Dissection Repair Device for
Above-the-Knee Interventions

Tack Endovascular System®

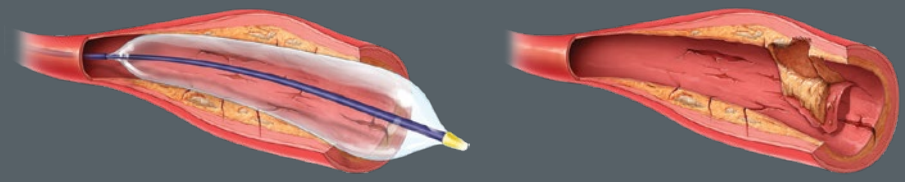
PURPOSE-BUILT. **PRECISION** REPAIR. **PRESERVES** OPTIONS.

intact® vascular

Dissections are inevitable

Balloon angioplasty is a proven and effective method to treat peripheral artery disease (PAD) in the superficial femoral (SFA) and popliteal arteries, but the mechanism of angioplasty inevitably creates arterial dissections. Left untreated, these dissections may obstruct blood flow both immediately and in the long term. They demonstrate high restenosis and reintervention rates so it is important to repair them when they occur in order to maintain vessel integrity and improve patency.

Balloon angioplasty uses multi-directional force to increase the arterial lumen, injuring the vessel wall.



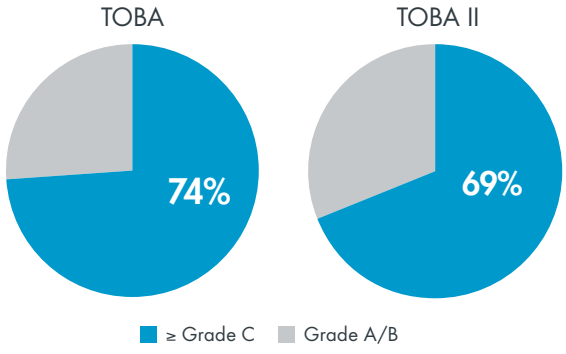
Increasing clinical evidence proves that dissections matter.

Dissections are prevalent, underdiagnosed & underestimated

Studies show that post-percutaneous transluminal angioplasty (PTA) dissections are prevalent, underdiagnosed and underestimated, leading to increased risk for PAD patients, even after undergoing treatment for their disease.

PREVALENT – Dissections are visible on angiography in up to 84% of above-the-knee (ATK) angioplasties.[1] In the Tack Optimized Balloon Angioplasty (TOBA and TOBA II) trials, the angiographic core lab adjudicated 69-74% of dissections as ≥ Grade C (**Figure 1**).[2-4]

Figure 1: Rates of Severe Dissection post-PTA
(core lab adjudicated)

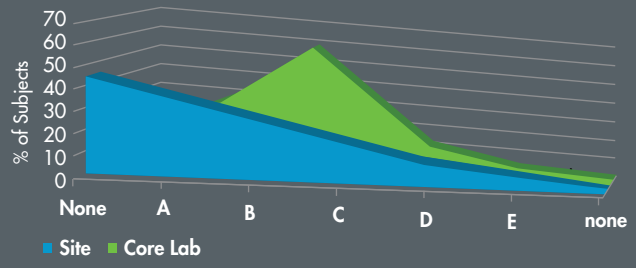


UNDERDIAGNOSED – Dissections can be misinterpreted or missed if viewed from only one angle, and/or without magnification. Studies using intravascular ultrasound (IVUS) have shown dissections are more numerous and more severe than what is seen angiographically.[5]

UNDERESTIMATED – In the TOBA trial, investigators graded dissections as ≥ Grade C in 25.8% of cases, compared with the core lab at 74.0% (**Figure 2**).[3] Correlation improved in TOBA II with dissection training (**Figure 3**).[4]

Figure 2.

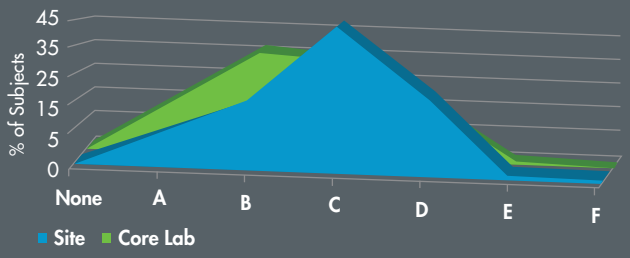
TOBA: BASELINE DISSECTION GRADE



Major disparity between site-reported and core lab dissection grade

Figure 3.

