Instructions for Use (IFU)
Duo Venous Stent System

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.	
	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

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

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
Duo Venous Stent System

DESCRIPTION
The *Duo Venous Stent System* consists of a portfolio of self-expanding venous stent configurations mounted on disposable delivery systems for improving luminal diameter in symptomatic venous outflow obstructions. The portfolio approach includes delivery systems with either a hybrid venous stent implant (Duo Hybrid Stent) or an extension venous stent implant (Duo Extend Stent), enabling the clinician to custom tailor treatment in the iliofemoral venous anatomy based on disease patterns and severity. The Vesper Duo Hybrid Stent is a hybrid stent design with varying mechanical characteristics such as radial force/crush resistance and flexibility along its length to target the variable dynamic loading conditions in the iliofemoral venous system related to the treatment of disease states including non-thrombotic iliac vein compression, May-Thurner syndrome, deep venous thrombosis, and post-thrombotic venous occlusion. The Duo Extend Stent consists of a highly flexible region with reinforcement rings at both ends. The Duo Hybrid Stent can be used independently or in conjunction with the Duo Extend Stent to personalize the treatment region.

Figure 1 below provides an overview of the *Duo Venous Stent System*.

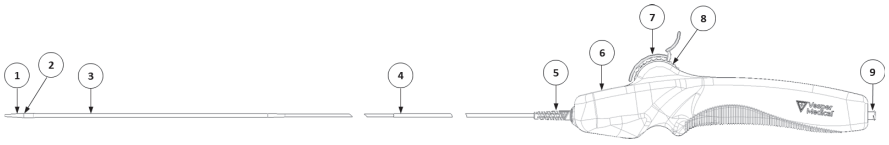

Figure 1 - Duo Venous Stent System

The Triaxial, over-the-wire delivery catheter has an effective length of 90cm or 120cm. The Inner Core Shaft (2) contains the Guidewire Lumen designed for compatibility with a 0.035inch guidewire which extends through the entire length of the Triaxial Delivery System and is bonded to the Luer hub (9) at the proximal end of the system that is fixed within the Handle Body (6). A soft, tapered Distal Tip (1) is bonded to the distal end of the Inner Core Shaft. The Outer Braided Sheath (3), which constrains the Stent implant, translates over the Inner Core Shaft (2), and is coupled to the deployment Thumbwheel (8) within the Handle body (6). A third Triaxial Sleeve (4) is fixed to the Handle Body (6) via the Strain Relief (5) to prevent unintended movement of the delivery system during Stent Deployment. Constrained within the Outer Braided Sheath, the self-expanding Stent implant is positioned on the Inner Core between two radiopaque (RO) Distal Inner Core Markers.
The catheter is flushed prior to the procedure through the Luer Hub (9). Prior to deployment, the Thumbwheel Safety Lock (7) must be removed and discarded. Stent implant positioning is achieved prior to deployment by using the RO Markers on the Inner Core Shaft and Stent implant (**Figure 2** and **Figure 3**). Deployment of the stent is initiated by rotating the thumbwheel in the proximal direction.

Figure 2 and **Figure 3** below provide an overview of the Duo Hybrid and Duo Extend Stents.

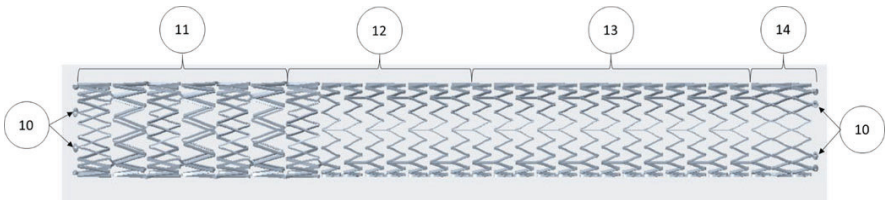

Figure 2 – Duo Hybrid Stent

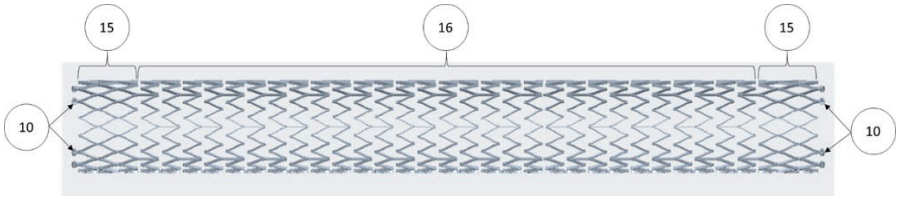

Figure 3 – Duo Extend Stent

The self-expanding Nitinol (nickel-titanium) Duo Hybrid Stent is designed with a "High Crush Resistance" segment (11) at the cranial end followed by a "Transition" segment (12) that transitions into a "Highly Flexible" segment (13) The caudal end of the Duo Hybrid Stent is designed with inflow "reinforcement ring" (14). Both the cranial and caudal ends of the Duo Hybrid Stent include four gold radiopaque markers (10) per end.

The self-expanding Nitinol (nickel-titanium) Duo Extend Stent is designed with a "Highly Flexible" (16) body with inflow reinforcement (15) on both ends. Both the cranial and caudal ends of the Duo Extend Stent include four gold radiopaque markers (10) per end.

The respective lengths of the stent segments are provided in **Table 1**:

Table 1. Length of Stent Segments

Stent Configuration	Labeled Stent Diameter	Labeled Stent Length	Stent Segment per FIGURE 2 and FIGURE 3	Stent Segment Length
Duo Hybrid Stent	12mm, 14mm	60mm, 80mm, 100mm, 120mm, 140mm, 160mm	"High Crush Resistance" segment (11)	38mm
	16mm, 18mm	60mm, 80mm, 100mm, 120mm, 140mm, 160mm		41mm
Duo Hybrid Stent	12mm, 14mm	60mm	"Transition" segment (12)	13mm
		80mm, 100mm, 120mm, 140mm, 160mm		17mm
	16mm, 18mm	60mm		13mm
		80mm, 100mm, 120mm, 140mm, 160mm		22mm
Duo Hybrid Stent	12mm, 14mm	60mm	"Highly Flexible" segment (13)	0mm
		80mm		17mm
		100mm		30mm
		120mm		50mm
		140mm		73mm
		160mm		92mm
	16mm, 18mm	60mm		0mm
		80mm		9mm
		100mm		26mm
		120mm		50mm
		140mm		70mm
		160mm		88mm
Duo Hybrid Stent	12mm, 14mm	60mm, 80mm	"Inflow reinforcement" (14)	8mm
		100mm, 120mm, 140mm, 160mm		11mm
	16mm, 18mm	60mm, 80mm, 100mm, 120mm, 140mm, 160mm		10mm
Duo Extend Stent	12mm, 14mm	40mm	"Inflow reinforcement" (15)	8mm
		60mm, 80mm, 100mm, 120mm, 140mm		11mm
	16mm	40mm, 60mm, 80mm, 100mm, 120mm, 140mm		10mm
Duo Extend Stent	12mm, 14mm	40mm	"Highly Flexible" segment (16)	20mm
		60mm		40mm
		80mm		60mm
		100mm		76mm
		120mm		93mm
		140mm		116mm
	16mm	40mm		21mm
		60mm		39mm
		80mm		61mm
		100mm		83mm
		120mm		100mm
		140mm		118mm

The Nitinol (nickel-titanium) stents self-expand upon deployment from the Delivery Catheter (**Figure 1**) into the target vessel. The self-expanding Nitinol (nickel-titanium) stents impart a radial outward force on the inner luminal surface of target vessel to establish patency.

Table 2. Duo Venous Stent System sizes			
Stent Type	Stent Diameter	Stent Lengths Available	Delivery System Size
Duo Hybrid Stent	12mm	60mm, 80mm, 100mm, 120mm, 140mm, 160mm	9F
	14mm		
	16mm		10F
	18mm		
Duo Extend Stent	12mm	40mm, 60mm, 80mm, 100mm, 120mm, 140mm	9F
	14mm		
	16mm		10F

INTENDED USE
The Duo Venous Stent System is intended for use in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction. The Duo Hybrid Stent is intended to be used in the iliac vein at the confluence of the inferior vena cava only. The Duo Extend Stent is intended for use in the common iliac and common femoral veins.

CONTRAINDICATIONS FOR USE
The *Duo Venous Stent System* is contraindicated for the following:

1. Patients with a known hypersensitivity to nickel-titanium alloy (Nitinol).
2. Patients unable to receive standard medication used for interventional procedures including anticoagulants, contrast agents and antiplatelet therapy.
3. Patients who are judged to have a lesion that prevents complete inflation of a balloon dilation catheter or proper placement of the stent or the stent delivery system.
4. Tortuous vascular anatomy significant enough to prevent safe introduction and passage of the device to its intended location.
5. Duo Hybrid jugular or contralateral vascular access.

