Patency Rates and Clinical Results of the VENOVO® Venous Stent

Data from the Arnsberg Venous Registry

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Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

1. Honoraria for lectures: CR Bard, Veniti, AB Medica, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Veryan

2. Honoraria for advisory board activities: Veniti, Optimed GmbH, Straub Medical, Biotronik, Veryan, Boston Scientific

3. Participation in clinical trials: Biotronik, CR Bard, Veryan, Straub Medical, Veniti, TVA Medical, Boston Scientific, LimFlow

4. Research funding: Biotronik, Boston Scientific, Veryan, Veniti, AB Medica

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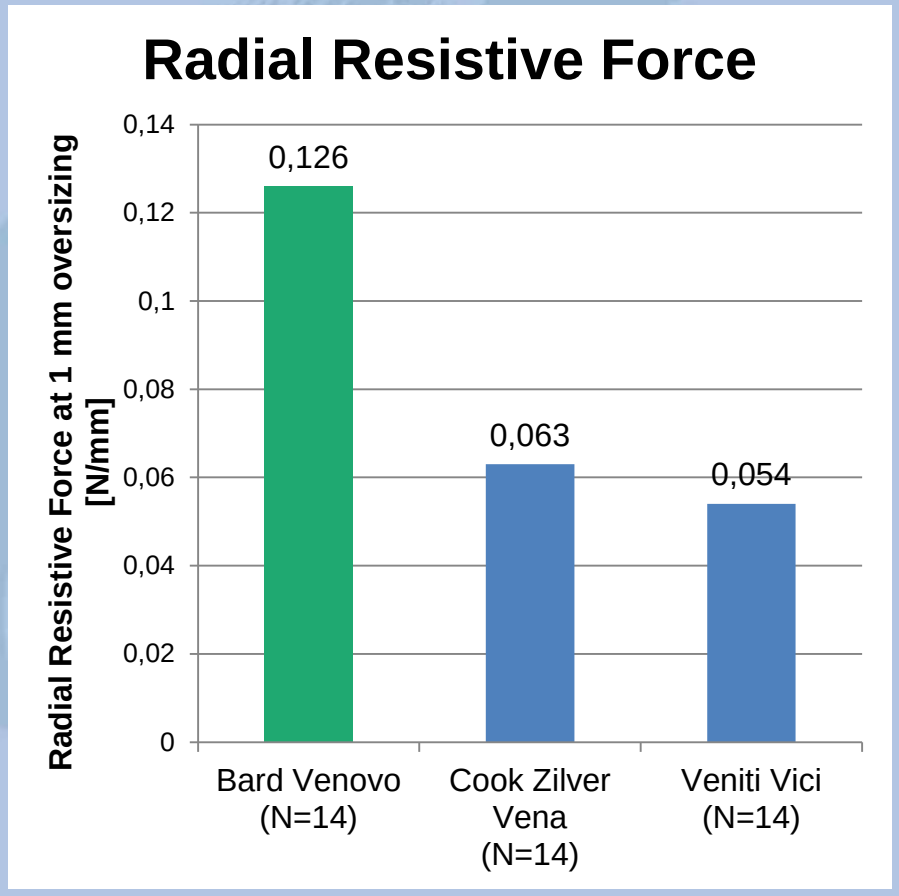
The opinions and clinical experiences presented herein are for informational purposes only. The results from these case studies may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes. This physician has been compensated by Bard Peripheral Vascular.

