

DILATION OF THE INFERIOR VENA CAVA AND THE ILIOCAVAL CONFLUENCE WITH AN OPEN- STRUCTURE LATTICE STENT

Presentation for the September 2025
ICD-10-PCS Coordination and
Maintenance Committee

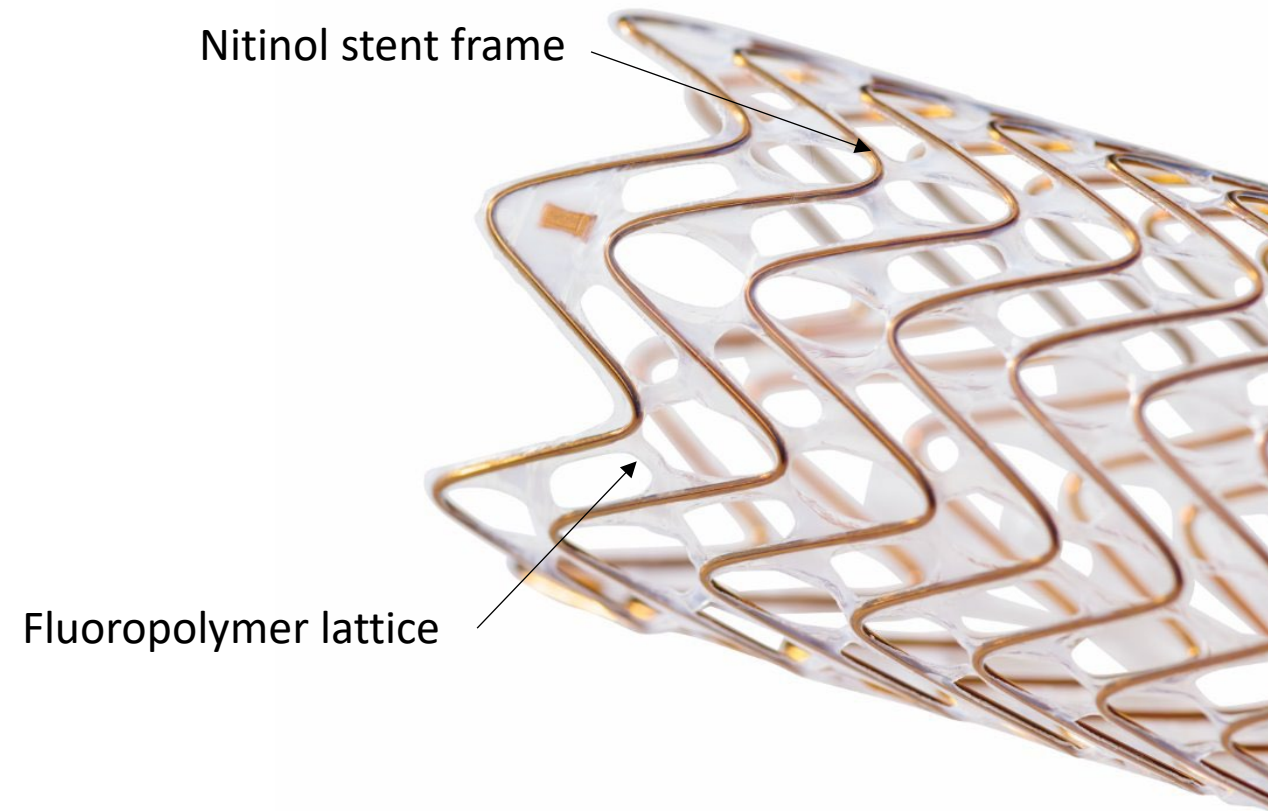
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CAUTION - Investigational device. Limited by United States law to investigational use.



Introduction to the GORE® VIABAHN® VIAFORT Venous Stent Device

- The GORE® VIABAHN® VIAFORT Venous Stent is a permanently implanted endoprosthesis for treatment of symptomatic Inferior vena cava (IVC) obstruction with or without combined Iliofemoral obstruction
- The GORE® VIABAHN® VIAFORT Venous Stent is an open-structured, polymer lattice stent that provides endoluminal support to the IVC and adjoining iliac and femoral veins
- The polymer lattice design allows a high degree of flexibility when subjected to bending and torsional deflections of the ilio caval veins
- The GORE® VIABAHN® VIAFORT Venous Stent was granted Breakthrough Medical Device Status by the FDA on July 20, 2020, and is expected to receive FDA approval early 2026.
- GORE® intends to submit for a New Technology Add-on Payment (NTAP) in October 2025 for an October 1, 2026, NTAP effective date.
- The GORE® VIABAHN® VIAFORT Venous Stent is part of the GORE® VIABAHN® device family