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. It is not recommended that Stent implants be used in patients that are allergic/intolerant to contrast media and are not amenable to pretreatment with steroids and/or antihistamines.
3. The Stent implant may cause a thrombus or thrombo-embolization or may migrate from the site.
4. Before insertion of the primary dilatation catheter, it is recommended that the appropriate antiplatelet and/or anticoagulant therapy be administered.
5. Perform all device deployment under fluoroscopic guidance.
6. Use caution when moving the *Duo Venous Stent System* catheter through already deployed stent implants.
7. This device should only be used by physicians who have received appropriate training.
8. Post stent implant balloon dilatation is recommended. Failure to adequately size the stent implant may result in inadequate tissue apposition and risk of stent migration or occlusion.
9. Use caution (advance slowly) during advancement of post-dilatation balloon catheter through deployed Stent implants.
10. Fully deflate post-dilatation balloon prior to withdrawing balloon catheter.
11. Do not use excessive force when using this device as this could result in damage to the device, including component fracture, or venous injury.
12. Do not use the system without the guidewire extending beyond the tip of the delivery catheter.
13. Failure to position and fix the delivery system during Stent implant deployment may result in improper placement of the Stent implant.
14. 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 properly deploy the Stent implant.
15. Rotation of the Delivery System Thumbwheel prior to repositioning the delivery system could result in inadvertent deployment of Stent implant.
16. If the Stent implant cannot deploy, remove the delivery catheter, and use a new device.
17. It is recommended that the Delivery System be used with a 0.035" guidewire.
18. Is recommended that the 9F and 10F Delivery Systems be used with 9F and 10F introducer sheaths, respectively.
19. *Duo Venous Stent System* Storage and Preparation
    a. The *Duo Venous Stent 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 the system cannot be flushed, do not use the system.
20. *Duo Venous Stent System* Handling
    a. Avoid contamination of the Stent 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 delivery system components.
    c. Do not expose the delivery system to organic solvents (e.g., alcohol).
21. Stent Implant Placement

a. The Duo Hybrid Stent (high crush resistance segment) is intended to be used in the common iliac vein at the confluence of the IVC only.
b. The Duo Extend Stent is intended for use in the common femoral vein and the external iliac vein.
c. Do not use with power injection systems.
d. If resistance is encountered at any time during the insertion procedure, do not force advancement of the delivery system. Forcing the delivery system through resistance may cause damage to Stent implant or vessel. Carefully withdraw the *Duo Venous Stent System* without deploying a Stent implant.
e. If resistance is felt when beginning deployment, do not force deployment. Carefully withdraw the *Duo Venous Stent System* without deploying the Stent implant.
f. The Duo Hybrid and Duo Extend Stent(s) are not designed for repositioning or recapturing.
g. Once the stent is partially or fully deployed, do not attempt to drag or reposition the Stent implant with the delivery system, as this may result in Stent or vessel damage.
h. Stenting across a major branch vessel could cause catheterization difficulties during future diagnostic or therapeutic procedures.
i. If a long lesion needs to be stented, consider using the longest available single stent rather than overlapping stents. If multiple stents are placed in an overlapping fashion, they should be of similar composition (i.e., Nitinol).
j. The Duo Extend Stent has not been clinically evaluated as a stand-alone device and should only be used in conjunction with the Duo Hybrid Stent.
k. The long-term outcomes following repeat dilatation of previously implanted stents are unknown.
l. The safety and effectiveness of this device for use in the arterial system have not been established.
m. In the event of symptomatic thrombosis within the Stent implant, thrombolysis/thrombectomy and balloon venoplasty should be attempted, per standard of care.

22. Stent Implant Removal
    a. In the event of a complication such as infection, surgical removal of a Stent implant may be required. Standard surgical procedure is appropriate.
23. Post Implant
    a. Re-crossing a Stent implant with adjunct devices should be performed with caution to avoid damage or displacement of the implanted stent.
    b. Do not attempt to re-sheath the device within the deployed Stent implant treatment area as this could result in displacement.
    c. Used products are considered biohazardous material and should be disposed of properly as per hospital or lab protocol.
    d. In patients requiring the use of antacids and/or H2-antagonists before or immediately after Stent implant placement, oral absorption of antiplatelet agents (e.g., aspirin) may be adversely affected.

POTENTIAL COMPLICATIONS

The following complications may be associated with intravascular Stent device implantation:

- Access failure or abrupt closure
- Allergic / anaphylactoid reaction to anticoagulant and/or antithrombotic therapy or contrast medium
- Allergic reaction to Nitinol
- Amputation
- Aneurysm
- Angina / coronary ischemia / myocardial infarction
- Arrhythmia
- Arteriovenous fistula
- Death
- Embolism (Thromboembolism)
- Extravasation
- Fever
- Gastrointestinal bleed from anticoagulation / antiplatelet medication
- Hematoma / hemorrhage
- Hypotension / hypertension
- Incorrect positioning of the stent requiring further stenting or surgery
- Intimal Injury/dissection
- Ischemia / infarction of tissue/organ
- Infection / abscess at insertion site
- Inflammation
- Malposition of stent
- Multi-organ failure
- Open surgical repair
- Pain
- Procedure Delay
- Pulmonary Embolism
- Pseudoaneurysm
- Renal insufficiency or failure
- Respiratory distress or failure
- Restenosis
- Septicemia / bacteremia (sepsis)
- Stent implant fracture
- Stent implant migration (device moves over time)
- Trauma to adjacent structures
- Vasospasm
- Venous occlusion/thrombosis, remote from puncture site
- Venous occlusion/thrombosis, near puncture site

- Venous occlusion/restenosis of the treated vessel

INFORMATION FOR THE PATIENT
The *Duo Venous Stent 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 Stent device(s) including the catalog number, lot number and location of the implanted Stent device(s), the date of the procedure. The card also provides company information and MRI Compatibility.

How Supplied

The *Duo Venous Stent 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 dark, dry place. **Caution:** Do not use if the package is damaged. In case of damage, contact Vesper Medical at 1-484-982-6340 or info@vespermedical.com.

INSTRUCTIONS FOR USE
Pre-Procedure

1. Pre-procedural anticoagulation and antiplatelet should be stopped **if required** by the institutional standards of care.
2. Antiplatelet and anticoagulant therapy should be administered per institutional standards of care.
3. The percutaneous placement of a Stent implant should be done in an appropriate fluoroscopic guided procedure room.
4. Appropriate diagnostic imaging (venography and/or IVUS + fluoroscopy) should be performed using the standard technique prior to, during and after Stent placement.
5. Venography should be performed to identify, evaluate, and mark the target treatment site.
6. Patient preparation and sterile precautions should be the same as for any endovascular procedure.

Select Stent Size

1. Measure the length of the target treatment zone to identify the appropriate length of stent(s) required. Ensure that the stent is long enough to permit the area cranial and caudal of the lesion to be covered by the stent (full lesion coverage).
2. The Duo Stent(s) foreshortening is <10%
3. Identify the diameter of the normal reference vessel using IVUS cranial and caudal to the lesion, and at an appropriate location of the normal reference vessel. To ensure secure placement, refer to the stent size selection table for proper sizing scheme (Table 3).

Table 3. Stent Size Selection Table

Reference Vessel Diameter	Stent Diameter	Stent Type	Foreshortening
9mm – 11mm	12mm	Duo Hybrid/Duo Extend	<3%
11mm – 13mm	14mm	Duo Hybrid/Duo Extend	<5%
13mm – 15mm	16mm	Duo Hybrid/Duo Extend	<4%
15mm – 17mm	18mm	Duo Hybrid	<6%

Procedure

1. Preparation of the *Duo Venous Stent System*
    a. Open the outer box and pouch to reveal the backing card containing the *Duo Venous Stent System*.
    b. Carefully inspect the backing card 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 sterile saline to expel any air. A 3cc syringe is recommended (to avoid damage to the delivery system).
        i. Flush through the Luer Hub until saline flows out of the Guidewire Lumen at the distal catheter end.
    d. Inspect the distal end of the catheter to ensure that the Stent implant is contained within the outer sheath. If a gap between the catheter tip and outer sheath tip exists, carefully rotate the thumbwheel in the distal direction until the gap is closed.
    e. Wipe the usable portion of the stent delivery catheter with saline.
2. Insertion of Introducer Sheath or Guide Catheter and Guidewire
    a. Access the treatment site with the appropriate accessory equipment compatible with the 9F/10F delivery system depending upon stent size to be implanted (reference TABLE 2).
    b. Place a 0.035" (0.89 mm) guidewire of sufficient length across the treatment site for Stent implantation via the introducer sheath or guide catheter.
3. Dilate Lesion
    a. Predilatation of chronic lesions with a balloon dilation catheter is recommended. If performed, select a balloon catheter that matches the size of the reference vessel.
    CAUTION: During dilation, do not over-size the balloon such that dissection or perforation could occur.
    b. While maintaining site access with a guidewire, remove the balloon catheter from the patient.
    CAUTION: Fully deflate balloon catheter prior to withdrawing.
4. Introduction of *Duo Venous Stent System*
    a. Advance the delivery catheter over the guidewire through the hemostatic valve and sheath introducer to the treatment site.
    NOTE: If resistance is met during delivery system introduction, the system should be withdrawn, and another system should be used. A stiffer guidewire may also be considered to facilitate device introduction and passage.

NOTE: The Duo Hybrid Stent (high crush resistance segment) is intended to be used in the cranial portion of the iliac vein at the confluence of the IVC only.
NOTE: The Duo Hybrid Stent is not designed for use in procedures that require jugular or contralateral access.
CAUTION: DO NOT USE the Duo Hybrid Stent from any access other than an ipsilateral venous access.
CAUTION: Always use an introducer sheath for the implant procedure to protect puncture site.

