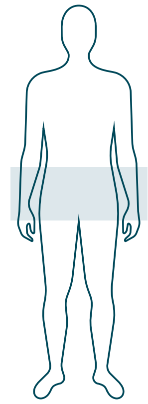
optimed

sinus-Obliquus

DEDICATED VENOUS EXCELLENCE

MASTERING ANATOMICAL CHALLENGES IN ILIAC STENTING



venous

10F
Ø device

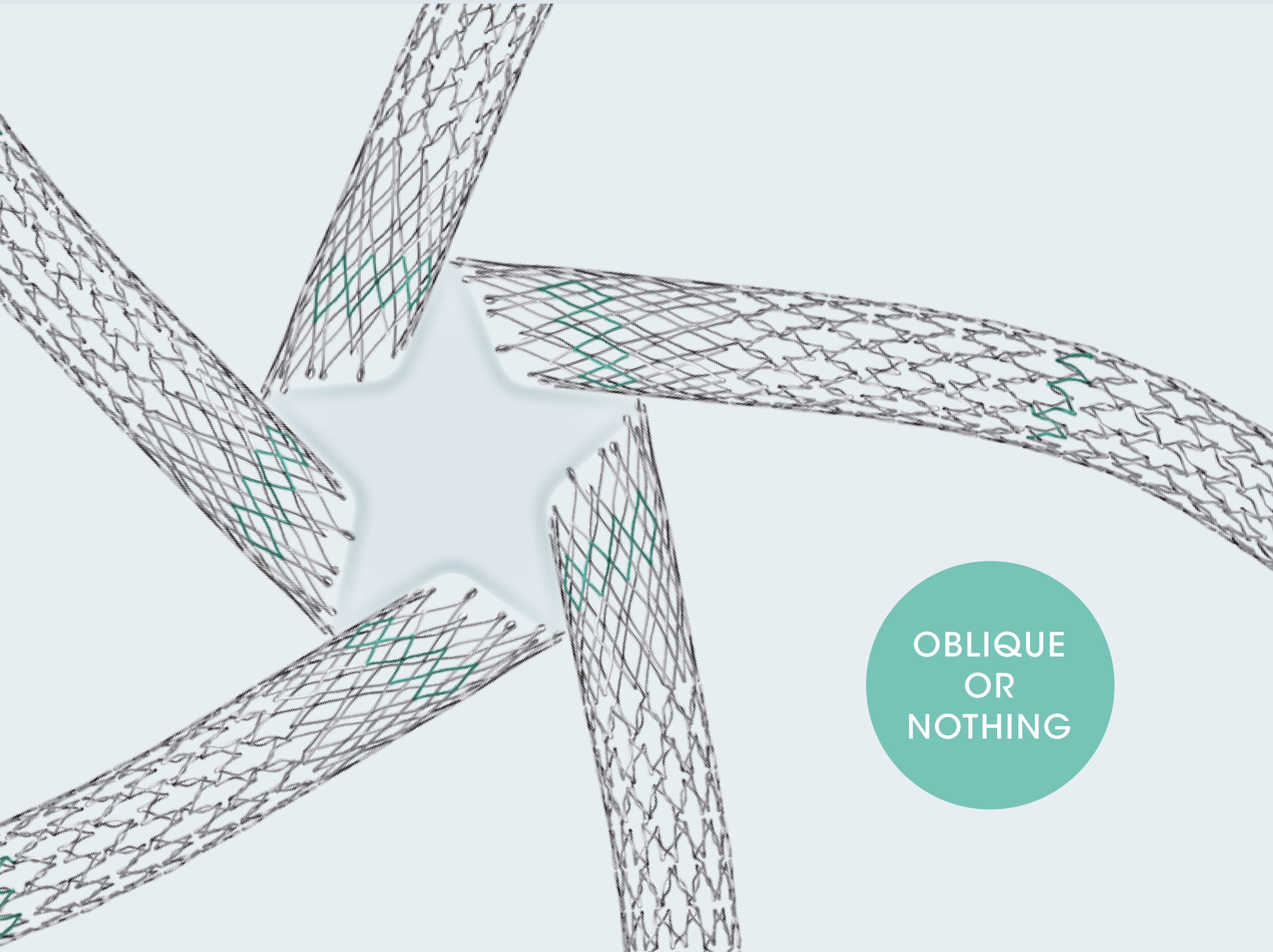
.035i
guide wire

hybrid design

NiTi
nitinol stent

radiopaque markers

anti-jump technique



OBLIQUE OR NOTHING

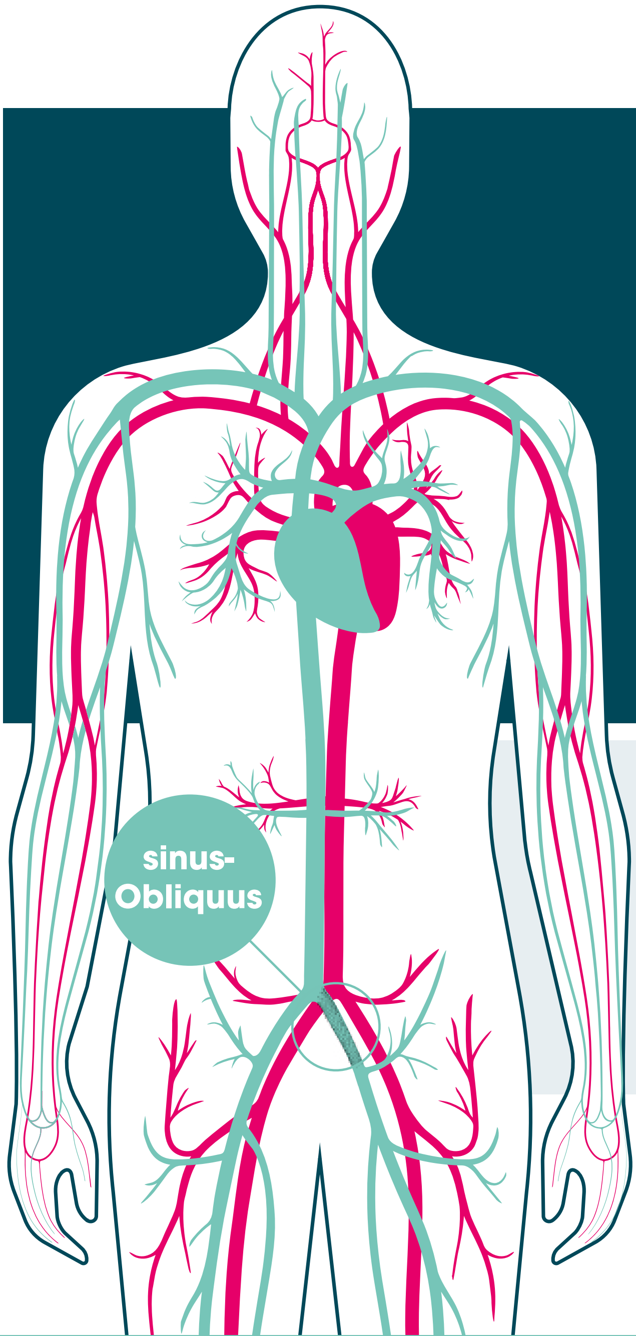
sinus-Obliquus

DEDICATED VENOUS EXCELLENCE

A NEW BENCHMARK IN STENT DESIGN

A self-expanding nitinol stent specifically designed to overcome all the challenges in stenting obstructions of the iliac vein - a hybrid design with three distinct segments combining ultra high radial force - flexibility and an excellent anatomical adaptation.