Anatomic Overview of the GORE® VIABAHN® VIAFORT Venous Stent Device

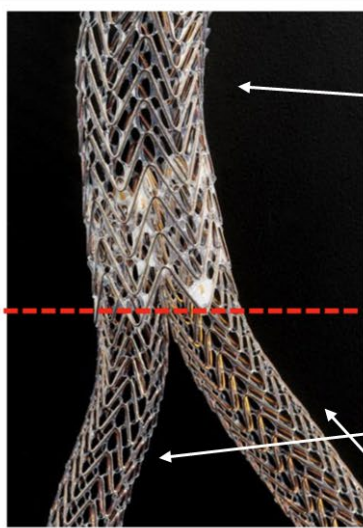
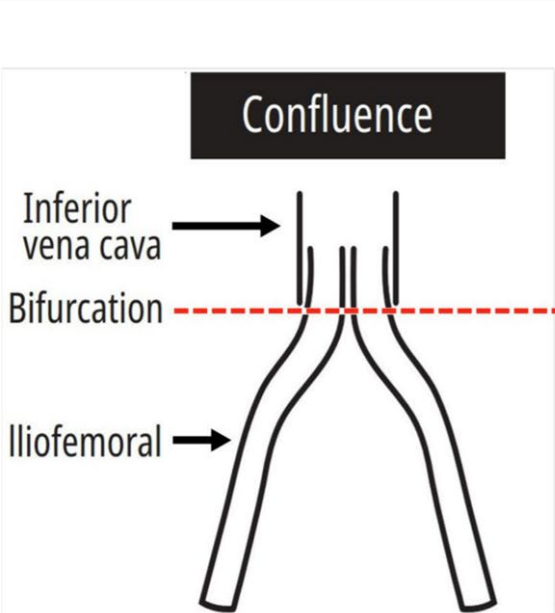
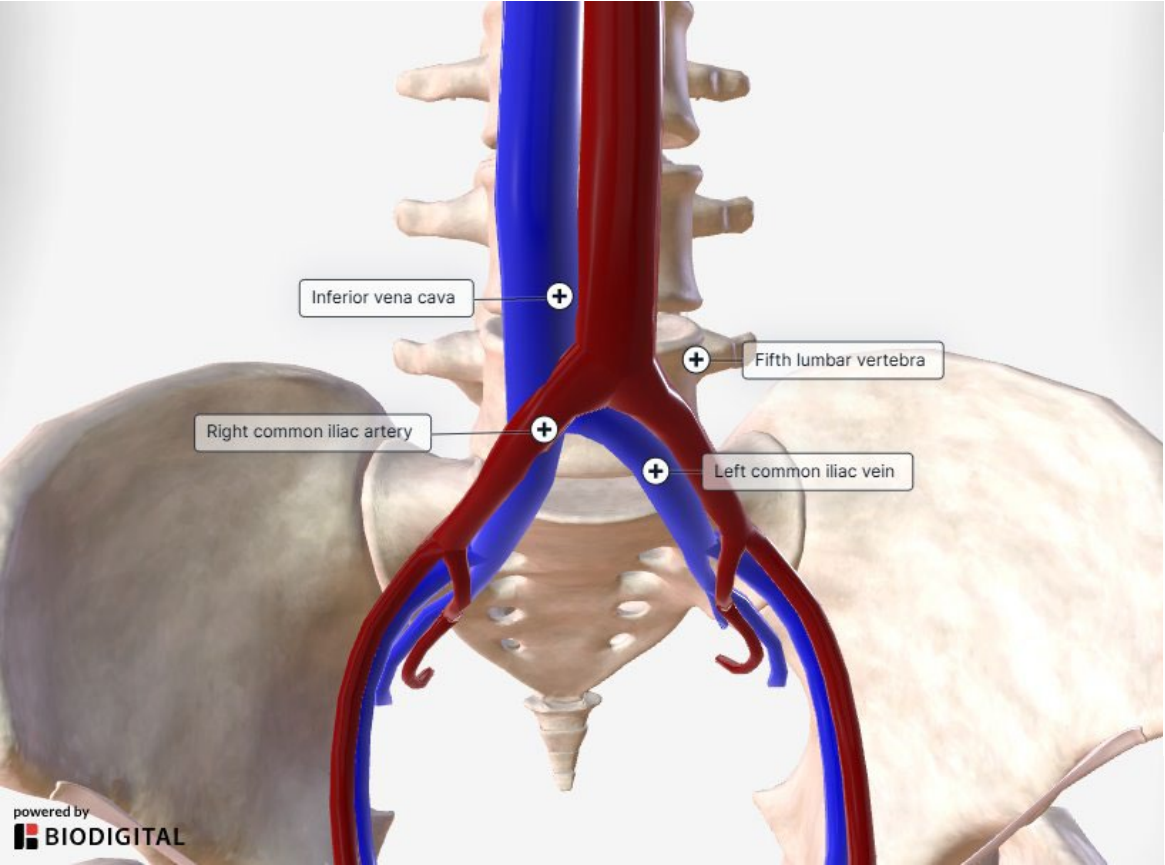


