
THIS CHANGES
EVERYTHING
AURYON



CONQUERING DISEASE WITH SCIENCE

Designed to treat the full spectrum of peripheral artery disease (PAD).

ADAPTABLE

Treats all levels of calcification[1-4]

- Cleared for in-stent restenosis*
- Treats infrainguinal lesions both above and below the knee (including below the ankle)
- Built-in off-centering mechanism for eccentric lesions in largest catheter
- Nonreactive to contrast media for simultaneous ablation and observation of fluoroscopy image

*Only the 2.0- and 2.35-mm catheters are cleared for in-stent restenosis (ISR).

PRECISE

Protective of the vessel wall[1-3,5-8]

- Performs targeted biological reactions to address risk of perforations
- Wavelength produces a photon energy that's hard on calcium and soft on vessel walls
- Vaporizes lesions without thermal ablation
- Can treat any lesion
- Built-in aspiration† addresses risk of embolization

†2.0- and 2.35-mm catheters.

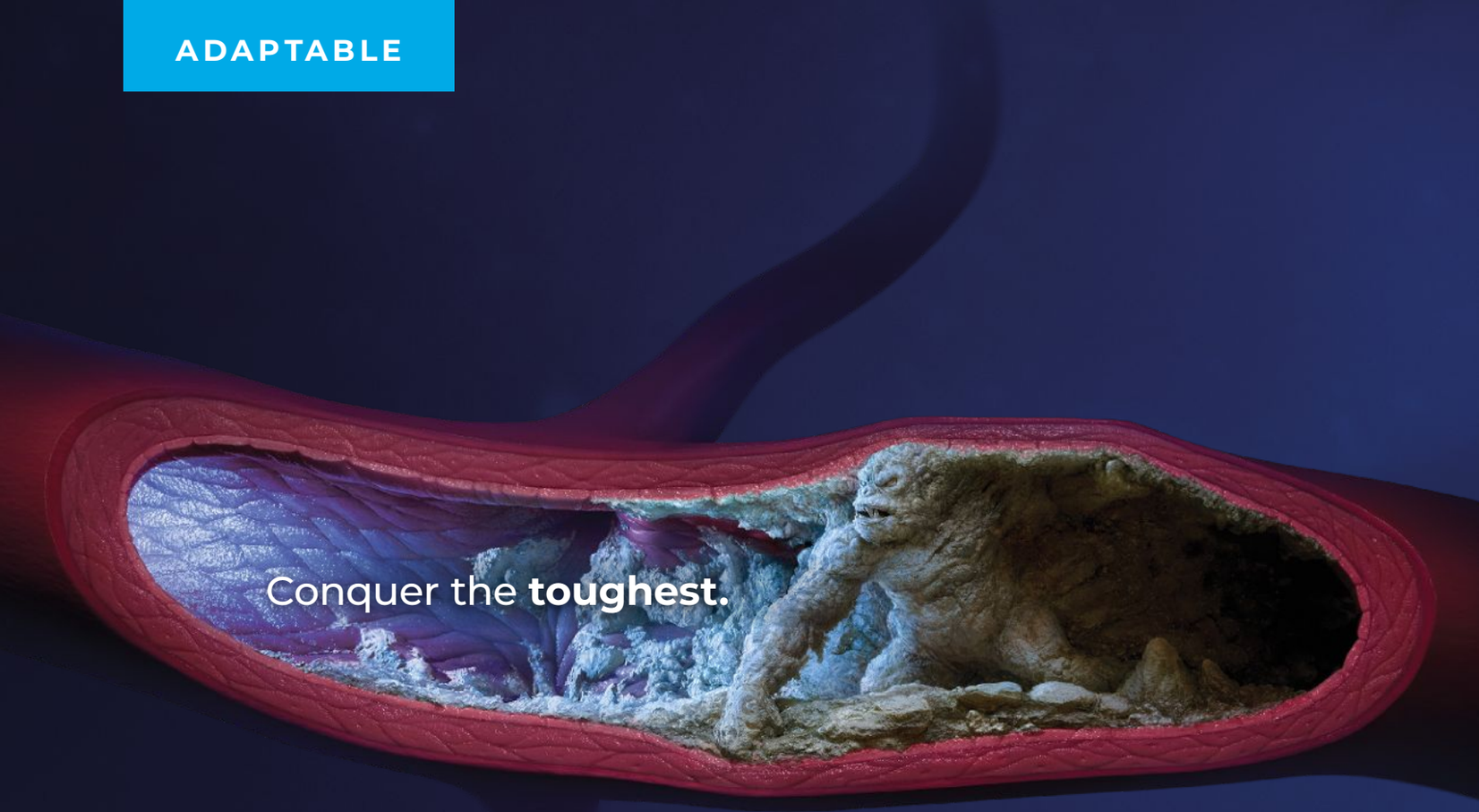


EFFICIENT

Performance designed for your lab[1-3,9]

- Defines a new standard in efficacy and safety outcomes
- Has the potential to debulk in fewer passes
- Small footprint, unparalleled portability, and simple storage
- Easy installation, using a 110V outlet, touchscreen, and low acoustic noise

ADAPTABLE



Resiliency in the face of all lesions

The Auryon System can handle it.

