Interim Results from the Prospective Study of the Zilver® Vena™ Venous Stent in the Treatment of Symptomatic Iliofemoral Venous Outflow Obstruction in Europe (VIVO-EU)

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Zilver® Vena™ Venous Stent

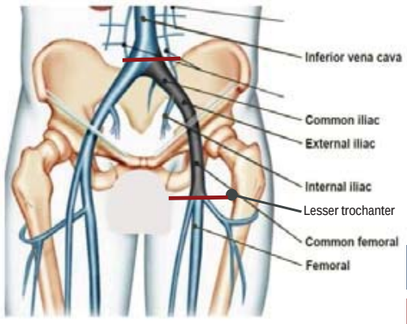
- CE Marked in 2010
- Intended for the treatment of symptomatic iliofemoral outflow obstruction
- Design characteristics:
  - Self-expanding nitinol stent
  - 7 Fr delivery system
  - 14 and 16 mm diameters
  - 60, 100, and 140 mm lengths

VIVO-EU Study Design

- Prospective, nonrandomized study in the EU
- Objective: to evaluate the Zilver Vena Venous Stent in the treatment of symptomatic iliofemoral outflow obstruction
- Enrollment: 35 patients with symptomatic iliofemoral outflow obstruction demonstrated by:
  - CEAP "C" ≥ 3, or
  - VCSS pain score ≥ 2
- Patients treated as per usual medical practice

Key Exclusion Criteria

- Planned surgical/interventional procedures of the target limb within 30 days prior to or any time after the study procedure
  - Except: thrombolysis, thrombectomy, or IVC filter placement prior to stent implantation
- Lesions with intended treatment lengths extending into the IVC or below the lesser trochanter
- Previous stent placement within the target vessel



Follow-up Schedule

	Pre-Procedure	Post-Procedure	Follow-up (months)				
			1	3	6	9	12
Clinical assessment and adverse events	X		X	X	X	X	X
Venography	X	X					
Duplex ultrasound		X			X		X
Telephone contact				X		X	

Patient Demographics and Medical History

Real World Patient Population

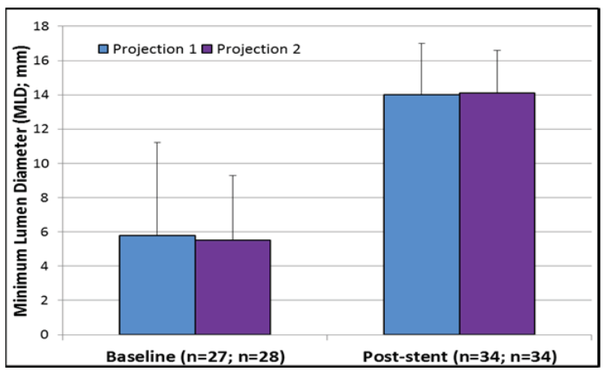
	Reported (N=35)
Age (years; mean ± SD)	45.1 ± 15.5
Female Gender	77.1% (27)
Bleeding diathesis/coagulopathy	14.3% (5)
Pulmonary embolism (history or current)	20.0% (7)
Deep vein thrombosis (DVT)	62.9% (22)
Acute DVT **Acute DVT on chronic DVT** **chronic DVT**	**40.9% (9/22)** **9.1% (2/22)** **50.0% (11/22)**
DVT (family history)	28.6% (10)
Cancer (history or current)	8.6% (3)

Baseline Lesion Data (Site Reported)

	Reported (N=35)
Lesion length (mm; mean ± SD)	106 ± 69 (range: 20-256)
Total occlusion	12.9% (4/31)
Left side	94.3% (33)
Lesion location	
Common iliac vein	54.3% (19)
External iliac, common iliac veins	25.7% (9)
Common femoral, external iliac, common iliac veins	20.0% (7)

Procedural Venography Results

>100% Diameter Improvement in Both Projections

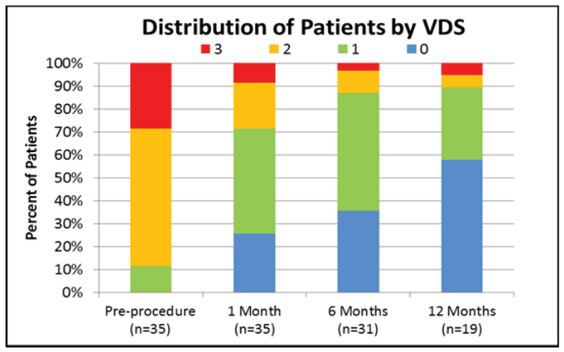


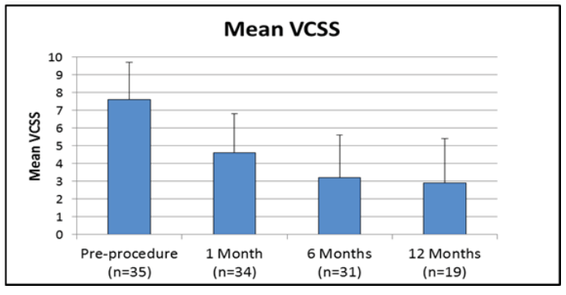
Major Adverse Events and 30-day Clinical Success

Major Adverse Events	Days Post-procedure
Symptomatic PE: treated by a change in study medication	1
Clinically driven reintervention for occlusion (associated with edema and a pre-intervention INR of 1.1): required additional stent placement	155
30-day Clinical Success	**Days Post-procedure**
Technical placement failure: caudal end of stent in obturator vein instead of common femoral vein, required additional stent placement	0
Unstable hip implant migrated into pelvis and collapsed the stented vessel, preventing flow through the stent	20

Clinical Outcome Measures

Clinical Symptoms Improved Following Stent Placement





Conclusions

- VIVO-EU included patients and lesions representative of the "real world" population with iliofemoral venous outflow obstruction
- Zilver Vena Venous Stent placement resulted in a greater than 100% luminal diameter improvement immediately post-procedure
- Based on interim analysis, venous clinical symptoms improved following treatment, suggesting that the stent is beneficial to patients