INSPIRED BY ANATOMY



FIELDS OF APPLICATION

- The perfectly adapted stent for the treament of the May Thurner syndrome
- Obstructions of the iliiac vein: NIVL (nonthrombotic iliac vein lesions), PTS (Post thrombotic syndrome), Deep vein thrombosis (DVT)

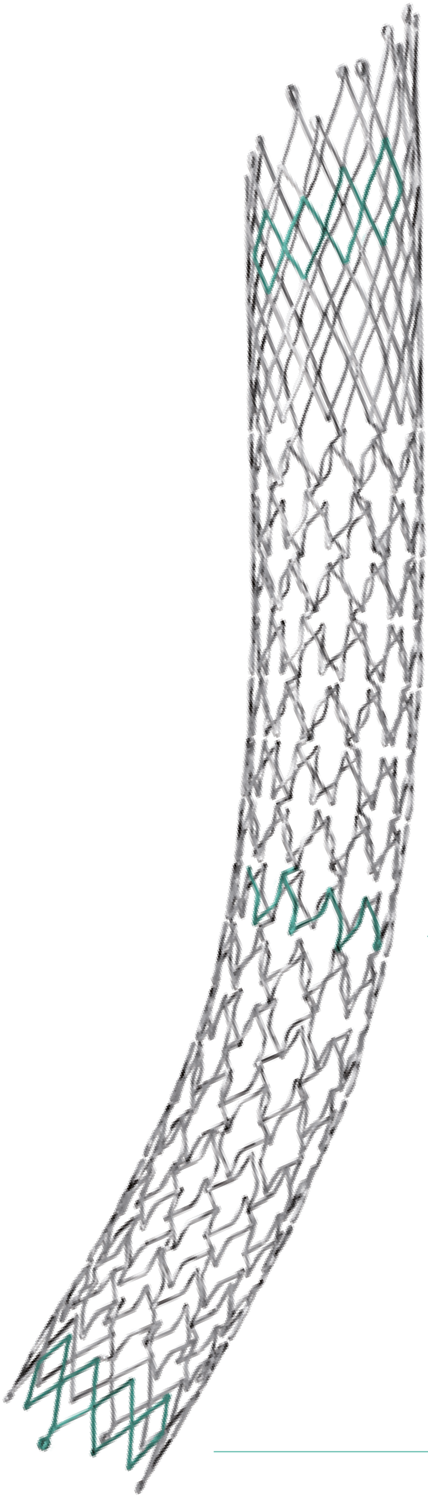
INTENDED USE

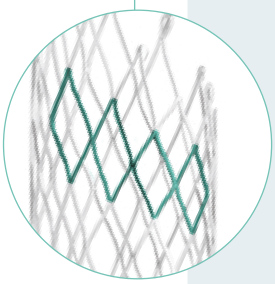
The sinus-Obliquus vascular stent system is intended to improve and maintain luminal diameter in the iliofemoral veins

Sources:
*Zhang X, Jing Y, Sang H, Chen Z, Sun Y, Li X. Long-term follow-up of the stenting across the iliocaval confluence in patients with iliac venous lesions. J Thromb Thrombolysis. 2019 Jan;47(1):134-139. doi: 10.1007/s11239-018-1757-4. PMID: 30328053.

DESIGNED FOR DEDICATED VENOUS POWER & OUTSTANDING ANATOMICAL ADAPTATION

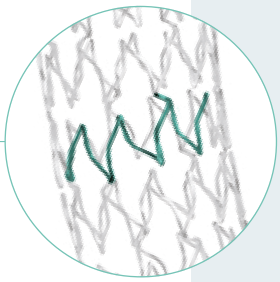
DEVELOPED TO REDUCE THE INCIDENCE OF CONTRALATERAL DEEP VEIN THROMBOSIS DUE TO ILIAC VEIN JAILING[*/**]





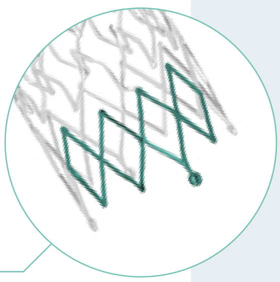
Power Crown

- Outstandingly high radial force to keep the vein open
- Oblique design adapted to the vessel anatomy at the bifurcation preventing protrusion into the vena cava or incomplete coverage of the obstruction point and thus reducing the risk for future reinterventions
- Maximal outflow on both sides



Smart Part

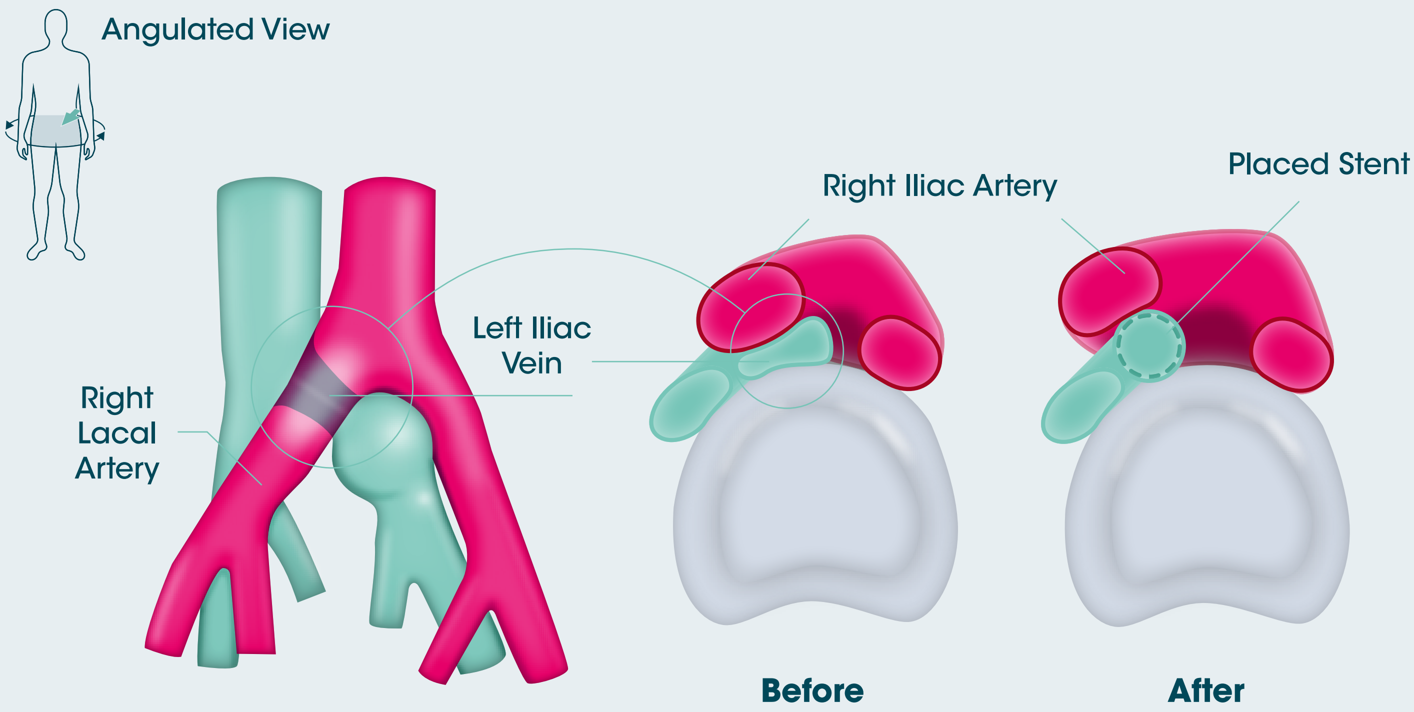
- Flexible middle segment made of open cells to ensure a high level of flexibility to adjust to the vessel anatomy and for a homogenous force distribution