- Clinical trials have shown the Auryon System can clear even the most calcified lesions[1,2]
- Any lesion you encounter can be ablated without harming the vessel wall[1]



Built-in aspiration* addresses risk of embolization[3]



Nonreactive to contrast media for simultaneous ablation and observation of fluoroscopy image[4]

*2.0- and 2.35-mm PAD catheter.

Treat any infrainguinal artery

Purpose-built hydrophilic catheters are designed to treat both above and below the knee, including the ankle.[3]



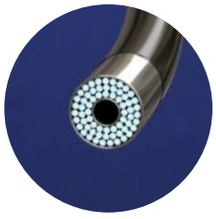
2.35-mm catheter

- Reference vessel diameter: ≥3.6 mm^2
- Built-in aspiration capability
- Off-centering mechanism
- Cleared for ISR and arterial thrombectomy
- French size 7 Fr



2.0-mm catheter

- Reference vessel diameter: ≥3.0 mm^2
- Built-in aspiration capability
- Cleared for ISR and arterial thrombectomy
- French size 6 Fr



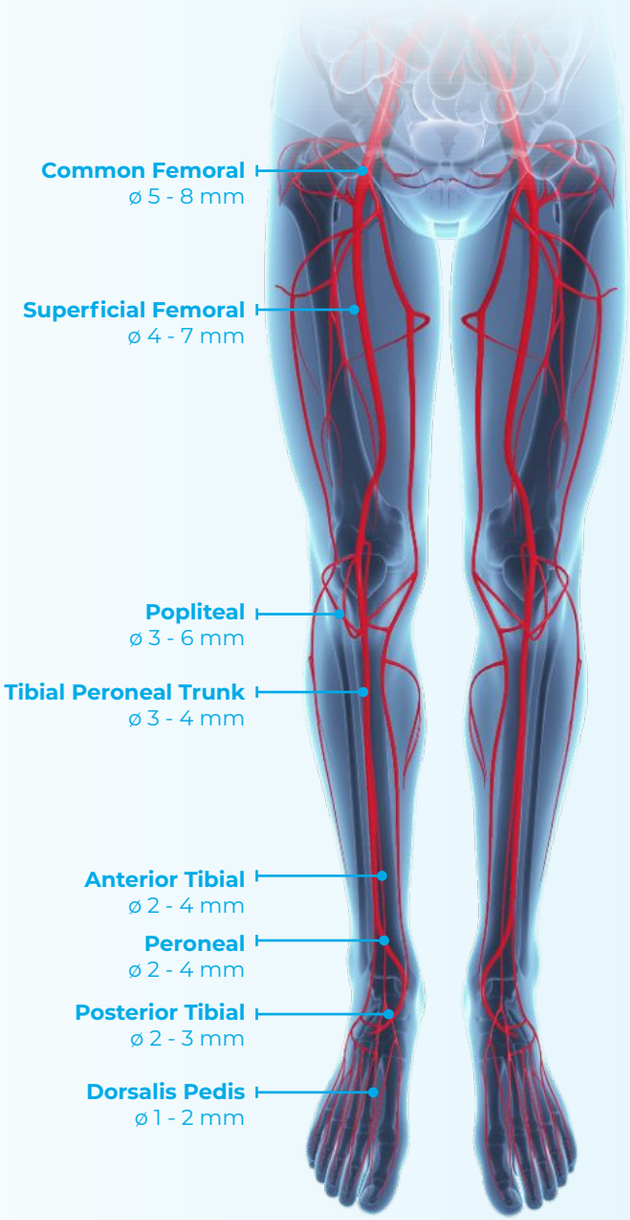
1.5-mm catheter

- Reference vessel diameter: ≥2.25 mm^2
- Below the knee
- French size 5 Fr



0.9-mm catheter

- Reference vessel diameter: ≥1.4 mm^2
- French size 4 Fr



All catheters work over a standard 0.014-inch guide wire.[3]

AURYON

PRECISE

Optimal waveform technology unlike any other

The Auryon System is designed to deliver an optimized wavelength and pulse width to remove all lesions while helping to preserve vessel wall endothelium.



AURYON



A longer wavelength that enables you to be hard on calcium and soft on vessel walls[6]



Powerful pulses so short, there's no time to damage vessel walls[1,6,7]

For illustrative purposes only.

Wavelength & photon energy

The Auryon System's 355-nm wavelength has a lower photon energy (3.5 eV) than a 308-nm wavelength, which allows the Auryon System to target plaque while preserving the vessel wall; a 308-nm wavelength lacks this distinction.[6]

