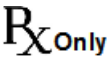
Instructions for Use (IFU)
The Tack Endovascular System® (4F, 1.5-4.5mm)

Symbols Glossary

Symbol	Ref. No. / Title	Description	Standard
	5.1.6 Catalog Number	Indicates the manufacturer's catalogue number so that the medical device can be Identified.	15223-1 Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements
	5.1.5 Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	
	5.1.4 Use-by Date	Indicates the date after which the medical device is not to be used.	
	5.1.1 Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	
	5.3.2 Keep away from sunlight	Indicates a medical device that needs protection from light sources.	
	5.3.4 Keep dry	Indicates a medical device that needs to be protected from moisture.	
	5.4.4 Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	
	5.4.3 Consult instructions for use	Indicates the need for the user to consult the instructions for use.	
	5.4.2 Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	
	5.2.3 Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide	

Symbol	Ref. No. / Title	Description	Standard
	5.2.6 Do not re-sterilize	Indicates a medical device that is not to be re-sterilized	
	5.2.8 Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	
	5.6.3 Non-pyrogenic	Indicates that a medical device is non-pyrogenic	
	MR Conditional	Item with demonstrated safety in the MR environment within defined conditions.	ASTM F2503 - Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
Symbols Not Derived from Standards			
	Prescription Only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner	21 CFR 801.109
RVD	Reference Vessel Diameter	Indicates the reference vessel diameter for the Tack implant	N/A

STERILE. The *Tack Endovascular System* is provided STERILE. Sterilized with ethylene oxide gas. Non-pyrogenic. For single use only. Do not re-sterilize and/or reuse the device.

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

These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

DEVICE NAME
Tack Endovascular System® (4F, 1.5-4.5mm)

DESCRIPTION

The *Tack Endovascular System® (4F, 1.5-4.5mm)* is designed to treat vascular dissections with *Tack®* implant(s) following angioplasty in the mid/distal popliteal, tibial and peroneal arteries, ranging 1.5 mm to 4.5 mm in diameter. The 4F (1.33 mm) catheter contains 4 independent self-expanding *Tack* implants made of a nickel-titanium alloy (Nitinol). When deployed, the *Tack* implants are designed to treat acute dissections of the inner wall or lining of an artery by Tacking the damaged tissue to the inner luminal surface through a low outward radial force.

The *Tack Endovascular System® (4F, 1.5-4.5mm)* consists of 4 self-expanding Nitinol implants and a 4F (1.33 mm) Delivery Catheter (See **Figure 1**). The numbers in parentheses in the following section refer to those in **Figure 1**.

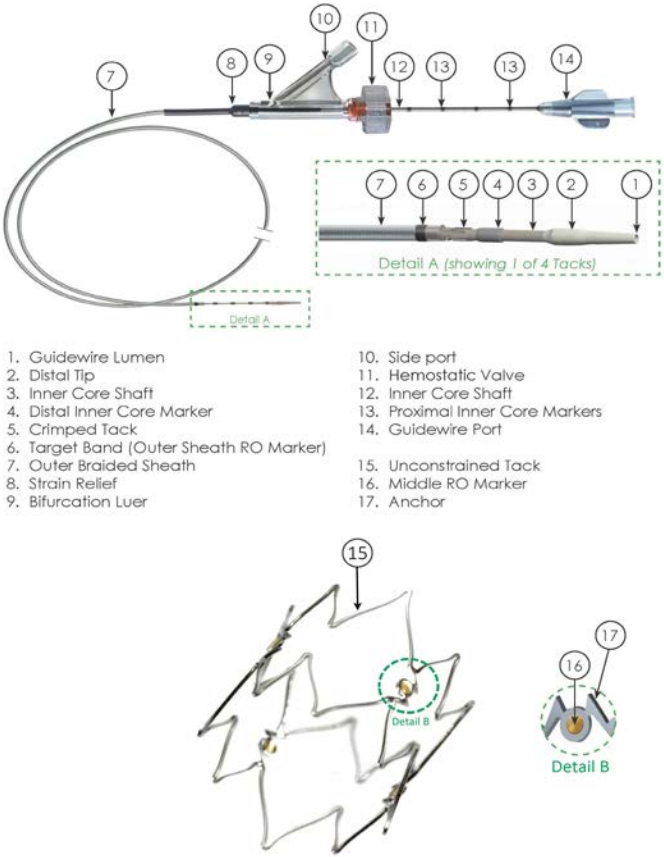


Figure 1. The *Tack Endovascular System® (4F, 1.5-4.5mm)*

The *Tack* implants are approximately 6 mm in length and expand to an unconstrained diameter of 5.7 mm (See Table 1). The *Tack* implants are designed with a relatively flat chronic outward force curve and may be used across all reference vessel diameters (RVDs) ranging from 1.5 mm to 4.5 mm. Four RO Markers (16) as well as four pairs of Anchors (17) are located around the centerline of each *Tack* implant. The anchors assist in maintaining proper *Tack* implant position.

Table 1. Tack Implant Length at Various Diameters	
Diameter	Length
1.1 mm (Constrained implant)	6.50
1.5 mm (Deployed implant)	6.48
4.5 mm (Deployed implant)	6.24
5.7 mm (Unconstrained implant)	5.90

The delivery catheter has effective lengths of 90 cm and 150 cm. The 4F Outer Braided Sheath (7), which constrains the *Tack* implants, is bonded proximally to the Bifurcation Luer (9) within the Strain Relief (8). The Hemostatic Valve (11) is integrated proximally to the Bifurcation Luer. The Inner Core Shaft (3) slides within the Hemostatic Valve and has five Proximal Inner Core Markers (13). The number of visible reference marks corresponds to the number of undeployed *Tack*

implants remaining in the distal end of the delivery system. A soft, tapered Distal Tip (2) is bonded to the distal end of the Inner Core Shaft for ease of advancement in the blood vessel. Constrained within the Outer Braided Sheath, each self-expanding *Tack* implant is positioned on the Inner Core Shaft (3) between two radiopaque Distal Inner Core Markers (4) spaced approximately 7 mm apart. A 1 mm radiopaque Target Band (6) is located on the distal end of the Outer Braided Sheath.

The catheter is flushed prior to the procedure through the side port of the Bifurcation Luer and the Guidewire Port. *Tack* implant positioning is achieved prior to deployment by using as reference the Middle RO Markers on the *Tack* implant and the Target Band on the outer sheath. During *Tack* implant deployment; the Hemostatic Valve is unlocked by rotating the valve counter-clockwise. The *Tack* implants are individually unsheathed by pinning the Proximal Inner Core Shaft and pulling back on the outer sheath the distance between proximal inner core markers. After each deployment, the Hemostatic Valve is locked by rotating the valve clockwise, ensuring that the proximal edge of the Target Band is secured directly over a Distal Inner Core Marker. Between deployments, both the proximal inner core markers and the distal inner core markers serve to visually represent the number of remaining *Tack* implants in the delivery catheter.

INTENDED USE

The *Tack Endovascular System® (4F, 1.5-4.5mm)* 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® (4F, 1.5-4.5mm)* 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.

WARNINGS / PRECAUTIONS

1. Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient.
2. This device is not approved for use in the central circulatory blood stream.
3. It is not recommended that Tack implants be used in patients that are allergic/intolerant to contrast media or are not amenable to pretreatment with steroids and/or antihistamines.
4. It is not recommended that the Tack Endovascular System be used in patients with poor renal function who may experience further deterioration of renal function.
5. The Tack implant may cause a thrombus or distal embolization, or may migrate from the site.
6. Before insertion of the primary dilatation catheter, it is recommended that the appropriate antiplatelet and anticoagulant therapy be administered.
7. Perform all device deployment under fluoroscopic guidance.
8. The clinical impact of overlapping Tack implants or Tack implants with deployed stents has not been tested.
9. Tack implants should be placed apart from each other, centered on the dissection or treatment area.
10. Avoid moving Tack Endovascular System catheter through already deployed Tack implants when possible.
11. This device should only be used by physicians who are trained in such interventional techniques as percutaneous transluminal angioplasty and in the use of this device.
12. Failure to perform a post Tack implant balloon inflation may result in inadequate tissue apposition and/or inability to seat the anchors.

13. Use a new balloon catheter for post-dilatation of the shortest length possible.
14. Use caution (advance slowly) during advancement of post-dilatation balloon catheter through deployed Tack implants.
15. Fully deflate post-dilatation balloon prior to withdrawing PTA catheter.
16. Do not use excessive force when using this device as this could result in damage to the device, including component fracture.
17. Do not use the system without the guidewire extending beyond the tip of the delivery catheter.
18. Failure to pin or secure the delivery catheter's inner core during Tack implant deployment may result in improper placement of a Tack implant.
19. Care should be taken not to kink the delivery system. If kinking occurs this could result in the inability to reach the target treatment site and to deploy the Tack implant(s).
20. Failure to tighten (lock) the hemostatic valve prior to repositioning the delivery system could result in inadvertent deployment of additional Tack implant(s).
21. If a Tack implant cannot deploy, remove the delivery catheter and use a new device.
22. It is recommended that the Delivery System be used with a 0.014" guidewire and a 4F (1.33 mm) introducer sheath.
23. Tack Endovascular System Storage and Preparation
    a. The *Tack Endovascular System* is designed and intended for single use only. DO NOT re-sterilize and/or reuse the device.
    b. Reuse of this product, including reprocessing and/or re-sterilization, may lead to a failure of the device to perform as intended and/or a loss of critical labeling/use information, all of which present a risk to patient safety.
    c. Store in a dark, dry place.
    d. Do not use if the pouch is open or damaged. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.
    e. Use prior to the "Use-by" date specified on the package.
    f. If system cannot be flushed, do not use the system.
24. Tack Endovascular System Handling
    a. Avoid contamination of the *Tack* implant(s). As with any type of vascular implant, contamination may lead to infection, thrombosis or pseudoaneurysm.
    b. Do not use with Ethiodol or Lipiodol contrast media to avoid possible damage to the *Tack* delivery system components.
    c. Do not expose the delivery system to organic solvents (e.g. alcohol).
25. Tack Implant Placement
    a. Do not use with power injection systems.
    b. If resistance is encountered at any time during the insertion procedure, do not force passage. Resistance may cause damage to *Tack* implant or vessel. Carefully withdraw the *Tack Endovascular System* without deploying a *Tack* implant.
    c. If resistance is felt when beginning deployment, do not force deployment. Carefully withdraw the *Tack Endovascular System* without deploying a *Tack* implant.
    d. Do not attempt to drag or reposition the *Tack* implant with the delivery system, as this may result in unintentional *Tack* implant deployment.
    e. Once the *Tack* implant is halfway deployed, it cannot be recaptured using the *Tack* implant delivery system. Do not attempt to recapture the *Tack* implant once the implant is halfway deployed.
    f. In the event of thrombosis within the *Tack* implant, thrombolysis and PTA should be attempted, per standard of care.
    g. When treating with multiple *Tack* implants, the most distal implant should be placed first, followed by the sequential placement of *Tack* implants, working distal to proximal. Placing in this order eliminates the need to cross *Tack* implants, reducing the chance of displacing *Tack* implants. It is recommended not to overlap *Tack* implants.
26. Tack Implant Removal

a. In the event of a complication such as infection, pseudoaneurysm or fistula, surgical removal of a *Tack* implant may be required. Standard surgical procedure is appropriate.

