INSTRUCTIONS FOR USE

0.9mm/1.5mm

Auryon Atherectomy Catheter - OTW

For Infra-Inguinal Atherectomy

Table of contents

1. Indications for use 2
2. Device Description 3
3. Contraindications for Use 6
4. Warnings 6
5. Precautions 6
6. Potential Complications 7
7. How Supplied 8
8. Direction for Use 8
9. Clinical Data 11
10. Limited Warranty 14

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN WITH APPROPRIATE TRAINING

1. Indications for use

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.

2. Device Description

The Auryon Atherectomy System includes (A) the Laser System, and (B) the "Auryon" Atherectomy Catheters in a variety of sizes.

The Laser System includes in addition to the laser itself, a pump, a sterile aspiration tube, a canister base, a reusable canister, a disposable sterile liner placed within the reusable canister, footswitch pedal, and power cord. For additional information, technical and specific details for the operation of the Laser System itself, please refer to Operator Manual, doc LBL0019. The Laser System has an RFID system for communicating with an RFID tag in each of the disposable catheters.

Note: you should not use any other accessories listed above that were not provided by AngioDynamics Inc, its affiliates or subsidiaries ("AngioDynamics").

The Auryon Atherectomy Catheter is a single patient, single use catheter that is made of an array of optic fibers and surrounded and supported by a circumferential blunt blade at its distal tip.
The catheter is connected to the Laser System via its connector (on the proximal end) and transmits energy through its active tip (on the distal end) at pre-set controlled level of fluence to the target lesion in the artery.
The Auryon catheter is a disposable device, carries an RFID tag and is supplied sterile. Catheters are available in either with or without coating on its outer diameter (OD). The coating is located on the catheter's shaft, beginning at the blade/shaft interface, and the coverage length varies per the catheter's size, as described in the table below.

All Auryon catheters work over 300cm 0.014" guide wires (GW) that have crossed the target lesion intraluminally.
Catheter sizing identification and compatibility to other accessories is printed on its package and described below.

Table 1. Auryon catheter models

Catheter Tip (outer) Diameter	No Hydrophilic coated / Hydrophilic coated Cat.#	Reference Vessel Diameter (mm)	GW Compat-ibility (in.)	Max Tip Diameter (mm/in.)	Max Shaft Diameter (Crossing Profile) (mm/in.)[a]	Total Working Length (cm)	Hydrophilic coating length (cm)[b]	Minimal Sheath (Fr.)	Inner Lumen for Aspiration	Additional features
0.9mm	EXM-4002-0000 / EXM-4002-H000	≥1.4	0.014	0.97/0.038	1.02/0.040	150	100 ±3	4	No	N/A
1.5mm	EXM-4001-0000 / EXM-4001-H000	≥2.25	0.014	1.51/0.059	1.56/0.061	150	65 ±3	5	No	N/A

[a] The hydrated coating may add up to 0.01mm to the dry diameter
[b] Applicable only for the hydrophilic coated catheter

Mechanism of action

The Auryon Atherectomy System uses laser energy emitted from the tip of the catheter (for partial tissue removal from lesion ("Atherectomy")), in peripheral artery disease (PAD) patients undergoing interventional procedures in the infra-inguinal arteries. The Auryon catheter's blunt blade encircles and supports an array of optical fibers at the tip of the catheter emitting laser energy of 50-60 mJ/mm^2 fluence (the Laser System default is 50 mJ/mm^2). Once the Auryon catheter is positioned proximally to the target lesion in the artery over a 300cm 0.014" guide wire (GW) that has crossed the lesion in the vessel's lumen, and the Laser System is turned "ON" and is in "ready" mode, short (10-25 ns) ultraviolet 355nm pulses are delivered at 40Hz to the tip of the catheter, in order to photo-ablate fibrous, calcific, thrombotic and atheromatous lesions, in de novo, and restenotic lesions. The laser beam focal point is several dozens of microns ahead of the supporting blunt blade as the device progresses through the locally superficial traumatized lesion.