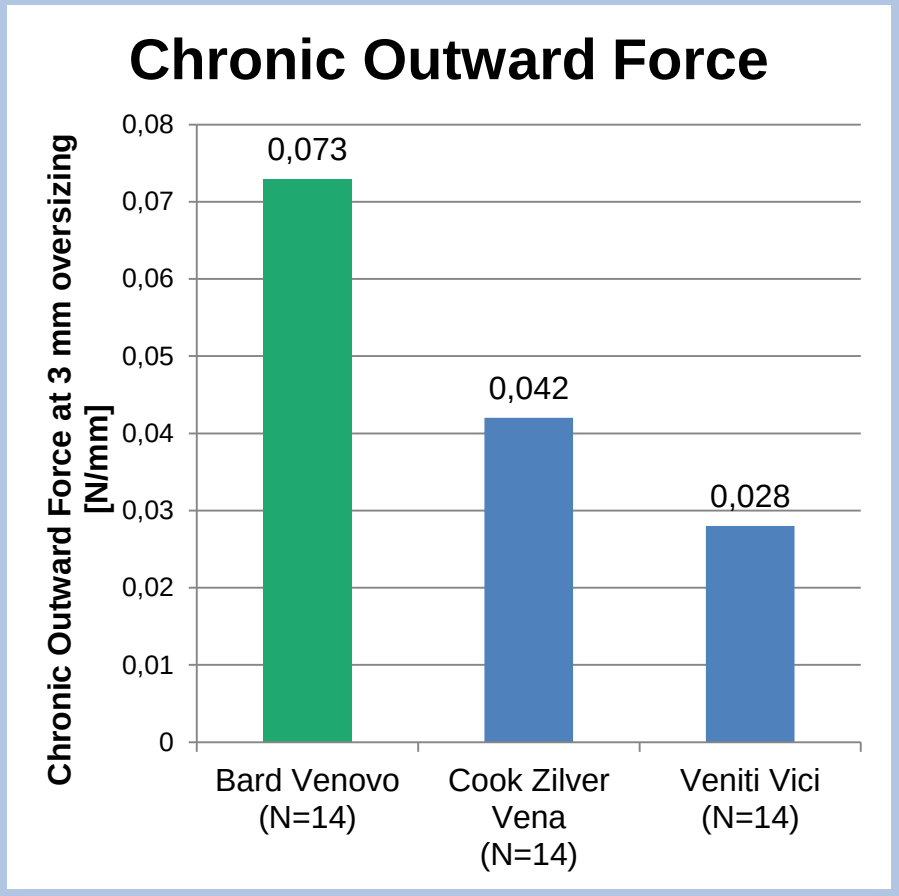
VENOVO® Venous Stent System

- Self-expanding nitinol
- Dedicated design for venous vessels
- 6 markers at each end (3 nitinol, 3 tantalum)
- Ends flared 3mm to ensure wall apposition
- Stent Diameters: 10, 12, 14, 16, 18, 20 mm
- Stent Lengths: 40-160 mm (in 20 mm increments)
- 8-10 F sheath depending on device diameter

- Tri-axial delivery system
- .035” OTW
- Dual-speed deployment thumbwheel
- Ergonomic handle