27. Post Implant
    a. Re-crossing a *Tack* implant with adjunct devices must be performed with caution to avoid damage or displacement.
    b. Do not resheath device within the deployed *Tack* implant treatment area as this could result in displacement.
    c. Used product is considered biohazardous material and should be disposed of properly as per hospital protocol.
    d. In patients requiring the use of antacids and/or H2-antagonists before or immediately after *Tack* implant placement, oral absorption of antiplatelet agents (e.g. aspirin) may be adversely affected.
    e. Recommended antiplatelet therapy should be maintained for at least 30 days post procedure or per institutional standard of care.

POTENTIAL COMPLICATIONS

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device:

- Access failure or abrupt closure
- Allergic / anaphylactoid reaction to anticoagulant and/or antithrombotic therapy or contrast medium
- Allergic reaction to Nitinol
- Amputation of lower extremity
- Anemia
- Angina / coronary ischemia / myocardial infarction
- Arrhythmia
- Arterial occlusion / (re) stenosis / dissection / thrombus
- Arterial spasm
- Arteriovenous fistula
- Blue toe syndrome
- Claudication or rest pain, worsened
- Death
- Disseminated intravascular coagulation
- Embolism
- Emergent repeat hospital intervention
- Fever
- Gangrene
- Gastrointestinal bleed from anticoagulation / antiplatelet medication
- Hematoma / hemorrhage
- Hypotension / hypertension
- Inadvertent venipuncture
- Infection / abscess at insertion site / Cellulitis
- Inflammation
- Multi-organ failure
- Pain
- Pseudoaneurysm
- Renal insufficiency or failure
- Respiratory distress or failure
- Reperfusion pain
- Septicemia / bacteremia (sepsis)
- Swelling / Edema, peripheral
- Tachycardia
- Tack implant embolization

- Tack implant migration (device moves over time)
- Tack implant occlusion / restenosis
- Tissue necrosis
- Trauma to adjacent structures
- Stroke / TIA (hemorrhagic / embolic)
- Vascular complications which may require surgical repair

INFORMATION FOR THE PATIENT

The *Tack Endovascular System*® Patient Implant Card (PIC) is designed for the patient to carry along with their insurance cards. This Patient Implant Card provides information pertaining to the *Tack* device(s) including the model, lot number, location of the implanted *Tack* device(s) and the date of the procedure. The card also provides company information and MRI Compatibility.

How Supplied

The Intact Vascular *Tack Endovascular System* is supplied sterile inside a pouch. The device is sterilized via Ethylene Oxide. The device is non-pyrogenic. The packaged device should be stored in a dry, dark place. **Caution:** Do not use if the package is damaged. In case of damage, contact Customer Service at 1-800-865-0214.

INSTRUCTIONS FOR USE

Pre-Procedure

1. Antiplatelet and anticoagulant therapy should be administered to the patient within 24 hours of the procedure, if deemed appropriate by the physician and/or per institutional standard of care.
2. The percutaneous placement of a *Tack* implant should be done in the angiographic procedure room. Angiography should be performed to map out to the extent of the lesion(s) and the collateral flow. Access vessels must be sufficiently patent to proceed with intervention. Patient preparation and sterile precautions should be the same as for any angioplasty procedure.

Procedure

1. Initial Angioplasty
    a. Initial angioplasty should be performed following the PTA balloon catheter manufacturer's instructions for use, observing all warnings and precautions.
    b. Special attention should be made to the recommended inflation parameters provided in **Step 3** below.
2. The recommendations for PTA balloon inflation are as follows:
    a. The operator should select a balloon diameter that can be inflated to a ratio of 1:1 relative to the target lesion proximal RVD.
    b. The length of the balloon should be appropriate for the treatment of the target lesion. When possible, a single PTA balloon should be selected that extends across the entire lesion.
3. PTA Balloon Inflation Recommendation: Inflate the balloon slowly and maintain inflation at the specified 1:1 diameter for a minimum of 60 seconds total.
4. Following dilatation of the lesion, an angiographic image should be recorded. Multiple angles of angiographic images and magnification may be used to help identify dissections.
5. Tack Implant Placement Criteria:
    a. Assess the dissection considered for *Tack* implant placement with a minimum of two angiographic views, for example, an anterior-posterior view and a 45-degree oblique view. Categorize all dissections identified for treatment with a *Tack* implant. If there are no dissections present, no *Tack* implants should be placed.
    b. Recommended Tacking paradigm for dissections: Place the first *Tack* implant to the distal edge of the target dissection. If additional *Tack* implants are required, a minimum gap distance of 4.0 mm between *Tack* implants (end to end) is recommended. Overlapping *Tack* implants is not recommended.
6. Preparation of the *Tack Endovascular System*

a. Open the outer box and pouch to reveal the tray containing the *Tack* Endovascular System.
b. Carefully inspect the tray and device for any damage. If damage is suspected, the sterility or performance of the device has been compromised; the device should not be used.
c. Flush the delivery system with heparinized saline to expel any air. A 3cc syringe is recommended (to avoid damage to delivery system).
    i. Flush through the Bifurcation Luer side port until heparinized saline flows from the distal catheter end.
    ii. Flush through the Guidewire Port until heparinized saline flows out of the Guidewire Lumen at the distal catheter end.
d. Inspect the distal end of the catheter to ensure that the *Tack* implants are contained within the outer sheath. If a gap between the catheter tip and outer sheath tip exists, unlock the hemostatic valve and gently pull the inner core in a proximal direction, while pinning the outer sheath, until the gap is closed. Lock the hemostatic valve after the adjustment by rotating the proximal end in a clockwise direction.

7. Insertion of Introducer Sheath or Guide Catheter and Guidewire
    a. Access the treatment site with the appropriate accessory equipment compatible with the 4F (1.33 mm) delivery system.
    b. Place a 0.014" (0.36 mm) guidewire of sufficient length across the lesion for *Tack* implantation(s) via the introducer sheath or guide catheter.
8. Introduction of *Tack Endovascular System*
    a. Ensure Hemostatic valve is locked.
    b. Advance the delivery catheter over the guidewire through the hemostatic valve and sheath introducer distal to the treatment site.
    NOTE: If resistance is met during delivery system introduction, the system should be withdrawn and another system should be used.
    CAUTION: Always use an introducer sheath for the implant procedure to protect puncture site. An introducer sheath of a 4F (1.33 mm) or larger size is recommended.
9. Slack Removal
    a. Advance the *Tack Endovascular System* past the treatment site.
    b. Pull back the *Tack Endovascular System* until the radiopaque outer sheath is distal to the target dissection site.
    c. Ensure the device outside the patient remains flat and straight.
    CAUTION: Slack in the catheter shaft, either outside or inside the patient, may result in deploying the *Tack* implant beyond the target dissection site.
10. *Tack* Implant Deployment
    a. Verify that the delivery system's radiopaque distal inner core markers are proximal and distal to the target dissection (the five distal inner core markers on the delivery catheters inner core shaft correspond to the 4 *Tack* implants in the delivery system). The first *Tack* implant is between the first two distal markers. The second *Tack* implant is between the 2nd and the 3rd distal markers. The subsequent two Tack implants complete this pattern.
    b. Ensure the access sheath or guiding catheter does not move during deployment.
    c. Initiate *Tack* implant deployment by unlocking the hemostatic valve while holding the inner core shaft in a fixed position.
    NOTE: Failure to maintain a fixed inner core shaft position may result in undesired *Tack* implant placement.
    d. While using fluoroscopy, maintain position of the radiopaque markers relative to the target dissection. Watch for the Target Band to meet with the radiopaque markers found on the center of the *Tack* implant. At this position, the distal edge of the Target Band will mark the landing zone for the middle of the *Tack* implant. Continue to slowly pull back on the outer sheath until the *Tack* implant is fully deployed.

e. Lock the hemostatic valve. Maintain a fixed inner core shaft to reposition delivery catheter if more than one *Tack* implant is required.
NOTE: The *Tack* implants are released independently by pulling back the outer sheath. The entire catheter can be repositioned to additional treatment areas after each *Tack* implant deployment.

f. Repeat sequence (10a through 10e) until all dissections are treated or a new delivery system is required.
NOTE: If an additional system or ancillary device is needed, follow step 11 and post-dilate any placed *Tack* implants, before introducing the new device.

11. *Tack* Implant Post-dilatation
    a. Recover the delivery system by slowly pulling the inner core shaft proximally, while clearing the recent deployed *Tack* implant(s). Once outside of the treatment area, the delivery catheter should be resheathed under fluoroscopy. Withdraw the entire delivery system as one unit, over the guidewire, into the catheter sheath introducer and out of the body. Remove the delivery device from the guidewire.
    b. Using fluoroscopy, visualize the *Tack* implant(s) to verify deployment.
    c. Following *Tack* implant deployment(s), using standard PTA techniques, the PTA balloon is inflated within the *Tack* implant(s) to ensure that tissue apposition is achieved by seating the anchors.
    d. The balloon size for post-dilatation should use the largest balloon diameter used during angioplasty prior to Tack implant placement and should be of the shortest length possible.
    NOTE: Inflation Recommendation: a minimum of 120 seconds.
    NOTE: When possible, only Tack-treated areas within the treated segment should receive post-deployment balloon dilatation. Never increase the pressure (atm) above pre-PTA pressures. Post Tack implant placement via balloon angioplasty should be performed with a new balloon catheter to reduce the risk of contact with deployed Tack implants while advancing the balloon catheter into place.
    e. Select the largest size used of the pre-PTA balloon catheter(s). Dilate the lesion with conventional techniques. Remove the PTA balloon from the patient.
    NOTE: Carefully advance the new PTA balloon through the *Tack* implant(s).
    CAUTION: Fully deflate PTA balloon prior to withdrawing.
12. Post Treatment
    a. Remove the guidewire and sheath from the body.
    b. Close entry wound as appropriate.
    c. Discard the delivery system, guidewire and sheath.
    NOTE: Physician experience and discretion will determine the appropriate post-procedure drug regimen for each patient.