Anchor Ring

- Closed-cell ring with high radial force that allows for fixation of the stent within the vessel to reduce the risk of stent migration
- Atraumatically rounded edges for reduced trauma to the vessel wall

**Duarte-Gamas L, Rocha-Neves JP, Pereira-Neves A, Dias-Neto M, Baekgaard N. Contralateral deep vein thrombosis after stenting across the iliocaval confluence in chronic venous disease - A systematic review. Phlebology. 2020 May;35(4):221-230. doi: 10.1177/0268355519889873. Epub 2019 Dec 2. PMID: 31793374.



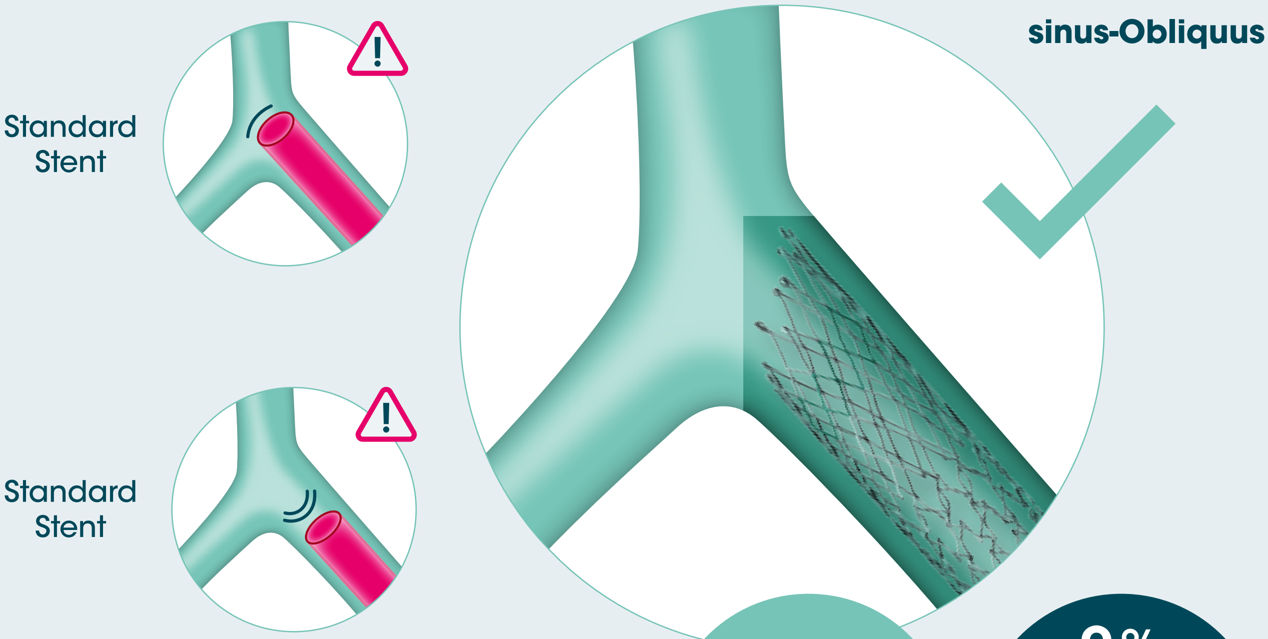
HIGH PERFORMANCE FOR SPECIAL REQUIREMENTS

EXPERIENCE THE DIFFERENCE

At least 50% of left-sided pelvic vein thrombosis cases are caused by obstructions due to May-Thurner Syndrome

In this anatomical anomaly the right common iliac artery overlies and compresses the left common iliac vein against the lumbar spine and at the same time exerts a pulsation force on the vein. Resulting turbulences facilitate the formation of Deep Vein Thrombosis (DVT).

Present therapies with conventional venous stents are satisfactory. However, when placed near the bifurcation, the distal end of the stent can protrude into the vena cava, causing a negative effect on the bloodflow. With an oblique stent design, optimed now offers an exceptional solution.



OBLIQUE OR NOTHING

0 %
Contralateral DVT development
after 24 months in the TOPOS study
- read more on page 8.

ENHANCED
ANATOMICAL ADAPTATION

EXPERIENCE THE DIFFERENCE

Very often it is not possible to achieve optimal vessel coverage using conventional stent designs.

In case the stent protrudes into the inferior vena cava, the distal stent end obstructs the bloodflow. In case the compressed vessel section is not completely covered by the stent, the obstruction persists. Both options are not ideal. The anatomy of the bifurcation requires a special approach.

