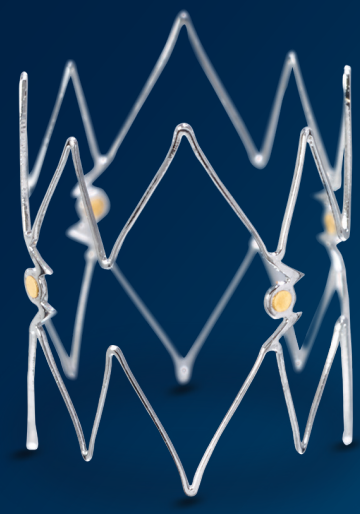
PHILIPS

Tack

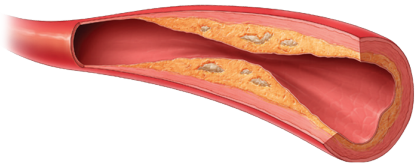
Endovascular system (4F)

Optimize below-the-knee PTA

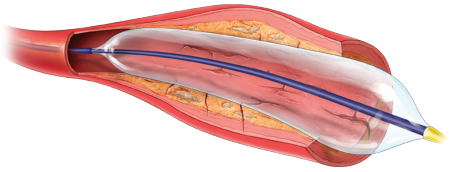
with precision dissection repair



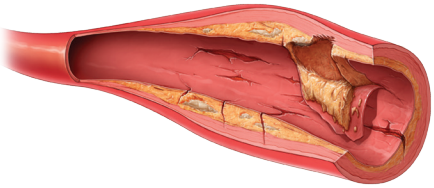
Critical limb ischemia
is serious and severe



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

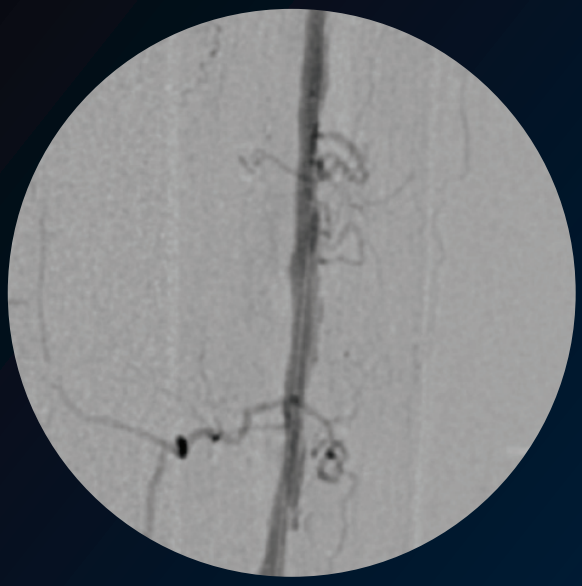
people suffer from CLI in the US and western Europe[1,2]

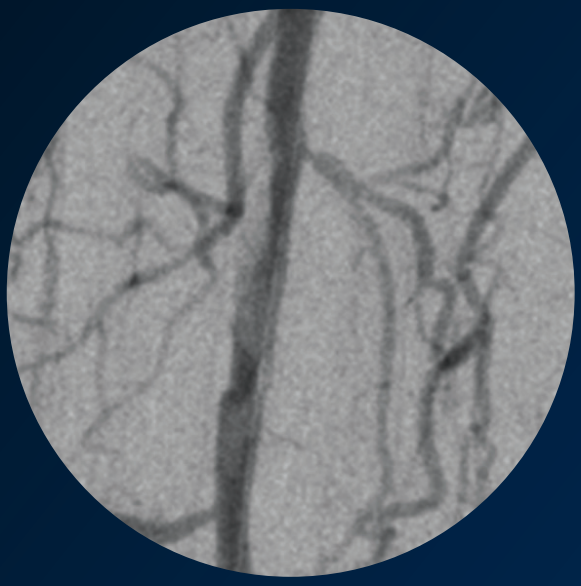
50% of patients

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]





