VIVO Clinical Study: Zilver Vena Venous Stent Treatment of Symptomatic Iliofemoral Venous Outflow Obstruction: 12-month Results

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Disclosure

Speaker name: Lawrence (Rusty) Hofmann

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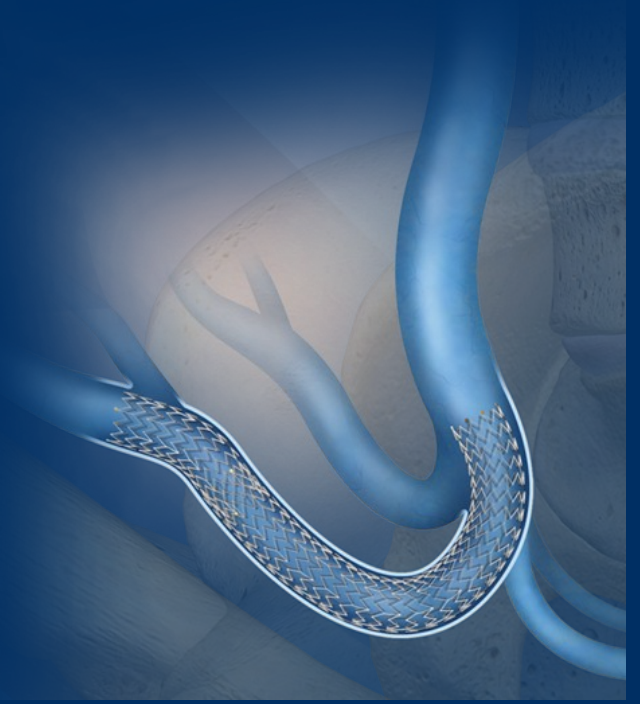
I have the following potential conflicts of interest to report:

- ☒ Consulting
- ☐ Employment in industry
- ☒ Stockholder of a healthcare company
- ☒ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any potential conflict of interest

Zilver Vena Venous Self-Expanding Stent

- Designed specifically for the treatment of symptomatic iliofemoral venous outflow obstruction
- CE Mark in the EU (2010), PMA approved in the US (2020), and available in many other global markets



Stent diameters*	14 and 16 mm
Stent lengths*	60, 100 and 140 mm

* Additional devices sizes available in the US includes a 40 mm length with 10 mm and 12 mm diameters.

VIVO Study Design

Study Objective	• To evaluate the safety and effectiveness of the Zilver® Vena™ Venous Stent in the treatment of symptomatic iliofemoral venous outflow obstruction
Study Design	• Prospective, multicenter, single-arm

Patient Population	• 243 patients in US and Taiwan
	  • 30% Acute (symptom onset ≤ 30 days)
	  • 70% Chronic (symptom onset > 30 days)

Study Endpoints	• Safety: 30-day freedom from MAEs • Effectiveness: 12-month primary quantitative patency (venography) • Secondary: VCSS change from baseline at 6 and 12 months

Inclusion Criterion

- Symptomatic venous outflow obstruction in one iliofemoral venous segment (i.e., one limb) per patient, demonstrated by:
  - **CEAP "C" ≥ 3, or**
  - **VCSS pain score ≥ 2**

Notable Exclusion Criteria

- Lesions with intended treatment lengths extending into the IVC or **below the level of the lesser trochanter**
- **Significant obstruction (i.e., >20%) of the inflow or outflow tract;** if treated prior to stenting the study lesion, treatment must result in <20% residual stenosis/obstruction
- **Lesion with malignant obstruction**

Real World Patient Population

Demographic	Mean ± SD (N, Min-Max) or Percent Patients (number/total number)
Age (years; Mean ± SD)	53.0 ± 15.3 (243, 18-89)
Female	70.0% (170/243)
BMI (Mean ± SD)	31.3 ± 8.5 (243, 17.5-64.8)
Current or past DVT	**67.5% (164/243)**
Current or past PE	14.8% (36/243)
Hypertension	43.6% (106/243)
Bleeding diathesis/coagulopathy	7.0% (17/243)
Hypercholesterolemia	31.7% (77/243)
History of cancer	16.9% (41/243)
Hormone-based contraception (females only)	11.8% (20/170)
Hormone replacement therapy	8.2% (20/243)