SUMMARY OF CLINICAL STUDY

The results of the TOBA II BTK pivotal study, conducted to assess the safety and efficacy of the Tack Endovascular System® *(4F, 1.5-4.5mm)* in the repair of post-PTA dissections in the mid/distal popliteal, tibial and peroneal arteries, are provided below.

1. TOBA II BTK Study Design

The prospective, multi-center, single-arm, non-blinded TOBA II BTK study investigated the safety and efficacy of the Tack Endovascular System® (4F, 1.5-4.5mm) for the repair of dissection(s) type(s) A through F resulting from percutaneous transluminal balloon angioplasty (PTA) in the mid/distal popliteal, tibial and peroneal arteries. Patients were treated between February 08, 2017 and December 26, 2018. The original database for this PMA reflected data collected through August 28, 2019 and the study enrolled 233 subjects at 41 clinical sites. Additionally, FDA requested a post-hoc analysis of all available 12-month follow-up data. The post-hoc 12 month analysis reflected data collected from 151 subjects through December 15, 2019.The primary objectives of this study were to demonstrate the following outcomes:

- Safety: Major adverse limb events (MALE) plus perioperative death (POD) at 30 days defined as a 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).

- Effectiveness: Freedom from MALE at 6 months + POD at 30 days.

These endpoints were evaluated against performance goals (PGs), as described below. The primary statistical method was a two-sided, single group, exact binomial test comparing the observed proportion of subjects with MALE plus POD at 30 days, and subjects free of MALE at 6 months plus POD at 30 days to the respective PG. The p-value associated with the test will be provided along with a two-sided 95% lower confidence bound on the point estimate observed.

An independent Clinical Events Committee (CEC) consisting of a team of clinical experts with experience in the conduct of clinical trials was formed to review clinical events reported by the investigators, or at the request of the Sponsor to determine if they meet the prespecified endpoint definitions. Additionally, an independent board of multi-disciplinary physicians and subject matter experts was convened to serve as the Data Safety and Monitoring Board (DSMB) for the study. All study-related angiographic, duplex ultrasound (DUS) and X-ray imaging were reviewed and analyzed by independent core laboratories.

TOBA II BTK Inclusion and Exclusion Criteria

Subjects enrolled in the TOBA II BTK study were required to meet ALL of the following inclusion criteria prior to enrollment:

1. Male or non-pregnant Female ≥18 years of age at the time of consent
2. Female subjects of childbearing potential must have had a negative pregnancy test prior to treatment and must use some form of contraception (abstinence is acceptable) through the duration of the study
3. Subject was informed of and understood the nature of the study and provided signed informed consent to participate in the study. If the subject possessed the ability to understand and provide informed consent but due to physical inability, the subject could not sign the ICF, an impartial witness could sign on behalf of the subject
4. Was willing to comply with all required follow-up visits
5. Wound, Ischemia, and foot Infection (WIfI) Wound grade of 0, 1 or modified 2
6. WIfI Foot Infection grade of 0 or 1
7. Rutherford Classification 4 or 5
8. Estimated life expectancy was >1 year

Subjects were to be excluded from the TOBA II BTK study if they met ANY of the following exclusion criteria:

1. Was pregnant or refused to use contraception through the duration of the study
2. Previous bypass graft in the target limb
3. Acute limb ischemia, defined as symptom onset occurring less than 14 days prior to the index procedure
4. Prior or planned above-ankle amputation or complete transmetatarsal amputation to the target limb (this did not apply to ray amputation of ≤2 digits, simple digital amputations or ulcer debridements)
5. WIfI Foot Infection grade 2 or 3
6. Any systemic infection or immunocompromised state. Patients that had an ascending infection/deep foot infection or abscess/white blood count (WBC)≥12,000/or febrile state
7. Endovascular or surgical procedure (not including diagnostic procedures, planned simple digital amputation or wound debridement) to the target limb less than 30 days prior to or planned for less than 30 days after the index procedure
8. Existing stent implant in the target vessel
9. Any other endovascular or surgical procedure (not including diagnostic procedures, planned simple digital amputation or wound debridement) less than 14 days prior to the index procedure or planned procedure less than 30 days after the index procedure
10. Known coagulopathy, hypercoagulable state, bleeding diathesis, other blood disorder, or a platelet count less than 80,000/microliter or greater than 500,000/microliter

11. WIfI Wound grade of 2 or 3
12. Antiplatelet, anticoagulant, or thrombolytic therapy was contraindicated
13. Myocardial infarction, coronary thrombolysis or angina less than 30 days prior to the Index Procedure
14. History of stroke or transient ischemic attack (TIA) less than 90 days prior to the Index Procedure
15. Currently on dialysis
16. Known hypersensitivity or contraindication to nickel titanium alloy (Nitinol)
17. Participating in another ongoing investigational clinical trial that had not completed its primary endpoint
18. Had other comorbidities that, in the opinion of the investigator, would preclude them from receiving this treatment and/or participating in study-required follow-up assessments
19. Known hypersensitivity or allergy to contrast agents that could not be medically managed
20. Subject was already enrolled into this study
21. Restenotic target lesion previously treated by means other than plain balloon angioplasty and/or less than 1 year prior to index procedure

Patient Follow-up Schedule

After hospital discharge, subjects were required to return to the study center for clinical assessments on Day 30 (-2 days/+14 Days), 6 months ± 30 days, 12 months ± 30 days, 24 months ± 30 days and 36 months ± 30 days. Adverse events and complications were recorded at all visits. A time and events schedule for all assessments is provided in **Table 2** below.

Table 2. Time and Events Schedule

Assessment	Baseline	Index Procedure	Pre-Discharge	30-day (-2/+14 Days)	6 Month (±30 Days)	12 Month (± 30 Days)	24 Month (± 30 Days)	36 Month (± 30 Days)	Unscheduled
Informed Consent	X								
Medical History / Brief Physical	X								
White Blood Count / Platelet Count	X								
Prothrombin Time (PT) / International Normalized Ratio (INR)	X								
Urine pregnancy test if female	X								
Ankle Brachial Index (ABI)/ Toe Brachial Index (TBI)	X			X	X	X	X	X	X
$TcPO_2$	X			X	X	X	X	X	X
Rutherford Classification	X			X	X	X	X	X	X

Table 2. Time and Events Schedule									
Assessment	**Baseline**	**Index Procedure**	**Pre-Discharge**	**30-day (-2/+14 Days)**	**6 Month (±30 Days)**	**12 Month (± 30 Days)**	**24 Month (± 30 Days)**	**36 Month (± 30 Days)**	**Unscheduled**
WIfI Classification	X			X	X	X	X	X	X
Wound Assessment	X			X	X	X	X	X	X
Pre-procedural Medications		X							
Angiogram		X							X
Study Medications	X	X	X	X	X	X	X	X	X
Duplex Ultrasound (DUS)				X	X	X			X
X-ray of Implanted Tacks						X			X
Adverse Event (AE) Assessment		X	X	X	X	X	X	X	X
EQ-5D-3L	X			X	X	X	X	X	X
Walking Impairment Questionnaire (WIQ)	X			X	X	X	X	X	X

Clinical Endpoints

Primary Safety Endpoint

With regard to safety, the primary endpoint was MALE plus POD at 30 days defined as a composite of all-cause death, above-ankle target limb amputation, or major re-intervention to the target lesion(s). The performance goal for this endpoint was set at 12% based on the information reported by Conte (2009)[1]. The primary statistical analysis was conducted in subjects who met the intent-to-treat (ITT) definition and have observed data for the primary safety endpoint. A subject was considered an ITT patient and officially enrolled in the study once the Tack Endovascular System (4F, 1.5-4.5mm) was advanced through the introducer sheath. A per protocol (PP) analysis was also performed and included a subset of the ITT population with evaluable data that met the definition for device success, excluding subjects with major protocol deviations such as a major inclusion / exclusion criterion violation; or major procedural deviation. For safety, the primary statistical method was a one-sample exact test comparing the proportion of subjects free from a MALE plus POD to the performance goal using a one-sided $\alpha = 0.025$. The exact one-sided 97.5% confidence interval for the proportion of subjects free from MALE plus POD was calculated.

[1] Conte MS, Geraghty PJ, Bradbury AW, Hevelone ND, Lipsitz SR, Moneta GL, Nehler MR, Powell RJ, Sidawy AN. Suggested objective performance goals and clinical trial design for evaluating catheter-based treatment of critical limb ischemia. J Vasc Surg. 2009;50:1462-73.

Primary Effectiveness Endpoint

With regard to effectiveness, the primary endpoint was freedom from MALE at 6 months plus POD at 30 days. The performance goal for this endpoint is 74%, which was also derived from the information reported in Conte (2009). To meet the study primary endpoint, the one-sided lower 97.5% confidence interval must be less than or equal to the performance goal of 74%.

Secondary Endpoints

A secondary endpoint of target lesion(s) tacked segment(s) patency at 6 months was defined as the presence of blood flow using duplex ultrasound. If angiography was available within the 6-month follow-up visit window, it was used in place of the duplex ultrasound. Evidence of no blood flow within the Tacked segment indicated restenosis/loss of patency. This secondary endpoint was formally tested against a performance goal of 64%. The performance goal of 64% was chosen as a result of a meta-analysis combining 13 papers that reported 6-month patency for standard PTA or from which the 6-month patency rate could be derived. A one-sided lower 97.5% confidence bound was calculated for this estimate using the continuity corrected standard normal approximation. The lower bound was compared to the performance goal of 64%.

An additional secondary endpoint of Target Limb Salvage, defined as freedom from any above-ankle target limb amputation at 6 months, was also collected.

