



Indications for Use

Turbo-Elite

US Only:

The Turbo-Elite devices are indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions. 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).

OUS:

For atherectomy of infrainguinal arteries.

Contraindications

No known contraindications.

Potential Adverse Events

Use of the **Turbo-Elite** may contribute to the following complications:

- Events Observed during Clinical Studies:
 - Procedural Complications: spasm, major dissection, thrombus, distal embolization, perforation, other.
 - Serious Adverse Events: death, reintervention, ALI, major amputation, bypass surgery, hematoma with surgery.
 - In-hospital Complications: re-occlusion, pseudoaneurysm, renal failure, bleeding.
- Potential Adverse Events NOT Observed during Clinical Studies: nerve injury, AV fistula formation, endarterectomy, infection, stroke, myocardial infarction, arrhythmia.

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