Venous Stent for the Iliofemoral Vein Investigational Clinical Trial Using the Duo Venous Stent System

The VIVID Trial: 24-Month Outcomes

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Unique Mechanical Demands of Deep Venous Stenting

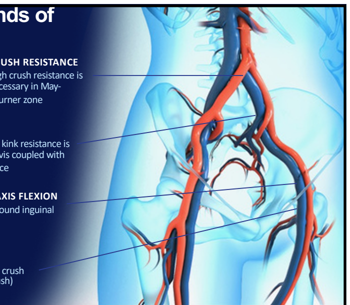
Varied dynamic loading in iliofemoral venous system drove stent design

CRUSH RESISTANCE
High crush resistance is necessary in May-Thurner zone

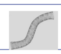
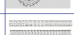
FLEXIBILITY
Flexibility and kink resistance is needed in pelvis coupled with crush resistance

DURABILITY FOR MULTI-AXIS FLEXION
High resistance to fracture around inguinal ligament

ROBUST STENT INFLOW
Maintain patent inflow with higher crush resistance at caudal edge (edge crush)



Dedicated Venous Stents IDE Trial Overview

Venous Stent		FDA Status	Stent Design	Disease States	PP Imaging	Stent Sizing Imaging	Study Outcomes
Bard Venovo		Approved 2019	Open Cell, Homogenous	NIVL PTS aDVT	Venogram	Venogram	Vernacular[1], N = 170 30d Safety: 93.5% 12mo Patency: 88.3% 24mo Patency: 84.4%
Boston Scientific VICI		Approved 2019	Closed Cell, Homogenous	NIVL PTS Excluded aDVT	Venogram	Venogram & IVUS	Virtus[2], N = 170 30d Safety: 98.8% 12mo Patency: 84% 24mo Patency: 79.1%
Cook Medical Zilver Vena		Approved 2020	Open Cell, Homogenous	NIVL PTS Included aDVT in PTS	Venogram	Venogram	VIVO[3], N = 243 30d Safety: 96.7% 12mo Patency: 89.9% 24mo Patency: 90.3%
Medtronic Abre		Approved 2020	Open Cell, Homogenous	NIVL PTS aDVT	DUS & Venogram	Venogram, IVUS Optional	Pivotal IDE[4], N = 200 30d Safety: 98% 12mo Patency: 88% 24mo Patency: 86.2%
Philips (Vesper) Duo Venous Stent System		Approved 2023	Open Cell, Hybrid, two stents	NIVL PTS aDVT	DUS & Venogram	IVUS Mandated	VIVID IDE[5], N = 162 30d Safety: 98.7% 12mo Patency: 90.2%

1. Dake, et al. Cardiovasc Inter Rad; 2021
2. Razavi, et al. Circ:CI; 2019 & Razavi, et al. JVIR; 2022
3. Hofmann, et al. JVS; 2023
4. Murphy, et al. Circ: CI; 2022 & Black, et al. JVIR; 2024
5. Razavi, et al. JVS-VL, 2024 (accepted)

Duo Venous Stent System

Unique portfolio with two distinct stent designs to address challenges of deep venous anatomy

- Designed specifically for venous anatomy
- Broad size matrix

Duo Hybrid

Duo Extend

VIVID Study Design

Venous stent for the Iliofemoral Vein Investigational clinical trial using the Duo Venous Stent System

Prospective, multi-center, single-arm, non-blinded study in US and Europe

162 subjects with nonmalignant iliofemoral venous outflow obstruction presenting with NIVL, PTS or acute DVT

Primary Safety Endpoint: **Freedom from MAEs, as adjudicated by the CEC or Core lab at 30 days**, including:
- Device or procedure-related death, major bleed, or venous injury
- Major amputation of the target limb
- Clinically significant pulmonary embolism
- Stent embolization
- Presence of new thrombus within the stented segment requiring surgical or endovascular intervention

Secondary Endpoints:
- Subject symptom relief via VCSS pain score at 12-months
- Primary assisted patency at 12-months
- Secondary patency at 12-months

Primary Efficacy Endpoint: **Primary patency of stented segment at 12-months** defined as freedom from:
- DUS core laboratory adjudicated stenosis or occlusion >50%
- CEC adjudicated CD-TLR

Key Observational Endpoints:
- Device, lesion and procedure success at index procedure
- Primary patency, primary assisted patency, secondary patency at 24 and 36 months
- Clinical, functional and quality of life assessments and scores through 36 months
- Stent fracture through 36 months

CAUTION: Investigational Device. Limited by Federal (United States) law to investigational use. The Duo Extend may only be used with the Duo Hybrid.

