THIS CHANGES **EVERYTHING**

AURYON

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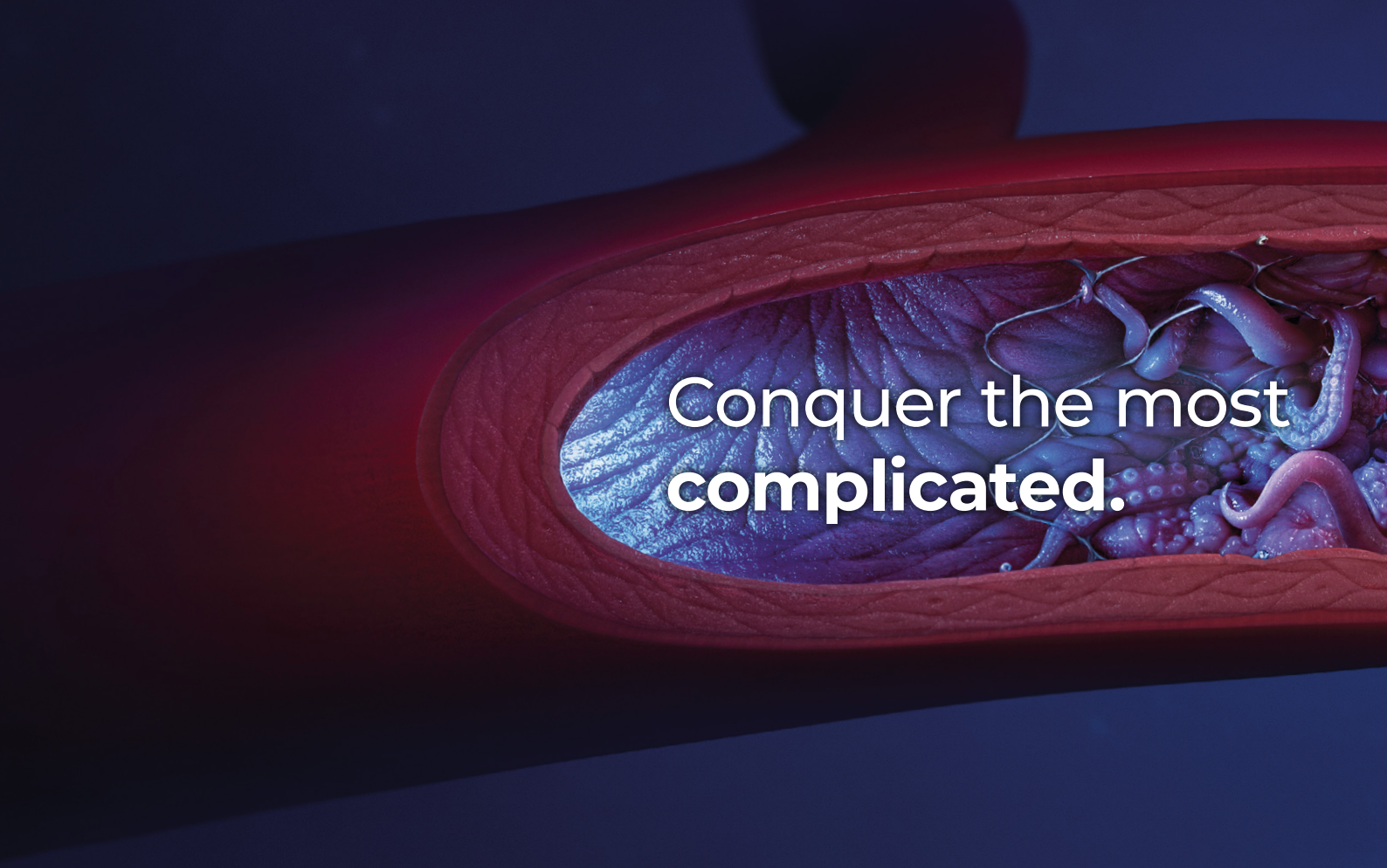

CONQUERING DISEASE WITH SCIENCE

Designed to treat the full spectrum of peripheral artery disease (PAD).[1-3]

ADAPTABLE

Treats all levels of calcification[1-4]

- Indicated for in-stent restenosis (ISR) and can be used to treat patients with acute limb ischemia (ALI)*
- Treats infrainguinal lesions both above and below the knee (including below the ankle)
- Nonreactive to contrast media for simultaneous ablation and observation of fluoroscopy image

*Only the 2.0- and 2.35-mm catheters are indicated for ISR and to aspirate thrombus adjacent to a stenosis.

PRECISE

Protective of the vessel wall[1-3,5,6]

- 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
- Built-in aspiration† addresses risk of embolization

†2.0- and 2.35-mm catheters.

