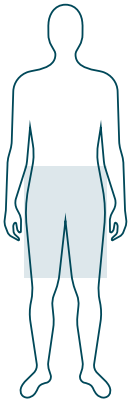
optimed

sinus-Venous

DEDICATED VENOUS EXCELLENCE
FOR ILIOFEMORAL STENTING



venous

10F
Ø device

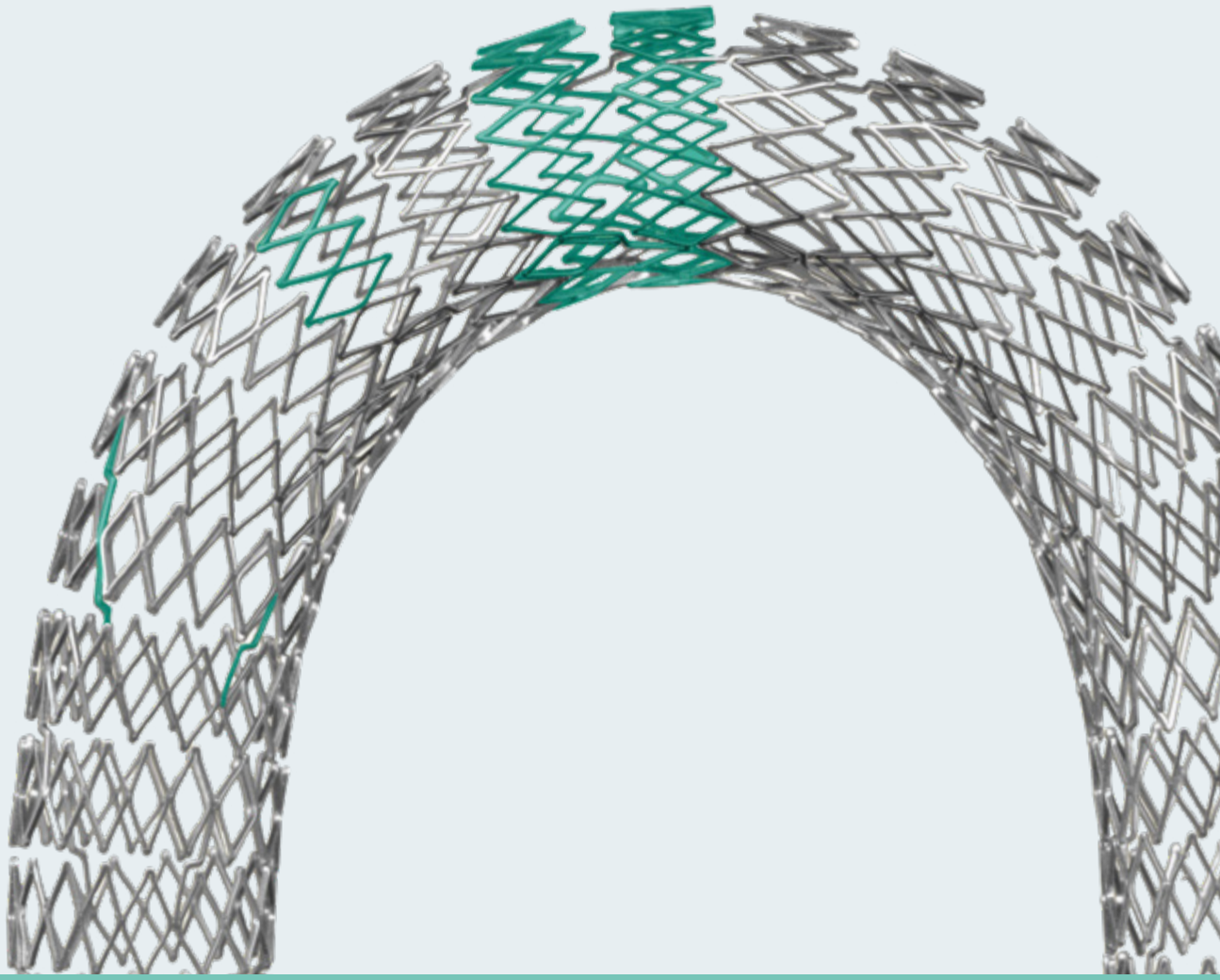
.035i
guide wire

hybrid design

NiTi
nitinol stent

radioopaque markers

anti-jump technique



sinus-Venous

DEDICATED VENOUS EXCELLENCE

THE SINUS-VENOUS SETS NEW STANDARDS IN TERMS OF STENT DESIGN

A self-expanding nitinol stent with a **unique** ring-design that combines **independent closed-cell ring segments** with highly flexible **Flash-Links.**