TOBA II: BASELINE DISSECTION GRADE



Strong correlation between site-reported and core lab dissection grade after training

Dissections matter

While there is consensus that severe dissections result in poorer outcomes, recent studies demonstrate that any untreated dissection can negatively impact vessel patency, target lesion revascularization (TLR) rates, and patient outcomes.[1,6]

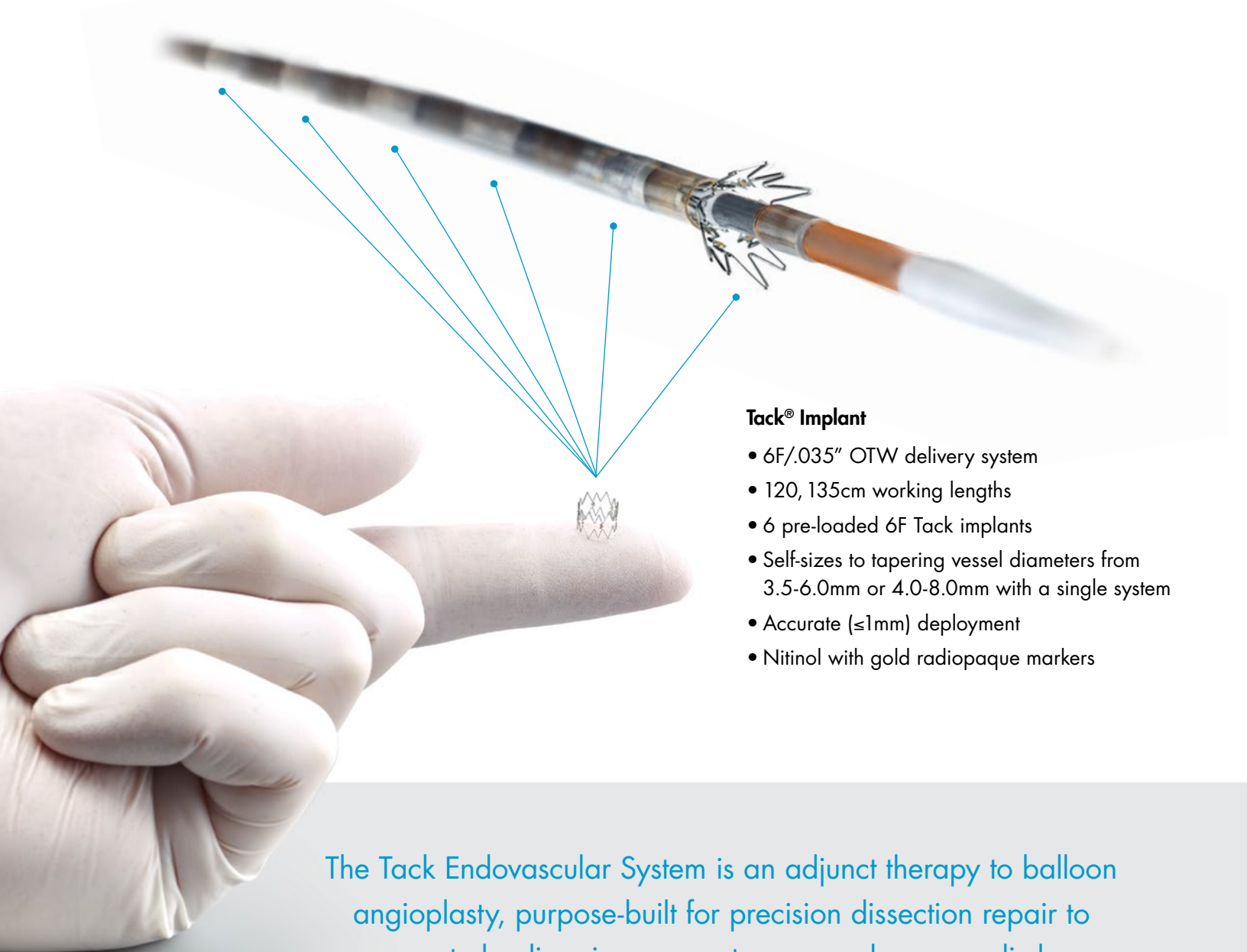
In the THUNDER study, Grade A-B dissections experienced similar rates of six-month TLR as did Grades C-E (33% and 44%, respectively). At 24 months, TLR rates increased to 43% for Grades A-B and 78% for Grades C-E.[6]

Dissections are an inherent result of angioplasty and they matter, regardless of severity.