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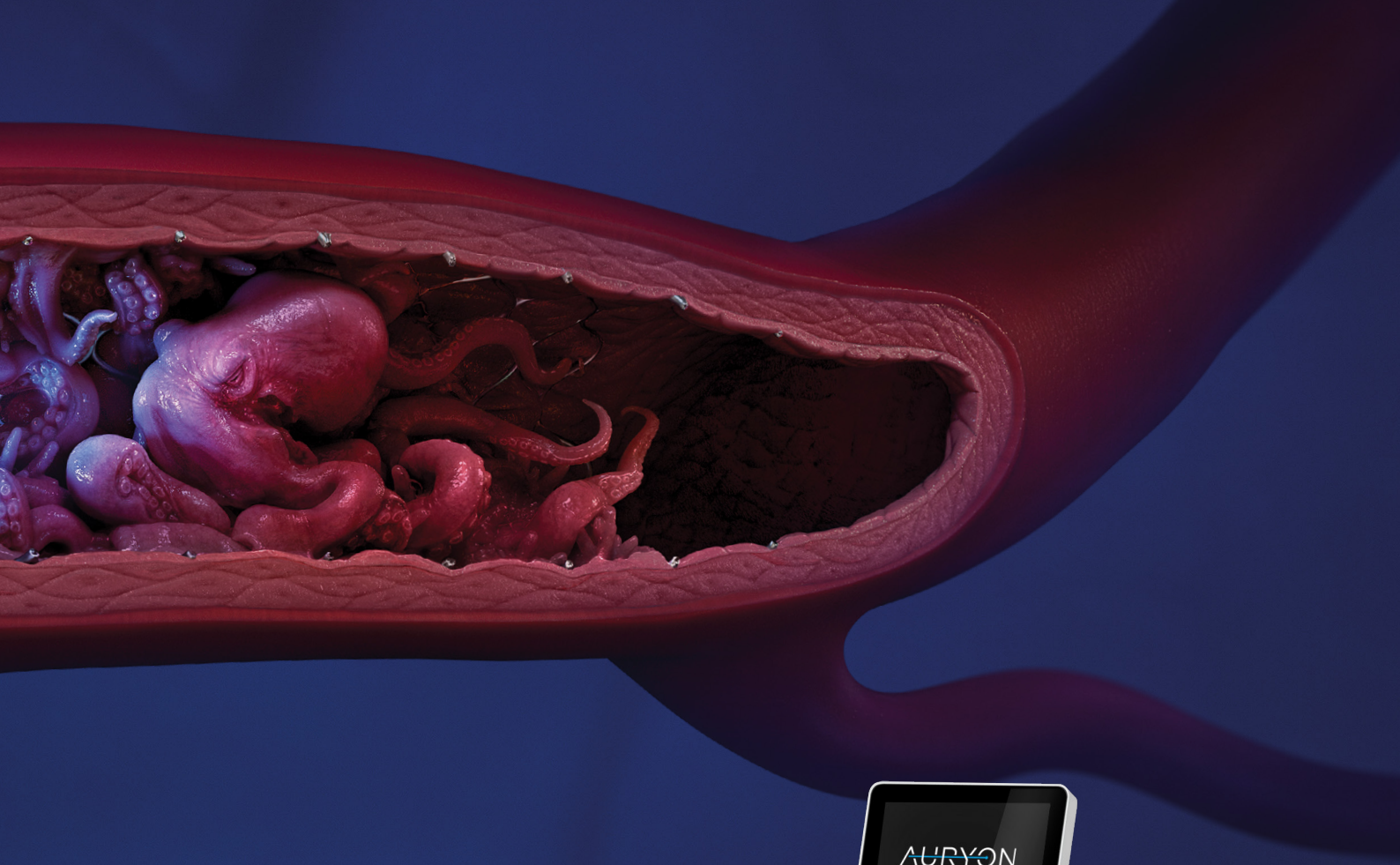

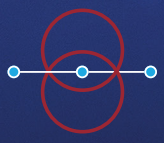

EFFICIENT

Performance designed for your lab[1-3]

- 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 220V outlet, touchscreen, and low acoustic noise

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ADAPTABLE

Treat any infrainguinal artery[1-3,12]

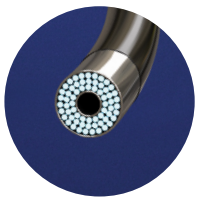
Purpose-built hydrophilic catheters are designed to treat both above and below the knee, including the ankle, through femoral or pedal access.

2.35-mm catheter

- Reference vessel diameter: ≥3.6 mm
- Built-in aspiration capability
- Off-centering mechanism
- Cleared for ISR and to aspirate adjacent thrombus
- Sheath size 7 Fr
- Working length 110 cm

2.0-mm catheter

- Reference vessel diameter: ≥3.0 mm
- Built-in aspiration capability
- Cleared for ISR and to aspirate adjacent thrombus
- Sheath size 6 Fr
- Working length 135 cm