Key Eligibility Criteria for VIVID

Key Inclusion Criteria	Key Exclusion Criteria
Presence of unilateral, non-malignant venous obstruction of the CFV, EIV, or CIV ≥50% reduction in diameter	Target limb symptoms caused by PAD
Symptomatic obstruction with at least one of the following: • CEAP score ≥ 3 • VCSS pain score ≥ 2 • Suspected DVT	Presence of unresolved significant pulmonary emboli
Successful treatment of acute thrombus	Presence of IVC obstruction
Adequate inflow to the target lesion(s) a landing zone in the CFV	Contralateral venous occlusive disease of the CFV, EIV, or CIV, presence of acute DVT located outside target limb
	Presence of known aggressive clotting disorders
	Prior surgical/endovascular procedures to target vessel
	Previous stenting of the target limb

Key Baseline Patient Characteristics
(Intent to Treat Population)

Demographics and Baseline Characteristics	N=162
Age	59.4 ± 15.8
Male, No. %	63.0%
White/Caucasian	82.7%
BMI, kg/m^3	30.1 ± 5.7
History of SARS-CoV-2 infection	8.0%
Superficial venous ablation to target limb	14.2%
Prev Dx & resolved DVT in target limb	14.8%
Prev Dx & resolved DVT in non-target limb	5.6%
Contralateral venous occlusive disease	5.6%
Onset of symptoms that led to venous stenting intervention	
≤ 14 days	15.4%
>14 days	84.6%

Disease Etiology	Definition	Enrollment % (#)
NIVL	Symptomatic subjects with iliofemoral venous obstruction and no history of DVT	64.2% (104)
PTS	Total occlusion/stenosis iliofemoral segments requiring stent; onset of symptoms >14 days	25.9% (42)
aDVT	Acute symptomatic DVT ≤ 14 days; evidence of acute clot and iliofemoral obstruction requiring stent placement	9.9% (16)

Key Procedural & Lesion Details

IVUS was utilized in 100% of subjects during the index procedure

Baseline Lesion and Procedural Details	N = 162 patients N = 219 Lesions
Target Limb	
Left	79.6%
Right	20.4%
Access Site	
Femoral	63%
Popliteal	28.8%
Jugular	0.5%
Other*	7.8%
Lesion Location (most caudal)	
Common Iliac Vein	35.3%
External Iliac Vein	46.0%
Common Femoral Vein	18.7%

Baseline Lesion and Procedural Details	N = 162
Pre-intervention area stenosis, %	71.2 ± 15.0
Post-intervention area stenosis, %	6.7 ± 9.6
Mean lesion length, mm	55.2 ± 44.6
Mean stented length, mm	126.4 ± 46.9
Stents extended below inguinal ligament, %	18.7%
Duo Hybrid Stent Alone	69.1%
Duo Hybrid Stent Placed with Duo Extend	30.9%
Procedure time, mins	56.9 ± 32.2
Fluoroscopy time, mins	13.4 ± 13.9
Site Location	
Hospital lab	59.3%
OBL	38.3%
ASC	2.5%

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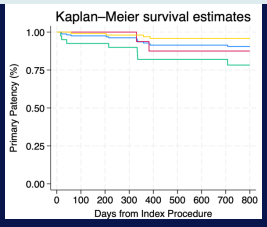
Primary Patency

Strong overall primary patency with >90% out to 24 months



Overall (ITT) @ 24 months
90.5%
(84.4%, 94.3%)