Observational Endpoints

Observational endpoints include the following:

- Device Success - Successful deployment of the Tack implant(s) at the intended target site(s) and successful withdrawal of the delivery catheter from the introducer sheath.
- Target Lesion Success: Demonstrated target lesion patency [<30% residual diameter stenosis (DS), by visual estimate] without the use of a bailout stent within the target lesion upon completion of the index procedure. This will be assessed for all lesions treated with a Tack implant. In addition, target lesion success will also be analyzed by lack of bailout stent to tacked segment only. Multiple target lesions treated as one lesion with PTA will be analyzed as one lesion.
- Procedural Success: Demonstrated target lesion patency (<30% residual DS, by visual estimate) without the use of a bailout stent within the target lesion and without the occurrence of MALE+POD upon completion of the index procedure
- Amputation-free survival (AFS): Freedom from above-ankle target limb amputation or all-cause death at 6 months
- Assisted primary target lesion Tacked segment patency (flow vs. no flow) at 6 months
- Secondary target lesion Tacked segment patency (flow vs. no flow) at 6 months
- PSVR patency at 6 months [Freedom from binary restenosis defined as Peak Systolic Velocity Ratio (PSVR) of ≥ 2.5 and/or angiographic percent diameter stenosis of ≥50%] assessed for the following:
    - Target Lesion(s), defined as the entire contiguous arterial segment treated with angioplasty, inclusive of an additional proximal and distal margin of 5 mm
    - Tacked Segment(s), defined as the Tack device and 5 mm of artery proximal and distal to each Tack. If Tacks are within 10 mm of each other, they will be considered as a single tacked segment for the purposes of this patency assessment.
- Clinically-driven target lesion revascularization (CD-TLR) through 6 months
- Clinically-driven target vessel revascularization (CD-TVR) through 6 months
- All-cause death through 6 months
- Any Target vessel revascularization (TVR) through 6 months
- Any Target lesion revascularization (TLR) through 6 months

In addition, the following observational endpoints were assessed at various time points through 36 months:

- Changes in Wound, Ischemia, and foot Infection (WIfI) Classification

- Changes in ankle brachial index (ABI) and toe brachial index (TBI)
- Changes in Rutherford Classification
- Changes in the EQ-5D-3L quality of life questionnaire
- Changes in the Walking Impairment Questionnaire (WIQ)
- Tack implant Integrity via X-ray (performed at 12-month visit)
- Progress of wound(s) present at study entry (healed, improved, unchanged, worsening, amputated)
- Appearance of new wound(s) after study entry
- Unplanned below-ankle target limb amputation(s): digit or transmetatarsal

Accountability of PMA Cohort

Subject Accountability

A total of 233 patients were enrolled in this trial. A summary of subject accountability is provided in **Figure 2** below.

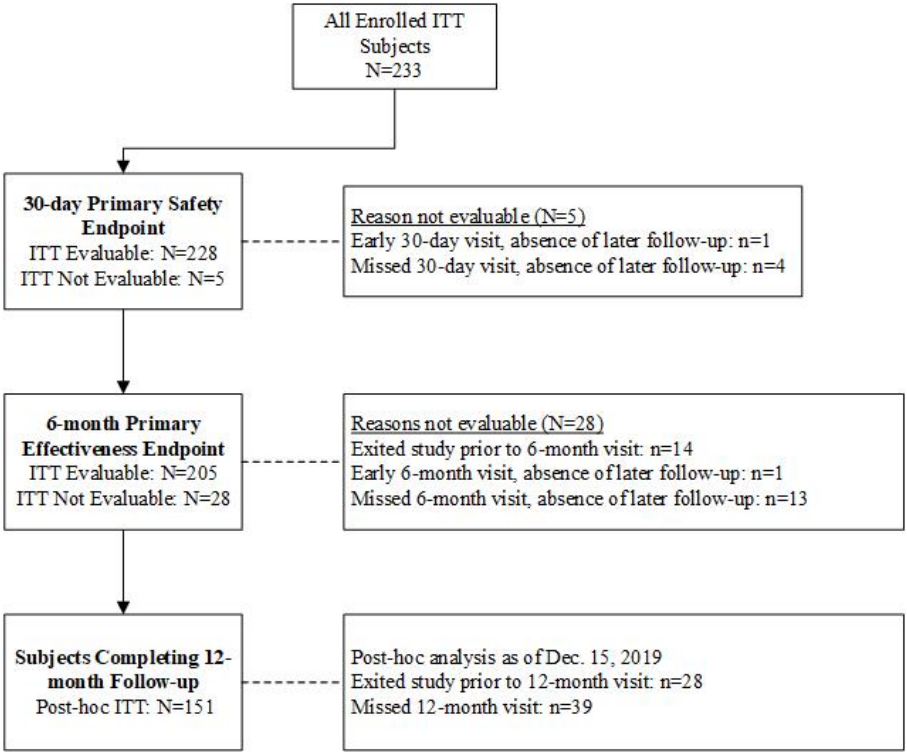


Figure 2. TOBA II BTK Subject Accountability

Study Population Demographics and Baseline Parameters

The TOBA II BTK population demographics, medical history and risk factors are summarized in **Tables 3-4**, below. The enrolled subjects were typical of a patient group undergoing endovascular treatment.

Table 3 Demographics and Baseline Characteristics	
Parameter	**Mean ±SD (N) (Min, Median, Max) or % (n/N)**
	ITT Subjects
Age at baseline (years)	74.4 ± 10.0 (233) (48.0, 75.0, 95.0)
Gender	
Male	67.4% (157/233)
Female	32.6% (76/233)
Ethnicity	
Hispanic or Latino	9.1% (21/230)
Not Hispanic or Latino	90.0% (207/230)
Unknown	0.0% (0/230)
Decline to answer	0.9% (2/230)
Race (Check all that apply)	
American Indian or Alaska Native	0.4% (1/233)
Asian	1.3% (3/233)
Black or African American	16.7% (39/233)
Native Hawaiian or Pacific Islander	0.0% (0/233)
White	80.3% (187/233)
Other	0.0% (0/233)
Unknown	0.4% (1/233)
Decline to answer	0.9% (2/233)
BMI	28.8 ± 5.6 (231) (16.4, 28.6, 56.9)
BMI >= 30	37.2% (86/231)
ABI in treated limb[1]	0.74 ± 0.27 (198) (0.00, 0.75, 1.29)
TBI in treated limb	0.43 ± 0.23 (117) (0.00, 0.41, 1.48)
Rutherford Classification	
0	0.0% (0/233)
1	0.0% (0/233)
2	0.0% (0/233)
3	16.3% (38/233)
4	33.5% (78/233)
5	50.2% (117/233)
6	0.0% (0/233)
Wound Grade	
0	52.4% (122/233)
1	39.1% (91/233)
modified 2	8.6% (20/233)
2	0.0% (0/233)
3	0.0% (0/233)
Ischemia Grade	
0	52.0% (115/221)
1	24.9% (55/221)
2	12.7% (28/221)
3	10.4% (23/221)
Foot Infection Grade	
0	83.3% (194/233)
1	16.7% (39/233)
2	0.0% (0/233)

Table 3 Demographics and Baseline Characteristics	
Parameter	**Mean ±SD (N) (Min, Median, Max) or % (n/N)**
	ITT Subjects
3	0.0% (0/233)
[1] Values ≥1.3 are censored as non-compressible.	

A summary of the medical history for all subjects is provided in **Table 4** below. The subjects presented with a host of comorbidities with the most common being arterial hypertension (93.6%) and hyperlipidemia (78.0%). In addition, 65.7% were diabetic and 56.1% had coronary artery disease. Previous peripheral interventions occurred in 50.2% of subjects.

Table 4 Medical History and Risk Factors	
	Mean ±SD (N) (Min, Median, Max) or % (n/N)
Parameter	**ITT Subjects**
Coronary Artery Disease	56.1% (129/230)
Myocardial Infarction	22.0% (51/232)
Coronary revascularization	43.9% (101/230)
Coronary Artery Bypass Graft (CABG)	18.9% (44/233)
Percutaneous Coronary Intervention (PCI)	31.3% (73/233)
History of Thrombolysis	0.9% (2/233)
Chronic angina pectoris	5.6% (13/232)
Congestive heart failure	15.1% (35/232)
Cerebrovascular event	21.6% (50/231)
Transient Ischemic Attack (TIA)	6.0% (14/233)
Stroke – Cerebrovascular Accident (CVA)	16.7% (39/233)
Gastrointestinal / genitourinary bleeding	3.4% (8/232)
Chronic renal insufficiency	24.1% (56/232)
On dialysis	0.4% (1/233)
Coagulopathy, hypercoagulable state, bleeding diathesis, or other blood disorder	0.9% (2/232)
Smoking	
Current	17.2% (40/233)
Former	45.1% (105/233)
Never	37.8% (88/233)
Diabetes mellitus	65.7% (153/233)
Type I	4.6% (7/153)
Type II	95.4% (146/153)
Arterial hypertension	93.6% (218/233)
Controlled with medication	99.5% (217/218)
Not controlled with medication	0.5% (1/218)
Hyperlipidemia	78.0% (181/232)
Controlled with medication	93.9% (170/181)
Not controlled with medication	6.1% (11/181)
Family history of premature atherosclerotic disease (e.g. MI, CABG, PCI before age 60)	18.2% (29/159)
History of previous peripheral artery intervention on either limb	50.2% (117/233)

Baseline lesion and vessel assessments are summarized in **Table 5** below. The majority (93.8%) of lesions were de novo. By core lab assessment, 64.9% of lesions were in the tibial artery or the tibial peroneal trunk. The core laboratory measured mean target lesion and injured lesion lengths were 80 ± 49 mm and 154 ± 100 mm, respectively. The mean pre-procedure stenosis was 85% and

47.6% were occluded. Calcification at grades higher than mild were reported in 35.8% (18.1% moderate; 17.7% severe) of subjects.

