Early Experience with the GORE® VIAFORT Venous Stent

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Disclosures

Andrew Holden, MBChB, FRANZCR:

Medical Advisory Board Member for Medtronic, Gore, Philips, Boston Scientific

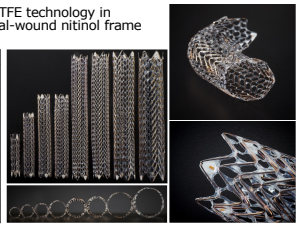
Clinical Investigator for Bard-BD, Boston Scientific, Cagent Medical, Cook Medical, Efemoral, Endologix, Endospan, Gore Medical, Intact Vascular, Medtronic, Nectero, Philips, Reflow Medical, Shape Memory, Shockwave Medical, Terumo

No other disclosures

GORE® VIAFORT Venous Stent Design

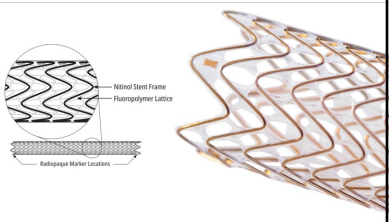
VIAFORT Vascular Stent utilizes ePTFE technology in conjunction with a single wire, sinusoidal-wound nitinol frame

Diameter (mm)	Stent Length (mm)			
	50	75	100	150
10	x	x	x	x
12	x	x	x	x
14	x	x	x	x
16	x	x	x	x
18	x	x	x	x
20	x	x	x	x
24	x	x	x	x
28	x	x	x	x



GORE® VIAFORT Venous Stent Design

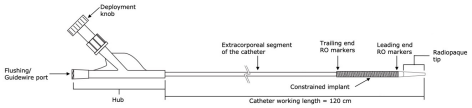
- Self expanding nitinol wire stent
- Fluoropolymer lattice designed for conformability and to allow cross luminal blood flow
- Radiopaque (RO) markers at each device end to facilitate fluoroscopic visualization



GORE® VIAFORT Venous Stent Design

Delivery system

10 Fr–14 Fr	Device profile varies from 10 Fr to 14 Fr, depending on the configuration.
Radiopaque tip	Delivery system includes a radiopaque tip for visibility of the leading end of the catheter.
120 cm	Catheter working length is 120 cm.



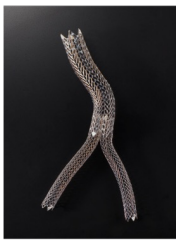
GORE® VIAFORT IDE Trial Design

Two separate studies: Indication for use in the IVC is being sought under the FDA Breakthrough Designation program

Both studies are prospective, non-randomized, multicenter, single-arm with 5-year follow-up

VNS 21-05 – "IVC Study"
Evaluation of the GORE® VIAFORT Vascular Stent for Treatment of Symptomatic Inferior Vena Cava Obstruction w or w/out Combined Iliofemoral Obstruction
111 Patients
US, AU/NZ, EU
US enrollment completed

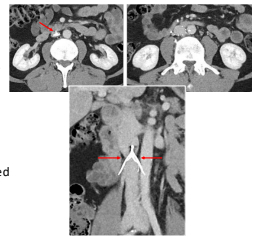
VNS 21-07 "Iliofemoral Study"
Evaluation of the GORE® VIAFORT Vascular Stent for Treatment of Symptomatic Iliofemoral Venous Obstruction
165 Patients
US Only
Study underway



GORE® VIAFORT First in Human Case

Patient History:

- 51 Year old male – BMI 26
- Sub-massive PE and DVT 2008 - IVC filter inserted, never removed
- Bilateral leg swelling 2019 – caval and iliac vein thrombosis partially treated with thrombectomy/thrombolysis
- Subsequent resolution of thrombus with anticoagulation but **caval stenosis** noted associated with filter with **strut penetration**



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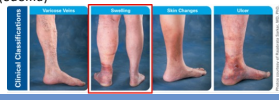
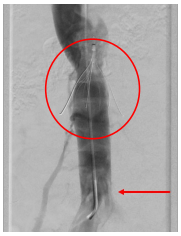
GORE® VIAFORT First in Human Case

Patient History:

- PTS symptoms since 2019
- Significant right leg swelling primary factor preventing normal use
- Venous claudication – pain, specially with exercise
- Right leg VCSS score 2 on 0-3 scale, CEAP C3 (edema)





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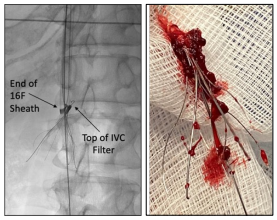
GORE® VIAFORT First in Human Case

Procedural Details:

<u>IVC Filter Removal</u>

- **Per protocol** all subjects with an IVC filter present within the target stent area, must have **IVC filter removal**
- IVC filter initial attempts at retrieval with snare unsuccessful
- Filter dislodged from IVC stenosis with steady, moderate force
- Top of filter would not enter 16Fr sheath
- After some manipulation the filter was removed using brachial forceps
- The room was happy!



