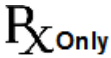
Instructions for Use (IFU)
The Tack Endovascular System® (6F)

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.

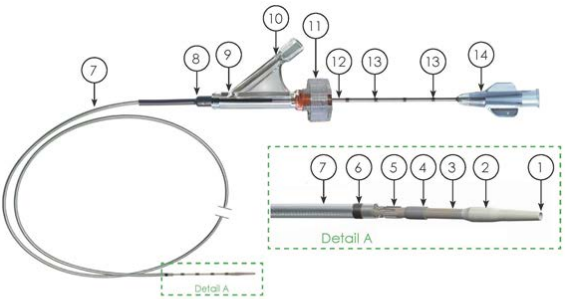
Caution: Federal (United States) law restricts this device to sale by or on the order of a physician.

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®

DESCRIPTION
The *Tack Endovascular System* is designed to treat vascular dissections with *Tack*® implant(s) following angioplasty in the superficial femoral and proximal popliteal arteries, ranging 3.5 mm to 6.0 mm in diameter. The 6F (2.0 mm) catheter contains 6 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* consists of 6 self-expanding Nitinol implants and a 6F (2.0 mm) Delivery Catheter (See **Figure 1**). The numbers in parentheses in the following section refer to those in **Figure 1**.



1. Guidewire Lumen
2. Distal Tip
3. Inner Core Shaft
4. Distal Inner Core Marker
5. Crimped Tack
6. Target Band (Outer Sheath RO Marker)
7. Outer Braided Sheath
8. Strain Relief
9. Bifurcation Luer
10. Side port
11. Hemostatic Valve
12. Inner Core Shaft
13. Proximal Inner Core Markers
14. Guidewire Port
15. Unconstrained Tack
16. Middle RO Marker
17. Anchor

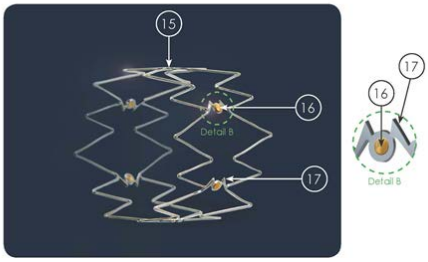


Figure 1. The *Tack Endovascular System*

The *Tack* implants are approximately 6mm in length and expand to an unconstrained diameter of 7.3 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 3.5 to 6.0mm. Six RO Markers (16) as well as six 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**
1.8 mm (Constrained implant)	6.5 mm
3.5 mm (Deployed implant)	6.4 mm
6.0 mm (Deployed implant)	6.2 mm
7.3 mm (Unconstrained implant)	6.1 mm

The delivery catheter has effective lengths of 80cm, 120cm and 135cm. The 6F 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 seven 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 7mm apart. A 1mm 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* is intended for use in the superficial femoral and proximal popliteal arteries ranging in diameter from 3.5mm to 6.0mm for the repair of post percutaneous transluminal balloon angioplasty (PTA) dissection(s).

CONTRAINDICATIONS FOR USE

The *Tack Endovascular System* is contraindicated for the following:

1. Patients with residual stenosis in the treated segment equal to or greater than 30% after PTA.
2. Tortuous vascular anatomy significant enough to prevent safe introduction and passage of the device.
3. Patients with a known hypersensitivity to nickel-titanium alloy (Nitinol).
4. Patients unable to receive standard medication used for interventional procedures such as anticoagulants, contrast agents and antiplatelet therapy.

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 0.035" guidewire and a 6F (2.0 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, 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

The following complications may be associated with intravascular *Tack* device implantation:

- 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 and location of the implanted *Tack* device(s), 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 angioplasty 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 Tack Endovascular System may be used in patients who have received PTA treatment with a standard or drug-coated balloon (DCB).
    NOTE: Requirements for pre-dilatation with a standard balloon (non drug-coated) preceding treatment with a DCB should be performed in accordance with the respective IFU. Once the DCB is introduced, it is recommended that inflations be performed as described below for balloon angioplasty. Operators should follow these recommendations unless patient safety concerns present.
    The recommendations for balloon inflation are as follows:
    a. The operator should select a balloon diameter that can be inflated to a ratio of 1.1:1 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 balloon should be selected that extends across the entire lesion. If a DCB is being used, then the relevant instructions for use should be followed.
3. Balloon Inflation Recommendation: Inflate the balloon slowly and maintain inflation at the specified 1.1:1 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 type A-F.
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: 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 permitted.

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 saline exits through the proximal valve.
            NOTE: Lock the Hemostatic valve and continue to flush until heparinized saline weeps 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 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 6F (2.0 mm) delivery system.
    b. Place a .035" (0.89 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 lesion 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 6F (2.0 mm) or larger size is recommended.
9. Slack Removal
    a. Advance the *Tack Endovascular System* past the lesion site.
    b. Pull back the *Tack Endovascular System* until the radiopaque outer sheath is distal to 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 seven proximal inner core markers on the delivery catheters inner core shaft correspond to the 6*Tack* implants in the distal delivery system). The first *Tack* implant is between the two distal markers. Subsequent *Tack* implants are loaded in sequence back to the last *Tack* implant located between the 6th and 7th distal deployment reference marks.
    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 braided sheath. The entire catheter can be repositioned to additional areas requiring treatment after each *Tack* implant deployment.

f. Repeat sequence (10a through 10f) until all dissections are treated or a new delivery system is required.