Figure: Complete Viafort Device

Large diameter vein stent
implanted in the Inferior
Vena Cava

Small diameter vein stents
implanted in the iliac and femoral
veins

The GORE® VIABAHN® VIAFORT Venous Stent Proposed Indication for Use:

STUDY VNS 21-05: The GORE® VIABAHN® VIAFORT Venous Stent is indicated for treatment of symptomatic inferior vena cava obstruction with or without combined Iliofemoral obstruction

The GORE® VIABAHN® VIAFORT Venous Stent is contraindicated for use in patients:

- With non-compliant lesions where full expansion of an angioplasty balloon catheter was not achieved during pre-dilation, or where lesions cannot be dilated sufficiently to allow passage of delivery system

Overview of the GORE® VIABAHN® VIAFORT Venous Stent and its Usage:

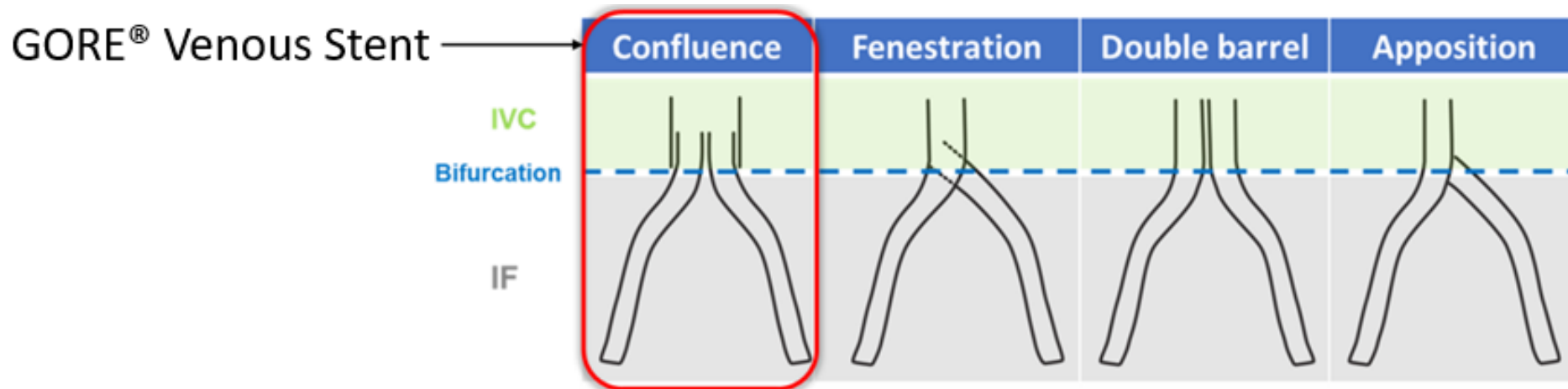
- The GORE® VIABAHN® VIAFORT Venous Stent is an open-structure, self-expanding, permanently implantable stent constructed of a wire-wound nitinol frame and a polymer lattice. The GORE® VIABAHN® VIAFORT Venous Stent will be the first FDA approved device to treat symptomatic obstruction in the Inferior Vena Cava with or without combined iliofemoral obstruction
- The GORE® VIABAHN® VIAFORT Venous Stent is intended for use as a vascular stent in the venous system and will serve as a scaffold to maintain an open vessel lumen
 - Since the first GORE® VIABAHN® VIAFORT Venous Stent implant, there have been no reported explants of the 102 patients that have been treated to date in our clinical trial VNS-21-05
- The GORE® VIABAHN® VIAFORT Venous Stent will be deployed in a stand-alone procedure and is anticipated to be implanted in both inpatient and outpatient sites of service. The device is likely to be listed in the surgical notes as:
 - GORE® VIABAHN® VIAFORT Venous Stent, GORE® VIABAHN® Venous Stent
- In terms of adverse events, no new risks or usability aspects have been notified in the clinical data that have not yet been addressed within the risk management process. The anticipated benefits to a patient when using the GORE® VIABAHN® VIAFORT Venous Stent outweighs the risks of suffering harm due to a residual risk of the device. Based on current knowledge from the field, the GORE® VIABAHN® VIAFORT Venous Stent has similar inherent risks as other endovascular devices used in the analogous applications

