Recanalization of Chronic Ilioferomal Venous Occlusion in a Patient with PAD

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Leipzig, 24. Jan 2021

Disclosure

Speaker name:

Dr. Houman Jalaie

I have the following potential conflicts of interest to report:

- ☒ Consulting for BD, Medtronic, Cook, Boston Scientific, Bentley, Optimed
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any potential conflict of interest

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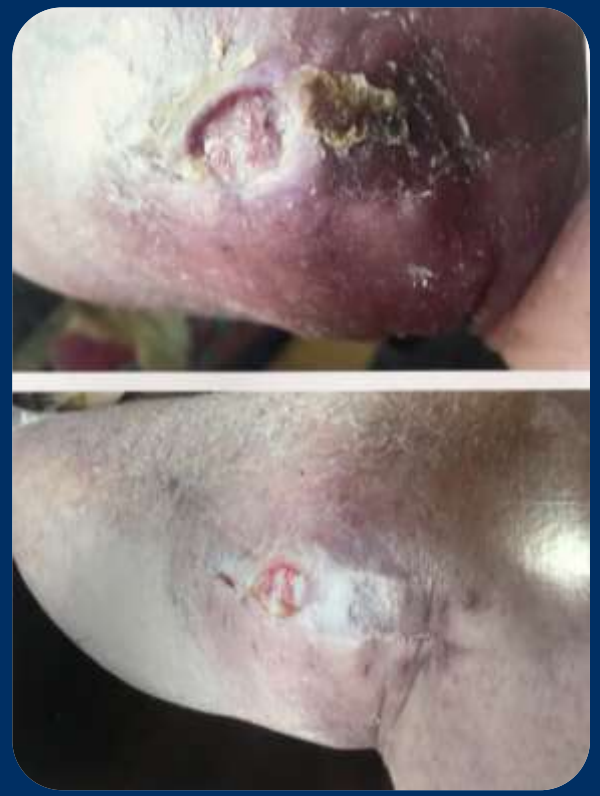
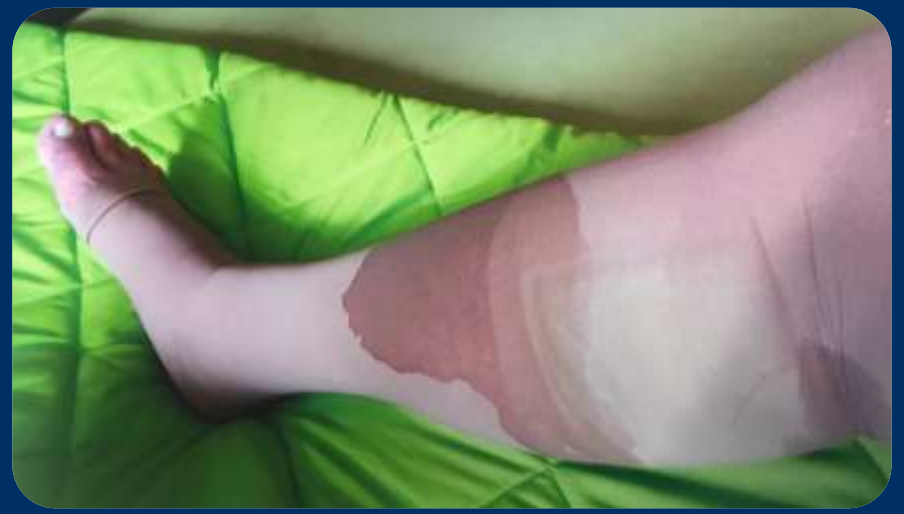
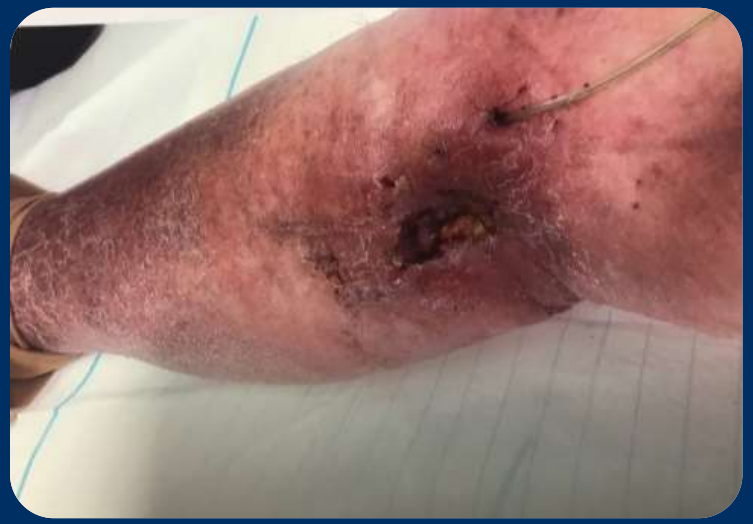
The opinions and clinical experiences presented herein are for informational purposes only. The results from this study report may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes.

