The Zilver Vena Venous Stent Trial: 3-Year Outcomes

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Disclosures

- Consultant for Cook Medical

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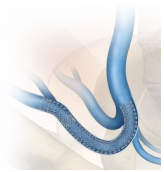
Zilver Vena Venous Self-Expanding Stent

- Designed to treat obstruction of the iliofemoral vein segment
- Available in over 40 countries, including US, EU, and China

U.S. Indication for Use	Improving luminal diameter in the iliofemoral veins for the **treatment of symptomatic iliofemoral venous outflow obstruction**
Stent Diameters*	10, 12, 14 and 16 mm
Stent Lengths*	40, 60, 100 and 140 mm

*The 40 mm length is available only with 10 mm and 12 mm diameter devices; these sizes are not available outside the U.S.



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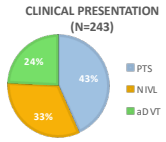
Aim of the Secondary Subgroup Analysis

The aim of this secondary subgroup analysis is to report on **3-year patency, clinical improvement, and stent integrity by patient subgroup;** categorized as post-thrombotic (PTS), non-thrombotic (NIVL), or acute DVT (aDVT) at baseline.



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Patient Demographics

Demographic	Mean ± SD (Min-Max) or Percent Patients (number/total number)			
	Overall (N=243)	**NIVL** (n=79)	**aDVT** (n=59)	**PTS** (n=105)
Age (years)	**53.0** ± 15.3 (18-89)	54.7 ± 14.9 (21 - 89)	52.5 ± 15.2 (20 - 78)	52.0 ± 15.7 (18 - 86)
Female	**70.0%** (170)	65.8% (52)	71.2% (42)	72.4% (76)
BMI	31.3 ± 8.5 (17.5-64.8)	30.2 ± 7.8 (18.7 - 51.4)	32.5 ± 9.7 (17.5 - 56.9)	31.5 ± 8.4 (18.6 - 64.8)
Current or past DVT	**67.5%** (164)	**0%** (0)	**100%** (59)	**100%** (105)
Current or past PE	**14.8%** (36)	**2.5%** (2)	**6.8%** (4)	**28.6%** (30)
Bleeding diathesis/coagulopathy	**7.0%** (17)	**0%** (0)	**1.7%** (1)	**15.2%** (16)
History of cancer	**16.9%** (41)	**16.5%** (13)	**16.9%** (10)	**17.1%** (18)

Subgroup patient characteristics were aligned with expectations; e.g., PTS patients were characterized by a higher number of patients with current/past DVT and bleeding diathesis/coagulopathy

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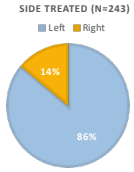
Baseline Lesion Characteristics

Demographic	Mean ± SD (Min-Max) or Percent Patients (number/total number)			
	Overall (N=243)	**NIVL** (n=79)	**aDVT** (n=59)	**PTS** (n=105)
Lesion Location				
Common iliac vein	88.1% (214/243)	87.3%(69/79)	91.5% (54/59)	86.7%(91/105)
External iliac vein	51.9% (126/243)	25.3% (20/79)	45.8% (27/59)	75.2% (79/105)
Common femoral vein	22.6% (55/243)	3.8% (3/79)	20.3% (12/59)	38.1% (40/105)
Femoral vein	2.1% (5/243)	0% (0/79)	3.4% (2/59)	2.9% (3/105)
Mean lesion length (mm)	**98.6** ± 68.8 mm (232, 3.5-319)	**64.8** ± 48.8 mm (73, 3.5-217.6)	**91.7** ± 62.3 mm (56, 9.7-276.7)	**126.3** ± 75.1 mm (103, 18-319)
Stent extension below the inguinal ligament	**32.5%** (79/243)	**10.1%** (8/79)	**23.7%** (14/59)	**54.3%** (57/105)
Total occlusions at baseline	**22.3%** (52/233)	**0%** (0/73)	**21.1%** (12/57)	**38.8%** (40/103)