Pulse width

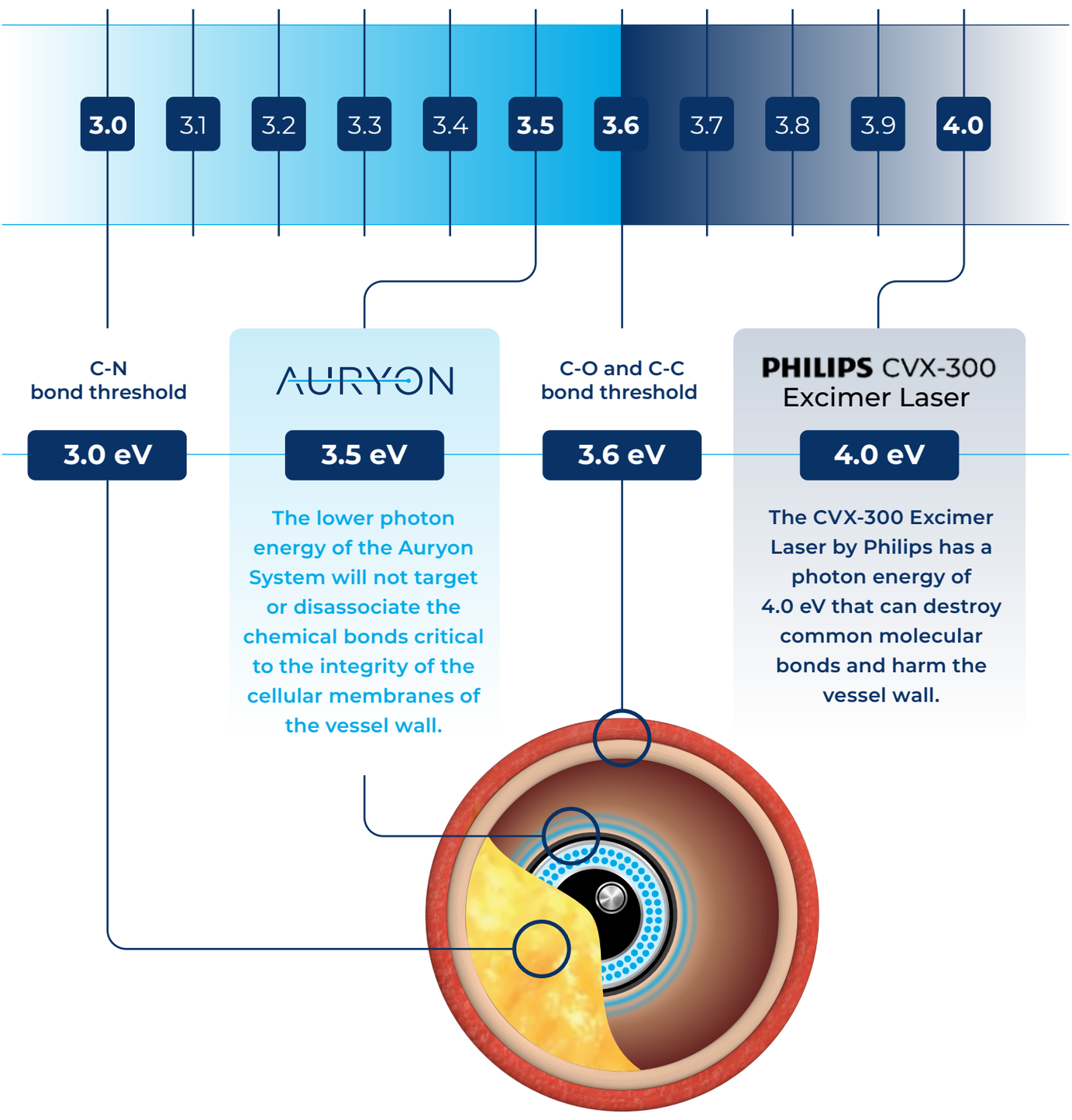
The Auryon System's modified pulse allows for enhanced ablation by separating into pulse segments. The modified pulse configuration provides optimized energy delivery for plaque removal.[10]

*Compared to single peak waveform lasers.

Target the lesion, spare the vessel

The Auryon System's 3.5 eV photon energy allows it to spare chemical bonds (C-C and C-O) found in the vessel wall.[6]

Key chemical bonds found in the vessel



Deliver a powerful, efficient pulse

The Auryon System focuses energy where it counts to manage patient risk.

