



**Veniti Vici™ Venous Stent System**

**Instructions for Use**



## INSTRUCTIONS FOR USE

### Veniti Vici™ Venous Stent System

**USA CAUTION: INVESTIGATIONAL DEVICE. Limited by USA federal law to investigational use only.**

#### Rx Only

The sale of the Veniti Vici™ Venous Stent System is restricted by or on the order of a physician.

#### WARNINGS



**Damage:** Do not use if packaging or product is damaged. If damage is found, call your VENITI representative.



**Sterile:** Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if the sterile barrier is damaged. If damage is found, call your VENITI representative.



**For Single Use Only.** Do not reuse, reprocess, or resterilize the System.

- Reuse, reprocessing, or resterilization might compromise the structural integrity of the device and/or lead to device failure which, in turn, might result in patient injury, illness, or death.
- Reuse, reprocessing, or resterilization might also create a risk of contamination of the device and/or cause patient infection or cross-infection including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device might lead to injury, illness, or death of a patient.

**Disposal:** After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policies.



**Instructions:** Carefully read all instructions prior to use. Observe all warnings and Precautions noted throughout these instructions. Failure to do so might result in complications.

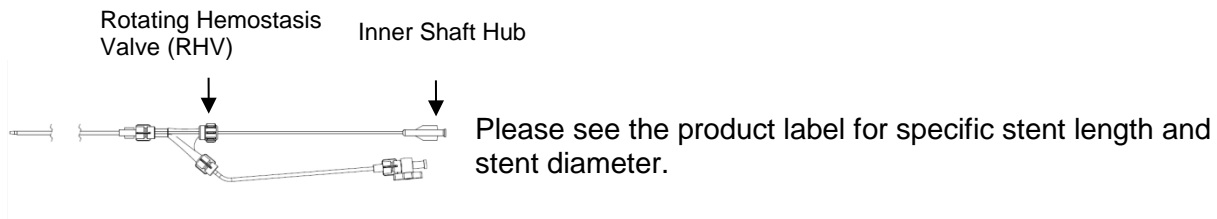
#### DESCRIPTION

The Veniti Vici™ Venous Stent System is composed of two components: the implantable stent and the stent delivery system.

The stent is a laser cut self-expanding stent composed of a nickel titanium alloy (nitinol) with closed-cell segments and flexible interconnections designed specifically for use in venous anatomy. It is available in 60-, 90- and 120-mm lengths and 12-, 14- and 16-mm diameters.

The delivery system is a coaxial design with an outer shaft to protect and constrain the stent prior to deployment. The delivery system is an Over-The-Wire system compatible with 0.89 mm

(0.035 in.) guidewires and a 9 French sheath introducer which allows delivery via either a jugular or femoral vein approach.



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One (1) Veniti Vici™ Venous Stent System

## RECOMMENDED MATERIALS

Additional items that may be required for this procedure are as follows:

- 9F sheath
- 0.89 mm (0.035 in.) guidewire
- Sterile syringe with luer lock for flushing
- Sterile, heparinized physiological saline

## INTENDED USE

The Veniti Vici™ Venous Stent System is intended for use in veins of the lower extremities and pelvis, including the iliac and common femoral veins, for the treatment of adult patients (age 18 and older) who exhibit symptomatic venous outflow obstruction.

## CONTRAINDICATIONS

The Veniti Vici™ Venous Stent System should not be implanted in patients with total venous occlusion unless the occlusion has been traversed by a guidewire and sufficiently dilated prior to placement.

## WARNINGS

- **Training:** Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects, and hazards commonly associated with interventional vascular procedures should use this device.
- **Use-By Date:** Do not use the device after the “Use By” date specified on the package label.
- **Storage:** Ensure that the device has been properly stored in a cool, dry place prior to use.
- **Sizing:** Do not deploy the Veniti Vici™ Venous Stent unless the target diameter has been properly measured. Improper stent size selection can lead to stent migration or stent jumping.
  - The diameter of the stent should be at least 2 mm greater than (“over”) the measured diameter of the surrounding “normal” vessel.
  - The stent should be at least 1 cm longer than the obstructive venous lesion (0.5 cm distally and 0.5 cm proximally).

