

iCHOR

iCHOR Vision

**Mechanical Thrombectomy using
a proven mechanism of action that is
easy and highly predictable**

1) 7F Arterial Clot Removal

7F

2) 14F Venous Clot Removal

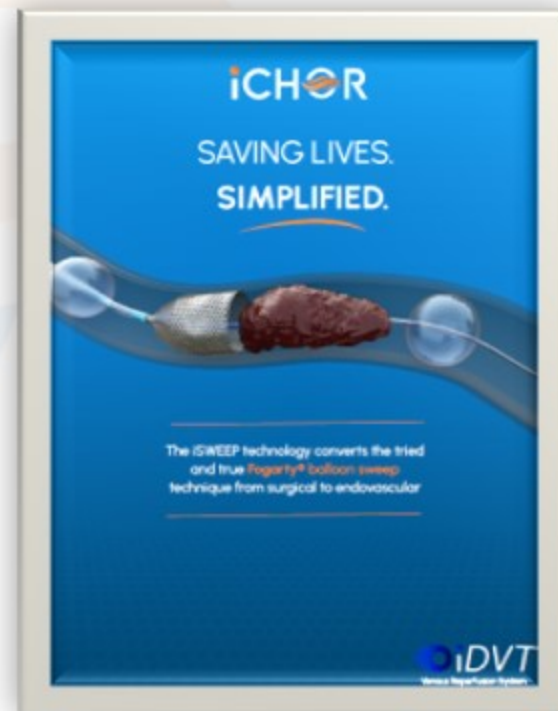
14F

**To become the “1st line on the table therapy”
in treating peripheral vascular occlusions by
developing a simplified and versatile
solution aimed at rapid reperfusion without
the need for surgery or thrombolytic drug
therapies.**

Occluded Bypass
Grafts

Embolectomy

Post Atherectomy
Tibial Debris



iCHOR's A HA Moment!

Treating peripheral vascular occlusions **surgically** with Vascular partners

- Loved the mechanism of action
- Proven and trusted technique for 60+ years
- Treating organized thrombus, acute issues, and embolic events
- Treating a wide range of anatomy (vessel sizes)

Why can't this be endovascular like everything else we do?

Percutaneous **"must haves"** for lower extremity revascularization (LER):

- Arterial / Venous Treatment Options
- Control blood flow (manage distal embolization and blood loss)
- Interventional Basics - Rapid Exchange / OTW
- Robust balloons



Creating History

The First Minimally Invasive Therapy

When asked to provide a few words about Thomas Fogarty, MD, for the occasion of his being honored as the 2004 New Cardiovascular Horizons Achievement Award recipient, a number of prominent endovascular specialists remarked on the way in which he could look at a complex problem in an elemental way, and then devise a simple solution to it. Dr. Fogarty's first invention was a clutch system for his scooter when he was a young man. This invention evolved to become a motorcycle clutch that is still in use today. Not long after he took a job as a scrub technician to help support his family, Dr. Fogarty began to see what he considered obvious flaws in a widely used surgical procedure, and true to his nature, he devised a simple solution. Most if not all of Dr. Fogarty's myriad inventions bear this characteristic, and an impressive number of them have come to be seen as revolutionary in their respective applications. His invention of the balloon embolectomy catheter did just that, essentially marking the birth of minimally invasive endovascular therapy.

Endovascular Today: Your work conceiving and designing the balloon embolectomy catheter was a revolution in vascular care. What was your early experience with the previous standard of care, and what did you observe in it that pushed you to go so far in another direction?

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"There was no FDA regulation at the time. We made one, and we used it."

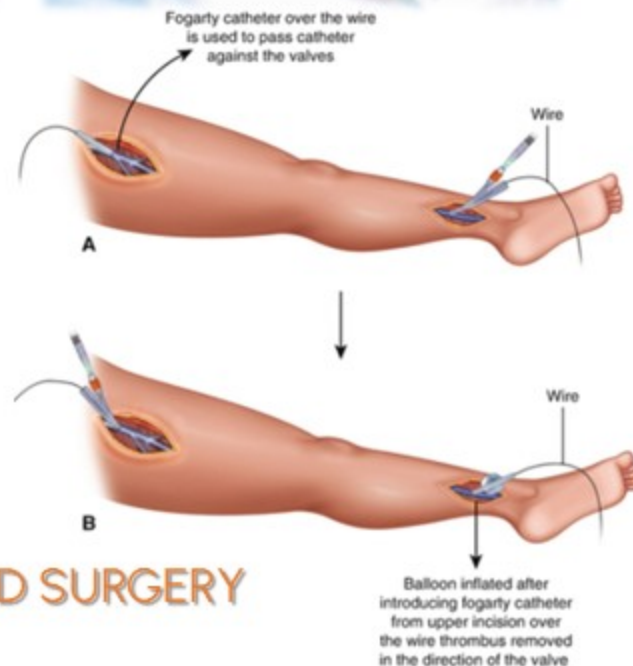
28 | ENDOVASCULAR TODAY | NOVEMBER/DECEMBER 2004

Peripheral Problem

Peripheral Vascular Occlusions are less studied or understood relative to Stroke or Coronary disease. Yet **arterial and venous disease of the lower limbs is a larger, faster growing market with significant mortality rates**. Tools and techniques have not improved outcomes in ~50 years yet costs are skyrocketing. Current options lack flexibility and broad utility!

Peripheral Gold Standard Therapies

- Drug Therapy / Thrombolysis (60%)
(Lytic drugs to dissolve or breakdown clot for 28-72 hours in ICU)
- Surgery (20%)
(Surgical cut down, blood loss, general anesthesia)
- Borrowed Stroke and Coronary Technologies (20%)
(No improvements over current options and expensive)



WE NEED TOOLS THAT OFFER BROAD UTILITY!

WE NEED NON-SURGICAL SOLUTIONS THAT REDUCE OR ELIMINATE LYTICS AND SURGERY

What Does iCHOR Vascular Do?

The iCHOR system replicates successful parameters of surgical clot removal with a proven mechanism of action (balloon sweep) combined with on-demand embolic protection.

- Non-surgical therapy
- Non-drug therapy
- Arresting flow avoids blood loss & distal embolization
- Designed to fit all anatomical vessels with a single device
- ALWAYS maintain sheath / wire access (*promotes multiple passes*)
- Avoids scarring or valve damage
- Does not require capital equipment

What we do? Mechanical Thrombectomy using a proven mechanism of action that is easy and highly predictable

Endovascular
TODAY

FEATURED TECHNOLOGY
ICHOR SYSTEM
Sponsored by ICHOR Vascular Inc.

The ICHOR Reperfusion System for Clot Removal in Lower Extremity Vascular Disease

An elegant yet versatile "on-the-table" solution to treat a wide range of peripheral vascular occlusions.

By Timothy Blair and Troy Long, MD

Arterial vascular occlusions are mainly caused by a progressive narrowing (atherosclerosis), blood clots (thrombus), or a harder, older clot from another part of the vascular system (embolic material). When blood flow becomes obstructed, the metabolic demands of the cells exceed the supply of nutrients, which leads to cell and tissue death.

Because peripheral artery disease (PAD) is more progressive than, for example, stroke, patients often wait until symptoms are near irreversible, which is a primary reason why amputation rates are so high—globally more than 200,000 amputations per year are related to PAD.¹ Patient awareness of and education for PAD are growing across the physician societies and industry, which is leading to higher patient volumes and patients presenting in earlier stages of disease. With advanced education and better diagnostics comes the need for evolved techniques and technologies aimed at improving outcomes with simplified designs that address the economic issues. The costs to treat arterial occlusions have skyrocketed, but the tools and techniques over nearly 40 years have not shown significant improvements in outcomes.

Peripheral vascular occlusions are generally less studied relative to stroke or coronary disease. Yet, arterial and venous disease of the lower limbs affects more patients, has significant mortality rates, and has an enormous economic impact to our health care system.