The Tack Endovascular System®

A purpose-built solution to successfully repair dissections caused by balloon angioplasty in ATK therapeutic interventions, the Tack Endovascular System (6F) provides precision treatment using minimal metal. This first-of-its-kind implant, designed to repair dissections with high rates of patency and freedom from CD-TLR, ultimately preserves future treatment options.

The Tack Endovascular System is an adjunct therapy to plain balloon angioplasty (POBA) and drug-coated balloon (DCB) procedures and is specifically designed to support long-term patency and improve outcomes. Pre-loaded with six self-expanding nitinol implants that can be precisely deployed to treat multiple dissections with a single catheter, a Tack® implant leaves behind >70% less metal than stents.[3]



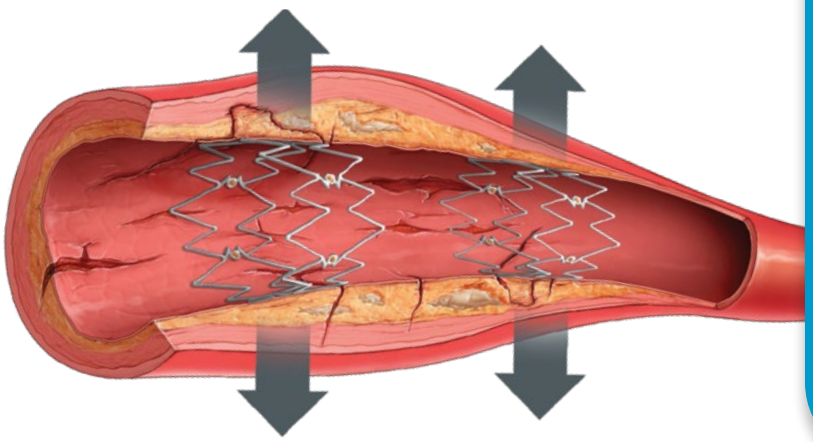
Tack® Implant

- 6F/.035" OTW delivery system
- 120, 135cm working lengths
- 6 pre-loaded 6F Tack implants
- Self-sizes to tapering vessel diameters from 3.5-6.0mm or 4.0-8.0mm with a single system
- Accurate (≤1mm) deployment
- Nitinol with gold radiopaque markers

The Tack Endovascular System is an adjunct therapy to balloon angioplasty, purpose-built for precision dissection repair to promote healing, improve outcomes and preserve limbs.

No More Device Sizing

Only the Tack Endovascular System features Adaptive Sizing™ — which allows a Tack implant to adapt to tapering anatomy while maintaining a relatively constant radial force. This means that a single size Tack implant can be used across a wide range of vessel diameters.



PURPOSE-BUILT:

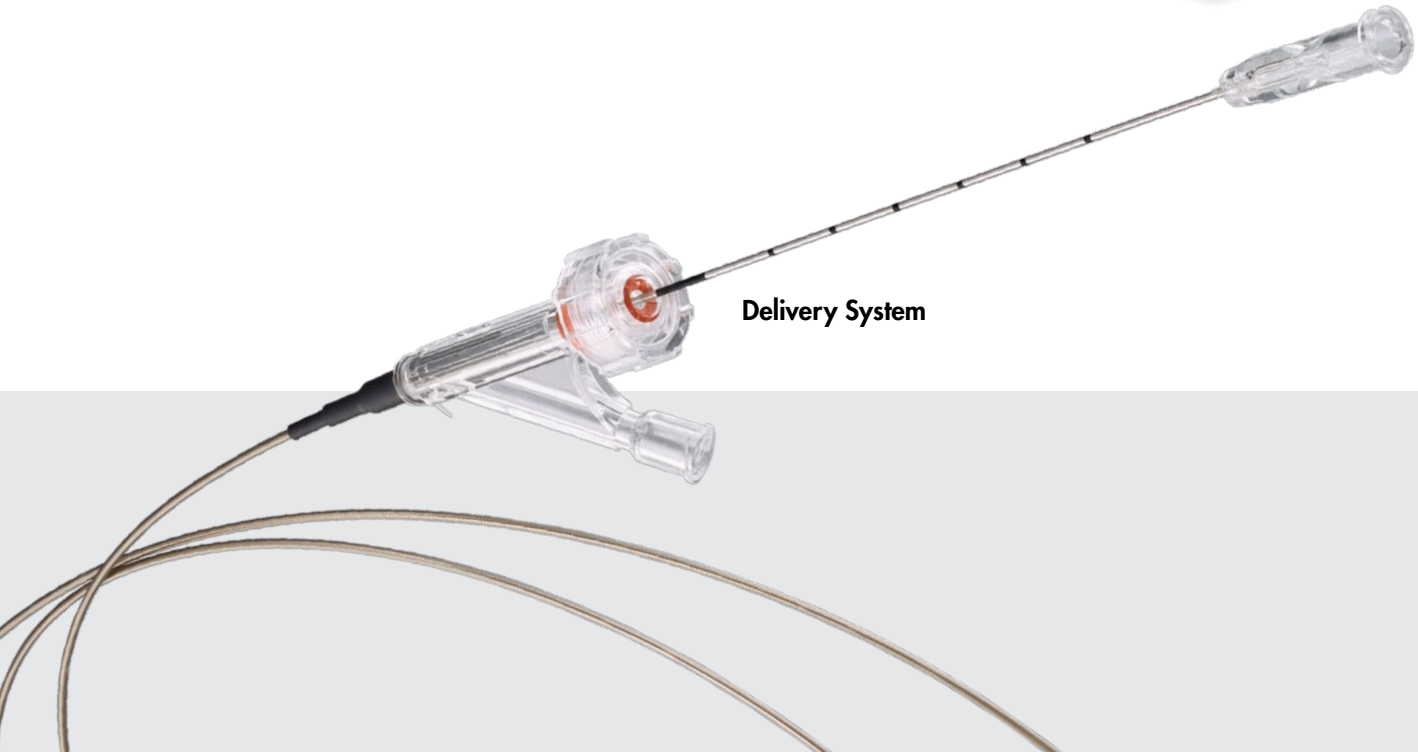
The Tack Endovascular System is purpose-built to repair peripheral arterial dissections following balloon angioplasty in ATK therapeutic interventions.

PRECISION REPAIR:

The Tack Endovascular System is a first-of-its kind solution for focal dissection repair.

PRESERVES OPTIONS:

A Tack implant leaves behind >70% less metal than stents,[3] preserving vessel integrity, future treatment options and – ultimately – limbs.



Clinical Data

TOBA II
TACK OPTIMIZED BALLOON ANGIOPLASTY

This multi-center, pivotal trial studied the Tack Endovascular System in patients with post-PTA dissection following POBA or Lutonix® DCB in the SFA and proximal popliteal arteries.* The trial enrolled 213 patients with at least one post-PTA dissection, with 69.4% adjudicated as severe.

KEY RESULTS[4]:

92.1%
Dissection Resolution

86.5%
12m K-M Freedom from CD-TLR

79.3%
12m K-M Primary Patency

100%
Freedom from Fracture

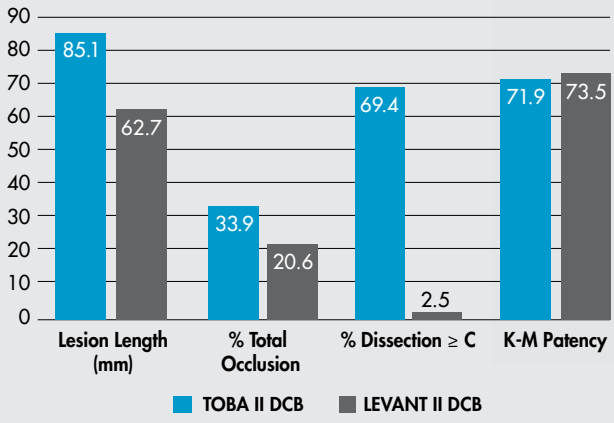
99.9%
12m Freedom from Implant Migration†

0.5%
Bail Out Stent Rate

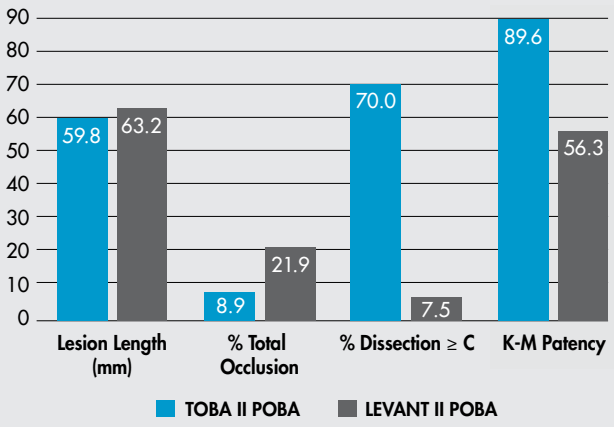
†2.6mm per core lab at 12m x-ray

PATENCY OBSERVATIONS IN TOBA II+

DCB patients had longer lesions and more total occlusions. Compared with the LEVANT II trial,[7] the Tack Endovascular System demonstrated a DCB-like patency rate in a more complicated (100% dissected vessels) patient population.



