Title:

Evaluation of the GORE® VIAFORT Vascular Stent for Treatment of Symptomatic Inferior Vena Cava Obstruction with or without Combined Iliofemoral Obstruction

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Statistical Analysis Plan

Study Acronym / Protocol #: VNS 21-05

Statistical Analysis Plan Date: 2-JUN-2025

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[redacted]

1.0 Introduction

This Statistical Analysis Plan (SAP) describes the statistical analyses planned to address the objectives of VNS 21-05. This SAP summarizes the analyses that will be performed to determine the safety and effectiveness of the GORE® VIAFORT Vascular Stent when used for the treatment of symptomatic inferior vena cava (IVC) obstruction with or without combined iliofemoral obstruction. This SAP outlines tables, figures, and listings that are included in reports for the VNS 21-05 clinical study.

2.0 Study Design Overview

2.1 Objectives

2.1.1 Primary Objective

Establish the safety and effectiveness of the GORE® VIAFORT Vascular Stent for treatment of symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction.

2.1.2 Health Economic Data Analysis

A Health Economic analysis will be performed using clinical study data and billing data where available. The objective of the Health Economic analysis is to understand the value of the treatment studied during the period of the clinical investigation.

2.2 Design Summary

This study is a confirmatory prospective, multicenter, non-randomized, single-arm study to evaluate the performance, safety, and efficacy of the GORE® VIAFORT Vascular Stent for treatment of symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction.

2.3 Study Endpoints

2.3.1 Primary Endpoint

Composite primary endpoint consisting of freedom from the following:

- Loss of primary patency through 12-month follow-up
- Stent embolization through 12-month follow-up
- Device- or procedure-related death through 30 days
- Clinically significant pulmonary embolism confirmed via Computed Tomography Angiography through 30 days
- Device- or procedure-related vascular injury through 30 days requiring surgical or endovascular intervention
- Device- or procedure-related major bleeding events through 30 days

2.3.2 Secondary Endpoints

The secondary endpoints are summarized below:

- Primary patency through 60-month follow-up
- Secondary patency through 60-month follow-up
- Clinically driven target lesion revascularization through 60-month follow-up
- Device fracture through 60-month follow-up
- Stent embolization through 12-month follow-up
- Device- or procedure-related death through 30 days

- Clinically significant pulmonary embolism confirmed via Computed Tomography Angiography through 30 days
- Device- or procedure-related vascular injury through 30 days requiring surgical or endovascular intervention
- Device- or procedure-related major bleeding events through 30 days
- Improvement in rVCSS Measurement through 60-month follow-up compared to baseline prior to treatment
- Improvement in rVCSS Pain Measurement through 60-month follow-up compared to baseline prior to treatment
- Improvement in VEINES Measurement through 60-month follow-up compared to baseline prior to treatment
- Improvement in Villalta Measurement through 60-month follow-up compared to baseline prior to treatment
- Improvement in EQ-5D-5L Measurement through 60-month follow-up compared to baseline prior to treatment
- Technical success
- Lesion success
- Procedural success

2.4 Statistical Hypotheses

2.4.1 Primary Endpoint

This study is designed to test the null hypothesis that percentage of freedom from the composite primary endpoint, when using the GORE® VIAFORT Vascular Stent, is equal to or lower than a performance goal (PG) established from literature sources, versus the alternative hypothesis that the freedom from the composite primary endpoint is higher than the performance goal.

H_0: $P \leq 58\%$

H_A: $P > 58\%$

α (United States (US) submissions) = 0.05 (one-sided)[1]

α (outside United States (OUS) submissions) = 0.025 (one-sided)[1]

[redacted]

[1] Differing alpha levels will be used for regulatory submissions in the US and outside of the US to meet regional regulatory requirements.

[redacted]

2.5 Sample Size Assumptions

The performance goal of 58% was based on an expected loss of primary patency of 18%, an expected combined safety event rate of 10%, and a 14% margin. The following assumptions were used to calculate the sample size:

Performance Goal: 58%

Power: 80%

One-Sided Alpha (US submissions): 0.05[1]

One-Sided Alpha (OUS submissions): 0.025[1]

Attrition: 10%

2.6 Sample Size Calculations

US submissions: Using the above assumptions, a sample size of 89 subjects would be treated for testing the hypothesis using binomial exact test.

OUS submissions: Using the above assumptions, a sample size of 111 subjects would be treated for testing the hypothesis using binomial exact test.

At least 45 of the total 111 subjects must be enrolled in the US.

Treated subjects may be excluded from the Per Protocol population based on the recommendation of the CEC if they are determined to be ineligible for the study using information available prior to treatment.