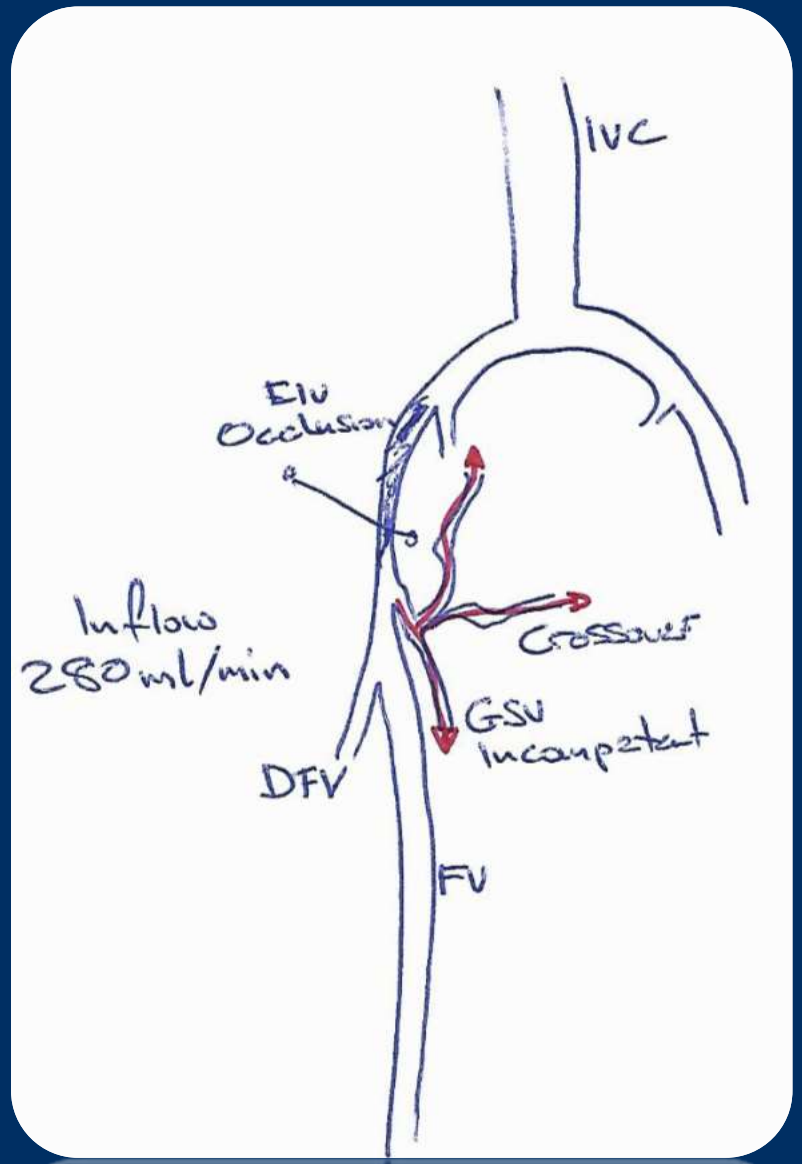
The clinicians have been compensated by Becton, Dickinson and Company to participate in this presentation.

- 68y, male
- PAD
- Below the knee bypass (contralat. GSV, reversed) 2018
- Wound healing disorder (since bypass procedure)
- Severe lymphorrhea (2 years)
- Hyperpigmentation, swelling, tension, pain, venous claudication