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 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

Inflation Recommendation: a minimum 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 (non-DCB) 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.

CAUTION: Fully deflate PTA dilatation catheter prior to withdrawing.

NOTE: Careful advancement of the PTA balloon through the *Tack* implant(s) is required.

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 pivotal study, conducted to assess the safety and efficacy of the Tack Endovascular System in the treatment of post-PTA dissections in the superficial femoral and proximal popliteal arteries, are provided below.

1. TOBA II Study Design

The prospective, multi-center, single-arm, non-blinded TOBA II study investigated the safety and efficacy of the Tack Endovascular System for the treatment of dissection(s) type(s) A through F resulting from percutaneous transluminal balloon angioplasty (PTA) using either standard and drug-coated balloon angioplasty in the superficial femoral and proximal popliteal arteries. The study enrolled 213 subjects at 33 clinical sites in the United States and Austria.
The primary objectives of this study were to demonstrate the following outcomes:

- Safety: Freedom from the occurrence of any new-onset major adverse event(s) (MAEs) defined as index limb amputation (above the ankle), CEC adjudicated clinically-driven target lesion revascularization (CD-TLR), or all-cause death at 30 days.
- Efficacy: Primary patency defined as freedom from CEC adjudicated clinically driven target lesion revascularization (CD-TLR) and freedom from core lab adjudicated duplex ultrasound derived binary restenosis at 12 months (defined as PSVR >2.5).

The performance goal for the primary safety endpoint was set at 88% per the recommendations of the VIVA physicians group. 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 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 MAE to the performance goal using a one-sided $\alpha = 0.05$. The exact one-sided 95% confidence interval for the proportion of subjects free from MAE was calculated.

Because the TOBA II study investigated the Tack Endovascular System in subjects treated with both standard PTA or DCB angioplasty, a composite performance goal was derived from the Levant 2 IDE study using the lower bound 95% confidence interval of patency rates observed from the Test DCB and Control PTA arms. The performance goal for primary efficacy was set at 52.7% based on the ratio of PTA and DCB subjects in the TOBA II study at time of enrollment completion. To meet the study primary patency endpoint, the TOBA II 12-month primary patency lower 95% confidence bound must be greater than 52.7%. The TOBA II clinical study protocol required physicians to treat any dissection (Type A – F) that was observed following PTA or DCB treatment. The study protocol did not require an attempt to resolve dissections with an alternative method prior to tacking.

The primary statistical method was a one-sample exact test comparing the proportion of subjects with primary patency to the performance goal using a one-sided $\alpha = 0.025$. The exact two-sided 95% confidence interval for the proportion of subjects with primary patency was calculated.
An independent Clinical Events Committee 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 that had potential to be classified as Major Adverse Events (as defined by the clinical protocol). 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 Patient Assessment (Inclusion and Exclusion Criteria)

Subjects enrolled in the TOBA II 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 a negative pregnancy test prior to treatment and must use some form of contraception (abstinence is acceptable) through the duration of the study
3. Target limb requires no additional treatment aside from the target lesion and the iliac artery(ies) during the index procedure
4. Subject has been informed of and understands the nature of the study and provides signed informed consent to participate in the study. If the subject possesses the ability to understand and provide informed consent but due to physical inability, the subject cannot sign the ICF, an impartial witness may sign on behalf of the subject
5. Willing to comply with all required follow-up visits
6. Rutherford Classification 2, 3 or 4
7. Estimated life expectancy >1 year
8. Eligible for standard surgical repair, if necessary
9. Subject is ambulatory (assistive devices such as a cane or walker is acceptable).

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

1. Rutherford Classification 0, 1, 5 or 6
2. Is pregnant or refuses to use contraception through the duration of the study
3. Previous infrainguinal bypass graft in the target limb
4. Planned amputation on the target limb
5. Systemic infection or Infection within the target limb and/or immunocompromised
6. Endovascular or surgical procedure (not including diagnostic procedures) on the target limb within 30 days prior to or within 30 days after the index procedure
7. Endovascular or surgical procedure (not including diagnostic procedures) on the non-target limb within 14 days prior to the index procedure or planned procedure within 30 days after the index procedure
8. Prior coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) procedure within 30 days prior to the index procedure or planned CABG/PCI within 30 days after the index procedure
9. Any other previous or planned surgical or endovascular procedure (not including diagnostic procedures) within 14 days prior to or 30 days post index procedure
10. Planned atherectomy, cryoplasty, stenting or any other treatment (with the exception of a crossing device) of the target lesion other than PTA during the index procedure
11. Known coagulopathy, hypercoagulable state, bleeding diathesis, other blood disorder, or a platelet count less than 80,000/microliter or greater than 500,000/microliter.
12. Known hypersensitivity or allergy to antiplatelet or anticoagulant therapy
13. Myocardial infarction within 30 days prior to enrollment
14. History of stroke within 90 days prior to enrollment
15. Serum creatinine of >2.5 mg/dL
16. Requires treatment of tibial or outflow vessels at the index procedure, which include the P2 and P3 segments of the popliteal artery and the tibioperoneal vessels.
17. Known hypersensitivity or contraindication to nickel-titanium alloy (Nitinol)
18. Participating in another ongoing investigational clinical trial that has not completed its primary endpoint
19. Has 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
20. Known hypersensitivity or allergy to contrast agents that cannot be medically managed
21. Thrombolysis of the target vessel within 72 hours prior to the index procedure, where complete resolution of the thrombus was not achieved

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. A time and events schedule for all assessments is provided in **Table 2** below.