3.0 Study Treatment Arms

3.1 Test Arm

GORE® VIAFORT Vascular Stent

3.2 Control Arm

Not applicable for a single arm study

4.0 Study Data Collection

The validated Clinical Study Database (CSD) for this study will be provided by Medrio. The sponsor maintains a separate Clinical Data Management Plan (CDMP) describing the procedures for verification, validation, and security of the CSD. The CDMP will describe and document procedures regarding data management processes for this investigation.

4.1 Study Data Collection Information

This study will report clinical data using the Medrio CSD web-based application. The CSD will be the database of record for the Protocol and subject to regulatory inspections and quality assurance review. All users will be trained to use the CSD and will comply with study specific guidelines/instructions as well as applicable regulatory requirements.

Subject data will be collected using Protocol-specific electronic case report forms (eCRFs). Site staff will enter data directly into the eCRF for transmission to the sponsor. The sites will be notified of any significant amendments to the eCRFs. Source documentation is defined as original records (paper or electronic). For any worksheets that contain collected data that has

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[redacted]

no prior written or electronic record, the worksheet must be signed and dated by the principal investigator or sub-investigator.

Once entered, data will be evaluated to confirm that it is complete, consistent, and logically sound. If changes to the data in the CSD are required, all changes, reasons for changes, and persons making the changes will be captured in the CSD audit trail. The sponsor will perform periodic data reviews throughout the entire study. Procedures and documentation for regular and ongoing data review are described in the CDMP.

See Protocol Section 5.2 for the schedule of events. See

Table 1 below for the follow-up visit windows.

Table 1. Follow-Up Visit Windows

Follow-Up Visit	Visit Window (days)
Procedure	0
Discharge	Before initial hospital discharge, regardless of length
1 Month	30 ± 7 (23-37)
6 Months	182 ± 30 (152-212)
12 Months	365 ± 30 (335-395)
24 Months	730 ± 60 (670-790)
36 Months	1095 ± 60 (1035-1155)
48 Months	1460 ± 60 (1400-1520)
60 Months	1825 ± 60 (1765-1885)

4.2 CRF Completion Schedule

CRFs will be completed and updated as soon as reasonably possible during or after each subject visit and monitoring visit.

4.3 Data & Safety Monitoring Board (DSMB) and Clinical Event Committee (CEC)

See Protocol Section 9.4.

4.4 Site Enrollment Restrictions

Each site may treat up to 22 subjects (including any subjects who have a Study Device introduced but none implanted). At least 45 of the total 111 treated subjects must be enrolled in the US.

4.5 Core Lab

See Protocol Section 6.4.

5.0 Statistical Analyses

5.1 Timing of Analyses

The primary and secondary endpoints will be analyzed after all available subjects in the study have completed the 12-month follow-up visit, have experienced a primary endpoint event, or have been withdrawn, whichever is earlier.

For the purpose of US regulatory submission, the primary and secondary endpoints will be analyzed after the first 89 subjects treated (with at least 45 from the US) have completed the 12-month follow-up visit, have experienced a primary endpoint event, or have been withdrawn, whichever is earlier.

Any primary and secondary endpoint analysis results will not be shared with enrolling investigators, CEC members, or Core Lab until all 111 subjects have completed the 12

[redacted]

month follow-up visit, have experienced a primary endpoint event, or have been withdrawn, whichever is earlier.

No interim analysis is planned to stop the study earlier.

5.2 Analysis Populations

The Per Protocol population, consisting of all subjects where an investigational device is introduced into the vasculature and were not determined to be ineligible for the study by the CEC, will be utilized for the primary analysis of study endpoints.

The Intent to Treat population, consisting of all subjects where an investigational device is introduced into the vasculature, will be utilized for an additional analysis of study endpoints.

5.3 Study Deviations

All study protocol deviations will be recorded and reviewed for possible impact on the study and included in the final study report for interpreting the analysis.

5.4 Pooling of Data

All sites in the study from all regions will follow substantively equivalent protocols and the data will be monitored to assure compliance. The data collection and handling procedures will be the same at all study sites. As such, there is no concern in pooling data from different sites together for analysis. For the purpose of US regulatory submission, Gore will conduct an analysis of the composite primary endpoint results using a generalized Fisher's exact test to justify the pooling of data. To align with the precedent set by previous studies within and outside of Gore and to ensure an adequate level of sensitivity, a 0.15 level of statistical significance will be used for each test between site and primary endpoint result, as well as for each test between geographical region and primary endpoint result. If the test by site or geographical region is significant ($p < 0.15$), the composite primary endpoint results with 95% confidence intervals will be presented by that subgroup. Gore may perform additional analyses to explore differences in device performance by gender, age, or any other subgroup of interest.