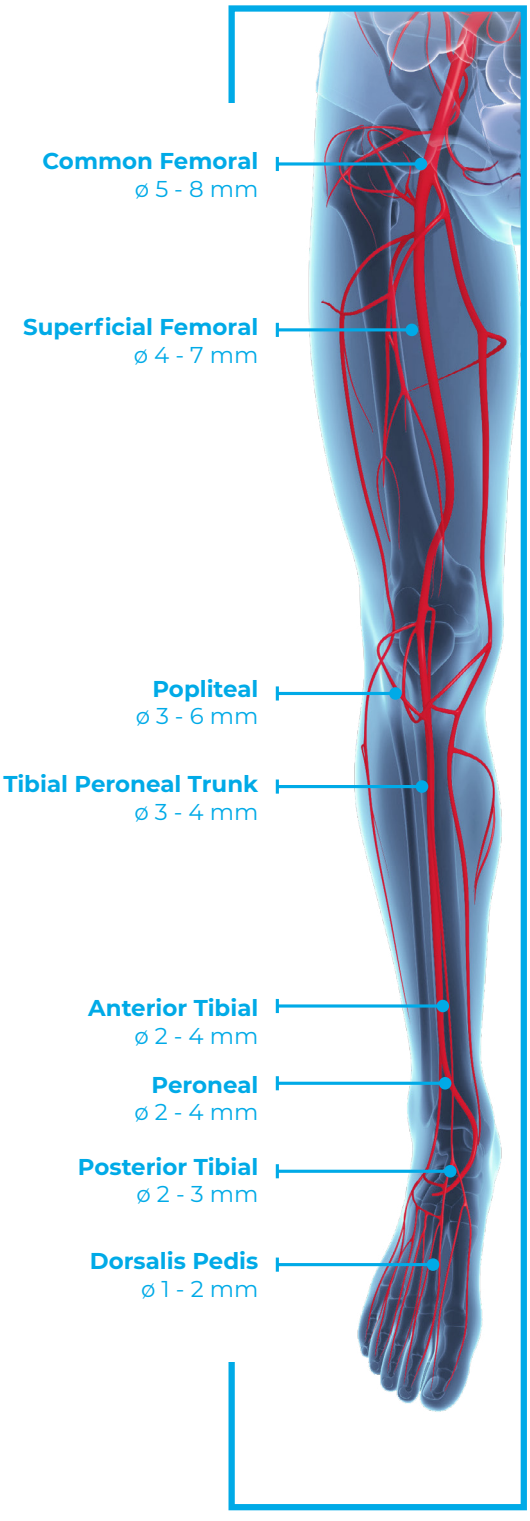


1.5-mm catheter

- Reference vessel diameter: ≥2.25 mm
- Sheath size 5 Fr
- Working length 150 cm

0.9-mm catheter

- Reference vessel diameter: ≥1.4 mm
- Sheath size 4 Fr
- Working length 150 cm



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

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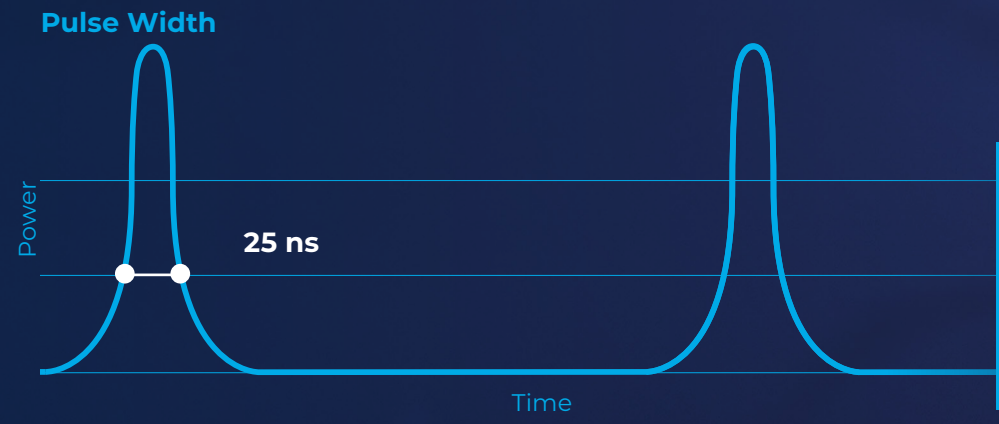
Optimal waveform technology unlike any other

The Auryon System is designed to deliver an optimized wavelength and pulse width to treat all lesions while helping to preserve vessel wall endothelium.[5,6]

AURYON

A 355 nm 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[1-3,6]

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.[6,8]

Pulse width

The Auryon System's modified pulse allows for enhanced ablation by separating into pulse segments. The Auryon System's short pulse width generates the peak power necessary to ablate intimal calcium and modify medial calcium deep within the vessel wall.[11]

