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Treating the Clot and the Cause: A Comprehensive Approach to Peripheral Thrombectomy



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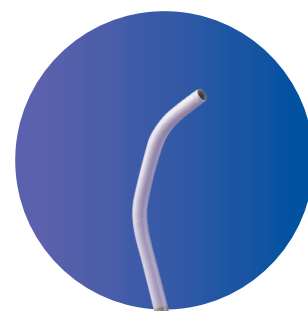




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With John Laird, MD; Nicole Ilonzo, MD; and Ajit Rao, MD

Early Real-World Experience With the Liberant™ Thrombectomy System Across Peripheral Arterial, Venous, and Arteriovenous Procedures

The Liberant™ thrombectomy system (Medtronic) is a mechanical endovascular aspiration device that is designed to restore blood flow by removing fresh, soft emboli or thrombi from vessels of the peripheral arterial and venous systems (Figure 1). It is currently available in several catheter sizes, including 6 Fr, 8 Fr (short and long), and 12 Fr, and tip shapes for use in a variety of vessel diameters (Figure 2A). Each catheter set includes a sterile single-use, guidewire-compatible catheter, dilator, clotbuster, aspiration tubing, and hemostasis valve.

POST-LIBERANT SYSTEM USE PHYSICIAN SURVEY

Following its United States market release in 2025, early real-world experience was captured via a physician survey completed postprocedure where the Liberant system—with or without adjunctive technologies, including the Excipio™ thrombectomy device (Contego Medical)—was used across a range of peripheral arterial, venous, and arteriovenous (AV) thrombectomy procedures. The reported experience included 162 procedures performed by 38 physicians at 21 hospitals (Figure 3). Of the 162 procedures performed, arterial thrombus or emboli represented the majority (49%) of cases, followed by venous thrombosis (28%) and AV thrombectomy cases (23%) (Figure 4).

Physicians were asked to determine procedure success, defined as removal of the fresh, soft emboli or thrombi and restoration of adequate blood flow inclusive of all endovascular therapies employed during the procedure. Of the reported procedures, 94% of procedures resulted in successful removal of emboli/thrombi (Figure 5).

The Liberant blood conservation unit (BCU) is a reusable, nonsterile electronic device that uses ultrasonic control to provide automated, consistent pulse rates across all catheter sizes (Figure 1E). The Liberant system is the only device on the market that directly measures blood flow with an ultrasonic flow sensor and automatically adjusts the aspiration rate through a pinch valve to help reduce blood loss. The BCU has two operating modes:

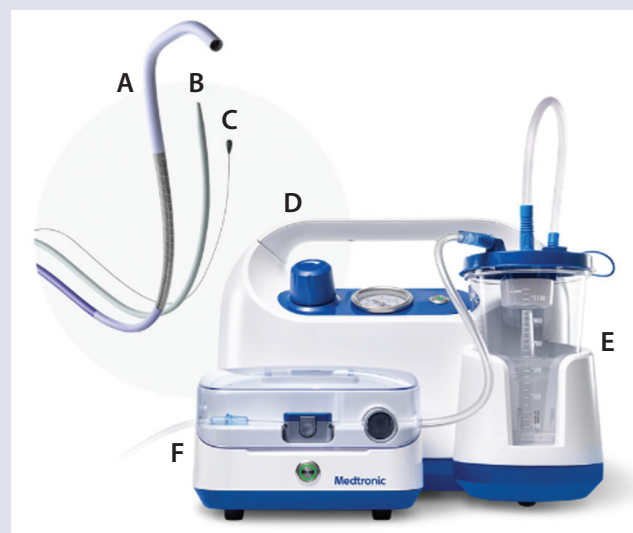


Figure 1. Liberant thrombectomy system and capital components: 12-Fr catheter (A), dilator (B), clotbuster (C), Riptide aspiration pump (D), canister (E), and blood conservation unit (F).

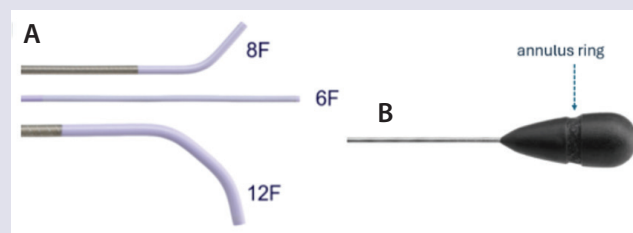


Figure 2. Liberant thrombectomy system catheter tip shapes: straight (6 Fr); single-angled (8 Fr); and double-angled (12 Fr) (A). Liberant system clotbuster bulb (B).

standard mode maintains a lower pulse rate to minimize blood loss during thrombus removal, while boost mode increases the pulse rate to improve procedural efficiency. The majority of procedures (65%) were performed in standard mode. Physicians estimated blood loss (EBL) at < 200 mL in 73% of the 162 early use cases (Figure 6).



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Figure 3. Physician-collected early procedure data for the Liberant thrombectomy system.

When asked to rate their satisfaction with blood loss performance using five response categories—from very satisfied to very dissatisfied (clinically unacceptable)—91% reported being satisfied or very satisfied.

The Liberant catheter shaft features a hybrid braid coil design that allows for flexibility and reduced kinking while maintaining a 1-to-1 torque response to transverse tortuous vasculature.[†] Figure 2A illustrates the available catheters with three (size-dependent) tip shapes: straight (6 Fr), single-angled (8 Fr), and double-angled (12 Fr). The Liberant thrombectomy system catheters are designed to maximize retention of their tip shape after use, ensuring reliable vessel navigability.[†] In the physician survey, 98% of respondents reported being satisfied or very satisfied with the catheter's deliverability and torqueability.

The Liberant clotbuster (Figure 2B) is an optional thrombectomy accessory designed to disrupt thrombus, improve clot capture into the aspiration catheter, and clear catheter occlusions during a procedure while

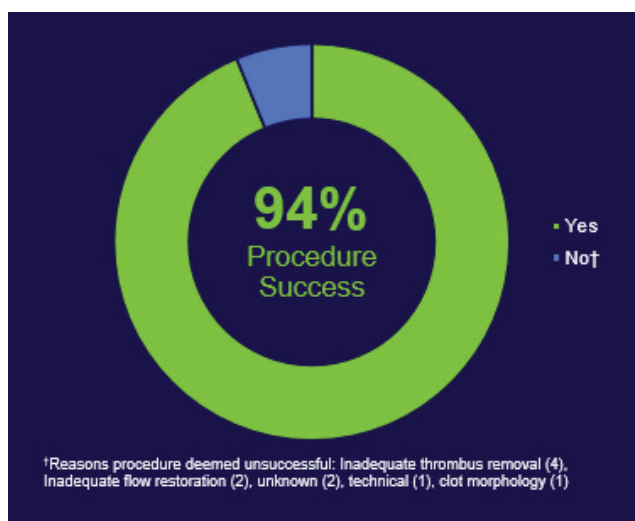


Figure 5. Physician-reported procedure success from early procedure data for the Liberant thrombectomy system (n = 162 cases).