5.5 Statistical Analysis of Primary Endpoint

Analysis of the primary endpoint to test the hypothesis will be performed using binomial exact test using one-sided 5% (US submissions) or 2.5% (OUS submissions) level of significance. Missing data at the time of analysis will not be imputed. For the purpose of US regulatory submission, the impact of missing data on the primary endpoint analysis will be assessed with a tipping point analysis based on one of the following actual hypothesis test result options:

- If the null hypothesis is rejected in the primary endpoint analysis, it will be assessed how many of the excluded subjects could have failed (had a primary endpoint event in timeframe) and still have met with the same conclusion or resulted in a failure-to-reject the null hypothesis.
- If the null hypothesis is not rejected in the primary endpoint analysis, it will be assessed how many of the excluded subjects would have had to succeed (not had a primary endpoint event in timeframe) to reject the null hypothesis.

Additional sensitivity analyses may be performed at the discretion of the sponsor. The following rules will apply for the determination of the primary composite endpoint:

- A subject with a primary endpoint event any time ≤395 days is a failure, regardless of missing follow-up imaging.

[redacted]

- A subject with imaging sufficient to evaluate applicable primary endpoints at the 12-month follow-up visit and with no primary endpoint events reported through 395 days is a success.
- A subject with missing imaging or insufficient imaging to evaluate applicable primary endpoint components at the 12-month follow-up visit is excluded from analyses.
- A subject with more than one primary endpoint event only counts once as a failure for the purpose of the primary endpoint.

5.6 Statistical Analysis of Secondary Endpoints

[redacted]

All [redacted] secondary endpoints will be summarized with descriptive statistics. There are no formal hypotheses for any secondary endpoints.

The following rules will apply for the analysis of the secondary endpoints:

- A subject remaining in follow-up (at risk) as of the beginning of the follow-up window is counted in that follow-up window.
- A subject with missing data or insufficient data to evaluate applicable secondary endpoints is excluded from analysis at that time point for that endpoint.

5.7 Adverse Events and Safety Monitoring

All adverse events will be presented descriptively with relationship to device / procedure / disease, severity, and MedDRA terms as defined in the Protocol.

6.0 Interim Analyses and Safety Monitoring Analyses

No interim analysis is planned for early termination / study stoppage due to effectiveness; however, the DSMB may recommend stopping the trial anytime due to safety.

7.0 Analysis Specifications

[redacted]

[1] Differing alpha levels will be used for regulatory submissions in the US and outside of the US to meet regional regulatory requirements.

[redacted]

[redacted]

8.0 Data Sets, Tables, Figures, and Listings

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]

PROTOCOL SUMMARY

Study Title	Evaluation of the GORE® VIAFORT Vascular Stent for Treatment of Symptomatic Inferior Vena Cava Obstruction with or without Combined Iliofemoral Obstruction
Protocol Number	VNS 21-05
Amendment 3	02 November 2023
IDE Number	G220109
Sponsor	W. L. Gore & Associates, Inc. Medical Products Division [redacted] Telephone: 800-437-8181
Local Representatives	W. L. Gore & Associates (Australia) Pty, Ltd. [redacted] Gore Authorised Representative (Europe) W. L. Gore & Associates B.V. [redacted]
Study Design	Prospective, non-randomized, multicenter, single-arm, global clinical study.
Study Objective	Establish the safety and effectiveness of the GORE® VIAFORT Vascular Stent for treatment of symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction.
Primary Study Endpoint	Composite primary endpoint consisting of freedom from the following: • Loss of primary patency through 12-month follow-up • Stent embolization through 12-month follow-up • Device- or procedure-related death through 30 days • Clinically significant pulmonary embolism confirmed via Computed Tomography Angiography through 30 days • Device- or procedure-related vascular injury through 30 days requiring surgical or endovascular intervention • Device- or procedure-related major bleeding events through 30 days
Secondary Study Endpoints	• Primary patency through 60-month follow-up • Secondary patency through 60-month follow-up