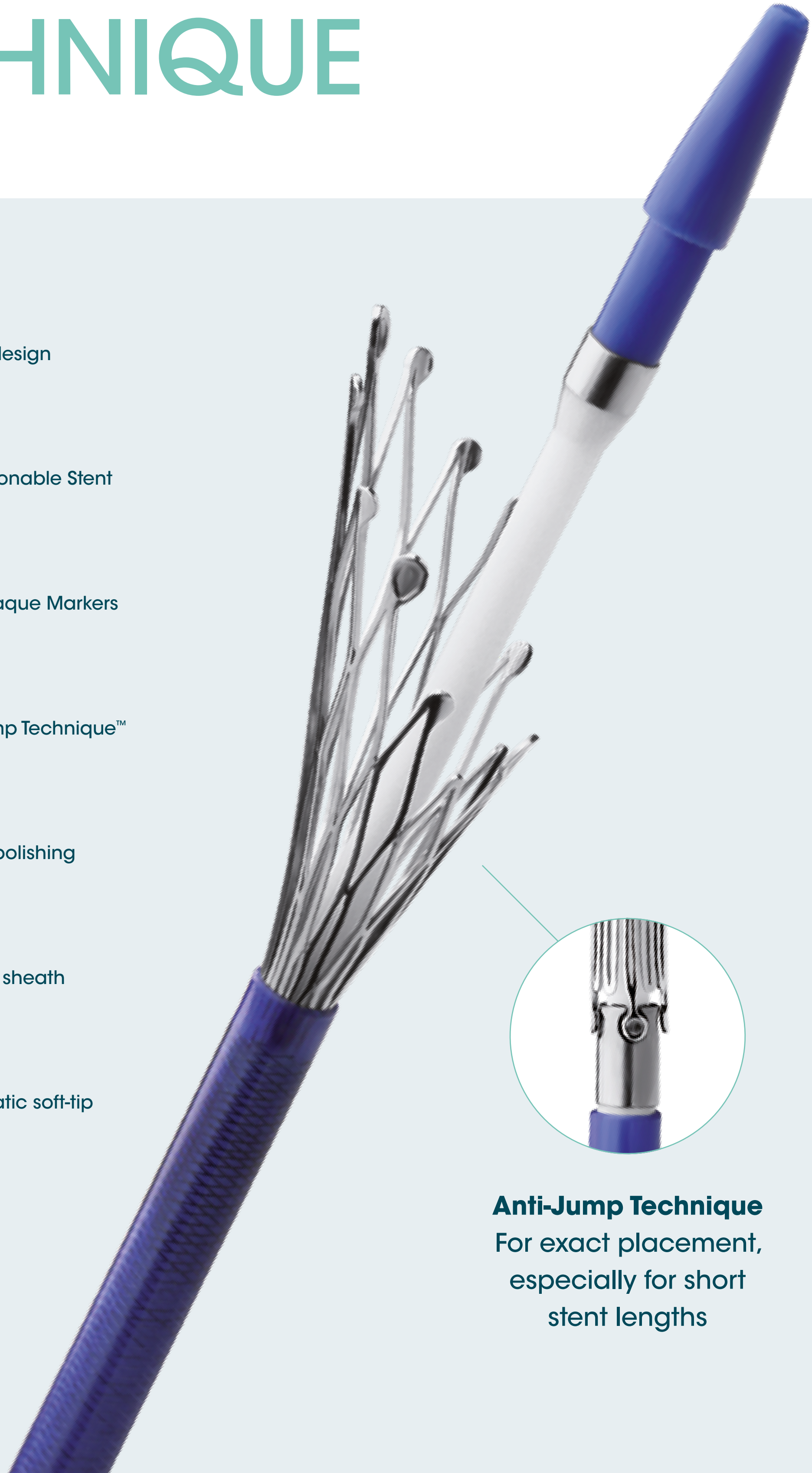
The sinus-Obliquus was specially designed for treating venous obstructions close to the bifurcation of the inferior vena cava.

OPTIMIZED DESIGN

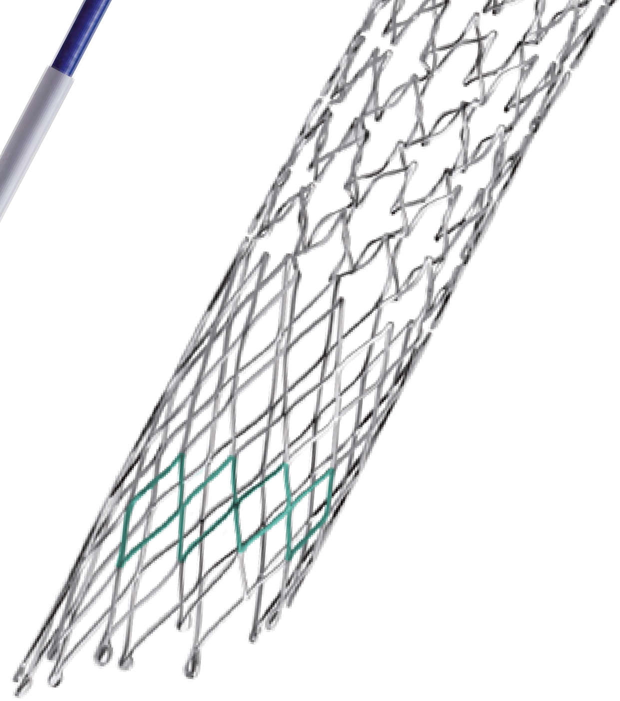
A unique oblique design offers the possibility to place the stent directly at the bifurcation – optimized to the requirements of treating May-Thurner Syndrome.

NEW PERSPECTIVES IN DESIGN AND TECHNIQUE

- Hybrid design
- Repositionable Stent
- Radiopaque Markers
- Anti-Jump Technique™
- Electro-polishing
- Braided sheath
- Atraumatic soft-tip



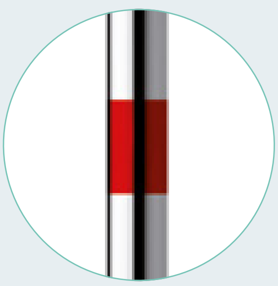
Anti-Jump Technique
For exact placement, especially for short stent lengths



REPOSITIONABLE
EASE OF PLACEMENT

To simplify stent placement - the stent is repositionable as long as the red marker is visible during deployment.

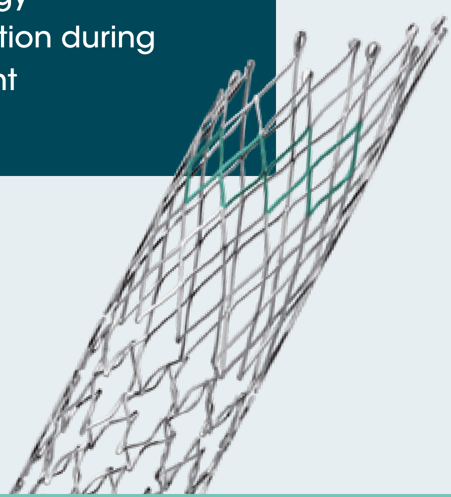
Blue Marker



Red Marker
"Point of
no return"

Repositionability Features

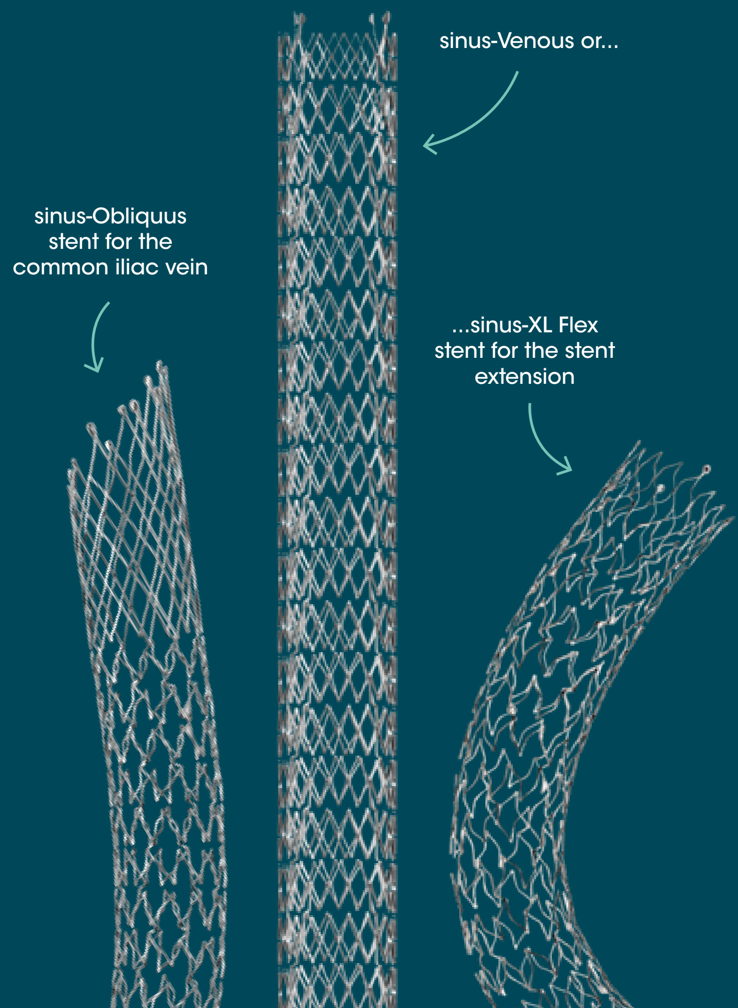
- Facilitate an even more precise stent placement for increased user comfort and reduced risk of reinterventions
- Anti-Jump Technology™ to avoid stent migration during the stent deployment



TOPOS Study

The Treatment of Post-thrombotic Syndrome with the Oblique Stent (TOPOS) study was a multinational, prospective, single-arm study designed to evaluate the safety and efficacy of the sinus-Obliquus stent in patients with PTS with concomitant iliac vein compression.