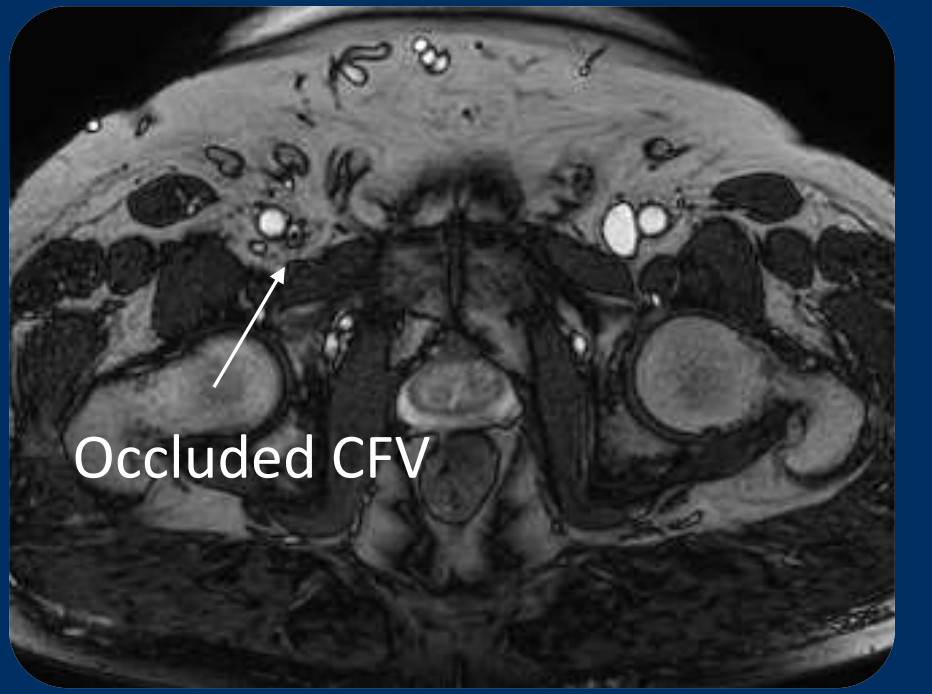


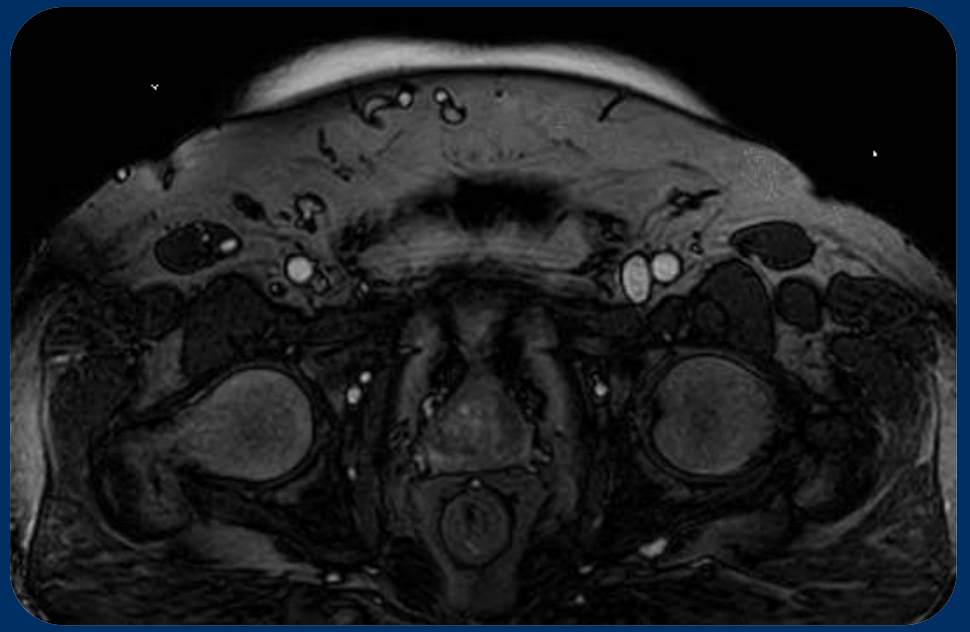




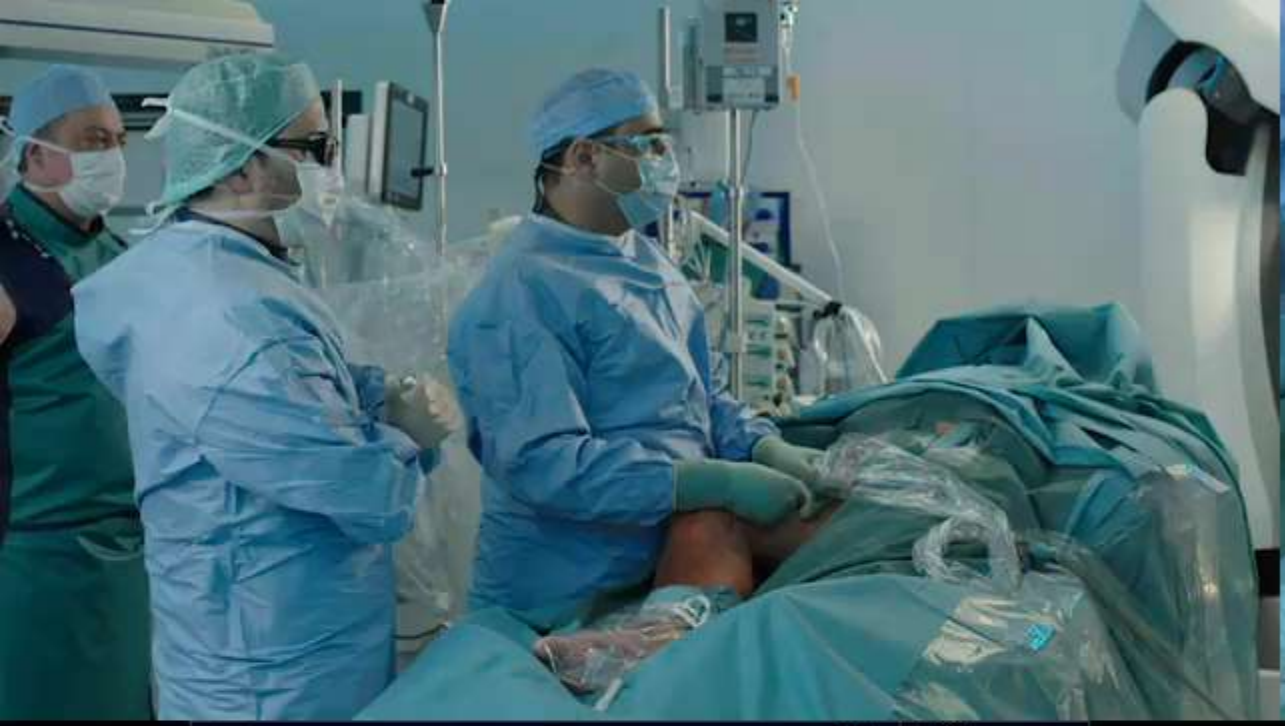


Venous map





MR-phlebo

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