Table 2. Time and Events Schedule

Assessment	Baseline	Implant Procedure	Pre-Discharge	30-day (-2 days/ +14 Days)	6 Month (±30 Days)	12 Month (± 30 Days)	24 Month (± 30 Days)	36 Month (± 30 Days)	Unscheduled
Informed Consent	X								
Medical History/Physical Exam	X								
Serum Creatinine	X								
PT/ INR	X								
Urine pregnancy test if female	X								
Ankle Brachial Index (ABI)	X		X	X	X	X	X	X	X
Rutherford Classification	X			X	X	X	X	X	X
Pre-procedural Medications		X							
Angiogram		X							X
Study Medications		X	X	X	X	X	X	X	X
Duplex Ultrasound (DUS)				X	X	X			X
X-ray of Implanted Tacks						X			X
Adverse Event Assessment		X	X	X	X	X	X	X	X
PAQ	X			X	X	X	X	X	X
EQ-5D-3L	X			X	X	X	X	X	X
WIQ	X			X	X	X	X	X	X

2. Accountability of PMA Cohort

Subject Accountability
A total of 213 patients were enrolled in this trial. A summary of subject accountability is provided in **Figure 2** below.

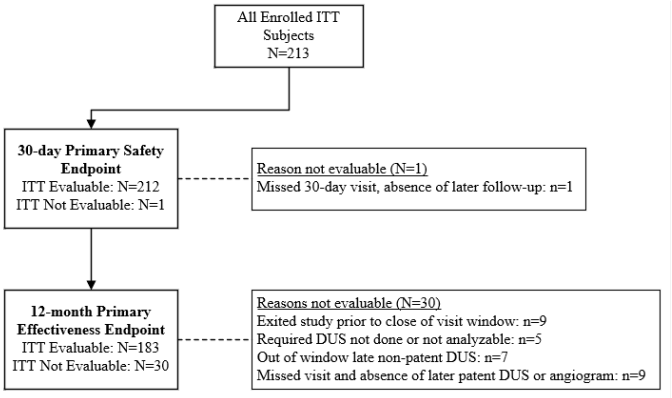


Figure 2. TOBA II Subject Accountability

3. Study Population Demographics and Baseline Parameters

The demographics of the study population are comparable to other interventional peripheral vascular studies conducted in the United States and European Union. The TOBA II population demographics, medical history and risk factors are summarized in **Tables 3-5**, below.

Table 3: Baseline Demographics

	ITT Subjects		
	ALL	**DCB**	**POBA**
Age at baseline (years), Mean ± SD (N) (Min, Median, Max)	68.2 ± 9.1 (213) (40.0,68.0,91.0)	66.8 ± 9.5 (123) (40.0,65.0,91.0)	70.2 ± 8.3 (90) (53.0,69.5,87.0)
Gender, n/N (%)			
Male	151/213 (70.9%)	88/123 (71.5%)	63/90 (70.0%)
Female	62/213 (29.1%)	35/123 (28.5%)	27/90 (30.0%)
Ethnicity, n/N (%)			
Hispanic or Latino	17/213 (8.0%)	4/123 (3.3%)	13/90 (14.4%)
Not Hispanic or Latino	195/213 (91.5%)	118/123 (95.9%)	77/90 (85.6%)
Unknown	1/213 (0.5%)	1/123 (0.8%)	0/90 (0.0%)
Decline to answer	0/213 (0.0%)	0/123 (0.0%)	0/90 (0.0%)
Race (Check all that apply), n/N (%)			
American Indian or Alaskan Native	0/213 (0.0%)	0/123 (0.0%)	0/90 (0.0%)
Asian	3/213 (1.4%)	0/123 (0.0%)	3/90 (3.3%)
Black or African American	29/213 (13.6%)	22/123 (17.9%)	7/90 (7.8%)
Native Hawaiian or Pacific Islander	0/213 (0.0%)	0/123 (0.0%)	0/90 (0.0%)
White	181/213 (85.0%)	101/123 (82.1%)	80/90 (88.9%)
Other	0/213 (0.0%)	0/123 (0.0%)	0/90 (0.0%)
Unknown	0/213 (0.0%)	0/123 (0.0%)	0/90 (0.0%)
Decline to answer	0/213 (0.0%)	0/123 (0.0%)	0/90 (0.0%)
BMI, Mean ± SD (N) (Min, Median, Max)	29.3 ± 6.1 (212) (15.4,28.5,67.4)	29.9 ± 6.8 (122) (15.4,28.6,67.4)	28.5 ± 4.7 (90) (18.2,28.2,42.7)
BMI ≥30, n/N (%)	83/212 (39.2%)	52/122 (42.6%)	31/90 (34.4%)
ABI in treated leg, Mean ± SD (N) (Min, Median, Max)	0.76 ± 0.21 (200) (0.30,0.75,1.37)	0.71 ± 0.20 (118) (0.31,0.71,1.37)	0.83 ± 0.19 (82) (0.30,0.83,1.28)
Non-compressible	7	3	4
ABI in contralateral limb, Mean ± SD (N) (Min, Median, Max)	0.90 ± 0.18 (190) (0.31,0.92,1.28)	0.90 ± 0.17 (105) (0.48,0.90,1.26)	0.90 ± 0.18 (85) (0.31,0.92,1.28)
Rutherford Classification, n/N (%)			
2	68/213 (31.9%)	22/123 (17.9%)	46/90 (51.1%)
3	136/213 (63.8%)	94/123 (76.4%)	42/90 (46.7%)
4	9/213 (4.2%)	7/123 (5.7%)	2/90 (2.2%)