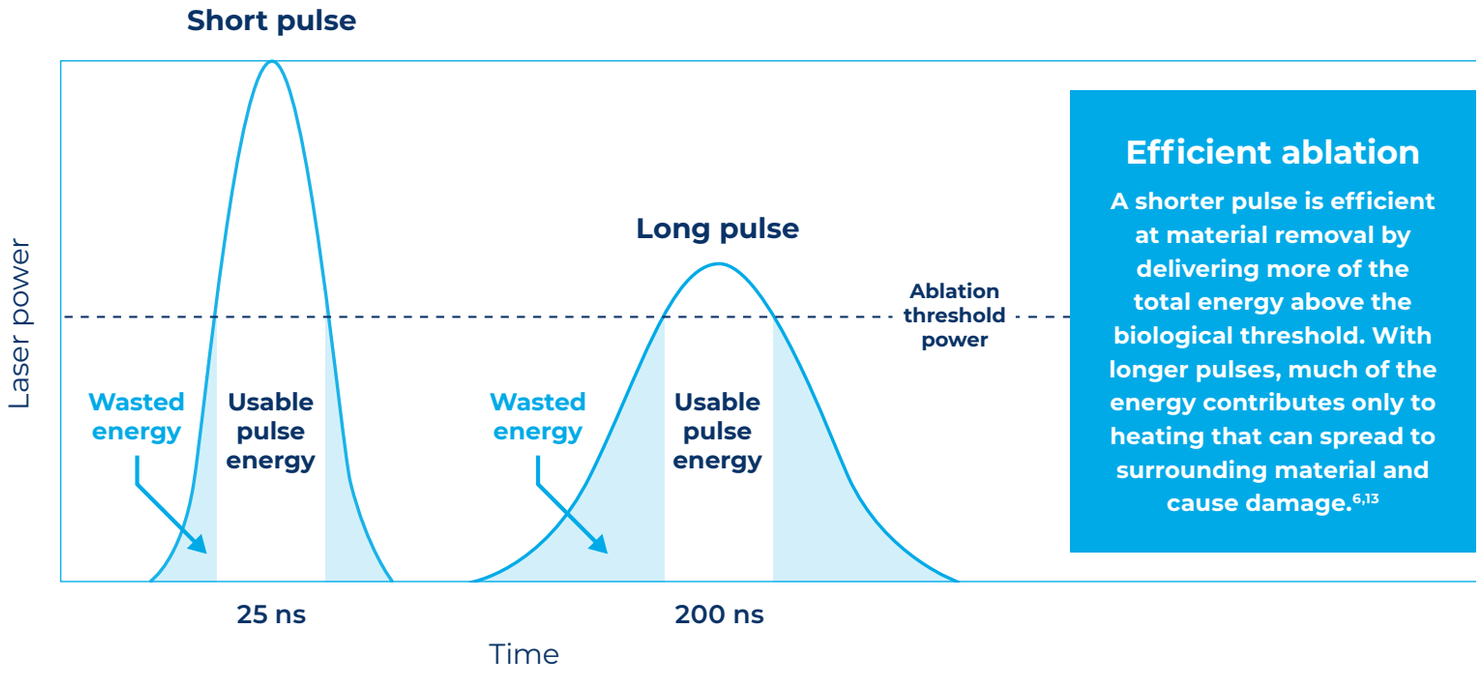
- Pulse widths that are an order of magnitude shorter than the Philips CVX-300 Excimer Laser, allowing for[11]:
  - Tissue relaxation between bursts, depositing energy before thermal diffusion can occur[6-8]
  - High-power pulsed energy[11]
  - Increased photo-mechanical impact on calcified tissue[12]

