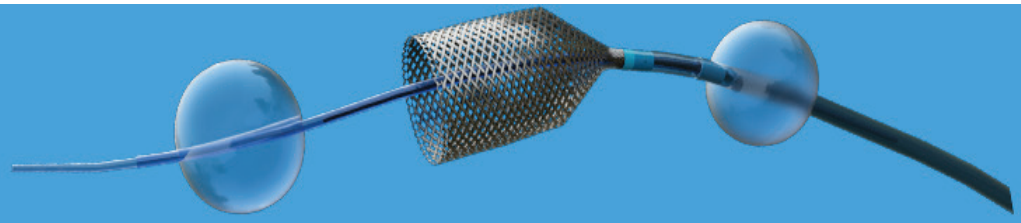


No Compromise Approach to Peripheral Thrombectomy

Why Current Peripheral Thrombectomy Too Often Imposes Compromises

Peripheral thrombectomy has evolved quickly from lytics and surgery to mechanical endovascular options, however the dominant tools still carry shortcomings.

Aspiration systems dominate the landscape; and while they can remove occlusive material, these tools come with a tradeoff of significant blood loss and potential hemolysis when blood is given back to the patient. Furthermore, aspiration systems may not fully engage wall-adherent thrombus or heavily organized thrombus due to the catheter tip being centered in the vessel.

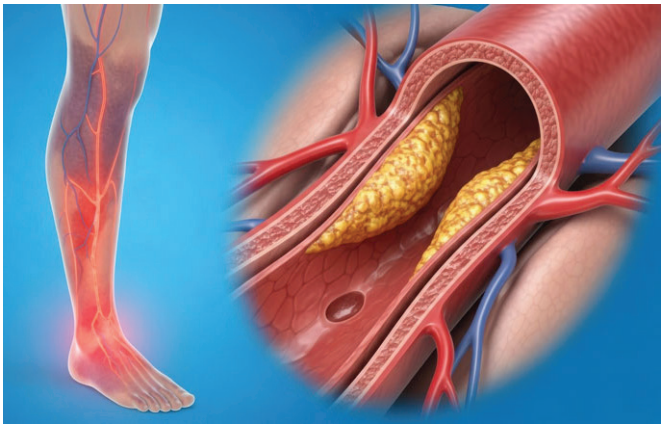
Aspiration tools are great, but they have shortcomings.

Metal draggers, typically steel or nitinol, are used to scrape, cut, or drag along the endothelial wall, often creating vessel trauma, scarring, inflammation and/or tissue necrosis. Vessel inflammation and scarring, whether a vein or an artery, has been shown to cause wall thickening and re-thrombosis which is only exacerbated when we drag across longer vessels in the peripheral vascular bed.

Metal dragging tools have a history of shortcomings in stroke, yet companies continue to try and make them work safely across lengthy peripheral treatment zones.

Lytic therapy, imported from life-or-death coronary and neurovascular indications, brings risks of intracranial and gastrointestinal bleeding which is no longer acceptable.

Lytics are relatively ineffective against chronic/organized clots and come with a higher cost of treatment driven by the drug costs and required ICU monitoring.



Other tradeoffs:
Most thrombectomy platforms are complex to set up and use, often requiring company representatives in the room along with additional ancillary equipment, supplies, and connective tubing.

That complexity adds cost without any direct impact to outcomes. This becomes a bigger problem when the representative is not present to properly deploy the devices or troubleshot algorithms and error codes.

No Compromise Approach to Peripheral Thrombectomy

Starting with a No-Compromise Design Philosophy

iCHOR took a focused approach to peripheral vascular occlusions with a fresh set of design inputs specific to lower extremity issues. Peripheral vascular disease has unique anatomical and morphological issues compared to what we see in stroke or coronary disease.

iCHOR approached lower extremity disease to eliminate the technology trade-offs by taking a surgical concept; a 60-year-old proven Fogarty balloon sweep, and patented it into a simple, effective, efficient catheter-based system.

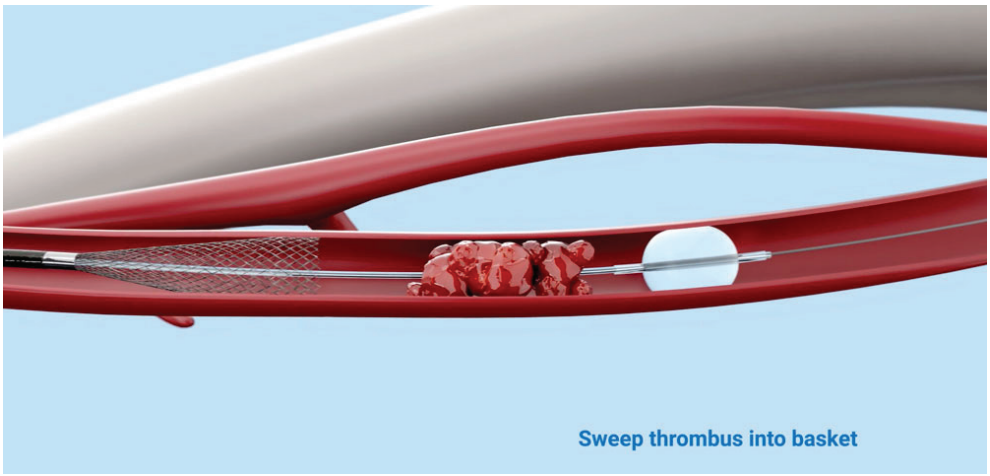
- The iSWEEP Mechanical Thrombectomy System uses three integrated components: a control sheath, a retrievable funnel-shaped guide catheter, and a long, compliant balloon catheter.

