

Tack Endovascular System

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KEY FEATURES

- 6-F/0.035-inch over-the-wire delivery system
- Six preloaded Tack implants on a single catheter
- Self-sizes to tapering vessel diameters from 3.5 to 6 mm with a single system
- Nitinol with gold radiopaque markers
- Accurate (≤ 1 mm) Tack implant deployment

The Tack Endovascular System is a first-of-its-kind dissection repair device that is purpose-built for precision treatment of peripheral arterial dissections after percutaneous transluminal angioplasty (PTA). The Tack Endovascular System (6 F) is intended for use in the superficial and proximal popliteal arteries ranging in diameter from 3.5 to 6 mm for the repair of post-PTA dissection(s).

The TOBA II pivotal trial evaluated post-PTA dissection repair after both standard and drug-coated balloon angioplasty above the knee. The results demonstrated 92.1% complete dissection resolution in a clinically challenging patient population (100% dissected vessels), 79.3% Kaplan-Meier vessel patency, and 86.5% Kaplan-Meier freedom from clinically driven reintervention at 12 months. Additionally, the TOBA II trial validated the Tack implants as stable and durable with zero implant fractures, 99.9% freedom from migration, and a 0.5% bailout stent rate.

"Postangioplasty dissections can significantly impact patient outcomes. Having a minimal metal solution that specifically addresses dissections and improves angioplasty results while preserving future treatment options is extremely exciting," said William Gray, MD. Dr. Gray is the System Chief of the Division of Cardiovascular Disease at Main Line Health and President of the Lankenau Heart Institute in Wynnewood, Pennsylvania, as well as Principal Investigator for the TOBA II trial.

The Tack Endovascular System (6 F) is FDA approved for use in the superficial and proximal popliteal arteries (3.5- to 6-mm reference vessel diameter) for treatment of post-PTA dissections. The Tack Endovascular System is CE Mark authorized under EC Directive 93/42/EEC. ■

