

PHILIPS

Laser System

Nexcimer

Treat more complex conditions faster

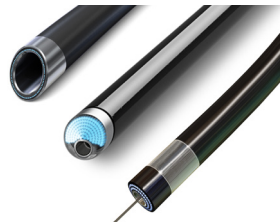
A broad range of applications

The Philips Laser System—Nexcimer—photoablates a wide spectrum of morphologies. Philips laser catheters are indicated in many vessel types and is the only laser system available for lead removal.



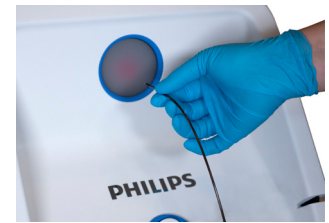
Simple: turn key ready in any room

- Ready in less than 30 seconds
- Touchscreen guided workflows
- 360° maneuverability and small lab footprint
- Powered by standard medical grade 100-240V outlets



Versatile: more vessels, more indications

- Seven indications for coronary vascular
- First technology proven effective for ISR in peripheral vasculature^{1,2}
- Only laser technology for lead removal
- Adjustable fluence and rate settings to optimize impact on various lesion morphologies



Proven: excimer laser technology

- Cool, ultraviolet laser with over 20 years of clinical experience
- More than 600,000³ procedures performed
- Only system compatible with catheters with Level I clinical data for ISR atherectomy¹



Coronary atherectomy

- In-stent restenosis (ISR)⁴
- Moderately calcified lesions
- Ostial lesions
- Lesions that previously failed PTCA
- CTO traversable by guidewire
- Occluded SVG
- Long lesions (> 20 mm)

Specifications

Power requirements	100V-240V, 16 amp, single phase power
Wavelength	308 nm
Class	Class IV laser system
Length	52 in / 132 cm
Height	42 in / 107 cm
Width	19 in / 48 cm
Weight	480 lb / 217.7 kg
Product number	LAS-100

Important safety information Philips Laser System—Nexcimer

The Philips Laser System is used in minimally invasive interventional procedures within the cardiovascular system and for the removal of problematic pacemaker and defibrillator cardiac leads. The Philips Laser System produces pulsed excimer radiation, which is delivered to the target site with proprietary fiber optic catheter technology, or other approved instruments or accessories, to complete the system.

For information on indications, contraindications, adverse events, and other important safety information, refer to the individual instructions for use that accompanies the Philips fiber-optic catheters.

Warnings and precautions

Important: Read the Operator's Manual thoroughly before operating the system. Pay particular attention to the notes, cautions, and warnings throughout the manual to ensure safe operating conditions at all times. Also, refer to the Instructions for Use that accompanies the Philips fiber-optic catheters. Indications and contraindications are included in the individual instructions for use for the catheters.

Warnings

- The Philips Laser System contains a Class IV laser that produces an invisible beam of high-energy ultraviolet radiation. Improper use of the system could result in serious personal injury. Observe all safety precautions for use of Class IV laser equipment.
- The system contains high voltages, which are potentially lethal. To avoid electrical shock, do not



Peripheral atherectomy

- In-stent restenosis (ISR)²
- Mixed morphologies
- Uncrossable CTOs
- Long lesions
- Thrombotic lesions



Lead extraction

- Manage every lead
- Adjust from 25 Hz to 80 Hz based on anatomical and procedural considerations
- Advance up to 62% more efficiently through tough binding sites⁵
- Use up to 55% less advancement force⁶

open the system cabinet. Internal maintenance must be performed solely by a certified field service engineer.

- The system is not intended to be used during a defibrillation event.
- Skin exposure to excimer radiation should be avoided
- Possible explosion hazard if used in the presence of flammable anesthetics.

Notice

- The system is intended for use only by licensed physicians. All persons who operate and service the system must be properly trained.
- The system contains a gas mixture that is 0.05% HCl, a respiratory irritant. To avoid injury, only a trained and certified field service engineer should handle the laser gas.

Safety precautions

- The laser system must be operated only by trained personnel.
- Always wear safety glasses with an Optical Density ≥ 9 @ 308 nm for eye protection against laser radiation.
- Establish a controlled-access laser operating area to limit access to persons instructed in the safe operation of lasers.
- Post "Laser in operation" warning signs at all entries to the laser operating area.
- Persons in the laser operating area including doctors, nurses, observers and the patient must wear the appropriate protective eyewear and protective gloves.

- Never look directly into the laser beam.
- Avoid uncontrolled reflections of the laser beam.
- Skin exposure to excimer laser radiation should be avoided.
- Do not allow direct or reflected laser radiation to go beyond the laser operating area.
- When not in use, the laser system should be protected against unauthorized use by removing the key.
- Special precautions are required regarding the Electromagnetic Compatibility (EMC) of the Philips Laser System. Refer to the user manual for details.

Caution: Federal law restricts this device to sale by or on the order of a physician.

1. Dippel et al. Randomized Controlled Study of Excimer Laser Atherectomy for Treatment of Femoropopliteal In-stent Restenosis: Initial ISR Results (2015). JACC 8(1): 92-101.
2. Turbo-Power is indicated for use in ISR.
3. Internal sales data.
4. Non X-80 ELCA models are indicated for use in ISR.
5. Comparison of average peak push forces required to advance Laser Sheath at 40 Hz vs. 80 Hz Pulse Repetition Rate through simulated fibrosis material at an advancement rate of 1.0 mm/second. Data on file at Philips, D015722.
6. Comparison of ablation force vs. advancement rate of laser sheath 40 Hz vs. 80 Hz by use of the data collected in D015786. Data on file at Philips.

