Results Of Revcore For Use In Chronic Deep Vein Stent Occlusion

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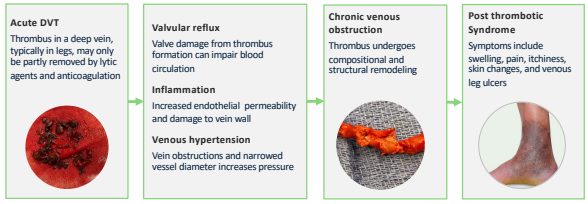
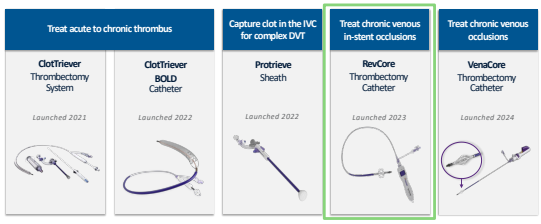
PERTINENT DISCLOSURES: INARI MEDICAL

DVT Pathophysiology and Chronic Sequela

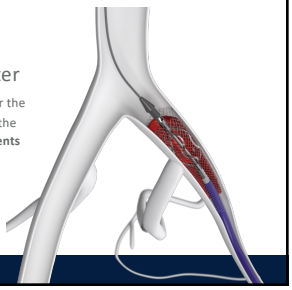


Purpose-built Toolkit for Venous Occlusions



RevCore Thrombectomy Catheter

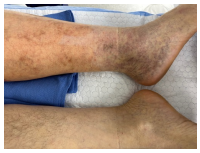
A single-use, sterile, over-the-wire catheter used for the minimally invasive treatment of thromboemboli in the peripheral vasculature system, **including venous stents**

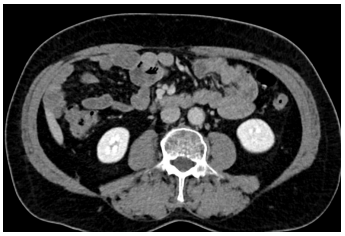


Published Clinical Case Studies

Case #1

Iliofemoral Venous Obstruction





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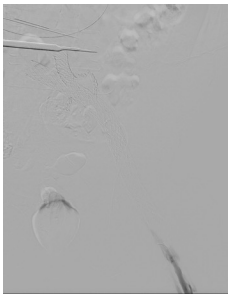
Case #1

Iliofemoral Venous Obstruction



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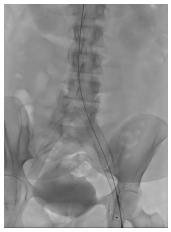
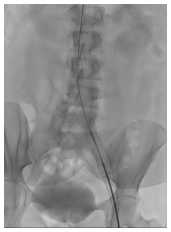
Using the Device





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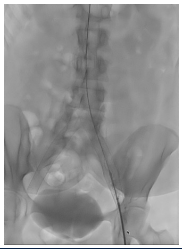

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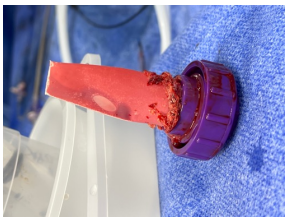
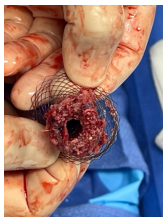
Case Flow

- Ascending Venogram
- Cross
- Place ProTreive
- Track Dilation
- Exposed Pullback
- Employ Device
- IVUS – Focal Treatment
- Aspirate ProTreive





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Recent RevCore Study in Review

Objective: Assess the safety and effectiveness outcomes of the novel mechanical thrombectomy catheter for patients with IST and restore stent patency.