5. Slack Removal
    a. Advance the *Duo Venous Stent System* past the treatment site.
    b. Pull back the *Duo Venous Stent System* to the intended location, then remove the Thumbwheel Safety Clip.
    CAUTION: Slack in the catheter shaft, either outside or inside the patient, may result in deploying the Stent implant in a non-target treatment site.
6. Stent Implant Deployment
    a. Verify that the delivery system and stent radiopaque markers are positioned cranial and caudal to the target treatment site.
    b. Ensure the access sheath does not move during deployment.
    c. Initiate Stent implant deployment by rotating the Thumbwheel in the proximal direction while holding the proximal handle in a fixed position.
    NOTE: Failure to maintain a fixed delivery system position may result in undesired Stent implant placement.
    d. While using fluoroscopy, maintain position of the radiopaque markers relative to the target treatment site. Watch for the stents first set of radiopaque markers to radially expand during deployment. Carefully, continue to retract the outer sheath until the stents first set of radiopaque markers are fully apposed to the vessel wall. Continue to slowly un-sheath the stent until it is fully deployed. The stent is fully deployed once the stents cranial and caudal radiopaque markers are fully apposed to the vessel wall.
    DO NOT attempt to recapture the stent.
    e. If overlapping of a Duo Extend Stent inside of a Duo Hybrid Stent is required to extend the treatment region, there should be a 10-20mm overlap of the Duo Hybrid and Duo- Extend Stent.
7. Stent Implant Post-dilatation
    a. Carefully remove the delivery system from the body.
    b. Using fluoroscopy, visualize the Stent implant to verify deployment.
    c. Post Stent expansion with a balloon catheter is recommended. If performed, select a balloon catheter that matches the size of the reference vessel, but is not larger than the stent diameter itself.
    d. Post-dilate the stent treated site with conventional techniques. Remove the balloon catheter from the patient following complete deflation of the balloon prior to removal.
    CAUTION: Fully deflate balloon catheter prior to withdrawing.
    e. Following stent deployment, a post intervention venogram and Intravascular Ultrasound are recommended to ensure adequate stent placement, full lesion coverage and full stent expansion.
8. Post Treatment
    a. Remove the guidewire and sheath from the body.
    b. Close entry wound/obtain hemostasis 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 THE PRIMARY CLINICAL STUDY

The results of the VIVID Study investigating the safety and effectiveness of the Duo Venous Stent System for treating symptomatic iliofemoral venous outflow obstructions, are presented below.

A. Study Design

The VIVID study is a prospective, multi-center, single-arm, non-blinded clinical trial designed to investigate the safety and efficacy of the Duo Venous Stent System as compared to a pre-defined performance goal (PG) established from published, peer reviewed scientific literature related to stenting of iliofemoral venous outflow obstructions.

Patients were treated between November 30, 2020, and December 6, 2021. The database for this PMA reflected data collected through June 15, 2023. The study enrolled 162 subjects at 30 clinical sites in the United States and European Union.

The study enrolled subjects with nonmalignant iliofemoral venous outflow obstruction presenting with non-thrombotic (NT), acute thrombotic (AT) or chronic post-thrombotic (CPT) disease pathogenesis. Any subject that received one or more Duo Stents was followed for 30-days, 6 months, 12 months, 24 months, and 36 months.

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. A medical monitor was employed to provide a first review of all Adverse Events to review unanticipated adverse device effects (UADE) potential, seriousness, severity, causality, and effectiveness. 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. The DSMB served as an independent body conducting a review and oversight of all key safety events to monitor the rate of occurrence (both site-reported and CEC-adjudicated events) as part of their mission to protect the rights and safety of research subjects.

i. Clinical Inclusion and Exclusion Criteria

Enrollment in the VIVID study was limited to patients who met the following inclusion criteria:

General Inclusion Criteria:

1. Males or non-pregnant, non-breastfeeding females ≥18 years of age at the time of consent.
2. Subject is able and willing to provide written informed consent prior to receiving any non-standard of care, protocol specific procedures.
3. Female subjects of childbearing potential must have a negative pregnancy test within 7 days prior to treatment and must use some form of contraception (abstinence is acceptable) throughout the time of clinical trial exit.
4. Willing and capable of complying with all required follow-up visits.
5. Estimated life expectancy ≥1 year
6. Subject is ambulatory (use of assistive walking device such as a cane or walker is acceptable)
7. Body mass index (BMI) <45
8. Clinically significant symptomatic venous outflow obstruction in one iliofemoral venous segment (one limb) per subject, is indicated for venoplasty and stenting, and meets at least one of the following clinical indicators:
    A. CEAP score ≥3
    B. VCSS (Venous Clinical Severity Score) pain score ≥2
    C. Suspected deep vein thrombosis (DVT) with symptoms occurring prior to receiving a Duo Stent
9. Subject is willing and able to comply with principal investigator (PI) recommendation for compression therapy, if required.
10. Presence of unilateral, non-malignant venous obstruction of the common femoral vein (CFV), external iliac vein (EIV), common iliac vein (CIV), or any combination thereof, defined as a ≥50% reduction in target vessel lumen diameter and confirmed by venographic or IVUS imaging. The cranial point of the obstruction may extend to the iliac vein confluence of the inferior vena cava (IVC) and the caudal point may be 2mm above either the inflow of the deep femoral (or profunda) or the lesser trochanter, whichever is most cranial.
11. Obstructive lesion(s) able to be treated with continuous stent coverage.
12. Adequate inflow to the target lesion(s) involving at least a patent femoral or deep femoral vein and a landing zone in the CFV free from significant disease requiring treatment.
13. Reference vessel diameter is of adequate size to accommodate the appropriate size stent as measured by IVUS.
14. All vessels from insertion site through target vessel can accommodate a 9F or 10F sheath, depending on the stent size used.
15. Ability to cross interventional devices through target lesion(s).
16. In DVT subjects, successful treatment of acute thrombus must have occurred prior to receiving any Duo Stents for an underlying obstructive lesion. Successful treatment of acute thrombus is defined as reestablishment of antegrade flow with ≤30% residual thrombus (confirmed by venogram or VUS) and freedom from bleeding and symptomatic pulmonary embolism (confirmed by imaging). After successful treatment of thrombus is confirmed, eligible obstructive lesion(s) can be treated with a Duo Stent during the same procedure.
17. All subjects must undergo a SARS-CoV-2 test and have a negative test result within 8 days prior to the index procedure. If a SARS-CoV-2 test is unavailable due to institution policy, a test shortage, or if there is a delay in test results, the subject must complete the COVID-19 questionnaire and must have answered NO to all questions to be eligible for enrollment. A SARS-CoV-2 test will not be required for enrollment if a subject has received a complete cycle of an authorized COVID-19 vaccine or has documented evidence of a positive COVID- 19 antibody test and is asymptomatic and has no long-lasting effects (per PI discretion) from a prior COVID-19 infection.
18. A measured temperature less than 99.5°F (37.5°C) on the day of the index procedure and no history of fever or feeling feverish within 14 days of the index procedure.
19. No prior history, within 60 days of the index procedure of a SARS-CoV-2 positive test, or COVID-19 symptoms.

Patients were not permitted to enroll in the VIVID study if they met any of the following exclusion criteria.

General Exclusion Criteria:

1. Target limb symptoms caused by peripheral arterial disease.
2. Presence of unresolved significant pulmonary emboli prior to use of the Duo Venous Stent System confirmed by chest computed tomography (CT). If subject has documented history of significant pulmonary embolism within the last 6 months, a chest CT is required to confirm significant pulmonary embolism is not currently present.
3. Presence of IVC obstruction or target venous obstruction that extends into the IVC.
4. Presence of acute DVT located outside target limb.
5. Contralateral venous occlusive disease of the CFV, E V, and/or CIV, with planned treatment ≤390 days after the index procedure
6. Uncontrolled or active coagulopathy or known, uncorrectable bleeding diathesis.
7. Coagulopathy causing INR >2 which is not amenable to medical treatment.
8. Platelet count <50,000 cells/mm3 or >1,000,000 cells/mm3 and/or White blood cell (WBC) <3,000 cells/mm3 or >12,500 cells/mm3
9. Uncorrected hemoglobin of ≤9 g/dL
10. Subject is on dialysis or has an estimated glomerular filtration rate (eGFR) <30 mL/min. In subjects with diabetes mellitus, eGFR <45 mL/min.
11. History of Heparin Induced Thrombocytopenia
12. Presence of known aggressive clotting disorders such as Lupus Anticoagulant Disorder, Antiphospholipid antibody syndrome, homozygous gene Factor V Leiden or Prothrombin gene abnormalities, Protein C and S deficiency or Antithrombin deficiency
13. Known hypersensitivity or contraindication to antiplatelet therapy or anticoagulation, nickel, or titanium.

14. Contrast agent allergy that cannot be managed adequately with pre-medication.
15. Intended concurrent adjuvant procedure (except for venoplasty) such as creation of temporary arteriovenous fistula, femoral endovenectomy, or saphenous vein ablation and/or saphenous vein stripping during the index procedure.
16. Subjects who have had any prior surgical or endovascular procedures to the target vessel. Note that subjects who have had successful catheter-directed or mechanical thrombolysis in the target vessel for DVT at least 90 days prior to the index procedure may be included.
17. Planned surgical or interventional procedures of the target limb (except thrombolysis and/or thrombectomy in preparation for the procedure or vena cava filter placement prior to stent implantation in subjects at high risk for pulmonary embolism) within 30 days prior to or 30 days after the index procedure.
18. Planned surgical or interventional procedures for other medical conditions (i.e., not associated with the target limb) 30 days prior to or 30 days after the index procedure.
19. Previous venous stenting of the target limb, the IVC, or contralateral limb if stents extend into the IVC.
20. Iliofemoral venous segment unsuitable for treatment with available sizes of Duo Stent implants
21. Lesions with intended treatment lengths extending into the IVC.
22. No safe landing zone at or above the profunda femoral confluence
23. Participating in another investigational study in which the subject has not completed the primary endpoint(s)
24. Has other comorbidities that, in the opinion of the PI, would preclude them from receiving this treatment and/or participating in study-required follow-up assessments.

ii. 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), 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 4**.