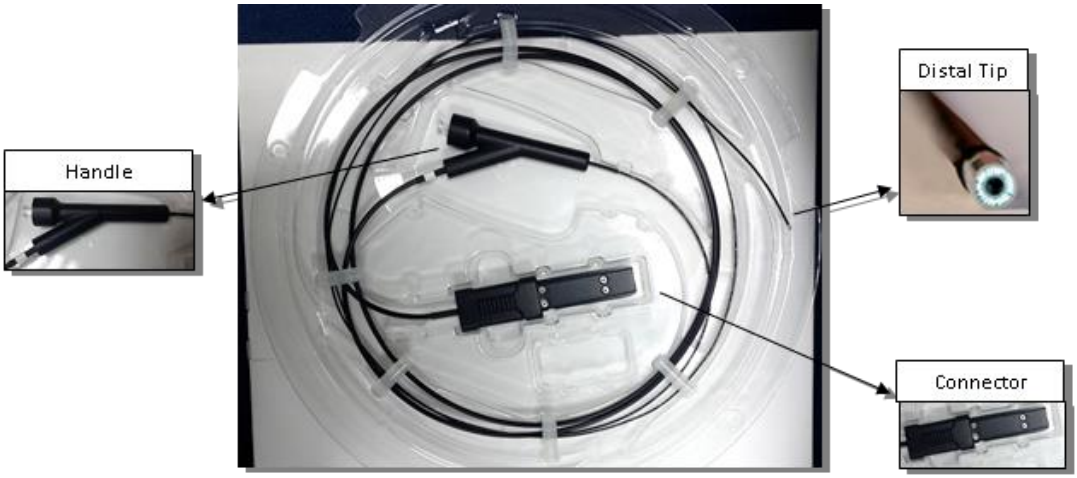
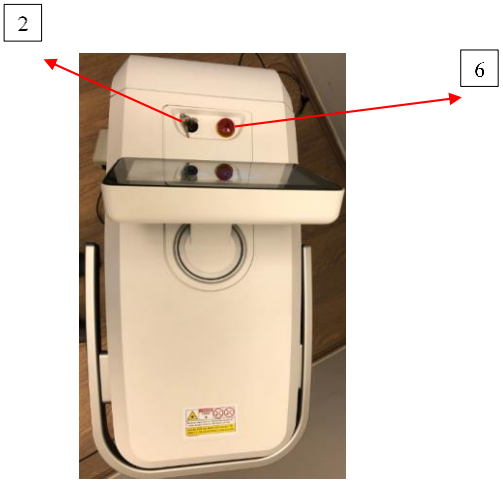
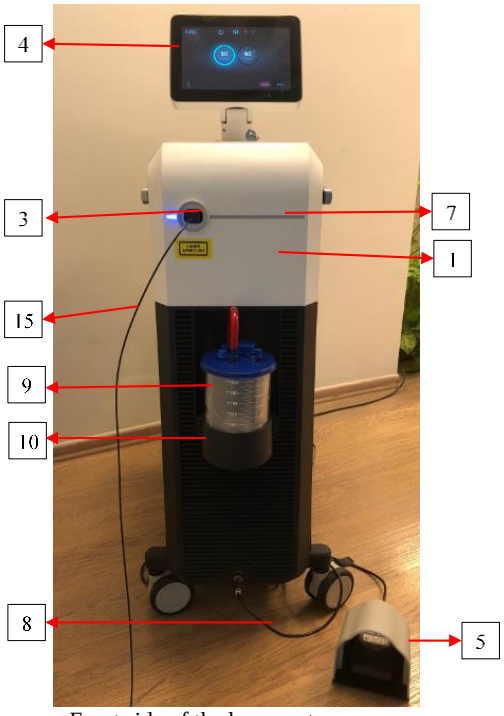


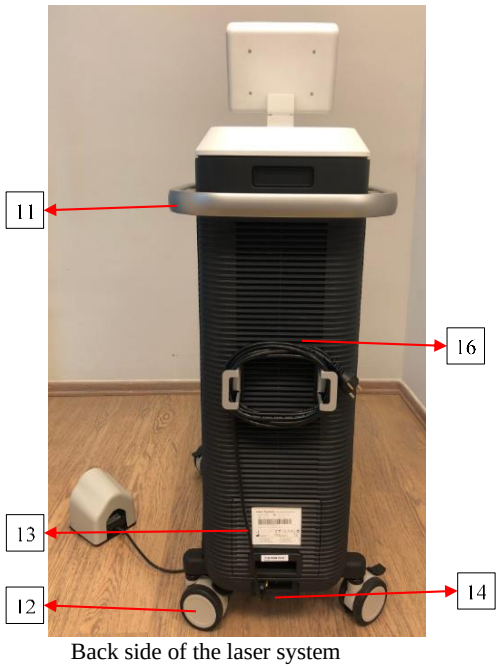
Figure 1: 0.9mm/1.5mm Auryon™ Catheter. Magnified view of the distal end tip shows several rows of fibers.