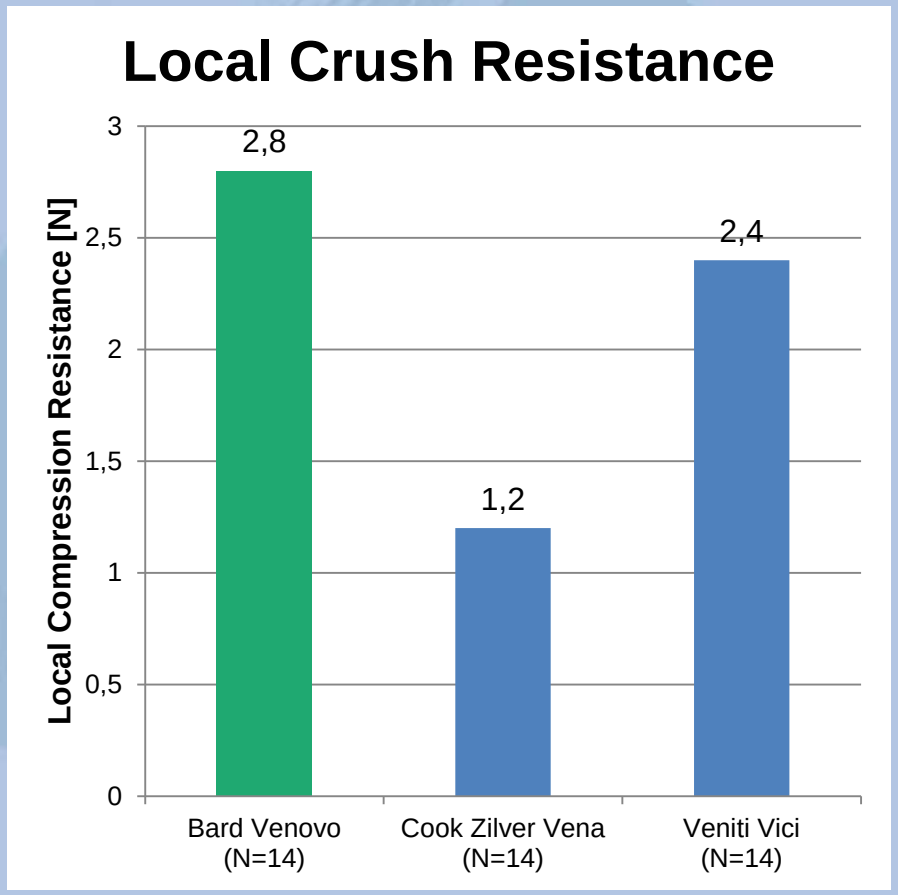
Bench Testing

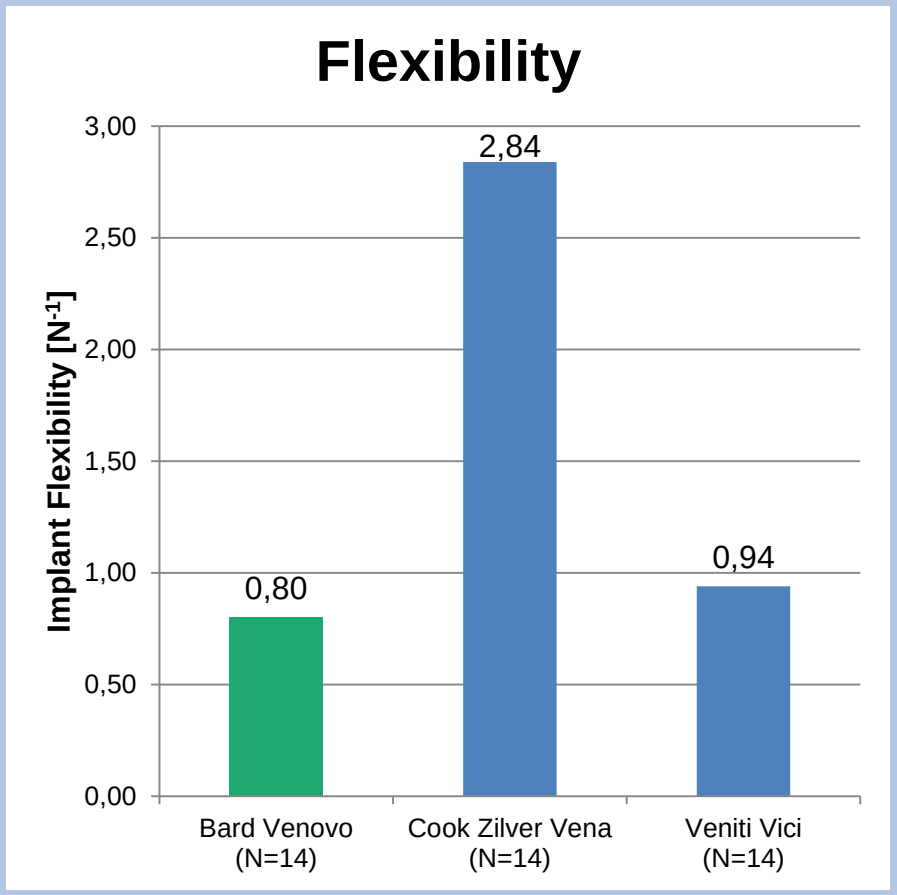




Data on file at Bard Peripheral Vascular, Inc., Tempe, AZ. Bench testing may not be indicative of clinical performance. Different test methods may yield different results.

Bench Testing





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Arnsberg Venous Registry

80 patients in VENOVO® cohort analysis

Objective	Assess safety & effectiveness in achieving patency of target venous lesion through 36 months post stent placement in patients with non thrombotic iliac vein lesions and post thrombotic iliac vein lesions.
Effectiveness	Primary Patency @ 12-M // Clincal outcome @ 12 -M
Principle Investigators	▪ Dr. Michael Lichtenberg ▪ Dr. Rick de Graaf
Study Design	Ongoing prospective, single arm, single center non-randomized registry **FU 1 (4 weeks), FU 2 (6 months), FU 3 (12 months),** FU 4 (24 months), FU 5 (36 months)
Patient Population	Subjects with clinically significant chronic non-malignant obstruction of the iliofemoral venous segment

Study is sponsored by German Venous Center Arnsberg

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Clinical Assessment

http://www.veinforum.org/uploadDocs/1/Revised-VCSS---June-2010.pdf

NAME:

		LEFT						RIGHT				
	Initial	Pre-Op	3-4 Days	3-4 Weeks	3-4 Months	1 Year	Initial	Pre-Op	3-4 Days	3-4 Weeks	3-4 Months	1 Year
DATE:												
CEAP (0-6)												
Fatigue: (Y/N)												
VCSS (0-3 Each)												
Pain												
Varicose Vein												
Venous Edema												
Pigmentation												
Inflammation												
Induration												
Active Ulcers												
Ulceration Duration												
Active Ulcer Size												
Compressive Therapy												
Total												
Complications: Blank (none) to 3 (severe)												
Hyperpigmentation												
Phlebitis												
Paresthesia												
Erythema												
Ecchymosis												
Infection												
Thermal Injury												
Other												
Patient Satisfaction: (None/Partly/Very)												
Varicose Veins:(None/ Residual/New/Recur)												
Outcome:(Not successful/ Successful/N/A)												

www.veinforum.org

Demographics/Medical History

Demographics/ Comorbidity	No. (%)
Age	57 (19-89)
Male	35 (44%)
Female	45 (56%)
Post-thrombotic	**50 (63%)**
Non-thrombotic	**30 (37%)**
Prev. PE	8 (10%)
Prev. DVT	43 (48%)
High Blood Pressure	40 (50%)
Renal Disease	6 (8%)
Stroke	3 (3%)
Cancer	9 (11%)
Diabetes	11 (14%)
Smoker	13 (16%)

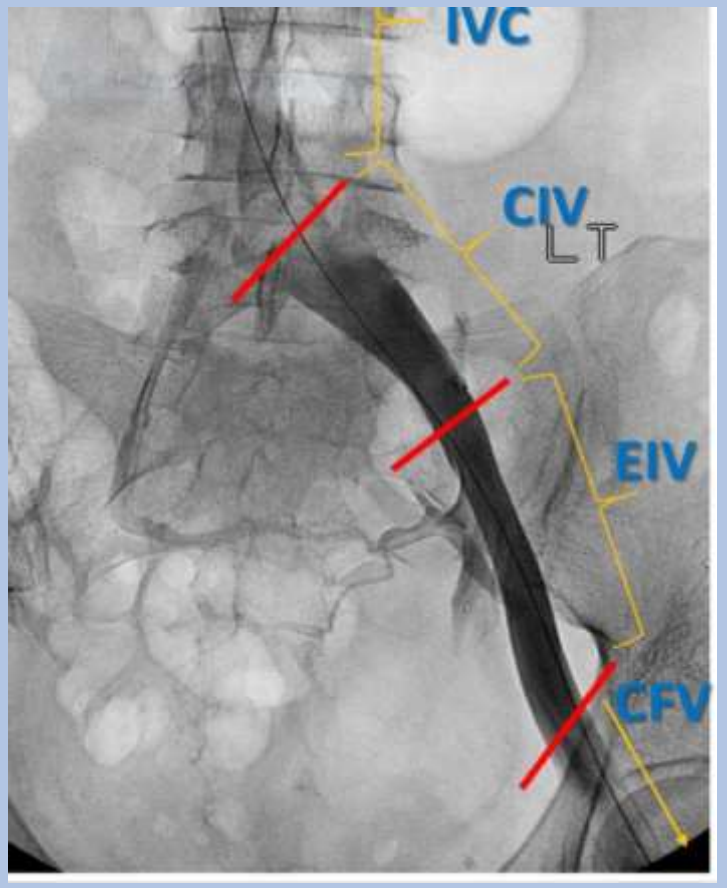
CEAP Score, prior stent	No. (%)
1	0 (0%)
2	1 (1%)
3	41 (51%)
4	28 (36%)
5	8 (10%)
6	2 (2%)
Signs/Symptoms prior stent	**No. (%)**
Pain (incl. venous claudication)	78 (98%)
Varicose Veins	63 (79%)
Edema	62 (78%)
Pigment Changes	41 (51%)
Ulcers	10 (8%)
Use Compression Stockings	68 (85%)

