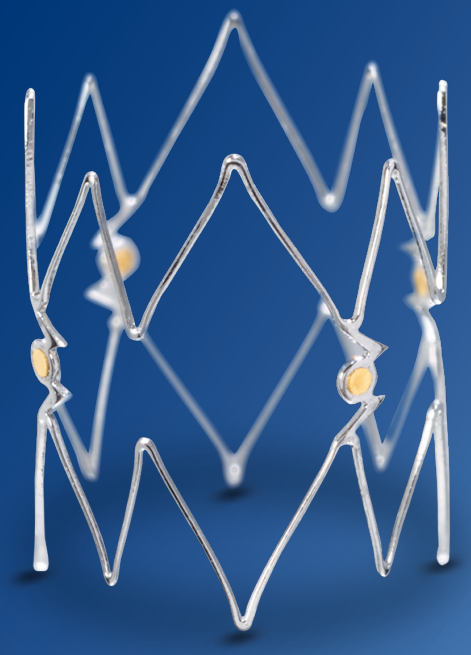
PHILIPS

Dissection Repair Solution

Tack Endovascular System

TOBA II BTK clinical study 36-month summary

Philips Dissection Repair Solution Tack Endovascular System (4F)



TOBA II BTK: 36-month clinical summary[1-3]

Study summary

TOBA II BTK objective:

- Evaluate safety and efficacy of the Philips Dissection Repair Solution – Tack Endovascular System in subjects with below-the-knee (BTK) peripheral arterial disease
- Treatment with standard POBA + Philips Tack only

Complex patient population:

- 83.7% CLI (RC 4+5)
- 47.6% CTO
- 80 mm mean lesion length

Primary endpoints met; patency studied through 12 months:

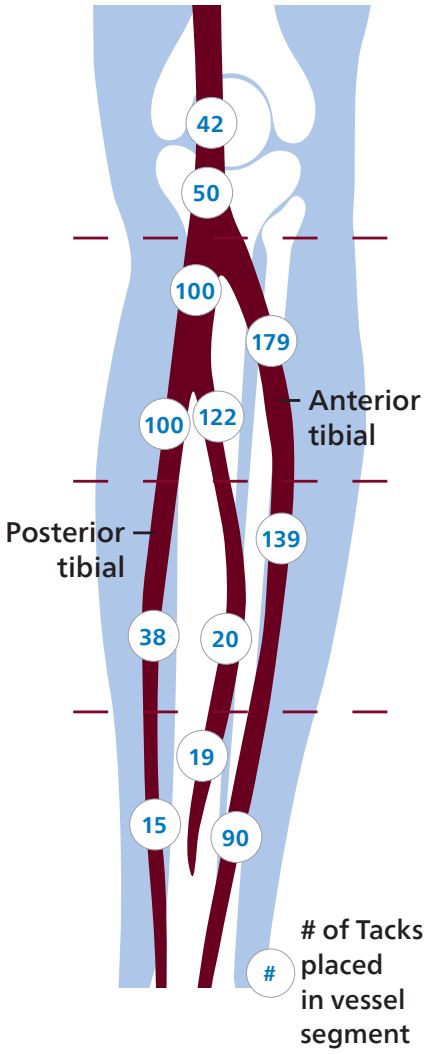
- 81.3% K-M tacked segment patency

Durability of dissection repair to 36 months:

- 69.6% K-M freedom from CD-TLR in all patients
- 93.9% K-M target limb salvage in CLI patients

Sustained, significant improvement through 36 months in:

- Rutherford category
- ABI/TBI
- Quality of life
- Mobility



Study design

Prospective, multi-center, single-arm pivotal IDE study

Population: Patients with CLI and angiographic evidence of a dissection post-PTA requiring repair in the mid/distal popliteal, tibial and/or peroneal arteries