1. Laser system – The "Laser System" is a console that incorporates the laser head and its optics, a controller, an electrical unit and an "off the shelf" dedicated vacuum pump supplied with the system. In addition, the console is composed of the following components.
2. Key switch – For main system "On" and "Off" control
3. System's aperture (connector housing)
4. Control touch panel – The interface for the laser operator
5. Footswitch pedal – To be pressed and released by the treating physician to activate and deactivate the laser energy
6. EMO (Emergency Machine Off) – A button to be pushed in case of an immediate need to shut off the laser system.
7. LED indicator panel – indicates different levels of laser status: stand by, ready, and active
8. Footswitch pedal cable
9. Reusable Canister (including disposable liner inside).
10. Canister base – to hold the canister for aspiration
11. System's handle
12. Wheels
13. Rear storage compartment to store the footswitch pedal
14. Power cord connector
15. Auryon OTW catheter
16. Power cord





Front side of the laser system



Back side of the laser system

Note: Not shown is the Sterile Aspiration Tube that will be connected on one side to the catheter handle and the other end to the Disposable Liner's cap (the blue cap shown in item 9 of the image).

*Parts 9 and 10 in this image are not relevant for the 0.9mm/1.5mm catheters

Figure 2: Entire system

3. Contraindications for Use

None.

4. Warnings

⚠ Preparation and Operation of the Laser System can be done only by a Laser Operator (technician/nurse/AngioDynamics representative) and the use of the catheter by a physician who were trained by AngioDynamics Inc. representatives for the proper operation of the Laser System, and as outlined within the Operator Manual supplied with each Laser System (See Auryon Atherectomy System Operator Manual, LBL0019) and these Instructions for Use.

⚠ Any deliberate use of the Auryon Atherectomy System outside its indications for use may result in a severe injury to the patient and will void the manufacturer warranty.

⚠ Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training.

⚠ Inspect the Auryon catheter and its package to verify that no damage has occurred as a result of shipping and handling. In the event of damage to the sterile packaging or to the catheter, **do not use the catheter,** but retain the package with its content and notify an AngioDynamics representative. Use of damaged components may result in system malfunction or patient injury

⚠ Pay careful attention while using the catheter, avoid excessive force and be on alert for any potential damage. Inadvertent movement of the catheter may result in patient injury.

⚠ Proximal vessel diameter must be ≥150% of the outer diameter of the Auryon catheter.

⚠ Always use fluoroscopic surveillance when advancing the Auryon catheter inside the patient vasculature to avoid misplacement, dissection, or perforation.

⚠ Based on physician discretion, an Embolic Protection Device (EPD) may be used during the procedure. Refer to the selected EPD's instructions for use (IFU) for details on its handling and use.

⚠ The Laser System is Class 4 laser. Laser safety goggles must be worn by all individuals present in the operating room. If not worn, individuals are subject to permanent damage to the eye by direct exposure or diffuse reflections while the Laser System is in active mode. Make sure to wear the appropriate laser safety goggles as instructed in the Operator Manual. In any case, the Laser System should be active only after the catheter is inside the vascular system and intended to be used at the lesion site.

⚠ The Laser System has been tested and found to comply with the electromechanical compatibility (EMC) limits for the Medical Device Directive 93/42/EEC (IEC/EN 60601-1-2), for both 110V and 220V electrical net (grid). These limits are designed to provide adequate protection against harmful interference in a typical medical installation. The equipment generates, uses and can radiate, ultraviolet energy and if not used in accordance with the instructions, may cause harmful interference to other devices in the vicinity.

⚠ Some sources of electromagnetic disturbance, such as, diathermy, lithotripsy, electrocautery, RFID, electromagnetic anti-theft systems, and metal detectors may possibly have interference with the Auryon Atherectomy System. Avoid the above sources from being in the area of the Auryon Atherectomy System when operating.

⚠ 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.

5. Precautions

⚠ Flush the Auryon catheter guide wire (GW) lumen using 5-10cc sterile saline (preferably heparinized) BEFORE introducing the Auryon catheter over the guide wire and insert the GW while continuously hydrating the GW with a soaked sterile pad.

⚠ Avoid wiping the hydrophilic coated device with dry gauze or excessive wiping, as this may damage the device coating. Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance. Do not soak the catheter for extended periods when the device is not in use. Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

⚠ In the event that the catheter should not move freely, it is recommended that the user determine the source of resistance, exercise caution when removing the device and/or other components as a unit and exchange the device for a new one to complete the procedure.