Precision
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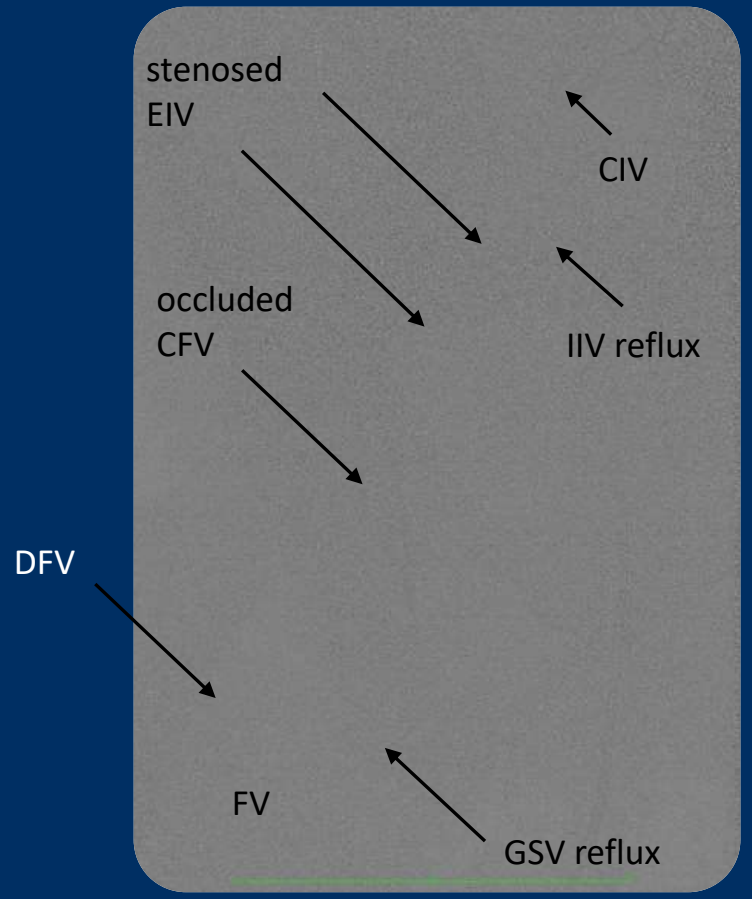
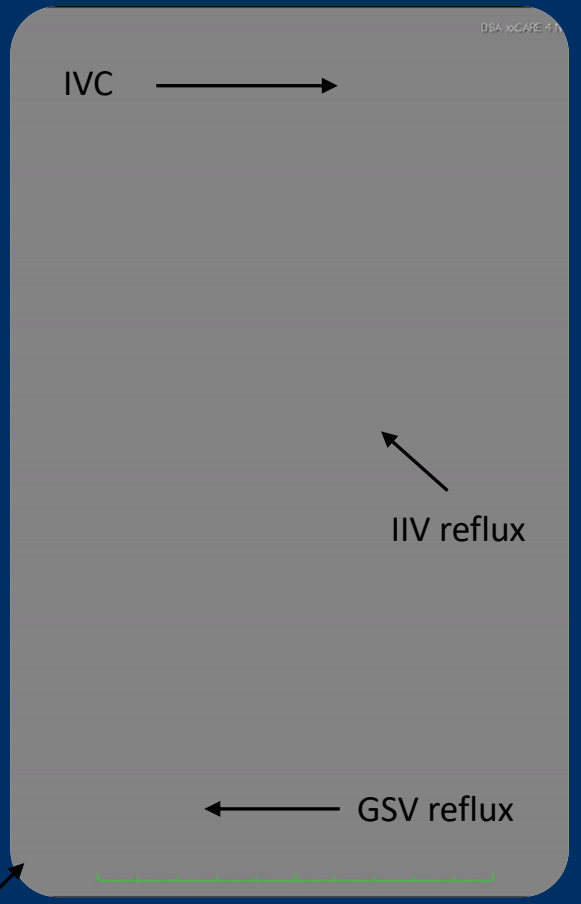
Angiographic Result