	• Clinically driven target lesion revascularization through 60-month follow-up • Device fracture through 60-month follow-up • Stent embolization through 12-month follow-up • Device- or procedure-related death through 30 days • Clinically significant pulmonary embolism confirmed via Computed Tomography Angiography through 30 days • Device- or procedure-related vascular injury through 30 days requiring surgical or endovascular intervention • Device- or procedure-related major bleeding events through 30 days • Improvement in Revised Venous Clinical Severity Scale (rVCSS) Measurement through 60-month follow-up compared to baseline prior to treatment • Improvement in rVCSS Pain Measurement through 60-month follow-up compared to baseline prior to treatment • Improvement in VEINES Measurement through 60-month follow-up compared to baseline prior to treatment • Improvement in Villalta Measurement through 60-month follow-up compared to baseline prior to treatment • Improvement in EQ-5D-5L Measurement through 60-month follow-up compared to baseline prior to treatment • Technical success • Lesion success • Procedural success
Subject Population	Adult patients (at least 18 years of age) with symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction. The population is largely expected to be patients with post-thrombotic syndrome; patients with malignant obstruction would be excluded.
Number of Treated Subjects	89 implanted subjects divided among multiple centers located in the United States, Europe, Australia, and New Zealand. At least 45 of these 89 subjects will be enrolled in the United States.
Number of Sites	Approximately 10 (with a maximum of 20) clinical sites located in the United States. Approximately 10 (with a maximum of 15) clinical sites located across Australia, New Zealand, and Europe. The sponsor shall maintain an updated list of principal investigators, investigational sites, and institutions. This list shall be kept separately from this Protocol.
Coordination PI	[redacted]

	
Significant Inclusion Criteria	• One of the following: Clinical severity class of CEAP 'C' classification ≥3 or rVCSS pain score ≥2. • Patient has adequate inflow to the target lesion(s), per investigator/sub-investigator discretion, involving at least a patent femoral or deep femoral vein. • Intraoperative Inclusion Criteria: o Presence of non-malignant obstruction of the inferior vena cava defined as occlusion or at least 50% reduction in target vessel lumen as measured by procedural IVUS and venogram, with or without non-malignant obstruction of the common femoral vein, external iliac vein, and/or common iliac vein. o Patient can accommodate an appropriately sized GORE® VIAFORT Vascular Stent as per reference vessel diameter (see IFU), as determined by intraoperative IVUS post pre-dilation. o Patient must have appropriate access vessels to accommodate the delivery sheath for the selected device size. o Patient has adequate landing zones free from significant disease requiring treatment within the native vessels beyond the proximal and distal margins of the lesion. o Patient has adequate inflow to the target lesion(s), per investigator/sub-investigator discretion, involving at least a patent femoral or deep femoral vein. o Lesion can be traversed with a guidewire. o Disease involves the inferior vena cava and may include iliofemoral segments with intent to stent all affected iliofemoral and caval segments. o Patient does not have significant (i.e., >20% residual thrombosis) acute thrombus within the target stent area at the time of investigational device placement.

	○ Patient does not have an inferior vena cava filter present within the target stent area at the time of investigational device placement.
Significant Exclusion Criteria	• Patient has clinically significant (e.g., symptoms of chest pain, hemoptysis, dyspnea, hypoxia, etc.) pulmonary embolism (confirmed via Computed Tomography Angiography) at the time of enrollment. • Patient has a known uncorrectable bleeding diathesis or active coagulopathy meeting the following definitions: uncorrected INR>2 (not as a result of warfarin or DOAC therapy), OR platelet count <50,000 or >1,000,000 cells/mm^3, OR white blood cell count <3,000 or >12,500 cells/mm^3. • Patient has impaired renal function (eGFR <30 mL/min/1.73m^2) or is currently on dialysis. • Patient has uncorrected hemoglobin of <9 g/dL. • Patient has significant peripheral arterial disease (chronic Rutherford Type 2 or greater, acute Rutherford Type IIa or greater).
Expected Time to Complete Enrollment	[redacted]
Expected Time of each Study Subject to Complete the Study	[redacted]
Total Expected Duration of the Study	[redacted]
Schedule of Events	<u>Screening:</u> • Informed Consent • Preoperative Inclusion/Exclusion Criteria • Demographics and Medical History • Pregnancy Test (if applicable) • Concomitant Medications • Physical Exam • Clinical Scoring • Quality of Life Assessments • Duplex Ultrasound (DUS) • Computed Tomography Venography (CTV) or Magnetic Resonance Venography (MRV) <u>Procedure:</u> • Intraoperative Inclusion Criteria • IVUS & Venogram <u>Discharge:</u> • Concomitant Medications • Physical Exam

	• Clinical Scoring <u>Follow-Up (1, 6, 12, 24, 36, 48, and 60 months post-treatment):</u> • Physical Exam • Clinical Scoring • Quality of Life Assessments • Duplex Ultrasound • Computed Tomography Venography, IVUS, and Venogram o 12M: CTV required o All other visits: CTV, IVUS, or venogram only required when DUS is inconclusive or CTV, IVUS, or venogram is clinically required. • X-Ray o 12M, 36M, and 60M
Vendor Information	Monitoring CRO, Core Lab, Data & Safety Monitoring Board (DSMB), and Clinical Events Committee (CEC) [redacted] Image Transfer [redacted] Electronic Data Capture (EDC) System [redacted]