A summary of the medical history for all subjects is provided in **Table 4** below. The subjects presented with a host of comorbidities. 89.7% have arterial hypertension while 87.2% are hyperlipidemic. 60.7% also have coronary artery disease with 41.7% having undergone some form of prior coronary revascularization. 43.2% are diabetic. 80.8% are current or former smokers. 13.6% of subjects have already experienced at least one intervention on the target limb while 33.3% have undergone treatment on the non-target limb.

Table 4: Medical History and Risk Factors			
	ITT Subjects [n/N (%)]		
	ALL	**DCB**	**POBA**
Coronary Artery Disease	128/211 (60.7%)	70/123 (56.9%)	58/88 (65.9%)
Myocardial Infarction	45/200 (22.5%)	27/116 (23.3%)	18/84 (21.4%)
Coronary revascularization	88/211 (41.7%)	52/122 (42.6%)	36/89 (40.4%)
Coronary Artery Bypass Graft (CABG)	33	16	17
Percutaneous Coronary Intervention (PCI)	55	36	19
Chronic angina pectoris	15/208 (7.2%)	11/120 (9.2%)	4/88 (4.5%)
Congestive heart failure	24/211 (11.4%)	12/121 (9.9%)	12/90 (13.3%)
Cerebrovascular event	24/209 (11.5%)	11/120 (9.2%)	13/89 (14.6%)
Transient Ischemic Attack (TIA)	10	4	6
Stroke – Cerebrovascular Accident (CVA)	14	7	7
Gastrointestinal / genitourinary bleeding	5/212 (2.4%)	2/123 (1.6%)	3/89 (3.4%)
Chronic renal insufficiency	19/213 (8.9%)	11/123 (8.9%)	8/90 (8.9%)
On dialysis	1/213 (0.5%)	0/123 (0.0%)	1/90 (1.1%)
Coagulopathy, hypercoagulable state, bleeding diathesis, or other blood disorder	0/213 (0.0%)	0/123 (0.0%)	0/90 (0.0%)
Smoking			
Current	66/213 (31.0%)	39/123 (31.7%)	27/90 (30.0%)
Former	106/213 (49.8%)	66/123 (53.7%)	40/90 (44.4%)
Never	41/213 (19.2%)	18/123 (14.6%)	23/90 (25.6%)
Diabetes mellitus	92/213 (43.2%)	48/123 (39.0%)	44/90 (48.9%)
Type I	3	0	3
Type II	89	48	41
Arterial hypertension	191/213 (89.7%)	108/123 (87.8%)	83/90 (92.2%)
Controlled with medication	180	101	79
Not controlled with medication	11	7	4
Hyperlipidemia	184/211 (87.2%)	108/121 (89.3%)	76/90 (84.4%)
Controlled with medication	174	103	71
Not controlled with medication	10	5	5
Family history of premature atherosclerotic disease (e.g. MI, CABG, PCI before age 60)	51/119 (42.9%)	27/67 (40.3%)	24/52 (46.2%)
History of claudication	191/213 (89.7%)	110/123 (89.4%)	81/90 (90.0%)
History of previous peripheral artery intervention in target limb	29/213 (13.6%)	14/123 (11.4%)	15/90 (16.7%)
History of previous peripheral artery intervention in non-target limb	71/213 (33.3%)	30/123 (24.4%)	41/90 (45.6%)

Baseline lesion and vessel assessments are summarized in **Table 5** below. Nearly all treated lesions were de novo lesions. By core lab assessment, 87.2% of lesions existed in the SFA alone. The average lesion length was 74.3mm with an average stenosis of 73.5%. 23.2% of lesions were occluded while 59.2% were moderately or severely calcified. 82.5% of lesions treated were single lesions while 17.5% were tandem or combination lesions.