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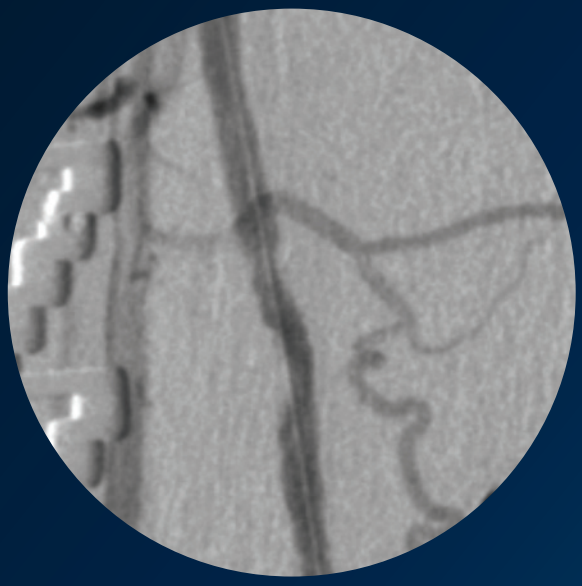
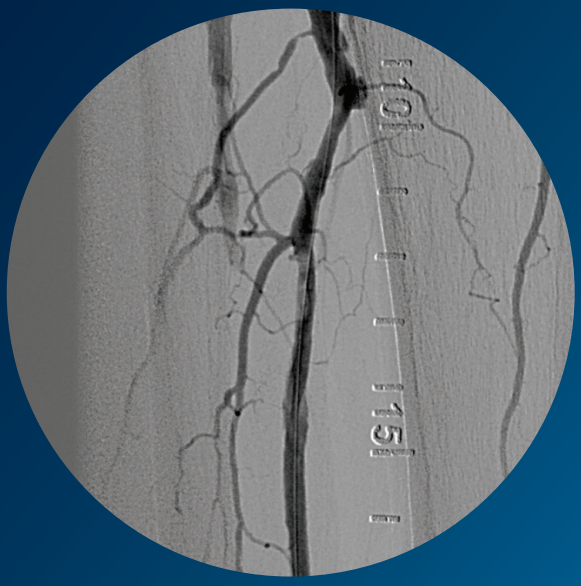




Images courtesy of Dr. med. Dipl. oec. med. Michael Lichtenberg and PD Dr. Christian Wissgott.