Design: Multi-center, retrospective analysis from March 2023 to December 2023

Inclusion Criteria

- Age ≥ 18 years
- Iliofemoral IST with at least 1 VLU
- Treated using the RevCore thrombectomy catheter at 1 of 4 enrolling centers between March 2023 and November 2023

Endpoints

- **Primary endpoint**: postprocedural effective diameter ≥ 50%
- **Secondary endpoints:** 30-day device-related major adverse events (MAEs)
  - Mortality
  - Readmission
  - Vessel perforation
  - Clinically significant pulmonary embolism

Study Population: 44 patients with 12 VLUs secondary to IST treated using the RevCore thrombectomy catheter

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Baseline Characteristics

Characteristic	Patient N = 44 Mean ± SD, n (%), median [IQR]
Age (years)	54.8 ± 17.1
Female	23 (52.3%)
Bilateral IST	4 (9.1%)
Treated limbs	**N = 48**
IST Symptom duration, weeks	8.0 [2.0–104.0]
CEAP C_6 disease	7 (14.6)
Treated stents	**N = 65**
Average effective diameter, %	20.2 ± 26.4
Average inner lumen area, mm^2	14.6 ± 25.2

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Procedural Data

Characteristic	Procedure N = 46 Mean ± SD, n (%), median [IQR]
Thrombus removed, %	90 [60–90]
Thrombectomy time, min	28.8 ± 13.5
Chronic thrombus extracted	28 (84.8%)
Treated stents	**N = 65**
Postprocedural effective diameter ≥50%	65 (100%)
Postprocedural average effective diameter, %	90.0 ± 9.7
Postprocedural average inner lumen area, mm^2	128.1 ± 56.3
Stent migration or entanglement	0 (0%)

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Safety Outcomes

Outcomes	Patient N = 44 Median [IQR], n(%)
Time to first follow-up, days	40.0 [29.0-62.5]
Mortality	0 (0%)
Readmission	0 (0%)
Pulmonary embolism	0 (0%)
Vessel Perforation	0 (0%)

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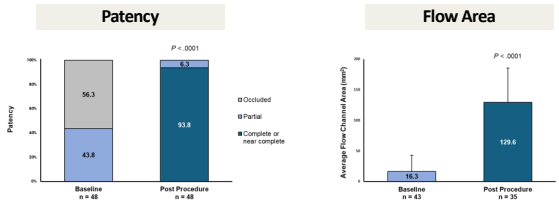
Stent Patency and Area



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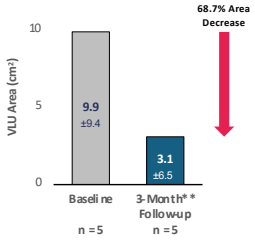
Venous Leg Ulcer Analyses

Outcome	Mean ± SD, n (%)
Last follow-up, months	3.1 ± 0.7
VLU healing	11 (100)
VLU resolved	4 (36.4)
VLU area, cm^2	3.1 ± 6.5



**3.1 ± 0.7 months

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RevCore for Treatment of In-Stent Thrombosis

A Real-world, Multicenter, Prospective Registry

REVIT – RevCore for Treatment of In-Stent Thrombosis

Global Co-PIs: Karem Harth, MD & Ronald Winokur, MD

Steering Committee: Steven Abramowitz, MD, Ryan Cobb, MD, Michael Lichtenberg, MD, Abdullah Shaikh, MD

100 PATIENTS | 30 US SITES

Patients with a thrombosed venous stent placed >6 weeks before enrollment

#1 PRIMARY ENDPOINT

Successful stent recanalization (defined as patency ≥50% luminal diameter), post procedure utilizing intravascular ultrasound

#2 SECONDARY ENDPOINTS

Device-related serious adverse events adjudicated by a clinical events committee through 30 days for mortality, clinically significant pulmonary embolism, vessel perforation, stent fracture/migration, rethrombosis

Imaging at 30-day, 6-month, and 1-year

- Presence of flow
- Recanalization of patency

Clinical outcomes at 30-day, 6-month, and 1-year

- Clinical-Etiology-Anatomy-Pathophysiology (CEAP) score
- Villalta score
- Quality of life with EQ-5D-5L

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Conclusions on RevCore for In-stent Thrombosis

- RevCore remains the only FDA-cleared device designed for in-stent thrombosis
- Promising efficiency and clinical outcomes. As with any device, more experience provides more learnings
- REVIT study (NCT06394739) is enrolling

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