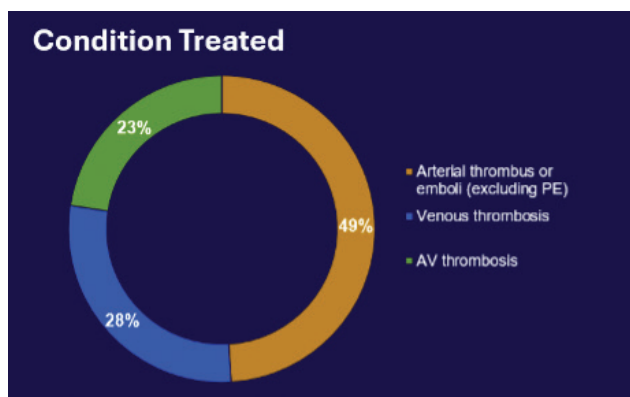


Figure 4. Distribution of early procedure data for the Liberant thrombectomy system by condition treated. PE, pulmonary embolism.

minimizing vessel trauma. Physicians used the clotbuster in 25% of procedures, and 80% reported being satisfied or very satisfied with its performance.

The Excipio thrombectomy device (Figure 7) is a rapid-exchange catheter with a mechanical basket designed to be used within an aspiration catheter, like the Liberant system. It can be used to assist with additional clot disruption and removal. The Excipio device comes in three sizes: SV for small vessels 4-8 mm; LV Prime for vessels 6-16 mm; and LV for vessels 10-25 mm. Excipio SV is compatible with the 8-Fr Liberant catheter, while Excipio LV Prime is compatible with the 12-Fr Liberant catheter. Physicians elected to use the Excipio thrombectomy device in 27% of procedures (35 cases with Excipio SV, 9 cases with Excipio LV Prime). Physicians rated performance as satisfied or very

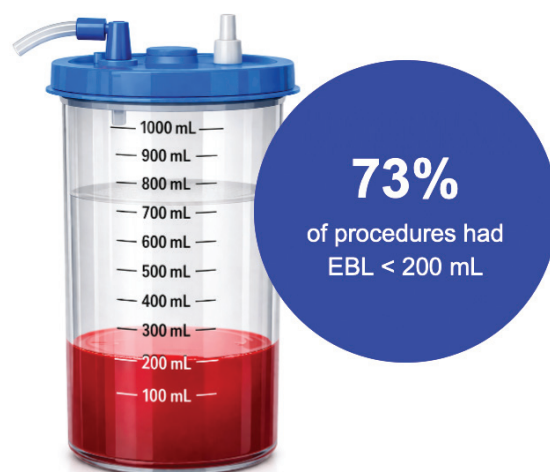


Figure 6. Physician-reported EBL from 162 early use cases of the Liberant thrombectomy system.

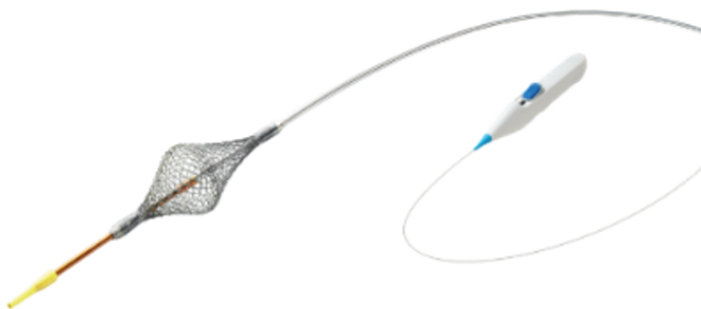


Figure 7. Excipio thrombectomy device.



Figure 8. 5-Fr Liberant RX aspiration catheter.

satisfied in 88% of evaluated Excipio SV device uses and 100% of evaluated Excipio LV Prime device uses.

CONCLUSION

The information collected from these early use cases provides an encouraging, descriptive view of the initial real-world experience with the Liberant thrombectomy system across peripheral arterial, venous, and AV thrombectomy procedures. Physicians reported successful embolus or thrombus removal in 94% of procedures and were satisfied or very satisfied by catheter deliverability and torqueability in 98% of cases. The 162 cases demonstrate use across a range of treated conditions, with ancillary devices incorporated according to procedural needs. These findings support the feasibility and versatility of the Liberant system in varied peripheral thrombectomy workflows and help identify areas for continued clinical experience and evidence generation.

The Liberant RX aspiration catheter (Figure 8) was released after the completion of the post-Liberant system use physician survey. This 5-Fr aspiration catheter is intended for removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system, and to subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion. The Liberant RX further expands the capabilities of the Liberant thrombectomy system. ■

[†] Internal data on file.



CASE STUDY

Extensive Echogenic DVT Managed With the Liberant™ Thrombectomy System



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PATIENT PRESENTATION

A female patient in her mid-40s presented to the emergency department with acute-onset swelling and pain in her right leg persisting for the last 6 days. This was preceded by an upper respiratory infection the week before. She denied any chest pain, shortness of breath, or palpitations. A review of her medical history revealed prior diagnoses of postural orthostatic tachycardia syndrome, ophthalmic stroke, and a gastrointestinal bleed.

PROCEDURAL DETAILS

Procedural Overview

Venous duplex ultrasound (DUS) demonstrated extensive echogenic thrombus and dilated veins involving

the popliteal, femoral, common femoral, and iliacs. CT demonstrated bilateral subsegmental pulmonary emboli without any evidence of right heart strain (Figure 1). The patient was started on a heparin drip.

Vascular surgery was consulted due to involvement of the iliofemoral segment. Her right lower extremity was visibly edematous and had cyanotic congestive discoloration. She continued to be in pain despite starting the heparin drip. Given the extensive nature of the deep vein thrombosis (DVT), her young age, and physical examination findings, the decision was made to proceed with percutaneous mechanical thrombectomy with the 12-Fr Liberant™ thrombectomy system (Medtronic).

Thrombectomy Technique

The patient was taken to the operating room and placed in a prone position. The right popliteal space was prepped and draped, and the below-knee popliteal vein was accessed. An 8-Fr, 10-cm Pinnacle™* sheath (Terumo Interventional Systems) was introduced via the Seldinger technique. This was later upsized to an 11-Fr,



Figure 1. Axial CT of the dilated left CIA.

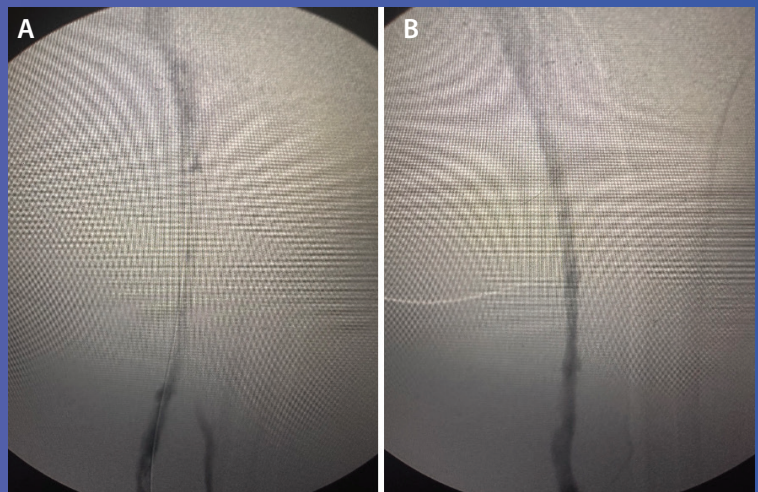


Figure 2. Fluoroscopic venogram of the left femoropopliteal vein with a guidewire (A) and catheter (B) at acute thrombus site.