Table 5: Baseline Angiographic Parameters						
	ITT Subjects					
	ALL		**DCB**		**POBA**	
	Investigator Reported	**Core Lab Adjudicated**	**Investigator Reported**	**Core Lab Adjudicated**	**Investigator Reported**	**Core Lab Adjudicated**
Target Lesion Type, n/N (%) De novo Restenotic	202/213 (94.8%) 11/213 (5.2%)	N/A	118/123 (95.9%) 5/123 (4.1%)	N/A	84/90 (93.3%) 6/90 (6.7%)	N/A
Target Vessel, n/N (%)						
SFA	192/213 (90.1%)	184/211 (87.2%)	107/123 (87.0%)	104/121 (86.0%)	85/90 (94.4%)	80/90 (88.9%)
P1	7/213 (3.3%)	12/211 (5.7%)	4/123 (3.3%)	7/121 (5.8%)	3/90 (3.3%)	5/90 (5.6%)
SFA and P1	14/213 (6.6%)	15/211 (7.1%)	12/123 (9.8%)	10/121 (8.3%)	2/90 (2.2%)	5/90 (5.6%)
Most distal target lesion location, n/N (%)						
Proximal SFA	12/213 (5.6%)	9/211 (4.3%)	3/123 (2.4%)	2/121 (1.7%)	9/90 (10.0%)	7/90 (7.8%)
Mid SFA	91/213 (42.7%)	43/211 (20.4%)	45/123 (36.6%)	22/121 (18.2%)	46/90 (51.1%)	21/90 (23.3%)
Distal SFA	89/213 (41.8%)	132/211 (62.6%)	59/123 (48.0%)	80/121 (66.1%)	30/90 (33.3%)	52/90 (57.8%)
P1	21/213 (9.9%)	21/211 (10.0%)	16/123 (13.0%)	13/121 (10.7%)	5/90 (5.6%)	8/90 (8.9%)
P2	0/213 (0.0%)	6/211 (2.8%)	0/123 (0.0%)	4/121 (3.3%)	0/90 (0.0%)	2/90 (2.2%)
Target lesion length (mm), Mean ± SD (N) (Min, Median, Max)	80.5 ± 39.3 (213) (10.0,75.0, 170.0)	74.3 ± 40.6 (210) (8.3,66.8, 222.6)	85.5 ± 40.4 (123) (10.0,80.0, 170.0)	85.1 ± 40.6 (120) (8.3,81.7, 222.6)	73.5 ± 36.7 (90) (20.0,70.0, 150.0)	59.8 ± 35.8 (90) (10.3,52.0, 152.4)
Lesion type, n/N (%)						
Single	183/213 (85.9%)	174/211 (82.5%)	102/123 (82.9%)	92/121 (76.0%)	81/90 (90.0%)	82/90 (91.1%)
Combination	16/213 (7.5%)	33/211 (15.6%)	13/123 (10.6%)	27/121 (22.3%)	3/90 (3.3%)	6/90 (6.7%)
Tandem	14/213 (6.6%)	4/211 (1.9%)	8/123 (6.5%)	2/121 (1.7%)	6/90 (6.7%)	2/90 (2.2%)
Proximal reference vessel diameter (mm), Mean ± SD (N) (Min, Median, Max)	5.3 ± 0.7 (213) (3.0, 5.2, 6.0)	5.3 ± 0.7 (211) (3.3, 5.4, 7.5)	5.2 ± 0.7 (123) (3.0, 5.0, 6.0)	5.2 ± 0.7 (121) (3.3, 5.2, 6.7)	5.4 ± 0.6 (90) (4.0, 5.5, 6.0)	5.5 ± 0.7 (90) (3.7, 5.5, 7.5)
Distal reference vessel diameter (mm), Mean ± SD (N) (Min, Median, Max)	5.3 ± 0.7 (213) (3.5, 5.0, 6.0)	5.5 ± 0.7 (211) (3.5, 5.5, 7.3)	5.2 ± 0.6 (123) (3.5, 5.0, 6.0)	5.4 ± 0.8 (121) (3.5, 5.5, 7.2)	5.4 ± 0.7 (90) (4.0, 5.5, 6.0)	5.5 ± 0.7 (90) (3.5, 5.6, 7.3)

Table 5: Baseline Angiographic Parameters						
	ITT Subjects					
	ALL		**DCB**		**POBA**	
	Investigator Reported	**Core Lab Adjudicated**	**Investigator Reported**	**Core Lab Adjudicated**	**Investigator Reported**	**Core Lab Adjudicated**
Baseline target lesion percent diameter stenosis (%), Mean ± SD (N) (Min, Median, Max)	87.5 ± 10.6 (213) (70.0,90.0, 100.0)	73.5 ± 18.2 (211) (35.8,71.6, 100.0)	90.5 ± 9.9 (123) (70.0,95.0, 100.0)	79.3 ± 17.8 (121) (35.8,77.1, 100.0)	83.5 ± 10.2 (90) (70.0,80.0, 100.0)	65.8 ± 15.7 (90) (41.9,62.4, 100.0)
Total Occlusion, n/N (%)	45/213 (21.1%)	49/211 (23.2%)	38/123 (30.9%)	41/121 (33.9%)	7/90 (7.8%)	8/90 (8.9%)
Presence of thrombus, n/N (%)	0/213 (0.0%)	0/211 (0.0%)	0/123 (0.0%)	0/121 (0.0%)	0/90 (0.0%)	0/90 (0.0%)
Calcification, n/N (%)						
None / Mild	131/213 (61.5%)	86/211 (40.8%)	84/123 (68.3%)	56/121 (46.3%)	47/90 (52.2%)	30/90 (33.3%)
Moderate	81/213 (38.0%)	113/211 (53.6%)	39/123 (31.7%)	58/121 (47.9%)	42/90 (46.7%)	55/90 (61.1%)
Severe	1/213 (0.5%)	12/211 (5.7%)	0/123 (0.0%)	7/121 (5.8%)	1/90 (1.1%)	5/90 (5.6%)
Number of patent infrapopliteal vessels, n/N (%)						
0	0/213 (0.0%)	6/207 (2.9%)	0/123 (0.0%)	3/120 (2.5%)	0/90 (0.0%)	3/87 (3.4%)
1	56/213 (26.3%)	72/207 (34.8%)	33/123 (26.8%)	40/120 (33.3%)	23/90 (25.6%)	32/87 (36.8%)
2	96/213 (45.1%)	86/207 (41.5%)	50/123 (40.7%)	50/120 (41.7%)	46/90 (51.1%)	36/87 (41.4%)
3	61/213 (28.6%)	43/207 (20.8%)	40/123 (32.5%)	27/120 (22.5%)	21/90 (23.3%)	16/87 (18.4%)

