PHILIPS

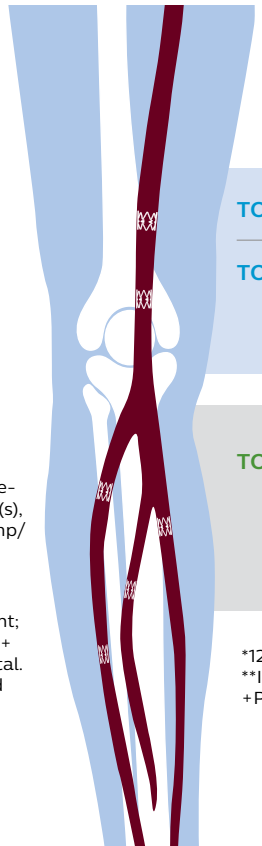
Tack

Endovascular system

# TOBA clinical studies overview

## A first-of-its-kind minimal metal implant with positive clinical data demonstrates some of the highest reported rates of safety, patency, and limb salvage.

**The Tack endovascular system** has been rigorously studied in the Tack Optimized Balloon Angioplasty (TOBA) trials. These trials are unique in that they are the only clinical trials to investigate **100% dissected vessels.** The TOBA II, TOBA III, and TOBA II BTK studies add to the large body of clinical evidence supporting the use of the Tack endovascular system, further demonstrating that post-PTA dissection repair with the Tack endovascular system improves outcomes for both POBA and DCB angioplasty for patients with PAD and CLI.



**Above the knee**

MAE: Freedom from index limb amputation (above the ankle), CD-TLR and all-cause death at 30 days.

Primary patency: Freedom from DUS-derived binary restenosis and freedom from CD-TLR.

**Below the knee**

MALE + POD: composite of all-cause death, above-ankle target limb amputation, and/or major re-intervention to the target lesion(s), defined as new bypass graft, jump/interposition graft revision, or thrombectomy/thrombolysis.

Tacked segment patency: DUS flow or no flow in Tacked segment; Tacked segment is Tack implant + 5 mm of artery proximal and distal. Tacks within 1 cm are considered same segment.

## Recent TOBA studies have shown that the Tack implant:

| | Repairs dissections | Is safe | Preserves treatment options | Optimizes PTA | Heals/improves wounds | Saves limbs |
|---|---|---|---|---|---|---|
| TOBA II[1] | 92.1% | No MAE at 30-days | 86.5% | 79.3% | | |
| TOBA III[2] | 97.7% Dissection resolution | No MAE at 30-days Safety | 97.5% 12-month K-M freedom from CD-TLR | 95.0% 12-month K-M primary patency | | |
| TOBA II BTK[3] | 100.0% Dissection resolution | 98.7% 30-day freedom from MALE + POD | 83.1% 12-month K-M freedom from CD-TLR* | 81.3% 12-month K-M Tacked segment patency* | 84.6% Wounds healed or improved at 12 months** | 96.1% 12-month K-M target limb salvage in CLI patients+ |

*12-month data has not been reviewed by FDA, ITT.
**Includes minor amputation; post-hoc analysis, has not been reviewed by FDA.
+Post-hoc analysis, has not been reviewed by FDA.

## TOBA II[1]

This multi-center, global pivotal trial studied the **Tack endovascular system (6F, 3.5-6.0 mm)** in patients with post-PTA dissection following POBA or Lutonix DCB in the SFA and proximal popliteal arteries.

### Key results (N=213)

**92.1%** Dissection resolution

**86.5%** 12-month K-M freedom from CD-TLR

**79.3%** 12-month K-M primary patency

**0.5%** Bail out stent rate

**100%** Freedom from fracture

**99.9%** 12-month freedom from implant migration

## TOBA III[2]

This European multi-center post-CE Mark study continues the evaluation of dissection repair with the **Tack endovascular system (6F, 3.5-6.0 mm)** following DCB with the IN.PACT Admiral in the SFA and proximal popliteal arteries.

### Standard lesion key results (n=169)

**97.7%** Dissection resolution

**97.5%** 12-month K-M freedom from CD-TLR

**95.0%** 12-month K-M primary patency

**0.6%** Bail out stent rate

### Long lesion key results (n=32)

**98.8%** Dissection resolution

**96.8%** 12-month K-M freedom from CD-TLR

**89.3%** 12-month K-M primary patency

**0.0%** Bail out stent rate

## TOBA II BTK[3]

This multi-center, global pivotal study evaluates the **Tack endovascular system (4F, 1.5-4.5 mm)** in patients with critical limb ischemia (CLI) and dissections resulting from percutaneous transluminal angioplasty (PTA) using a standard balloon in the mid/distal popliteal, tibial and peroneal arteries.

### Key results (N=233)

**98.7%** 30-day freedom from MALE + POD

**95.8%** K-M freedom from 6-month MALE + 30-day POD

**89.6%** 6-month K-M Tacked segment patency

**98.6%** 6-month K-M target limb salvage

### Sustained patient and clinical outcomes with no implant fracture, migration or embolization at 12 months

**100%** Dissection resolution

**83.1%** 12-month K-M freedom from CD-TLR*

**81.3%** 12-month K-M Tacked segment patency*

**96.1%** 12-month K-M target limb salvage in CLI patients+

**89.0%** 12-month K-M amputation-free survival in CLI patients+

**79.1%** of patients improved to RC ≤ 2 at 12 months+


1. Gray WA, Cardenas JA, Brodmann M et al. Treating post-angioplasty dissection in the femoropopliteal arteries using the Tack Endovascular System: 12-month results from the TOBA II study. *JACC Cardiovascular Interventions* 12.2 (2019): 75-84.
2. Brodmann M, Wissgott C, Brechtel K, et al. Optimized drug-coated balloon angioplasty of the superficial femoral and proximal popliteal arteries using the Tack Endovascular System: TOBA III 12-month results. *J Vasc Surg.* 2020;S0741-5214(20)30330-X.
3. Geraghty PJ, Adams GL, Schmidt A, Lichtenberg M, Wissgott C, Armstrong EJ, Hertting K, on behalf of the TOBA II BTK Investigators. "Twelve-month results of Tack-optimized balloon angioplasty using the Tack Endovascular System in below-the-knee arteries (TOBA II BTK)." *Journal of Endovascular Therapy* 27.4 (2020): 626-636.


**Intended use:** The Tack endovascular system (6F, 3.5-6.0 mm and 4.0-8.0 mm) is intended for use in the superficial femoral and proximal popliteal arteries ranging in diameter from 3.5 mm to 6.0 mm and 4.0 mm to 8.0 mm for the repair of post percutaneous transluminal balloon angioplasty (PTA) dissection(s).
The Tack endovascular system (4F, 1.5-4.5 mm) is intended for use in mid/distal popliteal, tibial and peroneal arteries, ranging in diameter from 1.5 mm to 4.5 mm, 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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