Novel laser-based atherectomy catheter: Results from the Eximo Medical B-Laser™ IDE+EU Study

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Disclosure

Speaker name:
Marianne Brodmann, MD

I have the following potential conflicts of interest to report:

☑ Consulting

Medtronic, BD BARD, Spectranetics, Intact Vascular, Soundbite Medical, Biotronik, Bayer, Daiichi Sankyo, Böhringer Ingelheim, Astra Zeneca
B-Laser™ Atherectomy System

- Small and light solid-state Nd:YAG laser
- No calibration and no warm-up time for laser system
- Indifferent to contrast media presence (Safety!)
- Three fold affinity to lesion type tissue vs artery’s endothelium (Safety!)
- 355 nm wavelength
- Short pulses (~10 ns) (Calcium!)
- ATK and BTK including calcified lesions, ISR, CTO
- Four OTW (0.014”) catheter sizes – 0.9mm, 1.5mm, 2.0mm and 2.35mm (fitting to 4F-7F sheaths)
- Aspiration capability (for the 2.0mm and 2.35 mm) to avoid emboli (Safety!)
- “Off-center” capability for large lumen creation and for non-concentric lesions (2.35mm)
EXIMO B-Laser™ offers a full line of laser catheters with unprecedented capabilities that open new market opportunities in PAD.

B-Laser™ catheters come in a range of diameters from 0.9 to 2.35mm.
B-Laser™ Clinical Experience of IDE study and EU study (1)

- **Studies Subjects:** 147 subjects (160 lesions)
  - 6 (IDE study) and 12 (Pilot study) month follow-up
- **Sites** 13 sites | 31 physicians | Used in both Hospital and OBL settings in the U.S. and EU
- **Summarized Results** Excellent clinical performance and safety profile

- EU study results publication is underway
- IDE acute and 30 days results publication was accepted by CRM Journal
- IDE entire study up to 6 months FU will be submitted soon
B-Laser™ Clinical Experience of IDE study and EU study (2)

- Studies were performed with a real world case mix including various lesion types, ATK and BTK, including ISR.

- B-Laser™ performance not impacted by calcification severity
  - EU Study: 88% of subjects had some level of calcification; >60% were moderate-severely calcified
  - IDE Study: 77% of subjects had some level of calcification; >25% were severely calcified

- Proven efficacy with subjects who suffered from Chronic Total Occlusion
  - EU Study: 79% had CTO lesions
  - IDE Study: 34.6% had CTO lesions & sub-total occlusions
B-Laser™ Clinical Experience of IDE study and EU study (3)

- None of the 147 study subjects (97 IDE + 50 EU) experienced device-related complications that required intervention (zero perforation and no flow-limiting dissections), by CoreLab.
- None of the 147 subjects experienced perioperative distal embolization (by CoreLab) with only 8 EPD used.
- TLR at 6 months- 3 / 141 subjects (2.1%)
- TLR at 12 months- 2 / 46 (4.3%)
- Bailout stenting – 1 / 147 (0.7%) (not device related)
- MAE at 30 days- 1 / 147 (0.7%) (not device related)
**B-Laser™ Clinical Experience of IDE and EU studies**

Residual stenosis - IDE and EU* studies (n=159 lesions)

*For EU study:
1. Post adjunctive therapy was evaluated per the investigator and not per corelab.
2. 2nd lesions (in 3 cases) were evaluated per the investigator and not per corelab.
B-Laser™ Clinical Experience of IDE and EU studies

*For EU study:
(1) Post adjunctive therapy was evaluated per the investigator and not per corelab.
(2) 2nd lesions (in 3 cases) were evaluated per the investigator and not per corelab.
B-Laser™ Clinical Experience of IDE and EU studies - DUS

Note: Patency is defined by PSVR <2.5. For IDE it was determined by the CoreLab, and for EU it was determined by site ultra-sonographers.
Patency rates at 30D and 6 Months- Lesion type

<table>
<thead>
<tr>
<th></th>
<th>30D (n=111)</th>
<th>6M (n=113)</th>
<th>30d (n=29)</th>
<th>6M (n=30)</th>
<th>30D (n=30)</th>
<th>6M (n=37)</th>
<th>30D (n=18)</th>
<th>6M (n=16)</th>
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<tbody>
<tr>
<td>General</td>
<td>97.3%</td>
<td>87.6%</td>
<td>100.0%</td>
<td>96.7%</td>
<td>93.3%</td>
<td>89.2%</td>
<td>94.4%</td>
<td>87.5%</td>
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<tr>
<td>Severely calcified</td>
<td>100.0%</td>
<td>87.6%</td>
<td>96.7%</td>
<td>93.3%</td>
<td>89.2%</td>
<td>94.4%</td>
<td>87.5%</td>
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<tr>
<td>CTO</td>
<td>93.3%</td>
<td>89.2%</td>
<td>93.3%</td>
<td>89.2%</td>
<td>94.4%</td>
<td>87.5%</td>
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<td>ISR</td>
<td>94.4%</td>
<td>89.2%</td>
<td>94.4%</td>
<td>89.2%</td>
<td>94.4%</td>
<td>87.5%</td>
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Patency rates at 30D and 6 Months - Calcification level

<table>
<thead>
<tr>
<th>Calcification Level</th>
<th>30d (n=24)</th>
<th>6M (n=22)</th>
<th>30d (n=39)</th>
<th>6M (n=43)</th>
<th>30d (n=19)</th>
<th>6M (n=18)</th>
<th>30d (n=29)</th>
<th>6M (n=30)</th>
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<tbody>
<tr>
<td>No calcification</td>
<td>95.8%</td>
<td>81.8%</td>
<td>94.9%</td>
<td>83.7%</td>
<td>100.0%</td>
<td>88.9%</td>
<td>100.0%</td>
<td>96.7%</td>
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<tr>
<td>Mild</td>
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<td>Moderate</td>
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<tr>
<td>Severe</td>
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Patency rate by calcification level (IDE+CE studies)
IDE- Clinical Outcome (ABI, Rutherford, WIQ n= number of the same subjects that have BL, 30D and 6M clinical outcome data)
B-Laser™ Clinical Experience – Typical angiograph with “off-centering”

5cm CTO in SFA, 2.35mm with “off-centering”

Before | After B-Laser™ | After B-Laser™ + Balloon
IVUS images (1.5mm in 5.5mm vessel)

Before Laser

After Laser

A lumen much larger than the nominal catheter diameter, was achieved
Thank You!
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