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Coordination PI	[redacted]

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Expected Time of each Study Subject to Complete the Study	[redacted]
Total Expected Duration of the Study	[redacted]
Schedule of Events	<u>Screening:</u> • Informed Consent • Preoperative Inclusion/Exclusion Criteria • Demographics and Medical History • Pregnancy Test (if applicable) • Concomitant Medications • Physical Exam • Clinical Scoring • Quality of Life Assessments • Duplex Ultrasound (DUS) • Computed Tomography Venography (CTV) or Magnetic Resonance Venography (MRV) <u>Procedure:</u> • Intraoperative Inclusion Criteria • IVUS & Venogram <u>Discharge:</u> • Concomitant Medications • Physical Exam • Clinical Scoring <u>Follow-Up (1, 6, 12, 24, 36, 48, and 60 months post-treatment):</u>

	• Physical Exam
	• Clinical Scoring
	• Quality of Life Assessments
	• Duplex Ultrasound
	• Computed Tomography Venography, IVUS, and Venogram
	  ○ 12M: CTV required
	  ○ All other visits: CTV, IVUS, or venogram only required when DUS is inconclusive or CTV, IVUS, or venogram is clinically required.
	• X-Ray
	  ○ 12M, 36M, and 60M

Vendor Information	Monitoring CRO, Core Lab, Data & Safety Monitoring Board (DSMB), and Clinical Events Committee (CEC) [redacted] Image Transfer [redacted] Electronic Data Capture (EDC) System [redacted]

PROTOCOL SUMMARY

Study Title	Evaluation of the GORE® VIAFORT Vascular Stent for Treatment of Symptomatic Inferior Vena Cava Obstruction with or without Combined Iliofemoral Obstruction
Protocol Number	VNS 21-05
Amendment 2	02 November 2023
EUDAMED No.	CIV-22-05-039591
Sponsor	W. L. Gore & Associates, Inc. Medical Products Division [redacted] Telephone: 800-437-8181
Local Representatives	W. L. Gore & Associates (Australia) Pty, Ltd. [redacted] Gore Authorised Representative (Europe) W. L. Gore & Associates B.V. [redacted]
Study Design	Prospective, non-randomized, multicenter, single-arm, global clinical study.
Study Objective	Establish the safety and effectiveness of the GORE® VIAFORT Vascular Stent for treatment of symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction.
Primary Study Endpoint	Composite primary endpoint consisting of freedom from the following: • Loss of primary patency through 12-month follow-up • Stent embolization through 12-month follow-up • Device- or procedure-related death through 30 days • Clinically significant pulmonary embolism confirmed via Computed Tomography Angiography through 30 days • Device- or procedure-related vascular injury through 30 days requiring surgical or endovascular intervention • Device- or procedure-related major bleeding events through 30 days
Secondary Study Endpoints	• Primary patency through 60-month follow-up • Secondary patency through 60-month follow-up

	• Clinically driven target lesion revascularization through 60-month follow-up • Device fracture through 60-month follow-up • Stent embolization through 12-month follow-up • Device- or procedure-related death through 30 days • Clinically significant pulmonary embolism confirmed via Computed Tomography Angiography through 30 days • Device- or procedure-related vascular injury through 30 days requiring surgical or endovascular intervention • Device- or procedure-related major bleeding events through 30 days • Improvement in Revised Venous Clinical Severity Scale (rVCSS) Measurement through 60-month follow-up compared to baseline prior to treatment • Improvement in rVCSS Pain Measurement through 60-month follow-up compared to baseline prior to treatment • Improvement in VEINES Measurement through 60-month follow-up compared to baseline prior to treatment • Improvement in Villalta Measurement through 60-month follow-up compared to baseline prior to treatment • Improvement in EQ-5D-5L Measurement through 60-month follow-up compared to baseline prior to treatment • Technical success • Lesion success • Procedural success
Subject Population	Adult patients (at least 18 years of age) with symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction. The population is largely expected to be patients with post-thrombotic syndrome; patients with malignant obstruction would be excluded.
Number of Treated Subjects	111 implanted subjects divided among multiple centers located in the United States, Europe, Australia, and New Zealand. At least 45 of these 111 subjects will be enrolled in the United States.
Number of Sites	Approximately 10 (with a maximum of 20) clinical sites located in the United States. Approximately 10 (with a maximum of 15) clinical sites located across Australia, New Zealand, and Europe. The sponsor shall maintain an updated list of principal investigators, investigational sites, and institutions. This list shall be kept separately from this Protocol.
Coordination PI	[redacted]