Subgroup lesion characteristics were aligned with expectations; e.g., PTS patients were characterized by a higher rate of occlusions and longer lesions, including extension below the inguinal ligament

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High Rates of 30-Day Freedom from Major Adverse Events

Primary Endpoint Analysis

Endpoint	Rate (95% Confidence Interval)	Performance Goal	P-value
30-day Freedom from MAE	96.7% (93.5%-98.6%)	87%	< 0.0001

Subgroup Analysis

Endpoint	Rate (95% Confidence Interval*)		
	NIVL (n=78)	Acute DVT (n=59)	PTS (n=103)
30-day Freedom from MAE	100% (95.4%-100%)	94.9% (85.9%-98.9%)	95.1% (89.0%-98.4%)

*Unadjusted confidence intervals

30-day Freedom from MAE outcomes for each subgroup were consistent with expectations based on baseline patient and lesion characteristics and previous investigations.

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High Rates of 12-Month Primary Quantitative Patency

Primary Endpoint Analysis: Venogram

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

Subgroup Analysis: Venogram

Endpoint	Rate (n/N)		
	NIVL	Acute DVT	PTS
12-Month Primary Quantitative Patency	100% (60/60)	89.1% (41/46)	83.1% (69/83)

Venographic 12-Month Primary Quantitative Patency outcomes for the subgroups were excellent. The variation in rates among subgroups is consistent with expectations based on baseline patient and lesion characteristics.

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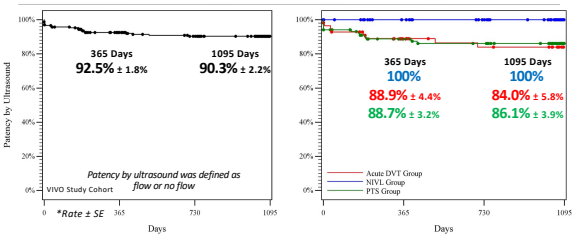
High 3-year Rate of Patency by Ultrasound



Patency by ultrasound through 3-years remained high for VIVO Study Cohort and Subgroups. Outcomes reflected the pattern observed for 12-month quantitative patency.

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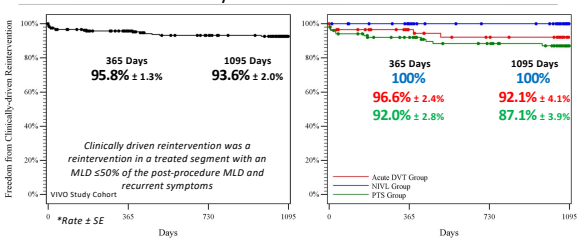
Maintained High 3-year Rate of Freedom from Clinically Driven Reintervention



Freedom from clinically-driven reintervention through 3-years remained high for VIVO Study Cohort and Subgroups. Outcomes reflect increased number of clinically-driven reinterventions in PTS and acute DVT subgroups.

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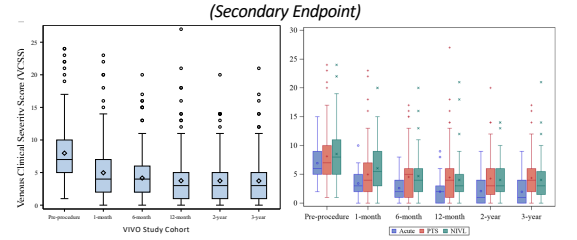
Sustained Improvement in VCSS

(Secondary Endpoint)



Mean change in VCSS from baseline was significantly improved ($p<0.0001$) for the VIVO study cohort at 1 month; improvement was maintained through 3 years. Mean VCSS score decreased by 4.2 points (95% CI: -4.6 to -3.5) from pre-procedure through 3 years for the VIVO Study Cohort. The same clinical improvement was observed for the subgroups, with decreases in mean VCSS of 3.6 points (PTS), 4.7 points (Acute DVT), and 4.8 points (NIVL).