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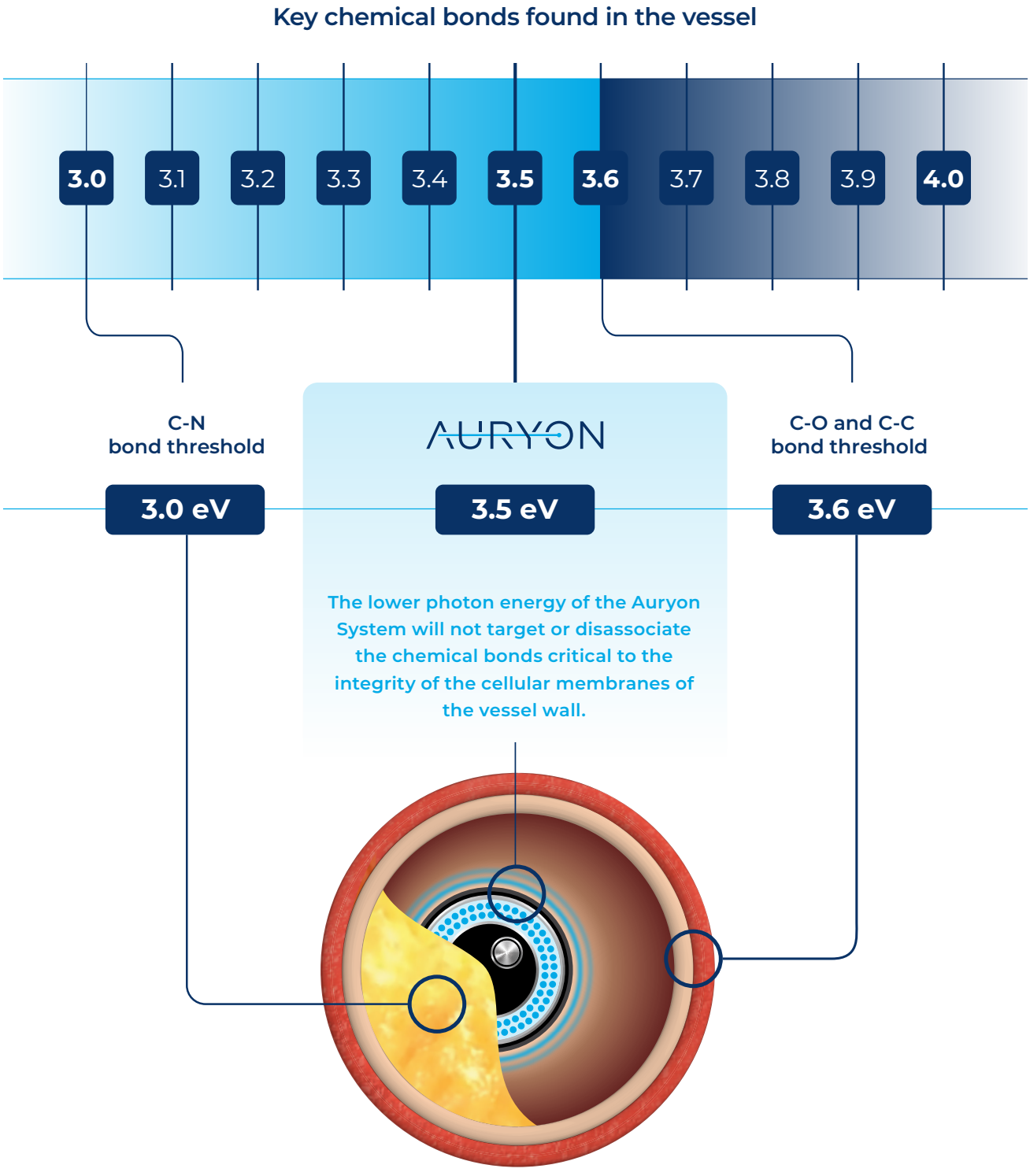
Target the lesion, spare the vessel

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]