Baseline Lesion Characteristics

Characteristic	Percent Patients (number/total number) or Mean ± SD (N, Min-Max)
Indication for stent placement **Iliac vein compression by iliac artery** Stenosis due to chronic obstruction Stenosis after treatment for acute DVT Iatrogenic stenosis Extrinsic compression from mass Other	 **78.6% (191/243)** 30.0% (73/243) 15.6% (38/243) 0.8% (2/243) 0.8% (2/243) 3.7% (9/243)
Left side treated	**86.0% (209/243)**
Lesion Location **Common iliac vein** External iliac vein Common femoral vein Femoral vein	 **88.1%(214/243)** 51.9% (126/243) 22.6% (55/243) 2.1% (5/243)
Mean lesion length (mm)	**98.6 ± 68.8 mm** (232, 3.5-319)
Total occlusions at baseline	**22.3%** (52/233)

High Technical and Procedural Success Rates

Measure	Success Rate (number/total number)
Technical success (able to deliver and deploy stent in intended location) per stent	97.3% (355/365)*
Procedural success (improved flow through the target vessel) per patient	96.7% (175/181)**

*Site-reported reasons for technical failure: stent deployed into IVC or not in exact intended location (n=5), foreshortening (n=2), migration (stent movement at placement, not resulting in reintervention; n=2) stent deployed short of intended target location or into an unintended collateral vessel (n=1)

**Improved flow demonstrated by diminished flow through collateral vein and/or reduced filling defect in the target vessel and no major adverse events before discharge, not all patients had collateral or filling defects at baseline

Primary Safety Analysis Exceeded the Performance Goal

30-day Freedom from MAE (%; number/total number)	95% Confidence Interval	Performance Goal	*P*-value
96.7% (232/240)	94.4% - 98.9%	87%	< 0.0001