Table 4. Time and Events Schedule

Assessment	Baseline[1]	Index Procedure	Post-Procedure/ Pre-Discharge[2]	30-day (-2 days/+14 Days)	6 Month (±30 Days)	12 Month (± 30 Days)	24 Month (± 30 Days)	36 Month (± 30 Days)
Informed Consent	X[3]							
Inclusion/Exclusion Criteria	X	X						
SARS-CoV-2 Test/COVID-19 Questionnaire[5]	X[4]			X	X	X	X	X
Demographics, Medical History and Risk Factors	X							
Brief Physical Exam (Height, Weight, Temp)	X							
Serum Creatinine, eGFR, WBC, Platelet Count, Hemoglobin	X							
Prothrombin Time (PT)/ International Normalized Ratio (INR)[6]	X		X					
Activated Partial Thromboplastin time (aPTT)[7]	X		X					
Urine or Blood Pregnancy Test[8]	X							
Venous Ulcer Assessment	X			X	X	X	X	X
CEAP Classification	X				X	X	X	X
Villalta Score	X				X	X	X	X
VCSS Pain Score	X				X	X	X	X
VEINES-QOL/Sym Questionnaire	X				X	X	X	X
EQ-5D-3L Questionnaire	X				X	X	X	X
Concomitant Medications	X	X	X	X	X	X	X	X

Duplex Ultrasound (DUS)[9]				X	X	X	X	X
Venogram[10]		X				X[11]	X	X
Intravascular Ultrasound (IVUS)[10]		X				X[11]	X	X
X-ray of Implanted Stent[10]						X	X	X
Adverse Event (AE) Assessment		X	X	X	X	X	X	X

[1] Assessments may be done up to 30 days prior to the index procedure, except for a pregnancy test and SARS-CoV-2 test.
[2] Assessments are to be completed post-index procedure and prior to the subject being discharged from the hospital/clinic.
[3] Informed Consent may be obtained up to 30 days prior to index procedure.
[4] All subjects must undergo a SARS-CoV-2 test and have a negative result within 8 days of the Index Procedure to be eligible for study inclusion.
[5] If a SARS-CoV-2 test is unavailable due to institution policy, a test shortage, or if there is a delay in test results, the subject must complete the COVID-19 questionnaire and answer NO to all questions to be eligible for study treatment.
[6] PT/INR to be obtained only if a subject is on chronic warfarin therapy.
[7] aPTT to be obtained only if a subject is on chronic heparin therapy.
[8] Negative urine or blood pregnancy test is required for female subjects of childbearing potential within 7 days of the index procedure.
[9] All scheduled DUS exams should be performed per the protocol established by the core laboratory. If a DUS is non-diagnostic (per the imaging protocol), the site should make every effort to obtain a repeat exam within the visit window.
[10] All imaging of the target limb acquired during scheduled visits or an interventional procedure to the target limb (such as venogram, IVUS, DUS, or X-ray) should be submitted to the respective core laboratory within 3 business days.
[11] Required if DUS suggests >50% stenosis or occlusion of the stented segment, or if the DUS is non-diagnostic or sub-optimal (i.e., due to obesity).

iii. Clinical Endpoints

Primary Safety Endpoint

The primary safety endpoint was to demonstrate freedom from major adverse events (MAEs) at 30 days post index procedure, as adjudicated by the Clinical Events Committee (CEC) or Core Laboratory, including:

- Device or procedure-related death
- Device or procedure-related bleed at the target vessel and/or the target lesion or at the access site requiring surgical or endovascular intervention or blood transfusion of ≥2 units
- Device or procedure-related venous injury occurring in the target vessel and/or the target lesion or at the access site requiring surgical or endovascular intervention
- Major amputation of the target limb
- Clinically significant pulmonary embolism (PE), confirmed by CT angiography
- Stent embolization outside of the target vessel
- Presence of new thrombus within the stented segment requiring surgical or endovascular intervention

Disease specific PG was calculated from the point estimates for major bleeding, pulmonary embolism and peri-procedural mortality from Razavi et al converted to freedom from estimates and application of a 10% delta. The resulting PGs were 89%, 87% and 88% for the non-thrombotic, acute thrombotic and chronic post-thrombotic, respectively. Given the similarity of the disease-state specific PGs, it was determined that a disease state specific goal was not necessary. A PG of 89% was adopted for the study in both the SARS-CoV-2 negative subset and overall.

Statistical hypothesis testing was performed as follows:

H0: Proportion of subjects with freedom from MAE (pMAE) is less than or equal to the PG) at 30 days, pMAE ≤89%
H1: Proportion of subjects with freedom from MAE is greater than the (PG) at 30 days, pMAE >89%

The primary statistical analysis was conducted in the full-analysis set (FAS) subset for the primary safety endpoint overall and in the SARS-CoV-2 negative subset. A subject was defined as an Intent-To-Treat (ITT) patient once the subject had the Duo Venous Stent System advanced through the introducer sheath. A subject is defined as full-analysis set (FAS) if they meet the ITT definition and have data evaluable for the primary endpoints. The Per-Protocol (PP) population was defined as ITT subjects with evaluable data that met the definition for Device Success and did not have any major protocol deviations. The primary statistical method is a one-sample exact test comparing the proportion of subjects free from a MAE to the PG using a one-sided α=0.025. The exact two-sided 95% confidence interval for the proportion of subjects free from MAE was calculated.

Primary Effectiveness Endpoint

The primary effectiveness endpoint is primary patency of stented segment at 12 months defined as freedom from:

- Duplex Ultrasound (DUS) core laboratory adjudicated stenosis or occlusion >50% within the stented segment. If DUS shows >50% stenosis or occlusion, confirmation by diagnostic intravascular ultrasound (IVUS) is required.
- CEC adjudicated clinically driven target lesion reintervention (CD-TLR) defined as endovascular or surgical procedure for new, recurrent, or worsening symptoms and core lab adjudicated >50% stenosis or occlusion within the stented segment confirmed by diagnostic IVUS.

The PG for primary effectiveness was set when all enrolled subjects completed the index procedure and was based upon the proportions of ITT subjects in each of the disease states, i.e., non-thrombotic, acute thrombotic and chronic post-thrombotic. The disease specific PGs were adopted as suggested in Razavi et al[1] with the lower 95% confidence limit minus 10%. The PGs were 83%, 70% and 66% for non-thrombotic, acute thrombotic and chronic post-thrombotic subjects respectively. The PG for the VIVID study is a weighted combination of these disease state specific PGs, where the weights are the proportion of subjects in each disease state in the ITT sample. Therefore, the performance goal (PG) was defined as

PG = (0.642)*0.83 + (0.099)*0.70 + (0.259)*0.66. = 77.3%

Statistical hypothesis testing was performed as follows:

H0: Proportion of subjects with primary patency (pp_pat) is less than or equal to performance goal (PG) at 12 months, pp_pat ≤P
H1: Proportion of subjects with primary patency is greater than the performance goal at 12 months, pp_pat >PG

The study device was considered to have met the effectiveness endpoint if the one-sided p-value from hypothesis testing, comparing the proportion of subjects in the FAS with primary patency to the PG using a one-sample Z-test, was less than 0.025.

Secondary Endpoints
The following secondary endpoints were evaluated through 12 months:
- Subject symptom relief via VCSS pain score at 12 months
- Primary assisted patency at 12 months
  - Defined as freedom from DUS core laboratory adjudicated occlusion or stenosis >50% within the stented segment following a clinically driven target lesion reintervention due to a >50% but <100% stenosis. If DUS shows >50% stenosis or occlusion, confirmation by diagnostic IVUS was required.
- Secondary patency at 12 months
  - Defined as freedom from DUS core laboratory adjudicated occlusion or stenosis >50% within the stented segment following a clinically driven target lesion reintervention. If DUS shows >50% stenosis or occlusion, confirmation by diagnostic IVUS was required.

Observational Endpoints
- Device Success defined as:
  - Successful deployment of the Duo Stent(s) at the intended target site, AND
  - Successful withdrawal of the delivery catheter(s) from the introducer sheath, AND
  - The Duo Stent remaining at the intended deployment location through completion of the index procedure as determined by the Principal Investigator (PI)
- Lesion success defined as target lesion patency of ≤50% residual diameter or area stenosis of the stented segment at the completion of the procedure*
- Procedural success defined as lesion success without the occurrence of CEC adjudicated major adverse events (MAEs) from the time start of the index procedure through discharge.
- Stent fracture via X-ray through 36 months*
- Stent migration via X-ray through 36 months*
- Stent embolization via X-ray or venogram through 36 months*
- Primary patency of the stented segment via DUS at 24 and 36 months. If DUS shows >50% stenosis or occlusion, confirmation by diagnostic IVUS may be required*
- Primary assisted patency of the stented segment via DUS at 24 and 36 months. If DUS shows >50% stenosis or occlusion, confirmation by diagnostic IVUS may be required*
- Secondary patency of the stented segment via DUS at 24 and 36 months. If DUS shows 50% stenosis or occlusion confirmation by diagnostic IVUS may be required*.
- Change in the CEAP classification through 36 months.
- Changes in the EQ-5D-3L through 36 months.
- Changes in the Villalta Score through 36 months.
- Changes in the VCSS Pain Score at 24 and 36 months.
- Changes in the VEINES QOL/Sym Score through 36 months.
- CEC adjudicated MAEs post 30 days through 36 months.
- CEC adjudicated CD-TLR through 36 months.
- CEC adjudicated CD-TVR through 36 months.
- Venous Ulcer Assessment through 36 months.