For stent extension, the sinus-XL Flex or sinus-Venous stents were used.



KEY FINDINGS AT A GLANCE:

12 MONTHS

Primary Patency (all) 84.2%

Assisted Primary Patency 91.1%

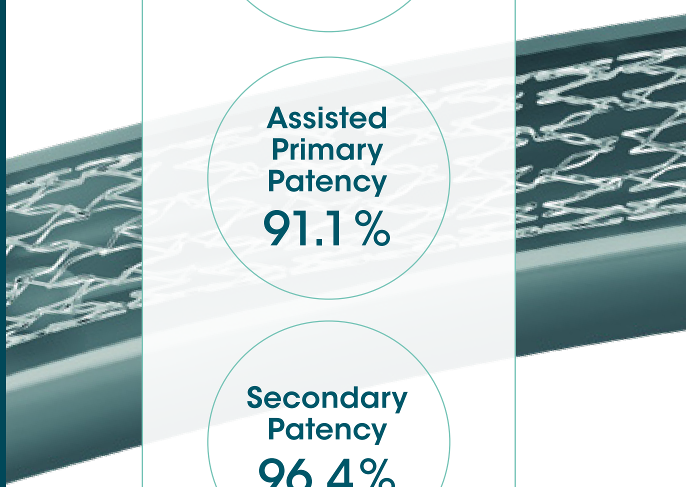
Secondary Patency 98.2%

24 MONTHS

Primary Patency (all) 80.7%

Assisted Primary Patency 91.1%

Secondary Patency 96.4%



TREATMENT OF THE POST-THROMBOTIC SYNDROME WITH OBLIQUE STENTS

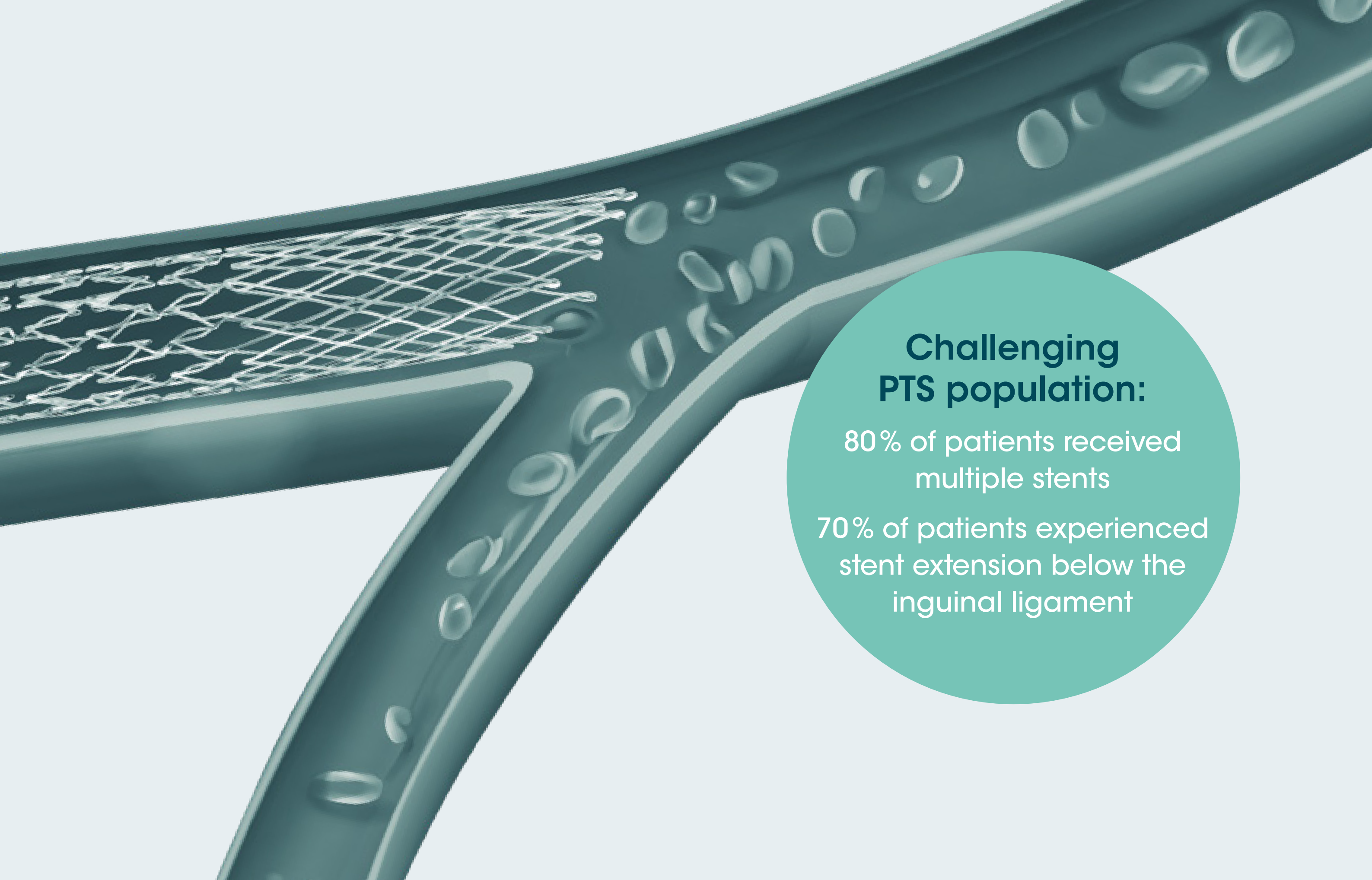
60 patients with post-thrombotic syndrome (PTS) treated with sinus-Obliquus and provisional distal stent extension were enrolled and underwent routine follow-up visits at 3, 6, 12, and 24 months after the endovascular procedure.

PRIMARY MEASUREMENT

- Primary stent patency rate at 12/24 months.

SECONDARY MEASUREMENTS

- Primary assisted stent patency rate.
- Secondary stent patency rates
- Changes in Villalta
- Revised Venous Clinical Severity Score (rVCSS)
- Visual Analog Scale (VAS) of pain
- Chronic Venous Insufficiency
- Quality of Life Questionnaire-20 (CIVIQ-20) scores at 12/ 24 month.