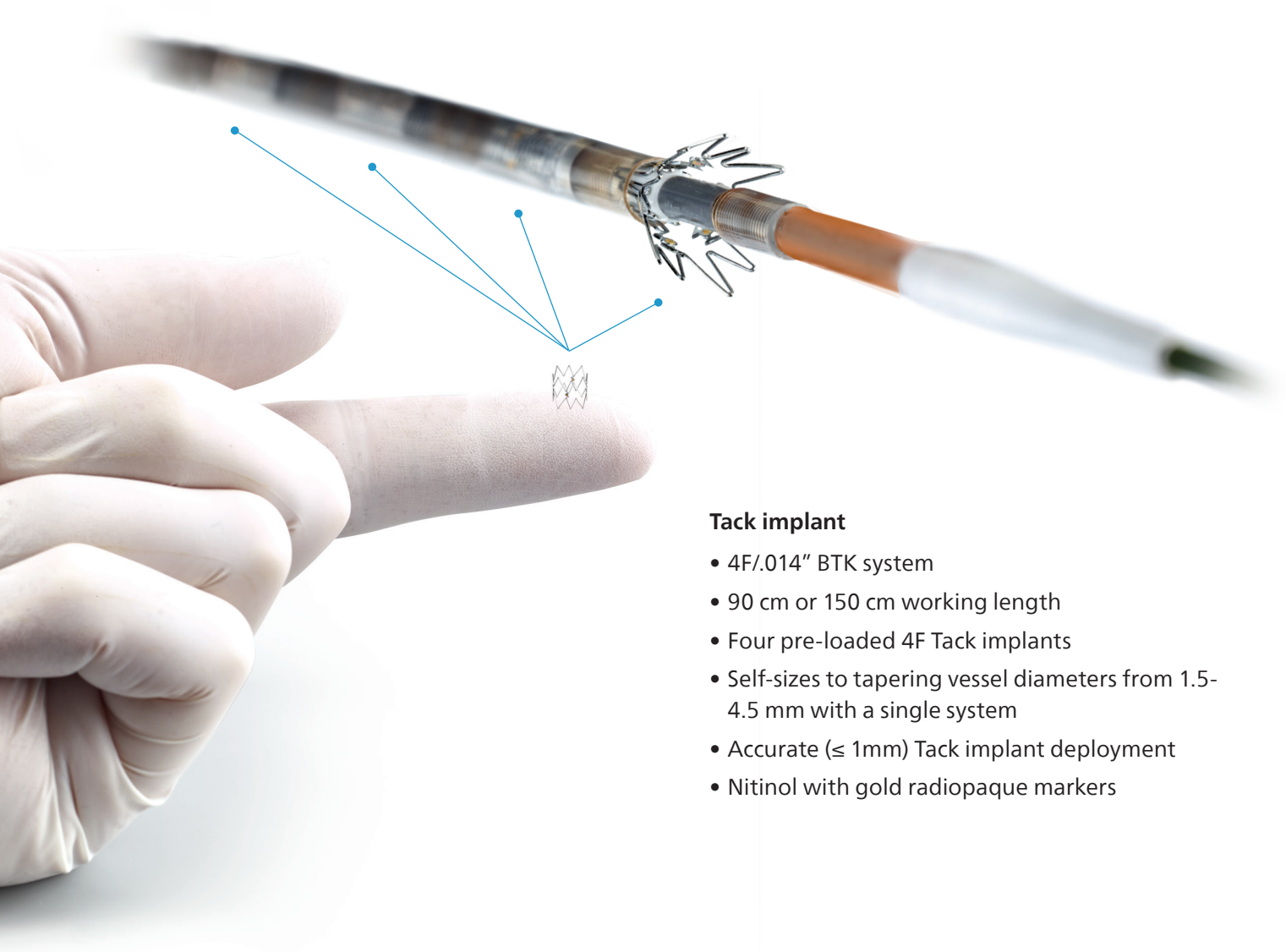
Optimizing PTA

with precision dissection repair

The Tack endovascular system (4F) is a purpose-built, minimal-metal solution for precision repair of post-PTA dissections.

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 a first-of-its-kind focal stent 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.[5] 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
- 90 cm or 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

Purpose-built

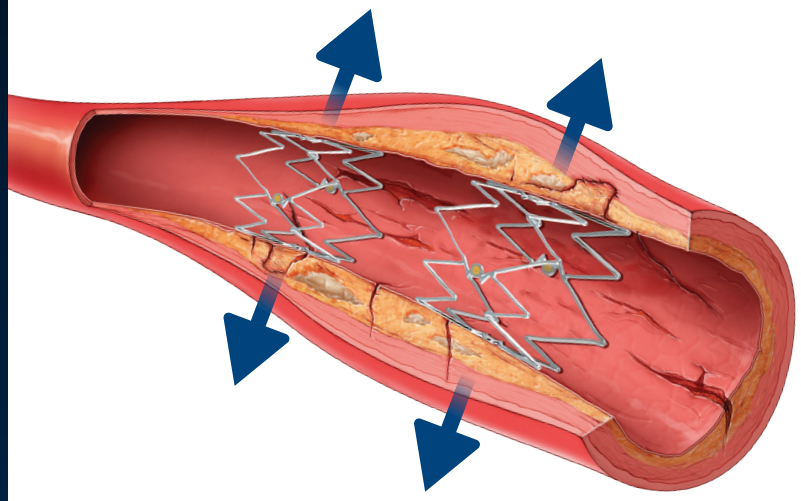
The Tack endovascular system is purpose-built to repair peripheral arterial dissections following balloon angioplasty in BTK therapeutic interventions.

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.



No more device sizing

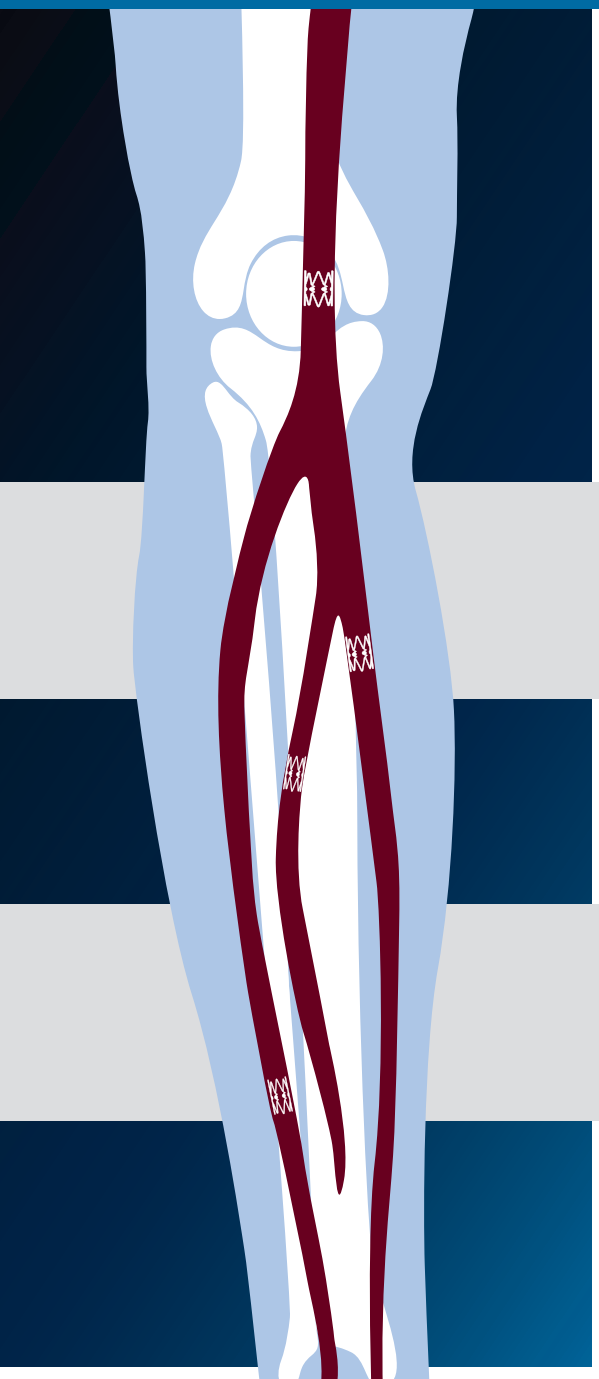
*Only the Tack endovascular system features **adaptive sizing** – which allows each Tack focal stent implant to adapt to tapering anatomy while maintaining a relatively constant radial force. This means that a single size Tack implant can be used across a wide range of vessel diameters.*