* *Core Laboratory Adjudicated*

B. Accountability of PMA Cohort

Of the 270 subjects consented for the VIVID study, 162 patients were enrolled and represent the Intent-to-Treat (ITT) population. The Per Protocol (PP) population includes 158 subjects and excludes three subjects that did not meet the criteria for device success and one subject that did not meet Inclusion Criteria #10. The Full-Analysis Set (FAS) is subjects who meet the ITT definition and have data evaluable for the primary endpoints. Of the 162 enrolled subjects, 155 completed 30-day follow-up or telemedicine/phone visit and 140 completed 12-month follow-up or telemedicine/phone visit per **Figure 4**.

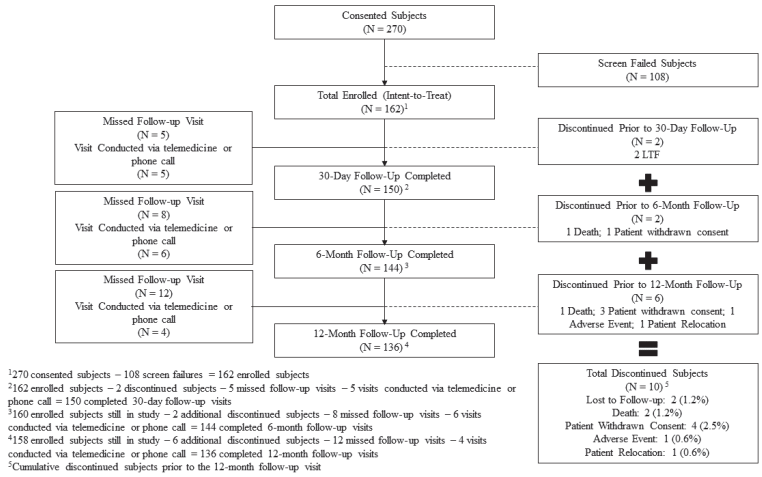

Figure 4. VIVID Study Subject Enrollment

C. Study Population Demographics and Baseline Parameters

Baseline demographics and clinical characteristics for subjects treated in the trial are summarized in **Table 5**. The mean age was 59.4 ± 15.8 years and males comprised 63.0% of the ITT population. CEAP clinical assessment category C3 (edema) comprised 66.0% of the subjects and an additional 20.5% were in category C4 (changes in skin and subcutaneous tissue secondary to venous disease). Most subjects reported pain rated as moderate (52.5%) or severe (25.6%) on the VCSS pain scale.

Table 5. VIVID Subject Demographics

	ITT Subjects
SARS-CoV-2 Status at Enrollment	
Positive	8.0% (13/162)
Negative	92.0% (149/162)
Age at consent (years)	59.4 ± 15.8 (162) (19.0, 61.0, 90.0)
Biological Gender	
Female	37.0% (60/162)
Male	63.0% (102/162)
Ethnicity	
Hispanic or Latino	12.3% (20/162)
Not Hispanic or Latino	84.0% (136/162)
Unknown	3.7% (6/162)
Race (Check all that apply)	
American Indian or Alaska Native	0.0% (0/162)
Asian	0.6% (1/162)
Black	9.3% (15/162)
Native Hawaiian or Pacific Islander	0.0% (0/162)
Caucasian	82.7% (134/162)
Other	1.9% (3/162)
Decline to Answer	1.9% (3/162)
Unknown	3.7% (6/162)
BMI	30.1 ± 5.7 (162) (18.4, 29.2, 43.7)
CEAP Clinical Assessment	
C0	1.2% (2/162)
C1	0.6% (1/162)
C2	0.6% (1/162)
C2r	0.0% (0/162)
C3	66.0% (107/162)
C4	5.6% (9/162)
C4a	13.0% (21/162)
C4b	1.9% (3/162)
C4c	0.0% (0/162)
C5	4.9% (8/162)
C6	5.6% (9/162)
C6r	0.6% (1/162)
VCSS Pain	

Table 5. VIVID Subject Demographics	
	ITT Subjects
0 - none	6.9% (11/160)
1 - mild	15.0% (24/160)
2 - moderate	52.5% (84/160)
3 - severe	25.6% (41/160)

Data presented as Mean ± SD (N) (Min, Median, Max) or % (#/#)

The risk factors for developing venous disease are summarized in **Table 6**. The most common include hyperlipidemia (48.8%) and hypertension (44.4%).

Table 6. VIVID Subject Risk Factors	
	ITT Subjects
Smoking	
Current	9.3% (15/162)
Former	29.6% (48/162)
Never	61.1% (99/162)
Diabetes Mellitus	19.1% (31/162)
Type I	2.5% (4/162)
Type II	16.7% (27/162)
Hypertension	44.4% (72/162)
Hyperlipidemia	48.8% (79/162)
Mobility	
Able to ambulate without assistance	90.1% (146/162)
Able to walk with walking device	9.9% (16/162)
Not ambulatory	0.0% (0/162)
Other	0.0% (0/162)
Knee replacement	9.3% (15/162)
Right	3.1% (5/162)
Left	3.1% (5/162)
Both	3.1% (5/162)
Hip replacement	4.9% (8/162)
Right	1.2% (2/162)
Left	2.5% (4/162)
Both	1.2% (2/162)
Family history of venous disease	
Yes	16.7% (27/162)
No	34.0% (55/162)
Unknown	49.4% (80/162)

Data presented as % (#/#)

A summary of the medical history for all subjects is provided in **Table 7**. As would be expected for this subject population, 66.0% and 31.5% have a history of May-Thurner Syndrome and varicosis, respectively. Previous diagnosis and resolution of DVT in the target limb was reported by 14.8% of subjects and 14.2% had a previous superficial venous ablation to the target limb.

Table 7. VIVID Subject Medical History	
	ITT Subjects
Stroke	2.5% (4/162)
Transient Ischemic Attack (TIA)	4.3% (7/162)
Angina	8.0% (13/162)
Myocardial Infarction	5.6% (9/162)
Congestive Heart Failure	6.8% (11/162)
Coronary Artery Disease	14.2% (23/162)
Vascular Heart Disease	4.9% (8/162)
Cardiomyopathy	2.5% (4/162)
Venous Valve Disease	13.0% (21/162)
Atrial Fibrillation	10.5% (17/162)
Arrythmia (Other than atrial fibrillation)	3.7% (6/162)
May-Thurner Syndrome	66.0% (107/162)
Peripheral Arterial Disease	10.5% (17/162)
Varicosis	31.5% (51/162)
Chronic Renal Insufficiency	3.1% (5/162)
Uremia	0.0% (0/162)
Uncontrolled or active coagulopathy or known uncorrectable bleeding diathesis	0.0% (0/162)
Clinically Significant Pulmonary Emboli	3.7% (6/162)
Cancer	14.8% (24/162)
Gastrointestinal Disease	17.3% (28/162)
Genitourinary Disorder	3.1% (5/162)
Respiratory Disorder	9.3% (15/162)
Liver Disease	1.2% (2/162)
Allergic reaction sensitivity or intolerance to nickel or titanium	0.0% (0/162)

Table 7. VIVID Subject Medical History	
Allergic reaction sensitivity or intolerance to contrast media antiplatelet anticoagulant or thrombolytic medications	1.9% (3/162)
Superficial venous ablation to the target limb	14.2% (23/162)
Previously diagnosed and resolved DVT in target limb	14.8% (24/162)
Previously diagnosed and resolved DVT in non-target limb	5.6% (9/162)
Contralateral venous occlusive disease	5.6% (9/162)
Onset of symptoms that led to venous stenting intervention	
≤14 days	15.4% (25/162)
>14 days	84.6% (137/162)

Data presented as %(#/#)

Core laboratory reported assessments of the target lesion are summarized in **Table 8**. The median lesion length was 43.3 mm but ranged widely from a minimum of 6.3 mm to a maximum of 295.0 mm. As such, the overall stented length also varied widely from the median of 110.0 mm from a minimum of 26.5 mm to 274.0 mm. The median pre- and post-procedure stenosis was 74% and 1%, respectively.

Table 8. VIVID Core Laboratory Reported Target Lesion Details	
	ITT Subjects
Most Cranial Lesion Location[1]	
IVC	2.0% (3/150)
Common Iliac Vein - Cranial	79.3% (119/150)
Common Iliac Vein - Mid	6.7% (10/150)
Common Iliac Vein - Caudal	5.3% (8/150)
External Iliac Vein - Cranial	6.0% (9/150)
External Iliac Vein - Mid	0.0% (0/150)
External Iliac Vein - Caudal	0.0% (0/150)
Common Femoral Vein	0.7% (1/150)
Most Caudal Lesion Location[1]	
IVC	0.0% (0/150)
Common Iliac Vein - Cranial	2.0% (3/150)
Common Iliac Vein - Mid	10.0% (15/150)
Common Iliac Vein - Caudal	23.3% (35/150)
External Iliac Vein - Cranial	9.3% (14/150)
External Iliac Vein - Mid	13.3% (20/150)
External Iliac Vein - Caudal	23.3% (35/150)
Common Femoral Vein	18.7% (28/150)
Reference Lumen Diameter (mm) [1]	14.0 ± 4.0 (143) (3.6, 13.9, 28.5)
Lesion Length (mm) [1]	55.2 ± 44.6 (145) (6.3, 43.3, 295.0)[3]
Pre-Intervention Stenosis (%)[2]	71.2 ± 15.0 (162) (23.0, 74.0, 95.0)
Pre-Intervention Occlusion (%)[2]	0.0% (0/162)
Post Stent Placement Stenosis (%)[2]	6.7 ± 9.6 (162) (0.0, 1.0, 41.0)
Overall Stented Length (mm) [1]	126.4 ± 46.9 (147) (26.5, 110.0, 274.0)
Minimum Lumen Diameter In-Stent (mm) [1]	13.9 ± 3.7 (144) (6.4, 13.5, 44.0)

Data presented as Mean ± SD (N) (Min, Median, Max) or % (#/#)

[1]Measured by venogram

[2]Measured by both IVUS and venogram. IVUS was preferred, and venogram was used only when IVUS was not available

A summary of the index procedure is provided in **Table 9**. The final disease state classification of the ITT subjects was primarily non-thrombotic (64.2%). Chronic post-thrombotic and acute thrombotic accounted for 25.9% and 9.9% of the subjects, respectively.