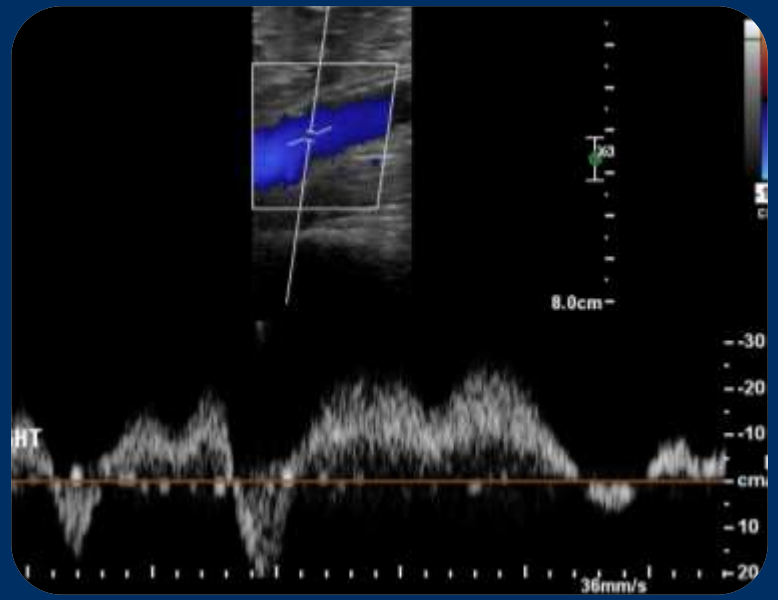


Phlebo

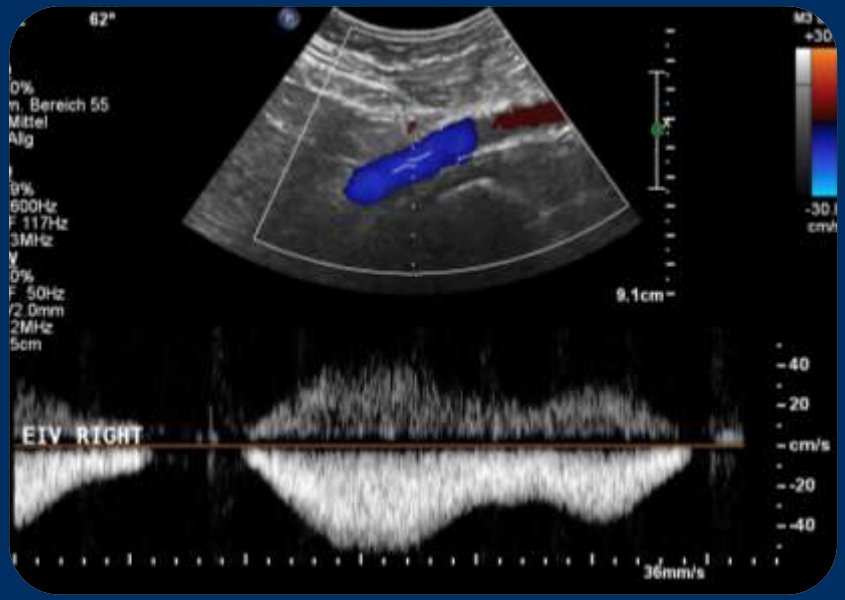


DFV

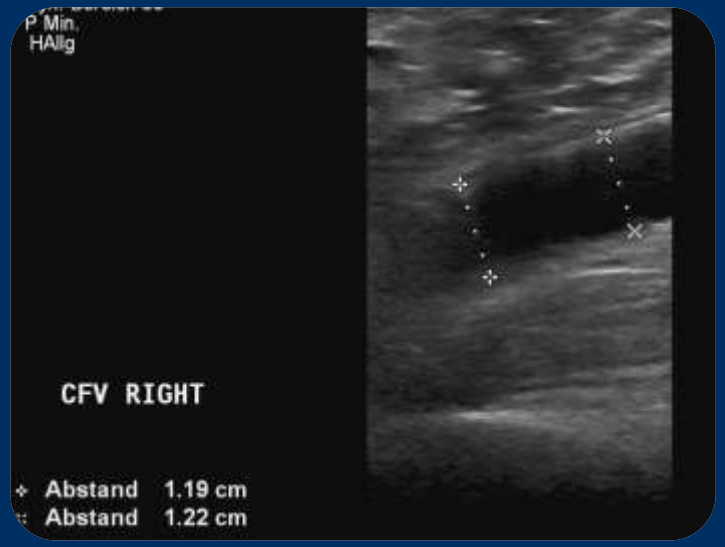
Completion angiogram



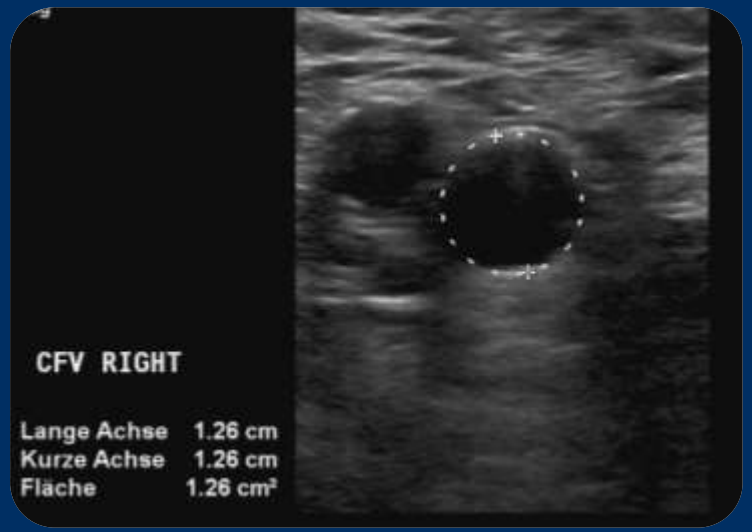
