# Auryon Laser Atherectomy System for PAD. Initial acute & 6-month results from the Pathfinder Registry

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## Purpose:

Evaluates the safety & efficacy of the *Auryon Laser Atherectomy System* in real-world treatment of a broad spectrum of infrainguinal PAD.

## Auryon's Features:

- 355nm short pulse laser-transmitted catheter;
- Consists of optical fibers surrounded by a blunt blade (with aspiration);
- Indicated for atherectomy of infrainguinal PAD, including ISR;
- Has higher affinity for atheroma than for endothelium;
- Indifferent to the presence of contrast material.

## Design & Methods:

- First post-market registry on Auryon;
- Prospective, multicenter (10 sites), single arm;
- Aimed for real world data collection on the cleared device in the US;
- All comers (excluding Rutherford 6);
- Angiographic core laboratory;
- Two years follow up.

## Population:

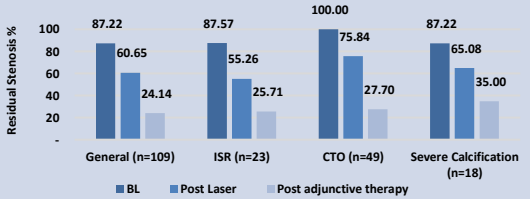
**104 subjects**
- 62.5% male
- 68.4 ± 10.2 years
- 46.1% CLI

**109 lesions**
- 13.5 cm long (0.5-52.0 cm)
- 22.0% ISR
- 37.6% mod-severe calcification
- 45.0% CTOs
- 43.1% below the knee

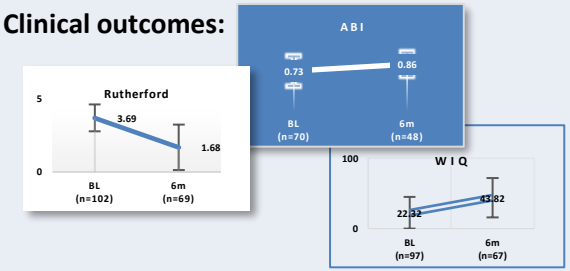
## Results:

- Successful crossing in 100% of the lesions;
- Residual stenosis of 24.2% ± 15.43% post final treatment;
- No procedural perforations, amputations, or deaths;
- 5 (4.1%) bail out stenting post final therapy, not laser related;
- 2 (1.7%) distal embolization events, resolved intra-procedurally without complications;
- 6 months clinical outcomes showed remarkable improvement from baseline, including very low TLR and amputation rates.

## Stenosis reduction:




## Clinical outcomes:




## Major adverse events:

| | 30 days (N=103) | 6 months (N=89) |
|---|---|---|
| No MAEs | 100 (97.0%) | 84 (94.4%) |
| Amputation | 1 (1.0%) | 1 (1.1%) |
| CD-TLR | 1 (1.0%) | 3 (3.4%) |
| TVR | 1 (1.0%) | 1 (1.1%) |
| Cardiovascular Death | 0 (0.0%) | 0 (0.0%) |

## Conclusions:

- Initial post market data on real-world cases with Auryon, in a variety of complex infrainguinal lesions demonstrates excellent safety & performance.
- Low CD-TLR rates with improved clinical presentation, were consistent with the previous clinical studies data.

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