Table 9. VIVID Index Procedure Details	
	ITT Subjects
Target Limb	
Left	79.6% (129/162)
Right	20.4% (33/162)
Index Procedure Location	
Ambulatory surgical center	2.5% (4/162)
Hospital	59.3% (96/162)
Office base labs	38.3% (62/162)
Sedation Type	
General	17.3% (28/162)
IV Sedation	82.7% (134/162)
PI Reported Pre-Intervention Stenosis (%)	77.6 ± 15.2 (162)

Table 9. VIVID Index Procedure Details	
	(38.9, 79.2, 100.0)
Procedure Length (min)	56.9 ± 32.2 (162) (8.0, 50.0, 245.0)
Total Fluoroscopy Time (min)	13.4 ± 13.9 (159) (0.0, 9.8, 139.0)
Total amount of contrast used (mL)	80.8 ± 53.0 (160) (0.0, 70.0, 426.0)
Final Disease State Classification	
Acute thrombotic	9.9% (16/162)
Chronic post-thrombotic	25.9% (42/162)
Non-thrombotic	64.2% (104/162)

Data presented as Mean ± SD (N) (Min, Median, Max) or % (#/#)

Stent placement details are provided in **Table 10**. Of the 162 patients enrolled, 112 (69.1%) received the Duo Hybrid Stent only while 50 (30.9%) received both the Duo Hybrid Stent and Duo Extend Stent to extend treatment. Overall, 166 Duo Hybrid Stents and 53 Duo Extend Stents were implanted.

Table 10. VIVID Stent Placement Details	
	ITT Subjects
Per Subject	
Stent Treatment	
Duo Hybrid Stent Alone	69.1% (112/162)
Duo Hybrid + Duo Extend Stent(s)	30.9% (50/162)
Number of Duo Stents per subject	
1	67.3% (109/162)
2	30.2% (49/162)
3	2.5% (4/162)
Number of Duo Hybrid Stents per subject	
1	97.5% (158/162)
2	2.5% (4/162)
3	0.0% (0/162)
Number of Duo Extend Stents per subject	
0	69.1% (112/162)
1	29.0% (47/162)
2	1.9% (3/162)
Per Stent	
Stent Type	
Duo Hybrid	75.8% (166/219)
Duo Extend	24.2% (53/219)
Stent Length	105.5 ± 29.8 (219) (40.0, 100.0, 160.0)
Stent Diameter	15.5 ± 1.5 (219) (12.0, 16.0, 18.0)
Approach for study device introduction	
Ipsilateral Antegrade	99.5% (218/219)
Contralateral Retrograde/Crossover	0.5% (1/219)
Access site location for study device introduction	
Femoral	63.0% (138/219)
Popliteal	28.8% (63/219)
Jugular	0.5% (1/219)
Other	7.8% (17/219)
Successful introduction of the device through the introducer sheath?	100.0% (219/219)
Duo Stent deployed?	100.0% (219/219)
Deployed at the intended target site?	99.1% (217/219)
Withdrawal of delivery catheter from the introducer sheath?	100.0% (219/219)
Duo Stent was post-dilated	90.4% (198/219)
Duo Stent implant remained in position from initial deployment through completion of procedure?	99.5% (218/219)

Data presented as Mean ± SD (N) (Min, Median, Max) or % (#/#)

Table 11 provides the size and lengths of all Duo Hybrid Stent and Duo Extend Stent placed. Almost all available stent diameters and lengths were utilized in the study.

Table 11. VIVID Duo Hybrid Stent and Duo Extend Stent Size and Length							
Stent Diameter (mm)	**Stent Length (mm)**						
	40	**60**	**80**	**100**	**120**	**140**	**160**
Duo Hybrid (N=166)							
12	N/A[1]	--	--	--	1	--	--
14		4	1	15	15	--	16
16		13	--	27	28	--	9

18		--	22	--	15	--	--
Duo Extend (N=53)							
12	--	--	4	--	--	--	N/A[2]
14	4	--	17	--	--	12	
16	--	--	13	--	1	2	

[1] Duo Hybrid is not available in 40mm length.
[2] Duo Extend is not available in 160mm length.

D. Safety and Effectiveness Results

i. Safety Results

The primary safety endpoint for the VIVID study is freedom from major adverse events (MAEs) at 30 days post index procedure, as adjudicated by the Clinical Events Committee (CEC) or Core Laboratory. There were only two patients who had a CEC Adjudicated MAE at 30 days, both of whom had new thrombus in the stented segment requiring surgical or endovascular intervention. Both patients were in the chronic post-thrombotic cohort. **Table 12** displays the analysis of all FAS subjects. In each case the lower confidence bound was >95% which met the pre-defined performance goal (p<0.0001).

Table 12. VIVID Primary Safety Endpoint - CEC Adjudicated MAES at 30 Days

Study Group	Freedom from MAE at 30 Days % (#/#) (95% CI) [1]	Performance Goal	p-value[1]	Study Endpoint
FAS – All	98.7% (157/159) (95.5%, 99.8%)	89%	<0.0001	MET

[1] One sample exact test for one proportion, p-value is one-sided, Exact Two-Sided 95% confidence interval

Adverse Effects that occurred in the PMA clinical study

Table 13 and **Table 14** present an overall summary of adverse events and serious adverse events that have been reported through 390 days by Body System Organ Class. No events were determined to be unanticipated. The types and occurrences of events that were reported are within expected rates.

Table 13. Adverse Events and Device or Procedure Related Events in Body System Organ Classes in ITT Subjects

	Adverse Events						Device or Procedure Related Events					
	Any		Within 30 Days		Within 390 Days		Any		Within 30 Days		Within 390 Days	
Body System Organ Class	# of events	# (%) of pts	# of events	# (%) of pts	# of events	# (%) of pts	# of events	# (%) of pts	# of events	# (%) of pts	# of events	# (%) of pts
Blood and lymphatic system disorders	6	3.1% (5/162)	1	0.6% (1/162)	4	1.9% (3/162)						
Cardiac disorders	17	7.4% (12/162)	2	1.2% (2/162)	14	6.8% (11/162)						
Congenital, familial, and genetic disorders	3	1.2% (2/162)			3	1.2% (2/162)						
Ear and labyrinth disorders	1	0.6% (1/162)			1	0.6% (1/162)						
Gastrointestinal disorders	22	11.7% (19/162)	1	0.6% (1/162)	16	9.3% (15/162)	1	0.6% (1/162)			1	0.6% (1/162)
General disorders and administration site conditions	44	19.1% (31/162)	14	7.4% (12/162)	36	15.4% (25/162)	10	5.6% (9/162)	6	3.1% (5/162)	8	4.3% (7/162)
Immune system disorders	2	1.2% (2/162)	1	0.6% (1/162)	1	0.6% (1/162)	1	0.6% (1/162)	1	0.6% (1/162)	1	0.6% (1/162)
Infections and infestations	51	24.1% (39/162)	6	3.7% (6/162)	41	19.1% (31/162)	1	0.6% (1/162)	1	0.6% (1/162)	1	0.6% (1/162)
Injury, poisoning and procedural complications	14	8.0% (13/162)	3	1.9% (3/162)	12	6.8% (11/162)	1	0.6% (1/162)	1	0.6% (1/162)	1	0.6% (1/162)
Investigations	2	1.2% (2/162)			1	0.6% (1/162)						
Metabolism and nutrition disorders	2	1.2% (2/162)			2	1.2% (2/162)						
Musculoskeletal and connective tissue disorders	47	19.8% (32/162)	11	6.2% (10/162)	37	17.9% (29/162)	6	3.1% (5/162)	5	2.5% (4/162)	6	3.1% (5/162)
Neoplasms benign, malignant and unspecified (incl cy	2	1.2% (2/162)	1	0.6% (1/162)	1	0.6% (1/162)						
Nervous system disorders	23	9.9% (16/162)	3	1.9% (3/162)	20	9.3% (15/162)						
Pregnancy, puerperium, and perinatal conditions	1	0.6% (1/162)										
Product issues	1	0.6% (1/162)	1	0.6% (1/162)	1	0.6% (1/162)	1	0.6% (1/162)	1	0.6% (1/162)	1	0.6% (1/162)
Psychiatric disorders	2	1.2% (2/162)			2	1.2% (2/162)						
Renal and urinary disorders	5	2.5% (4/162)			3	1.2% (2/162)						
Reproductive system and breast disorders	5	2.5% (4/162)	1	0.6% (1/162)	5	2.5% (4/162)						
Respiratory, thoracic, and	17	8.0% (13/162)	2	1.2% (2/162)	15	8.0% (13/162)	1	0.6% (1/162)			1	0.6% (1/162)