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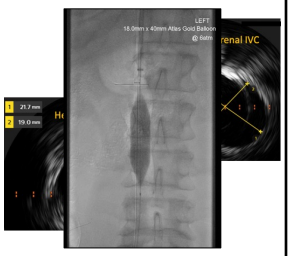
GORE® VIAFORT First in Human Case

Procedural Details:

<u>Confirmed Landing Zones and Stent Sizing</u>

- Stent sized using IVC distal to stenosis
- IVC immediately adjacent to renals (proximal to stenosis) significantly larger
- 24mm diameter x 75mm length VIAFORT device chosen
- Indicated vessel range 18-22mm
- Stenosis pre-dilated using a 20mm Atlas balloon



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Device Diameter (mm)	Recommended Vessel Diameter (mm)	Introducer Sheath Size (Fr)[1]	Recommended Balloon Diameter for Device Touch-Up (mm)
10	7-9	10	10
12	9-11	11	12
14	11-13	11	14
16	13-15	11	16
18	15-17	12	18
20	17-19	12	20
24	18-22	14	24
28	22-26	14	28

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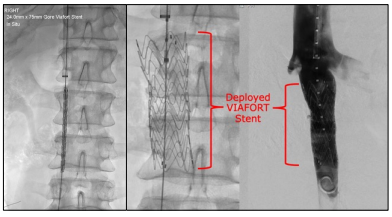
Procedural Details:

<u>Stent Deployment</u>

- Accuracy was good and stent landed "beautifully"
- Post-dilation performed with 20mm Atlas balloon to ~6atm



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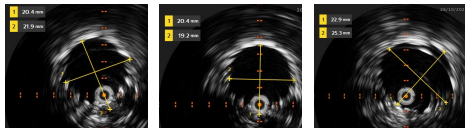
Post-Stent Deployment

- Lumen widely patent with a circular cross-section (optimal laminar flow)
- Patient discharged the following day with immediate resolution of swelling
  - rVCSS swelling score of 0 out of 3 (down from 2)



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Follow Up:

30-day

- Within his 30d window this patient did not experience any of the primary composite endpoints
- He remains free from death, PE, vascular injury, or major bleeding

12-month

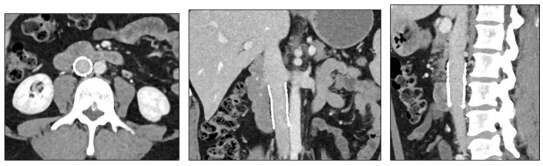
- Within his 12m window this patient did not experience any of the primary composite endpoints
- He remains free from loss of primary patency or stent embolization. This was confirmed with DUS

Long-Term Follow-Up

- This patient is now 24 months post-stent implantation
- He has experienced no serious adverse or adverse events related to the device or procedure
- His last follow-up was on day 706

GORE® VIAFORT First in Human Case

6 Month CT:



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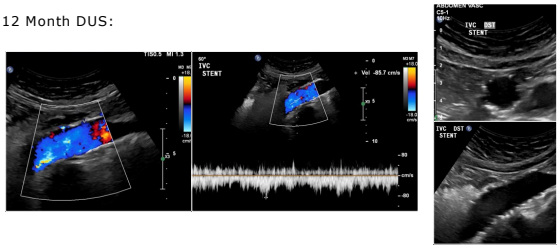
12 Month DUS:



Early Experience with GORE® VIAFORT Venous Stent

- Only venous stent specifically designed for iliac veins and IVC
- Unique design provides high radial resistive force with excellent conformability
- Early clinical experience very positive
- "IVC Study" has completed enrolment in the US
- "Ilio-femoral Study" (US only) still enrolling

Early Experience with the GORE® VIAFORT Venous Stent

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