4. Safety and Effectiveness Results

Safety Results

Primary Safety

The primary safety endpoint for the TOBA II study is freedom from the occurrence of any new-onset major adverse event(s) (MAEs) defined as index limb amputation (above the ankle), CEC adjudicated clinically-driven target lesion revascularization (CD-TLR), or all-cause death at 30 days. The primary safety endpoint was MET as no MAEs were reported in the first 30 days of follow-up. See **Table 6** below.

Table 6: Primary Safety Endpoint at 30 days in ITT Subjects

Event Type	n/N (%) (95% CI)[1]	VIVA Performance Goal	p-value[1]	Study Endpoint
Freedom from MAE	212/212 (100.0%) (98.6%,)	88%	<0.0001	MET
Index Limb Amputation	0/212 (0.0%)	N/A	N/A	N/A
CD-TLR	0/212 (0.0%)			
All-Cause Death	0/212 (0.0%)			

[1] Fisher's exact test for one proportion, p-value and 95% CI are one-sided

Adverse Effects

Table 7 below presents an overall summary of adverse events that have been reported through 390 days, displaying the events by device or procedure-related and by severity. No events were determined to be unanticipated. The types and occurrences of events that were reported are within expected rates.

Table 7: Adverse Events with Onset Date within 390 Days Post Index Procedure

Body System Organ Class	Adverse Events		Device or Procedure Related Events		Serious Adverse Events		Serious Device or Procedure Related Events	
	N	#(%) of pts	N	#(%) of pts	N	#(%) of pts	N	#(%) of pts
Blood and lymphatic system disorders	5	5 (2.3%)	.	.	2	2 (0.9%)	.	.
Cardiac disorders	52	26 (12.2%)	.	.	40	23 (10.8%)	.	.
Congenital, familial and genetic disorders	1	1 (0.5%)	.	.	.		.	.
Ear and labyrinth disorders	4	4 (1.9%)	.	.	.		.	.
Endocrine disorders	1	1 (0.5%)	.	.	.		.	.
Eye disorders	7	5 (2.3%)	.	.	5	4 (1.9%)	.	.
Gastrointestinal disorders	22	18 (8.5%)	.	.	13	11 (5.2%)	.	.
General disorders and administration site conditions	28	26 (12.2%)	7	7 (3.3%)	14	12 (5.6%)	4	4 (1.9%)
Hepatobiliary disorders	6	6 (2.8%)	.	.	2	2 (0.9%)	.	.
Immune system disorders	3	3 (1.4%)	1	1 (0.5%)	2	2 (0.9%)	1	1 (0.5%)

Table 7: Adverse Events with Onset Date within 390 Days Post Index Procedure								
Body System Organ Class	**Adverse Events**		**Device or Procedure Related Events**		**Serious Adverse Events**		**Serious Device or Procedure Related Events**	
	N	**#(%) of pts**	**N**	**#(%) of pts**	**N**	**#(%) of pts**	**N**	**#(%) of pts**
Infections and infestations	42	31 (14.6%)	1	1 (0.5%)	17	15 (7.0%)	.	.
Injury, poisoning and procedural complications	53	41 (19.2%)	20	20 (9.4%)	29	25 (11.7%)	13	13 (6.1%)
Investigations	1	1 (0.5%)	.	.	.	.	.	.
Metabolism and nutrition disorders	6	6 (2.8%)	.	.	.	.	.	.
Musculoskeletal and connective tissue disorders	40	28 (13.1%)	1	1 (0.5%)	10	9 (4.2%)	1	1 (0.5%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	3 (1.4%)	.	.	1	1 (0.5%)	.	.
Nervous system disorders	30	19 (8.9%)	.		12	10 (4.7%)	.	.
Renal and urinary disorders	8	7 (3.3%)	1	1 (0.5%)	4	4 (1.9%)	1	1 (0.5%)
Reproductive system and breast disorders	5	4 (1.9%)	.	.	.	.	.	.
Respiratory, thoracic and mediastinal disorders	25	20 (9.4%)	.	.	8	8 (3.8%)	.	.
Skin and subcutaneous tissue disorders	8	8 (3.8%)	.	.	1	1 (0.5%)	.	.
Vascular disorders	107	77 (36.2%)	21	19 (8.9%)	74	57 (26.8%)	17	17 (8.0%)
TOTAL	**457**	**139 (65.3%)**	**52**	**47 (22.1%)**	**234**	**115 (54.0%)**	**37**	**36 (16.9%)**

Effectiveness Results

Primary Effectiveness

Primary Effectiveness Endpoint

Primary patency was defined as freedom from CEC adjudicated clinically driven target lesion revascularization (CD-TLR) and freedom from core lab adjudicated duplex ultrasound derived binary restenosis at 12 months (defined as PSVR >2.5). As shown in **Table 8** below, the TOBA II primary patency at 12 months was 65.6% with a lower 95% confidence bound of 58.2%, which met the PG of 52.7%.