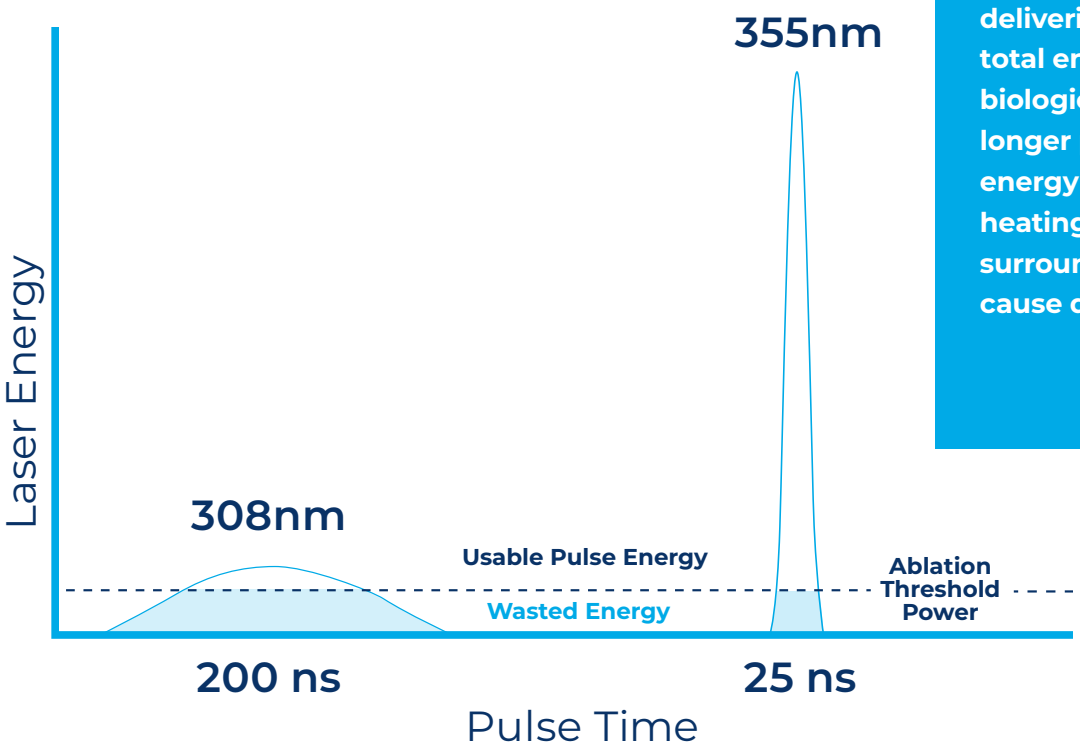
Deliver a powerful, efficient pulse

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

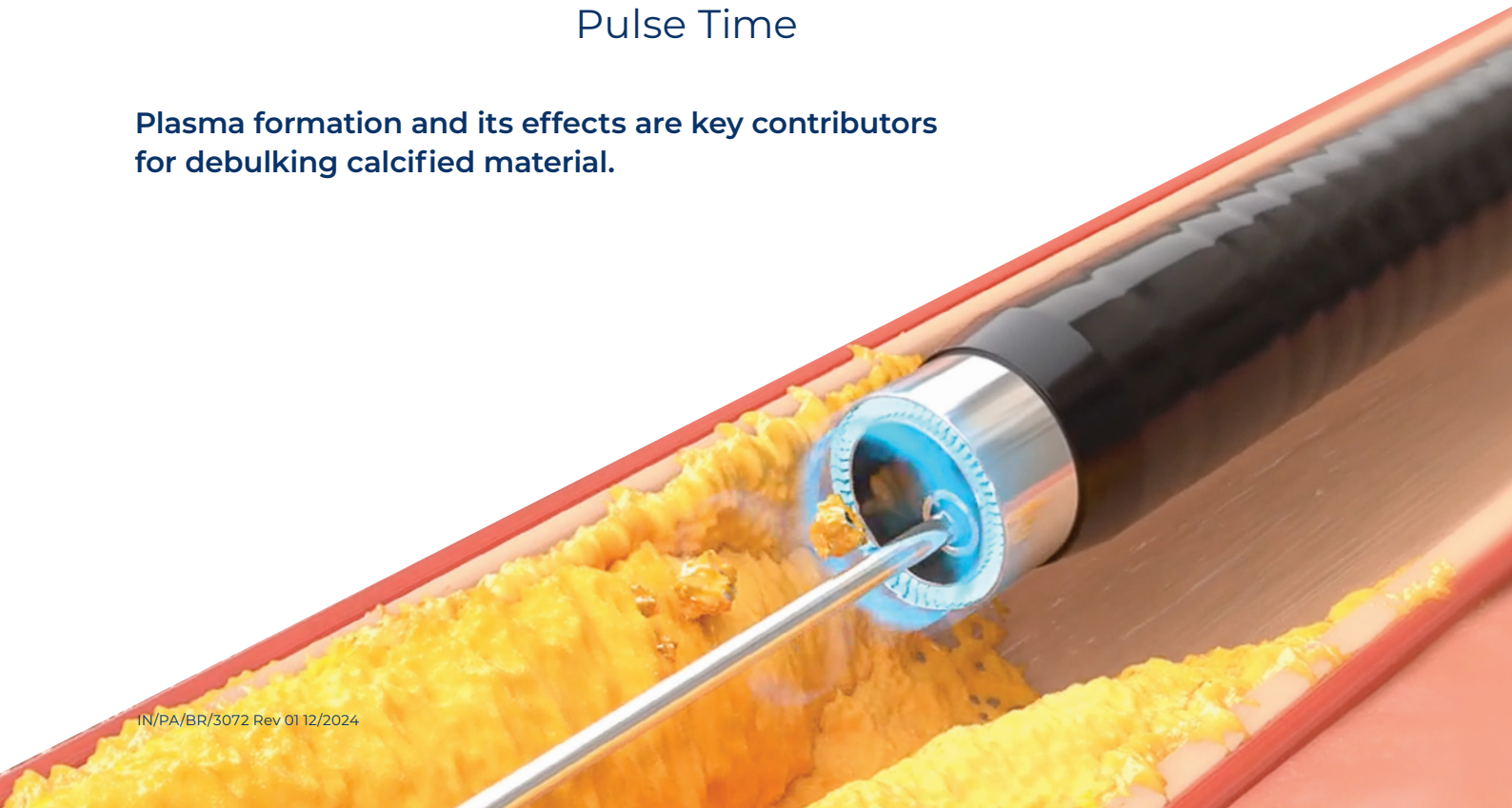
- A shorter pulse allows for:
  - Tissue relaxation between bursts, depositing energy before thermal diffusion can occur[6-8]
  - High-power pulsed energy[11]
  - Increased photo-mechanical impact on calcified tissue[12]