Calculating "on" time: pulse rate x pulse width

The Auryon System
40 Hz x 25 ns = 1000 ns

Philips CVX-300 Excimer Laser
40 Hz x 200 ns = 8000 ns

8x more efficient

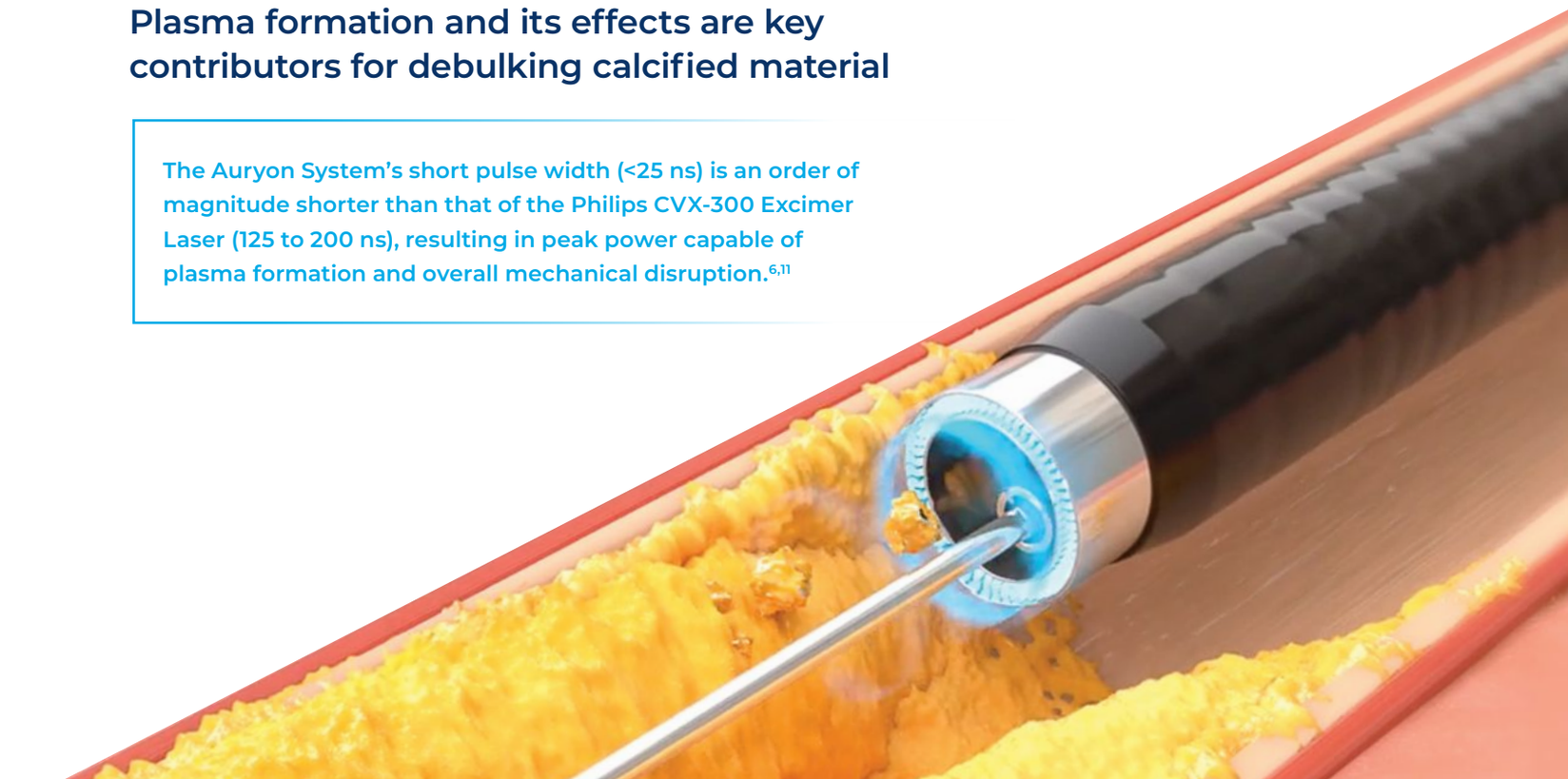


Efficient ablation

A shorter pulse is efficient at material removal by delivering more of the total energy above the biological threshold. With longer pulses, much of the energy contributes only to heating that can spread to surrounding material and cause damage.[6,13]

Plasma formation and its effects are key contributors for debulking calcified material

The Auryon System's short pulse width (<25 ns) is an order of magnitude shorter than that of the Philips CVX-300 Excimer Laser (125 to 200 ns), resulting in peak power capable of plasma formation and overall mechanical disruption.[6,11]

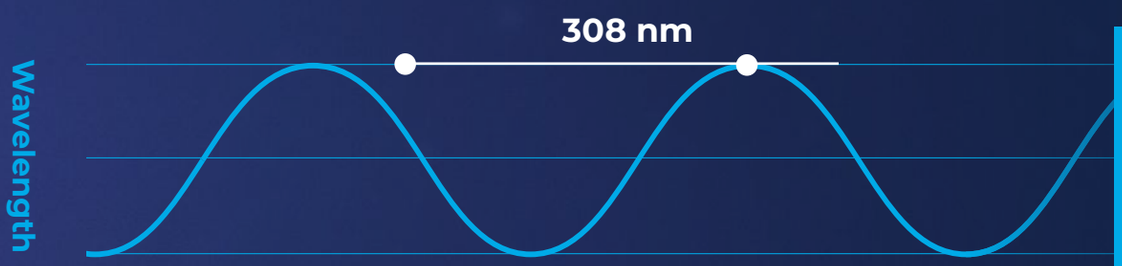


Different science, different outcomes

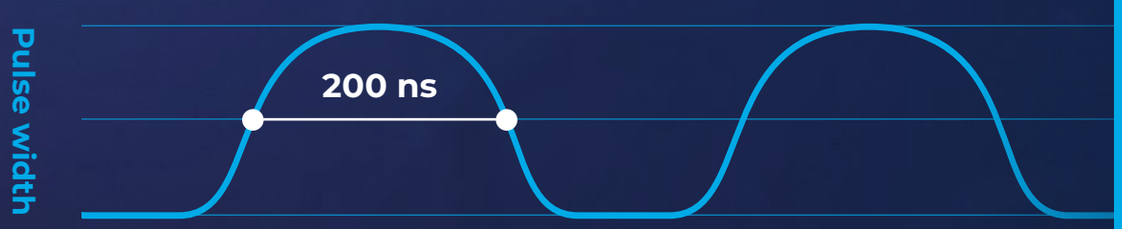
Laser atherectomy devices are not created equal: There are tangible scientific differences between the Auryon System and Philips CVX-300 Excimer Laser.



PHILIPS CVX-300 Excimer Laser



A shorter wavelength that doesn't distinguish between calcium and vessel walls[6]



Longer, inefficient pulses can potentially put vessel walls at risk[6]

The Auryon System's shorter pulse width and longer wavelength give it the ability to treat any lesion you encounter, potentially with less damage

EFFICIENT

97 patients. 107 lesions. No problem.

The Auryon System demonstrated clinically proven performance in a broad range of disease severity.

A multinational pivotal trial* involved 97 symptomatic (Rutherford 2-4) patients with PAD (107 lesions) from both office-based labs and hospitals.[1,2]

PATIENT AND LESION CHARACTERISTICS[1]	
74%	femoral, 8% popliteal, and 18% tibial
22%	occluded
21%	restenotic
86%	stenotic
77%	had calcification *38% had moderate to severe calcium*

KEY 6-MONTH CLINICAL EFFICACY RESULTS[1,2]	
31% TO 38%	reduction in stenosis prior to any adjunctive therapy **regardless of calcification level, lesion type, lesion length, or catheter used†** *17.7% final stenosis after percutaneous transluminal angioplasty (PTA)*
3%	of lesions had clinically driven target lesion revascularizations (CD-TLRs) *0 TLRs were ISR*
93%	of patients showed improvement in Rutherford *2-point average improvement*