Table 8: Primary Patency at 12 Months						
ITT or PP			**n/N (%) (95% CI)[1]**	**Target Performance Goal**	**p-value[1]**	**Study Endpoint**
ITT	Primary Patency		120/183 (65.6%) (58.2%, 72.4%)	52.7%	0.0006	MET
	Reason for Lack of Patency	CD-TLR	31/183 (16.9%)	N/A	N/A	N/A
		Binary Restenosis	32/183 (17.5%)			
PP	Primary Patency		116/176 (65.9%) (58.4%, 72.9%)	52.7%	0.0005	MET
	Reason for Lack of Patency	CD-TLR	29/176 (16.5%)	N/A	N/A	N/A
		Binary Restenosis	31/176 (17.6%)			

[1] Fisher's exact test for one proportion, p-value and 95% CI are two-sided

5. Observational Endpoints

Observational endpoints include the following:

- Device Success
- Device Success per patient
- Procedure Success

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

- All-cause death
- Amputation of the target limb (above the ankle)
- Clinically-driven target vessel revascularization (CD-TVR)
- Clinically-driven target lesion revascularization (CD-TLR)
- Target vessel revascularization (TVR)
- Target lesion revascularization (TLR)
- Changes from Baseline in Rutherford Classification
- Changes from Baseline in Ankle Brachial Index (ABI) measurement
- Changes from Baseline in the Peripheral Artery Questionnaire (PAQ)
- Changes from Baseline in the EQ-5D-3L quality of life questionnaire
- Changes from Baseline in the Walking Impairment Questionnaire (WIQ)
- Tack Integrity via X-ray (only performed at 12-month visit)
- Duplex Ultrasound (DUS) derived lesion and vessel patency (performed at each visit through 12 months)

Table 9 displays the Device and Procedure Success analysis. Both device and procedure success were acceptably high indicating that the investigators were able to deploy and place the Tack implants where needed with no major adverse events during the procedure.

Table 9: Device and Procedure Success		
Event Type	**ITT Subjects n/N (%)**	**PP Subjects n/N (%)**
Device Success per device introduced	230/239 (96.2%)	**NA**
Device Success per patient	204/213 (95.8%)	NA
Procedural Success per subject	212/213 (99.5%)	204/204 (100.0%)
Device Success is defined as successful deployment of the Tack(s) at the intended target site(s) and successful withdrawal of the delivery catheter from the introducer sheath. If the study device was introduced but the subject did not receive a Tack due to user error and not a device malfunction, this device was not included in the device success assessment. **Device Success per patient** - Device success as an observational endpoint was measured per device but the per protocol analysis definition required that all devices used in a **single patient** that were evaluable per the device success observational endpoint were successes. **Procedure Success** is defined as demonstrated vessel patency (<30% residual diameter stenosis, by visual estimate) without the use of a bailout stent or the occurrence of MAE upon completion of the index procedure.		

Table 10 details the Kaplan-Meier estimates of the other safety-related endpoints that were pre-defined for the trial for the ITT population. No device-related deaths or major amputations have occurred through 12 months.

Table 10: Summary of Other Endpoints (Kaplan Meier Analysis) – ITT Population			
Parameter	**Estimate # events, # at risk**		
	30 Day	**180 Day**	**360 Day**
Survival	100.0% 0, 213	99.5% 1, 207	97.9% 4, 153
Freedom from amputation of the target limb (above the ankle)	100.0% 0, 213	100.0% 0, 207	100.0% 0, 153
Freedom from clinically driven target vessel revascularization (CD-TVR)	100.0% 0, 213	95.7% 9, 198	85.5% 29, 134
Freedom from clinically driven target lesion revascularization (CD-TLR)	100.0% 0, 213	96.2% 8, 199	86.5% 27, 136
Freedom from target vessel revascularization (TVR)	100.0% 0, 213	95.7% 9, 198	85.0% 30, 134
Freedom from target lesion revascularization (TLR)	100.0% 0, 213	96.2% 8, 199	86.5% 27, 136

By 12 months, 71.7% of subjects in the ITT population reported either no symptoms or mild claudication (Rutherford 0-1). Also, importantly, only five subjects were reported with critical limb ischemia (Rutherford 4-6) at the same time-period. 81.2% are reported to show an improvement of one or more Rutherford class from baseline to 12 months.