48% > CEAP C4

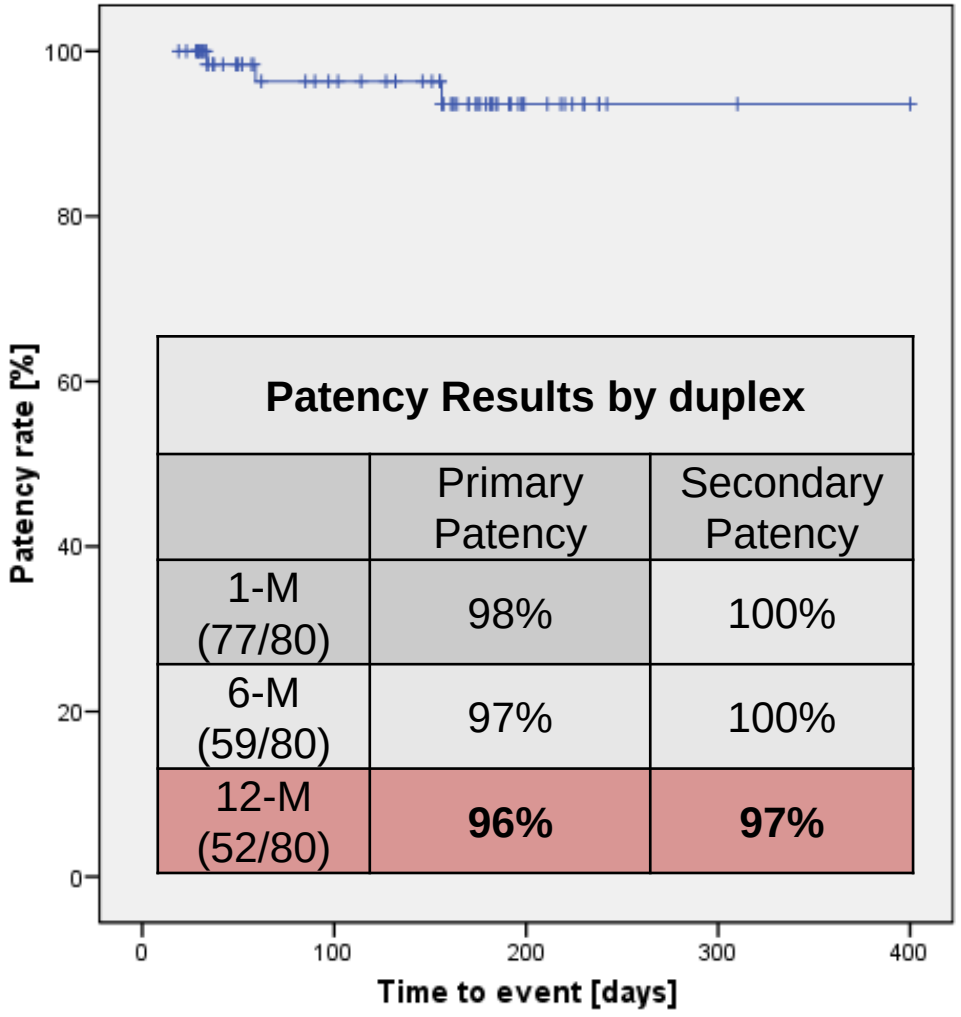
Target Lesion Location

Target Limb	N=80 (100 %)
Both	6 (7%)
Left	56 (70 %)
Right	18 (23 %)

Left	56 (70%)
CIV	30 (38%)
CIV + EIV + CFV	18 (22%)
EIV + CFV	5 (6%)
CFV	3 (4%)
Right	**18 (23%)**
CIV	3 (4%)
CIV + EIV + CFV	14 (18%)
EIV + CVF	1 (1%)