10-cm sheath. Diagnostic venography was performed, which demonstrated findings compatible with the venous DUS (Figure 2). Systemic heparin was readily given at 100 units/kg. The wire was advanced with a GlideCath™* catheter (Terumo Interventional Systems) to the inferior vena cava (IVC). Cavography confirmed no thrombus burden above the confluence site.

I have found that the Liberant thrombectomy system works best by initiating aspiration in open flow prior to engaging the thrombus. Thus, I advanced the 12-Fr Liberant device with the inner dilator over the wire, into the IVC, and past the confluence. After the first pass, I removed the wire and was able to freely advance the catheter without difficulty. I have found that the torqueability of the Liberant catheter is one of its greatest strengths.

Given that the thrombus appeared and felt very acute, I opted not to use the clotbuster or the Excipio™* thrombectomy device (Contego Medical), which is a helpful adjunct in subacute thrombotic cases. I was able to advance the device a total of three times (back and forth) and successfully cleared out the entirety of the thrombus with an estimated blood loss of 120 mL. Follow-up venography demonstrated wide patency (Figure 3), and intravascular ultrasound (IVUS) did not reveal any need for iliac vein angioplasty/stenting. The sheath was removed from the popliteal space, and after hemostasis was achieved, a compression bandage was used from the foot to the groin. The heparin drip was

readily restarted in the recovery area. The patient was transitioned to rivaroxaban and was discharged the following day.

Postprocedure Follow-Up

I follow up with all my patients who have undergone thrombectomy after 1 month with a venous DUS. This patient's DUS demonstrated widely patent veins apart from chronic thrombus in the proximal posterior tibial veins. The patient had no complaints and was back to pursuing her normal lifestyle.

REFLECTIONS

I believe percutaneous mechanical aspiration venous thrombectomy may play an important role in selected patients with acute iliofemoral DVT by accelerating symptom relief and functional recovery, while reducing the severity of postthrombotic syndrome and its associated long-term sequelae.^{1,2} It is very important to assess with IVUS to rule out underlying mechanical causes and correct them readily. I have also found it to be crucial to restart anticoagulation immediately after the intervention while the patient is in the recovery area. ■

1. Comerota AJ, Kearon C, Gu CS, et al. Endovascular thrombus removal for acute iliofemoral deep vein thrombosis. *Circulation*. 2019;139:1162-1173. doi:10.1161/CIRCULATIONAHA.118.037425

2. Vedantham S, Desai KR, Weinberg J, et al. Society of Interventional Radiology position statement on the endovascular management of acute iliofemoral deep vein thrombosis. *J Vasc Interv Radiol*. 2022;34:284-299.e7. doi: 10.1016/j.jvir.2022.10.038.

Disclosures: None.

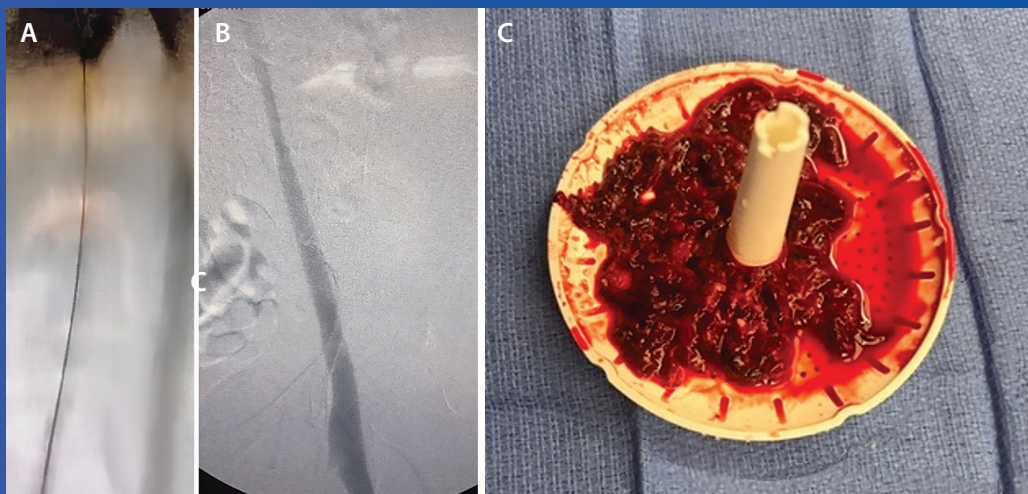


Figure 3. Follow-up fluoroscopic venogram of the femoropopliteal segment (A). Venogram demonstrating patent iliac venous flow after thrombectomy (B) and remnants of soft tissue blockage from index aspiration (C).



CASE STUDY

Liberant™ Thrombectomy System to Remove Adherent Left Iliofemoral Vein Thrombus



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PATIENT PRESENTATION

An ambulatory female in her 40s with a past medical history of obesity presented to the emergency department with 5 days of worsening left leg pain and swelling. On examination, the patient had severe swelling of the left leg and thigh with palpable pedal pulses and an intact neurologic exam.

The patient was found to have an occlusive left leg deep vein thrombosis (DVT) in the left femoral vein (FV) extending proximally to the common femoral vein on venous duplex ultrasound (DUS). A CT venogram of the abdomen and pelvis was obtained, revealing an iliofemoral DVT with possible underlying May-Thurner anatomy. The patient was started on intravenous (IV) heparin and was taken to the operating room for further management.

PROCEDURAL DETAILS

Procedural Overview

The patient was placed in the supine position, and the procedure was performed under sedation. Under venous DUS guidance, left popliteal vein access was obtained with the leg in a frog leg position. The micropuncture sheath was then exchanged for an 11-Fr sheath. IV heparin was administered and re-dosed throughout the procedure. Left leg venography demonstrated an occluded FV with reconstitution in the inferior vena cava (IVC) (Figure 1).

Device Selection and Settings

A 12-Fr Liberant™ thrombectomy system catheter (Medtronic) was selected to remove the thrombus in the left iliofemoral vein. Three passes were advanced using the Liberant device. Standard mode was used for the first two passes. Boost mode was used for the last pass in the left common iliac vein (CIV) given the large vein size and anticipated large degree of clot burden.

Thrombectomy Technique

The catheter was advanced while rotating the device to utilize the angled tip to aid in mural thrombus removal. Thrombectomy was largely performed without the

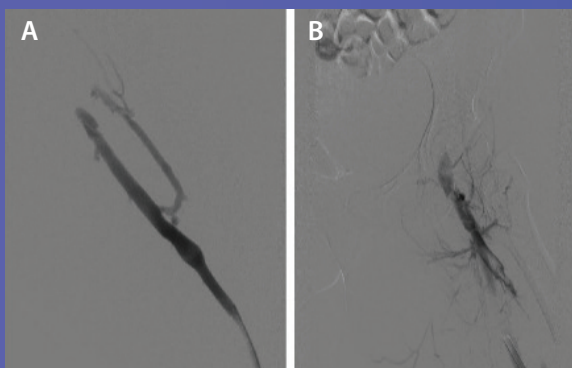


Figure 1. Left popliteal vein (A) and left FV pretreatment (B).