- **NOTE**: Pressurized saline (preferably heparinized) should be continuously fed through the introducer sheath or the guiding catheter that is positioned as close as possible to the Auryon catheter distal tip at a rate of 100ml/min. Saline should be fed during catheter activation.
- **NOTE**: Do not use the Auryon catheter with any other Laser System.
- If there is a need to move the bed during the procedure, note not to stretch the catheter's proximal part connected to the Laser System.
- **NOTE**: Vasodilator and anticoagulant therapy (according to the medical facility's protocol) should be administered to the patient during use of the Auryon Atherectomy System and post procedure as commonly practiced.
- After use, dispose of the catheter (and any other disposable components) in accordance with applicable and local instructions relating to hospital waste, and potentially biohazardous materials
- Do not attempt to open the Laser System console. The Laser System may be opened/repaired/maintained/fixed only by an AngioDynamics Inc.'s technician (not by the Laser Operator in the site trained by AngioDynamics Inc.).
- In case of any technical error or any malfunction, the catheter should not be used. You must use care when handling the Auryon catheter. If you suspect catheter damage, replace this catheter with a new one. Any deliberate misuse by bending, twisting or any other severe physical manipulation may result in injury to the patient and will void the manufacturer warranty.

6. Potential Complications

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

Procedural Complications:	Other Adverse Events	Serious Adverse events:
• Spasm • Major dissection • Thrombus • Distal embolization • Perforation	• Nerve injury • AV fistula formation • Infection • Myocardial Infarction • Arrhythmia • Pulmonary embolism/infarct	• Death • Re-intervention • Acute Limb Ischemia • Major amputation • Bypass surgery • Hematoma with surgery • Stroke
In hospital complications: • Re-occlusion • Pseudoaneurysm • Renal failure • Bleeding • Sterile inflammation or granulomas at the access site		

7. How Supplied

7.1 Sterilization and sterility period.

The Auryon catheters are single use only. Do not re-sterilize and/or reuse.

The Auryon catheters are supplied sterile. Sterility is guaranteed only if the package is unopened undamaged and used before the expiry date.

7.2 Inspection Prior to Use

Before use, visually inspect the sterile package to ensure that seals have not been broken and that the "use by date" has not expired. All equipment to be used for the procedure, including the catheter, should be examined carefully for defects. Examine the Auryon catheter for bends, kinks, or other damage. Do not use if it is damaged or suspected to be damaged.

8. Direction for Use

NOTE: The atherectomy procedure must be conducted by an AngioDynamics trained physician and an assistant (both must work in sterile conditions). Laser System preparation and operation will be done only by a staff technician trained by AngioDynamics ("Laser Operator"). The Laser Operator will work in non-sterile conditions.

8.1. A recommended matrix for catheter selection per treated lesion's Reference Vessel Diameter (RVD).

Table 2. Auryon Atherectomy catheter use matrix.

Catheter Tip (outer) Diameter	No Hydrophilic coated / Hydrophilic coated cat. #	Reference Vessel Diameter (mm) [1]
0.9mm	EXM-4002-0000 / EXM-4002-H000	≥1.4
1.5mm	EXM-4001-0000 / EXM-4001-H000	≥2.25

[1] The RVD should be ≥150% of each catheter diameter tip. It means that a specific size of a catheter should not be inserted to a vessel that has proximal diameter smaller than indicated.

8.2. For Hydrophilic coated catheter - Preparation of the hydrophilic coating prior to use

Hydrate the outer shaft of the catheter to activate the hydrophilic coating. Either dip the catheter in a basin or wipe with wet gauze using an appropriate sterile solution (sterile solution can be water, saline, or heparinized saline).

NOTE: Avoid wiping the device with dry gauze or by excessive wiping, as this may damage the device coating. Avoid using alcohol, antiseptic solutions, or other solvents to avoid unpredictable changes in the coating which could affect the device safety and performance. Do not soak the catheter for extended periods when the device is not in use. Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

8.3. Auryon catheter insertion over the guide wire until laser activation:

NOTE: For all procedures that involve placing a device into the patient's body, use fluoroscopic guidance.

8.3.1. Once arterial access is achieved, perform baseline angiography to evaluate the PAD and plan on the appropriate catheter size, as well as any accessories that may allow better pushability of the catheter, once inserted. This may include a long sheath and/or guiding catheter (depending on the access approach: retrograde or antegrade). The distal end of the longer sheath/guiding catheter should be placed as close as possible to the lesion, in case of retrograde ("contralateral" or "crossover") approach, tortuous anatomy or highly calcified lesions. Please refer to Table 1 for selecting the minimal sheath size.

8.3.2. Instruct the Laser Operator to prepare the Laser System and instruct the staff on size of the Auryon catheter you wish to operate in this specific procedure.

8.3.3. You may use any other GW to cross the lesion, but the final GW that Auryon catheters will track over should be 300cm 0.014", and preferably stiff GWs. Once this GW is angiographically verified to cross the lesion in the vessel's lumen, it is ready for Auryon catheter insertion over the guide wire.