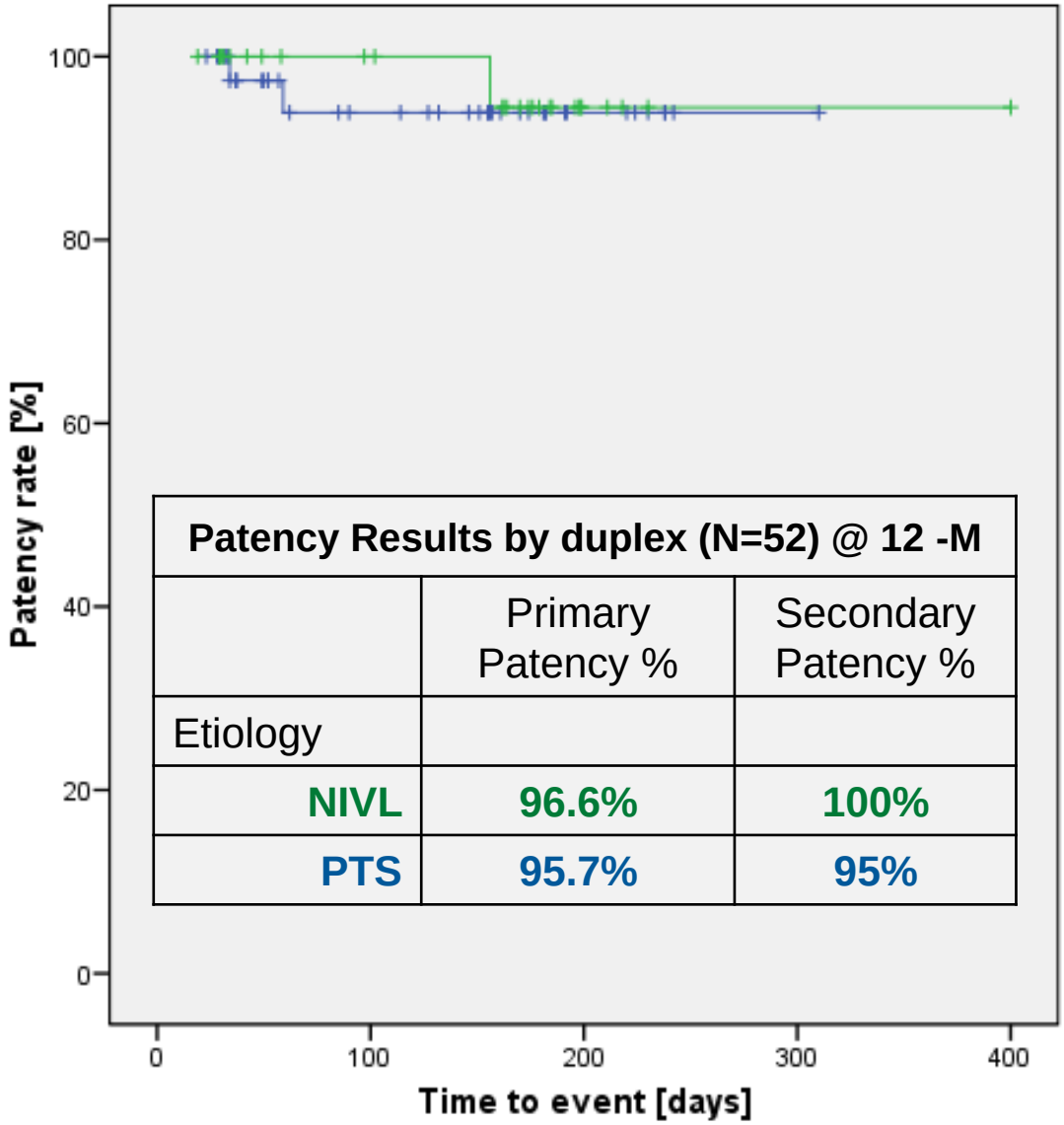
Patency Analysis (restenosis < 50% by duplex)



Patency Results by duplex

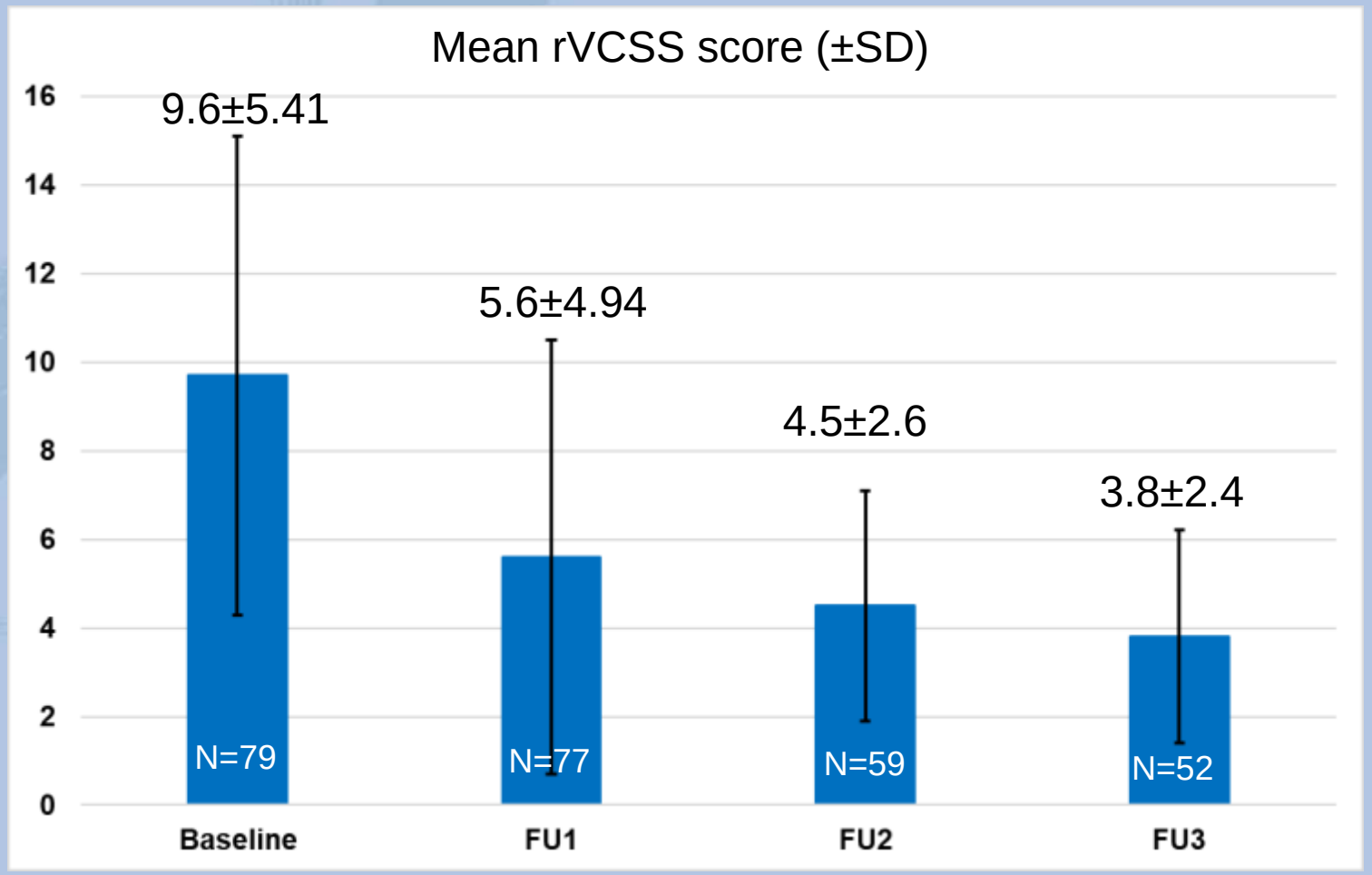
	Primary Patency	Secondary Patency
1-M (77/80)	98%	100%
6-M (59/80)	97%	100%
12-M (52/80)	**96%**	**97%**