Efficient Ablation

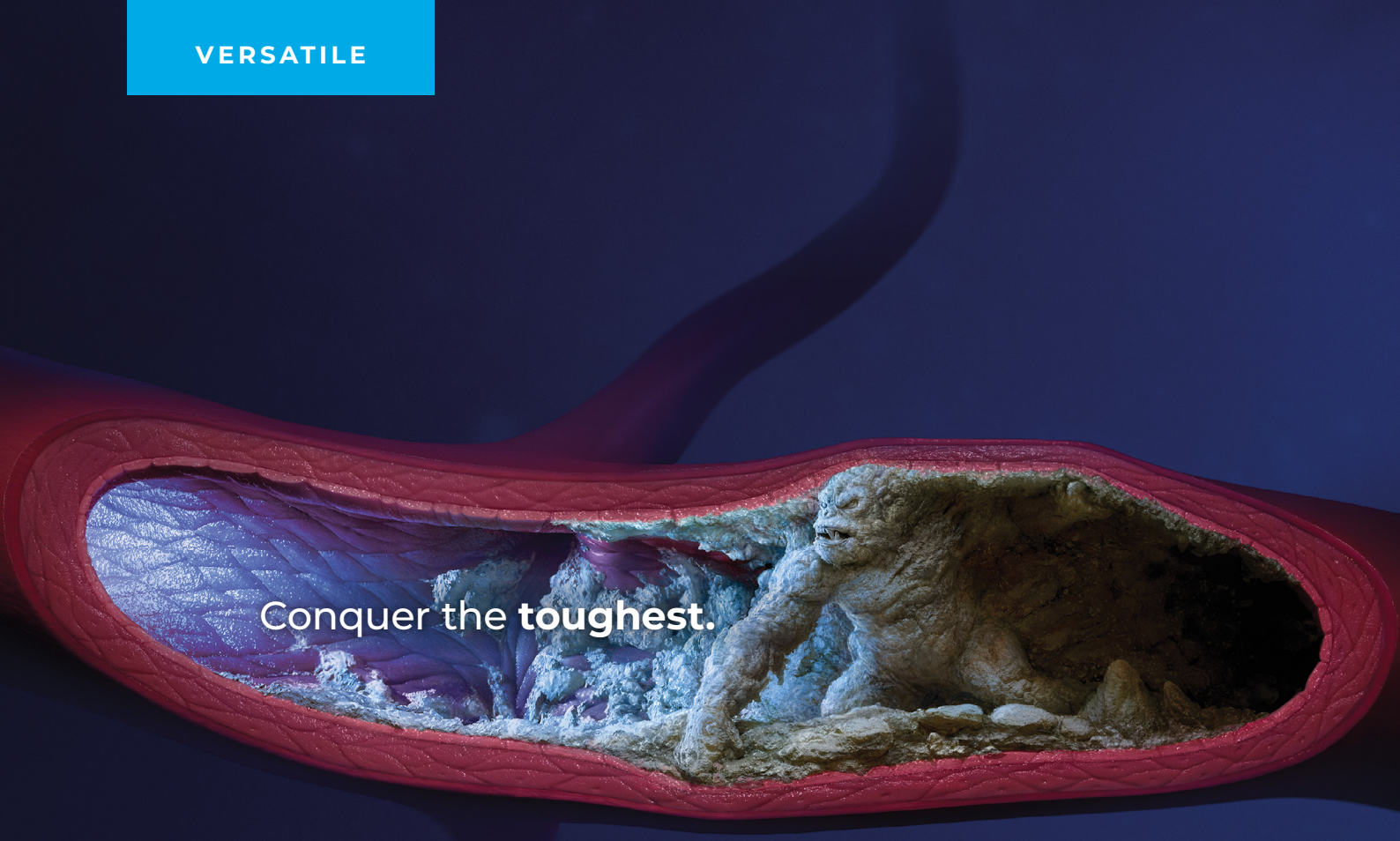
A shorter pulse is efficient at material debulking by delivering more of the total energy above the biological threshold. With longer pulses, much of the energy contributes only to heating that can spread to surrounding material and cause damage.[6,10]



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



VERSATILE



All-in-One Solution for Tough Calcium

The Auryon System is the only atherectomy device proven to crack medial arterial calcification below the knee[11]

DUAL IMPACT

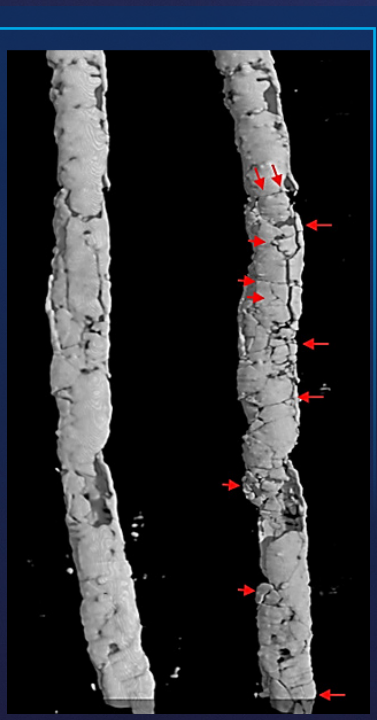
Fracture medial arterial calcium while debulking intimal morphologies[11]

BELOW THE KNEE

Proven success in below-the-knee arteries,[12] where calcium tends to be more prevalent[13]

SAFETY

Treat with confidence by minimizing the risk of embolization and dissection[1-3]



Pre-Auryon Treatment[11] | Post-Auryon Treatment[11]

Read the published study here:

This study was performed on cadavers, not on human subjects, and these results have not been validated in subsequent human research.