- When selecting stent length, the expected foreshortening (approximately 10-20%) should be taken into account
- **Delivery System Position:** Failure to maintain delivery system position during stent deployment might lead to placement of the stent in an unintended site.
  - Do not push the inner shaft hub forward as this could result in a failure to release the stent or deployment in a sub-optimal location.
- **Stent Deployment:** The Veniti Vici Venous Stent cannot be retracted into the delivery system once it is partially expanded. Doing so could result in damage to the vessel.
- **Delivery System Removal:** The nose cone of the inner shaft must be retracted into the outer shaft before removing the delivery system. Failure to do so could result in the nose cone catching on the stent.
- **Overlapping Stents:** The safety and effectiveness of multiple overlapping stents have not been established; technical and clinical studies evaluating this condition are ongoing. However, when multiple stents are required, stent materials should be of similar composition.
- **Nickel Allergy:** The Veniti Vici Venous Stent is constructed of a nickel-titanium alloy (nitinol), which is generally considered safe; however, patients who are allergic to nickel or who have a history of metal allergies could have an allergic reaction to this device.

## PRECAUTIONS

- **Training:** The Veniti Vici™ Venous Stent should be placed by physicians thoroughly trained in the placement of endovascular prostheses.
- **Inspection:** Inspect the packaging and device prior to use for any bends, kinks, or breaks. If damage is noted, do not use the device and contact your VENITI representative.
- **Proper Handling:** Exercise care in handling the Veniti Vici Venous Stent Delivery System to reduce the possibility of accidental breakage, bending, kinking, or compromise of the sterile field.
- **Flush Lumens:** Always ensure air is removed from all lumens via flushing prior to use of the device.
- **Product Compatibilities:**
  - Always check compatibility of the introducer size used.
  - Ensure compatibility of other medical products used in the procedure. See “Recommended Materials” section.
- **Fluoroscopic Guidance Required:** Never advance a guidewire or introducer sheath/dilator or deploy the stent without fluoroscopic guidance.
- **Resistance:** Never advance or withdraw an endovascular device against resistance until the cause of the resistance is determined. Movement of the device against resistance can result in damage to the device or vessel.
- **Kinks:** Do not use if the delivery system is kinked.
- **Introducer/Guide Sheath Required:**
  - Always use an introducer or guide sheath for the implant procedure to protect the access site.
  - Only advance the stent delivery system over a guidewire

- **Sizing:** The minimally acceptable sheath French size is printed on the package label. Do not attempt to pass the stent delivery system through a smaller size sheath introducer than indicated on the label.
- **Thrombus:** If thrombus is noted once the stent is expanded, thrombolysis and/or PTA should be considered.
- **Procedural Complications:** In the event of procedural complications such as infection, pseudoaneurysms, or fistula formation, surgical removal of the stent might be required.

## COMPLICATIONS

Implantation of the Veniti Vici™ Venous Stent should not be attempted by physicians who are not familiar with the possible complications that could occur during interventional endovascular procedures.

Potential procedural complications of such procedures include, but are not limited to:

- Access site complications including: bleeding, pain, tenderness, pseudoaneurysm, hematoma, nerve or vessel damage, or infection
- Stent fracture
- Stent migration, jumping, or embolization
- Allergic or hypersensitivity reactions
- Renal failure
- Vessel thrombosis
- Cerebrovascular dysfunction and/or stroke
- Organ failure
- Death
- Restenosis
- Pneumothorax or respiratory distress, pneumonia and/or atelectasis
- Thrombophlebitis
- Obstruction of venous tributaries
- Vessel perforation
- Myocardial infarction, ischemia, angina, or other cardiovascular disturbance



## MAGNETIC RESONANCE IMAGING (MRI)

- The Veniti Vici™ Venous Stent was determined to be MR Conditional according to ASTM F2503-05 “Standard Practice for Marking Medical Devices and Other Items for Safety in Magnetic Resonance Environment.”
- A patient with the Veniti Vici Venous Stent can be scanned safely under the following conditions:
  - Static magnetic field of 1.5 Tesla or 3.0 Tesla
  - Maximum spatial gradient magnetic field of 720 Gauss/cm or less
  - Maximum MR system-reported, whole-body averaged specific absorption rate (SAR) of 2 W/Kg for 15 minutes of scanning
  - Normal operating mode for the MRI system
  - Under the scan conditions described above, the Veniti Vici Venous Stent is expected to produce a maximum temperature rise of 3.9°C or 2.6°C at a maximum MR system-reported, whole-body averaged specific absorption rate (SAR) of 2.9 W/kg for 15 minutes of continuous MR scanning in a 1.5-Tesla MRI

system (Magnetom, Software Numaris/4, Siemens Medical Solutions, Malvern, PA) or a 3.0 Tesla MRI system (Excite, Software 14X.M5, GE Healthcare, Milwaukee, WI), respectively.