Table 13. Adverse Events and Device or Procedure Related Events in Body System Organ Classes in ITT Subjects

	Adverse Events						Device or Procedure Related Events					
	Any		Within 30 Days		Within 390 Days		Any		Within 30 Days		Within 390 Days	
Body System Organ Class	**# of events**	**# (%) of pts**	**# of events**	**# (%) of pts**	**# of events**	**# (%) of pts**	**# of events**	**# (%) of pts**	**# of events**	**# (%) of pts**	**# of events**	**# (%) of pts**
mediastinal disorders												
Skin and subcutaneous tissue disorders	14	6.2% (10/162)	5	1.9% (3/162)	11	4.3% (7/162)	2	0.6% (1/162)	2	0.6% (1/162)	2	0.6% (1/162)
Surgical and medical procedures	4	1.9% (3/162)	1	0.6% (1/162)	3	1.2% (2/162)						
Vascular disorders	33	16.7% (27/162)	3	1.9% (3/162)	27	14.2% (23/162)	10	6.2% (10/162)	2	1.2% (2/162)	10	6.2% (10/162)
Not Coded	7	3.7% (6/162)			1	0.6% (1/162)						
Total	**325**	**63.0% (102/162)**	**56**	**23.5% (38/162)**	**257**	**55.6% (90/162)**	**34**	**18.5% (30/162)**	**19**	**9.9% (16/162)**	**32**	**17.3% (28/162)**

Table 14. Serious Adverse Events and Serious Device or Procedure Related Events in Body System Organ Classes in ITT Subjects

	Serious Adverse Events						Serious Device or Procedure Related Events					
	Any		Within 30 Days		Within 390 Days		Any		Within 30 Days		Within 390 Days	
Body System Organ Class	# of events	# (%) of pts	# of events	# (%) of pts	# of events	# (%) of pts	# of events	# (%) of pts	# of events	# (%) of pts	# of events	# (%) of pts
Blood and lymphatic system disorders	1	0.6% (1/162)	1	0.6% (1/162)	1	0.6% (1/162)						
Cardiac disorders	6	3.1% (5/162)			4	2.5% (4/162)						
Congenital, familial, and genetic disorders	1	0.6% (1/162)			1	0.6% (1/162)						
Gastrointestinal disorders	5	3.1% (5/162)	1	0.6% (1/162)	4	2.5% (4/162)						
General disorders and administration site conditions	7	4.3% (7/162)	2	1.2% (2/162)	4	2.5% (4/162)	5	3.1% (5/162)	1	0.6% (1/162)	3	1.9% (3/162)
Infections and infestations	9	4.9% (8/162)	1	0.6% (1/162)	7	3.7% (6/162)	1	0.6% (1/162)	1	0.6% (1/162)	1	0.6% (1/162)
Injury, poisoning and procedural complications	4	2.5% (4/162)			2	1.2% (2/162)						
Metabolism and nutrition disorders	1	0.6% (1/162)			1	0.6% (1/162)						
Musculoskeletal and connective tissue disorders	2	0.6% (1/162)			2	0.6% (1/162)						
Nervous system disorders	5	1.9% (3/162)	2	1.2% (2/162)	5	1.9% (3/162)						
Pregnancy, puerperium, and perinatal conditions	1	0.6% (1/162)										
Product issues	1	0.6% (1/162)	1	0.6% (1/162)	1	0.6% (1/162)	1	0.6% (1/162)	1	0.6% (1/162)	1	0.6% (1/162)
Psychiatric disorders	1	0.6% (1/162)			1	0.6% (1/162)						
Renal and urinary disorders	1	0.6% (1/162)										
Reproductive system and breast disorders	4	1.9% (3/162)	1	0.6% (1/162)	4	1.9% (3/162)						
Respiratory, thoracic, and mediastinal disorders	3	1.9% (3/162)	1	0.6% (1/162)	3	1.9% (3/162)	1	0.6% (1/162)			1	0.6% (1/162)
Skin and subcutaneous tissue disorders	1	0.6% (1/162)			1	0.6% (1/162)						
Surgical and medical procedures	3	1.2% (2/162)	1	0.6% (1/162)	3	1.2% (2/162)						
Vascular disorders	11	5.6% (9/162)	2	1.2% (2/162)	8	4.3% (7/162)	5	3.1% (5/162)	1	0.6% (1/162)	5	3.1% (5/162)
Total	**67**	**28.4% (46/162)**	**13**	**7.4% (12/162)**	**52**	**22.2% (36/162)**	**13**	**8.0% (13/162)**	**4**	**2.5% (4/162)**	**11**	**6.8% (11/162)**

ii. Effectiveness Results

The primary effectiveness endpoint was primary patency of the stented segment at 12 months defined as freedom from:

- Duplex Ultrasound (DUS) core laboratory adjudicated stenosis or occlusion >50% within the stented segment. If DUS showed >50% stenosis or occlusion, confirmation by diagnostic intravascular ultrasound (IVUS) is required.
- CEC adjudicated clinically driven target lesion reintervention (CD-TLR) defined as endovascular or surgical procedure for new, recurrent, or worsening symptoms and core lab adjudicated >50% stenosis or occlusion within the stented segment confirmed by diagnostic IVUS.

In the FAS group, 132/162 patients were evaluable for the 12M primary effectiveness endpoint. The primary endpoint was met by 90.2% of subjects with a lower confidence bound of 87.2% thus meeting the target performance goal (p=0.0002). In the PP group, 115/162 patients were evaluable for 12M primary for the 12M primary effectiveness endpoint. The primary endpoint was met by 89.8% of subjects with a lower confidence bound of 82.7% thus meeting the target performance goal (p=0.0003).

Table 15. Primary Effectiveness Endpoint – Primary Patency at 12 Months in FAS and PP Subjects					
	Analysis Group	**% (#/#) (95% CI)[1]**	**Target Performance Goal**	**p-value[1]**	**Study Endpoint**
Primary Patency at 12M	FAS	90.2% (119/132) (87.2%, 93.2%)	77.3%	0.0002	MET
	PP	89.8% (115/128) (82.7%, 97.01%)		0.0003	MET

[1] One sample Z-test for a proportion, p-value is one-sided, Two-Sided 95% confidence interval. The variation in the proportion is estimated under the null (see statistical plan).

Table 16 summarizes additional analyses conducted in FAS subjects by baseline disease state. Primary patency by disease state in the FAS cohort was 86.7% in the acute thrombotic cohort, 95.2% in the non-thrombotic cohort, and 79.4% in the chronic post-thrombotic cohort.

Table 16. Primary Effectiveness Endpoint at 12 Months in FAS Subjects Overall and by Disease State				
		Disease State		
	FAS Subjects	**Acute Thrombotic**	**Non-Thrombotic**	**Chronic Post Thrombotic**
Primary Patency at 12M	90.2% (119/132)	86.7% (13/15)	95.2% (79/83)	79.4% (27/34)
◆ CD-TLR	7	0	3	4
◆ Not patent finding in the absence of CD-TLR	6	2	1	3

Data shown as % (n/N)

iii. *Secondary Endpoints*

Secondary endpoints are summarized in **Table 17 - Table 21**. As seen in **Table 18** below, there was a sustained decrease in Venous Clinical Severity Score (VCSS) – Pain Score from baseline to 12 months.

Table 17. VCSS Pain Score and Changes in VCSS from Baseline in ITT Patients			
Parameter	**Baseline**	**6 months**	**12 months**
VCSS Pain Score			
At Follow-up	2.0 ± 0.8 (160)	0.5 ± 0.8 (149)	0.5 ± 0.8 (138)
	(0.0, 2.0, 3.0)	(0.0, 0.0, 3.0)	(0.0, 0.0, 3.0)
Change from Baseline	--	-1.4 ± 1.1 (148)	-1.4 ± 1.1 (137)
		(-3.0, -2.0, 3.0)	(-3.0, -2.0, 2.0)

Data shown as mean ± SD (N) (min, median, max)

Primary assisted patency was defined as freedom from DUS core laboratory adjudicated occlusion or stenosis > 50% within the stented segment following a clinically driven target lesion reintervention (CD-TLR) due to a > 50% but < 100% stenosis at 12 months while secondary patency was defined as freedom from DUS core laboratory adjudicated occlusion or stenosis > 50% within the stented segment following a clinically driven target lesion reintervention at 12 months due to greater than 50% stenosis or occlusion within the stented segment. For both endpoints, if site reported or core laboratory adjudicated DUS showed > 50% stenosis or occlusion, confirmation by diagnostic IVUS was required. As with the primary patency endpoint, DUS, IVUS and venogram imaging were used to evaluate the endpoint. As shown in **Table 18**, primary assisted patency and secondary patency at 12M were 94.7% (124/131) and 95.4% (125/131), respectively.

Table 18. Primary Assisted Patency and Secondary Patency at 12 Months in ITT Subjects	
Parameter	**Patency at 12M**
Primary Assisted Patency at 12M	94.7% (124/131) (89.4, 97.4)
◆ CD-TLR for 100% occlusion	1
◆ Not patent finding in the absence of CD-TLR for 100% occlusion	6
Secondary Patency at 12M	95.4% (125/131) (90.4%, 97.9%)

[1] *Data shown as % (n/N) (Wilson's 95% CI)*

iv. *Observational Endpoints*

Device, lesion, and procedural success were evaluated using the following definitions:

- Device success is defined as successful deployment at the intended target site and successful withdrawal of the delivery catheter from the introducer sheath. The following must be met to be considered a Device Success:
  - Successful deployment of the Duo Stent(s) at the intended target site, AND
  - Successful withdrawal of the delivery catheter(s) from the introducer sheath, AND

- The Duo Stent remaining at the intended deployment location through completion of the index procedure as determined by the Principal Investigator (PI)

- Lesion success is defined as target lesion patency of ≤50% residual diameter or area stenosis of the stented segment at the completion of the procedure (core laboratory adjudicated).
- Procedural success is defined as lesion success without the occurrence of major adverse events from the time of treatment to discharge (CEC and/or core laboratory adjudicated).

