



TOBA II and TOBA III



TOBA II: Study Summary

- Design

- ▶ Prospective, multi-center, single-arm, non-blinded study designed to investigate the safety and efficacy of the Tack Endovascular System®

- Number of Sites and Subjects

- ▶ Sites: Up to 40 U.S. and Europe
- ▶ Subjects: 210

- Subject Population

- ▶ Subjects with *de novo* or re-stenotic or occluded lesions located in the SFA and P1 arteries with RVD of 2.5 to 6.0 mm
- ▶ Subjects with <30% residual stenosis AND evidence of dissection post PTA (POBA or DCB)



TOBA III: Study Summary

- Design

- ▶ Prospective, multi-center, single-arm, non-blinded study designed to investigate the safety and efficacy of the Tack Endovascular System

- Number of Sites and Subjects

- ▶ Sites: approximately 15 in Europe
- ▶ Subjects:
 - 170 with lesions \leq 150mm (90% power)
 - 30 with lesions $>$ 150mm

- Subject Population

- ▶ Subjects with *de novo* or re-stenotic or occluded lesions located in the SFA and P1 arteries with RVD of 2.5 to 6.0 mm
- ▶ Subjects with $<$ 30% residual stenosis AND evidence of dissection post PTA (Medtronic DCB)