Specifically engineered to withstand the crushing forces of venous disease, Vici delivers the radial strength required to maintain a widely patent lumen, restore flow effectively, and optimize clinical outcomes.
Resists Crush in Venous Anatomy

To thrive in the venous system, a stent must be able to endure the intense compressive and obstructive characteristics of venous disease. Vici is a stent dedicated to creating and maintaining an open lumen to treat venous pathology.

UNIQUELY DESIGNED FOR CRUSH RESISTANCE
Vici is a laser-cut nitinol stent with a distinctive closed-cell design that provides significant crush resistance. Its high scaffold thickness-to-strut ratio is tuned for venous pathology to maintain durability. Its 24 strut pairs and alternating curved bridges work together to balance its strength with the necessary flexibility for everyday patient movement.

Improves Flow with an Open Lumen

The crush-resistant strength of Vici creates a circular lumen that reduces turbulence and restores flow, optimizing outcomes for patients with deep venous disease.

LUMEN SHAPE AFFECTS FLOW
Research shows that lumen shape impacts flow. Specifically, a flatter lumen causes higher pressure and lower flow. In fact, a crushed lumen with a 2:1 length-to-width ratio loses 49% of its volume.

* Dr. Lowell Kabnick, “Does Lumen Shape Matter” presented at AVF 2018
VICI VENOUS STENT

VICI VENOUS STENT SYSTEM and VICI RDS SYSTEM

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. As prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE: The VICI VENOUS STENT System and VICI RDS Venous Stent System are both indicated for improving luminal diameter in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction.

CONTRAINDICATIONS: The VICI VENOUS STENT System and VICI RDS Venous Stent System are both contraindicated for use in: (i) Patients who are subject to a lesion that prevents complete inflation of a balloon dilatation catheter or proper placement of the stent or the stent delivery system; (ii) Patients who cannot receive intraprocedural anti-coagulation therapy.

WARNINGS: Safety and efficacy for stenting outside of the Common Iliac Vein (CIV), External Iliac Vein (EIV) and Common Femoral Vein (CFV) with the VICI VENOUS STENT and the VICI RDS™ Venous Stent have not been studied. Stenting in the region of the iliac bifurcation in some patients may result in an increased risk of stent fracture. Use compression devices in the region of the VICI VENOUS STENT and the VICI RDS™ Venous Stent do not need to be extended across the Inferior Vena Cava (IVC). Physicians should extend the stent up to 10cm beyond the compressive lesion. The VICI VENOUS STENT System and the VICI RDS™ Venous Stent System have not been evaluated for contralateral access. This access approach is not recommended.

ACCESS: This device is designed for a position of overlap of the ilial and superficial veins only. Access site should allow for safe and adequate access to the vein. Gaining. To eliminate risk of stent migration or stent movement, do not deploy the VICI VENOUS STENT or VICI RDS Venous Stent unless the target diameter has been properly measured. Improper stent size selection can result in stent migration or inadvertent stent movement. The diameter of the stent should be 3mm more than the "measured diameter of the surrounding normal venous wall." A post-implantation duodenal vein, target veins should be pre-dilated to the reference vein diameter. As non-thrombotic lesions, size stent diameter to ensure stent engagement in areas of focal luminal compressive lesions (e.g. varicose veins) and adequate wall apposition in peripheral normal veins. (Stented veins present to lumen are not normal veins, and therefore should not be used to measure reference ven diameter and stent diameter selection. Excessive oversizing of stents has been reported to contribute to poor operator patient patency.) The stent length should be at least 1 cm longer than the obstructive venous lesion (at least 5 cm shorter and 1 cm perpendicular). Stent Deployment: The VICI VENOUS STENT and the VICI RDS™ Venous Stent cannot be re-telescoped into the delivery system once it is partially deployed. Attempted retrieval may result in damage to the veins. Caution should be used to avoid stenting or re-stenting the stent during deployment, as this may increase risk of stent fracture. During deployment, maintain the position of the inner shaft hub. Alcohol Injuries: The VICI VENOUS STENT and the VICI RDS™ Venous Stent are constructed of a nickel-titanium alloy (Nitinol) and tantalum, which are generally considered safe however, patients who are allergic to these materials or who have a history of metal allergies may have an allergy reaction to this device.

