Rotarex™S: Rotational Atherothrombectomy catheter for an extreme rescue of a previous iliofempop endovascular treatment for CTLI

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Disclosure

I have the following potential conflicts of interest to report: ***advisory board, consulting, speaking, training, proctoring****.*

- Abbott
- Bard/BD
- Cardiva
- Cook
- Cordis/Cardinal Health
- Ivascular
- Medtronic
- Prim
- Straub Medical
- Terumo
- W.L. Gore & Associates
- World Medica

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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.

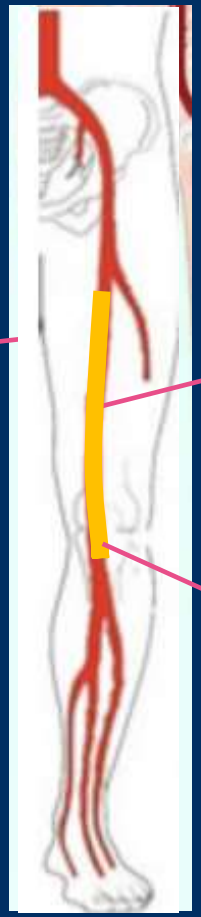
The clinicians have been compensated by Becton, Dickinson and Company to participate in this presentation.

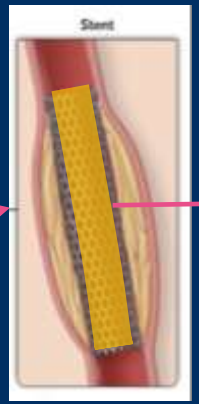
Clinical History (11.12.2020)

- **69-year-old female with RC 5 on her left foot**
- Former smoker
- Hyperlipidemia
- Hypertension
- Treatment: aspirin, clopidogrel, statin, ACEI

Vascular History

18/05/15 (RC3)

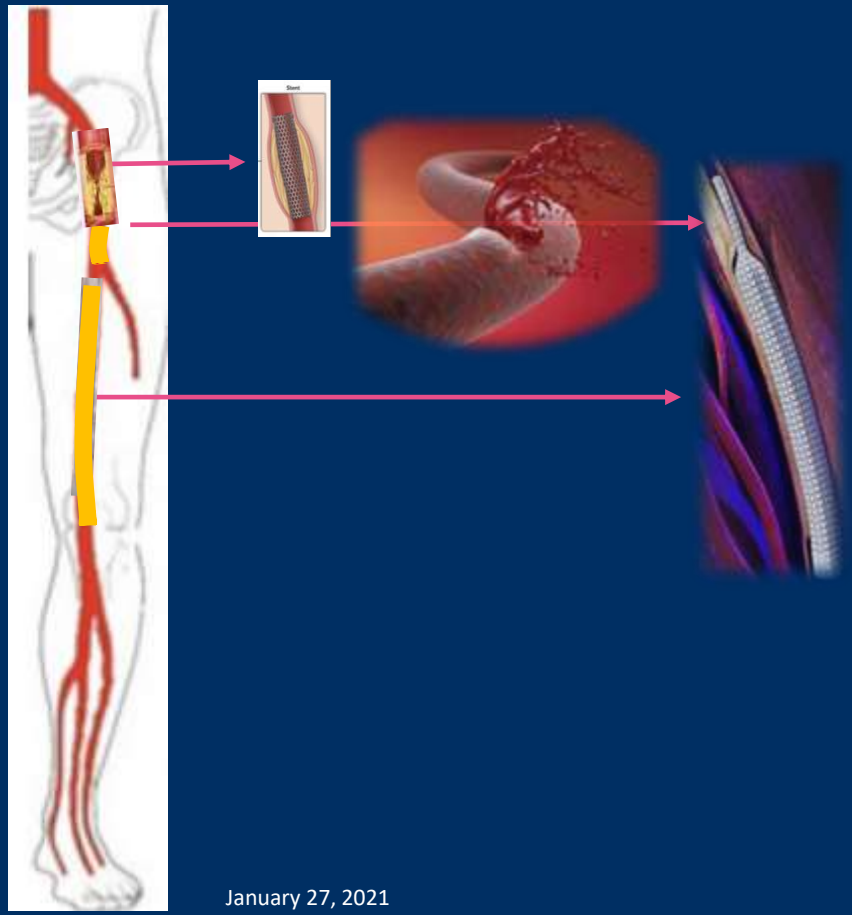




28/07/16 (RC3)