Observational Endpoints

High device, lesion and procedural success

Observational Endpoints	ITT	NT	PTS	aDVT
Device success				
• Per stent	98.6% (216/219)	97.6% (124/127)	100% (71/71)	100% (21/21)
• Per subject	98.1% (159/162)	97.1% (101/104)	100% (42/42)	100% (16/16)
Lesion Success	100% (162/162)	100% (104/104)	100% (42/42)	100% (16/16)
Procedural success	100% (162/162)	100% (104/104)	100% (42/42)	100% (16/16)

Observational Endpoints

Minimal safety events, including no stent migration or fracture out to 24 months

Observational Endpoints	ITT	NT	PTS	aDVT
KM Freedom from MAEs				
12-Month	95.5%	97.0%	89.9%	100%
24-Month	92.7%	94.8%	87.0%	93.8%
Stent Fracture				
12-month	0	0	0	0
24-month	0	0	0	0
Stent Migration				
12-Month	0	0	0	0
24-Month	0	0	0	0
Stent Embolization				
12-Month	0	0	0	0
24-Month	0	0	0	0

Observational Endpoints

Strong patency out to 24 months

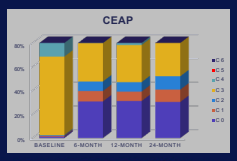
Observational Endpoints	ITT	NT	PTS	aDVT
Primary Patency				
12-Month	90.2% (119/132)	95.2% (79/83)	79.4% (27/34)	86.7% (13/15)
24-Month	89.9% (107/119)	94.8% (73/77)	77.4% (24/31)	90.9% (10/11)
Primary Assisted Patency				
12-Month	94.7% (124/131)	98.8% (81/82)	88.2% (30/34)	86.7% (13/15)
24-Month	95.7% (112/117)	100% (75/75)	87.1% (27/31)	90.9% (10/11)
Secondary Patency				
12-Month	95.4% (125/131)	98.8% (81/82)	91.2% (31/34)	86.7% (13/15)
24-Month	96.5% (113/117)	100% (75/75)	90.3% (28/31)	90.9% (10/11)
KM Freedom from CD-TLR				
12-Month	96.2%	98.0%	89.9%	100%
24-Month	94.1%	95.8%	87.0%	100%
KM Freedom from CD-TVR				
12-Month	95.6%	97.1%	89.9%	100%
24-Month	93.4%	94.8%	87.0%	100%

No stent fx nor migration

CEAP Classification Improvement

Significant improvements in CEAP classification continuing to 24 months

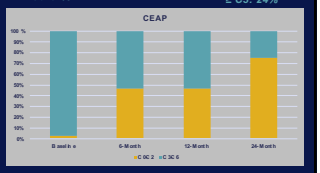
Improvement at 6,12 & 24 months months



Baseline ≥ C3: 97%

6 & 12 Months ≥ C3: 53%

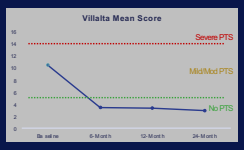
24 Months ≥ C3: 24%



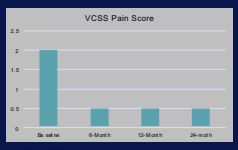
Clinical & Functional Scores Improve

Significant decrease in pain and PTS symptoms seen at 6 months and sustained out to 24 months

Significant improvement in PTS symptoms at 6,12 & 24 months



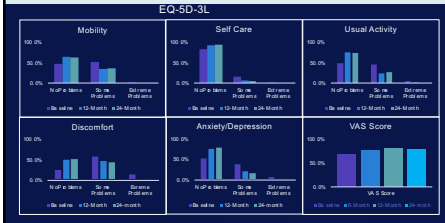
Significant and sustained decrease in VCSS pain score from baseline



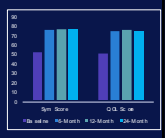
Quality of Life Improvements

Self Assessment of QoL significantly improved at 6, 12 & 24 months compared with baseline

EQ-5D-3L



VEINES



VAS Score

Summary

- **Continued safety and efficacy of the Duo Venous Stent System** in treating nonmalignant iliofemoral venous outflow obstruction in patients presenting with NIVL, PTS or acute DVT **out to 24-months**
  - 24-month KM FF MAE – 92.7%
  - 24-month primary patency – 89.9%
  - Sustained improvement in functional and quality of life assessments
  - No stent migration or fracture out to 24-months