Postop DUS evaluation CFV



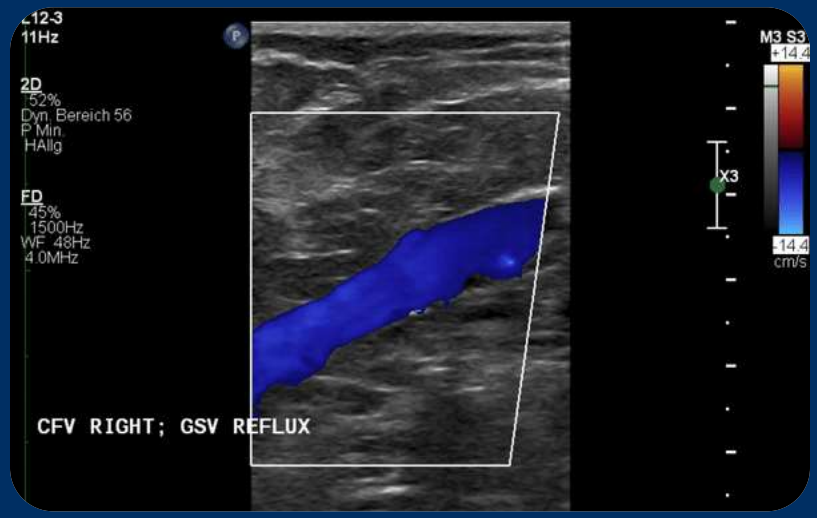
Postop DUS evaluation EIV



Diameter of the stent (CFV)

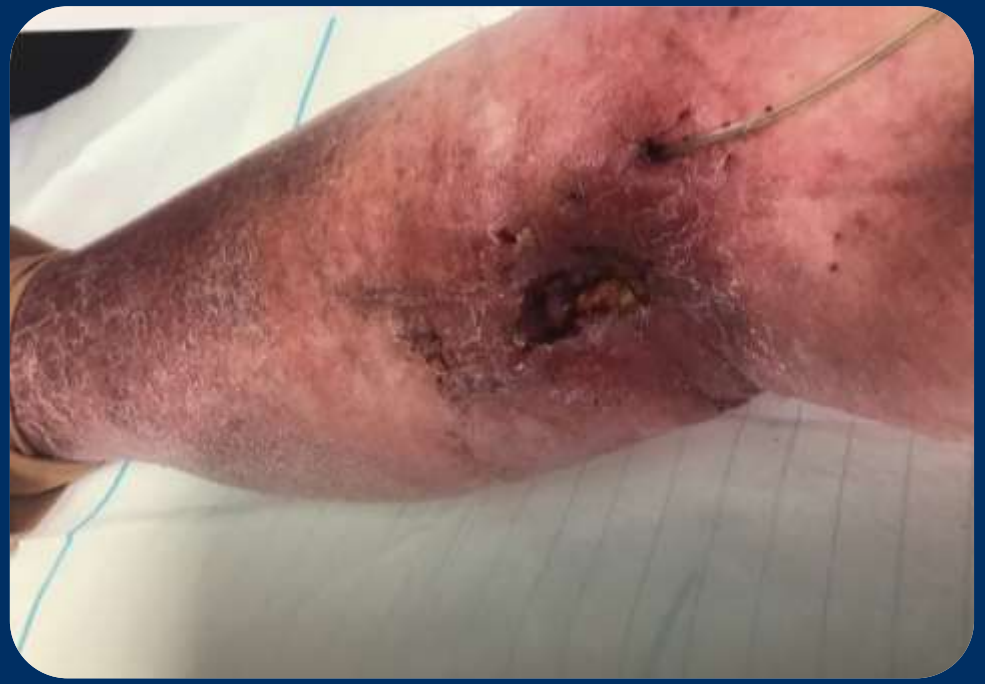


area of the stent (CFV)