As summarized in **Table 19**, all subjects met the criteria for lesion and procedural success and 159/162 (98.1%) met the criteria for device success. Of the three subjects that did not meet the criteria for device success, two subjects did not have successful deployment at the target site and one subject did not have the stent remaining at the intended target location through the index procedure. No adverse events were associated with these failures.

Table 19. Device, Lesion, and Procedural Success in ITT Subjects

	% (#/#) (95% CI)[1,2]
	ITT Subjects
Device Success per stent introduced	98.6% (216/219) (97.1%, 100.2%)[1]
Device Success per subject	98.1% (159/162) (94.7%, 99.4%)[2]
Lesion Success per subject	100.0% (162/162) (97.7%, 100.0%)[2]
Procedural Success per subject	100.0% (162/162) (97.7%, 100.0%)[2]

Data shown as % (n/N) (Wilson's 95% CI)

[1]Generalized estimating equations.

[2]Wilson's 95% confidence interval.

Stent fracture and migration were evaluated via X-ray through 36 months and stent embolization via X-ray or venogram through 36 months. There were no instances of stent fracture, migration, or embolization through 12 months.

Several quality-of-life measures were also included as observational endpoints. The clinical CEAP score, all EQ-5D-3L categories, Vilalta score, VEINES-QOL and VEINES-Sym scores all improved from baseline to 12 months as summarized in **Table 20**.

Table 20. Quality of Life Measures at Baseline and Follow-up in ITT Subjects

Clinical Measures	**ITT % (#/#)**		
	Baseline	**6M**	**12M**
Clinical CEAP Score			
C0	1.2% (2/162)	30.9% (46/149)	31.2% (43/138)
C1	0.6% (1/162)	8.7% (13/149)	8.0% (11/138)
C2	0.6% (1/162)	8.1% (12/149)	5.8% (8/138)
C2r	0.0% (0/162)	0.0% (0/149)	2.2% (3/138)
C3	66.0% (107/162)	32.2% (48/149)	31.2% (43/138)
C4	5.6% (9/162)	2.7% (4/149)	2.9% (4/138)
C4a	13.0% (21/162)	6.0% (9/149)	7.2% (10/138)
C4b	1.9% (3/162)	2.0% (3/149)	2.2% (3/138)
C5	4.9% (8/162)	6.0% (9/149)	8.7% (12/138)
C6	5.6% (9/162)	2.7% (4/149)	0.7% (1/138)
C6r	0.6% (1/162)	0.7% (1/149)	0.0% (0/138)
EQ-5D-3L Questionnaire	**Baseline**	**6M**	**12M**
EQ-5D-3L Mobility Score			
1 – No problems	47.8% (76/159)	66.4% (93/140)	64.9% (85/131)
2 – Some problems	51.6% (82/159)	33.6% (47/140)	35.1% (46/131)
3 – Extreme problems	0.6% (1/159)	0.0% (0/140)	0.0% (0/131)
EQ-5D-3L Self-Care Score			
1 – No problems	83.0% (132/159)	91.4% (128/140)	93.1% (122/131)
2 – Some problems	15.7% (25/159)	8.6% (12/140)	6.9% (9/131)
3 – Extreme problems	1.3% (2/159)	0.0% (0/140)	0.0% (0/131)
EQ-5D-3L Usual Activity Score			
1 – No problems	49.1% (78/159)	67.1% (94/140)	75.4% (98/130)

Table 20. Quality of Life Measures at Baseline and Follow-up in ITT Subjects			
2 – Some problems	45.9% (73/159)	30.7% (43/140)	23.8% (31/130)
3 – Extreme problems	5.0% (8/159)	2.1% (3/140)	0.8% (1/130)
EQ-5D-3L Pain/Discomfort Score			
1 – No problems	25.2% (40/159)	52.1% (73/140)	50.4% (66/131)
2 – Some problems	59.7% (95/159)	45.7% (64/140)	47.3% (62/131)
3 – Extreme problems	15.1% (24/159)	2.1% (3/140)	2.3% (3/131)
EQ-5D-3L Anxiety/Depression Score			
1 – No problems	54.1% (86/159)	70.7% (99/140)	76.3% (100/131)
2 – Some problems	39.0% (62/159)	25.0% (35/140)	21.4% (28/131)
3 – Extreme problems	6.9% (11/159)	4.3% (6/140)	2.3% (3/131)
EQ-VAS Score (0 = worst imaginable health state and 100 = best imaginable health state)			
At follow-up	67.7 ± 23.6 (158)	77.7 ± 18.1 (140)	79.7 ± 16.7 (130)
Change from Baseline	--	8.6 ± 23.2 (137)	10.6 ± 22.1 (127)
Villalta Score	**Baseline**	**6M**	**12M**
At follow-up	10.4 ± 4.8 (159)	3.4 ± 4.1 (149)	3.3 ± 3.9 (138)
Change from Baseline	--	-6.7 ± 5.5 (146)	-6.9 ± 5.7 (135)
VEINES-QOL/Sym Score	**Baseline**	**6M**	**12M**
VEINES - Sym			
At follow-up	52.6 ± 24.9 (157)	75.9 ± 22.7 (139)	76.9 ± 21.9 (132)
Change from Baseline	--	22.6 ± 23.8 (135)	23.4 ± 25.8 (128)
VEINES - QOL			
At follow-up	51.4 ± 23.8 (157)	75.0 ± 22.7 (139)	75.9 ± 23.6 (132)
Change from Baseline	--	23.6 ± 24.7 (135)	24.3 ± 25.8 (128)

Data presented as Mean ± SD (N) or % (#/#)

v. Subgroup Analysis

Table 21 displays the results of the primary analysis by the pre-determined subgroups of FAS subjects: Gender, geography (US vs OUS), age (≤ 61 vs > 61), race, and ethnicity. In general, there were no differences in the primary efficacy endpoint between any of the pre-defined sub-groups, with the exception of US vs OUS. The OUS sample size was only 8.5% of the total FAS subject population, so the differences may be due to the small numbers of OUS subjects.

Table 21. Subgroup Analyses of Primary Patency at 12M in FAS Subjects				
Subgroup	**Primary Patency at 12M % (#/#)**			
	FAS	**Acute Thrombotic**	**Non-Thrombotic**	**Chronic Post Thrombotic**
Gender				
Male	87.8% (43/49)	83.3% (5/6)	100.0% (26/26)	70.6% (12/17)
Female	91.6% (76/83)	88.9% (8/9)	93.0% (53/57)	88.2% (15/17)
Geography				
Inside United States (US)	93.3% (112/120)	92.9% (13/14)	95.1% (77/81)	88.0% (22/25)
Outside United States (OUS)	58.3% (7/12)	0.0% (0/1)	100.0% (2/2)	55.6% (5/9)
Age				
≤ Median Age=61	88.6% (62/70)	88.9% (8/9)	97.6% (40/41)	70.0% (14/20)
> Median Age=61	91.9% (57/62)	83.3% (5/6)	92.9% (39/42)	92.9% (13/14)
Race				
White	89.2% (99/111)	90.9% (10/11)	94.1% (64/68)	78.1% (25/32)
Black	90.9% (10/11)	75.0% (3/4)	100.0% (7/7)	0
Other/Decline/Unknown	100.0% (10/10)	0	100.0% (8/8)	100.0% (2/2)
Ethnicity				
Not Hispanic or Latino	89.3% (100/112)	83.3% (10/12)	94.4% (68/72)	78.6% (22/28)
Hispanic or Latino	93.3% (14/15)	100.0% (2/2)	100.0% (7/7)	83.3% (5/6)
Unknown	100.0% (5/5)	100.0% (1/1)	100.0% (4/4)	0

vi. Covid Analysis

Given that COVID-19 has been associated with a hypercoagulable state, which has the potential to increase MAE occurrence and decrease patency, the study included a test of both the primary safety and effectiveness hypotheses in both the SARS-CoV-2 negative subset and all subjects (regardless of SARS-CoV-2 status). The performance goals for both primary safety and primary effectiveness were met for both cohorts. COVID-19 status did not affect primary outcomes in this study.

vii. Pediatric Extrapolation

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

9. MRI Safety Information

Non-clinical testing has demonstrated that the Duo Venous Stent 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 field gradient of 4,000-gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg (Normal Operating Mode)
- Circularly polarized (quadrature-driven) coil only

Under the scan conditions defined, an implant from the Vesper Duo Venous Stent is expected to produce a maximum temperature rise of less than 2.0°C after 15-minutes of continuous scanning (i.e. per pulse sequence).

In non-clinical testing, the image artifact caused by an implant from the Vesper Duo Venous Stent extends approximately 5-mm from this device when imaged with a gradient echo pulse sequence and a 3-T MR system. The lumen of this stent could be visualized on the T1-weighted, spin echo and gradient echo MR images.

Additional Information
The heating effect in the MRI environment for fractured stents is unknown. The presence of other implants or the health state of the patient may require reduction of the MRI limits listed above.

Vesper Medical recommends that patients register the conditions under which this Stent implant can be MRI scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.


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