Optimize below-the-knee PTA with precision dissection repair
Critical limb ischemia (CLI) is the most severe form of peripheral artery disease (PAD) with a high risk of amputation and death. The primary goal of treating CLI is to restore unobstructed blood flow, thus healing wounds, relieving pain and preventing limb loss.

There have been limits in the endovascular technologies available to treat CLI below the knee. Balloon angioplasty is the first line therapy for infrapopliteal interventions but it comes with challenges, including balancing the difficulty of achieving optimal luminal gain with managing dissections—resulting in less than desirable outcomes.

The mechanism of angioplasty inevitably creates arterial dissections. Left untreated, these dissections can lead to acute thrombosis and occlusion of the vessel, causing worsening symptoms and/or repeat procedures. Until now there was no therapeutic intervention option to optimally treat below-the-knee (BTK) dissections with confidence.

7.6 million people suffer from CLI in the US and western Europe\(^1,2\)

50% of patients with untreated CLI will undergo a major amputation or die within the first year\(^3\)

$40–66 billion Revascularization (surgical or endovascular) and amputation costs are $40–66 billion annually\(^4\)
The mechanism of angioplasty inevitably creates arterial dissections.
Optimizing PTA
with precision dissection repair

The Tack endovascular system (4F) is a purpose-built, minimal-metal solution for precision repair of post-PTA dissections. This novel dissection repair device is the first ever vascular implant FDA approved for below-the-knee therapeutic interventions.

It is crucial to repair dissections in BTK vessels to help restore obstructed blood flow, heal wounds, relieve pain, and prevent amputation. The Tack endovascular system (4F) is the only vascular implant to give physicians the ability to confidently treat challenging post-PTA BTK dissections and improve outcomes for patients with CLI.

An adjunct therapy to balloon angioplasty, Tack optimized PTA repairs BTK dissections with high rates of patency and freedom from CD-TLR, ultimately preserving future treatment options. Pre-loaded with four self-expanding and self-sizing nitinol implants, the system can be deployed to treat multiple dissections with a single catheter.

Tack implant
- 4F/014" BTK system
- 150 cm working length
- Four pre-loaded 4F Tack implants
- Self-sizes to tapering vessel diameters from 1.5-4.5 mm with a single system
- Accurate (≤ 1mm) Tack implant deployment
- Nitinol with gold radiopaque markers
No more device sizing

Only the Tack endovascular system features **adaptive sizing** – which allows each 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 BTK therapeutic interventions.

Precision repair
Focal treatment with minimal metal treats only the area where dissections are present and avoids covering portions of healthy tissue.

Preserves options
A Tack implant leaves behind significantly less metal than stents, preserving vessel integrity, future treatment options and – ultimately – limbs.
**Clinical data**

**TOBA II BTK** This multi-center, global pivotal study evaluates the **Tack endovascular system (4F, 1.5-4.5 mm)** in patients with CLI and dissections resulting from PTA using a standard balloon in the mid/distal popliteal, tibial and peroneal arteries. The trial enrolled 233 patients who had dissections requiring repair after standard PTA.5

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**TOBA II BTK 12-month results confirm that the Tack endovascular system (4F, 1.5-4.5 mm) is a durable, below-the-knee implant for post-PTA dissection repair that optimizes angioplasty to save limbs.**

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The study showed that the Tack endovascular system:

<table>
<thead>
<tr>
<th>Repairs dissections</th>
<th>Is safe</th>
<th>Preserves treatment options</th>
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<tr>
<td><strong>100%</strong> Dissection resolution</td>
<td><strong>98.7%</strong> 30-day freedom from MALE+POD*</td>
<td><strong>83.1%</strong> 12-month K-M freedom from CD-TLR**</td>
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<td><strong>81.3%</strong> 12-month K-M tacked segment patency†</td>
<td><strong>84.7%</strong> Wounds healed or improved at 12-months§</td>
<td><strong>96.1%</strong> 12-month K-M target limb salvage in CLI patients§</td>
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The TOBA II BTK study is the first to enroll patients with advanced CLI disease and 100% dissected vessels.

Patients reported sustained improvement in quality of life at 12 months in EQ-5D-3L scores.

Optimize PTA

The Tack endovascular system (4F) enables confident repair of challenging below-the-knee disease and delivers unprecedented post-PTA results to save limbs. This first-of-its-kind vascular implant is positioned to be the new standard of care for optimized balloon angioplasty, demonstrating improved outcomes in BTK interventions and patients with CLI.⁵
**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.**

**12 month data has not been reviewed by US FDA.**

1. Tacked segment patency: 12-month DUS flow/no flow in Tacked segment (Tack implant + 5 mm artery proximal and distal; Tacks within 1 cm are considered same segment); 12 month data has not been reviewed by US FDA.

2. Includes minor amputation; post-hoc analysis has not been reviewed by US FDA.

3. Target limb salvage: freedom from above ankle target limb amputation; post-hoc analysis, has not been reviewed by US FDA.

**References**


**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 including 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.

Tack endovascular system and Tack are registered trademarks of Intact Vascular, Inc. Adaptive sizing is a trademark of Intact Vascular, Inc.

Caution: Federal law restricts this device to sale by or on the order of a physician.