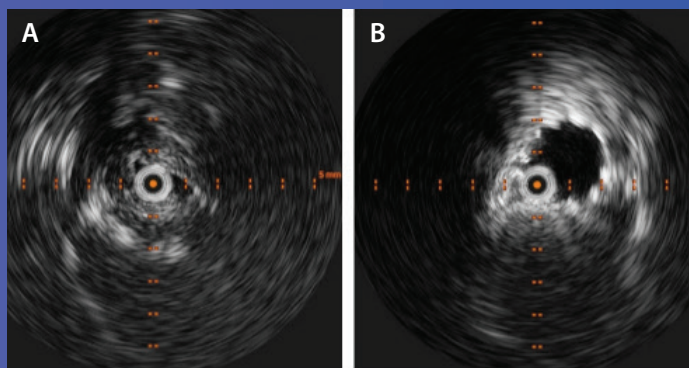


Figure 2. IVUS of the left CIV before (A) and after (B) stenting.

use of a wire and the Liberant catheter tracked without resistance through the entire iliofemoral segment. A 0.035-inch wire was utilized to cross into the IVC at the origin of the left CIV due to severe compression.

Repeated venograms demonstrated an area of adherent thrombus in the left FV. Excipio™ LV Prime thrombectomy device (Contego Medical) was utilized to remove this adherent thrombus. The basket was opened proximally to the area of thrombus and then pulled back while aspiration was active in the Liberant catheter. This was repeated twice for a successful thrombus extraction.

Post-Thrombectomy Treatment

An Amplatz stiff guidewire was exchanged into the IVC. Intravascular ultrasound (IVUS) was performed on the treated segment, which demonstrated resolution of all significant thrombus burden. IVUS demonstrated multiple areas of left iliac vein compression and severe narrowing at the origin of the left CIV (Figure 2A). A 16- X 150-mm Abre™ venous self-expanding stent system (Medtronic) was deployed into the left CIV and left external iliac vein and postdilated with a 16-mm balloon. Repeat IVUS demonstrated resolution of the left CIV compression (Figure 2B). Final venography demonstrated resolution of all stenoses with brisk flow into the IVC (Figure 3). Total blood loss for the procedure was under 250 mL.

Postprocedure Course

The patient did well postoperatively. She was maintained on IV heparin on postoperative day 0. Her swelling and pain significantly improved. She was discharged on postoperative day 1 with apixaban and compression stockings. She was most recently seen at her 6-month clinic follow-up with complete symptom resolution. An in-office venous DUS at 6-month follow-up showed a patent left iliac vein stent and iliofemoral venous system.

REFLECTIONS

The Liberant thrombectomy system met my expectations of safety and performance in removal of thrombus in the lower extremity. In our experience, the device has been efficient at removing large thrombus burden in both the arterial and venous system with an acceptably low amount of blood loss. It has been our preference to use the device in standard mode with selective use of boost mode in areas of large thrombus burden. We use Excipio LV Prime as a mechanical adjunct to facilitate removal of adherent and mural thrombus when using the Liberant system. ■

Disclosures: Consultant to Medtronic and Penumbra, Inc.

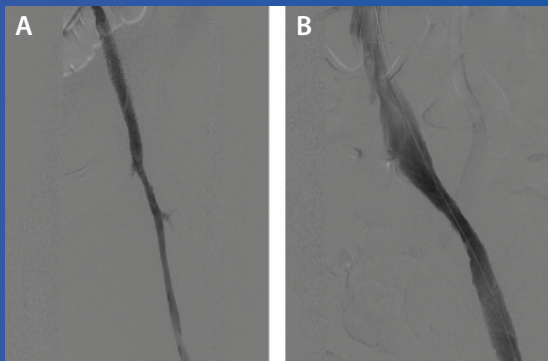


Figure 3. Left FV (A) and left iliac vein (B) posttreatment.



CASE STUDY

Liberant™ Thrombectomy to Remove Thrombus From a Stenosed Brachiobasilic AVF



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PATIENT PRESENTATION

A male patient in his late 80s with a history of end-stage renal disease, congestive heart failure, and diabetes presented to the emergency department with a malfunctioning arteriovenous (AV) brachiobasilic fistula. Due to his advanced age and comorbidities, his thrombectomy was deferred to the hospital setting. Upon initial examination, we observed that his AV fistula (AVF) was thrombosed. The patient was prepped and draped for fistulography and thrombectomy.

PROCEDURAL DETAILS

Procedural Overview

This AV case required multiple steps to clear the clot. First, to restore blood flow through the clotted dialysis fistula, tissue plasminogen activator (tPA) and the Liberant™ thrombectomy system (Medtronic) were used

to remove thrombus from the venous outflow. Further imaging revealed severe narrowing in the outflow, which we addressed with balloon angioplasty and a covered stent. The remaining arterial plug in the arterial connection was disrupted and removed with combination mechanical aspiration thrombectomy.

Outflow Thrombectomy

tPA was administered, and subsequent imaging confirmed mural thrombus within the fistula (Figure 1). We used a 8-Fr Liberant catheter to intervene in the brachiobasilic AVF. The Liberant catheter was advanced initially without a guidewire through the outflow (Figure 2A) using the standard aspiration mode. After two passes, the outflow was completely patent (Figure 2B and 2C). Further imaging revealed > 75% hemodynamically significant stenosis of the outflow vein. This was treated with plain old balloon angioplasty (POBA; 10- X 60-mm EverCross™ PTA catheter; Medtronic) (Figure 3A) and stent placement (10- X 60-mm Covera™ vascular covered stent; BD) (Figure 3B).

Inflow Thrombectomy

To treat the inflow, an 8-Fr sheath was advanced toward the brachial artery fistula anastomosis. A 0.014-inch guidewire was advanced into the axillary artery through a

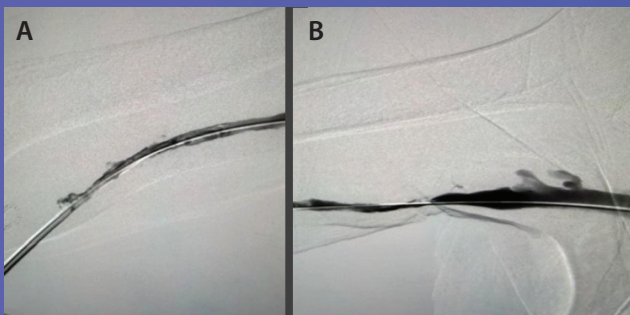


Figure 1. Initial fistulogram demonstrated a brachiobasilic fistula with thrombus (A) and an outflow with severe stenosis (B).



Figure 2. Initial pass with an 8-Fr Liberant catheter without a wire (A) revealed a patent outflow of the brachiobasilic fistula (B) and patent outflow (C).

Berenstein catheter. The 8-Fr (short) Liberant sheath was then advanced over the wire toward the arterial anastomosis and distally positioned 2 cm from the target vessel connection. Angiography confirmed patent brachial and outflow vessels, and an expected thrombus within the inflow segment of the AVF.