8.3.4. Open the chosen Auryon catheter as instructed and hand the connector to the Laser Operator for connecting the catheter to the Laser System. Confirm and verify with the Laser Operator that the chosen catheter's size was identified by the RFID system.

⚠ Flush the Auryon catheter guide wire's lumen from the handle's luer lock port, using 5-10cc saline (preferably heparinized).

The entire guide wire must be soaked with saline before insertion into the GW lumen. The GW is inserted from the distal tip of the catheter toward the handle. The GW lumen is located in the center of the catheter shaft.

8.3.5. Introduce the distal tip of the Auryon catheter over the soaked guide wire, and once in the vessel, under fluoroscopy control, guide the Auryon catheter to the lesion, until the distal tip of the catheter shown on the fluoroscopic monitoring screen is proximal to the lesion. **Only at this point of the procedure, instruct the Laser Operator to put the Laser System in Ready mode.**

Once the Laser Operator has set the Laser System to Ready mode, the Laser System will prepare itself for approximately 15 seconds. During this time, a blue color horizontal LED light on the control touch panel is blinking and at the end of 15 seconds, the blinking ceases and the LED light becomes steady, and this activates the footswitch pedal for use.

Once the LED light is steady blue, you may activate the Laser System for "start and stop" by pressing and releasing the footswitch pedal, respectively.

8.4. Routine Laser activation and advancement of Auryon catheter through the lesion:

8.4.1. Once the footswitch is pressed and the laser becomes active, begin advancing the Auryon catheter.

NOTE: The recommended catheter advancement rate is **1mm/sec**. The advancement rate should generally be kept faster than 0.1mm/sec and slower than 3 mm/sec. Avoid higher advancement rates as plaque removal efficiency may be reduced.

NOTE: Pressurized saline (preferably heparinized) should be continuously fed through the introducer sheath at a rate of 100ml/min. Saline should be fed during laser activation.

NOTE: In case of failure of saline infusion set, stop the laser by releasing the footswitch. After stopping the laser, resume infusion and then activate the laser again.

CAUTION: In the unlikely event that the laser does not stop by releasing the footswitch, immediately ask the Laser Operator to power down the entire Laser System by pushing the emergency machine off (EMO) button. Then check for the reason for the footswitch failure and see if can be resolved. If resolvable, ask the Laser Operator to deactivate the EMO and activate the laser again with the footswitch. If not resolvable, remove the catheter from the patient's body, continue the procedure by other means, and call AngioDynamics' representative. Do not use the Laser System until the issue is resolved by AngioDynamics' representative.

8.4.2. Once the desired area is crossed with the Auryon catheter, release the footswitch to stop the laser. At this point, you may choose to repeat lasing at areas of the treated lesion that seemed difficult to cross compared to other areas of the treated lesion. If difficulty to cross was noted, you should retrieve the catheter proximally to the lesion area and advance the catheter to the point(s) where difficulty(ies) was (were) noted and press the footswitch pedal at this(ese) area(s) only. If no difficulty to cross was noted, then one pass is enough, and you can remove the catheter from patient's the body, and you may or may not visualize the effect at this point.

NOTE: If you experience difficulties in retracting the Auryon catheter, do not apply excessive force. The cause of the resistance should be determined under direct fluoroscopic observation before continuing.

NOTE: It is expected, especially with chronic total occlusion (CTO) lesions at the cap, that the advancement rate may be slower. In any such case, and in any other occasion that the catheter does not seem to be advancing at a certain point, please follow the instructions below:

a) Do not to exceed 10 seconds of continuous lasing at the same location. If you experience any difficulty advancing the Auryon catheter, immediately start a 10-seconds self-count-down. Self-count-down should start the moment you experience non-advancement of the Auryon catheter. When advancement resumes, stop the self-count-down and resume it if additional difficulty advancing the Auryon catheter is experienced.

b) If the Auryon catheter cannot be advanced by the 10th second of laser activation, release the footswitch to stop the laser, retract the catheter approximately 3-4 mm, and try to advance again while rotating the catheter shaft approximately 90 degrees to either side, while resuming the 10-second self-count-down .

c) If the Auryon catheter still cannot be advanced with the above-mentioned rotation manipulation for the additional 10-seconds, immediately stop the laser activity by releasing the footswitch .

d) Ask the Laser Operator to raise the fluence to the 60mJ/mm^2.

e) Activate the laser and try again to advance the Auryon catheter through the lesion.

f) If the Auryon catheter cannot be advanced, resume the 10-second self-count-down.

g) If the Auryon catheter cannot be advanced in this attempt, stop the laser activity, withdraw the Auryon catheter and use a new catheter.