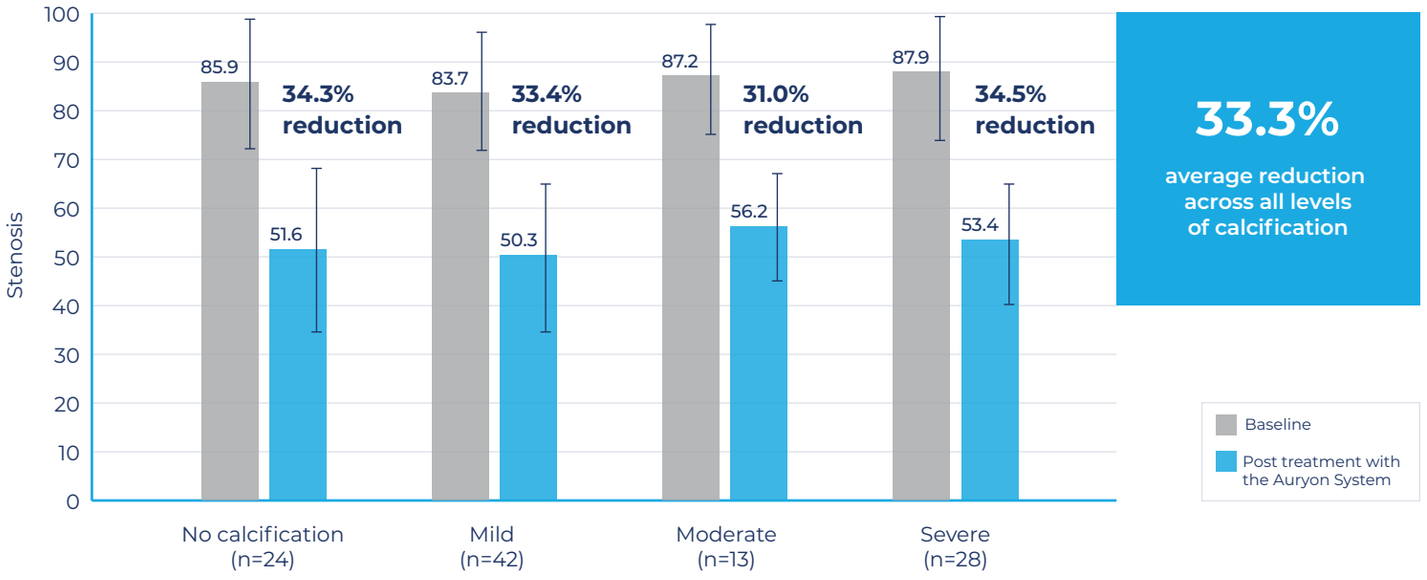
Studied in a real-world patient population[2]

Population included patients with comorbidities, including 42% with diabetes.[1]

Consistency despite calcification

Improvements in stenosis and patency were consistent across all levels of calcification and types of lesions.[1,2]

Comparable reduction in stenosis regardless of calcification level[1]



33.3%
average reduction across all levels of calcification

Individual results may vary.



Low incidence of adverse events 6 months post procedure

Key 6-month safety results – 107 lesions[1]

0%	0%	0%	3%	1%
Flow-limiting dissections	Device-related complications requiring intervention	Distal embolizations	CD-TLRs; none were ISR	Major adverse event (non-device-related death)

The Auryon System helps address the risks of atherectomy, delivering power and precision that targets the lesion and spares the vessel.

*__Study design__[1]: EX-PAD-03 (clinicaltrials.gov identifier: NCT03157531) was a pivotal study under investigational device exemption from the FDA. EX-PAD-03 was a prospective, single-arm, international, multicenter, open-label clinical study that assessed the safety and efficacy of the Auryon System in subjects with symptomatic (Rutherford 2-4) infrainguinal PAD at 8 US and 3 EU sites.