THE CHALLENGES OF DVT

Deep vein thrombosis (DVT) is a medical condition that occurs when a blood clot forms in a deep vein, usually in the lower leg, thigh, or pelvis.² It is estimated that more than 400,000 lower limbs are treated for DVT annually and

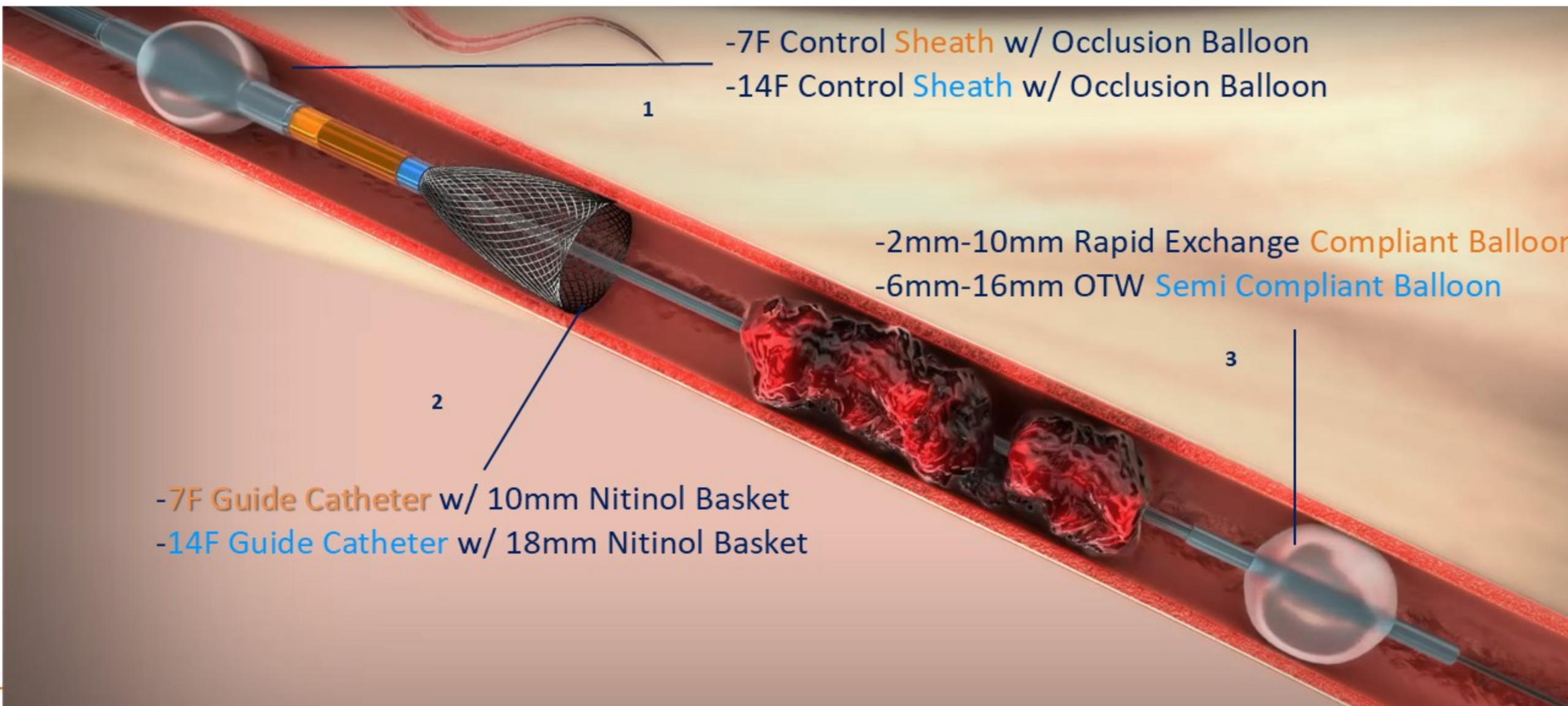
KEY FEATURES OF THE ICHOR PERCUTANEOUS REPERFUSION SYSTEM

- Non-drug therapy
- Non-surgical therapy
- Avoids blood loss
- Avoids distal embolization
- Avoids scarring or valve damage
- Does not require capital equipment

are responsible for 60,000 to 100,000 deaths per year. Of the DVT patient population, 10% to 30% will die within 1 month of diagnosis and one-third of all people with DVT will have recurrence within 10 years. Obesity, inactivity, and smoking are major risk factors for DVT; however, pregnancy, childbirth, birth control, hormone replacement, and cancer diagnosis are also significant risk factors.³ Although treatment options for cancer patients prolong life, these patients unfortunately have a five- to sevenfold increased risk of developing venous thrombosis, which is the second most common cause of mortality for cancer patients.⁴

One-third to one-half of people who have a DVT will have long-term complications caused by the damage the clot does to the valves in the vein (postthrombotic syndrome [PTS]).⁵ People with PTS have symptoms such as swelling, pain, discoloration, and in severe cases, scaling or ulcers in the affected part of the body. In some cases, symptoms can be severe and disabling. DVT is a serious condition with potential deadly outcomes; however, it is equally important

2 Systems: iCHOR Arterial (7F) and Venous (14F) Vascular Systems

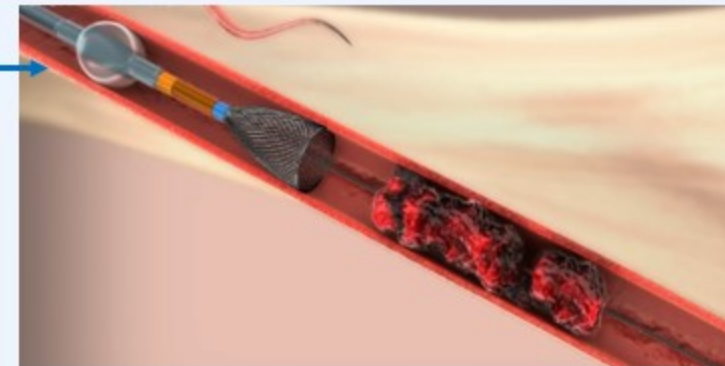


Procedural Steps 1,2,3

- ✓ Non-surgical therapy
- ✓ Non-drug therapy
- ✓ Arresting flow avoids blood loss & distal embolization
- ✓ Designed to fit all anatomical vessels with a single device
- ✓ ALWAYS maintain sheath / wire access (*promotes multiple passes*)
- ✓ Avoids scarring or valve damage
- ✓ Does not require capital equipment

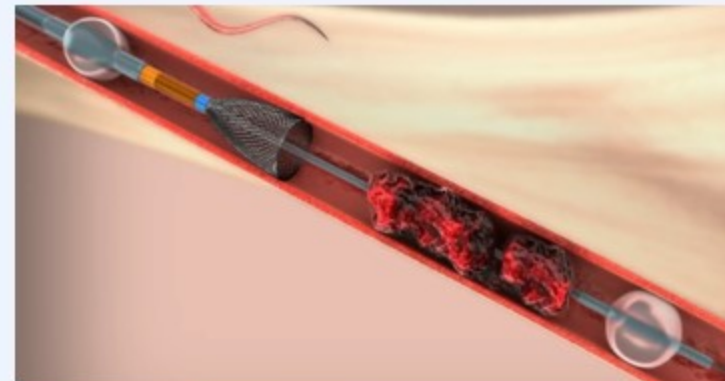
STEP 1: EMBOLIC PROTECTION

The control sheath and the guide catheter are inserted and deployed proximal to the clot to arrest blood flow and provide access to the vessel.