When done, release the footswitch to stop the laser, and then retrieve the catheter out of the body.

8.4.3. Perform adjunctive therapy such as balloon angioplasty or stenting, if deemed necessary, and conclude the procedure per common practice.

9. Clinical Data

EX-PAD-01

The EX-PAD-01 clinical study was a prospective, single-arm, multi-center, international, open-label, non-randomized clinical study to assess safety, performance and efficacy of the Auryon Atherectomy Catheter in subjects with Peripheral Artery Disease (PAD) in lower extremity arteries. Fifty (50) subjects were enrolled from October 2015 until July 2017 in two European investigational sites. The primary safety endpoints were perioperative (until discharge) freedom from clinically significant device related adverse events requiring intervention (perforation, dissection, distal embolization or pseudo-aneurysm) and freedom from Major Adverse Events (MAE) at 30 days, defined as target lesion revascularization, unplanned target limb amputation above the ankle, and cardiovascular deaths. The primary efficacy endpoint was technical success, defined as the ability of the Auryon catheter to cross the target lesion stenosis over the guide wire (in true lumen) while the Minimal Lumen Diameter (MLD) is smaller than the Auryon catheter diameter. The perioperative freedom from clinically significant device related adverse events was 100%. Freedom from MAE at 30-days was 100% (50/50), freedom from MAE at 6 months was 100.0% (50/50), and freedom from MAE at 12 months in 46 subjects that completed the follow up was 95.6% (44/46). Technical success was achieved in 100.0% (49/49) of the treated lesions. Table 3 below summarizes the safety and effecacy data resulting from the EX-PAD-01 study.

Table 3: Summary of safety and efficacy results in EX-PAD-01 study

Parameter	Results (n=50 subjects, 53 lesions)
Demographics	
Male	76% (38/50)
Age (years)	64.0 ± 8.5
Diabetes Mellitus	18% (9/50)
Target Lesion characteristics	
Superficial Femoral Artery (SFA)	85.0% (45/53)
Popliteal	7.6% (4/53)
Femoro-Popliteal	3.8% (2/53)
Tibial-Peroneal Trunk	3.8% (2/53)
Moderate-Severe Calcification	60.8% (31/51)
Average Lesion length (cm)	7.4 ± 5.5
% residual stenosis Pre-Auryon	95.3 ± 10.3
% residual stenosis Post-Auryon	61.3 ± 25.5
Final Diameter stenosis (%)	14.0 ± 14.0
Procedural Settings	
Number of catheters used [SD]	1.2 ± 0.5
Technical success[1]	100% (52/52)
Safety results	
30 days Major Adverse events[2] and perioperative until discharge clinically significant device related adverse events requiring intervention	0.0% (0/50)[3,4]

[1] Defined as the ability of the Auryon catheter to cross the target lesion stenosis over the guide wire while the stenotic flow diameter is smaller than the Auryon catheter diameter

[2] Major Adverse Events were defined as cardiovascular death, TLR, unplanned amputation above the ankle or emergent surgical revascularization of the target limb

[3] There were 2 post procedure access site hematoma unrelated to the device, which required limited local surgical treatment that led to prolongation of hospitalization (non-device related SAE), and were resolved by discharge.

6 months Major Adverse events	0.0% (0/50)[5]
12 months Major Adverse events	4.3% (2/46)[6]
Efficacy results	
Baseline ABI	0.57 ± 0.1
30 days ABI	0.94 ± 0.1
6 months ABI	0.84 ± 0.2
12 months ABI	0.77 ± 0.2
Baseline Rutherford	2.82 ± 0.52
30 days Rutherford	0.66 ± 0.76
6 months Rutherford	0.90 ± 1.03
12 months Rutherford	1.21 ± 1.0

EX-PAD-03

The EX-PAD-03 clinical study was a pivotal, prospective, single-arm, multi-center, international, open-label clinical study to assess safety and efficacy of the Auryon Atherectomy catheter in subjects with infra-inguinal Peripheral Artery Disease (PAD). Ninety-seven (97) subjects were enrolled from September 2017 until March 2018 in eight (8) US investigational sites and three (3) European investigational sites. The primary safety endpoint was freedom from Major Adverse Events (MAE) through a 30-day follow-up period, as adjudicated by the Clinical Event Committee (CEC), defined as clinically driven target lesion revascularization (CDTLR), unplanned target limb amputation above the ankle, and cardiovascular deaths. This endpoint is considered to be met if the rate is greater than 85%. The primary efficacy endpoint was acute technical success, defined as reduction from baseline in residual diameter stenosis (measured in percent), prior to any adjunctive therapy, achieved by the Auryon Atherectomy catheter, as assessed quantitatively by the core laboratory based upon the procedure angiograms. This endpoint is considered to be met if the mean reduction in residual diameter stenosis is greater than 20%, prior to any adjunctive therapy. Freedom from MAE at 30-days was 98.9% (92/93). The reduction from baseline in residual diameter stenosis (measured in percent), achieved by the Auryon Atherectomy catheter, as assessed quantitatively by the core laboratory based upon the procedure angiograms was 33.6% (± 14.2%). Table 4 below summarizes the safety and efficacy data resulting from the EX-PAD-03 study.