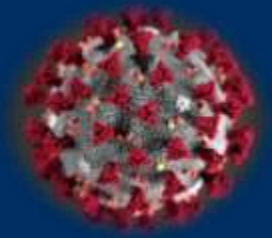
Vascular History

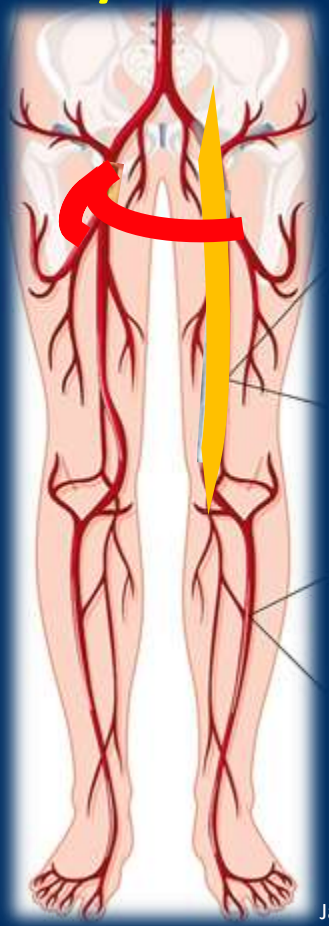
14/02/20 (RC4)

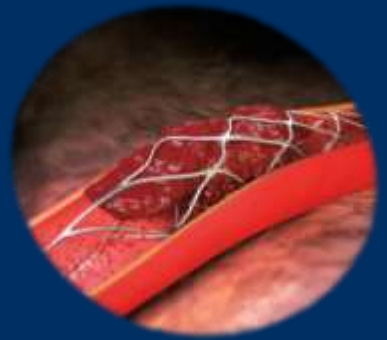


Vascular History

20/07/20 (RC4)

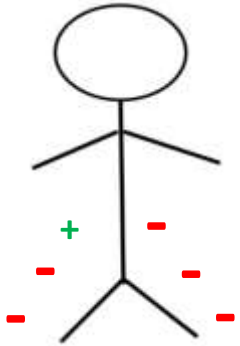






Vascular Exam (11.12.2020)

- LLL: severe rest pain, cold and cyanotic. Ulcer on the forefoot



- **Duplex ultrasound**
  - Right CFA stenosis/occlusion; short BP patency; monophasic curve (PSV 30 cm/s) in crossover BP
  - GSV is not suitable in either lower limb

Plan

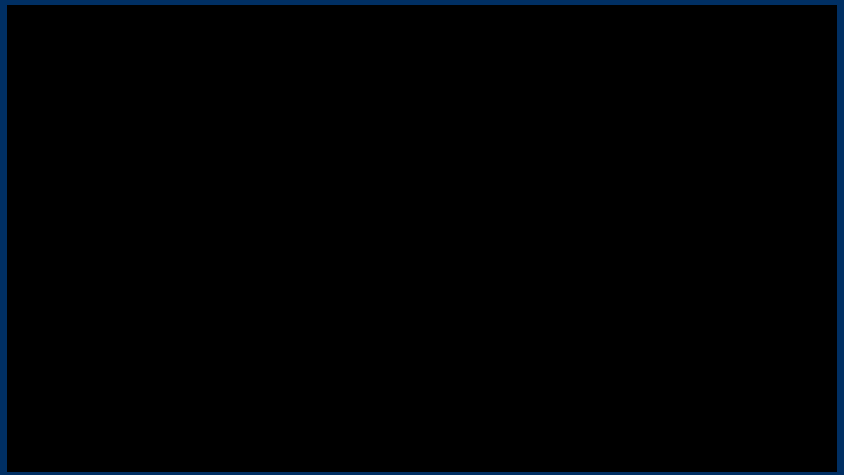
Left brachial artery US-guided access using a micropuncture set to save previous BPs, treat RLL and facilitate, therefore, US-guided right proximal SFA puncture & contralateral approach for left iliac-fem-pop recanalization and treatment

