Datapoints

VERNACULAR clinical study summary

(36-Month results)

Lead Principal Investigator:
Michael Dake, MD

Co-Principal Investigator:
Gerard O'Sullivan, MD

Design

The Venovo™ Venous Stent System was evaluated through an Investigational Device Exemption (IDE) study in the prospective, multi-center, non-randomized, single-arm VERNACULAR study for the treatment of symptomatic iliofemoral venous outflow obstruction.

Safety and effectiveness measures for subjects receiving the Venovo™ Venous Stent were compared to performance goals derived from clinical literature. The study was conducted at 21 investigational sites in the U.S., Europe and Australia, and included follow-up evaluations at 30-days, 6-, 12-, 24-, and 36-months. The primary safety endpoint was analyzed at 30 days and the primary effectiveness endpoint was analyzed at 12 months. Predetermined secondary endpoints were also reported at the index procedure and at follow-ups.

Results

Primary effectiveness

Primary patency at 12 months post-index procedure, defined as: freedom from tvr and freedom from thrombus occlusion and stenosis > 50% as measured by DUS.

(P-value <0.0001)

Literature-derived performance goal:74%

Weighted primary patency:	**88.6%** (133/150)
Pts:	81.7% (67/82)
Nivl:	97.1% (66/68)

Primary Safety

Freedom from major adverse events (MAE) through 30-days post-index procedure[2] (p-value=0.0322)

Literature-derived performance goal: 89%

Primary Safety:	**93.5%** (159/170)
Pts:	88.2% (82/93)
Nivl:	100.0% (77/77)

Mean % Diameter Stenosis[1]

Pre-stent:	Post-stent:
PTS: 81.0%	PTS: 16.2%
NIVL: 69.3%	NIVL: 11.9%
Total: 75.7%	**Total: 14.2%**

Primary patency at 36-months* **84.0%** Primary Patency **74.8%** PTS **95.5%** NIVL

*Kaplan-meier estimated primary patency

Secondary endpoints

100% Lesion success

Attainment of ≤50% residual stenosis at the conclusion of the index procedure

100% Acute technical success

Successful deployment of stent(s) to the intended target site with adequate lesion coverage as assessed by investigator

0 Stent fractures[3]

At 36-month x-ray analysis

1 162 Subject images were analyzed to provide interpolated values.

2 List of mae includes: target vessel revascularization · device and/or procedure related death · major amputation of target limb · pulmonary embolism · vascular injury requiring surgical/endovascular intervention · embolization/migration of stent · device or procedure related acute dvt involving the treated limb

3 Stents were evaluated at the 36-month follow-up for fracture analysis. An anteroposterior and lateral x-ray for each evaluated stent

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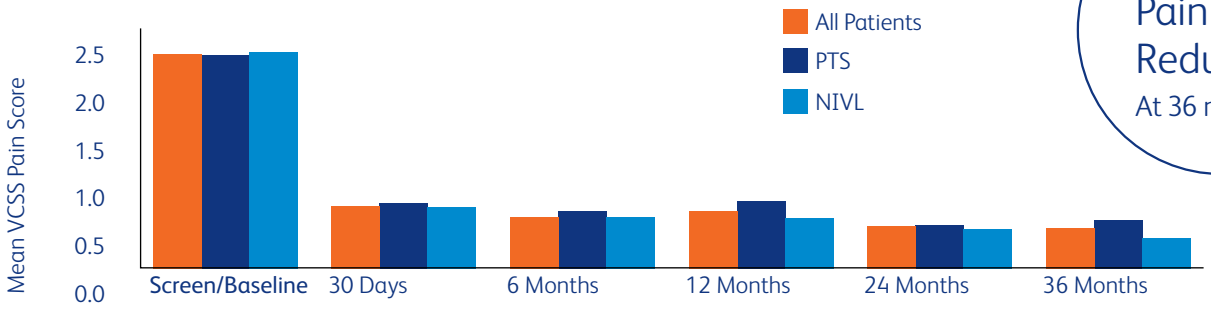
Patient Outcomes

The Venovo™ Venous Stent demonstrated significant improvement in both VCSS pain scores and quality of life (CIVIQ-20) compared to baseline at 36-months. The CIVIQ-20 assessment demonstrated an average change from baseline in the total study population of -16.8 and the VCSS leg pain assessment demonstrated an average change from baseline in the total study population of -1.8.