Arterial Plug Thrombectomy

To remove the remaining arterial plug thrombus (Figure 4A), we aspirated with the 8-Fr (short) Liberant catheter in standard mode, and the Excipio™ SV thrombectomy device (Contego Medical) was then advanced into the mid-brachial artery and partially deployed to match the vessel diameter. The device was then used to extract the thrombus. Completion fistulography confirmed thrombus clearance (Figure 4B). Estimated blood loss (EBL) was about 100 mL (Figure 4C).

Post-Thrombectomy Outcomes

At completion of the case, the patient had a palpable thrill and completed dialysis successfully that day. The Liberant thrombectomy system and

Excipio device combine aspiration and extraction technology to remove thrombus successfully from the stenosed AVF.

REFLECTIONS

In this AVF case, a wire was not required for thrombectomy of the outflow since the Liberant catheter tracked well without a wire (Figure 2B). However, a 0.014-inch wire is required for using the Excipio device. In my experience, I typically avoid hydrophilic wires to prevent unnecessary vessel wall gripping.

The Excipio device functions similarly to an over-the-wire Fogarty device. The benefit of Excipio, however, is that it is compatible with aspiration technology, such as the Liberant catheter. This helps achieve removal of thrombus that may not be completely retrieved with suction alone. Care must be taken to ensure size match when advancing the Excipio device through the brachial artery. Of note, the Excipio SV thrombectomy device is compatible with vessels ranging from 4 to 8 mm. ■

Disclosures: Consultant to Medtronic, Stryker, and Abbott.

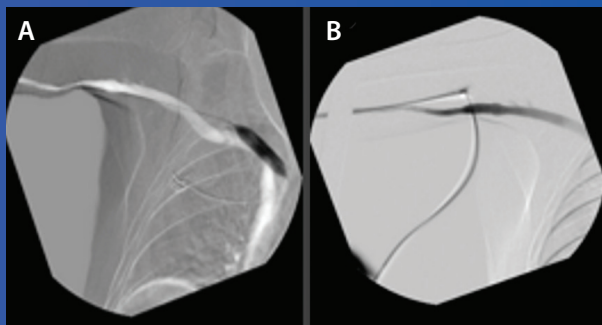


Figure 3. POBA of the axillary vein (A) and a patent axillary vein after angioplasty and stenting (10-X 60-mm Covera) (B).

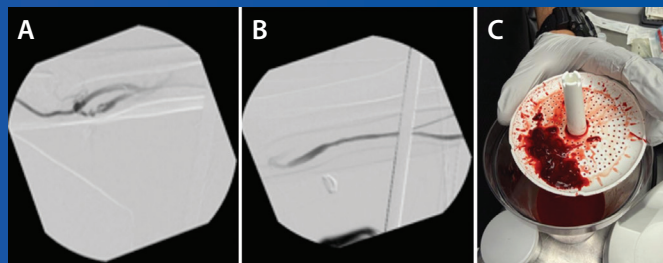


Figure 4. Arterial plug thrombus (A), patent AVF (B), and an EBL of 100 mL in the blood collection canister (C).



CASE STUDY

Acute Thrombus in the Proximal SFA Managed With the Liberant™ Thrombectomy System



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PATIENT PRESENTATION

A woman in her late 60s presented to the emergency department with a 10-day history of worsening right leg pain and new-onset numbness that disrupted her sleep after undergoing a left lower extremity angiography at an outpatient clinic (Figure 1A). The patient reported she could walk only short distances with a cane because of the new pain. Her medical record included coronary artery disease with stent placement, hypertension, hyperlipidemia, liver cirrhosis, hyperthyroidism, vertigo, stage 1 chronic kidney disease, and peripheral artery disease.

PROCEDURAL DETAILS

During diagnostic evaluation, the patient's right foot was cold to the touch. Motor function and sensation in the toes were intact, and the foot was nontender. She had a prior right hallux amputation and nonpalpable distal pulses. Doppler ultrasound findings were consistent with Rutherford class 2a acute limb ischemia (ALI) of the right leg, with superficial femoral artery (SFA) occlusion and peroneal runoff (Figure 1A).

Device Selection

Based on symptom presentation and CTA (Figure 1B and 1C), we determined that an acute thrombus was present in the proximal SFA, likely related to a prior interventional closure device injury. We selected the Liberant™ thrombectomy system (Medtronic) because of our clinic's confidence in the device's radiographic trackability and ease of use.

We used the 6-Fr Liberant catheter in the SFA, followed by the HawkOne™ directional atherectomy system, 5-mm SpiderFX™ embolic protection system, and IN.PACT™ 018

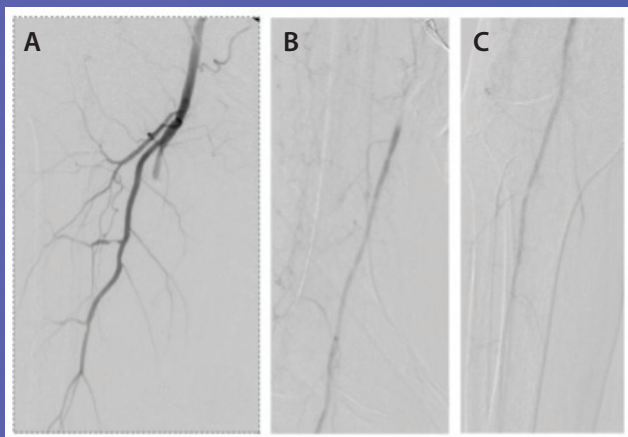


Figure 1. Angiography demonstrated an occlusion of the SFA through the closure device (A), an acute clot in the proximal SFA (B), and peroneal runoff (C).

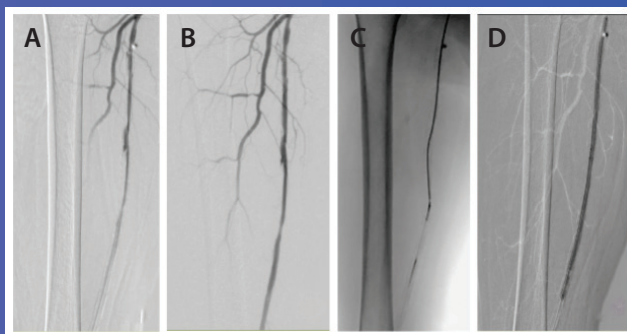


Figure 2. Angiogram after one back-and-forth pass (A) and two additional passes (B) with the 6-Fr Liberant catheter. Calcified vessel before directional atherectomy using the HawkOne device (C) and post-DCB angioplasty of the diseased segment (D).

drug-coated balloon (DCB) (all Medtronic) in the popliteal artery. Our clinic prefers directional atherectomy for plaque removal to help reduce downstream disease progression. We have performed a tremendous number of directional atherectomy cases without adverse events, supporting the rigorous clinical research in safety data available.¹

Procedure Techniques and Outcomes

Three passes with the Liberant system were completed, resulting in clot removal and vessel patency (Figure 2A and 2B). Six passes with the HawkOne directional atherectomy system were then performed to remove plaque buildup in the popliteal artery, followed by DCB angioplasty (Figure 2C and 2D). A closure device–related injury caused a dissection that required bailout stenting with a 5.5- X 60-mm Supera™* stent (Abbott) and a 6- X 40-mm EverFlex™ self-expanding stent system (Medtronic). The intervention was successful, and no adverse events were reported.