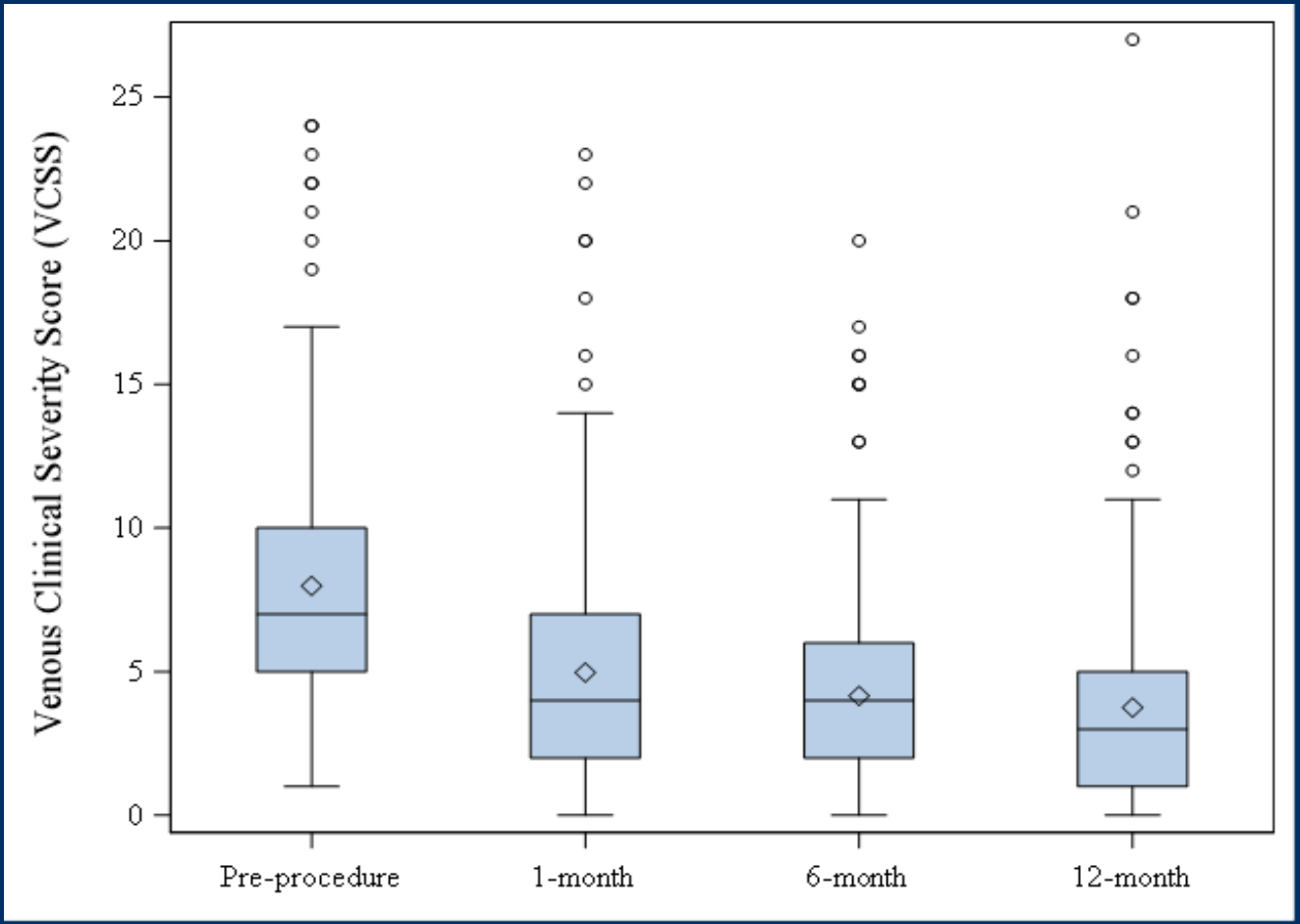
Major Adverse Events (0-30 days)	Number of Patients
Clinically driven target lesion reintervention	7
New symptomatic PE	1
Procedural bleeding requiring transfusion	0
Procedure- or device-related death	0
Clinical migration	0
Procedure-related perforation requiring open surgical repair	0
Flow-limiting dissection of the target vessel	0

Primary Effectiveness Analysis Exceeded the Performance Goal

- Primary quantitative patency (i.e., **venographic assessment** demonstrating **MLD was >50%** of the immediate post-procedure MLD)

12-month Primary Quantitative Patency (%)	95% Confidence Interval	Performance Goal	*P*-value
89.9%	85.1% - 93.4%	76%	< 0.0001

Mean VCSS Improved Significantly Following Treatment



- Mean change in VCSS from baseline was significant ($p<0.0001$) at 1 month; improvement was maintained through 12 months
- Mean **VCSS score decreased by 4.2 points from pre-procedure to 12 months**

Excellent Stent Durability Through 12 Months

- 243 patients were implanted with 365 Zilver Vena Stents
  - **32.5%** (79/243) of patients had stent extension **below the inguinal ligament**

Stent Measure	Parameter	365 days
Core laboratory reported freedom from *fracture*	Number at risk	308
	Cumulative events	0
	Cumulative censored	36
	Kaplan Meier estimate	**100%**
Core laboratory reported freedom from *migration*	Number at risk	312
	Cumulative events	1*
	Cumulative censored	32
	Kaplan Meier estimate	**99.7% ± 0.3%**

*One clinical migration to the pulmonary artery identified on 6-month imaging. Adjudicated as technique-related by the CEC: the device was undersized, likely only fixated in the lesion temporarily before migration.

Conclusions

- VIVO study patients were consistent with those in previous literature reports and reflective of a real-world population, including:
  - acute and chronic disease, and
  - thrombotic and non-thrombotic lesions
- Results of the VIVO clinical study support the safety and effectiveness of the Zilver Vena Venous Stent
  - High technical and procedural success rates
  - Primary safety and effectiveness endpoints were met
  - Significant improvement in VCSS