Table 5 Baseline Angiogram		
	ITT Subjects Mean ±SD (N) (Min, Median, Max) or % (n/N)	
Parameter	Investigator Reported	Core Lab Adjudicated
LESION LEVEL VARIABLES		
Most proximal target lesion location		
Mid Popliteal	4.7% (13/277)	12.1% (30/248)
Distal Popliteal	10.5% (29/277)	12.1% (30/248)
Anterior Tibial	36.5% (101/277)	33.5% (83/248)
Posterior Tibial	16.2% (45/277)	13.3% (33/248)
Tibioperoneal Trunk	17.0% (47/277)	18.1% (45/248)
Peroneal	15.2% (42/277)	10.9% (27/248)
Other	0.0% (0/277)	0.0% (0/248)
Most distal target lesion location		
Mid Popliteal	0.7% (2/277)	4.0% (10/248)
Distal Popliteal	5.4% (15/277)	1.2% (3/248)
Anterior Tibial	41.2% (114/277)	41.1% (102/248)
Posterior Tibial	23.1% (64/277)	22.6% (56/248)
Tibioperoneal Trunk	7.2% (20/277)	10.1% (25/248)
Peroneal	22.0% (61/277)	21.0% (52/248)
Other	0.4% (1/277)	0.0% (0/248)
Target lesion length	116 ± 100 (277) (3, 76, 400)	80 ± 49 (248) (8, 71, 237)
Injured lesion length (per Core Lab)	-	154 ± 110 (238) (13, 120, 438)
Lesion type		
DeNovo	93.8% (257/274)	-
Restenotic	6.2% (17/274)	-
Proximal reference vessel diameter (mm)	3.1 ± 0.7 (276) (1.8, 3.0, 4.5)	3.5 ± 1.0 (248) (1.7, 3.3, 8.1)
Distal reference vessel diameter (mm)	2.8 ± 0.6 (276) (1.5, 3.0, 4.5)	2.6 ± 0.7 (248) (1.2, 2.5, 5.5)
Baseline target lesion percent diameter stenosis (%)	91 ± 10 (277) (70, 95, 100)	85 ± 17 (248) (31, 92, 100)
Total Occlusion	39.0% (108/277)	47.6% (118/248)
Calcification		
None / Mild	50.4% (139/276)	64.1% (159/248)
Moderate	43.1% (119/276)	18.1% (45/248)
Severe	6.5% (18/276)	17.7% (44/248)

Safety and Effectiveness Results

Safety Results

Primary Safety

The primary safety endpoint was MALE (defined as a composite or all-cause death, above-ankle target limb amputation, or major re-intervention to the target lesion(s)) plus perioperative death (POD) at 30 days. The primary safety endpoint was MET. Three (1.3%) MALE events (two above the ankle amputations and one subject death) were reported in the first 30 days. The upper two-sided 95% confidence interval was 3.8% versus the PG of 12% ($p<0.0001$). See **Table 6** below.

Table 6 Primary Safety endpoint at 30 days					
Event Type	**ITT or PP**	**% (n/N) (CI)[1]**	**Performance Goal**	**p-value[1]**	**Study Endpoint**
MALE + POD at 30 Days	ITT	1.3% (3/228)[2]	12%	<.0001	MET
[CI]		(0.3%, 3.8%)			
Above-ankle target limb amputation at 30 Days		0.9% (2/229)			
All-Cause Death at 30 Days		0.4% (1/229)			
Major re-intervention to the target lesion at 30 Days		0.0% (0/229)			
MALE + POD at 30 Days	PP	0.9% (2/212)[2]	12%	<.0001	MET
[CI]		(0.1%, 3.4%)			
Above-ankle target limb amputation at 30 Days		0.5% (1/213)			
All-Cause Death at 30 Days		0.5% (1/213)			
Major re-intervention to the target lesion at 30 Days		0.0% (0/213)			

[1] Exact binomial test for one proportion. Confidence interval is the two-sided exact 95%.
[2] One subject was not evaluable for the primary safety endpoint due to an early 30 day visit and no additional visits beyond 30 days. This subject was therefore not included in the denominator for the primary safety endpoint analysis.

Adverse Effects

Table 7 below presents a summary of adverse events reported through 210 days, displaying the events by device or procedure-relatedness and severity. No events were determined to be unanticipated. At 6 months, there were 28 subject deaths, none of which were attributable to the device. Table 7a provides this analysis using the 12-month post-hoc analysis data.

Table 7 All Treatment Emergent Adverse Events with Onset Date within 210 Days Post Index Procedure in ITT Subjects								
	Adverse Events		**Device or Procedure Related Events**		**Serious Adverse Events**		**Serious Device or Procedure Related Events**	
Adverse Event Type (MedDRA SOC / LLT)	**# of Events**	**#(%) of Pts**	**# of Events**	**#(%) of Pts**	**# of Events**	**#(%) of Pts**	**# of Events**	**#(%) of Pts**
Blood and lymphatic system disorders	5	5 (2.1%)			5	5 (2.1%)		
Cardiac disorders	38	32 (13.7%)			37	32 (13.7%)		
Ear and labyrinth disorders	1	1 (0.4%)			1	1 (0.4%)		
Gastrointestinal disorders	14	12 (5.2%)	2	1 (0.4%)	13	12 (5.2%)	1	1 (0.4%)
General disorders and administration site conditions	16	16 (6.9%)	8	8 (3.4%)	12	12 (5.2%)	4	4 (1.7%)
Hepatobiliary disorders	1	1 (0.4%)			1	1 (0.4%)		
Infections and infestations	40	25 (10.7%)	15	11 (4.7%)	38	23 (9.9%)	14	10 (4.3%)

Table 7 All Treatment Emergent Adverse Events with Onset Date within 210 Days Post Index Procedure in ITT Subjects

	Adverse Events		Device or Procedure Related Events		Serious Adverse Events		Serious Device or Procedure Related Events	
Adverse Event Type (MedDRA SOC / LLT)	**# of Events**	**#(%) of Pts**	**# of Events**	**#(%) of Pts**	**# of Events**	**#(%) of Pts**	**# of Events**	**#(%) of Pts**
Injury, poisoning and procedural complications	49	38 (16.3%)	27	24 (10.3%)	24	19 (8.2%)	10	10 (4.3%)
Metabolism and nutrition disorders	11	8 (3.4%)			11	8 (3.4%)		
Musculoskeletal and connective tissue disorders	8	8 (3.4%)			6	6 (2.6%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6	5 (2.1%)			5	5 (2.1%)		
Nervous system disorders	12	12 (5.2%)			12	12 (5.2%)		
Psychiatric disorders	3	3 (1.3%)			3	3 (1.3%)		
Renal and urinary disorders	10	9 (3.9%)	1	1 (0.4%)	10	9 (3.9%)	1	1 (0.4%)
Reproductive system and breast disorders	1	1 (0.4%)			1	1 (0.4%)		
Respiratory, thoracic and mediastinal disorders	7	6 (2.6%)	1	1 (0.4%)	7	6 (2.6%)	1	1 (0.4%)
Skin and subcutaneous tissue disorders	8	7 (3.0%)	4	4 (1.7%)	8	7 (3.0%)	4	4 (1.7%)
Surgical and medical procedures	1	1 (0.4%)			1	1 (0.4%)		
Vascular disorders	73	55 (23.6%)	29	27 (11.6%)	57	43 (18.5%)	20	18 (7.7%)
TOTAL	304	137 (58.8%)	87	67 (28.8%)	252	117 (50.2%)	55	46 (19.7%)

[1]When an event is CEC adjudicated for device or procedure relatedness, the CEC adjudication will be used in the analysis. Otherwise, the investigator reported device or procedure relatedness will be used.

Table 7a All Treatment Emergent Adverse Events with Onset Date within 390 Days Post Index Procedure in ITT Subjects

	Adverse Events		Device or Procedure Related Events		Serious Adverse Events		Serious Device or Procedure Related Events	
Adverse Event Type (MedDRA SOC / LLT)	**# of Events**	**#(%) of Pts**	**# of Events**	**#(%) of Pts**	**# of Events**	**#(%) of Pts**	**# of Events**	**#(%) of Pts**
Blood and lymphatic system disorders	5	5 (2.1%)			5	5 (2.1%)		
Cardiac disorders	59	44 (18.9%)			58	44 (18.9%)		
Ear and labyrinth disorders	1	1 (0.4%)			1	1 (0.4%)		

Table 7a All Treatment Emergent Adverse Events with Onset Date within 390 Days Post Index Procedure in ITT Subjects								
	Adverse Events		Device or Procedure Related Events		Serious Adverse Events		Serious Device or Procedure Related Events	
Adverse Event Type (MedDRA SOC / LLT)	# of Events	#(%) of Pts	# of Events	#(%) of Pts	# of Events	#(%) of Pts	# of Events	#(%) of Pts
Eye disorders	3	3 (1.3%)			3	3 (1.3%)		
Gastrointestinal disorders	22	19 (8.2%)	2	1 (0.4%)	21	19 (8.2%)	1	1 (0.4%)
General disorders and administration site conditions	24	23 (9.9%)	8	8 (3.4%)	18	17 (7.3%)	4	4 (1.7%)
Hepatobiliary disorders	1	1 (0.4%)			1	1 (0.4%)		
Infections and infestations	57	34 (14.6%)	16	12 (5.2%)	55	32 (13.7%)	15	11 (4.7%)
Injury, poisoning and procedural complications	57	44 (18.9%)	27	24 (10.3%)	29	22 (9.4%)	10	10 (4.3%)
Investigations	1	1 (0.4%)			1	1 (0.4%)		
Metabolism and nutrition disorders	14	10 (4.3%)			14	10 (4.3%)		
Musculoskeletal and connective tissue disorders	13	12 (5.2%)			9	8 (3.4%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9	8 (3.4%)			8	8 (3.4%)		
Nervous system disorders	20	18 (7.7%)			20	18 (7.7%)		
Product issues	1	1 (0.4%)	1	1 (0.4%)				
Psychiatric disorders	4	4 (1.7%)			4	4 (1.7%)		
Renal and urinary disorders	13	11 (4.7%)	1	1 (0.4%)	13	11 (4.7%)	1	1 (0.4%)
Reproductive system and breast disorders	1	1 (0.4%)			1	1 (0.4%)		
Respiratory, thoracic and mediastinal disorders	11	10 (4.3%)	1	1 (0.4%)	11	10 (4.3%)	1	1 (0.4%)
Skin and subcutaneous tissue disorders	11	10 (4.3%)	4	4 (1.7%)	11	10 (4.3%)	4	4 (1.7%)
Surgical and medical procedures	1	1 (0.4%)			1	1 (0.4%)		
Vascular disorders	96	69 (29.6%)	32	30 (12.9%)	77	54 (23.2%)	22	20 (8.6%)
Not MedDRA Coded	4	4 (1.7%)			3	3 (1.3%)		
TOTAL	428	160 (68.7%)	92	70 (30.0%)	364	145 (62.2%)	58	48 (20.6%)

[1]When an event is CEC adjudicated for device or procedure relatedness, the CEC adjudication will be used in the analysis. Otherwise, the investigator reported device or procedure relatedness will be used.