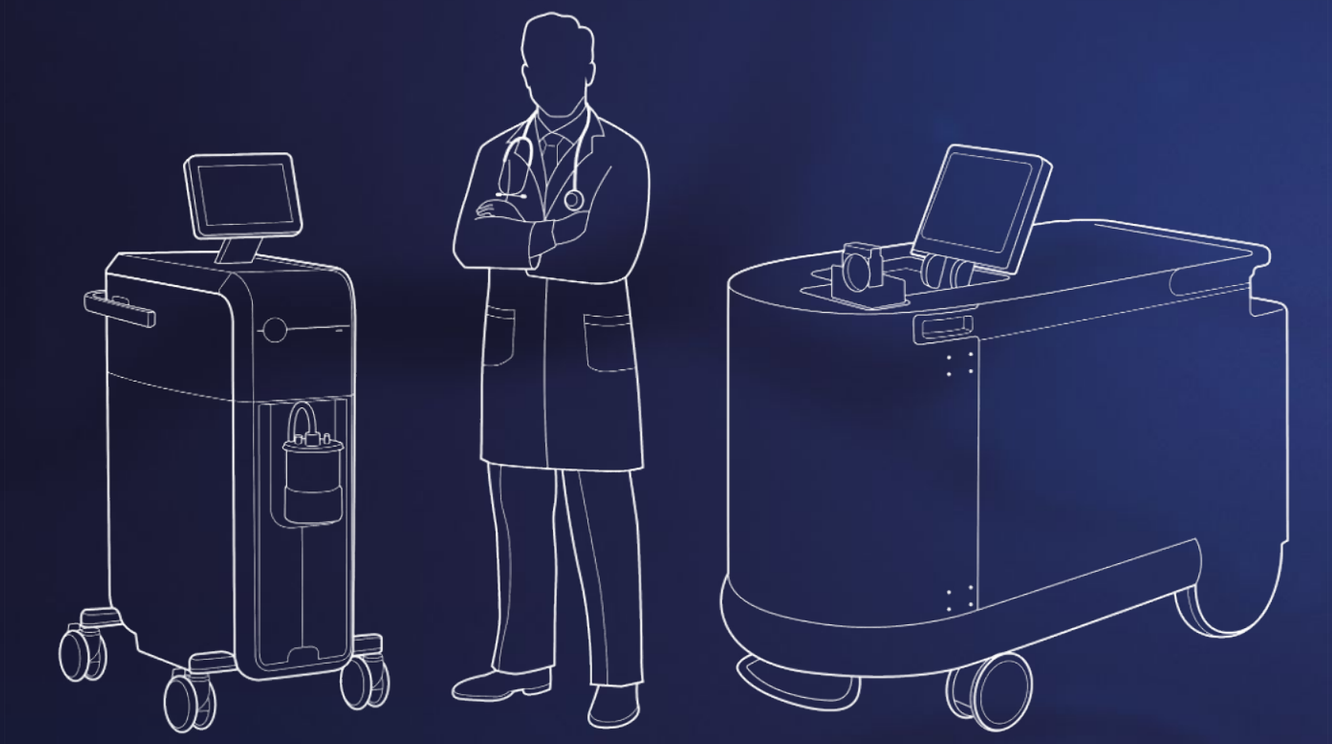
†Segments analyzed by Core Lab and included calcification level: none, mild, moderate, severe; lesion type: general, ISR, chronic total occlusion (CTO), severe calcification; lesion length: 0-50 mm, 51-100 mm, 101-150 mm, 151-250 mm; catheter: 0.9+1.5 mm, 2.0 mm, 2.35 mm.

AURYON

EFFICIENT

The Auryon System is like no other

It's a big deal in an efficient package.



AURYON

Weight	Length	Height	Width
180 lb	24 in	42.5 in	13.3 in

Wavelength

355 nm class IV laser system

Power type

110V wall outlet

Aspiration capability

2.0 mm and 2.35 mm

Efficient, portable, quiet, and easy to operate.

PHILIPS CVX-300 Excimer Laser

Weight	Length	Height	Width
650 lb	49 in	41.9 in	24 in

Wavelength

308 nm class IV laser system

Power type

208-230 VAC single phase power US wall outlet receptacle NEMA L6-30R, Hubble Part # HBL2620, 250BAC, 30A, wall mount twist lock

Aspiration capability

N/A

Conquer every lesion you encounter with the most advanced peripheral atherectomy technology ever: **The Auryon System**



Clear all lesion types, including ISR, **with a single device**



Revolutionize how you treat, **above and below the knee**



Practice with confidence by **minimizing the risk of embolization**

Experience the Science and Safety at **Auryon-System.com**

RISK INFORMATION

Caution: Federal (USA) law restricts the use of the system by or on the order of a physician.

Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications prior to use of the product.

Indications for Use:

The Auryon Atherectomy System and Auryon Atherectomy Catheters with aspiration are indicated for use as atherectomy devices for arterial stenoses, including in-stent restenosis (ISR), and to aspirate thrombus adjacent to stenoses in native and stented infra-inguinal arteries.

The Auryon Atherectomy System and Auryon Atherectomy Catheters without aspiration are indicated for use in the treatment, including atherectomy, of infra-inguinal stenoses and occlusions.

Warnings:

- The AURYON Atherectomy System is a Class IIb medical device which contains a Class IV laser that produces an invisible beam of high-energy ultraviolet radiation. Improper use of the AURYON Atherectomy System could result in serious personal injury. Observe all safety precautions for use of Class IV laser equipment.
- The AURYON Atherectomy System contains high voltages which are potentially lethal. To avoid electrical shock, do not open the AURYON Atherectomy System cover. Internal maintenance of the system must be performed only by personnel from AngioDynamics.
- Ensure the system is connected to the proper voltage. The voltage rating is marked on the back panel of the laser controller. Operating the system at the incorrect voltage may result in damage to the system units.
- The system is not intended to be used during a defibrillation event.
- Skin exposure to laser radiation should be avoided.
- Possible explosion hazard if the laser is used in the presence of flammable anesthetics or other solutions and gases. The laser beam may ignite solvents of adhesives and flammable solutions. Allow flammable materials to evaporate before the laser is used.
- Only catheters approved by AngioDynamics are allowed to be used in the AURYON Atherectomy System. AngioDynamics supplies sterile fiber optic catheters. Sterility is guaranteed only if the package is unopened, undamaged and before the expiry date.