Table 11: Rutherford Classification and Changes in Rutherford Class from Baseline in ITT Patients				
Parameter	***Baseline***	***30 Day***	***6 Month***	***12 Month***
Rutherford Class, n/N (%)				
0-Asymptomatic	0/213 (0.0%)	119/208 (57.2%)	104/196 (53.1%)	102/191 (53.4%)
1-Mild Claudication	0/213 (0.0%)	36/208 (17.3%)	38/196 (19.4%)	35/191 (18.3%)
2-Moderated Claudication	68/213 (31.9%)	35/208 (16.8%)	27/196 (13.8%)	30/191 (15.7%)
3-Severe Claudication	136/213 (63.8%)	14/208 (6.7%)	20/196 (10.2%)	19/191 (9.9%)
4-Ischemic Rest Pain	9/213 (4.2%)	4/208 (1.9%)	5/196 (2.6%)	3/191 (1.6%)
5-Minor Tissue Loss	0/213 (0.0%)	0/208 (0.0%)	2/196 (1.0%)	2/191 (1.0%)
6-Ulceration or gangrene	0/213 (0.0%)	0/208 (0.0%)	0/196 (0.0%)	0/191 (0.0%)
Rutherford Change from Baseline, n/N (%)				
Worsened 3 classes	N/A	0/208 (0.0%)	0/196 (0.0%)	1/191 (0.5%)
Worsened 2 classes	N/A	2/208 (1.0%)	6/196 (3.1%)	1/191 (0.5%)
Worsened 1 class	N/A	1/208 (0.5%)	6/196 (3.1%)	9/191 (4.7%)
No change	N/A	34/208 (16.3%)	27/196 (13.8%)	25/191 (13.1%)
Improved 1 class	N/A	32/208 (15.4%)	30/196 (15.3%)	33/191 (17.3%)
Improved 2 classes	N/A	49/208 (23.6%)	47/196 (24.0%)	45/191 (23.6%)
Improved 3 classes	N/A	83/208 (39.9%)	75/196 (38.3%)	72/191 (37.7%)
Improved 4 classes	N/A	7/208 (3.4%)	5/196 (2.6%)	5/191 (2.6%)

Ankle Brachial index (ABI) was measured at baseline, discharge and then again at each follow-up visit. **Table 12** describes the results of the changes in ABI from baseline through follow-up in the ITT populations. The average ABI was higher at discharge versus baseline and remained stable throughout follow-up.

Table 12: ABI and Changes in ABI from Baseline in ITT Patients					
Parameter	***Baseline***	***Discharge***	***30 Day***	***6 Month***	***12 Month***
ABI in the Target Limb					
# Non-Compressible	7	9	7	8	9
At follow-up Mean ± SD (N) (Min, Median, Max)	0.76 ± 0.21 (200) (0.30,0.75,1.37)	0.92 ± 0.17 (194) (0.01,0.95,1.38)	0.97 ± 0.15 (199) (0.39,0.97,1.37)	0.91 ± 0.17 (185) (0.33,0.92,1.27)	0.91 ± 0.17 (180) (0.32,0.93,1.38)
Change from Baseline Mean ± SD (N) (Min, Median, Max)	NA	0.17 ± 0.21 (189) (-1.19,0.16,0.68)	0.22 ± 0.23 (194) (-0.46,0.22,0.83)	0.16 ± 0.24 (180) (-0.46,0.16,0.73)	0.15 ± 0.23 (175) (-0.45,0.13,0.76)

IVI also collected information regarding changes from baseline in PAQ, EQ-5D-3L and WIQ. Positive changes were seen from baseline to 12 months in all three quality of life measures.

An X-ray assessment was required at the 12-month follow-up visit to assess Tack integrity for all subjects in whom at least one Tack was placed during the index procedure. The x-rays were subsequently reviewed by the core lab for embolization, migration or fracture. **Table 13** details the results of the X-ray analysis. The Tack implant is quite durable as evidenced by no fractures visualized 12 months post-procedure. Additionally, no embolization occurred and only one Tack implant migration was noted (1/730 Tack implants in 184 subjects reviewed via X-ray at 12 months for migration). The subject had five Tacks implanted and one of the implants was noted to have moved 2.6mm caudally during the follow-up period. No other adverse events have been reported for this subject and the artery is patent at 12 months.

Table 13: Tack Integrity at 12 Months in the Intent-to-Treat patients	
Event	**ITT Subjects n/N (%)**
Tack Embolization	0/186 (0.0%)
Tack Migration	1/184 (0.5%)
Tack Fracture	0/186 (0.0%)

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 in these patients were not studied in the TOBA II trial.

Subgroup analyses were performed for the following:

- Balloon Type
- Gender
- Geography

The TOBA II study was not powered to demonstrate statistical significance within the subgroups for the primary efficacy and safety endpoints. Note, the TOBA II trial was non-randomized so choice of POBA or DCB was at the treating physician's discretion based on medical judgement of what is best for the subject. Note that DCB patients had clinical trends towards longer lesions, more total occlusions, and more severe pre-treatment percentage stenosis.

Table 14: Subgroup Analyses of Primary Endpoints		
Subgroup	**Primary Safety Endpoint** n/N (%)	**Primary Efficacy Endpoint** n/N (%)
ITT	212/212 (100%)	120/183 (65.6%)
Balloon Type		
DCB	123/123 (100.0%)	66/109 (60.6%)
POBA	89/89 (100.0%)	54/74 (73.0%)
Gender		
Male	150/150 (100.0%)	86/131 (65.6%)
Female	62/62 (100.0%)	34/52 (65.4%)
Geography		
Inside United States	172/172 (100.0%)	98/144 (68.1%)
Outside of United States	40/40 (100.0%)	22/39 (56.4%)

Overall Conclusions

The results from preclinical and clinical studies indicate that the Tack Endovascular System meets safety and performance specifications. The results from the TOBA II multi-center clinical trial support the conclusion that the Tack Endovascular System is safe and effective for the treatment of post-PTA dissections in the superficial femoral and proximal popliteal 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* 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 T only
- Maximum spatial gradient magnetic field of 4000 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 2.1ºC after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the device extends approximately 10 mm from the *Tack* implant when imaged with a gradient echo pulse sequence and a 3 T MRI system. The artifact does not obscure the device lumen.

The effect of heating in the MRI environment for *Tack* implants with fractured struts is not known.

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.

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