INTENTED USE

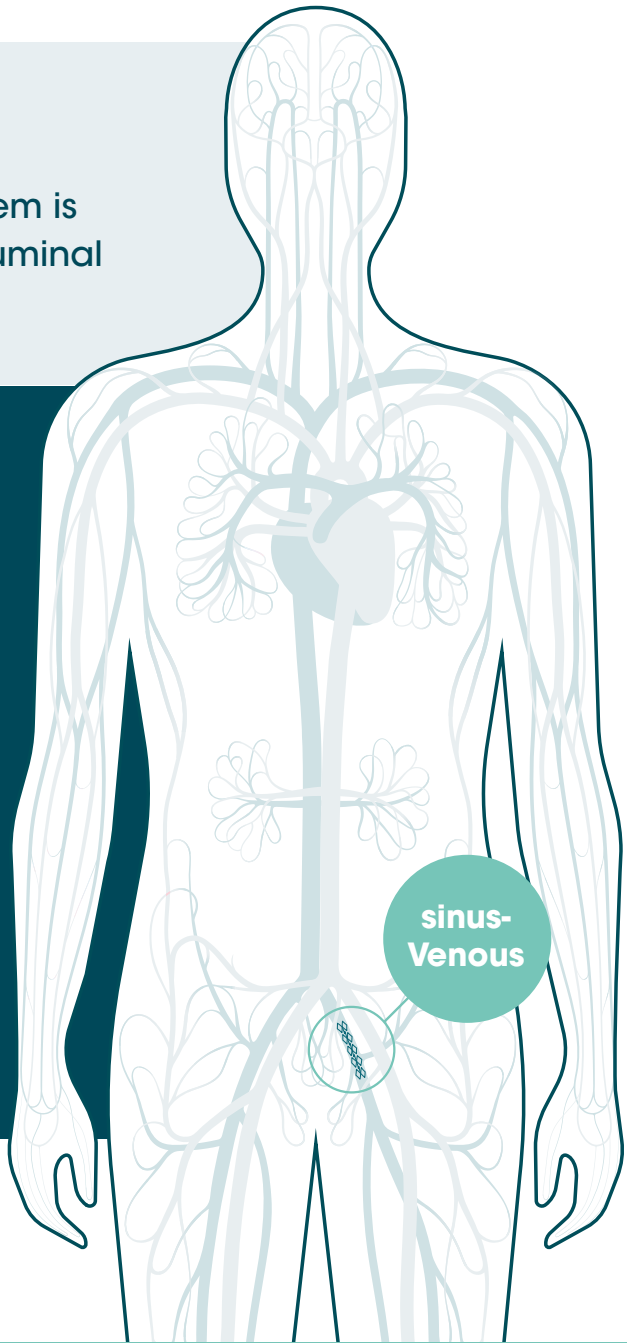
The sinus-Venous vascular stent system is intended to improve and maintain luminal diameter in the iliofemoral veins.