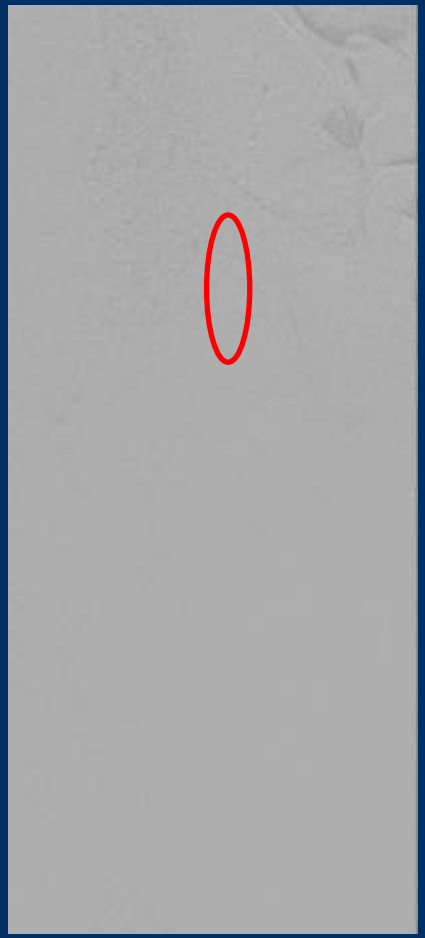
Brachial puncture

Basal angio from brachial

EIA dissection pre-BPs

Right CFA disease

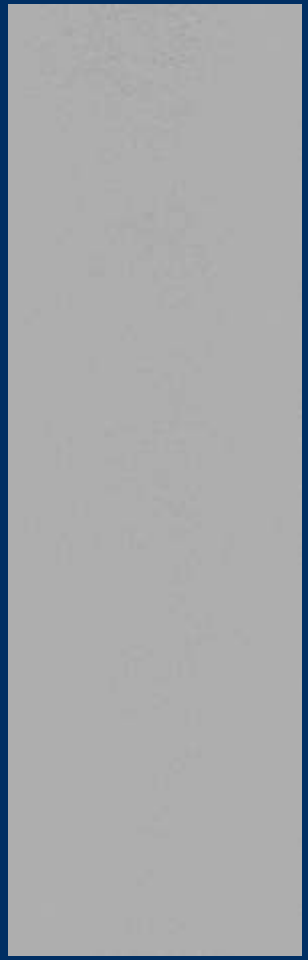


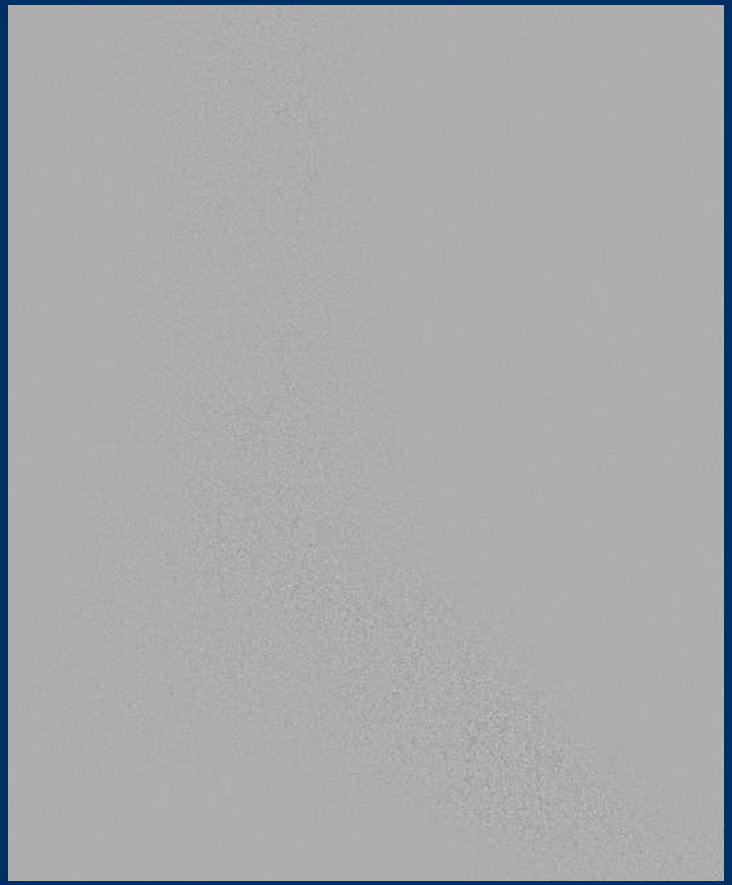


Treatment of RLL from brachial

Right proximal SFA puncture & Crossover

Outflow