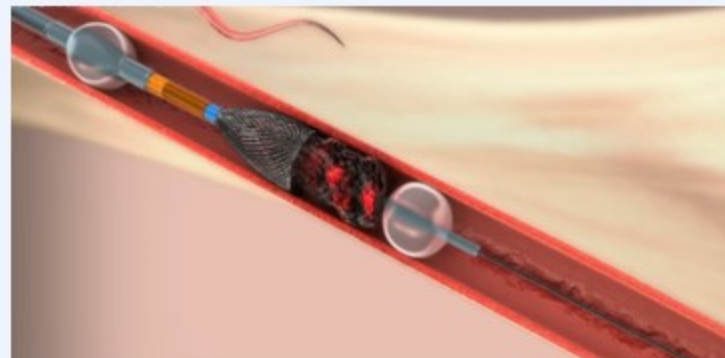
STEP 2: CROSS THE CLOT

The guide catheter with funnel will capture and remove blood clots



STEP 3: SWEEP & ASPIRATE

Compliant (gentle) balloon catheter is deployed and retracted while aspirating, sweeping the clot into the funneled guide catheter for removal



Historically Proven Surgical Procedure – Now Endovascular

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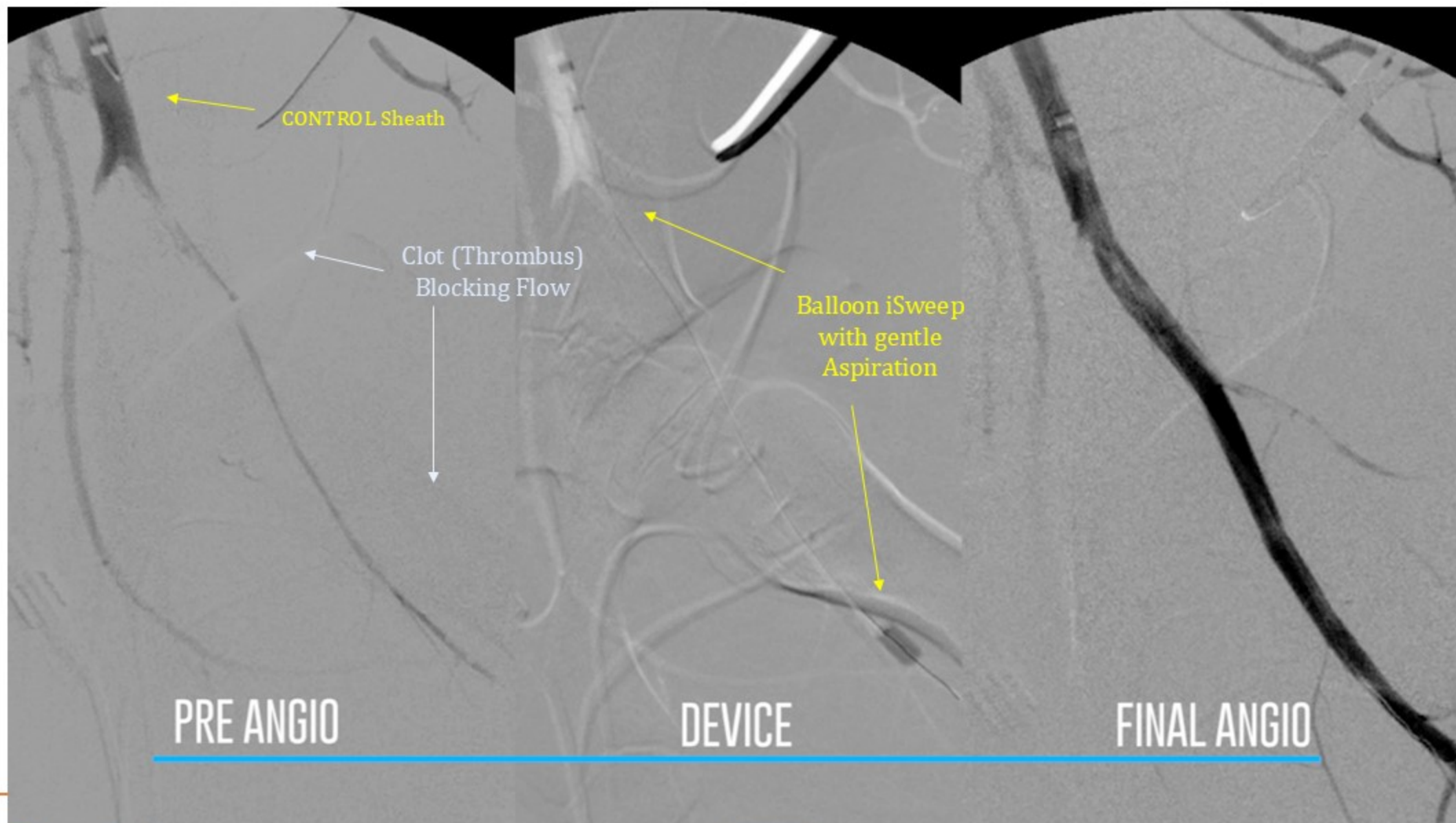
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iSWEEP Arterial Clot Removal Procedure

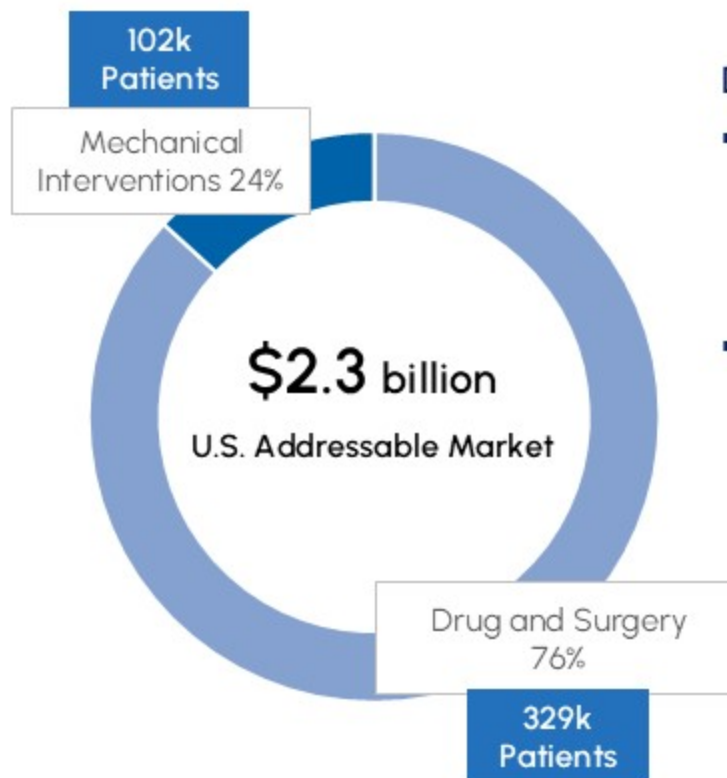
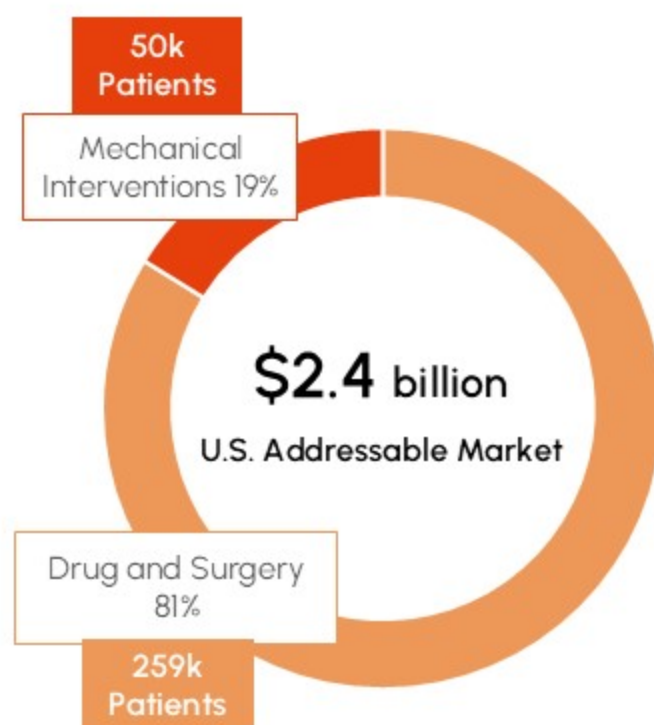


Massive ~\$5B US Market

The use of mechanical thrombectomy continues to increase each year, growing at 6-7% CAGR and trending to become the standard of care. The current addressable market for peripheral vascular occlusions is approximately **\$5 billion in the U.S.** and \$20 billion OUS, presenting a tremendous opportunity for iCHOR.