FEATURES

High radial force, comparable to closed-cell nitinol stents

Flexible open-cell design for a very good vessel adaptation

Anti-Jump Technology™ to avoid stent migration during the stent deployment

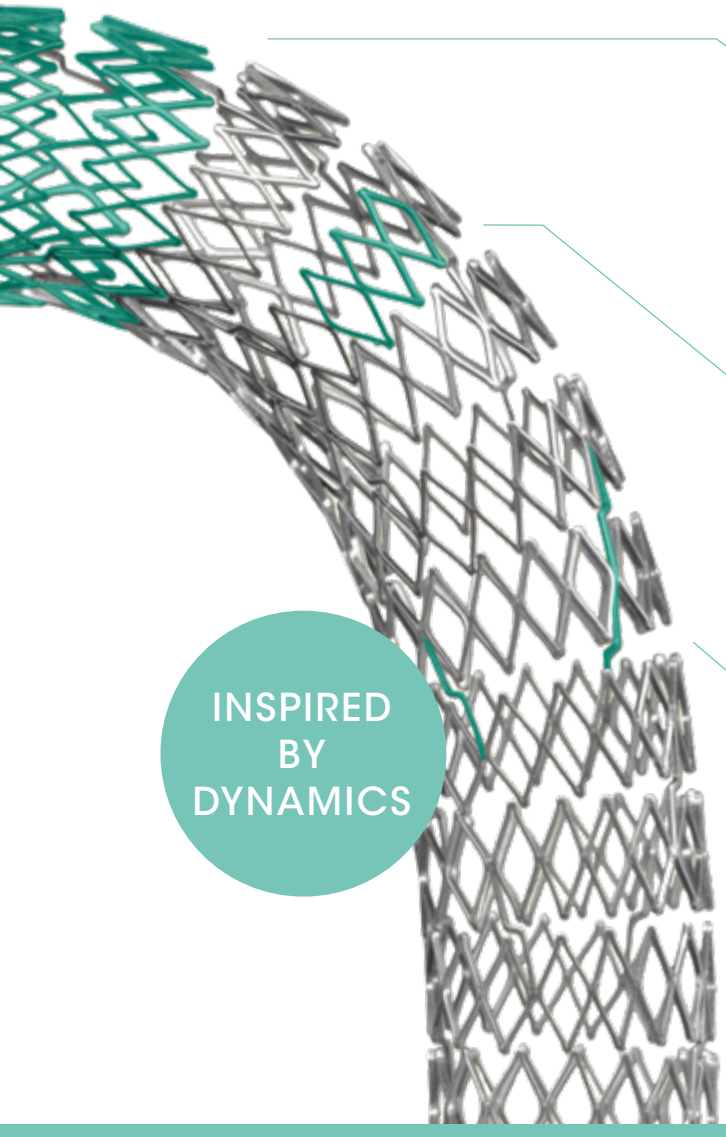


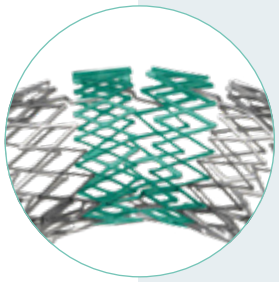
DESIGNED FOR DEDICATED VENOUS POWER & FLEXIBILITY

Fields of application:

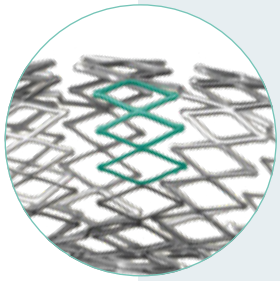
- Recurring iliofemoral vein thrombosis
- Post thrombotic syndrome (PTS)
- Deep vein thrombosis (DVT)
- Tumor-related stenoses

- hybrid design
- radioopaque markers
- anti-jump technique™
- electro-polishing
- braided sheath
- atraumatic soft-tip

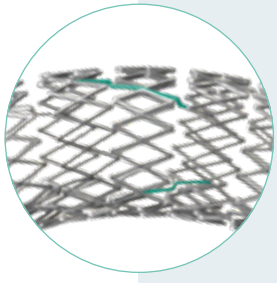




Independent Ring System
- High vessel wall covering
- Even force distribution



Power Diamonds
- Atraumatic rounded edges
- High radial force



Flash-Links
- Highly flexible
- High resistance
- 90 degree offset for each ring segment

STEVECO Trial

STENT VERSUS CONSERVATIVE TREATMENT IN PATIENTS WITH DEEP VENOUS OBSTRUCTION

PRIMARY MEASUREMENT

- VEINES-QoL (Quality of life) changes @ 12 months
- VEINES-Sym (Symptoms)

SECONDARY MEASUREMENTS

- QoI @ 6 weeks
- DVT recurrence
- Working days lost
- For stent Group only: Vessel Patency (0.5, 1.5, 3, 6, 12 months)
- For stent Group Only: Serious adverse events and related actions

A randomized controlled trial comparing venous stenting to conventional treatment, that measures the Quality of Life of the patient[1]

KEY FINDINGS AT A GLANCE: 12 MONTHS FU

Primary Patency
91.4%

Assisted Primary Patency
94.2%

Secondary Patency
97.2%

OBJECTIVE

Deep venous obstruction (DVO) presents a great burden on the healthcare system and patients' quality of life (QoL). Case series show stenting is **safe and effective;** however, most studies lack control groups and QoL changes have not been compared with conventional treatment.

