LASER ATERECTOMY + PTA

Proven more effective and safer than PTA alone for In-Stent 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. The Turbo-Tandem and Turbo-Elite devices with PTA, have been proven superior in efficacy and safety for the treatment of FemPop ISR.

Superior Efficacy

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

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

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<thead>
<tr>
<th></th>
<th>Turbo-Tandem™ + PTA</th>
<th>PTA Alone</th>
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<tbody>
<tr>
<td>Major adverse events at 30 days</td>
<td>5.8%</td>
<td>20.5%</td>
</tr>
<tr>
<td>Major dissection</td>
<td>2.4%</td>
<td>7.4%</td>
</tr>
<tr>
<td>Risk of stent interaction</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 debunks 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 atherectomy 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.

*There is a **NEW** Standard of Care to Treat FemPop ISR.*
Important Safety Information

Turbo-Tandem

The 7 and 8 French Turbo-Tandem systems are indicated for atherectomy of infrainguinal arteries.

The 7 French Turbo-Tandem System is indicated for laser atherectomy of de novo or restenotic lesions in native infrainguinal arteries and for the treatment of femoropopliteal artery in-stent restenosis (ISR) in bare nitinol stents, with adjunctive Percutaneous Transluminal Angioplasty (PTA). A > 2.0mm pilot channel must be present for treatment using the Turbo-Tandem.

No long-term adverse effects on the arterial vessel wall, due to peripheral excimer laser recanalization, are known at this time.

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at anytime during and/or after the procedure. Potential complications include but are not limited to: perforation of the vessel wall, major dissection, pseudoaneurysm, arteriovenous fistula, spasm, distal embolization, thrombosis, reocclusion, hematoma at the puncture site, bleeding or Acute Limb Ischemia (ALI), any of which may require a reintervention, bypass surgery or amputation; infection, renal failure, nerve injury, stroke, myocardial infarction, arrhythmia, death and other.

This information is not intended to replace a discussion with your healthcare provider on the benefits and risks of this procedure to you.

Turbo-Elite

The Turbo-Elite Laser Catheter devices are indicated for use in the treatment of infrainguinal stenosis and occlusions. When used in conjunction with the Turbo-Booster and/or as an accessory to the Turbo-Tandem System, the devices are indicated for atherectomy of infrainguinal arteries.

The 0.014” and 0.018” Over-the-wire (OTW) Turbo-Elite laser catheters are also indicated for use as an accessory to the use of the Turbo-Tandem System in the treatment of femoropopliteal artery in-stent restenosis (ISR) in bare nitinol stents, when used in conjunction with Percutaneous Transluminal Angioplasty (PTA).

Potential adverse events associated with procedures used to treat PAD may include: a sudden, temporary or ongoing re-closure of the treated artery; blood clot or obstruction of the artery by plaque debris; a tear, rupture or damage to the artery (or nearby vein or nerve); minor bleeding or bruising at the entry site. Other complications may occur.

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 important safety information, please visit www.spnc.com/IFU.

REFERENCES


3 EXCITE Trial Clinical Study Report, Spectranetics data on file, July 2014.


5 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).

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