Patency Analysis NIVL vs. PTS

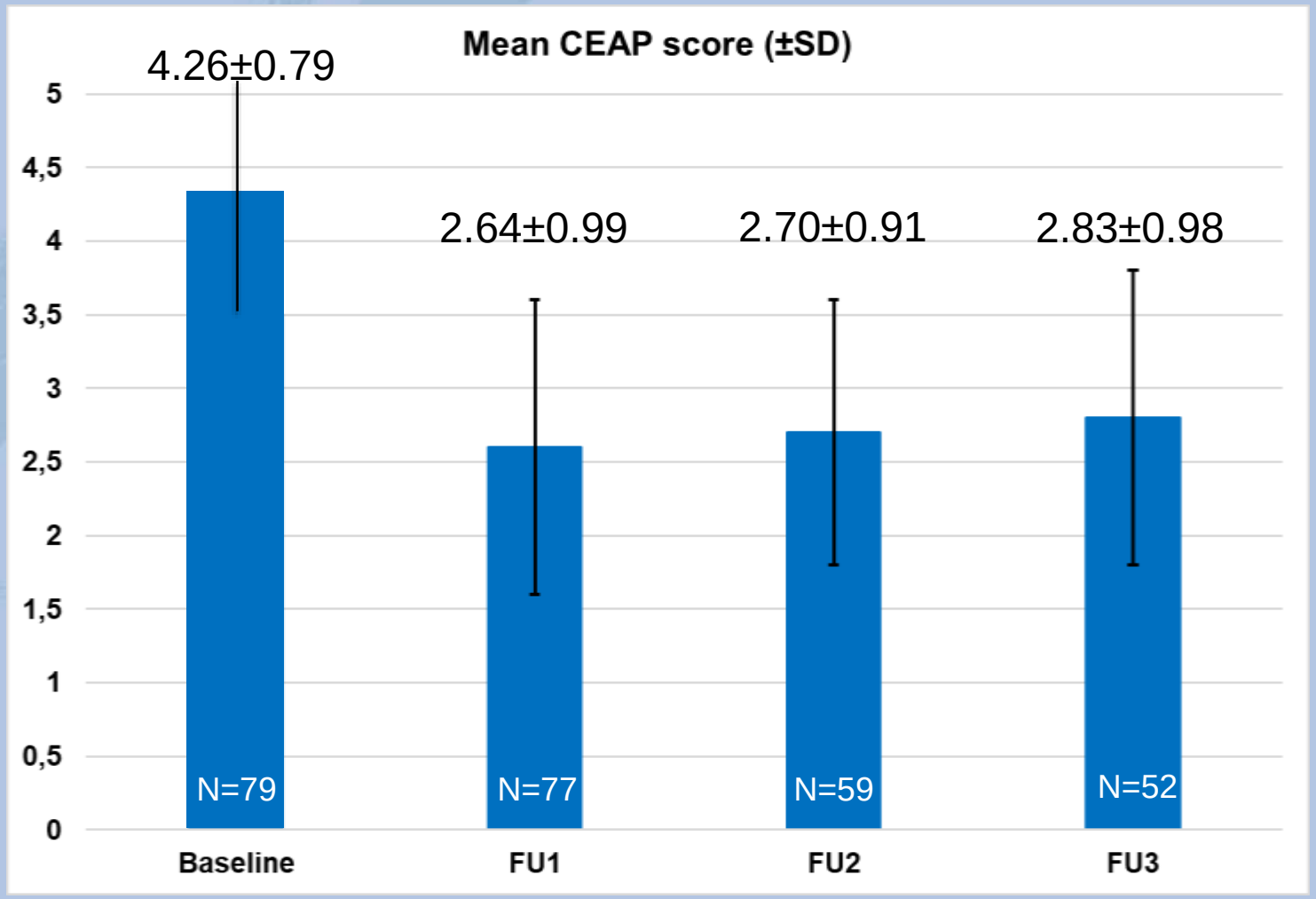


--- NIVL
--- PTS

Patency Results by duplex (N=52) @ 12 -M		
	Primary Patency %	Secondary Patency %
Etiology		
NIVL	**96.6%**	**100%**
PTS	**95.7%**	**95%**