The patient was discharged the same day on an anticoagulation regimen, with no recurrence and significant improvement upon clinical examination. At the 3-month follow-up visit, duplex ultrasound continued to show a patent popliteal artery and tibioperoneal runoff, with resolution of disease post-intervention (Figure 3).

Rationale for Treatment Approach

ALI at an advanced Rutherford stage requires prompt revascularization. In this setting, clinicians should use a technology with a high likelihood of success or consider open surgery. In our practice, the Liberant system has been effective and easy to use, with no adverse events observed. The device is gentle enough to support trackability yet robust enough to achieve effective thrombus removal.

REFLECTIONS

The guiding principle for device selection is deliverability. Thrombectomy devices have one primary purpose: *to clear the clot*. When a device performs efficiently, it can increase procedural confidence and support interventional performance. Without that efficiency, interventionalists may need to convert to open surgery and/or lengthy endovascular options with higher resource utilization and risks. Training has strengthened our team's ability to select the appropriate device for each patient and provided valuable support in managing these cases. ■

1. Carr JG, Langhoff R, DeRubeis BG, et al. Published evidence on peripheral atherectomy: a meta-analysis and systematic literature review of more than 300 original investigations. *J Soc Cardiovasc Angiogr Interv.* 2025;4:104009. doi: 10.1016/j.jscv.2025.104009

Disclosures: Consultant to Medtronic.



Figure 3. Angiogram demonstrating patent flow and resolution of disease post-intervention.



Generating Real-World Evidence: The Case-Specific Health Care Professional (HCP) Clinical Survey of the Liberant™ Thrombectomy System

The management of patients with venous and arterial thrombosis has changed dramatically in recent years. There has been continuous evolution away from systemic or intra-arterial/intravenous thrombolytic therapy toward mechanical thrombectomy devices that offer the possibility of same-day procedures. As these devices continue to evolve, there is a strong need for clinical evidence confirming their safety and effectiveness. Although prospective, multicenter, randomized trials are always desirable, newer study designs are being explored to more rapidly capture outcome data in this fast-moving space. The Liberant™ thrombectomy system (Medtronic) obtained FDA clearance in June 2025 and has since been used in hundreds of patient cases. A clinical assessment was designed as an early evidence generation effort to systematically characterize real-world physician experience with the Liberant system.

OBJECTIVE

The purpose of the Case-Specific Health Care Professional (HCP) Clinical Survey of the Liberant Thrombectomy System (NCT07335341), also known as the Liberant Clinical Assessment, is to collect first-in-human clinical data to confirm the safety and performance of the Liberant thrombectomy system when used for the removal of fresh, soft emboli or thrombi from the vessels of the peripheral arterial and venous systems.

CLINICAL ASSESSMENT DESIGN

The Liberant Clinical Assessment is a multicenter, prospective, real-world survey that collects periprocedural data for thrombectomy procedures performed within arterial, venous, or arteriovenous fistula vessel beds. Data will be entered for at least 50 cases over an approximate data collection period of 8 months. At least 10 HCPs will participate in this assessment. This survey population will consist of vascular interventionalists who perform a high volume of thrombectomy procedures in their clinical practices and have used the Liberant system. The participating HCPs will document their individual case experience following routine utilization of Liberant, with or without the Excipio™* thrombectomy device (Contego Medical), in accordance with the approved device labeling within 72 hours of device use. Each survey response will be

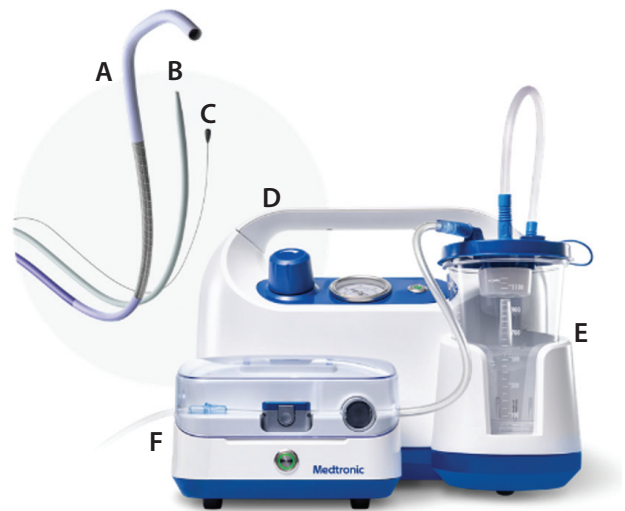


Figure 1. Liberant thrombectomy system and capital components: 12-Fr catheter (A), dilator (B), clotbuster (C), Riptide aspiration pump (D), canister (E), and blood conservation unit (F).

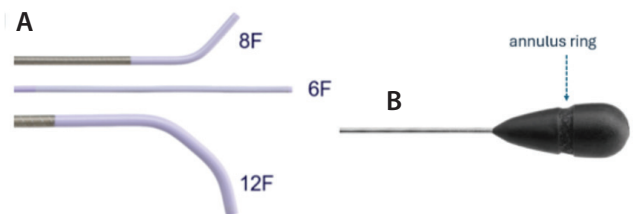


Figure 2. Liberant thrombectomy system catheters. Liberant system catheter tip shapes: straight (6 Fr); single-angled (8 Fr); and double-angled (12 Fr) (A). Liberant system clotbuster bulb (B).

based on physician recollection, and there are no patient follow-ups. The responses will be aggregated by a third-party vendor.

DEVICE DESCRIPTION

The Liberant system is designed and indicated to restore blood flow in vessels and arteries by removing fresh, soft emboli or thrombi from the vessels of peripheral arterial and venous systems (Figure 1). The system is composed of the device cath-

TABLE 1. ADDITIONAL PHYSICIAN-REPORTED CLINICAL ASSESSMENT DATA COLLECTED

Demographics	Baseline Characteristics	Procedure Variables	Safety Variables
- Age range - Sex - BMI range	- Medical history - Patient condition treated - Anatomic treatment location	- Catheter use - Adjunctive device use - Procedural time - EBL	- Adverse events - Serious adverse events - Device-related events - Device deficiencies

Abbreviations: BMI, body mass index; EBL, estimated blood loss.



Figure 3. Clinical Assessment endpoints.

eters (Figure 2), dilator, clotbuster, hemostasis valve, aspiration tubing, Liberant blood conservation unit (BCU) with two modes (standard and booster) (Figure 1F), and the Riptide™ aspiration system pump (Medtronic) and collection canister (Figure 1D).

ENDPOINTS

Primary Outcomes

The primary safety endpoint of this assessment is the physician-reported rate of device-related serious adverse events (SAEs) during the index procedure (Figure 3). SAEs are defined as any event leading to death, life-threatening illness or injury, permanent impairment, prolonged hospitalization, or unplanned or additional medical or surgical interventions to prevent serious harm.