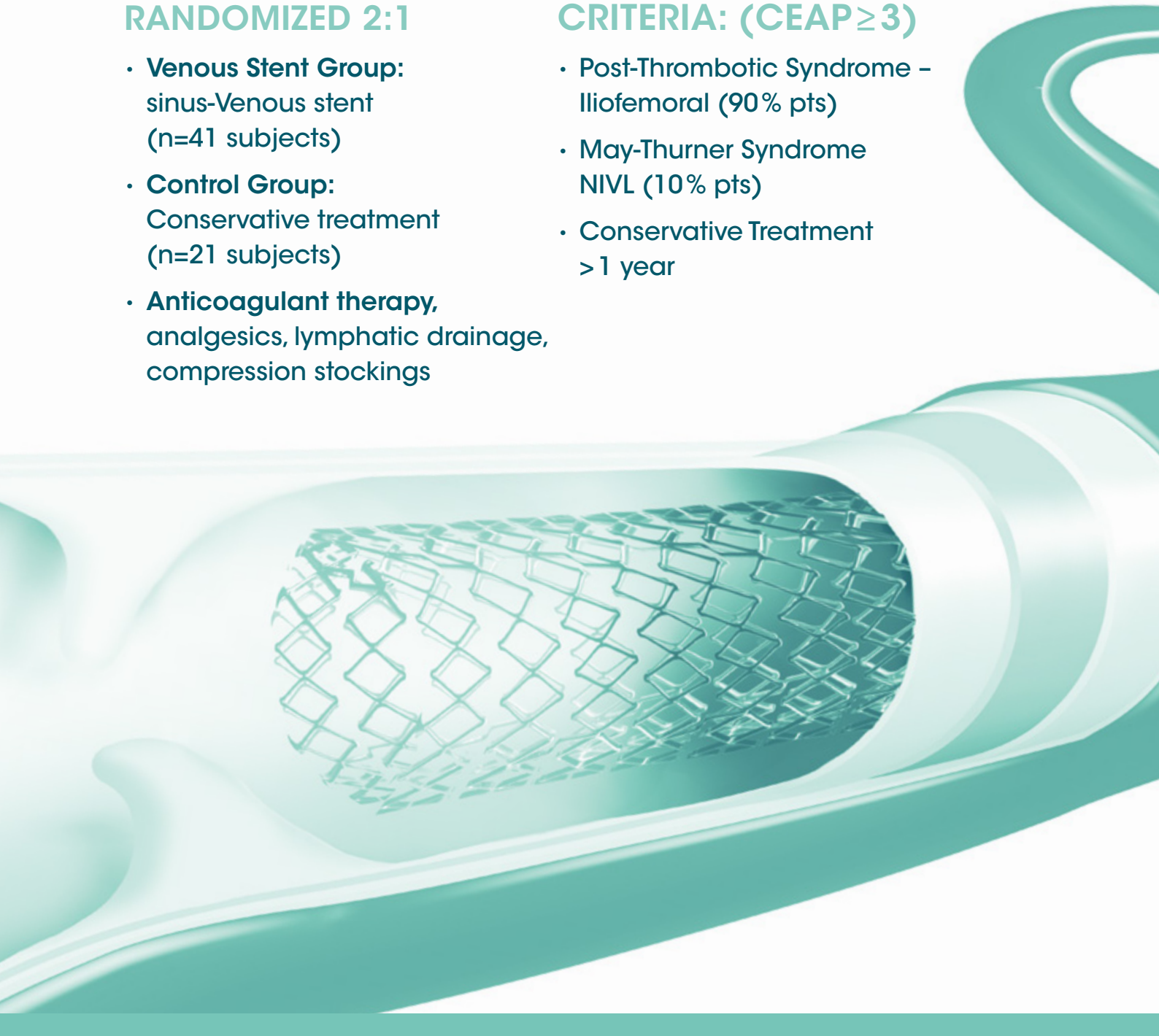
The aim of the STEVECO trail was to assess the **difference in QoL changes** from baseline to 12 months between stent and conventionally treated patients with DVO.