Effectiveness Results

Primary Effectiveness Endpoint

In the ITT population, the primary effectiveness endpoint of freedom from MALE at 6 months plus POD at 30 days was 95.6% with a two-sided 95% lower confidence bound of 91.8%, which met the pre-defined PG of 74% (p<0.0001). The freedom from MALE at 6 months plus POD at 30 days in the PP subjects was 95.8% with a two-sided 95% lower confidence interval of 91.8%.

Table 8 Freedom from MALE at 6 months + POD at 30 days

	% (n/N) (CI)[1]	Performance Goal	p-value[1]	Study Endpoint
Freedom MALE at 6 months + POD at 30 days ITT	95.6% (196/205)	74%	<.0001	MET
[CI]	(91.8%, 97.8%)			
MALE at 6 months	3.9% (8/205)			
Above-ankle target limb amputation	1.5% (3/205)			
Major re-intervention to the target lesion	2.4% (5/205)			
POD at 30 days	0.4% (1/229)			
Freedom MALE at 6 months + POD at 30 days PP	95.8% (183/191)	74%	<.0001	MET
[CI]	(91.8%, 98.0%)			
MALE at 6 months	3.7% (7/191)			
Above-ankle target limb amputation	1.0% (2/191)			
Major re-intervention to the target lesion	2.6% (5/191)			
POD at 30 days	0.5% (1/213)			

[1] Continuity corrected z-test for one proportion. Two-sided 95% confidence bound.

Secondary Endpoints

Primary Patency of the Tacked Segment of the Treated Lesion at 6 months

Target lesion(s) tacked segment(s) patency at 6 months was defined as the presence of blood flow using DUS or angiography if performed during the designated follow-up window. The PG for this endpoint was 64% and the analysis of this endpoint is summarized in **Table 9.** Patency of target lesions in Tacked segments in the ITT subjects was 82.1% with a two-sided 95% lower confidence bound of 77.2%, which met the pre-defined PG (p<0.0001). The same measure in PP subjects was 81.6% with a two-sided 95% lower confidence interval of 76.5% (p<0.0001).

Table 9 Target lesion(s) tacked segment(s) patency at 6 months

	ITT or PP	% (n/N) (CI)[1]	Performance Goal	p-value[1]	Study Endpoint
Target lesion(s) tacked segment(s) patency	ITT	82.1% (247/301)	64%	<.0001	MET
[CI]		(77.2%, 86.2%)			
Target lesion(s) tacked segment(s) patency	PP	81.6% (230/282)	64%	<.0001	MET
[CI]		(76.5%, 85.9%)			

[1] Continuity corrected z-test for one proportion. Two sided 95% confidence bound.

Target Limb Salvage at 6 Months

Target limb salvage was defined as freedom from any above-ankle target limb amputation at 6 months. There was no formal hypothesis for this endpoint. Per **Table 10**, the target limb salvage at 6 months for the ITT population was 98.5% with a lower two-sided 95% confidence interval of 95.8%.

Table 10 Target Limb Salvage at 6 months		
	ITT Subjects % (n/N) (95% CI)[1]	**PP Subjects % (n/N) (95% CI)[1]**
Target Limb Salvage	98.5% (202/205)	99.0% (189/191)
[95% CI]	(95.8%, 99.7%)	(96.3%, 99.9%)

[1] Exact 95% Confidence Interval

Table 11 displays the Device, Target Lesion, and Procedure Success analysis. All measures of device and procedure success were acceptably high (>96%) indicating that the investigators were able to deploy and place the Tack implants, have acceptable index procedure outcomes, and have no MALE or POD events during the procedure.

Table 11 Device and Procedure Success		
	ITT Subjects % (n/N) (95% CI)[1]	**PP Subjects % (n/N) (95% CI)[1]**
Device Success per device introduced	96.5% (303/314)	100.0% (291/291)
[95% CI]	(93.8%, 98.2%)	(98.7%, 100.0%)
Device Success per subject	96.1% (224/233)	100.0% (217/217)
[95% CI]	(92.8%, 98.2%)	(98.3%, 100.0%)
Target Lesion Success per target lesion	98.8% (256/259)	99.2% (241/243)
[95% CI]	(96.7%, 99.8%)	(97.1%, 99.9%)
Target Lesion Success per target lesion (lack of bailout stent to tacked segment only) [2]	99.6% (258/259)	99.6% (242/243)
[95% CI]	(97.9%, 100.0%)	(97.7%, 100.0%)
Procedural Success per subject	98.7% (230/233)	99.1% (215/217)
[95% CI]	(96.3%, 99.7%)	(96.7%, 99.9%)

[1] Exact 95% confidence interval

[2] Of the 3 subject/lesions with bailout stenting indicated, 1 was located in a tacked region and 2 were located outside of the tacked region.

Time to event observational endpoints are summarized in **Table 12.** At the end of the 6-month visit window, Target Limb Salvage was 98.1% and overall survival was 95.0%. Freedom from target vessel and target lesion revascularization (both clinically-driven and overall) were 88.2% and 89.4%, respectively. In the 12-month post-hoc analysis cohort, Target Limb Salvage was 98.1% and overall survival was 87.0%. Freedom from target vessel and target lesion revascularization (both clinically-driven and overall) were 82.4% and 82.7%, respectively.

Table 12. Summary of time to event endpoints in ITT Subjects (Kaplan Meier Analysis)					
	Estimate # events, # at risk				
Parameter	**30 Days**	**180 Days**	**210 Days**	**360 Days**	**390 Days**
Target Limb Salvage - Freedom from amputation of the target limb (above the ankle)	99.1% 2, 225	98.6% 3, 183	98.1% 4, 156	98.1% 4, 97	98.1% 4, 18
Amputation Free Survival	98.7% 3, 225	95.9% 9, 192	93.2% 14, 165	90.2% 19, 107	85.5% 21, 28

Table 12. Summary of time to event endpoints in ITT Subjects (Kaplan Meier Analysis)					
	Estimate # events, # at risk				
Parameter	**30 Days**	**180 Days**	**210 Days**	**360 Days**	**390 Days**
Survival	99.6% 1, 225	97.2% 6, 192	95.0% 10, 165	91.9% 15, 107	87.0% 17, 27
Freedom from Unplanned below-ankle target limb amputation(s): digit or transmetatarsal	98.7% 3, 223	93.4% 14, 173	93.4% 14, 149	91.4% 17, 94	91.4% 17, 20
Freedom from clinically driven target vessel revascularization (CD-TVR)	100.0% 0, 225	91.7% 17, 169	88.2% 23, 140	82.4% 32, 82	82.4% 32, 18
Freedom from any target vessel revascularization (TVR)	100.0% 0, 225	91.7% 17, 169	88.2% 23, 140	82.4% 32, 82	82.4% 32, 18
Freedom from clinically driven target lesion revascularization (CD-TLR)	100.0% 0, 225	92.2% 16, 170	89.4% 21, 141	82.7% 31, 82	82.7% 31, 18
Freedom from any target lesion revascularization (TLR)	100.0% 0, 225	92.2% 16, 170	89.4% 21, 141	82.7% 31, 82	82.7% 31, 18
Freedom from MALE+POD	98.7% 3, 225	95.8% 9, 178	95.2% 10, 151	95.2% 10, 94	95.2% 10, 18

Table 13 provides a summary of patency results based on the Kaplan-Meier Analysis at 6 months and in the post-hoc cohort analysis at 12 months.

Table 13. Summary of 6 and 12-Month Patency in ITT Subjects (Kaplan Meier Analysis)					
	Estimate # events, # at risk				
Parameter	**30 Days**	**180 Days**	**210 Days**	**360 Days**	**390 Days**
Tacked Segment Patency	99.6% 1, 253	89.8% 26, 228	88.6% 29, 225	79.1% 53, 201	75.6% 62, 0
Assisted Tacked Segment Patency	99.6% 1, 253	89.8% 26, 228	88.6% 29, 225	79.1% 53, 201	75.6% 62, 0
Secondary Tacked Segment Patency	100.0% 0, 234	100.0% 0, 234	100.0% 0, 234	94.4% 13, 221	88.0% 28, 0
Tacked Segment PSVR patency	99.6% 1, 243	86.5% 33, 211	83.6% 40, 204	67.6% 79, 165	62.3% 92, 0
Assisted Target Lesion Patency	99.4% 1, 160	88.2% 19, 142	86.3% 22, 139	77.0% 37, 124	71.4% 46, 0
Secondary Target Lesion Patency	100.0% 0, 150	100.0% 0, 150	100.0% 0, 150	93.3% 10, 140	84.0% 24, 0
Target Lesion PSVR patency	99.4% 1, 155	85.3% 23, 133	80.8% 30, 126	61.5% 60, 96	53.2% 73, 0

Table 13. Summary of 6 and 12-Month Patency in ITT Subjects (Kaplan Meier Analysis)					
	Estimate # events, # at risk				
Parameter	**30 Days**	**180 Days**	**210 Days**	**360 Days**	**390 Days**
Assisted Patient Level Target Lesion Patency	99.3% 1, 148	89.3% 16, 133	87.2% 19, 130	77.2% 34, 115	71.1% 43, 0
Secondary Patient Level Target Lesion Patency	100.0% 0, 140	100.0% 0, 140	100.0% 0, 140	92.9% 10, 130	82.9% 24, 0
Patient level target lesion PSVR patency	99.3% 1, 144	86.9% 19, 126	82.1% 26, 119	62.1% 55, 90	53.1% 68, 0

[1] Based on analysis of 12-month DUS results.

The WIfI classification system was developed by the Society for Vascular Society to grade the severity of the three major risk factors leading to amputation: wound, ischemia and foot infection. The scale for each factor ranges from 0 (none present) to 3 (severe). Subjects were evaluated at baseline and follow-up visits per **Table 14**. At 6 months, there were significant ($p<0.05$) improvements in all three risk factors from baseline. These improvements continued in the 12-month post-hoc analysis cohort.