	
Significant Inclusion Criteria	• One of the following: Clinical severity class of CEAP 'C' classification ≥3 or rVCSS pain score ≥2. • Patient has adequate inflow to the target lesion(s), per investigator/sub-investigator discretion, involving at least a patent femoral or deep femoral vein. • Intraoperative Inclusion Criteria: o Presence of non-malignant obstruction of the inferior vena cava defined as occlusion or at least 50% reduction in target vessel lumen as measured by procedural IVUS and venogram, with or without non-malignant obstruction of the common femoral vein, external iliac vein, and/or common iliac vein. o Patient can accommodate an appropriately sized GORE® VIAFORT Vascular Stent as per reference vessel diameter (see IFU), as determined by intraoperative IVUS post pre-dilation. o Patient must have appropriate access vessels to accommodate the delivery sheath for the selected device size. o Patient has adequate landing zones free from significant disease requiring treatment within the native vessels beyond the proximal and distal margins of the lesion. o Patient has adequate inflow to the target lesion(s), per investigator/sub-investigator discretion, involving at least a patent femoral or deep femoral vein. o Lesion can be traversed with a guidewire. o Disease involves the inferior vena cava and may include iliofemoral segments with intent to stent all affected iliofemoral and caval segments. o Patient does not have significant (i.e., >20% residual thrombosis) acute thrombus within the target stent area at the time of investigational device placement.

	○ Patient does not have an inferior vena cava filter present within the target stent area at the time of investigational device placement.
Significant Exclusion Criteria	• Patient has clinically significant (e.g., symptoms of chest pain, hemoptysis, dyspnea, hypoxia, etc.) pulmonary embolism (confirmed via Computed Tomography Angiography) at the time of enrollment. • Patient has a known uncorrectable bleeding diathesis or active coagulopathy meeting the following definitions: uncorrected INR>2 (not as a result of warfarin or DOAC therapy), OR platelet count <50,000 or >1,000,000 cells/mm^3, OR white blood cell count <3,000 or >12,500 cells/mm^3. • Patient has impaired renal function (eGFR <30 mL/min/1.73m^2) or is currently on dialysis. • Patient has uncorrected hemoglobin of <9 g/dL. • Patient has significant peripheral arterial disease (chronic Rutherford Type 2 or greater, acute Rutherford Type IIa or greater).
Expected Time to Complete Enrollment	[redacted]
Expected Time of each Study Subject to Complete the Study	[redacted]
Total Expected Duration of the Study	[redacted]
Schedule of Events	<u>Screening:</u> • Informed Consent • Preoperative Inclusion/Exclusion Criteria • Demographics and Medical History • Pregnancy Test (if applicable) • Concomitant Medications • Physical Exam • Clinical Scoring • Quality of Life Assessments • Duplex Ultrasound (DUS) • Computed Tomography Venography (CTV) or Magnetic Resonance Venography (MRV) <u>Procedure:</u> • Intraoperative Inclusion Criteria • IVUS & Venogram <u>Discharge:</u> • Concomitant Medications • Physical Exam

	• Clinical Scoring <u>Follow-Up (1, 6, 12, 24, 36, 48, and 60 months post-treatment):</u> • Physical Exam • Clinical Scoring • Quality of Life Assessments • Duplex Ultrasound • Computed Tomography Venography, IVUS, and Venogram o 12M: Venogram or CTV required o All other visits: CTV, IVUS, or venogram only required when DUS is inconclusive or CTV, IVUS, or venogram is clinically required. • X-Ray o 12M, 36M, and 60M
Vendor Information	Monitoring CRO, Core Lab, Data & Safety Monitoring Board (DSMB), and Clinical Events Committee (CEC) [redacted] Image Transfer [redacted] Electronic Data Capture (EDC) System [redacted]

PROTOCOL SUMMARY

Study Title	Evaluation of the GORE® VIAFORT Vascular Stent for Treatment of Symptomatic Inferior Vena Cava Obstruction with or without Combined Iliofemoral Obstruction
Protocol Number	VNS 21-05
Amendment 2	02 November 2023
Sponsor	W. L. Gore & Associates, Inc. Medical Products Division [redacted] Telephone: 800-437-8181
Local Representatives	W. L. Gore & Associates (Australia) Pty, Ltd. [redacted] Gore Authorised Representative (Europe) W. L. Gore & Associates B.V. [redacted]
Study Design	Prospective, non-randomized, multicenter, single-arm, global clinical study.
Study Objective	Establish the safety and effectiveness of the GORE® VIAFORT Vascular Stent for treatment of symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction.
Primary Study Endpoint	Composite primary endpoint consisting of freedom from the following: • Loss of primary patency through 12-month follow-up • Stent embolization through 12-month follow-up • Device- or procedure-related death through 30 days • Clinically significant pulmonary embolism confirmed via Computed Tomography Angiography through 30 days • Device- or procedure-related vascular injury through 30 days requiring surgical or endovascular intervention • Device- or procedure-related major bleeding events through 30 days
Secondary Study Endpoints	• Primary patency through 60-month follow-up • Secondary patency through 60-month follow-up • Clinically driven target lesion revascularization through 60-month follow-up • Device fracture through 60-month follow-up