TREATMENT GROUPS: RANDOMIZED 2:1

- **Venous Stent Group:** sinus-Venous stent (n=41 subjects)
- **Control Group:** Conservative treatment (n=21 subjects)
- **Anticoagulant therapy,** analgesics, lymphatic drainage, compression stockings

PATIENT INCLUSION CRITERIA: (CEAP≥3)

- Post-Thrombotic Syndrome – Iliofemoral (90% pts)
- May-Thurner Syndrome NIVL (10% pts)
- Conservative Treatment >1 year



RESULTS

Table 1:

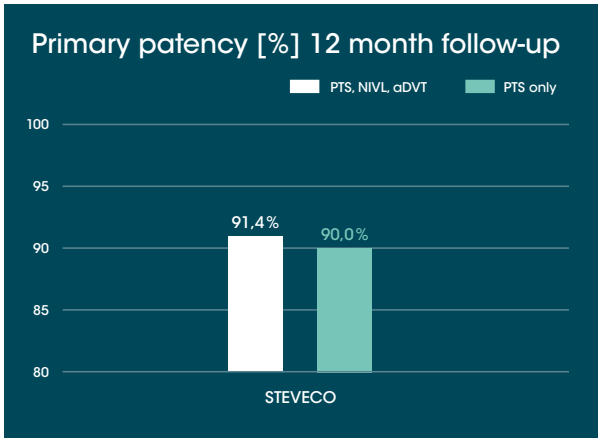


Table 1:

12 month follow-up of Primary patency in all patients (PTS, NIVL, aDVT) compared to PTS patients only.

Table 2:

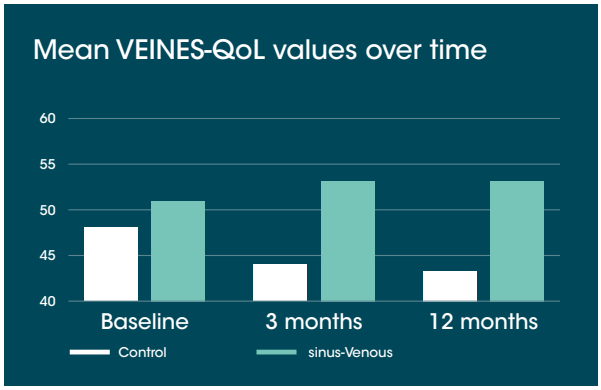
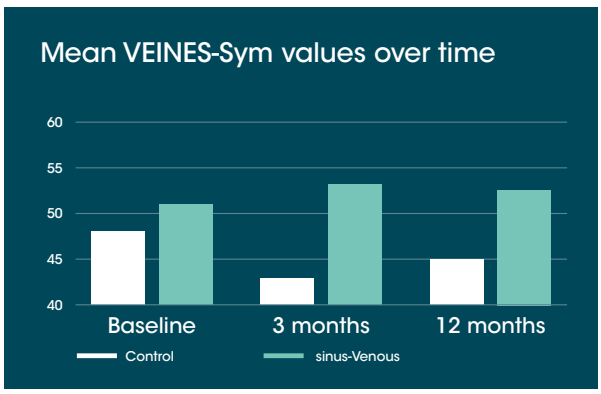


Table 3:



Tables 2 & 3:

Mean values for VEINES-Sym and VEINS-QoL at baseline, 3-months and 12-months.*

VEINES-QoL/Sym: Venous Insufficiency Epidemiological and Economic Study-Quality of Life/ Symptoms - higher score indicates better QoL.