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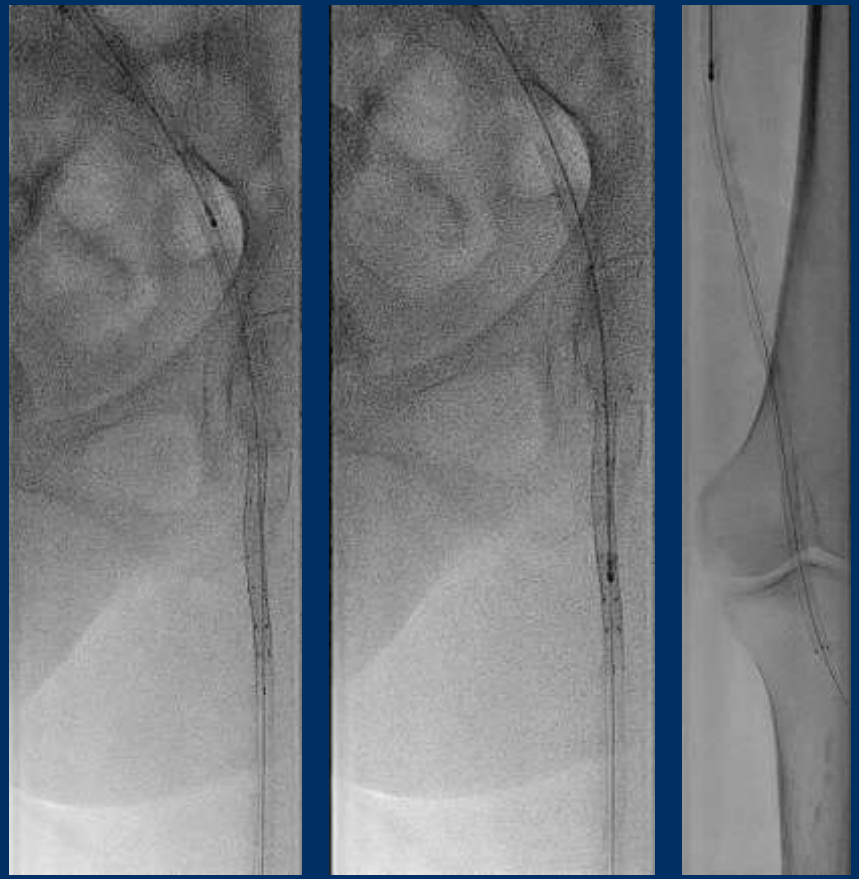
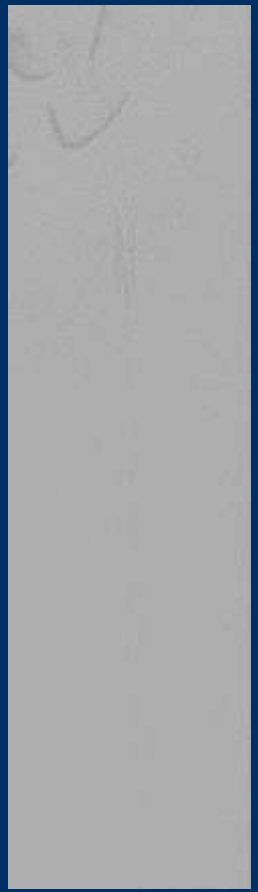
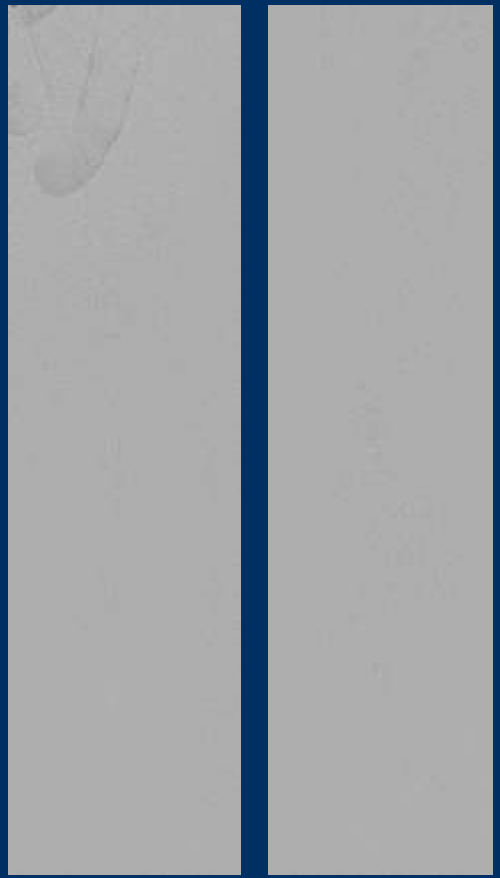
- ✓**Proper coagulation** is mandatory
- ✓**Start motor in the proximal open vessel**
- ✓**Proceed slowly** especially in the last cm