Delivery system

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]

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.



The study showed that the Tack endovascular system:

Repairs dissections

100%
Dissection resolution

Is safe

98.7%
30-day freedom from MALE+POD*

Preserves treatment options

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

Optimizes PTA

81.3%
12-month K-M tacked segment patency+

Heals/improves wounds

84.7%
Wounds healed or improved at 12-months‡

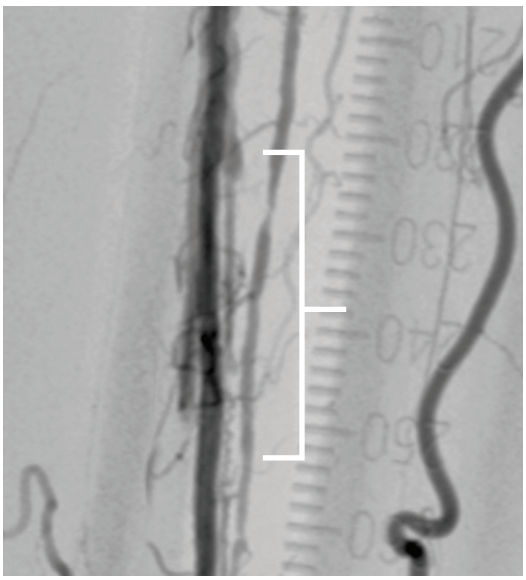
Saves limbs

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

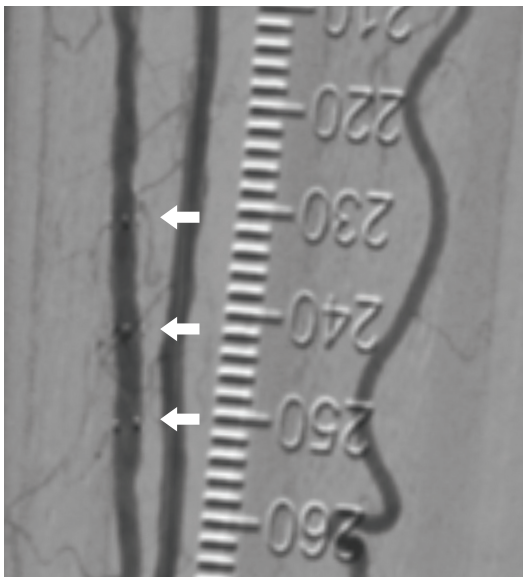
The TOBA II BTK study is the first to enroll patients with advanced CLI disease and 100% dissected vessels.

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

Pre-Tack implant



Post-Tack implant



Images courtesy of PD Dr. Christian Wissgott

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 focal stent 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.

+ 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.

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

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

References

1.Yost M, The Sage Group 2016. [Press Release - THE SAGE GROUP Releases New Estimates for the United States Prevalence and Incidence of Peripheral Artery Disease (PAD) andCritical Limb Ischemia (CLI)]
2. Yost M, The Sage Group 2017. [Press Release - According to THE SAGE GROUP, Peripheral Artery Disease (PAD) Afflicts 28 Million Western Europeans and 4.2 Million Suffer From Critical Limb Ischemia (CLI)]
3. Hirsch AT, Jaskal ZJ, Hertzer NR, et al. ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): executive summary a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease) endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. *J Am Coll Cardiol.* 2006;47(6):1239-312.
4.Yost M, The Sage Group; The economic cost of PAD, CLI & venous disease: how big is the market? presented at NCVH 2016.
5. 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 (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.

Tack endovascular system is CE Mark authorized under EC Directive 93/42/EEC.

Approved for external distribution.
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