Warnings (continued):

- Pay attention when handling the AURYON OTW catheter to ensure that the fibers at the distal and proximal ends are not damaged.
- When moving the AURYON Atherectomy System be careful to avoid crashing or sudden impacts. Before moving the system, release the wheels from locking, disconnect the footswitch pedal cable from its connector in the laser system and place the footswitch pedal in the rear storage compartment. After the system is positioned for use, lock the wheels, take out the footswitch pedal from the rear storage compartment, connect the footswitch pedal cable to the laser system and place the footswitch pedal on the floor.
- The safety and effectiveness of the catheters (including the coated ones) has not been established, or is unknown, in vascular regions other than those specifically indicated.
- Use caution when manipulating, advancing and/or withdrawing the catheter through needles, metal cannulas, stents, or other devices with sharp edges, or through tortuous or calcified blood vessels. Manipulation, advancement, and/or withdrawal past sharp or beveled edges may result in destruction and/or separation of the outer coating, which may lead to clinical adverse events requiring additional intervention, resulting in coating material remaining in the vasculature or device damage.

Adverse Events:

As with the use of similar therapies, the following potential complications may occur with the use of this catheter, accessories and adjunctive therapies (Balloon/stent). These complications may include but are not limited to:

- Serious Adverse events: Death, re-intervention, ALI, major amputation, bypass surgery, hematoma with surgery, stroke
- Procedural Complications: Spasm, major dissection, thrombus, distal embolization, perforation
- In hospital complications: Re-occlusion, pseudoaneurysm, renal failure, bleeding, sterile inflammation or granulomas at the access site
- Other AEs: Nerve injury, AV fistula formation, infection, MI, arrhythmia, pulmonary embolism/infarct

References: 1. Rundback J, Chandra P, Brodmann M, Weinstock B, Sedillo G, Cawich I, et al. Novel laser-based catheter for peripheral atherectomy: 6-month results from the Eximo Medical B-Laser™ IDE study. *Catheter Cardiovasc Interv.* 2019;1-8. **2.** Shammas NW, Chandra P, Brodmann M, Weinstock B, Sedillo G, Cawich I, et al. Acute and 30-day safety and effectiveness evaluation of Eximo Medical's B-Laser™, a novel atherectomy device, in subjects affected with infrainguinal peripheral arterial disease: results of the EX-PAD-03 trial. *Cardiovas Revasc Med.* 2020;21(1):86-92. **3.** Auryon. Instructions for use. AngioDynamics; 2019. **4.** Herzog A, Steinberg I, Gaisenberg E, Nomberg R, Ishaaya AA. A route to laser angioplasty in the presence of fluoroscopy contrast media, using a nanosecond-pulsed 355-nm laser. *IEEE J Sel Top Quantum Electron.* 2016;22(3):342-347. **5.** Herzog A, Bogdan S, Glikson M, Ishaaya AA, Love C. Selective tissue ablation using laser radiation at 355 nm in lead extraction by a hybrid catheter; a preliminary report. *Lasers Surg Med.* 2016;48(3):281-287. **6.** Vogel A, Venugopalan V. Mechanisms of pulsed laser ablation of biological tissues. *Chem Rev.* 2003;103(2):577-644. **7.** Akkus NI, Abdulbaki A, Jimenez E, Tandon N. Atherectomy devices: technology update. *Med Devices (Auckl).* 2015;8:1-10. **8.** Cross FW, Bowker TJ. The physical properties of tissue ablation with Excimer lasers. *Med Instrum.* 1987;21(4):226-230. **9.** Kuczmik W, Kruszyna L, Stanisic MG, et al. Laser atherectomy using the novel B-laser catheter, for the treatment of femoropopliteal lesions: twelve-month results from the EX-PAD-01 study. Not yet published. **10.** Data on file. AngioDynamics. **11.** Herzog A, Oszkinis G, Planer D, et al. Atherectomy using a solid-state laser at 355 nm wavelength. *J. Biophotonics.* 2017;10(10):1271-1278. **12.** Herzog A, Steinberg I, Ishaaya A. Shaping photomechanical effects in tissue ablation using 355 nm laser pulses. *J Biophotonics.* 2016;1-9. **13.** Photonics Media. Shorter pulse widths improve micromachining. https://www.photonics.com/Articles/Shorter_Pulse_Widths_Improve_Micromachining/a54123. Published June 2013. Accessed March 20, 2020.

Call 1-800-772-6446 (OPT 2) to order components for the Auryon System

Now with Hydrophilic Coating

Part Number	Description	French size	UOM	QPB
EXM-2001-1100	Laser System Auryon Atherectomy 100-120 VAC		BX	1
EXM-4002-H000	Catheter Auryon Atherectomy 0.9 mm	4 Fr	EA	1
EXM-4001-H000	Catheter Auryon Atherectomy 1.5 mm	5 Fr	EA	1
EXM-4003-H000/US	Catheter Auryon Atherectomy 2.0 mm with disposable liner and vacuum tubing	6 Fr	EA	1
EXM-4004-0000/US	Catheter Auryon Atherectomy 2.35 mm with disposable liner and vacuum tubing	7 Fr	EA	1

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