Challenging PTS population:

80% of patients received multiple stents

70% of patients experienced stent extension below the inguinal ligament

Meaningful improvement in quality of life and venous functional assessments

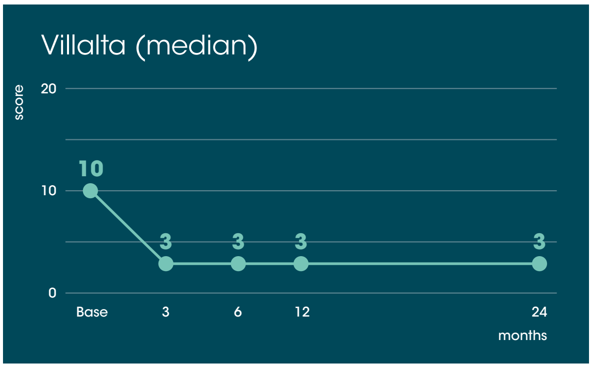


Figure 1: Villalta Score: Categorizes PTS severity (mild 5 - 9; moderate 10 – 14; severe ≥ 15 or venous ulcer)

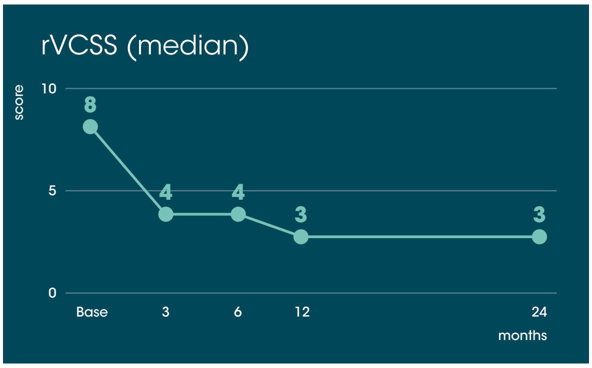


Figure 2: rVCSS: revised Venous Clinical Severity Score (rVCSS): measures severity ranging from 0 (no disease) to 30 (severe disease)

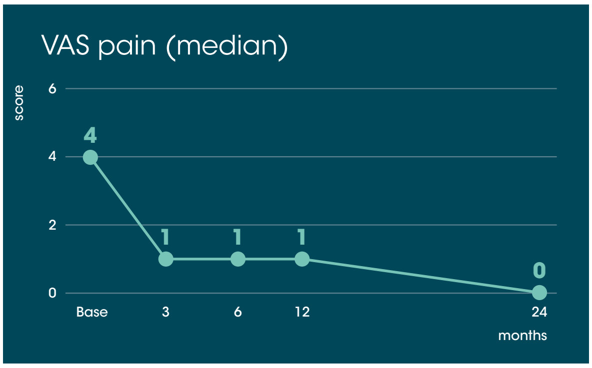


Figure 3: VAS for pain: Visual Analog Scale (VAS): Measure perceived pain intensity along a scale 0 (no pain) to 10 (worst possible pain)

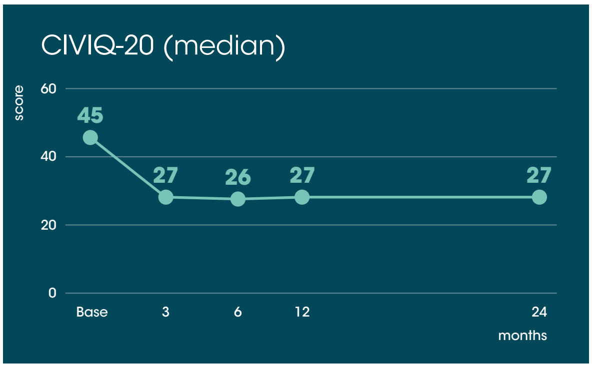


Figure 4: CIVIQ-20: Consisting of 20 questions; It generates a score ranging from 0–100 with lower scores indicating better quality of life

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

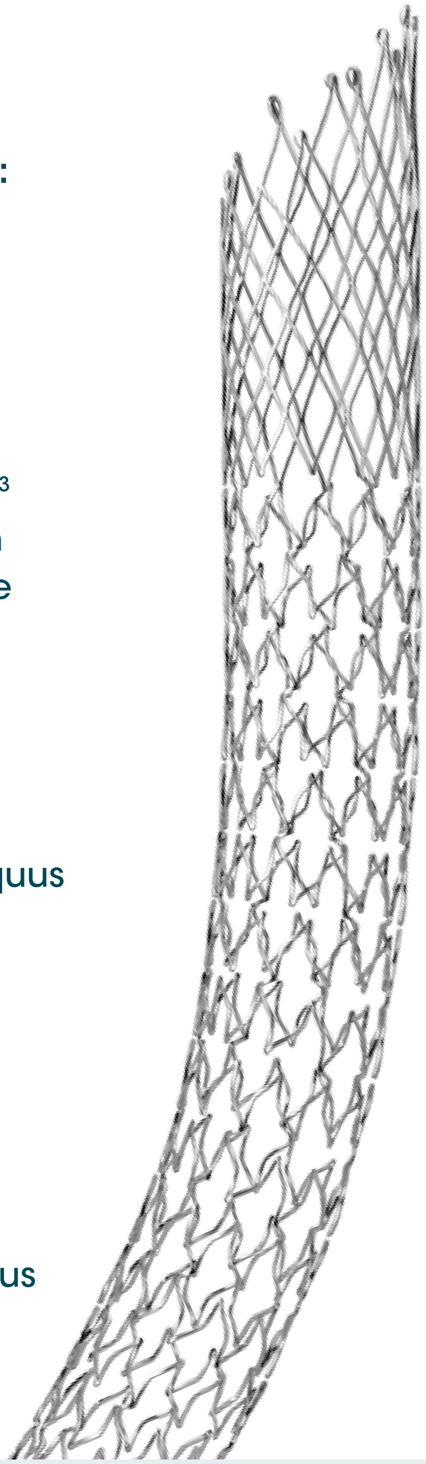
2) Presentation "A randomized controlled trial comparing venous stenting with conservative treatment in patients with deep venous obstructions STEVECO trial" – presented by Houman Jalaieduring LINC 2022 (6th June 2022)

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 TOPOS PAPER ONLINE NOW...