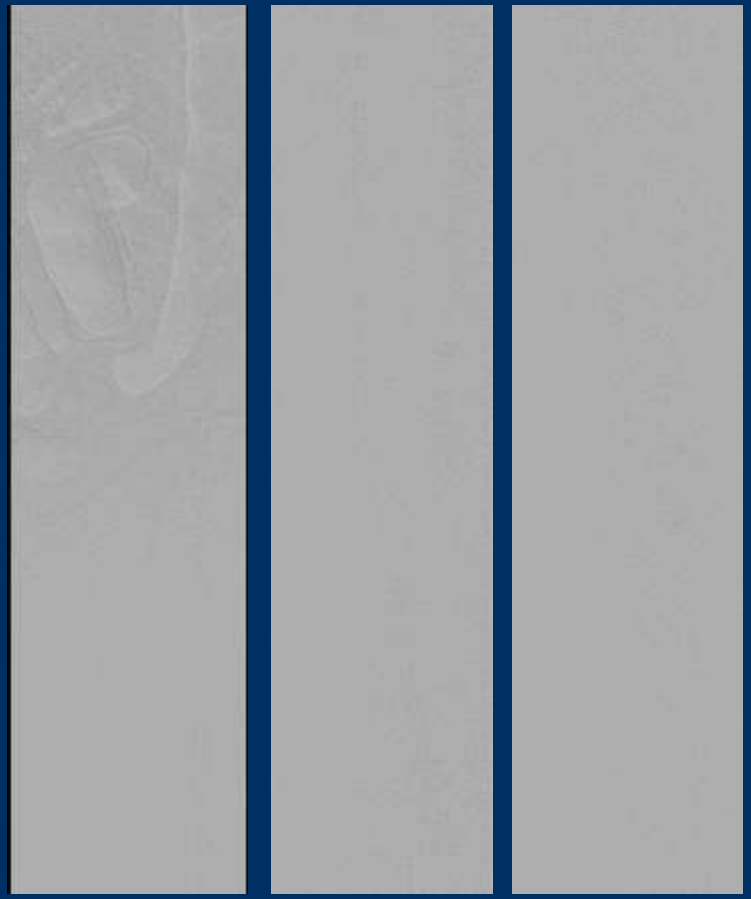
After 2 passages



After 3 passages



Final results



Follow-Up

- **11.01.21**
  - No rest pain
  - Wound is healed
  - PT pulse +

- ASA + clopidogrel + LWMH: 3 months
- ASA + clopidogrel: long time

Summary

- Rotarex™S can be used to remove thrombotic or atherothombotic material from acute, subacute, or chronic lesions of the peripheral arteries
- Rotarex™S can be used in native arteries, for in-stent or stent graft restenosis, or to treat restenosis of arterial bypasses outside of the cardiopulmonary, coronary, and/or cerebral vascular circulations

Thank you for your kind attention!

Questions?