The primary performance endpoints are technical and procedural success during the index procedure (Figure 3). Technical success is defined as a successful introduction of the catheter into peripheral vasculature; delivery of the Liberant system to the target location; aspiration of the soft, fresh embolus or thrombus; and retrieval of the system during

the index procedure. Procedural success is defined as successful removal of the soft, fresh, embolus or thrombus and restoration of adequate blood flow to the vessels following completion of the index procedure, inclusive of all endovascular therapies used in the index procedure (eg, percutaneous transluminal angioplasty, atherectomy, stents).

Ancillary Outcomes

The ancillary endpoints will characterize procedural, clinical user experience, and device performance outcomes (Figure 3). Procedural measures will include a qualitative assessment of any adjunctive therapies used in the index procedure, including the use of other thrombectomy devices and any additional treatment of the underlying lesions. Other endpoints include procedural outcomes, such as the estimated blood loss and rate of conversion to open surgery. Clinical outcomes will include all-cause periprocedural mortality and device-related adverse events. User experience will be recorded as satisfaction scores on a 1 to 5 scale. Device performance will be evaluated through any reported device deficiencies, reliability or usability concerns, and device malfunctions. Additional data collected from physician surveys are listed in Table 1.

STATISTICAL PLAN

Sample Size

At least 50 use cases will be recorded from approximately 10 HCPs. No formal statistical sample size estimates were calculated for this quantitative survey. Data collected will be analyzed as quantitative and descriptive statistics, including means, standard deviation, medians, minimum/maximum values, total counts, and percentages. A two-tailed 96% CI will be generated for primary safety and performance endpoints.

SUMMARY

There is a need for clinical data to support use of the Liberant system in this rapidly evolving thrombectomy space. The Case-Specific HCP Clinical Survey of the Liberant Thrombectomy System is a novel approach to gain expeditious, real-world experience with the Liberant system. In addition to traditional safety and efficacy endpoints, data will be collected on physician satisfaction with the system and overall catheter/system performance. The results from the Liberant Clinical Assessment will help guide future research efforts and provide valuable information to physician users regarding techniques in mechanical and aspiration thrombectomy. ■



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Treating the Clot in Practice: How Physicians Navigate Thrombus Removal With Mechanical Thrombectomy

Moderator John Laird, MD, talks with panelists Nicole Ilonzo, MD, and Ajit Rao, MD, about their current approaches to thrombus removal and their thoughts on the recently launched Liberant™ thrombectomy system.



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I will also ask for their thoughts about a newer thrombectomy platform that has the capability to combine mechanical aspiration and extraction to increase our chances of success in even the toughest of cases.

Dr. Laird: There are multiple technologies for treating thrombus. How long have you been incorporating mechanical aspiration thrombectomy devices into your practice? What challenges and limitations have you historically encountered with these devices?

Dr. Ilonzo: I have been incorporating mechanical aspiration thrombectomy into my practice since I began practicing in 2014. I utilize either mechanical aspiration thrombectomy or nitinol-based extraction thrombectomy depending on the clinical scenario. That decision depends on the individual patient, the extent of disease, and the age and characteristics of the thrombus, including whether it is acute, subacute, or wall-adherent.

In my experience, the main challenges with thrombectomy include difficulty navigating devices through acute-on-chronic lower extremity arterial disease, limited effectiveness in removing organized or firmly adherent venous thrombus, and the inability to consistently advance catheters into small distal vessels. Typically, I avoid hydrophilic wires to prevent the devices from becoming stuck when advanced through vasculature. Additionally, the potential for distal embolization is always an important consideration when performing thrombectomies.

Dr. Rao: I am a long-term user of mechanical aspiration thrombectomy since the early generation devices were released into the market in the early 2000s. I believe mechanical aspiration is the sweet spot for thrombectomy given its versatility, excellent thrombus extraction, and ability to treat complex anatomy in a single session without need for lytic therapy. Limitations of the technology traditionally include removal of more chronic or organized thrombus.

Managing thrombotic lesions remain one of the most challenging and stressful aspects of vascular practice. Whether it is a swollen, painful leg; an immediately threatened limb in the middle of the night; a thrombosed dialysis access site; or a distally embolized post-proximal thrombotic lesion: vascular specialists continue to seek safer and reliable solutions to high-risk thrombotic cases. There are now numerous commercially available thrombectomy systems for these difficult cases, including mechanical extraction, mechanical aspiration, rheolytics, maceration, and lytic-enhanced systems; however, each has limitations that keep us searching for better options.

Today, I am fortunate to be able to have a discussion with two very busy vascular surgeons, Drs. Nicole Ilonzo and Ajit Rao, about their current approaches to thrombus removal.

Dr. Laird: Can a single thrombectomy device effectively address arterial, venous, and arteriovenous fistula (AVF) use cases, or do you prefer different tools depending on the scenario?

Dr. Ilonzo: I prefer different tools for different scenarios. I have been fortunate to have exposure to a large gamut of thrombectomy devices, so I know what works quickly and efficiently depending on the patient and depending on the pathology.

Dr. Rao: In general, no single device or approach can treat all anatomy and clinical scenarios. However, I believe mechanical aspiration thrombectomy is the most versatile approach and is my go-to device. I can utilize this technology for the vast majority of all thrombectomy cases.

Dr. Laird: Medtronic recently launched the Liberant™ thrombectomy system. What key differences have you noted with Liberant compared to other mechanical aspiration thrombectomy systems?

Dr. Ilonzo: The Liberant thrombectomy system met my expectations of safety and performance—it tracks well and efficiently removes thrombus. The compatibility of the Excipio™* thrombectomy device (Contego Medical) is an added benefit of the Liberant system. It adds a mechanical component to an aspiration case, which raises the possibilities for procedural effectiveness and efficiency when it comes to treating patients with thrombotic disease.

Dr. Rao: My experience with the Liberant thrombectomy system has been very positive. The device offers a unique selection of catheter choices to treat nearly any anatomy encountered. I have found notable attributes of the Liberant device, including its trackability due to the dilator that comes with the kit, ability to easily torque the device, and the option to use the Excipio device to disrupt adherent and mural thrombus.

Dr. Laird: Can you describe how the Liberant catheter performs in terms of torque response and deliverability and how that influences your ability to reach and navigate target vessels?

Dr. Ilonzo: I have used the various sizes—6 Fr, 8 Fr, and 12 Fr—and have not had issues with kinking. The ease of navigation through challenging vasculature allows for atraumatic access with good angular maintenance while advancing through target vessels.

Dr. Rao: Noteworthy strengths of the Liberant catheters include the deliverability of the device with the dilator and torque response. I can navigate and track the catheter through tortuous anatomy and bifurcations with ease.

Dr. Laird: What factors influence your decision to use the Excipio thrombectomy device, and what is your preferred technique for the combined use of Liberant and Excipio?

Dr. Ilonzo: Excipio is very useful to me, especially if I am doing a mechanical aspiration case where there is extensive thrombus. Having the opportunity at my practice for first-hand experience with new devices has shaped my preferences, especially with hands-on training.