	• Stent embolization through 12-month follow-up • Device- or procedure-related death through 30 days • Clinically significant pulmonary embolism confirmed via Computed Tomography Angiography through 30 days • Device- or procedure-related vascular injury through 30 days requiring surgical or endovascular intervention • Device- or procedure-related major bleeding events through 30 days • Improvement in Revised Venous Clinical Severity Scale (rVCSS) Measurement through 60-month follow-up compared to baseline prior to treatment • Improvement in rVCSS Pain Measurement through 60-month follow-up compared to baseline prior to treatment • Improvement in VEINES Measurement through 60-month follow-up compared to baseline prior to treatment • Improvement in Villalta Measurement through 60-month follow-up compared to baseline prior to treatment • Improvement in EQ-5D-5L Measurement through 60-month follow-up compared to baseline prior to treatment • Technical success • Lesion success • Procedural success
Subject Population	Adult patients (at least 18 years of age) with symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction. The population is largely expected to be patients with post-thrombotic syndrome; patients with malignant obstruction would be excluded.
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Number of Sites	Approximately 10 (with a maximum of 20) clinical sites located in the United States. Approximately 10 (with a maximum of 15) clinical sites located across Australia, New Zealand, and Europe. The sponsor shall maintain an updated list of principal investigators, investigational sites, and institutions. This list shall be kept separately from this Protocol.
Coordination PI	[redacted]

	[redacted]
Significant Inclusion Criteria	• One of the following: Clinical severity class of CEAP 'C' classification ≥3 or rVCSS pain score ≥2. • Patient has adequate inflow to the target lesion(s), per investigator/sub-investigator discretion, involving at least a patent femoral or deep femoral vein. • Intraoperative Inclusion Criteria: o Presence of non-malignant obstruction of the inferior vena cava defined as occlusion or at least 50% reduction in target vessel lumen as measured by procedural IVUS and venogram, with or without non-malignant obstruction of the common femoral vein, external iliac vein, and/or common iliac vein. o Patient can accommodate an appropriately sized GORE® VIAFORT Vascular Stent as per reference vessel diameter (see IFU), as determined by intraoperative IVUS post pre-dilation. o Patient must have appropriate access vessels to accommodate the delivery sheath for the selected device size. o Patient has adequate landing zones free from significant disease requiring treatment within the native vessels beyond the proximal and distal margins of the lesion. o Patient has adequate inflow to the target lesion(s), per investigator/sub-investigator discretion, involving at least a patent femoral or deep femoral vein. o Lesion can be traversed with a guidewire. o Disease involves the inferior vena cava and may include iliofemoral segments with intent to stent all affected iliofemoral and caval segments. o Patient does not have significant (i.e., >20% residual thrombosis) acute thrombus within the target stent area at the time of investigational device placement. o Patient does not have an inferior vena cava filter present within the target stent area at the time of investigational device placement.

Significant Exclusion Criteria	• Patient has clinically significant (e.g., symptoms of chest pain, hemoptysis, dyspnea, hypoxia, etc.) pulmonary embolism (confirmed via Computed Tomography Angiography) at the time of enrollment. • Patient has a known uncorrectable bleeding diathesis or active coagulopathy meeting the following definitions: uncorrected INR>2 (not as a result of warfarin or DOAC therapy), OR platelet count <50,000 or >1,000,000 cells/mm^3, OR white blood cell count <3,000 or >12,500 cells/mm^3. • Patient has impaired renal function (eGFR <30 mL/min/1.73m^2) or is currently on dialysis. • Patient has uncorrected hemoglobin of <9 g/dL. • Patient has significant peripheral arterial disease (chronic Rutherford Type 2 or greater, acute Rutherford Type IIa or greater).
Expected Time to Complete Enrollment	[redacted]
Expected Time of each Study Subject to Complete the Study	[redacted]
Total Expected Duration of the Study	[redacted]
Schedule of Events	Screening: • Informed Consent • Preoperative Inclusion/Exclusion Criteria • Demographics and Medical History • Pregnancy Test (if applicable) • Concomitant Medications • Physical Exam • Clinical Scoring • Quality of Life Assessments • Duplex Ultrasound (DUS) • Computed Tomography Venography (CTV) or Magnetic Resonance Venography (MRV) Procedure: • Intraoperative Inclusion Criteria • IVUS & Venogram Discharge: • Concomitant Medications • Physical Exam • Clinical Scoring Follow-Up (1, 6, 12, 24, 36, 48, and 60 months post-treatment):