Table 14. WIfI Classification and Changes in WIfI Classification from Baseline in ITT Subjects				
Parameter	**Baseline**	**30 Day**	**6 Month**	**12 Month**
Wound Grade				
0	52.4% (122/233)	68.8% (148/215)	82.1% (160/195)	87.3% (131/150)
1	39.1% (91/233)	22.3% (48/215)	13.3% (26/195)	8.7% (13/150)
Modified 2	8.6% (20/233)	7.0% (15/215)	3.6% (7/195)	3.3% (5/150)
2	0.0% (0/233)	0.0% (0/215)	0.0% (0/195)	0.7% (1/150)
3	0.0% (0/233)	1.9% (4/215)	1.0% (2/195)	0.0% (0/150)
Wound Grade Change from Baseline				
Worsened 4 steps	-	0.5% (1/215)	0.0% (0/195)	0.0% (0/150)
Worsened 3 steps	-	0.9% (2/215)	0.5% (1/195)	0.0% (0/150)
Worsened 2 steps	-	0.5% (1/215)	1.0% (2/195)	0.0% (0/150)
Worsened 1 step	-	1.4% (3/215)	2.1% (4/195)	5.3% (8/150)
No change	-	79.1% (170/215)	66.2% (129/195)	58.7% (88/150)
Improved 1 step	-	17.7% (38/215)	28.2% (55/195)	31.3% (47/150)
Improved 2 steps	-	0.0% (0/215)	2.1% (4/195)	4.7% (7/150)
Improved 3 steps	-	0.0% (0/215)	0.0% (0/195)	0.0% (0/150)
Improved 4 steps	-	0.0% (0/215)	0.0% (0/195)	0.0% (0/150)
p-value[1]	-	0.0002	<.0001	-
Foot Infection Grade				
0	83.3% (194/233)	90.2% (194/215)	94.3% (183/194)	94.7% (142/150)
1	16.7% (39/233)	6.5% (14/215)	3.6% (7/194)	4.0% (6/150)
2	0.0% (0/233)	2.8% (6/215)	1.5% (3/194)	1.3% (2/150)
3	0.0% (0/233)	0.5% (1/215)	0.5% (1/194)	0.0% (0/150)
Foot Infection Grade Change from Baseline				

Table 14. WIfI Classification and Changes in WIfI Classification from Baseline in ITT Subjects				
Parameter	**Baseline**	**30 Day**	**6 Month**	**12 Month**
Worsened 3 steps	-	0.5% (1/215)	0.5% (1/194)	0.0% (0/150)
Worsened 2 steps	-	0.9% (2/215)	0.0% (0/194)	0.7% (1/150)
Worsened 1 step	-	2.8% (6/215)	4.1% (8/194)	3.3% (5/150)
No change	-	87.9% (189/215)	83.0% (161/194)	83.3% (125/150)
Improved 1 step	-	7.9% (17/215)	12.4% (24/194)	12.7% (19/150)
Improved 2 steps	-	0.0% (0/215)	0.0% (0/194)	0.0% (0/150)
Improved 3 steps	-	0.0% (0/215)	0.0% (0/194)	0.0% (0/150)
p-value[1]	-	0.4396	0.0171	-
[1] Wilcoxon Signed Rank Test.				

Table 15 summarizes Rutherford Category by visit and changes from baseline. By protocol, all subjects were Rutherford class 3 (Rev A of protocol only), 4, or 5 at baseline. At 6 months, 71.8% of ITT subjects were class 2 or lower (moderate claudication to asymptomatic) and there was significant ($p<0.0001$) improvement in Rutherford Category with 68.4% of subjects improving 2 or more steps. Importantly, only 3 (1.5%) subjects had worsening Rutherford category classification at 6 months. In the 12-month post-hoc analysis cohort, 81.3% ITT subjects were class 2 or lower (moderate claudication to asymptomatic) and 76.7% of subjects improved 2 or more steps. Importantly, only 4 (2.7%) subjects had worsening Rutherford category classification at 12 months.

Table 15. Rutherford Category and Changes in Rutherford Clinical Category from Baseline in ITT Subjects				
Parameter	**Baseline**	**30 Day**	**6 Month**	**12 Month**
Rutherford Category				
0-Asymptomatic	0.0% (0/233)	23.7% (52/219)	26.1% (52/199)	32.0% (48/150)
1-Mild Claudication	0.0% (0/233)	25.1% (55/219)	29.6% (59/199)	33.3% (50/150)
2-Moderated Claudication	0.0% (0/233)	11.9% (26/219)	16.1% (32/199)	16.0% (24/150)
3-Severe Claudication	16.3% (38/233)	4.6% (10/219)	7.0% (14/199)	4.0% (6/150)
4-Ischemic Rest Pain	33.5% (78/233)	3.2% (7/219)	3.0% (6/199)	2.0% (3/150)
5-Minor Tissue Loss	50.2% (117/233)	30.1% (66/219)	17.1% (34/199)	12.7% (19/150)
6-Ulceration or gangrene	0.0% (0/233)	1.4% (3/219)	1.0% (2/199)	0.0% (0/150)
Rutherford Change from Baseline				
Worsened 4 steps	-	0.0% (0/219)	0.0% (0/199)	0.0% (0/150)
Worsened 3 steps	-	0.0% (0/219)	0.0% (0/199)	0.0% (0/150)
Worsened 2 steps	-	0.0% (0/219)	0.0% (0/199)	0.0% (0/150)
Worsened 1 step	-	1.4% (3/219)	1.5% (3/199)	2.7% (4/150)
No change	-	32.9% (72/219)	19.1% (38/199)	12.7% (19/150)
Improved 1 step	-	7.8% (17/219)	11.1% (22/199)	8.0% (12/150)
Improved 2 steps	-	13.7% (30/219)	18.1% (36/199)	16.7% (25/150)
Improved 3 steps	-	20.1% (44/219)	16.1% (32/199)	19.3% (29/150)

Table 15. Rutherford Category and Changes in Rutherford Clinical Category from Baseline in ITT Subjects				
Parameter	**Baseline**	**30 Day**	**6 Month**	**12 Month**
Improved 4 steps	-	17.4% (38/219)	22.1% (44/199)	24.7% (37/150)
Improved 5 steps	-	6.8% (15/219)	12.1% (24/199)	16.0% (24/150)
p-value[1]	-	<.0001	<.0001	-
[1] Wilcoxon Signed Rank Test.				

Ankle Brachial index (ABI) and TBI were measured at baseline and at each follow-up visit. **Table 16** describes the results of the changes in AB and TBI from baseline through follow-up for ITT subjects. The mean ABI and TBI were significantly (p<0.0001) higher at 30 day and 6 month visits versus baseline, and the trend appeared to continue with the 12 month post-hoc analysis data.

Table 16. ABI and Changes in ABI from Baseline in ITT Subjects				
Parameter	**Baseline**	**30 Day**	**6 Month**	**12 Month**
ABI in the Target Limb				
At follow-up	0.74 ± 0.27 (197) (0.00, 0.75, 1.29)	0.97 ± 0.19 (176) (0.00, 0.99, 1.29)	0.91 ± 0.19 (166) (0.16, 0.94, 1.29)	0.91 ± 0.20 (129) (0.30, 0.93, 1.27)
p-value[1]	-	<.0001	<.0001	-
TBI in the Target Limb				
At follow-up	0.43 ± 0.23 (118) (0.00, 0.41, 1.48)	0.66 ± 0.28 (123) (0.00, 0.64, 1.63)	0.59 ± 0.28 (142) (0.00, 0.58, 1.82)	0.61 ± 0.28 (124) (0.00, 0.60, 1.89)
p-value[1]	-	<.0001	<.0001	-
[1] Wilcoxon Signed Rank Test.				

IVI also collected information regarding changes from baseline in EQ-5D-3L and WIQ. Positive changes were seen from baseline to 12 months in both quality of life measures. Tack integrity was evaluated at 12 months. At the time of the post-hoc analysis of 12-month follow-up data, 125 subjects had radiographic evaluations of their implants performed. There were no Tack embolizations, migrations, or fractures in any of these subjects per **Table 17.**

Table 17. Tack Integrity at 12 Months in the Intent-to-Treat subjects	
Event	**ITT Subjects % (n/N)**
Tack Embolization	0.0% (0/125)
Tack Migration	0.0% (0/125)
Tack Fracture	0.0% (0/125)

Subgroup Analysis

Applicability to Pediatric Populations

Peripheral artery disease is not typically found in pediatric populations except for rare cases of homozygous lipid disorders. Accordingly, safety and effectiveness of the Tack Endovascular System® (4F, 1.5-4.5mm) in these patients were not studied in the TOBA II BTK trial.

Gender/Geography

Subgroup analyses were performed for the following and are summarized in **Table 18 – Table 20** below:

- Gender

- Geography
- Dissection

Table 18 Subgroup Analyses of Primary Endpoints – By Gender and Region		
	Primary Safety Endpoint % (n/N)	**Primary Efficacy Endpoint % (n/N)**
Gender		
Male	1.3% (2/152)	95.7% (135/141)
Female	1.3% (1/76)	95.3% (61/64)
P-Value[1]	1.0000	1.0000
US vs. OUS		
US	0.8% (1/128)	95.6% (109/114)
OUS	2.0% (2/100)	95.6% (87/91)
P-Value[1]	0.5831	1.0000
1 P-Value from Fisher's Exact test.		

Table 19 Primary and Secondary Endpoints at 6 months stratified by dissection grade				
			Secondary Endpoints	
	Primary Safety Endpoint (MALE + POD at 30 days)	**Primary Efficacy Endpoint** (Freedom from MALE at 6 months plus POD at 30 days)	**Tacked Segment Patency at 6 months**	**Target Limb Salvage at 6 months**
Dissection Grade[1]				
A	0.0% (0/47)	97.6% (41/42)	91.7% (44/48)	100.0% (42/42)
B	1.1% (1/90)	97.6% (80/82)	82.8% (106/128)	100.0% (82/82)
C	0.0% (0/26)	96.2% (25/26)	82.9% (29/35)	100.0% (26/26)
D	3.4% (2/59)	90.4% (47/52)	73.0% (65/89)	94.2% (49/52)
E	0.0% (0/2)	100.0% (1/1)	100.0% (2/2)	100.0% (1/1)
F	-	-	-	-
[1] Worst dissection by subject per Core Lab.				

Table 20 Additional Subgroup Analyses for 12 Month Endpoints			
	Freedom from MALE at 12 Months + POD	**Tacked Segment Patency**	**Target Limb Salvage**
Dissection Grade[1]			
A	94.1% (32/34)	90.7% (39/43)	97.1% (33/34)
B	96.4% (54/56)	78.9% (75/95)	100.0% (56/56)
C	93.8% (15/16)	76.7% (23/30)	100.0% (16/16)
D	88.4% (38/43)	64.0% (55/86)	93.0% (40/43)
E	100.0% (1/1)	-	100.0% (1/1)
F	-	-	-
[1] Worst dissection by subject per Core Lab.			

