter damage³



360-degree precise tissue ablation

Efficiency meets certainty

Streamline advanced IVC filter retrievals without added complexity. CavaClear's laser-assisted technology reduces force needed for retrieval⁴ and has been shown to capture embedded IVC filters with less than one minute of laser activation,^{*5} helping you finish cases more efficiently and with predictable results.

- Simplifies integration with a design that's easy to learn and adopt,⁴ working seamlessly within laser-enabled endovascular workflows using the Philips Laser System or CVX-300
- Delivers predictable performance that minimizes the risk of complications that could lead to procedural escalation^{1,4}

Proven for complex removals

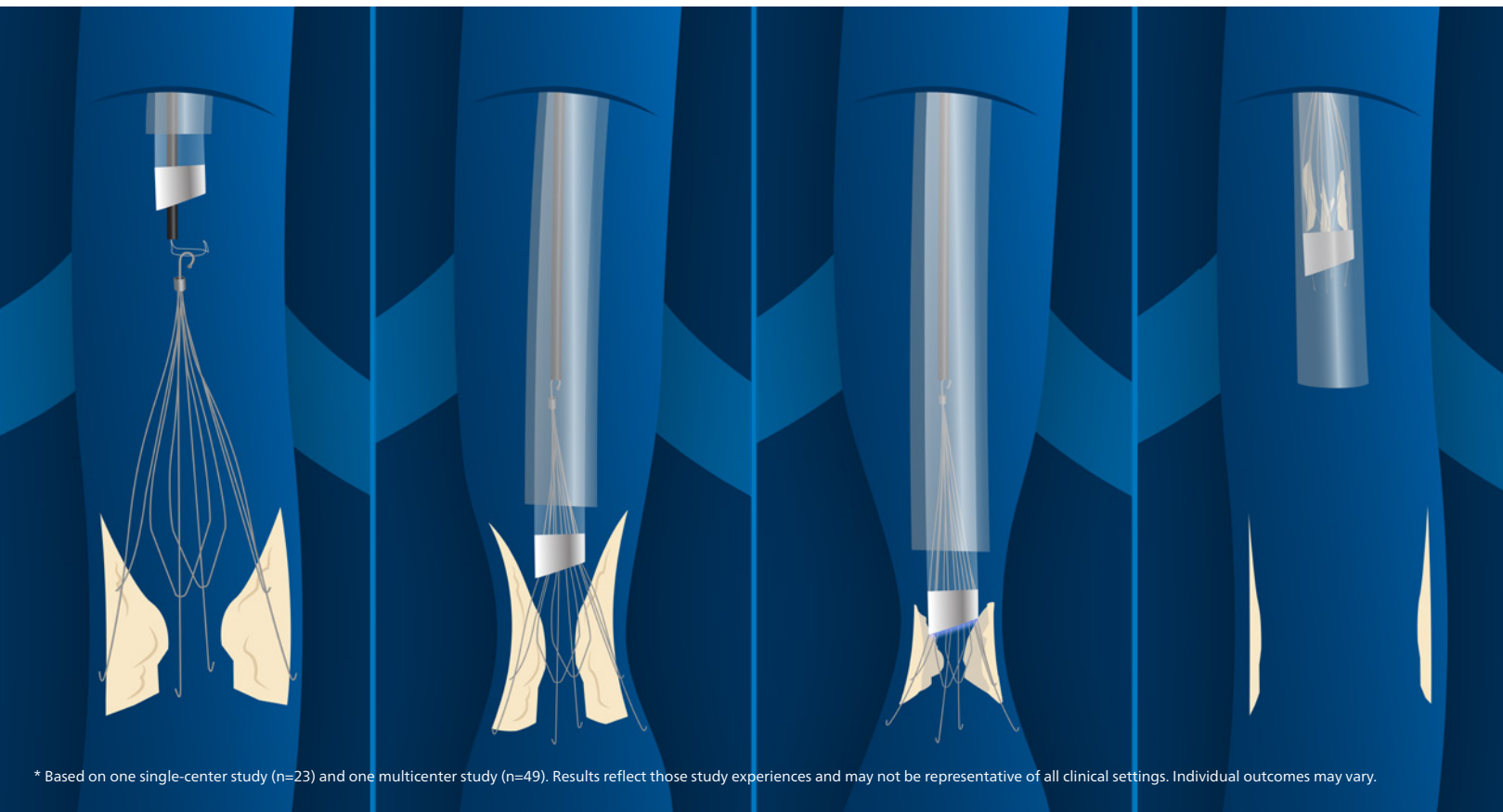
Achieve more predictable IVC filter retrievals, backed by clinical evidence. CavaClear is the first and only FDA-cleared solution for advanced IVC filter removal, delivering proven success in the most challenging cases.

- Gives you confidence in successful outcomes backed by peer-reviewed clinical evidence
- Aligns with FDA guidelines for timely filter removal⁶
- Provides a solution for patients who might otherwise live with an embedded IVC filter

Two independent and prospective clinical studies demonstrated CavaClear's clinical success rates of 96-99.4% with a major adverse event rate of 0.7-2%.^{1,4}

Study	Kuo et al. (2020) ¹ n=500	Desai et al. (2020) ⁴ n=441 (143 with laser assistance)
Success rate	99.4% (497/500)	96% (134/143)*
Mean filter dwell time	50.2 months (range, 1.2–330.3; >27.5 years)	56.6 months, 54.4 among closed-cell filters and 58.5 among open-cell filters (P=0.63)
Major complication rate	2.0% (10/500) (95% CI, 1.0%–3.6%), laser-related complications were 0.6% (3/500) (95% CI 0-1.3%)	3 (0.6%) major adverse events, one of which occurred in a laser-assisted case
Avg. force used during retrieval	6.4 lb during failed attempts without laser vs. 3.6 lb during laser-assisted retrievals (P<0.0001)	Not measured

*Among cases in which laser was not employed, standard retrieval was successful in 39.9% (119/298), with remaining cases requiring advanced retrieval techniques to achieve success.



* Based on one single-center study (n=23) and one multicenter study (n=49). Results reflect those study experiences and may not be representative of all clinical settings. Individual outcomes may vary.