PRECAUTIONS: (i) The minimally acceptable sheath size is printed on the package label. Do not attempt to pass the stent delivery system through a smaller size introducer sheath than indicated on the label. (ii) Time-stitch is noted on the stent is expanded. Thrombosis and/or PTFE should be considered. (iii) Use the device in the event of procedural complications such as infection, pseudoaneurysms, or hematoma formation. Surgical removal of the device may be required. (iv) MRI Safety Information: (a) Non-clinical studies have demonstrated that the VICI VENOUS STENT System and the VICI RDS™ Venous Stent System are MR Conditional. A patient with the VICI VENOUS STENT or VICI RDS™ Venous Stent can be scanned safely, immediately prior to, in an MR system meeting the following conditions: Static magnetic field of 1.5T or 3T only; Maximum gradient magnetic field of 50Gauss/cm (50T/m); A maximum system-reported, whole body averaged specific absorption rate (SAR) of 2W/kg (Normal Operating Mode). Under the scan conditions defined, the VICI VENOUS STENT and VICI RDS™ Venous Stent are expected to produce a maximum temperature rise of 6°C after 15 minutes of continuous scanning. (b) In non-clinical testing, the image artifact caused by the VICI VENOUS STENT and VICI RDS™ Venous Stent extend approximately 1cm from the device when imaged with a gradient echo pulse sequence with a 3.0T system. The image artifact caused by the VICI VENOUS STENT or VICI RDS™ Venous Stent cannot be visualized on the gradient echo or T1-weighted, spin echo pulse sequences. (c) The VICI VENOUS STENT and VICI RDS™ Venous Stent are expected to produce a maximum temperature rise of 6°C after 15 minutes of continuous scanning. (d) In non-clinical testing, the image artifact caused by the VICI VENOUS STENT and VICI RDS™ Venous Stent extend approximately 1cm from the device when imaged with a gradient echo pulse sequence with a 3.0T system. The image artifact caused by the VICI VENOUS STENT or VICI RDS™ Venous Stent cannot be visualized on the gradient echo or T1-weighted, spin echo pulse sequences. (e) ADVISORY EVENTS: Removal of the VICI VENOUS STENT or VICI RDS™ Venous Stent should not be attempted by physicians who are not familiar with the possible complications that may occur during interventional endovascular procedures. Potential device or procedure-related complications of interventional endovascular procedures include, but are not limited to: (i) Access: Access site complications including bleeding, pain, tenderness, pseudoaneurysms, hematoma, or venous damage, or infection. Allergies or hypersensitivity reactions (Drug, contrast, device or other); (ii) Amputation: Arteriovenous fistula formation and rupture; (iii) Back pain: Contrast-induced myelopathy and/or cramps; (iv) Embolization: Embolectomy of delivery system in deployed stent; (v) Fever; (vi) Bleeding: Hemorrhage, hyperfusion, Myocardial infarction, ischemia, angina, or other cardiovascular disturbances; (vi) Other: Severe cardiac or pulmonary disease; (vii) Severe GI bleeding; (viii) Severe respiratory distress, pneumonitis and/or atelectasis; (ix) Renal failure; (x) Severe infection; (xi) Stent fracture; (xii) Stent migration, malpositioning, angulation, or embolization; (xiii) Stent occlusion; (xiv) Venous occlusion; (xv) Venous thrombosis; (xvi) Venous outflow obstruction; (xvii) Venous injury; (xviii) Examples include dissection, intimal tear, rupture or perforation. 01215282.3

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PI-593803-AB