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EFFICIENT

Real World Evidence of Safety and Efficacy

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

The PATHFINDER Study, involving 102 patients with PAD (121 lesions),[3] builds upon the foundational IDE study.[1]

PATHFINDER PATIENT AND LESION CHARACTERISTICS[3]	
51% femoral, 34% popliteal, and 47% tibial*	
44%	chronic total occlusions
22%	in-stent restenosis
45%	CLI (Rutherford 4-6)
>57%	had calcification *37% had moderate to severe calcium*

Studied in a real-world patient population

Population included patients with comorbidities, including 53% with diabetes.[3]

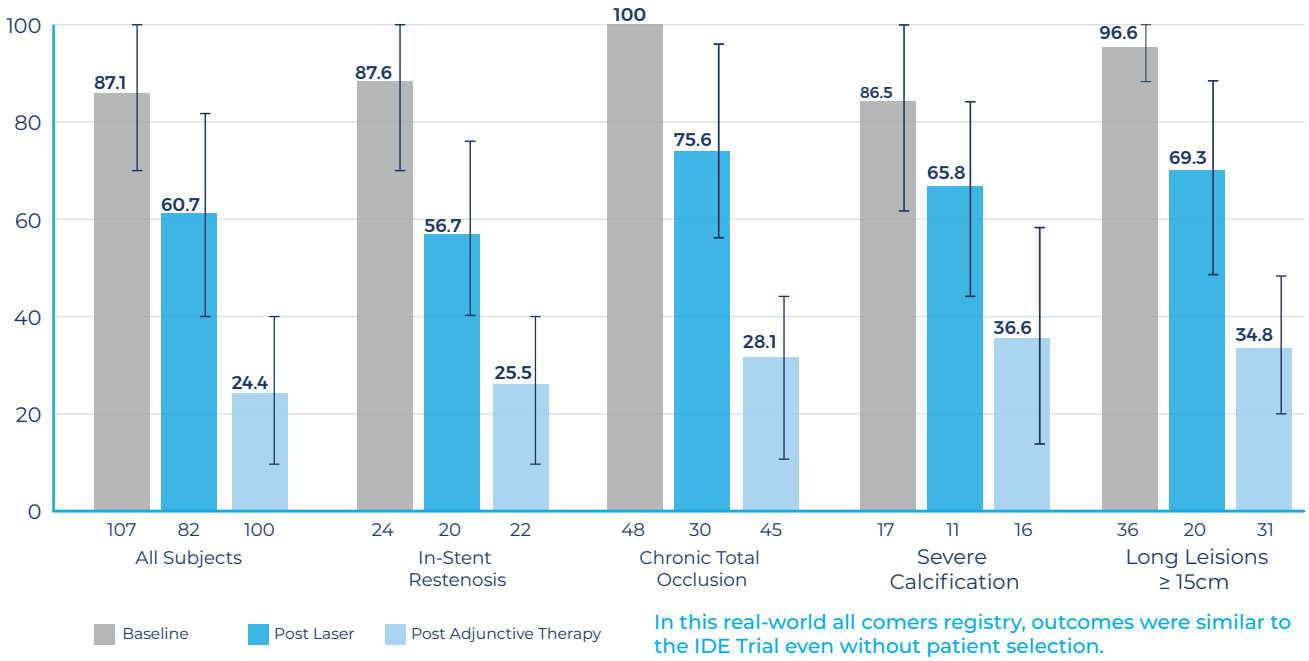
KEY 12-MONTH CLINICAL EFFICACY RESULTS[1,2]	
26%	reduction in stenosis prior to any adjunctive therapy **regardless of calcification level, lesion type, lesion length, or catheter used†** *24% final stenosis after percutaneous transluminal angioplasty (PTA)*
7%	of lesions had clinically driven target lesion revascularizations (CD-TLRs) *0 TLRs were ISR*
94%	of patients showed improvement in Rutherford

Sustained clinical outcomes through 12-months

Ankle-brachial index, walking impairment questionnaire, and Rutherford classification all improved at 6- and 12-month follow up.[1,9]

*More than one entry is possible as lesions can involve several arteries

Comparable reduction in stenosis regardless of complex lesion subgroups[3]



In this real-world all comers registry, outcomes were similar to the IDE Trial even without patient selection.

Individual results may vary.

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EFFICIENT

The Auryon System is like no other

It's a big deal in an efficient package.