- 51% had “substantial clinical improvement” (rVCSS ≥2) @12-M
- Venous claudication and persistent swelling improved
- 8/10 venous ulceration were healed @ 12 - M



8/10 venous ulceration were healed @ 12 - M

Registered Complications

Adverse Event	No. (%)
Access-site complications	4/80 (5%)
Hematoma	3/80 (4%)
Infection	1/80 (1%) After AV fistula
Stent early reocclusion (within 3 days)	3 (4%)
Stent migration	0 (0%)
Clinical sig. pulmonary embolism	0 (0%)
Venous rupture	0 (0%)
Blood transfusion	2/80 (3%)

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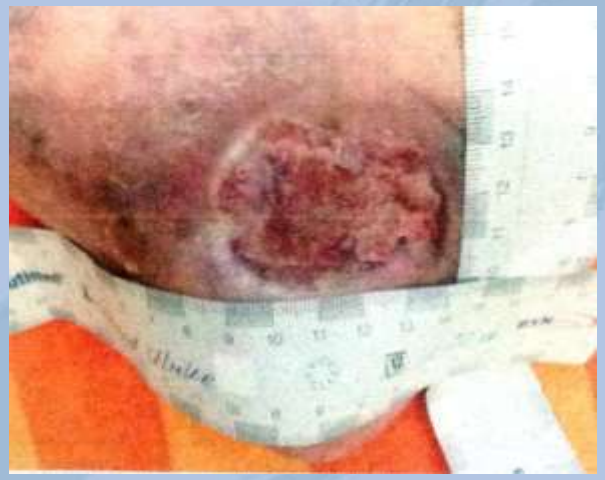
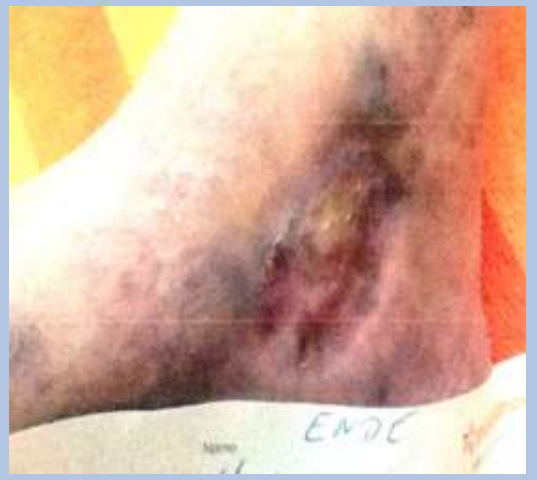
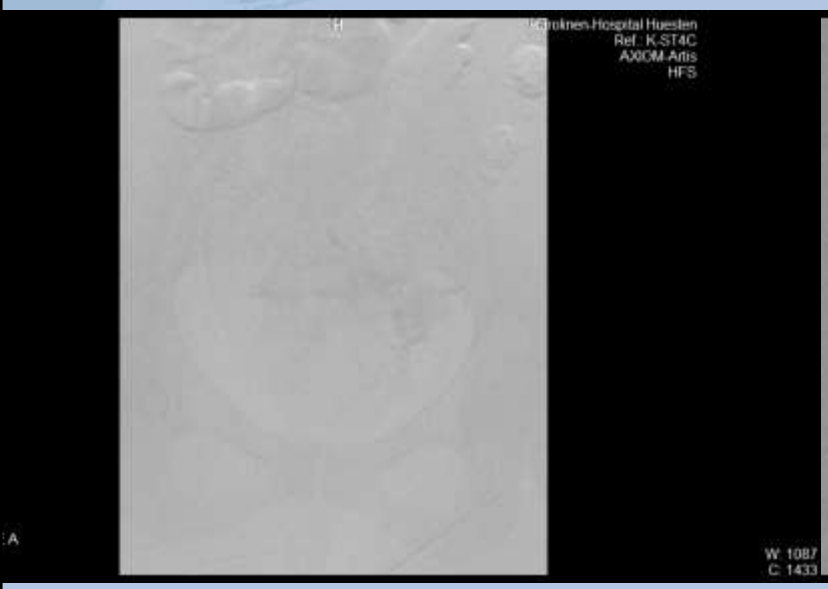
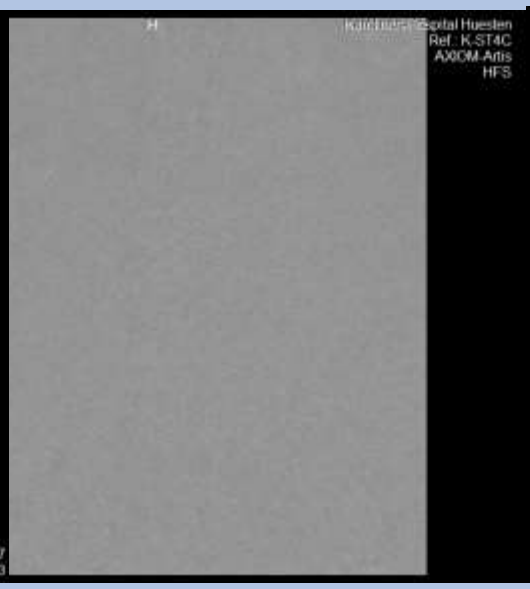
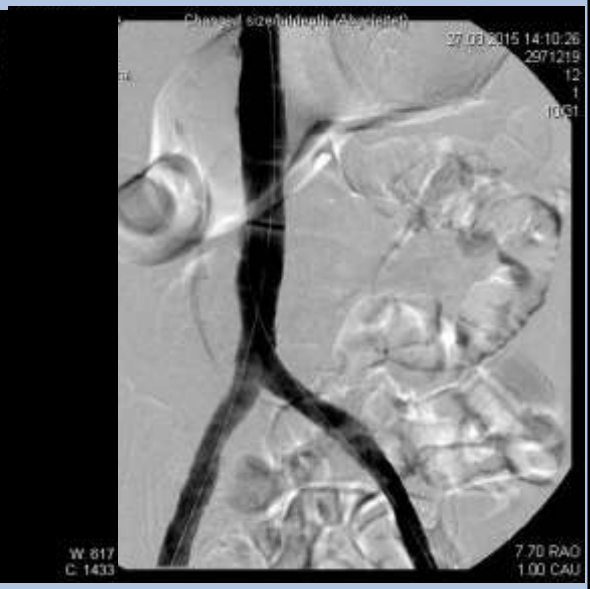
Patient example