Table 4: Summary of safety and efficacy results in EX-PAD-03 study

Parameter	**Results (n=97 subjects, 107 lesions)**
Demographics	
Male	52.5% (51/97)
Age (years)	70.5 ± 9.9
Diabetes Mellitus	42.3% (41/97)
Target Lesion characteristics	
Iliac-SFA	0.9% (1/107)
CFA-SFA	5.6% (6/107)
SFA	61.7% (66/107)
SFA-Popliteal	6.5% (7/107)

[4] No dissections/perforations revealed after catheter pass. In 3 cases, as expected, dissections were noted only post balloon inflation, and which were treated with stent or did not require treatment, and all 3 cases were considered unrelated to the Auryon System.
[5] Two subjects did not come to their follow up at 6 months clinic visit yet confirmed freedom from MAE by phone.
[6] Four subjects were lost to follow up at 12 months visit, resulting in 46 subjects who confirmed freedom from MAE.

Popliteal	7.5% (8/107)
Popliteal-TPT	2.8% (3/107)
Popliteal-AT	1.9% (2/107)
Popliteal-Peroneal	2.8% (3/107)
TPT	0.9% (1/107)
TPT-Peroneal	0.9% (1/107)
TPT-PT	0.9% (1/107)
AT	5.6% (6/107)
Peroneal	0.9% (1/107)
PT	0.9% (1/107)
Chronic Total Occlusion or sub-occlusions (stenosis > 95%)	32.7% (32/107)
Moderate Calcification	12.1% (13/107)
Severe Calcification	26.2% (28/107)
RVD – proximal (mm)	4.5 ±1.1
Lesion length (cm)	5.4 ± 4.3
% residual stenosis Pre-Auryon	85.7 ± 12.2
% residual stenosis Post-Auryon	52.1 ± 14.9
% reduction of residual stenosis post Auryon	33.6 ± 14.2
Final Diameter stenosis (%)	17.7 ± 11.0
Procedural Settings	
Number of catheters used [SD]	1.2 ± 0.5
Primary efficacy endpoint	33.6% ± 14.2
Primary safety endpoint	
Freedom from Major Adverse Events (MAE)[7] through a 30-day follow-up period, as adjudicated by the Clinical Event Committee (CEC)	98.9% (92/93)
Secondary Efficacy results	
Baseline ABI	0.71±0.19 (N=88)
30 days ABI	0.95 ± 0.14 (N=88)
Baseline Rutherford	2.77±0.6 (N=97)
30 days Rutherford	0.98 ± 1.01 (N=94)
Baseline WIQ questionnaire	0.23 ± 0.22 (N=93)
30 days WIQ questionnaire	0.50 ± 0.32 (N=84)

[7] Major adverse events were defined as: Unplanned target limb amputation above the ankle, Clinically Driven Target Lesion Revascularization (CDTLR), Cardiovascular related deaths

10. Limited Warranty

Warranty Summary

- The Auryon Atherectomy System and Auryon Atherectomy Catheters ("Products") are warranted free from defects in material or workmanship for 1 year from the date of delivery to the purchaser.
- Warranty repairs can be obtained by calling AngioDynamics' customer service department at +1 800-772-6446.
- All returned products must be prepaid and have a return materials authorization (RMA) number.
- Certain hardware and software updates or upgrades may be provided at no charge during the Warranty Period when Products are returned to AngioDynamics.
- Unauthorized repairs, misuse, or abuse of the Products will void the warranty.

AngioDynamics warrants to the initial purchaser that the Products will be free from defects in material or workmanship, under normal, proper, and intended usage, for a period of one (1) year from the date of initial shipment to purchaser ("Warranty Period"). Excluded from this warranty are expendable components and supply items such as, but not limited to, power cords, footswitches, and cables. AngioDynamics' obligations under this warranty are to repair or replace any Products (or part thereof) that AngioDynamics reasonably determines to be covered by this warranty and to be defective in workmanship or materials, provided that the purchaser has given notice of such warranty claim within the Warranty Period and the Product is returned to AngioDynamics with freight prepaid. Repair or replacement of Products under this warranty does not extend the Warranty Period.