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

...AND DISCOVER THE STEVECO TRIAL

featuring the optimed sinus-Venous vascular stent system

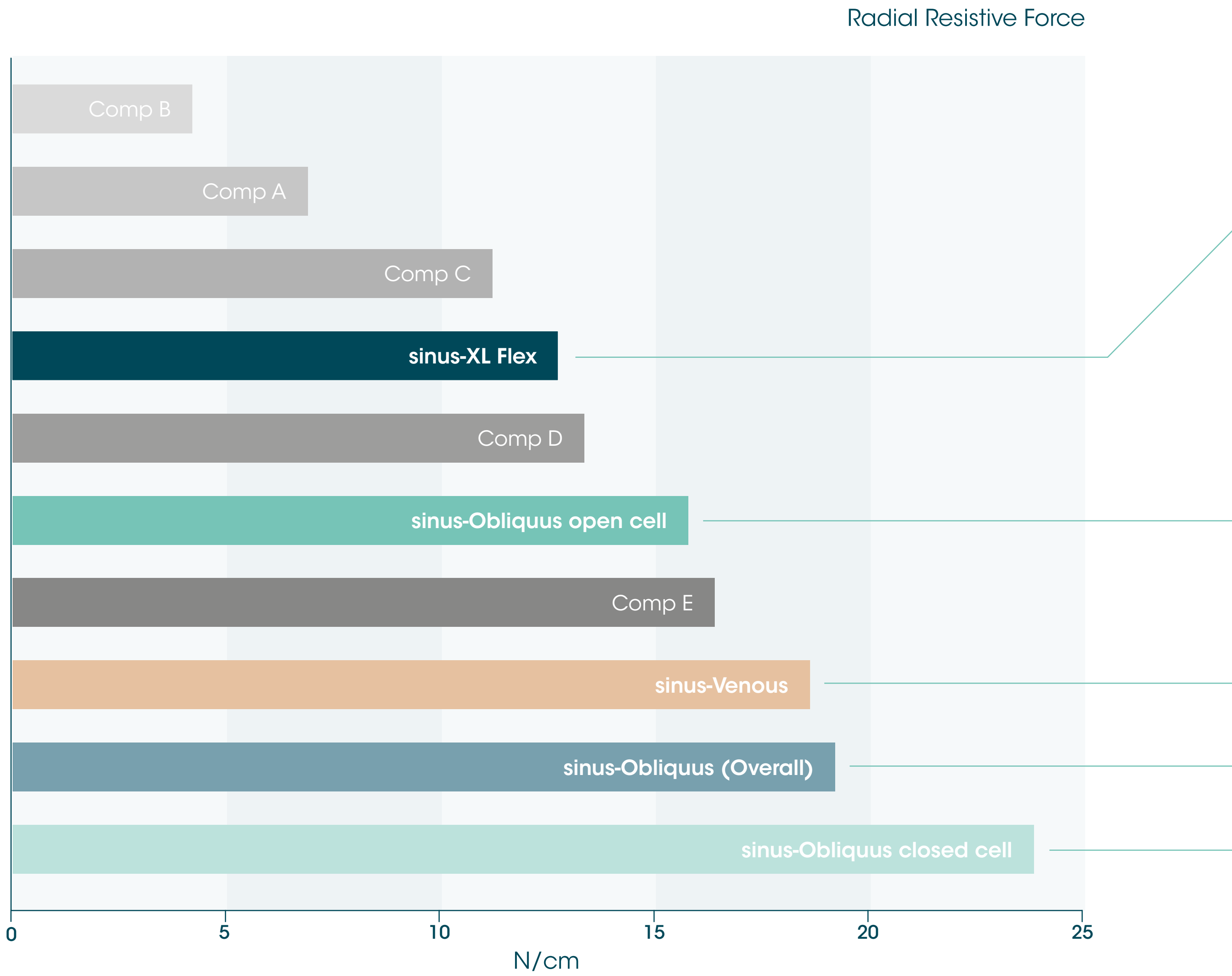
3) van Vuuren, Timme Maj et al. "A randomised controlled trial comparing venous stenting with conservative treatment in patients with deep venous obstruction: research protocol." BMJ open vol. 7,9 e017233. 11 Sep. 2017, doi:10.1136/bmjopen-2017-017233. Data has been provided by paper Shekarchian, Soroosh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

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

RADIAL RESISTIVE FORCE

SINUS-OBLIQUUS STRENGTH 1

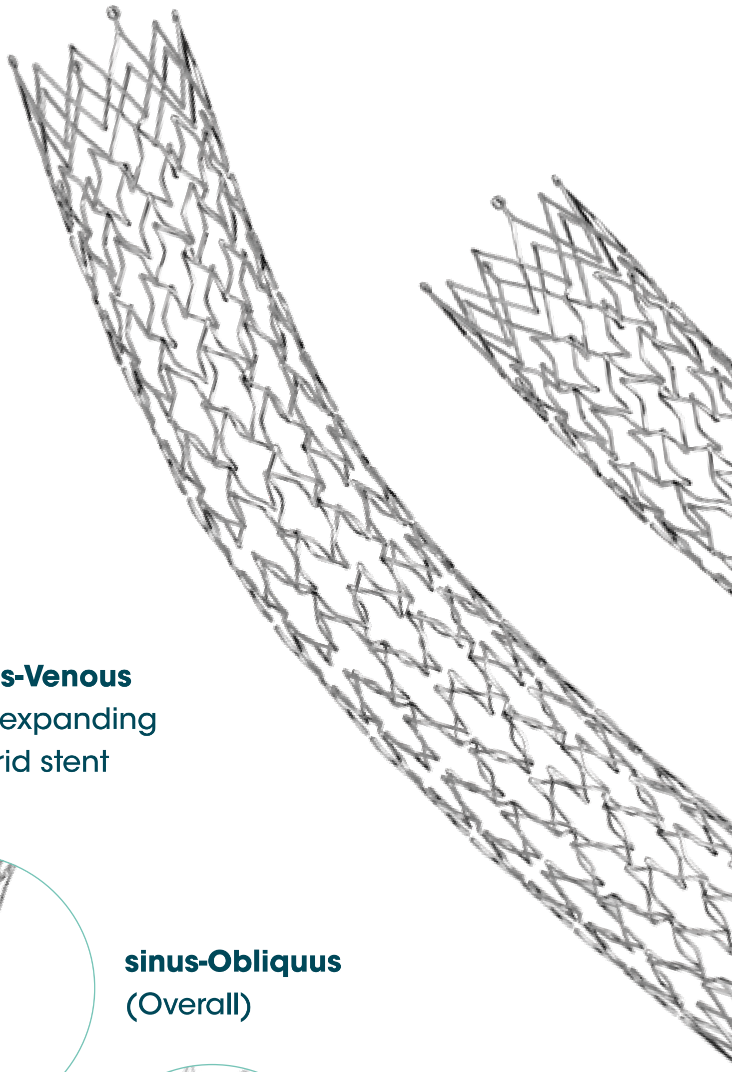
Sinus-Obliquus displayed the highest radial resistive force among all tested stents

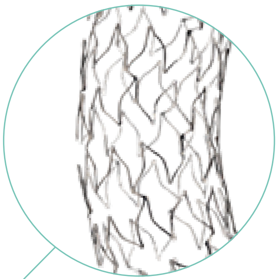


SOURCES

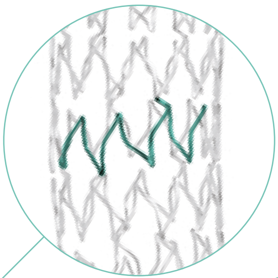
Source:Dabir D, Feisst A, Thomas D, Luetkens JA, Meyer C, Kardulovic A, Menne M, Steinseifer U, Schild HH, Kuetting DLR. Physical Properties of Venous Stents: An Experimental Comparison. Cardiovasc Intervent Radiol. 2018 Jun;41(6):942-950. doi: 10.1007/s00270-018-1916-1. Epub 2018 Feb 28. PMID: 29492633 https://pubmed.ncbi.nlm.nih.gov/29492633/