	• Physical Exam
	• Clinical Scoring
	• Quality of Life Assessments
	• Duplex Ultrasound
	• Computed Tomography Venography, IVUS, and Venogram
	  ○ 12M: CTV required
	  ○ All other visits: CTV, IVUS, or venogram only required when DUS is inconclusive or CTV, IVUS, or venogram is clinically required.
	• X-Ray
	  ○ 12M, 36M, and 60M

Vendor Information	Monitoring CRO, Core Lab, Data & Safety Monitoring Board (DSMB), and Clinical Events Committee (CEC) [redacted] Image Transfer [redacted] Electronic Data Capture (EDC) System [redacted]

PROTOCOL SUMMARY

Study Title	Evaluation of the GORE® VIAFORT Vascular Stent for Treatment of Symptomatic Inferior Vena Cava Obstruction with or without Combined Iliofemoral Obstruction
Protocol Number	VNS 21-05
Amendment 2	02 November 2023
Sponsor	W. L. Gore & Associates, Inc. Medical Products Division [redacted] Telephone: 800-437-8181
Local Representatives	W. L. Gore & Associates (Australia) Pty, Ltd. [redacted] Gore Authorised Representative (Europe) W. L. Gore & Associates B.V. [redacted]
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Subject Population	Adult patients (at least 18 years of age) with symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction. The population is largely expected to be patients with post-thrombotic syndrome; patients with malignant obstruction would be excluded.
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Coordination PI	[redacted]

[redacted]	
Significant Inclusion Criteria	• One of the following: Clinical severity class of CEAP 'C' classification ≥3 or rVCSS pain score ≥2. • Patient has adequate inflow to the target lesion(s), per investigator/sub-investigator discretion, involving at least a patent femoral or deep femoral vein. • Intraoperative Inclusion Criteria: o Presence of non-malignant obstruction of the inferior vena cava defined as occlusion or at least 50% reduction in target vessel lumen as measured by procedural IVUS and venogram, with or without non-malignant obstruction of the common femoral vein, external iliac vein, and/or common iliac vein. o Patient can accommodate an appropriately sized GORE® VIAFORT Vascular Stent as per reference vessel diameter (see IFU), as determined by intraoperative IVUS post pre-dilation. o Patient must have appropriate access vessels to accommodate the delivery sheath for the selected device size. o Patient has adequate landing zones free from significant disease requiring treatment within the native vessels beyond the proximal and distal margins of the lesion. o Patient has adequate inflow to the target lesion(s), per investigator/sub-investigator discretion, involving at least a patent femoral or deep femoral vein. o Lesion can be traversed with a guidewire. o Disease involves the inferior vena cava and may include iliofemoral segments with intent to stent all affected iliofemoral and caval segments. o Patient does not have significant (i.e., >20% residual thrombosis) acute thrombus within the target stent area at the time of investigational device placement. o Patient does not have an inferior vena cava filter present within the target stent area at the time of investigational device placement.

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Expected Time to Complete Enrollment	[redacted]
Expected Time of each Study Subject to Complete the Study	[redacted]
Total Expected Duration of the Study	[redacted]

Schedule of Events

Screening:

- Informed Consent
- Preoperative Inclusion/Exclusion Criteria
- Demographics and Medical History
- Pregnancy Test (if applicable)
- Concomitant Medications
- Physical Exam
- Clinical Scoring
- Quality of Life Assessments
- Duplex Ultrasound (DUS)
- Computed Tomography Venography (CTV) or Magnetic Resonance Venography (MRV)

Procedure:

- Intraoperative Inclusion Criteria
- IVUS & Venogram

Discharge:

- Concomitant Medications
- Physical Exam
- Clinical Scoring

Follow-Up (1, 6, 12, 24, 36, 48, and 60 months post-treatment):

	• Physical Exam
	• Clinical Scoring
	• Quality of Life Assessments
	• Duplex Ultrasound
	• Computed Tomography Venography, IVUS, and Venogram
	  ○ 12M: CTV required
	  ○ All other visits: CTV, IVUS, or venogram only required when DUS is inconclusive or CTV, IVUS, or venogram is clinically required.
	• X-Ray
	  ○ 12M, 36M, and 60M

Vendor Information	Monitoring CRO, Core Lab, Data & Safety Monitoring Board (DSMB), and Clinical Events Committee (CEC) [redacted] Image Transfer [redacted] Electronic Data Capture (EDC) System [redacted]