Peripheral Arterial Disease

- Approximately 70k ALI limbs
- 50k+ fem-pop bypass failures
- 50k+ pre-CLI organized clot
- Occluded SFA stents
- Under-reported emboli from peripheral interventions



Deep Vein Thrombosis

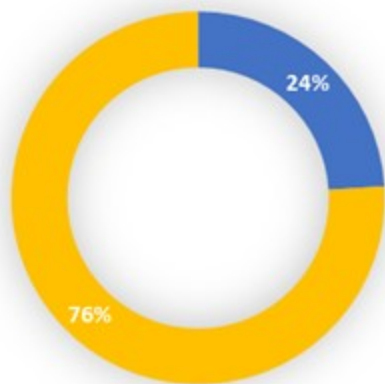
- U.S. venous thromboembolism (VTE) market is experiencing significant growth due to mechanical thrombectomy increasing adoption
- Pulmonary Embolization (PE) indication adds another \$3.5 billion to the addressable US market

Market Drivers: Physicians make money doing procedures, Hospitals make money doing procedures, Hospitals win by eliminating ICU time
Same drivers in Coronary and Stroke!

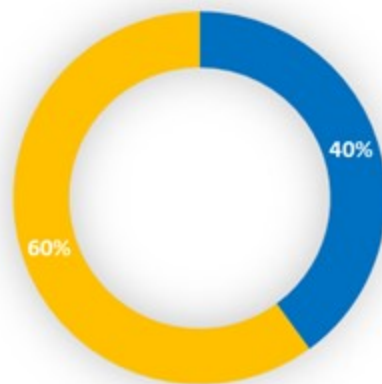
Peripheral Vascular Clot Removal Trends and Drivers

Market Trends: Aging Population; Increased Disease Prevalence; Increased use of Oncology Drugs and Opiates, and Disease Awareness are all contributing to a \$5B US existing market trending towards faster, lower cost treatment options.

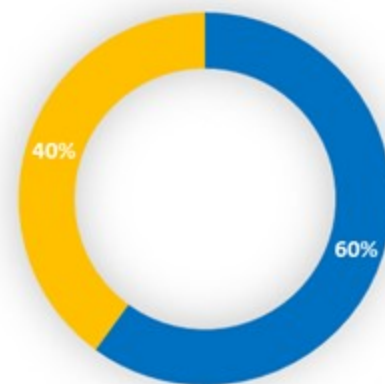
Lower Extremity Market 2023



Lower Extremity Market 2025



Lower Extremity Market 2027



■ Drug and Surgical Therapies
■ Catheter Based Solutions

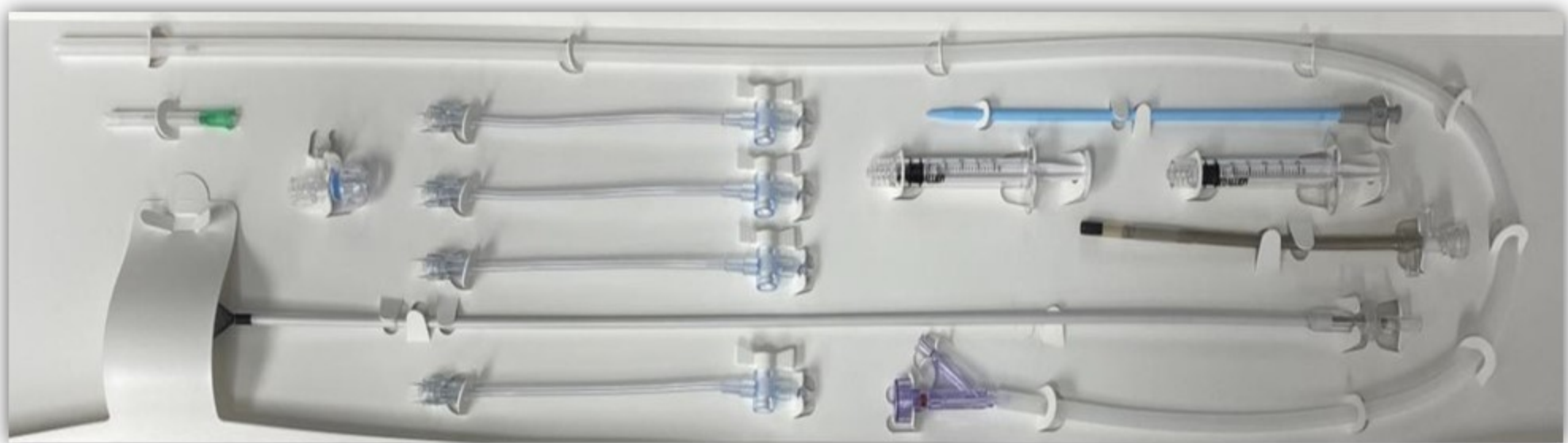
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14F

14F Venous Reperfusion System
(in Limited Market Release)

Recent 14F Venous Procedures - LMR



Single Package, No Capital Equipment

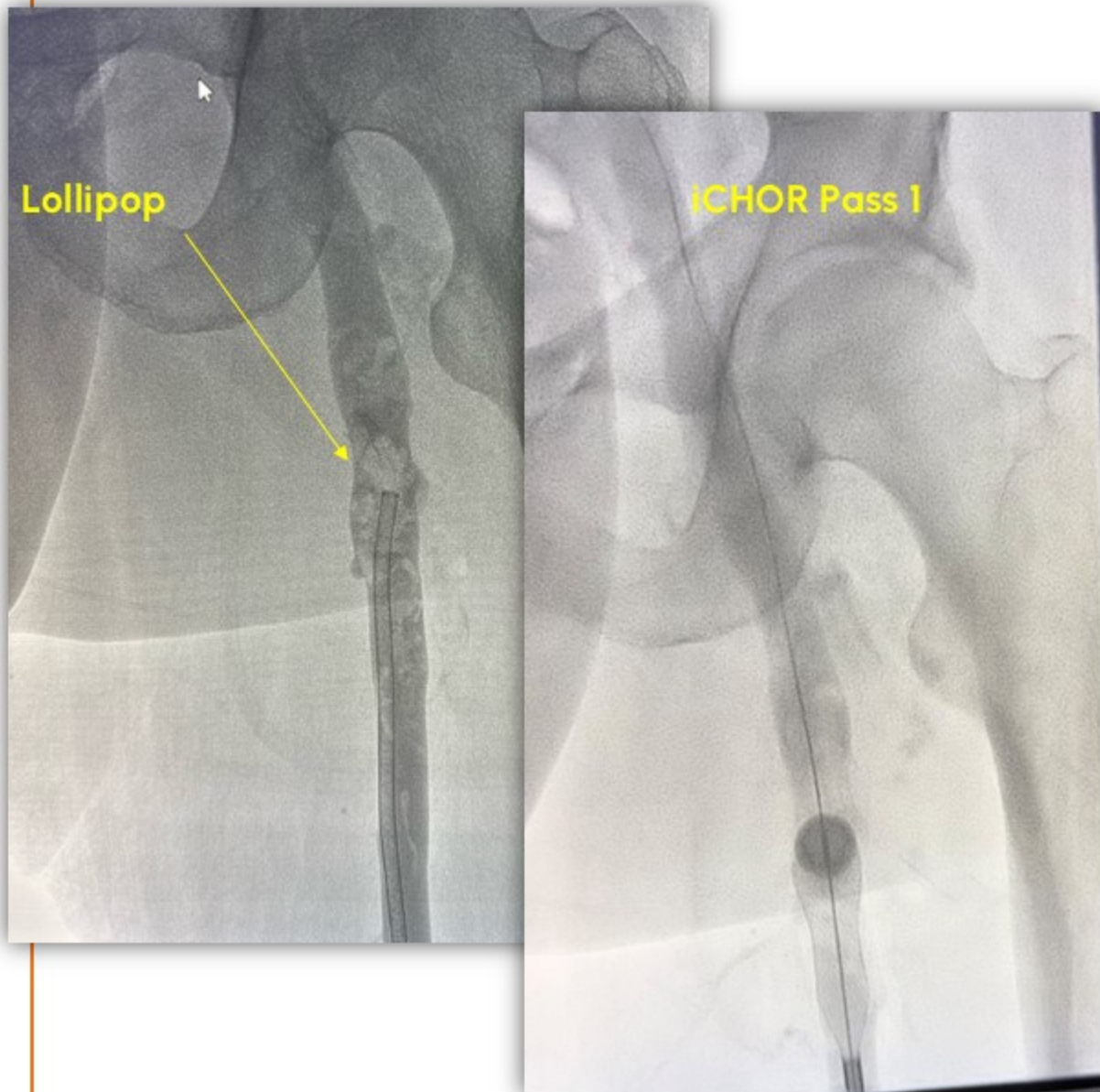
1. Introducer Sheath (w Occlusion Balloon)
2. Guide Catheter (w Nitinol Basket)
3. Endo Fogarty Treatment Balloon