What Diagnoses are associated with or indicated for the use of the GORE® VIABAHN® VIAFORT Venous Stent?

- The GORE® VIABAHN® VIAFORT Venous Stent is seeking approval for treatment of patients with symptomatic obstruction in the Inferior Vena Cava with or without combined Iliofemoral obstruction
- The associated ICD-10-CM codes:
 - I87.1 Compression of vein
 - I87.2 Venous insufficiency (chronic) (peripheral)
- There are other various miscellaneous codes for thrombus and embolism for IVC and distal vessels that may be used to describe procedures using the GORE® VIABAHN® VIAFORT Venous Stent

Current Alternatives for Patients Indicated for Treatment with the GORE® VIABAHN® VIAFORT Venous Stent

- Currently, there are no approved devices that would provide similar benefits for the treatment of patients with symptomatic IVC obstruction, particularly patients who require stent placement in the IVC and spanning into iliofemoral vein(s) at the iliocaval confluence.
 - The GORE® VIABAHN® VIAFORT Venous Stent will be the first FDA approved device indicated for treatment of symptomatic IVC obstruction with or without combined Iliofemoral obstruction in the US market
- There are stents on the US market that are used currently outside of their approved indications to treat this patient population
 - Current techniques require the use of different stent systems that are not designed to be used together and/or not designed for iliocaval placement

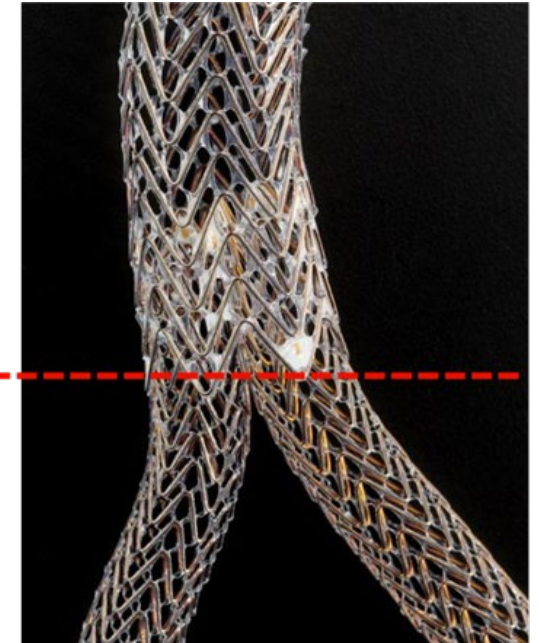
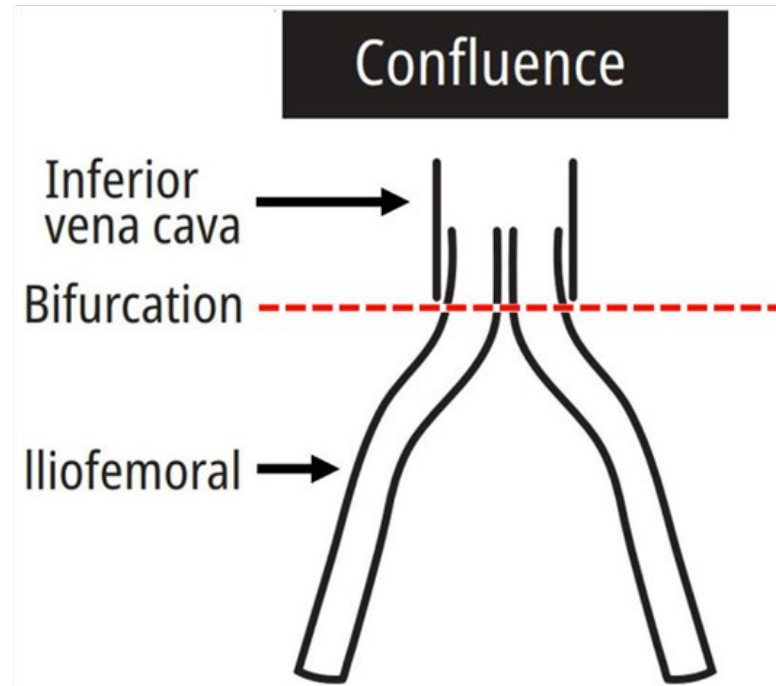