- Image quality might be compromised if the area of interest is in the exact area of, or relatively close to, the position of the Veniti Vici Venous Stent. Therefore, optimization of MR imaging parameters to compensate for the presence of the implant might be required. In non-clinical testing, the image artifact caused by the device extends approximately 5 mm relative to the size and shape of the Veniti Vici Venous Stent when imaged with a 1.5 Tesla or 3.0 Tesla MRI system.
- It is recommended that patients with a Veniti Vici Venous Stent register the MR Conditions with the MedicalAlert Foundation ([www.medicalert.org](http://www.medicalert.org)).

## PROCEDURE

The following instructions provide technical direction, but do not obviate the necessity of training in the use of the Veniti Vici™ Venous Stent System. The techniques and procedures described do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient.

### Step 1-Obtain Access

- Prepare, drape, and anesthetize the skin puncture site in standard fashion.
- Obtain access using either the Seldinger technique or cutdown.

### Step 2-Preparations for Use

- Ensure all luers are securely fastened.
- Flush the inner shaft lumen with heparinized saline. Tighten the rotating hemostasis valve (RHV).
- Flush outer shaft lumen with heparinized saline or suitable isotonic solution. Close the stopcock after flushing of the outer shaft lumen is complete.

### Step 3-Stent Placement

- The following steps must be completed under fluoroscopic guidance.
  - Advance the Sheath Introducer into body.
  - Position the Sheath Introducer tip.
  - Advance the guidewire through the Sheath Introducer and past the obstruction to be treated.
  - Determine the vessel diameter and length of the lesion at the target placement location. The stent diameter should be at least 2 mm greater than (“over”) the measured diameter of the “normal” vessel.
  - Advance the delivery system over the guidewire and into the Sheath Introducer until the distal end of the stent extends approximately 0.5 cm beyond the end of the lesion.
    - **Note:** *This defines the location of the implanted stent.*

### Step 4-Stent Deployment




- Loosen the rotating hemostasis valve (RHV).
  - **Note:** *Do not loosen the luer end of the rotating hemostasis valve as this will increase the difficulty of stent deployment or prevent stent deployment.*

- Secure the inner shaft hub and retract the rotating hemostasis valve to deploy the stent.
  - **Warning:** Failure to select appropriate stent length and diameter based on lesion and vessel characteristics could lead to embolization; i.e. stent too small.
  - **Warning:** Failure to maintain delivery system position during stent deployment might lead to placement of the stent in an unintended site. Do not push the inner shaft hub forward as this could result in a failure to release the stent or deployment in a sub-optimal location.
  - **Warning:** Do not advance or retract the delivery system once the stent is partially expanded to prevent vessel damage. The Veniti Vici™ Venous Stent cannot be retracted into the delivery system once it is partially expanded.
- Confirm that the stent is fully deployed.

### Step 5-Removal & Confirmation

- Remove the stent delivery system.
  - **Warning:** Before removing the delivery system, the nose cone of the inner shaft must be retracted into the outer shaft. Failure to do so might result in the nosecone catching on the sheath introducer.
- Perform a venogram to confirm proper positioning and full approximation of the stent to the vessel wall.

### HANDLING & STORAGE

-  Do not use if package is opened or damaged. Contact your VENITI representative.
-  Do not use if package label is incomplete or illegible. Contact your VENITI representative.
-  Store in a dry, cool place at room temperature.

### STERILIZATION

The Veniti Vici™ Venous Stent System has been sterilized with ethylene oxide.

### DISPOSAL

After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.

### LIMITED WARRANTY

VENITI, Inc. warrants that the Veniti Vici™ Venous Stent System is free from defects in workmanship and material prior to the stated expiration date. Liability under this warranty is limited to refund or replacement of any product which has been found by VENITI, Inc. to be defective in workmanship or materials. VENITI, Inc. shall not be liable for any incidental, special, or consequential damages arising from the use of the Veniti Vici™ Venous Stent System.

Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty.

No employee, agent, or distributor of VENITI, Inc. has any authority to alter or amend this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against VENITI, Inc.

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