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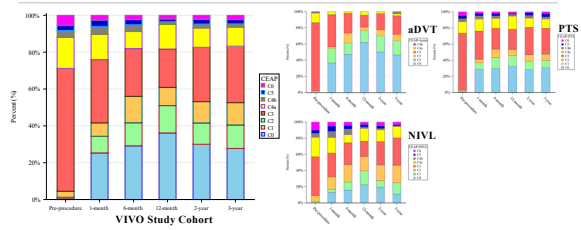
Sustained Improvement in CEAP "C" Classification



Patients were categorized by fewer symptoms according to the CEAP "C" scale; the correlation between time and CEAP "C" classification was highly significant ($p<0.0001$). Patient improvement was observed by 1 month and was sustained through 3 years. Similar trends to the overall cohort data were observed among the patient subgroups.

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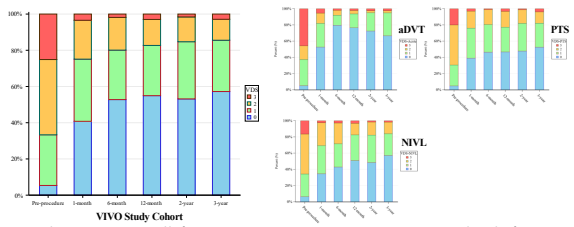
Sustained Improvement in Venous Disability Score (VDS)



VIVO Study patients were categorized by fewer symptoms according to VDS; the correlation between time and VDS classification was highly significant ($p<0.0001$). Patient improvement was observed by 1 month and was sustained through 3 years. Similar trends to the overall cohort data were observed among the patient subgroups.

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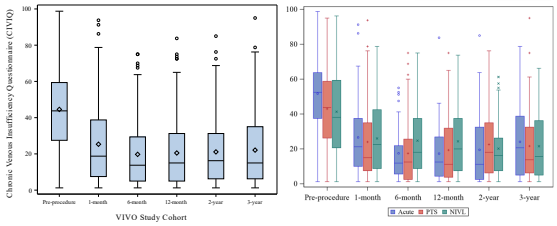
Sustained Improvement in CIVIQ Score



Mean change in CIVIQ from baseline was significant ($p<0.0001$) for the VIVO study cohort at 1 month; improvement was sustained through 3 years. Mean CIVIQ score decreased by 22.6 points (95% CI: -26.2 to -19.0) from pre-procedure through 12 months and by 20.8 points (95% CI: -24.8 to -16.8) from pre-procedure through 3-years. The same improvement was observed for the subgroups, with decreases in mean CIVIQ of 22.8 (PTS), 30.6 (Acute DVT), and 17.0 (NIVL).

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Stent Extension Below the Inguinal Ligament was Not Associated with Fracture

- 243 patients in VIVO cohort received 365 Zilver Vena Stents; 79 patients (32.5%) had stents extend below the inguinal ligament
- Core laboratory review of available imaging identified no fractures through 3 years:

Stent Measure	Parameter	365 Day	730 Day	1095 Days
Core laboratory reported freedom from fracture	Number at risk	308	287	135
	Cumulative events	0	0	0
	Cumulative censored	36	57	209
	Kaplan Meier estimate	**100%**	**100%**	**100%**

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Conclusions

- The VIVO Study enrolled a real-world population, including patients with acute and chronic disease onset, and multiple disease states (PTS, NIVL, and acute DVT)
- Results through 3 years continue to support the safety and effectiveness of the Zilver Vena Venous Stent
  - High rates of patency by ultrasound and freedom from clinically driven reintervention were demonstrated
  - Clinical improvement after stent placement as demonstrated by change in VCSS, VDS, CEAP "C", and CIVIQ scores
  - No stent fractures
- Excellent outcomes were demonstrated for the patient subgroups; trends were consistent with baseline patient and lesion characteristics and previous investigations

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Thank You

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