VCSS Leg Pain Score at 36 Months (ITT Subjects)



Sustained Pain Reduction
At 36 months

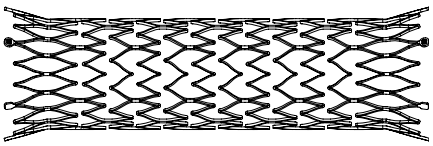
Patient Demographics

55% PTS
(n=93)
Post-thrombotic syndrome

45% NIVL
(n=77)
Non-thrombotic iliac vein lesion

N=170

Average Age: **52**
63% Female (n=107)
Average Stents Per Patient: **1.3**
Target Lesions Per Patient: **1.1**



Lesion Characteristics

Location

Common Iliac Vein:		External Iliac Vein:		Common Femoral Vein:	
PTS:	92.1% (82/89)	PTS:	58.4% (52/89)	PTS:	14.6% (13/89)
NIVL:	97.3% (72/74)	NIVL:	18.9% (14/74)	NIVL:	2.7% (2/74)
Total:	**94.5% (154/163)**	**Total:**	**40.5% (66/163)**	**Total:**	**9.2% (15/163)**

Pre-Procedural Lesion Characteristics

Mean Lesion Length:		Thrombus Present:		No Blood Flow (Occluded):	
PTS:	80.5 mm	PTS:	14.8% (13/88)	PTS:	38.6% (34/88)
NIVL:	55.2 mm	NIVL:	1.4% (1/74)	NIVL:	4.1% (3/74)
Total:	**67.8 mm**	**Total:**	**8.6% (14/162)**	**Total:**	**22.8% (37/162)**

Device Characteristics

Mean Stent Length:		Mean Stent Diameter:	
PTS:	100.1 mm	PTS:	15.4 mm
NIVL:	83.0 mm	NIVL:	16.6 mm
Total:	**93.5 mm**	**Total:**	**15.9 mm**

Indications for Use: The Venovo™ Venous Stent System is indicated for the treatment of stenoses and occlusions in the iliac and femoral veins.

Contraindications: The Venovo™ Venous Stent System is contraindicated for use in patients with a known hypersensitivity to nitinol (nickel-titanium) and tantalum, who cannot receive intraprocedural anti-coagulation therapy, or who are judged to have a lesion that prevents complete inflation of a balloon dilatation catheter or proper placement of the stent or the stent delivery system.

Warnings: The Venovo™ Venous Stent System is supplied sterile and is intended for single use only. Do not resterilize and/or reuse the device. Reuse, resterilization, reprocessing and/or repackaging may create a risk to the patient or user, may lead to infection or compromise the structural integrity and/ or essential material and design characteristics of the device, which may lead to device failure, and/ or lead to injury, illness, or death of the patient. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/ or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications or death. Do not use in patients with total venous occlusion that cannot be dilated to allow passage of the guidewire. Do not use the device with contralateral access. Do not use if pouch is opened or damaged. Do not use the device after the "Use By" date specified on the label. Persons with allergic reactions to nitinol (nickel-titanium) alloy and/or tantalum may suffer an allergic response to this implant. Do not expose the delivery system to organic solvents, e.g., alcohol. The stent is not designed for repositioning or recapturing. Stenting across a major branch could cause difficulties during future diagnostic or therapeutic procedures. If a long lesion needs to be stented consider using the longest available stent rather than overlapping stents. If multiple stents are placed in an overlapping fashion, they should be of similar composition (i.e., nitinol). The long-term outcomes following repeat dilatation of endothelialized stents are unknown. The safety and effectiveness of this device for use in the arterial system have not been established. **Please consult product labels and instruction for use for indications, contraindications, hazards, warnings, and precautions.**

CE 2797
BD Switzerland Sarl, Terre Bonne Park – A4, Route De Crassier, 17, 1262 Eysins, Vaud. Switzerland. Tel: +41 21 556 30 00. Fax: +41 44 722 5370

bd.com