Rotarex™S:

Indications for use:
Rotarex™S: catheters in combination with the Straub Medical Drive System (REF SRS-Set/80300) are intended for the percutaneous transluminal removal of thrombotic, thromboembolic and atherothrombotic material from fresh, subacute and chronic occlusions of blood vessels outside the cardiopulmonary, coronary and cerebral circulations.
Indicated for: Native blood vessels or vessels fitted with stents, stent grafts or native or artificial bypasses outside the cardiopulmonary, coronary and cerebral circulations.
Technical limitations/ contraindications: Vessels of the cardiopulmonary, coronary or cerebral circulations, undersized or oversized vessel diameters, impossibility to pass the lesion completely with the guidewire, subintimal position of the guidewire – even if only in short segments, use in stents, stent grafts, or vena cava filters if the guidewire has become threaded at any point in the wire mesh / construction of stent, stent graft, or vena cava filter or the lining of the stent graft, if the introducer sheath, the guide catheter, the guidewire or the Rotarex®S catheter sustains any damage, especially kinking in the fracture areas of broken stents, known or suspected allergy to any of the components of the system or to a medicinal product to be administered in connection with the planned procedure, persistent vasospasm, during imaging by Magnetic Resonance Imaging (MRI), during use of a defibrillator on the patient, during use of electrosurgery on the patient, for veterinary purposes
Warnings: Before using a product, the user must verify that the recommended maintenance interval shown on the maintenance label visible on the Straub Medical Drive System, as recommended in the user manual, is valid. Before using the product, the user must verify that the measures to ensure electromagnetic safety, as recommended in the user manual, are followed. The Straub Endovascular System and its components must not be used if magnetic resonance imaging (MRI) is being employed for imaging purposes: the products contain magnetizable material. The Straub Endovascular System and its components must not be used if a defibrillator is being used on the patient: the products are electrically conductive. Remove catheter and guidewire from patient before using a defibrillator. The Straub Endovascular System and its components must not be used if electrosurgery is being used on the patient: the products are electrically conductive. Remove catheter and guidewire from patient before using electrosurgery. Straub Medical catheters are delivered sterile. The sterilization method is gasification with ethylene oxide. Further details are shown on the relevant product labels. The products are for single use and must not be resterilized. Reprocessing or resterilising may severely impair the function of the product, which can cause injury, illness or death of the patient. Products contaminated with blood may not be reused or resterilized. If the product is contaminated, there is a high risk of cross-infection between patients. Do not use the products if their sterile blister packaging barriers have been compromised or damaged. Do not use the products after the expiration date.
Rotarex®S catheters should only be used if the benefit clearly outweighs the risk: in patients with haemodynamic instability or shock, in patients with severe coagulatory disorders, in situations where an embolism potentially triggered by the use of the catheter may have a very harmful effect on the patient CAUTION: If necessary, the use of a suitable endovascular filter system compatible with use of Rotarex®S catheters may be indicated. If used inside or via narrow vessel radii or in tortuous vessel courses (radius of curvature < 2 cm), in severely calcified vessel segments, in aneurysmatically altered vessel segments, in veins, in known or suspected infection, especially of the puncture site or the vessel segment being treated, known, unhealed pre-existing mechanical damage to the vessel wall, especially caused by surgical procedures or interventional complications, if used in immature or not fully healed dialysis accesses or bypass grafts, in broken stents
Cautions: The catheter sets do not contain any parts that need to be maintained or serviced by the end-user. Do not repair or change the configuration of the product. An annual service is recommended for the Straub Medical Drive System (see Straub Medical Drive System user manual).The user must be entirely familiar with the operating instructions of the Straub Medical Drive System and Straub rotational catheters before using the Straub Endovascular System and its components.
Potential Adverse Events: Vessel wall injury or valve damage, vessel dissection, perforation / rupture, perforation as a result of mural calcium being torn out of the vessel wall, arteriovenous fistula / pseudo-aneurysm, haematoma, bleeding, haemorrhage, organ perforation, implants such as stents / stent grafts / bypass grafts, getting damaged, caught or dislodged, disruption of the catheter and/or guidewire: debris, remaining in the body, allergic reactions to catheter material catheter-induced sepsis

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