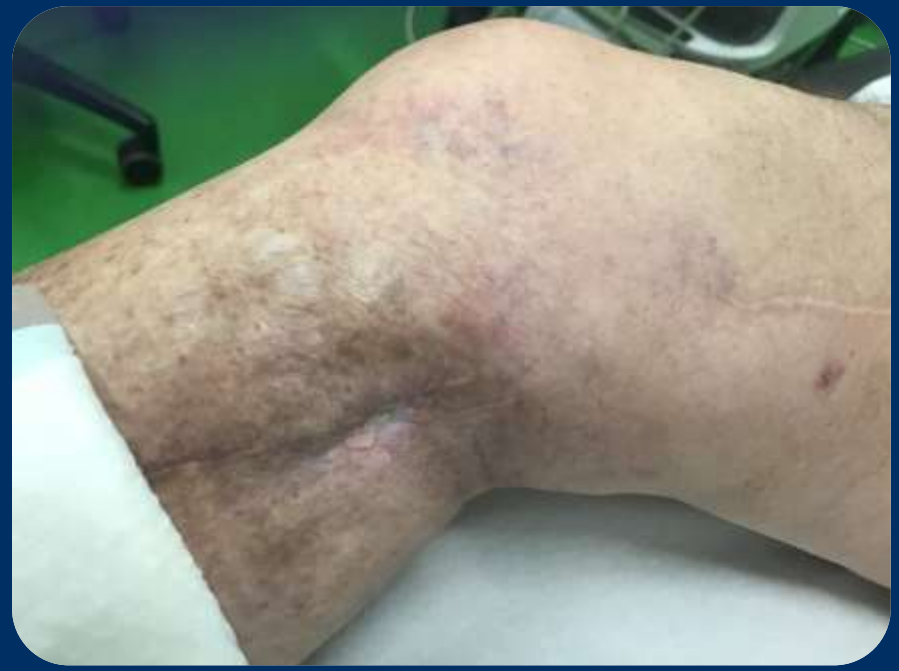


DUS showing reflux in GSV during valsalva

Clinical Result



Preop photo 12th February 2020



Postop evaluation 20th May 2020

Thank you

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VENOVO™ Venous Stent System

Indication for Use

The VENOVO™ Venous Stent System is indicated for the treatment of stenoses and occlusions in the iliac and femoral veins.

Contraindications

The VENOVO™ Venous Stent System is contraindicated for use in:

• Patients with a known hypersensitivity to nitinol (nickel-titanium), and tantalum • Patients who cannot receive recommended antiplatelet and/or anti-coagulation therapy • Patients who are judged to have a lesion that prevents complete inflation of a balloon dilatation catheter proper placement of the stent or the stent delivery system.

Warnings

•The VENOVO™ Venous Stent System is supplied sterile and is intended for SINGLE USE ONLY. DO NOT RESTERILIZE and/or REUSE the device. Reuse, resterilization, reprocessing and/or repackaging may create a risk to the patient or user, may lead to infection or compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness, or death of the patient. Reusing this medical device bears the risk of cross-patient contamination as medical devices - particularly those with long and small lumina, joints, and/or crevices between components- are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications or death. • DO NOT use in patients with total venous occlusion that cannot be dilated to allow passage of the guidewire. • DO NOT use the device with contralateral access. • DO NOT use the pouch is opened or damaged. • DO NOT use the device Il!!fil the "Use By" date specified on the label. • Persons with allergic reactions to nitinol (nickel-titanium) alloy and/or tantalum may suffer an allergic response to this implant. • DO NOT expose the delivery system to organic solvents, e.g., alcohol. • The stent is not designed for repositioning or recapturing. • Stenting across a major branch could cause difficulties during future diagnostic or therapeutic procedures. • If a long lesion needs to be stented consider using the longest available stent rattier than overlapping stents. If multiple stents are placed in an overlapping fashion, they should be of similar composition (i.e., nitinol) • The long-term outcomes following repeat dilatation of endothelialized stents are unknown. • The safety and effectiveness of this device for use in the arterial system have not been established.

Precautions

• The device is intended for use by physicians who have received appropriate training. • During system flushing, observe that saline exits at the catheter tip. • The delivery system is not designed for use with power injection systems. • Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution. • Prior to stent deployment, remove slack from the delivery system catheter outside the patient. • If excessive force is felt during stent deployment, do not force the delivery system. Remove the delivery system and replace with a new unit. • Store in a cool, dark, dry place. • Do not attempt to break, damage, or disrupt the stent after placement.