- The funnel is simply positioned proximal to the thrombus; the control sheath is deployed to arrest flow; the funnel is position proximal to the thrombus; then a compliant balloon is advanced over-the wire beyond the clot and withdrawn with the same surgical technique - sweeping wall-to-wall thrombus into the funnel for removal.

- iCHOR devices always maintain sheath and wire access which promotes faster procedure times and currently a massive tradeoff for most thrombectomy tools.

This mechanism of action mirrors the 60 year surgical Fogarty experience, long proven to be effective and safe on vessels but now void of surgical complications, general anesthesia, or systemic thrombolytics.

Many vascular physicians have commented on the iCHOR system's ability to control the balloon variability across variable sized anatomy in conjunction with fluoroscopy (no longer a blind procedure) to be a huge advantage compared to fixed aspiration catheters and fixed metal dragging tools that offer little compliance or variability.



No Compromise Approach to Peripheral Thrombectomy

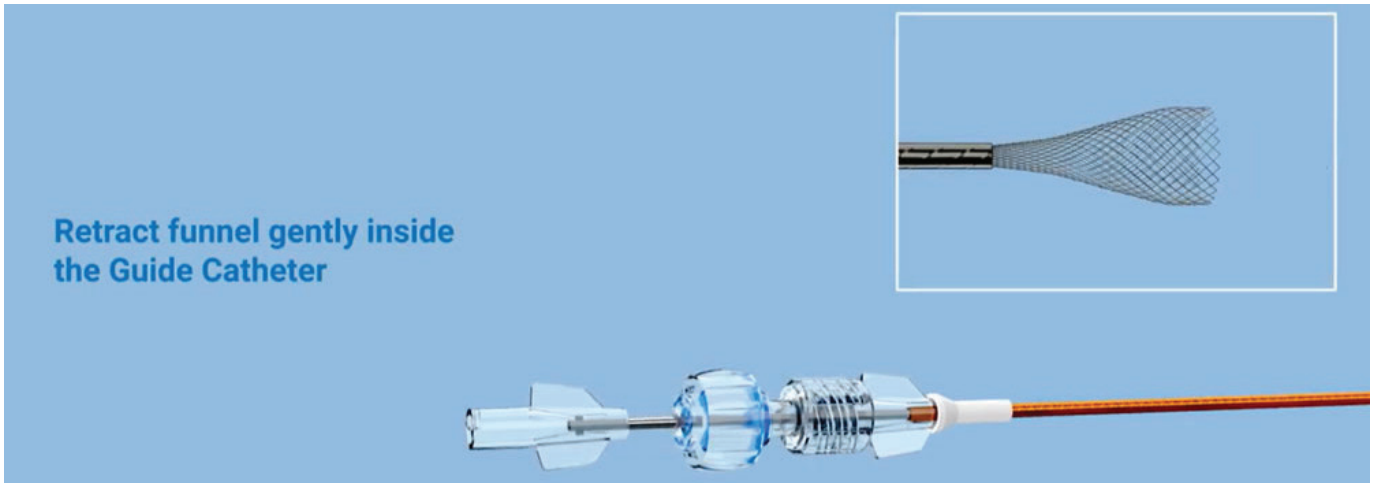
iSWEEP Solutions Overview

System overview

There are currently two devices in the iSWEEP family: the 7F iART system, optimized for peripheral arterial clot removal, and the 14F iDVT system, designed for large-vein thrombus.

- The control sheath provides proximal flow arrest, embolic protection, and stable access throughout the case.
- The nitinol funnel guide catheter is designed to maximize capture of both acute and organized thrombus.
- The compliant balloon provides circumferential wall contact as it is withdrawn, minimizing vessel or valve trauma compared with rigid, fixed metal devices.

The mechanism of action eliminates blood loss and vessel damage which are major tradeoffs with current mechanical options. The single-kit format supports vessel diameters roughly 3–10 mm (arterial) and 6-18 mm (venous).