SOURCES

1) Shekarchian, Soroosh et al. "Quality of Life after Stenting for Iliofemoral Venous Obstruction: A Randomised Controlled Trial with One Year Follow Up." European journal of vascular and endovascular surgery : the official journal of the European Society for Vascular Surgery, S1078-5884(23)00610-X. 28 Jul. 2023, doi:10.1016/j.ejvs.2023.07.044

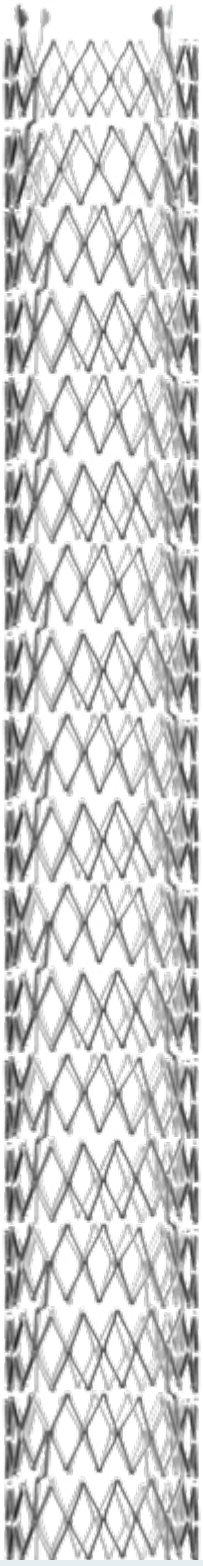
2) Presentation "A randomized controlled trial comparing venous stenting with conservative treatment in patients with deep venous obstructions STEVECO trial" – presented by Houman Jalaieduring LINC 2022 (6th June 2022)

CONCLUSION

Symptomatic patients with DVO who received dedicated venous stents had **significantly higher:**

- VEINES-QoL/Sym scores
- pain disability index (PDI)
- venous clinical severity score (VCSS)

at 12 months compared with the control group[1,2,3] but the between-group difference was lower than the pre-specified clinically relevant QoL difference of at least 14 points.



READ THE FULL STEVECO PAPER ONLINE NOW...

featuring the optimed sinus-Venous vascular stent system

...AND DISCOVER THE TOPOS TRIAL

featuring the optimed sinus-Obliquus and sinus-Venous / sinus-XL Flex vascular stent systems

Prospective single-arm trial at 7 experienced European centers with 24 months follow-up

3) van Vuuren, Timme Maj et al. "A randomised controlled trial comparing venous stenting with conservative treatment in patients with deep venous obstruction: research protocol." BMJ open vol. 7,9 e017233. 11 Sep. 2017, doi:10.1136/bmjopen-2017-017233. Data has been provided by paper Shekarchian, Soroosh et al

*Exact data on file. Graphic does not represent full decimal points.

10F / 100cm delivery system

Adapted to 0.035 inch guide wire

Box / 1 unit

ORDER CODES

Lengths

Ø (mm)	60	80	100	120	150
Ø 10	8710-01-8060	8710-01-8080	8710-01-8100	8710-01-8120	8710-01-8150
Ø 12	8712-01-8060	8712-01-8080	8712-01-8100	8712-01-8120	8712-01-8150
Ø 14	8714-01-8060	8714-01-8080	8714-01-8100	8714-01-8120	8714-01-8150
Ø 16	8716-01-8060	8716-01-8080	8716-01-8100	8716-01-8120	8716-01-8150
Ø 18	8718-01-8060	8718-01-8080	8718-01-8100	8718-01-8120	8718-01-8150

LENGTHS

60 mm

80 mm

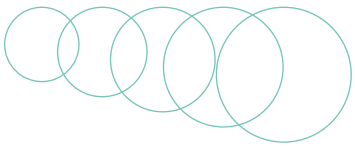
100 mm

120 mm

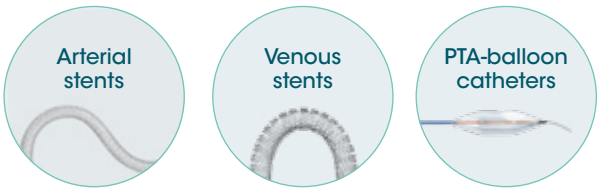
150 mm

LARGE DIAMETERS up to ø 18mm:

10 – 18 mm
in 2 mm steps



FOR MORE VASCULAR INTERVENTION HIGHLIGHTS VISIT OUR WEBSITE



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CE 0124

Order Code 9997-0020EN
Rev. 08/2024 |