14F

iCHOR 14F iDVT

51-year-old Male; Right Fem Pop, 1st Gen Aspiration
iCHOR 2 Passes, 10 min. with iCHOR device



14F

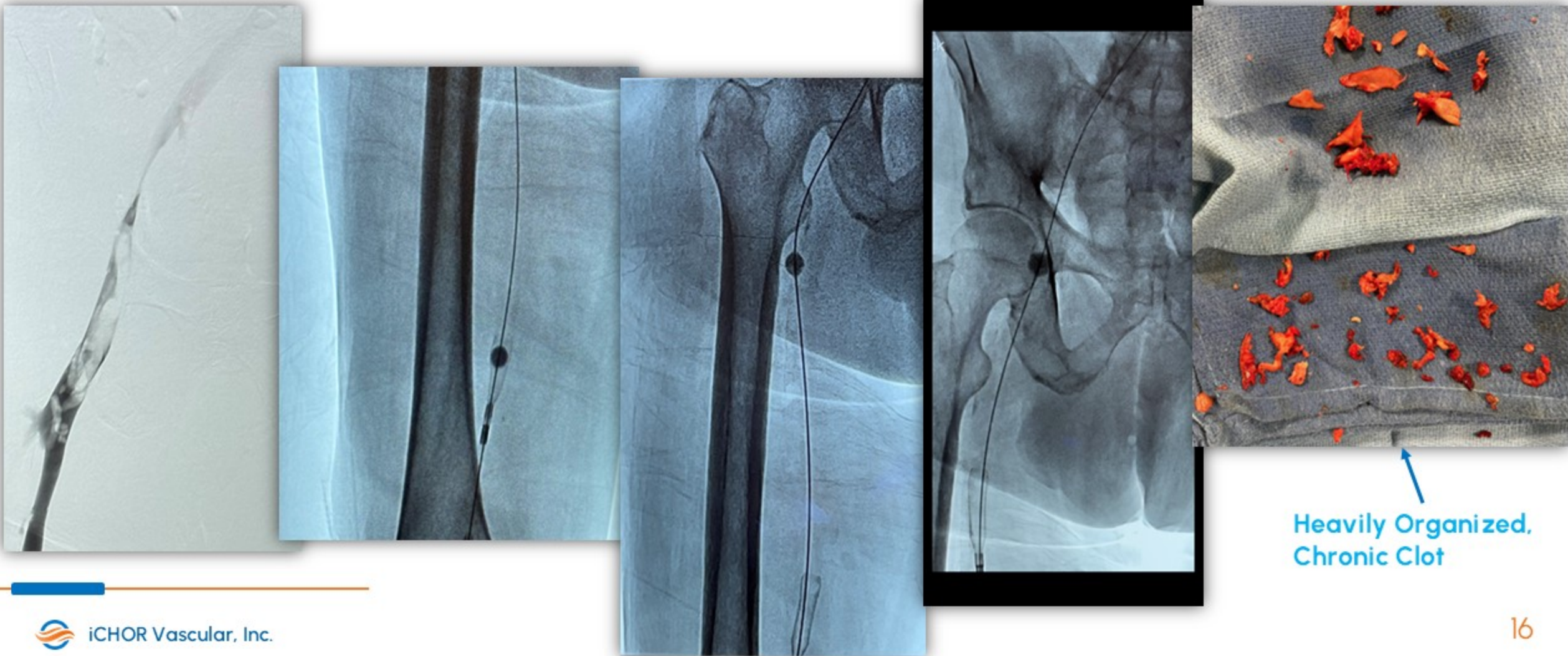
iCHOR 14F iDVT

73-year-old Male; 5 passes, heavily organized, 25 minutes
OBL Procedure (Cost Effective)



14F

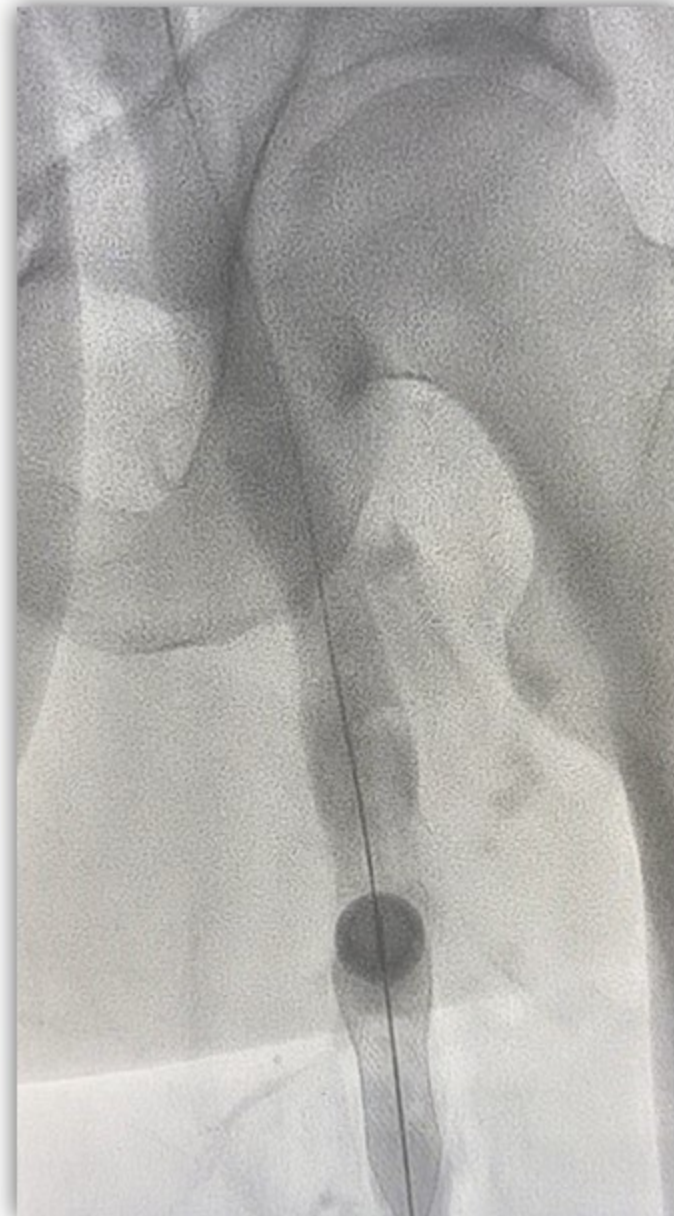
58-year-old Male; Iliac to Popliteal disease; 14mm to 12mm vessel diameters. Heavily organized clot, chronic in areas. iDVT made 8 successful passes with excellent clot removal and subsequent reperfusion. Procedure time from wire access to final balloon pass with follow-on POBA - 45 minutes.