Specific benefits

For physicians and hospitals, this design delivers several concrete advantages:

- **Non-surgical, non-drug therapy:** avoids surgical and drug complications and reduces length of stay (LoS).
- **Controlled flow and embolic protection:** proximal + distal balloon and funnel configuration reduce distal embolization.
- **Vessel and valve preservation:** compliant balloon sweep is intended to avoid endothelial scarring and valve damage common with rigid metal draggers.
- **Minimal blood loss:** flow arrest and proven mechanism of action result in low estimated blood loss (EBL) in clinical use.
- **Workflow simplicity:** all components are in one disposable system, no capital equipment, straightforward setup that fits standard endovascular workflows.

iART and iDVT in More Detail

Clinical Evidence: 7F iART Arterial Experience

A 25 patient limited market release (LMR) of the initial iCHOR percutaneous reperfusion system (7F iART) provides an early look at how this design performs across real-world arterial and some venous cases.

- The LMR cohort included acute limb ischemia, organized thrombus, embolic occlusions, occluded SFA stents and bypass grafts, and post-atherectomy debris, both above and below the knee.
- Achieved 100% technical success, with no device-related adverse events reported.
- Procedurally, the system was used to aspirate, sweep, and, in some cases, snare thrombus while maintaining continuous sheath and wire access, enabling immediate transition to angioplasty or stenting to treat any underlying issues.

The platform showed clinical utility in lower-extremity arterial anatomy without the use of lytics or surgery, with operators noting avoidance of significant blood loss, distal embolization, vessel scarring, and valve damage.

These LMR findings helped underpin FDA 510(k) clearance of the 7F peripheral reperfusion system and informed further refinement of the iART configuration.

Clinical Evidence: 14F iDVT Venous Experience

For the 14F iDVT venous system, emerging data from a 60 patient multi-center evaluation presented at VEITH symposium outline performance in iliofemoral, common femoral and popliteal veins.

- 60 patients were treated across more than 5 centers by~10 users (vascular surgeons and interventional radiologists).
- Vein diameters ranged from 9–20 mm, with thrombus lengths of 2 to 40cm (mean around 21.4 cm), reflecting real-world utility for many patients with acute to complex DVT.

Key performance metrics from this early experience include:

- Residual thrombus: mean less than 10% at the end of the procedure.
- Blood loss: no significant observed blood loss across the cohort.
- Procedure duration: approximately 31 minutes from vessel access to final treatment.
- Number of passes: mean 4.1 passes (range 1–10) per case.
- Adjunctive therapy: iCHOR plus PTA used in 64% of cases, and iCHOR plus PTA with venous stenting in 18%.

These data suggest that iDVT can efficiently clear extensive venous thrombus with minimal blood loss and low residual clot burden, while preserving valves and reducing or eliminating the need for thrombolytics.

No Compromise Approach to Peripheral Thrombectomy

Physician Perspectives and Case Scenarios

iART in lower-extremity artery disease
Interventionalists in the LMR described the arterial system as an "on-the-table" solution able to handle acute, acute-on-chronic, and organized clot above and below the knee with a single kit. They emphasized that the ability to aspirate and sweep clots under flow arrest, while keeping sheath and wire access intact, reduced the need to swap devices or rely on lytics and avoided the scarring and valve damage they associated with traditional metal draggers.

In one published case, a man in his early 50s with organized SFA occlusions and prior atherectomy had residual organized thrombus and debris after plaque debulking. The iCHOR system was used to sweep the obstruction into the funnel under controlled flow, restoring brisk perfusion, preserving existing stent patency, and avoiding open surgery or thrombolytics.

iDVT in iliofemoral DVT
Venous users have highlighted how the 14F system handles both acute and organized thrombus while focusing on vessel and valve preservation. In the 60 patient series, operators reported that many patients were treated without systemic lytics, procedures were quick, minimal blood loss, and low residual thrombus, supporting its role as a mechanical first-line option both in hospital and non-hospital environments.

What "No Compromise" Looks Like in Practice

Bringing these elements together, no-compromise thrombectomy in the peripheral space means:

- Treating a wide range of clot morphologies and vessel sizes (arterial and venous, above and below the knee) with a single, intuitive system.
- Achieving high technical success with excellent clot extraction, low blood loss, and protection of vessel and valve integrity.
- Reducing or eliminating reliance on lytics, surgery, and capital equipment, thereby lowering overall risk, ICU utilization, and system cost.
- Simplifying workflows so that teams can set up and run cases without heavy dependence on company representatives or complex consoles.

Technologies like iSWEEP, embodied in iART and iDVT, demonstrate that peripheral thrombectomy does not have to compromise. It's a proven mechanism of action that addresses shortcomings of blood loss, vessel damage, valve damage, distal embolization, and cost.

The iCHOR iSWEEP systems have the potential to become the standard of care for endovascular practices much like the Fogarty balloon was the standard of care for surgical practices: effective, efficient, easy to use, predictable, without compromise.