Potential Complications and Adverse Events

Complications and Adverse Events which may occur include, but are not limited to the following: • Allergic/anaphylactoid reaction • Amputation • Aneurysm • Arteriovenous fistula • Death related to procedure • Death unrelated to procedure • Dissection • Embolization, venous • Embolization, stent • Extravasation • Fever• Hemorrhage/bleeding requiring a blood transfusion • Hematoma, remote site • Hematoma, puncture site • Hypotension/hypertension • Incorrect positioning of the stent requiring further stenting or surgery • Intimal injury/dissection • ischemia/infarction of tissue/organ • Local infection • Mal position (failure to deliver the stent to the intended site) • Open surgical repair• Pain • Pulmonary embolism

Pseudoaneurysm • Renal failure • Respiratory arrest • Restenosis • Rupture • Septicemia/bacteremia • Stent Fracture • Stent Migration • Vasospasm • Venous occlusion/thrombosis, remote from puncture site • Venous occlusion/thrombosis, near the puncture site • Venous occlusion/restenosis of the treated vessel.

Please consult product labels and instructions for use for indications, contraindications, hazards, warnings and precautions.

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Atlas® Gold PTA Dilatation Catheter

Indications for Use: Atlas® Gold PTA Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the iliac arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of stents and stent grafts in the peripheral vasculature. This catheter is not for use in coronary arteries.

Contraindications: None known.

Warnings: 1) Contents supplied STERILE using ethylene oxide (EO). Nonpyrogenic. Do not use if sterile barrier is opened or damaged. Single patients use only. Do not reuse, reprocess, or re-sterilize. 2) This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices - particularly those with long and small lumina, joints, and/or crevices between components - are difficult or impossible to dean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications. 3) Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing, and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes. 4) To reduce the potential for vessel damage, the inflated diameter and length of the balloon should approximate the diameter and length of the vessel just proximal and distal to the stenosis. 5) To reduce the potential for stent or stent graft damage and/or vessel damage from the stent or stent graft, the diameter of the balloon should be no greater than the diameter of the stent or stent graft. Refer to the stent or stent graft IFU for safety information including the WARNINGS, PRECAUTIONS, and potential ADVERSE EFFECTS regarding the use of balloon post-dilatation. 6) When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated. If resistance is met during manipulation, determine the cause of the resistance before proceeding. Applying excessive force to the catheter can result in tip breakage or balloon separation. 7) Do not exceed the RBP recommended for this device. Balloon rupture may occur if the RBP rating is exceeded. To prevent over pressurization, use of a pressure monitoring device is recommended. 8) After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state, and federal laws and regulations.

Precautions: 1) Carefully inspect the catheter prior to use to verify that catheter has not been damaged during shipment and that its size, shape, and condition are suitable for the procedure for which it is to be used. Do not use if product damage is evident 2) The Atlas® Gold PTA Dilatation Catheter shall only be used by physicians trained in the performance of Percutaneous Transluminal Angioplasty. 3) The minimal acceptable sheath French size printed on the package label. Do not attempt to pass the PTA catheter through a smaller size sheath introducer than indicated on the label. 4) Do not remove the guidewire in situ to shoot contrast through the wire lumen or perform a wire exchange. If the wire is removed while the balloon catheter is situated in tortuous anatomy, the risk of kinking the catheter is increased. 5) Use the recommended balloon inflation medium (a range of 30-500/o contrast medium/a range of 50-700/o sterile saline solution). It has been shown that a 30/700/o contrast/saline ratio has yielded faster balloon inflation/deflation times. 6) Never use air or other gaseous medium to inflate the balloon. 7) If resistance is felt during post procedure withdrawal of the catheter through the introducer sheath, determine if contrast is trapped in the balloon with fluoroscopy. If contrast is present, push the balloon out of the sheath and then completely evacuate the contrast before proceeding to withdraw the balloon. 8) If resistance is still felt during post procedure withdrawal of the catheter, it is recommended to remove the balloon catheter and guidewire(introducer sheath as a single unit 9) Do not continue to use balloon catheter if the shaft has been bent or kinked. IO) Prior to re-insertion through the introducer sheath, the balloon should be wiped clean with gauze, rinsed with sterile normal saline, and refolded with the balloon re-wrap tool. Balloon re-wrapping should only occur while the balloon catheter is supported with a guidewire.

Potential Adverse Reactions: The complications which may result from a peripheral balloon dilatation procedure include: Additional intervention: • Allergic reaction to drugs or contrast medium • Aneurysm or pseudoaneurysm • Arrhythmias • Embolization • Hematoma • Hemorrhage, including bleeding at the puncture site • Hypotension/hypertension • Inflammation • Occlusion • Pain or tenderness • Pneumothorax or hemothorax • Sepsis/infection • Shock • Short term hemodynamic deterioration • Stroke • Thrombosis • Vessel dissection, perforation, rupture, or spasm

Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions and instructions for use. Warning: Do not exceed RBP as balloon rupture may occur. To prevent over pressurization, use of a pressure monitoring device is recommended.

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