Enrollment: 233 patients at 41 US and international sites

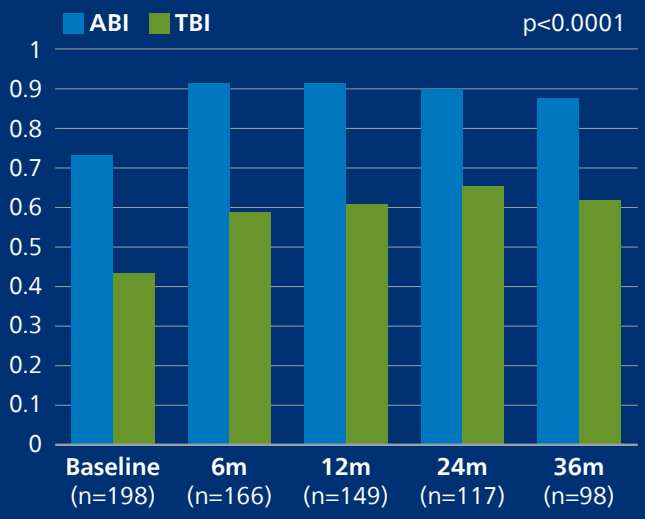
Primary endpoints:

- **Safety:** MALE + POD at 30d
- **Efficacy:** Freedom from MALE at 6m + POD at 30d

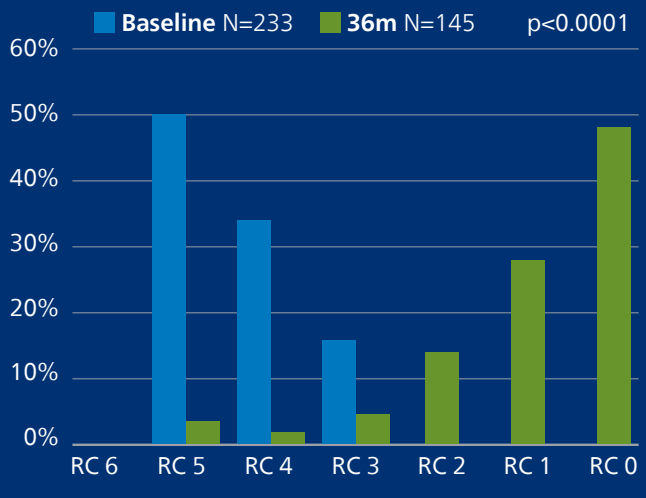
MALE + POD: composite of all-cause death, above-ankle target limb amputation, or major re-intervention to the target lesion(s), defined as new bypass graft, jump/interposition graft revision, or thrombectomy/thrombolysis

Sustained clinical improvement to 36 months (ITT population)

