LASER AHERECTOMY + PTA

Proven more effective and safer than PTA alone for restenosis in the femoropopliteal artery.
THE RIGHT PATH IS CLEAR

In-stent restenosis in the femoropopliteal artery contains complex lesions, including neointimal hyperplasia and thrombus. Only the Turbo-Tandem and Turbo-Elite devices with PTA, have been proven superior in efficacy and safety for the treatment of FemPop ISR.1,3

Superior Efficacy1,3,5

The EXCITE prospective randomized controlled clinical trial proved that use of Turbo-Tandem in conjunction with PTA is superior to PTA alone even in treating the most complex Class II (long, diffuse) and Class III (occluded) ISR lesions.

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<tr>
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<th>Turbo-Tandem™ + PTA*</th>
<th>PTA Alone</th>
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<tbody>
<tr>
<td><strong>Procedural success</strong></td>
<td>93.5%</td>
<td>82.7%</td>
</tr>
<tr>
<td><strong>Freedom from TLR at 6 months</strong></td>
<td>73.5%</td>
<td>51.8%</td>
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<tr>
<td><strong>Any dissection</strong></td>
<td>7.7%</td>
<td>17.2%</td>
</tr>
<tr>
<td><strong>Bailout stenting after treatment</strong></td>
<td>4.1%</td>
<td>11.1%</td>
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Superior Safety1,3,5

Using Turbo-Tandem with PTA has been proven superior in safety to PTA alone.3 The pulsed laser operates within the UV range as a cool laser.

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<th>Turbo-Tandem™ + PTA*</th>
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<tr>
<td><strong>Major adverse events at 30 days</strong></td>
<td>5.8%</td>
<td>20.5%</td>
</tr>
<tr>
<td><strong>Major dissection</strong></td>
<td>2.4%</td>
<td>7.4%</td>
</tr>
<tr>
<td><strong>Risk of stent interaction</strong></td>
<td>Minimal</td>
<td>Minimal</td>
</tr>
</tbody>
</table>

* Turbo-Elite can be used with Turbo-Tandem to create a pilot channel if needed.
Prospective randomized controlled clinical trial data prove that Turbo-Tandem with PTA effectively debulks ISR lesions. Turbo-Elite can be used in conjunction with Turbo-Tandem to create a pilot channel if needed.

Financially Sound
Laser catheters have a strong history of safety and efficacy, providing a cost-effective solution that’s frequently less expensive solution than mechanical atherectomy catheters. Laser catheters can optimize both clinical and financial outcomes, while also potentially minimizing the costs associated with adverse events.

Turbo-Tandem with PTA, is the only solution indicated for treatment in FemPop ISR by the FDA. Its use reduces the liability risk that comes with using a non- or contraindicated atherectomy device when an indicated device is available.

The Spectranetics Promise
The Spectranetics vision is to eradicate restenosis and amputation safely, predictably and responsibly. We take each procedure extremely seriously, just like you do. We offer robust training, including procedural training, educational symposia, roundtable educational events, web-based educational events, and a mobile learning lab. We can also train you in your own lab, so you get exactly the education you need. Spectranetics offers the only atherectomy simulator available.

If you are not 100% satisfied with Turbo-Tandem, simply return it to us.

Only Turbo-Tandem with PTA, is cleared by the FDA to treat FemPop ISR.
Important Safety Information

The 7 French Turbo-Tandem systems is indicated for atherectomy of infrainguinal arteries and for laser atherectomy of de novo or restenotic lesions in native infrainguinal arteries and for the treatment of femoropopliteal artery in-stent restenosis (ISR) only in bare nitinol stents, with adjunctive Percutaneous Transluminal Angioplasty (PTA). Rare but serious potential adverse events include: the need for urgent additional procedures or surgery due to bleeding, vascular damage, loss of blood flow or other complications; decrease or loss of kidney function due to contrast exposure; the need for amputation due to inability to restore blood flow; and infection, stroke, irregular heartbeat, heart attack or death. This information is not intended to replace a discussion with your healthcare provider on the benefits and risks of this procedure to you. For the complete listing of indications, contraindications, warnings and adverse events, please see the Instructions For Use.

REFERENCES

4 Spectranetics internal data on file, 2014.
6 Major adverse events are defined as all cause death, major amputation in the target limb, or target lesion revascularization (TLR) (surgical or interventional) from procedure to 30 days (+ 7 days).