Overall Conclusions

The results from preclinical and clinical studies indicate that the Tack Endovascular System (4F, 1.5-4.5mm) meets safety and performance specifications. The results from the TOBA II BTK multi-center clinical trial support the conclusion that the Tack Endovascular System (4F, 1.5-4.5mm) is safe and effective for the repair of post-PTA dissections in the mid/distal popliteal, tibial and peroneal arteries when used in accordance with device labeling and the instructions for use (IFU).

MRI Safety Information

Non-clinical testing has demonstrated that the *Tack* implant (6 mm length) of the *Tack Endovascular System® (4F, 1.5-4.5mm)* is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T or 3.0 T only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the *Tack* implant is expected to produce a maximum temperature rise of 3.0ºC after 15 minutes of continuous scanning (i.e., per pulse sequence).
In non-clinical testing, the image artifact caused by the device extends approximately 2 mm from the *Tack* implant (6 mm length) when imaged with a gradient echo pulse sequence and a 3.0 T MRI system. The artifact does not obscure the device lumen.
Intact Vascular, Inc. recommends that patients register the conditions under which this *Tack* implant can be MRI scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

intact vascular

Tack Endovascular System® (4F, 1.5-4.5mm)

6mm

1.5-4.5mm RVD

1.5 - 4.5mm x 6mm

90cm | 4Fr

90cm

0.014" (0.36mm) OTW

4Fr (1.33mm)

Catalog No. REF 154090041

Batch Code LOT 12345

Use-by Date yyyy-mm-dd

Contents: 4 Tack® implants per system

1.5 - 4.5mm x 6mm | 90cm | 4Fr

LOT 12345

yyyy-mm-dd

(01) 0 0863328 00018 9

(17) 000000 (10) 12345

Manufactured By:
Intact Vascular Inc
1285 Drummers Lane
Suite 200
Wayne, PA 19087, USA
Phone: +1 800-865-0214
www.intactvascular.com

LBL1501-01 Rev D

intact vascular
Tack Endovascular System® (4F, 1.5-4.5mm)
1.5 - 4.5mm x 6mm | 90cm | 4Fr
LOT 12345
yyyy-mm-dd
(01) 0 0863328 00018 9 (17) 000000 (10) 12345
Manufactured By: Intact Vascular Inc 1285 Drummers Lane Suite 200 Wayne, PA 19087, USA Phone: +1 800-865-0214 www.intactvascular.com
LBL1501-01 Rev D

Tack Endovascular System® (4F, 1.5-4.5mm)

Not made with natural rubber latex
See Symbols Glossary in IFU

Catalog No.	Batch Code	Use-by Date
REF 154090041	LOT 12345	yyyy-mm-dd

Contents: 4 Tack® implants per system

(01) 0 0863328 00014 1
(17) 000000 (10) 12345

Tack Endovascular System®
(4F, 1.5-4.5mm)

(01) 0 0863328 00014 1
(17) 000000 (10) 12345

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LBL1500-01 Rev D

Tack Endovascular System®
(4F, 1.5-4.5mm)

1.5 - 4.5mm x 6mm
90cm 4Fr

6mm
1.5-4.5mm RVD

90cm
0.014" (0.36mm) OTW

4Fr
(1.33mm)

Catalog No. REF 154090041
Batch Code LOT 12345
Use-by Date yyyy-mm-dd

Contents: 4 Tack® implants per system

(01) 0 0863328 00014 1
(17) 000000 (10) 12345

Tack Endovascular System®
(4F, 1.5-4.5mm)

(01) 0 0863328 00014 1
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Patient Implant Card

Tack Endovascular System® (4F, 1.5-4.5mm)

LBL 1503-01 Rev E

Tack Endovascular System® (4F, 1.5-4.5mm)

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the Tack® implant of the Tack Endovascular System® (4F, 1.5-4.5mm) is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T or 3.0 T only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the Tack implant is expected to produce a maximum temperature rise of 3.0° C after 15 minutes of continuous scanning (i.e. per pulse sequence).

In non-clinical testing, the image artifact caused by the device extends approximately 2 mm from the Tack implant (6 mm length) when imaged with a gradient echo pulse sequence and a 3.0 T MRI system. The artifact does not obscure the device lumen.

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Tarjeta de implante para el paciente

Tack Endovascular System® (4F, 1.5-4.5mm)

LBL 1503-01 Rev E

Tack Endovascular System® (4F, 1.5-4.5mm)

INFORMACIÓN DE SEGURIDAD SOBRE LA RM

Pruebas preclínicas han demostrado que el implante Tack® del Tack Endovascular System® (4F, 1.5-4.5mm) es condicional respecto de la RM. Un paciente que tenga instalado el dispositivo puede someterse sin riesgo a un estudio de RM si el sistema cumple con las condiciones siguientes:

- Campo magnético estático 1.5 T o 3.0 T solamente
- Campo magnético con un gradiente espacial máximo de 4,000 gauss/cm (40 T/m) o menos
- Máximo sistema de RM notificado, tasa de absorción específica (SAR, por su sigla en inglés) promedio de cuerpo entero de 2 W/kg (Modo de operación normal)

Según las condiciones de RM descritas anteriormente, se espera que el implante Tack produzca un aumento de temperatura máximo de 3.0 °C luego de 15 minutos de escaneo continuo (secuencia de eco de gradiente y un sistema de RM de 3.0 T. El artefacto no implde ver el lumen del dispositivo.

En pruebas preclínicas, el artefacto de imagen causado por el dispositivo se extiende unos 2 mm desde el implante Tack (6 mm de longitud) cuando la imagen se crea con una secuencia de pulsos de

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Patienten-Implantatkarte

Tack Endovascular System® (4F, 1.5-4.5mm)

LBL 1503-01 Rev E

Tack Endovascular System® (4F, 1.5-4.5mm)

MRT-SICHERHEITSINFORMATION

Nicht-klinische Tests haben erwiesen, dass das Tack®-Implantat des Tack Endovascular System® (4F, 1.5-4.5mm) bedingt MR-tauglich ist Ein mit diesem Vorrichtung behandelter Patient kann sicher einem Scan in einem MRT-System unterzogen werden, das die folgenden Bedingungen erfüllt:

- Statisches Magnetfeld von nur 1,5 T oder 3,0 T
- Maximales raumliches Gradienten-Magnetfeld von 4000 Gauß/cm (40 T/m) oder weniger
- Maximal für das MRT-System berichtete durchschnittliche Ganzkörper-SAR (spezifische Absorptionsrate) von 2 W/kg (Normaler Betriebsmodus)

Unter den oben definierten Scanbedingungen wird das Tack-Implantat voraussichtlich einen maximalen Temperaturanstieg von 3,0 °C nach 15 Minuten durchgehendem Scannen zeigen (Pulssequenz).

In nicht-klinischen Tests erstreckt sich das Bildartefakt, das vom Gerät verursacht wird, auf zirka 2 mm vom Tack-Implantat (6 mm Länge), wenn es mit einer Gradientenecho-Pulssequenz und einem 3,0 T MRT-System aufgenommen wird. Das Artefakt verdeckt das Lumen des Gerätes nicht.

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Implantaatkaart voor de patiënt

Tack Endovascular System® (4F, 1.5-4.5mm)

LBL 1503-01 Rev E

Tack Endovascular System® (4F, 1.5-4.5mm)

INFORMATIE MRI-VEILIGHEID

Niet-klinische testen hebben aangetoond dat het Tack®-implantaat van het Tack Endovascular System® (4F, 1.5-4.5mm) MRI-veilig onder voorwaarde is. Een patiënt met dit hulpmiddel kan veilig worden gescand in een MRI-systeem dat aan de volgende voorwaarden voldoet:

- Statisch magnetisch veld van 1,5 T of 3,0 T
- Maximale ruimtegradiënt van het magnetische veld van 4000 gauss/cm (40 T/m) of minder
- Maximale, voor het MRI-systeem gerapporteerde, voor het gehele lichaam gemiddelde, specifieke absorptie (SAR) van 2 W/kg (normale bedrijfsmodus)

Onder de hierboven gedefinieerde scanconditties wordt verwacht dat het Tack-implantaat een maximum temperatuurverhoging van 3,0 °C produceert na 15 minuten continu scannen (pulssequentie).

In niet-klinische testen strekt het door het hulpmiddel veroorzaakte beeldartefact zich ongeveer 2 mm uit vanaf het Tack-implantaat (lengte 6 mm) wanneer voor het beeld gebruik wordt gemaakt van een gradiëntechopulssequentie en een MRI-systeem van 3,0 T. Het artefact bedekt het lumen van het hulpmiddel niet.

Tack Endovascular System® (4F, 1.5-4.5mm)
Patienten-Implantatkarte

ANWEISUNGEN

Bitte diese Karte immer bei sich tragen. Wenn Sie medizinisch betreut werden, zeigen Sie Ihre Patienten-Implantatkarte dem medizinischen Personal, das Sie möglicherweise behandelt.

Patientenname: _____

Implantationsdatum: _____ Anzahl der Implantate: _____

Position des Implantats (Körperteil und Gefäß): _____

Implantierender Arzt: _____

Telefonnummer des Arztes: _____

Etikett(en) hier anbringen

Tack Endovascular System® (4F, 1.5-4.5mm)
Implantaatkaart voor de patiënt

INSTRUCTIES

Draag deze kaart altijd bij u. Als u medische zorg ontvangt, laat dan uw implantaat-kaart zien aan al het medische personeel dat u behandelt.

Naam patiënt: _____

Datum implantaat: _____ Aantal implantaten: _____

Plaats implantaat (ledemaat en bloedvat): _____

Implanterende arts: _____

Telefoonnummer arts: _____

Label(s) hier bevestigen

Tack Endovascular System® (4F, 1.5-4.5mm)
Patient Implant Card

INSTRUCTIONS

Please carry this card at all times. If you receive medical care, show your Patient Implant Card to any medical personnel who may treat you.

Patient Name: _____

Implant Date: _____ No. of Implants: _____

Implant Location (limb & vessel): _____

Implanting Physician: _____

Physician Phone Number: _____

Attach Label(s) Here

Tack Endovascular System® (4F, 1.5-4.5mm)
Tarjeta de implante para el paciente

INSTRUCCIONES

Lleve consigo esta tarjeta en todo momento. Si recibe atención médica, muestre su Tarjeta de implante para el paciente a todo el personal médico que pueda tratarlo.

Nombre del paciente: _____

Fecha del implante: _____ Núm. de implantes: _____

Sitio del implante (miembro y vaso): _____

Médico que implantó: _____

Teléfono del médico: _____

Adjuntar etiquetas aquí