If the technology is a device or implant, is only one device/implant routinely inserted, or can multiple devices/implants be utilized?

- The GORE® VIABAHN® VIAFORT Venous Stent Open-structured, Polymer Lattice Stent comes in a variety of sizes, both large and small diameter.
 - The large diameter stents are intended for wall-to-wall apposition in the inferior vena cava while the small diameter stent sizes are reserved for the iliac and femoral veins
- For cases with symptomatic IVC obstruction at the iliocaval confluence and obstruction extending into bilateral iliac veins, typically one large diameter open-structured polymer lattice stent is implanted in the IVC, and depending on the patient presentation and severity, at least one smaller diameter open-structured polymer lattice stent will be placed into each of the iliac veins at the iliocaval confluence
 - 94% of our clinical trial patients (VNS 21-05) required stents in the IVC and bilateral iliac veins with an average of 5.2 stents per case

Identifying the GORE® VIABAHN® VIAFORT Venous Stent

- There are existing ICD-10-PCS codes to describe the devices used outside of their approved indications in these procedures. However, these codes do not adequately describe the GORE® VIABAHN® VIAFORT Venous Stent Open-structured, Polymer Lattice Stent
- Therefore, GORE is formally requesting the creation of an ICD-10-PCS code(s) to describe the GORE® VIABAHN® VIAFORT Venous Stent Open-structured, Polymer Lattice Stent Procedure



What are the Procedural Steps Involved?

1. Gain vessel access
2. Intravascular ultrasound (IVUS) the diseased vessel
3. Pre-dilate all vessels with a percutaneous transluminal angioplasty (PTA) balloon
4. Deploy large diameter stent into IVC
5. PTA IVC stent post deployment
6. Deploy both small diameter stents into each of the common iliac veins, with 3cm of the iliac stents extending into the large diameter IVC stent
7. PTA both common iliac stents, post stent deployment
8. Follow up with IVUS to verify stent placement prior to procedure completion

What are the Detailed Procedural Steps Involved?

1. Gain vessel access, and insert an appropriately sized introducer sheath into the vessel
2. Utilize Intravascular ultrasound (IVUS) on the diseased vessel to:
 - Achieve accurate vessel measurements
 - Correctly identify both diseased and healthy vessel segments
 - Ensure precise sizing and placement of the GORE® VIABAHN® VIAFORT Venous Stent Implant
3. Pre-dilate the diseased vessel using a percutaneous transluminal angioplasty (PTA) balloon
4. Inflate balloon to nominal pressure, prior to stent implantation, using the balloon manufacturers' instructions for use, ensuring full expansion of the balloon in the vessel
5. Advance the stent into the vessel, using fluoroscopic guidance for proper placement, and deploy stent
6. Once the IVC stent has been deployed as described above, including post-dilation balloon touch-up, extend the smaller device(s) 3 cm into the larger IVC device and repeat the deployment and balloon touch-up process
7. After deployment, remove the delivery system
8. Follow up the procedure with IVUS or contrast angiography to evaluate the treated segment prior to procedure completion

THANK YOU.

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Clinical Presenter

Kush R Desai, MD FSIR

Professor of Radiology, Surgery, and Medicine

Northwestern University Feinberg School of Medicine

Chief, Division of Interventional Radiology

Northwestern Memorial Hospital

Medical Director, Supply Chain/Value Analysis

Northwestern Memorial HealthCare

kdesai007@northwestern.edu

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W.L. Gore Representative

Stephanie Booth MBA, BSN-RN, CCS, CPC-A

Americas Reimbursement & Policy Strategist

W. L. Gore & Associates, Inc.

sbooth@wlgore.com

(602) 919-3889