To request repair or replacement under this warranty, purchaser should contact AngioDynamics directly (see contact information on the back cover of this manual). AngioDynamics will authorize purchaser to return the Product (or part thereof) to AngioDynamics. AngioDynamics shall determine whether to repair or replace Products and parts covered by this warranty and all Products or parts replaced shall become AngioDynamics' property. In the course of warranty service, AngioDynamics may, but shall not be required to, make engineering improvements to the Product or part thereof. If AngioDynamics reasonably determines that a repair or replacement is covered by the warranty, AngioDynamics shall bear the costs of shipping the repaired or replacement Product to purchaser. All other shipping costs shall be paid by purchaser. Risk of loss or damage during shipments under this warranty shall be borne by the party shipping the Product. Products shipped by purchaser under this warranty shall be packaged in the original shipping container or equivalent packaging to protect the Product. If purchaser ships a Product to AngioDynamics in unsuitable packaging, any physical damage present in the Product on receipt by AngioDynamics (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of purchaser.

This warranty does not extend to any Products or part thereof: that have been subject to misuse, neglect, or accident; that have been damaged by causes external to the Product, including but not limited to failure of or faulty electrical power; that have been used in violation of AngioDynamics' instructions; that have been affixed to any nonstandard accessory attachment; on which the serial number has been removed or made illegible; that have been modified by anyone other than AngioDynamics; or that have been disassembled, serviced, or reassembled by anyone other than AngioDynamics, unless authorized by AngioDynamics. AngioDynamics shall have no obligation to make repairs, replacements, or corrections which result, in whole or in part, from normal wear and tear. AngioDynamics makes no warranty (a) with respect to any products that are not Products; (b) with respect to any products purchased from a person other than AngioDynamics or an AngioDynamics-authorized distributor; or (c) with respect to any product sold under a brand name other than AngioDynamics.

THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY FOR ANGIODYNAMICS' PRODUCTS, EXTENDS ONLY TO THE PURCHASER, AND IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION ANY WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ANGIODYNAMICS' MAXIMUM LIABILITY ARISING OUT OF THE SALE OF THE PRODUCTS OR THEIR USE, WHETHER BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE, SHALL NOT EXCEED THE ACTUAL PAYMENTS RECEIVED BY ANGIODYNAMICS IN CONNECTION THEREWITH. ANGIODYNAMICS SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE (INCLUDING WITHOUT LIMITATION LOST PROFITS)

DIRECTLY OR INDIRECTLY ARISING FROM THE SALE, INABILITY TO SELL, USE OR LOSS OF USE OF ANY PRODUCT. EXCEPT AS SET FORTH HEREIN, ALL PRODUCTS ARE SUPPLIED "AS IS" WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED. THESE TERMS MAY NOT BE ALTERED, AMENDED, REPLACED, SUBSTITUTED, OR RESCINDED BY ANY EMPLOYEE, AGENT, INDEPENDENT CONTRACTOR, OR CONSULTANT OF ANGIODYNAMICS. ANY SUCH ALTERATION, AMENDMENT, REPLACEMENT, SUBSTITUTION, OR RESCISSION SHALL NOT BE BINDING UPON ANGIODYNAMICS, ITS AFFILIATES, OR SUBSIDIARIES.

Performing unauthorized service or repairs not described in these instructions for use or a Product manual will void the Product's warranty.

Products marked as "single-use" are for single use only. Purchaser shall not reuse, reprocess, or reserialize single-use Products. Reuse, reprocessing, or reserialization may compromise the structural integrity of the Product and/or lead to Product failure, which may result in patient injury, illness, or death. Reuse, reprocessing, or reserialization may also create a risk of contamination of the Product and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the Product may lead to injury, illness, or death of the patient. AngioDynamics assumes no liability with respect to single-use Products reused, reprocessed, or reserialized and makes no warranties, express or implied, including, without limitation, any implied warranties of merchantability or fitness for a particular purpose, with respect to any such Product.

For additional product information or to report any technical issue with the products, please contact: customerservice@angiodynamics.com

Eximo Medical Ltd.
3 Pekeris, Einstein building, Tamar Park,
Rehovot,7670203, Israel
Phone: +972 (8) 6307630
Fax: +972 (8) 6307631

Distributed in the US by:

AngioDynamics, Inc.

603 Queensbury Avenue

Queensbury, NY 12804

USA

USA Customer Service 800-772-6446