TESTED STENTS

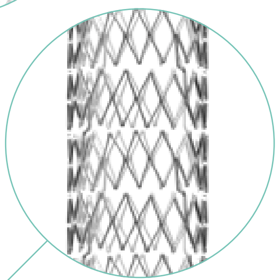




sinus-XL Flex
Flexible self-expanding
open-cell stent

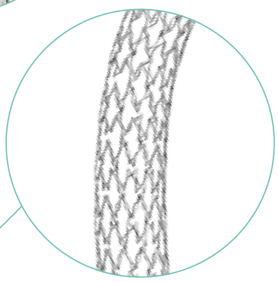


sinus-Obliquus
(Open cell)

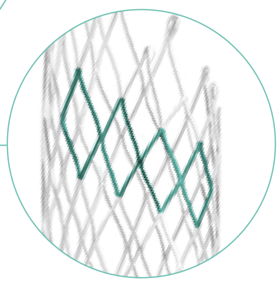


sinus-Venous
Self-expanding
hybrid stent

HIGH PERFORMANCE ACROSS OUR RANGE



sinus-Obliquus
(Overall)



sinus-Obliquus
(Closed Cell)

SOURCES

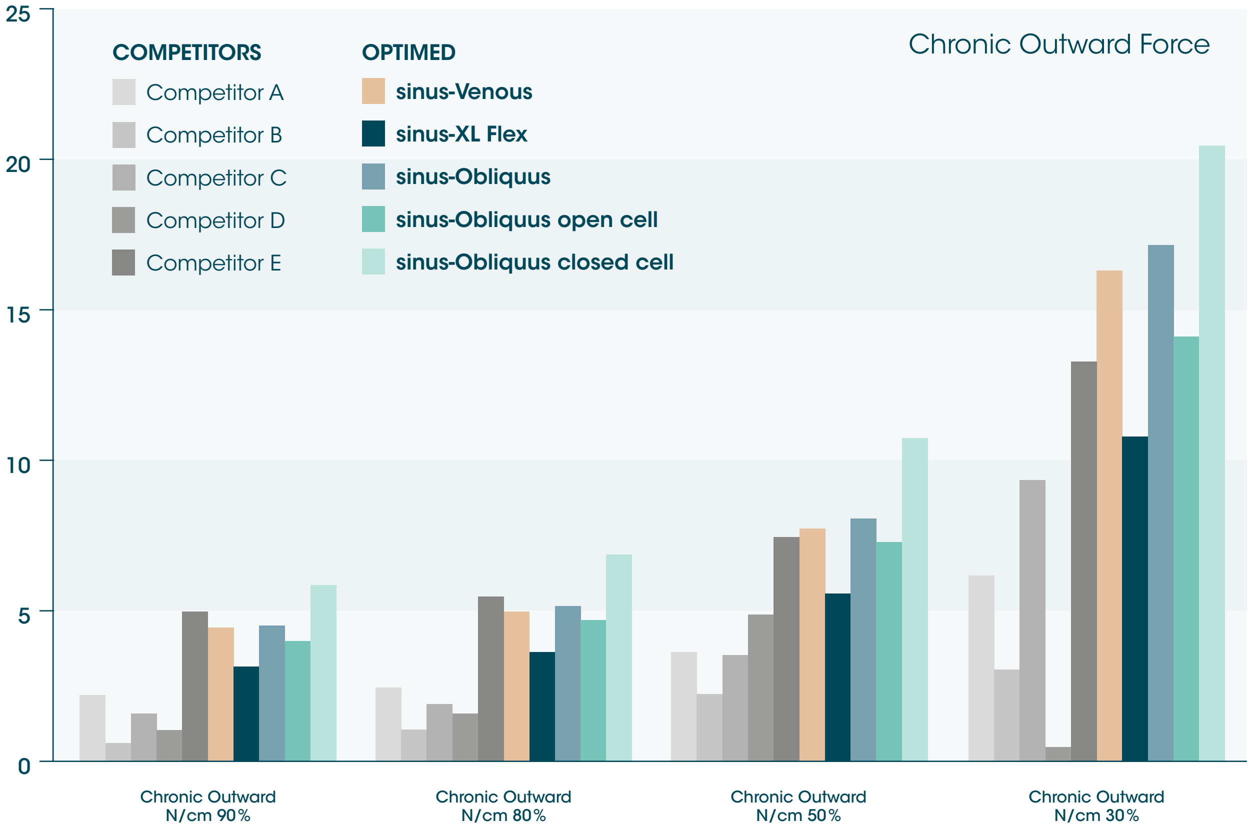
https://evtoday.com/articles/2021-nov/appropriateness-in-venous-stenting-a-nonthrombotic-iliac-vein-obstruction-case-review

CHRONIC OUTWARD FORCE

SINUS-OBLIQUUS STRENGTH 2

Chronic Outward Force increased with decreasing stent diameters in all investigated stents.

During standard measurements, the closed-cell segment of the sinus-Obliquus (closed cell) displayed the highest chronic outward force at all diameters (90, 80, 50, and 30%) followed by the sinus-Obliquus (hybrid), the sinus-Venous, and competitors.



SOURCES

Source: Dabir D, Feisst A, Thomas D, Luetkens JA, Meyer C, Kardulovic A, Menne M, Steinseifer U, Schild HH, Kuetting DLR. Physical Properties of Venous Stents: An Experimental Comparison. Cardiovasc Intervent Radiol. 2018 Jun;41(6):942-950. doi: 10.1007/s00270-018-1916-1. Epub 2018 Feb 28. PMID: 29492633 https://pubmed.ncbi.nlm.nih.gov/29492633/

CRUSH RESISTANCE

SINUS-OBLIQUUS STRENGTH 3

A prospective single-arm study demonstrated that a threshold of a 61 % diameter stenosis of the compressed segment, relative to a normal ipsilateral venous reference diameter (ie, the caudal external iliac vein [EIV]), yielded clinical improvement in NIVL patients treated with iliac vein stents.

sinus-Obliquus

achieved the highest crush resistance at a nominal diameter of 50 %

SOURCES

https://evtoday.com/articles/2021-nov/appropriateness-in-venous-stenting-a-nonthrombotic-iliac-vein-obstruction-case-review

10F / 100 cm delivery system

Adapted to 0.035 inch guide wire

Box /1 unit

ORDER CODES

Lengths (mm)

ø (mm)	80	100	120	150
Ø 14	8414-01-8080	8414-01-8100	8414-01-8120	8414-01-8150
Ø 16	8416-01-8080	8416-01-8100	8416-01-8120	8416-01-8150
Ø 18	8418-01-8080	8418-01-8100	8418-01-8120	8418-01-8150

LENGTHS

80 mm

100 mm

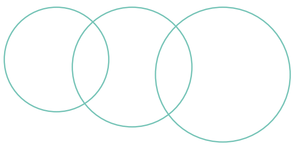
120 mm

150 mm

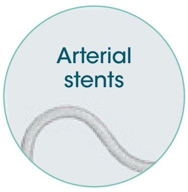
LARGE DIAMETERS up to ø 18mm:

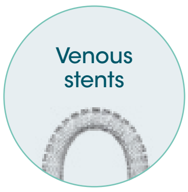
14 – 18 mm

in 2 mm steps



FOR MORE VASCULAR INTERVENTION HIGHLIGHTS VISIT OUR WEBSITE





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