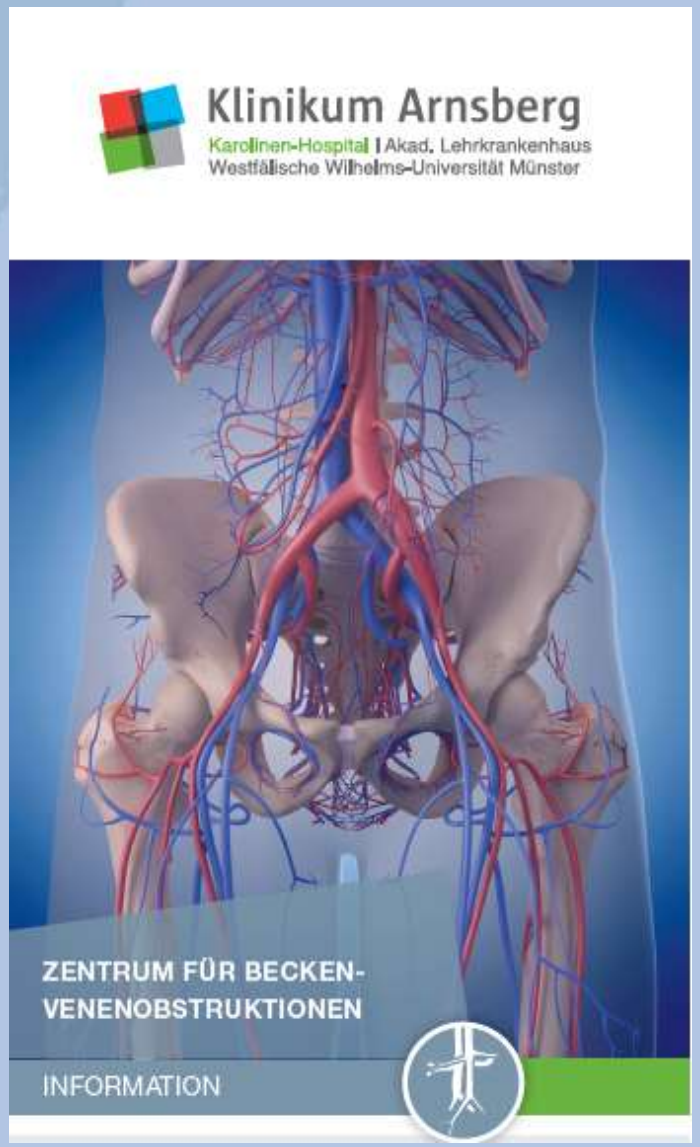
Conclusions

- Initial 6 and 12-Month efficacy data in the Arnsberg Registry are very promising:

	NIVL	PTS
Primary patency:	96.6%	95.7%
Secondary Patency:	100%	95%

- Safety data raise no concerns
- Patients feel substantially better
  - VCSS dropped from 9.6 to 3.8, CEAP from 4.26 to 2.83, after 12 months
  - Especially improvement of venous claudication and ulceration (8/10)
- Venous anatomy and disease require dedicated venous stents

Thank you for your attention



United States

The VENOVO® Venous Stent is currently undergoing an investigational device exemption (IDE). This device is limited by United States law to investigational use only. This device is not available for sale or distribution in the U.S.

International

Indication 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 recommended antiplatelet and/or 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. 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.

Precautions: The device is intended for use by physicians who have received appropriate training. During system flushing, observe that saline exits at the catheter tip. The delivery system is not designed for use with power injection systems. Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution. Prior to stent deployment, remove slack from the delivery system catheter outside the patient. If excessive force is felt during stent deployment, do not force the delivery system. Remove the delivery system and replace with a new unit. Store in a cool, dark, dry place. Do not attempt to break, damage, or disrupt the stent after placement.

Potential Complications and Adverse Events: Allergic/anaphylactic reaction; Amputation; Aneurysm; Arteriovenous fistula; Death related/unrelated to procedure; Dissection; Embolization; Extravasation; Fever; Hemorrhage/bleeding requiring a blood transfusion; Hematoma; Hypotension/hypertension; Incorrect positioning of the stent requiring further stenting or surgery; Intimal injury/dissection; Ischemia/infarction of tissue/organ; Local infection; Malposition (failure to deliver the stent to the intended site); Open surgical repair; Pain; Pulmonary embolism; Pseudoaneurysm; Renal failure; Respiratory arrest; Restenosis; Rupture; Septicemia/bacteremia; Stent Fracture; Stent Migration; Vasospasm; Venous occlusion/thrombosis/restenosis

Please consult package insert for more detailed safety information and instructions for use.

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