POBA patients had fewer total occlusions, yet more severe dissections. The Tack Endovascular System had a notably higher patency rate than the POBA arm in LEVANT II.



*Balloon choice was at the discretion of the physician.
+Observational data only; patient populations and study methodology differed; not powered for statistical significance.

The Tack Endovascular System® has been rigorously studied in the TOBA trials. These trials are unique in that they are the only clinical trials to investigate **100% dissected vessels**.

TOBA III
TACK OPTIMIZED BALLOON ANGIOPLASTY

This European multi-center post-CE Mark study continues the evaluation of dissection repair with the Tack Endovascular System following DCB with the IN.PACT™ Admiral™ in the SFA and proximal popliteal arteries (N=201). The study enrolled 169 patients with standard lesions ≤150mm, and 32 patients with long lesions >150mm and ≤250mm.

STANDARD LESION KEY RESULTS[8]:

97.7%	97.5%	95.0%	0.6%
Dissection Resolution	12m K-M Freedom from CD-TLR	12m K-M Primary Patency	Bail Out Stent Rate

LONG LESION KEY RESULTS:

98.8%	96.8%	89.3%	0.0%
Dissection Resolution	12m K-M Freedom from CD-TLR	12m K-M Primary Patency	Bail Out Stent Rate

TOBA II and TOBA III successfully met primary safety and efficacy endpoints demonstrating that post-PTA dissection repair with the Tack Endovascular System improves patency and freedom from CD-TLR for both POBA and DCB angioplasty.

Dissections Matter

While post-PTA dissections are consistently underdiagnosed and underestimated, they are inevitable and should be repaired to reduce the risk of revascularization and optimize patient outcomes. **The Tack Endovascular System is a first-of-its-kind minimal metal implant that effectively repairs dissections and improves post-angioplasty outcomes regardless of balloon choice.**

REFERENCES
1. Fujihara M, Takahara M, Sasaki S et al. Angiographic dissection patterns and patency outcomes after balloon angioplasty for superficial femoral artery disease. *J Endovasc Ther* 2017;1-9.
2. National Heart, Blood and Lung Institute. Coronary artery angiographic changes after PTCA. In: Manual of operations: NHLBI PTCA registry. Bethesda, MD: *NHLBI*; 1985. p. 6-9.
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5. Shammas NW, Torey JT, Shammas WJ et al. Intravascular ultrasound assessment and correlation with angiographic findings demonstrating femoropopliteal arterial dissections post atherectomy: results from the iDissection study. *J Invasiv Cardiol* 2018;30(7):240-244.
6. Tepe G, Zeller T, Schnorr B et al. High-grade, non-flow-limiting dissections do not negatively impact long-term outcome after paclitaxel-coated balloon angioplasty: an additional analysis from the THUNDER study. *J Endovasc Ther* 2013;20:792-800.
7. Rosenfield K, Jaff MR, White CJ et al. Trial of a paclitaxel-coated balloon for femoropopliteal artery disease. *N Engl J Med* 2015;2:145-53.
8. Data on file with Intact Vascular, Inc.

INTENDED USE: The Tack Endovascular System (6F, 3.5mm-6.0mm and 4.0mm-8.0mm) is intended for use in the superficial femoral and proximal popliteal arteries ranging in diameter from 2.5mm to 6.0mm and 4.0mm to 8.0mm for the repair of post percutaneous transluminal balloon angioplasty (PTA) dissection(s).

CONTRAINDICATIONS FOR USE: The Tack Endovascular System is contraindicated for the following:
1. Patients with residual stenosis in the treated segment equal to or greater than 30% after PTA.
2. Tortuous vascular anatomy significant enough to prevent safe introduction and passage of the device.
3. Patients with a known hypersensitivity to nickel-titanium alloy (Nitinol).
4. Patients unable to receive standard medication used for interventional procedures such as anticoagulants, contrast agents and antiplatelet therapy.

Prior to using the Tack Endovascular System, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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www.intactvascular.com

Intact Vascular, Inc. | 1285 Drummers Lane, Suite 200 | Wayne, PA 19087
Tel: 484.253.1048 | Fax: 484.253.1047 | email: info@intactvascular.com

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