Ankle and toe brachial index

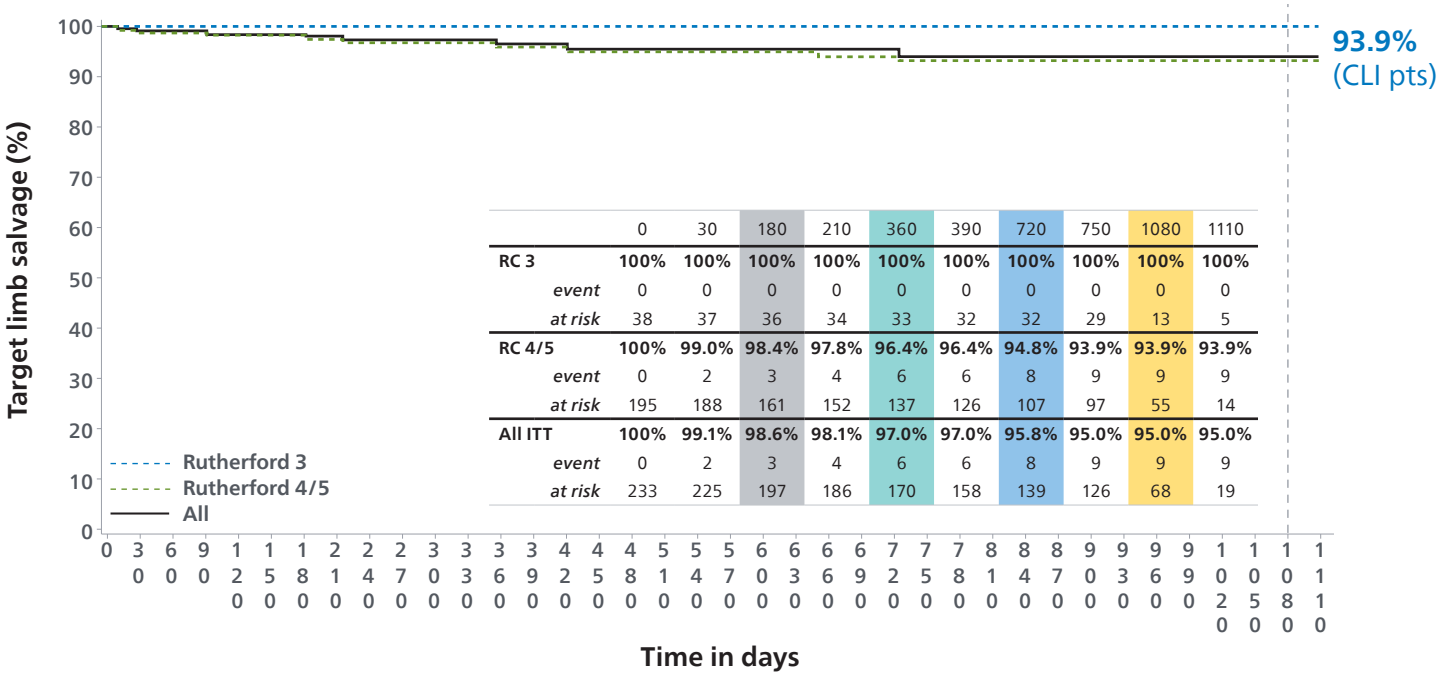


Rutherford category



36-month target limb salvage

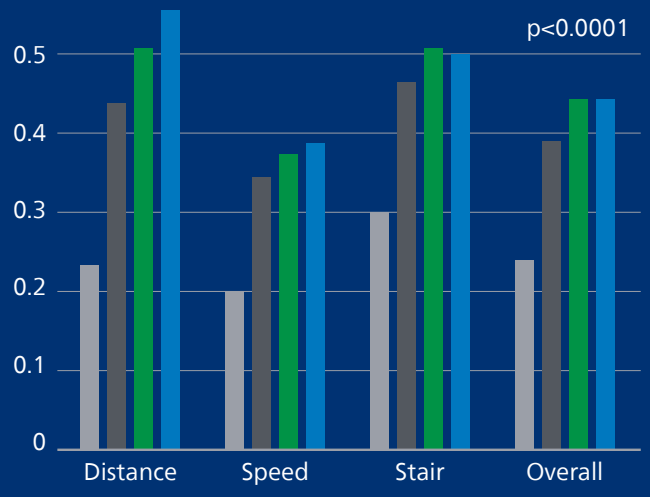
Distal tibial delivery with no fracture, and sustained target limb salvage to 36 months
(ITT population by baseline Rutherford, core lab adjudicated)



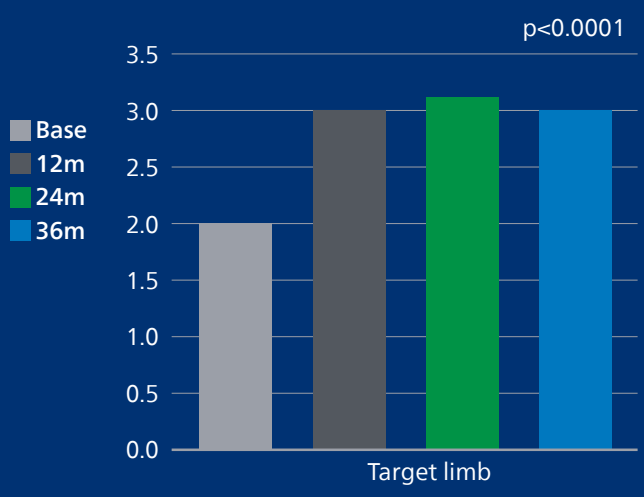
Dissection repair with Tack saves limbs.

Sustained improvement in mobility to 36 months (ITT population)

Walking impairment questionnaire (WIQ)



Peripheral artery questionnaire (PAQ)



1. Geraghty PJ, Adams GL, Schmidt A, on behalf of the TOBA II BTK Investigators. Six-month pivotal results of Tack optimized balloon angioplasty using the Tack Endovascular System in below-the-knee arteries. J Vasc Surg. 2021 Mar;73(3):918-929.e5.
2. 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). (TOBA II BTK). J Endovasc Ther 2020 27;4:626-636.
3. Adams GL. TOBA II BTK 36m Results. New Cardiovascular Horizons (NCVH). New Orleans, LA, USA June 2022 [presentation].

Intended use: The Tack Endovascular System (4F, 1.5 mm-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 treatment 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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Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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