AURYON

Weight	Length	Height	Width
90 kg	74 cm	95 cm	34 cm

Wavelength

355 nm class IV laser system

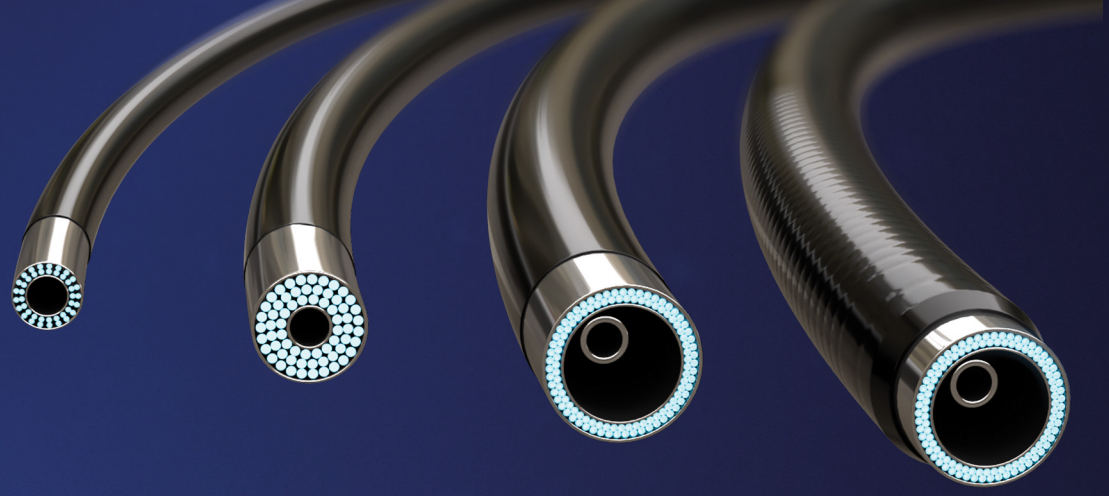
Power type

110V and 220V wall outlet

Aspiration capability

2.0 mm and 2.35 mm

Efficient, portable, quiet, and easy to operate.



Part Number	Description	Sheath Size	Working Length	UOM	QPB
EXM-2001-1000	Auryon Laser System, 200-240V, CE marked			BX	1
EXM-4E02-H000	Catheter Auryon Atherectomy 0.9 mm	4 Fr	150 cm	EA	1
EXM-4E01-H000	Catheter Auryon Atherectomy 1.5 mm	5 Fr	150 cm	EA	1
EXM-4E03-H000	Catheter Auryon Atherectomy 2.0 mm	6 Fr	135 cm	EA	1
EXM-4E04-H000	Catheter Auryon Atherectomy 2.35 mm	7 Fr	110 cm	EA	1

AURYON

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

Clear all lesion types,[1-3] including ISR,* **with a single device**

*Only the 2.0- and 2.35mm catheters are indicated for ISR and to aspirate adjacent thrombus

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

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

Experience the Science and Safety
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:

CE Mark Indication for Use:
The Auryon Atherectomy System used together with Auryon Atherectomy Catheters with aspiration are indicated for use as atherectomy devices for arterial stenoses and occlusions, including in-stent restenosis (ISR), and to aspirate thrombus adjacent to stenoses in native and stented infra-inguinal arteries

The Auryon Atherectomy System used together with the Auryon Atherectomy Catheters without aspiration are indicated for use as atherectomy devices for arterial stenoses and occlusions, including in-stent restenosis (ISR), in native and stented infra-inguinal arteries.

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.
- 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

The Auryon System is not available in all regions. Please contact your AngioDynamics representative for availability.

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-LaserTM 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-LaserTM, 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.** Das et al. Solid state, pulsed-wave 355 nm UV laser atherectomy debulking in the treatment of infrainguinal peripheral arterial disease: The Pathfinder Registry. Catheter Cardiovasc Interv. 2024;1–14. **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.** Data on file. AngioDynamics. **8.** 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. 9. Herzog A, Steinberg I, Ishaaya A. Shaping photomechanical effects in tissue ablation using 355 nm laser pulses. J Biophotonics. 2016;1-9. **10.** 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. **11.** Rundback et al. Treatment effect of medial arterial calcification in below-knee after Auryon laser atherectomy using micro-CT and histologic evaluation, Cardiovascular Revascularization Medicine, 2023,ISSN 1553-8389, https://doi.org/10.1016/j.carrev.2023.06.027. **12.** Shammas et al. Prospective, Multi-center, Single-Arm Study of the Auryon Laser System for Treatment of Below-the-Knee Arteries in Patients With Chronic Limb-Threatening Ischemia: 30-Day Results of the Auryon BTK. Am J C ardiol. 2024 Mar7:219:1-8. doi: 10.1016/j.amjcard.2024.03.008. **13.** Paul D. Bishop, Lindsay E. Feiten, Kenneth Ouriel, Sean P. Nassoiy, Mircea L . Pavkov, Daniel G. Clair, Vikram S. Kashyap, Arterial Calcification Increases in Distal Arteries in Patients with Peripheral Arterial Disease, Annals of Vascular Surgery, Volume 22, Issue 6, 2008, Pages 799-805, ISSN 0890-5096, https://doi.org/10.1016/j.avsg.2008.04.008.

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