14F

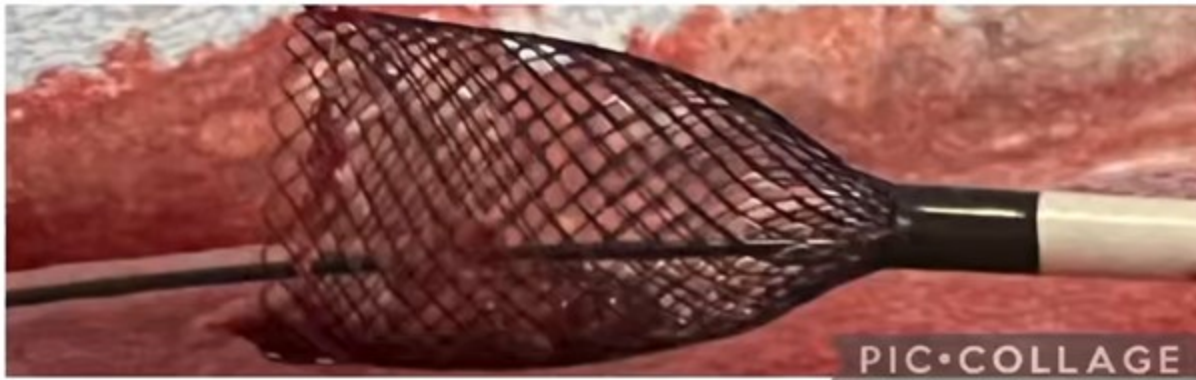
51-year-old Male; Moderate DVT with acute, re-occurrent organized thrombus, some thick occlusions.
2 Successful iDVT sweeps to pull the thick bolus occlusions that were occluding aspiration catheters.
Roughly 10 minutes!

14F Balloon Sweep



14F

Office Based Lab (OBL) – Single setting, acute, adherent, 4 week+ organized thrombus, segmental but thickening morphology. iCHOR 14 device used to treat popliteal to femoral clot. **Patient went home the same evening.**



iCHOR 14F iDVT - Stent Management

16mm venous stent -
2 passes to declot
organized thrombus and
restore flow.

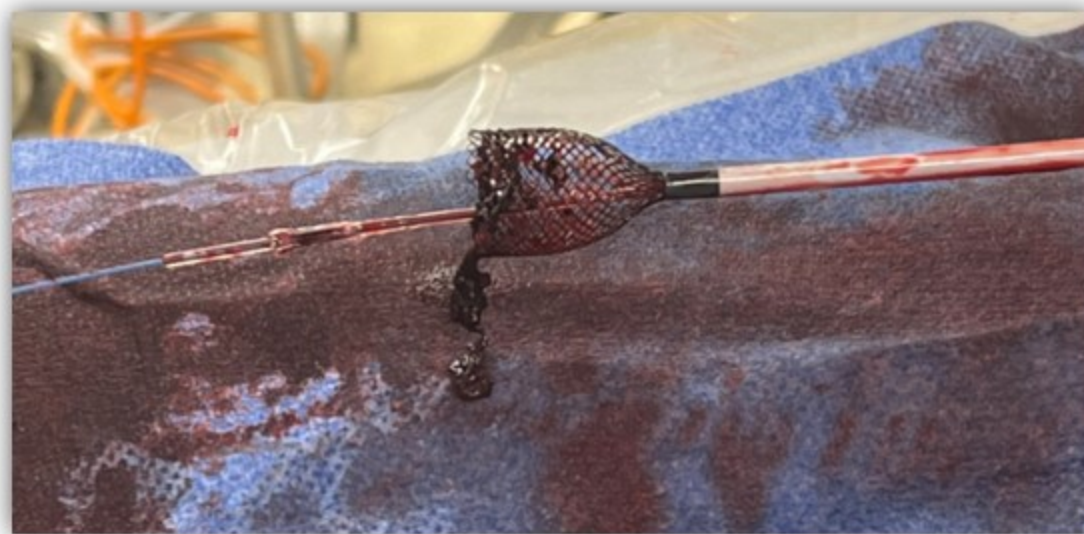
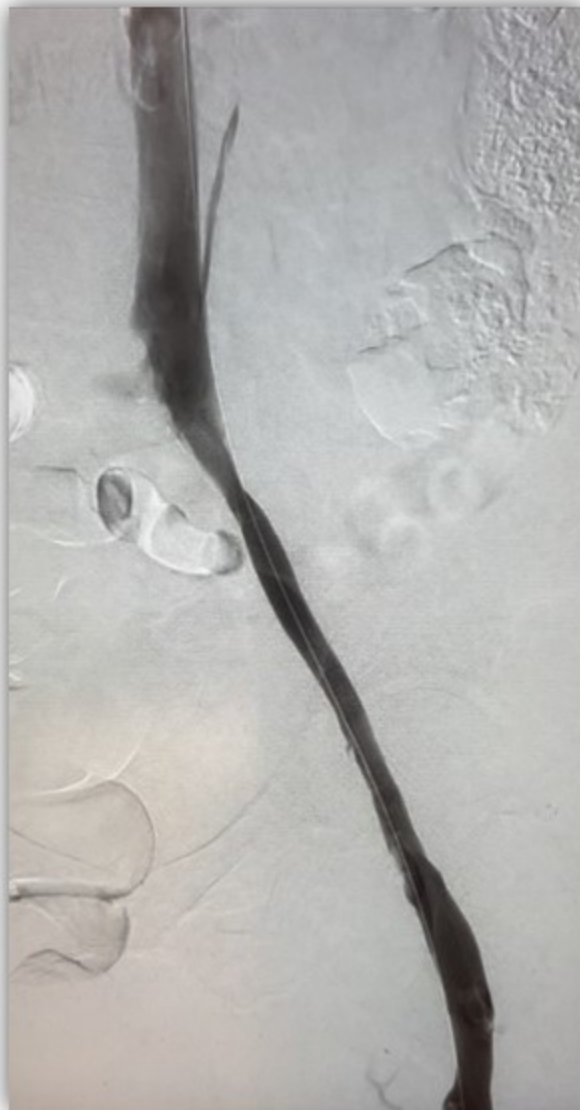
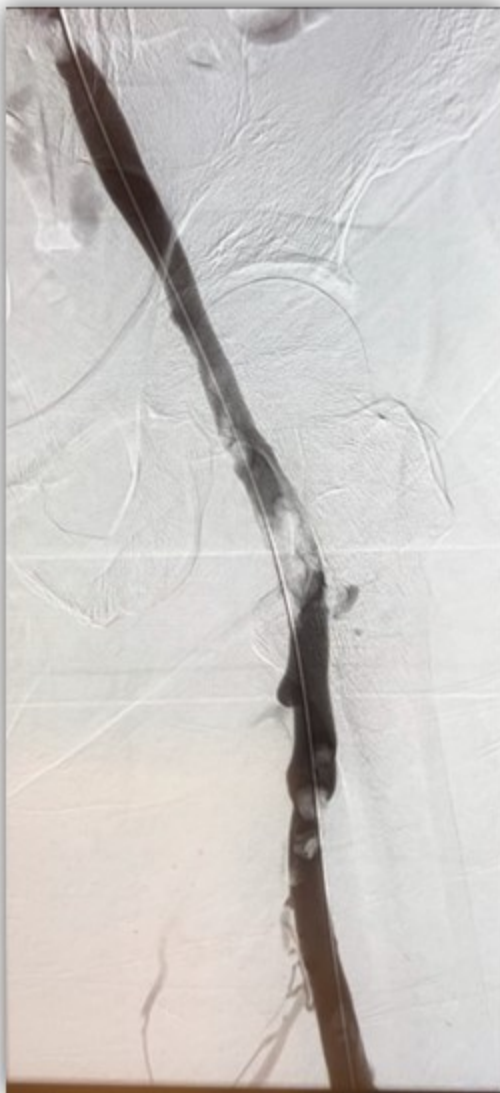
Example of robust balloons

Example of routine Venous
Stent Management in the
Office Based Lab (OBL)



14F

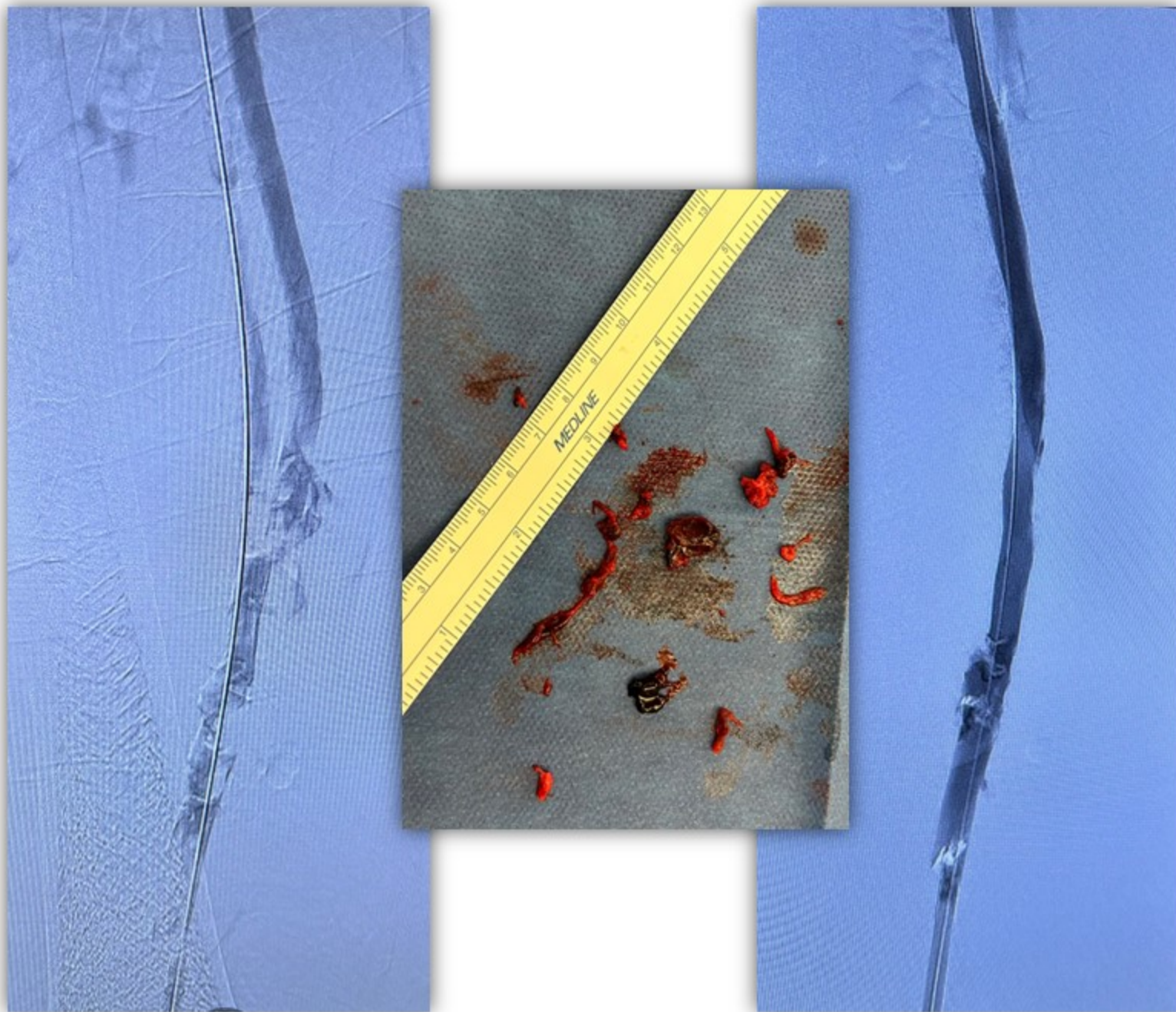
67-year-old Male, Fem Pop, 4 passes, 25 minutes from access to final venogram. Lower leg pain relieved and home the next day.



Routine iCHOR Case Example:

CFV, FV, and Popliteal disease treated 15mm to 10mm. Moderate, segmental clot morphology starting to organize. iDVT made 4 successful passes with excellent clot removal and subsequent reperfusion.

Procedure time from wire access to final balloon pass was less than 30 minutes including POBA
10mmx60mm



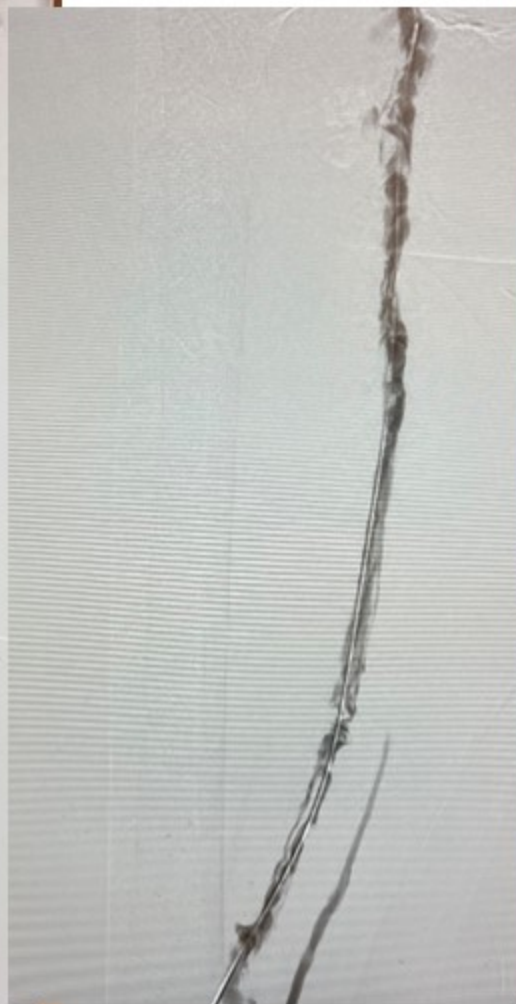
14F

Routine iCHOR Case Example: Iliac to Popliteal disease treated 14mm to 12mm vessels. Heavily organized clot morphology, iDVT made 5 successful passes with excellent clot removal and subsequent reperfusion. Procedure time from wire access to final balloon pass was less than 20 minutes.



14F

63-year-old Male, Fem Pop, 8 passes with Resident, 40 minutes from access to final venogram.

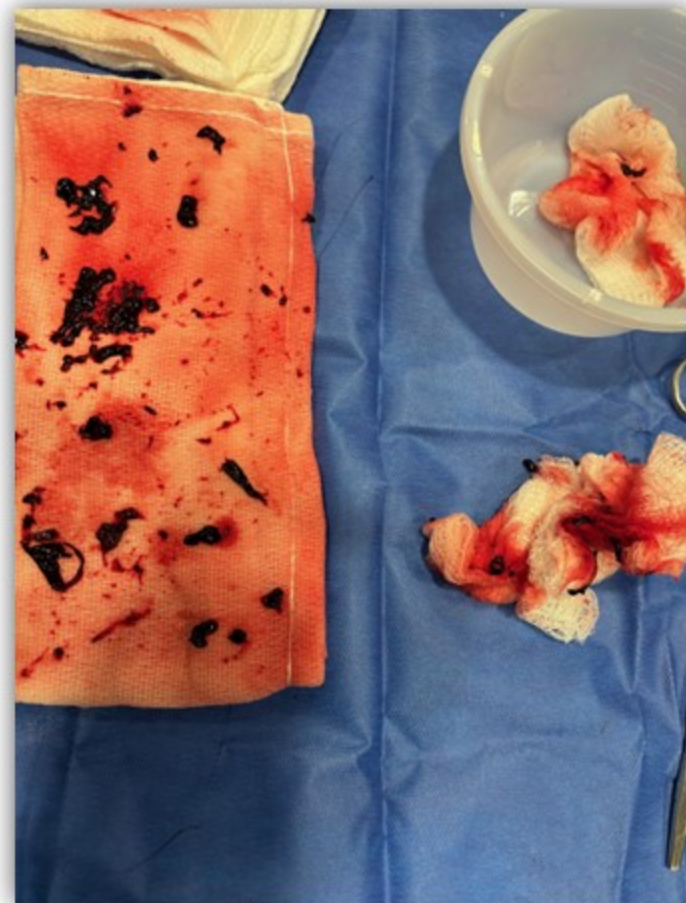
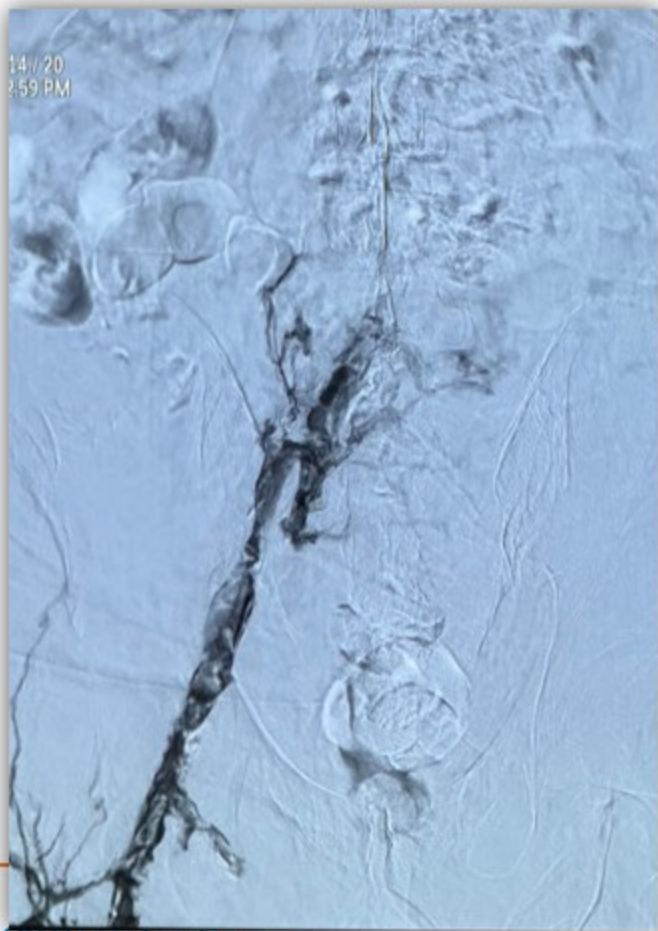


14F

12mm popliteal disease to 15mm iliac disease. ~100 mm in length with heavy clot burden throughout. Patient had "no IVC" which was genetic, and lead to tremendous collateral flows coming off the common femoral and iliac veins. Clot was organized and adherent. Attempted the Bard Aspirex System to clear the cul-de-sac to no avail. Unsuccessful!

iDVT made 4 successful passes with excellent clot removal and subsequent reperfusion.

- Procedure time from wire access to final balloon pass was less than 20 minutes.



Large Animal Histopathology Study

Mechanism of Action: Compliant Balloon vs Metal Scraping

A Non GLP Swine Study, Comparative Effectiveness Evaluation Using the iCHOR
14F Device Compared to the Inari Clot Trier Device

Histopathology Protocol Summary

- Healthy swine IVC vessels treated according the IFUs with equal number of retractions (4 pull-backs)
 - Inari Clotriever with Protriver Sheath (right)
 - iCHOR Vascular 14F iDVT System (left)
- Vessels will be harvested, treated, and shipped overnight to an independent pathology lab
- **Histopathology lab is blinded** to the study protocol and methods
- Histopathologist to analyze pictures and interpretate vessel integrity (R&L)

Histopathology Results (Blinded)

A Non GLP Swine Study, Comparative Effectiveness Evaluation Using the iCHOR 14F Device Compared to the Inari Clot Trier Device

Purpose:

The primary purpose was to evaluate vessel integrity and any thrombus creation using comparative devices according to the IFU. (iCHOR 14 Reperfusion System vs Inari Clot Trier System with Pro Trier introducer sheath). Harvesting of all treated iliofemoral vessels using a 3rd party histopathology lab for preparation, evaluation, and results. 5 evaluation points in each vessel; distal and proximal native vessel (2) and distal, medial, proximal treated segments (3). The Histopathology lab was blinded to the study design or products involved.

The secondary purpose was to determine the durability of the device components used in the study.

Methods:

A comparative effectiveness study using a single swine with identical access in the Right and Left iliofemoral veins to evaluate vessel injury between 2 different thrombectomy devices.

- (1) Inari Clot Trier with Pro Trier Sheath in the right iliofemoral vein
- (2) iCHOR Vascular 14F Reperfusion System in the left iliofemoral vein

The end-user was a vascular surgeon trained and highly experienced in using thrombectomy systems. Both devices were used according to the IFU included in the sterile packages.

The Inari device (1) made 4 passes of the identified right treatment zone. The iCHOR device (2) made 4 passes of the left identified treatment zone to best compare both devices using an equal number of passes. Both devices require wall contact as the mechanism of action which was confirmed using venography during the treatment. The surgeon conducted venograms before, during, and post treatment to properly capture procedural steps, any vessel injuries, as well as vessel diameter which ranged between 10-14mm.

The Clinical Pathologist was blinded to the device and treatment methods.

Treated and untreated iliofemoral veins (R&L) were harvested and prepared for clinical pathology evaluation. Harvested vessels were

Results:

Intraluminal fibrin thrombi with inflammation and necrosis were present in the right vein (Inari vessel) while the left vein (iCHOR vessel) did not have thrombi but demonstrated changes included mild to moderate neointimal hyperplasia as the primary lesion. In general, intraluminal fibrin thrombi with significant inflammation and necrosis were present in the right vein (Inari vessel) while the left vein (iCHOR vessel) did not have thrombi and changes included mild to moderate neointimal hyperplasia as the primary lesion.

Both devices had good procedural integrity and durability.

Inflammation of the lumen and endothelial layer was evident in the right iliofemoral vein (Inari vessel). There was additionally neointimal hyperplasia with thickening of the intima, inflammation and increased microvasculature of the media and muscularis.

The study used a single swine, 2 comparative vessels, and 2 devices used head-to-head. Sample size of one (1) – no statistical significance, only an observational study. No thrombus or vessel injury was seen in venograms prior to device use. The findings suggest aggressive scraping may cause immediate and possibly long-term scarring, inflammation, thrombosis, and necrosis and worth studying more comprehensively as new tools and methods become available.

Histopathology Summary

- Healthy swine IVC vessels were treated according the IFUs with equal number of retractions (4 pull-backs)
- Both devices demonstrated good procedural integrity and durability
- Vessels were harvested, treated, and shipped overnight to an independent, blinded pathology lab for analysis and reports.

>24 hours post treatment:

- Inari treated vessels had significant fibrin thrombi, significant inflammation, and necrosis present.
- iCHOR treated vessels showed no thrombi and only moderate neointimal hyperplasia.

Discussion:

- Are metal dragging tools causing unnecessary inflammation and damage to some patients?
- Are there methods to treat many patients more effectively without drug, surgical, or post treatment thrombi / necrosis?
- More needs to be done to understand the vessel histopathology of metal dragging /cutting tools in otherwise healthy vessels.



iCHOR Future Developments

✓ 2025 Product Development

14F Venous System *(Recently 510k cleared)*

- Continue the LMR (limited market release) data collection process + iterative elements
- Development on the 22mm "tacky" [balloon to treat larger vessels](#) and to be more aggressive when appropriate

7F Arterial System *(Recently 510k cleared)*

- Enter the LMR in Q2 2025, follow the iDVT process and iterate accordingly
- Eventual Post Market Study / Registry

7F /8F [Dialysis System](#) (ideal for grafts and many fistulae)

- Tighten up the market feedback and specs to begin development in Q1 2025



Built PE Prototypes

- ✗ Won't enter PE – too rep/clinical dependent, and highly competitive space in thrombectomy

7F Arterial Reperfusion System
(available Q2 2025)

Summary



Devices work and will 100% compete with market leaders (Simplicity)

- Proven mechanisms of action (60+ years)
- Versatile & economical
- Only getting better and better



A big market, well validated, continues to be underserved

- iCHOR Focused on Lower Extremity Reperfusion (LER)
- PE is too busy, but lower extremity issues and dialysis are not



FDA-cleared devices with demonstrated success and growing proof



1st technology to convert the standard of care Fogarty surgical technique to an Endo-Fogarty procedure



Strong platform / pipeline with potential for several future indications

- 7F Arterial
- 14F Venous
- 7F / 8F Dialysis



Best in class team, advisors, and partners who believe in what we do – It just makes sense!