Dr. Rao: I believe Excipio is a useful adjunct to the Liberant catheter, which I selectively use in thrombectomy cases. Specifically, I use Excipio in conjunction with the Liberant catheter to help disrupt thrombus and remove adherent mural thrombus that does not clear with aspiration alone. The combination of the expandable Excipio basket and Liberant aspiration improves procedural efficiency, allowing me to devote more time to patient counseling, care coordination, and follow-up planning.

Dr. Laird: The blood conservation unit (BCU) leverages ultrasonic controlled thrombectomy. Have you experienced less blood loss with Liberant compared to alternative aspiration thrombectomy systems? Do you have a preference or treatment algorithm for standard versus boost mode, and how does it vary by vessel bed?

Dr. Ilonzo: It is important to be mindful of estimated blood loss throughout the case to avoid losing more blood than necessary. The Liberant system has comparable blood loss relative to existing aspiration systems. I rarely use boost mode because I can quickly complete the thrombectomy with standard mode alone in most cases.

Dr. Rao: The BCU has been effective at reducing blood loss by automatically adapting the aspiration power. My algorithm is to start on standard mode and selectively use boost mode in segments with a large degree of thrombus burden. I find that I am more often utilizing boost mode in larger vessels such as the iliac artery and iliac vein when there is occlusive thrombus.

Dr. Laird: Do you have any closing remarks to add for the readers?

Dr. Ilonzo: Thrombectomy is rarely an elective case, and every thrombectomy catheter has nuances that are unable to be learned by just one initial use. Therefore, getting familiar with a thrombectomy system in an emergency setting is never ideal. I found that AV access thrombectomy has been a good way to see the benefits of the Liberant system in a lower-intensity setting. I have seen how the 8-Fr catheter platform works in removing thrombus with just a couple of passes. I have used the Liberant and Excipio devices to help



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remove wall-adherent thrombus in AV grafts that have been thrombosed for longer than usual. Indeed, there is some maneuvering the Excipio length mismatch to the short 8-Fr sheath for AV access thrombectomy, but the torqueability of the Liberant catheter makes this achievable in challenging anatomy. Overall, in my thinking, where the thrombectomy experience gets a bit more novel and interesting is how one can incorporate nitinol extraction with aspiration.

Dr. Rao: The Liberant device is a great addition to the thrombectomy space and has several noteworthy strengths, including trackability, ease of torque, and the use of combination therapy with Excipio. These new tools have allowed me to treat challenging anatomy and cases with a large degree of thrombus burden in a single session.

Global Distribution Statement

This material should not be considered the exclusive source of information, it does not replace or supersede information contained in the device manual(s). Please note that the intended use of a product may vary depending on geographical approvals. See the device manual(s) for detailed information regarding the intended use, the procedure, indications, contraindications, warnings, precautions, and potential adverse events. Medtronic products placed on markets comply with legislation (if applicable) on medical devices.

If you are located in the United States, please refer to the brief statement(s) below to review applicable indications, safety and warning information. If you are located outside the United States, see the device manual for detailed information. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.com.

Liberant™ thrombectomy system

Reference Statement

Indications for Use:

The Liberant thrombectomy system is indicated for the removal of fresh, soft emboli or thrombi from the vessels of the peripheral arterial and venous systems.

Contraindications

Do not use the Liberant thrombectomy system in the coronary vasculature or neurovasculature. Do not use in patients for whom anticoagulant or antiplatelet therapy is contraindicated.

Potential Adverse Effects of the Device on Health

The potential complications include, but are not limited to the following: allergic reaction to device materials; anemia; death; embolization; hemorrhage; hypotension; infection; inability ischemia or infarction; pain; thrombosis; total occlusion of treated vessel; venous or valvular damage; including arteriovenous fistula, dissection, perforation, pseudoaneurysm, or vascular aneurysm; adverse events associated with endovascular procedures, including acute renal impairment, allergic reaction to contrast medium, cerebrovascular accident, hemorrhage or hematoma at access site, hypertension.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Important information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device, or contact a Medtronic representative.

Integrated Risk Statement

Risks include, but are not limited to, embolization, hemorrhage, thrombosis, and vessel damage.

Excipio™ LV Thrombectomy Device

Reference Statement

Indications for Use

The Excipio™ LV thrombectomy device is indicated for the nonsurgical removal of emboli and thrombi from peripheral blood vessels.

Contraindications

- Not intended for use in the coronary arteries, pulmonary vasculature or neurovasculature.
- Do not use on patients with known hypersensitivity to nickel-titanium.

Potential Adverse Effects

The potential complications include, but are not limited to the following: access site complications, acute occlusion, allergic reaction, arrhythmia, anemia, death, hematoma or hemorrhage at access site, hemorrhage, hypotension, inability to completely remove thrombus, intimal disruption, ischemia, infection, renal impairment or acute renal failure from contrast media, thromboembolic events, tip separation and distal embolization; vessel spasm, thrombosis, dissection, or perforation.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Important information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device, or contact a Medtronic representative.

Excipio™ SV Thrombectomy Device

Reference Statement

Indications for Use

The Excipio™ SV thrombectomy device is indicated for the non-surgical removal of soft emboli and thrombi from peripheral blood vessels.

Contraindications

- Not intended for use in the coronaries or the neuro-vasculature.
- Do not use on patients with known hypersensitivity to nickel-titanium.

CLOSING REMARKS FROM DR. LAIRD

Thank you both for these valuable insights. It is exciting to hear that this combination of mechanical aspiration thrombectomy with a disruption device plays such an important role in your clinical practice and allows you to treat these tough cases more safely and quickly. My takeaways from this discussion are that the Liberant catheters are deliverable in difficult anatomy, kink resistant, and more easily torqueable. The combination of the Liberant and Excipio devices provide enhanced capability to disrupt and remove fresh as well as wall adherent thrombus. The combination of these two platforms addresses many of the limitations of other commercially available thrombectomy devices. ■

Potential Adverse Effects

The potential complications include, but are not limited to the following: access site complications, allergic reaction, arterial dissection, arterial thrombosis, death, distal embolization of blood clots and atherosclerotic plaque, hematoma, hemorrhage, ischemia, infection, perforation and/or vessel rupture, tip separation and distal embolization, vasospasm

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Important information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device, or contact a Medtronic representative.

HawkOne™ directional atherectomy system

Reference Statement

Indications for Use

The HawkOne™ directional atherectomy system is intended for use in atherectomy of the peripheral vasculature. The HawkOne™ catheter is indicated for use in conjunction with the SpiderFX™ embolic protection device in the treatment of severely calcified lesions. The HawkOne™ catheter is NOT intended for use in the coronary, carotid, iliac, or renal vasculature.

Contraindications

Do not use in the coronary arteries, carotid artery, or in the iliac, or renal vasculature.
Do not use for in-stent stenosis at the peripheral vascular site.

Potential Adverse Events

The potential complications include, but are not limited to the following: Amputation, aneurysm, arterial dissection, arterial perforation, arterial rupture, arterial spasm, arteriovenous fistula, bleeding complications, death, embolism or arterial thrombosis, emergency or non-emergency arterial bypass surgery, entry site complications, hypotension, infection, ischemia, restenosis of the treated segment, total occlusion of the peripheral artery, and vascular complications that could require surgical repair.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Important information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device, at www.medtronic.com/manuals or contact a Medtronic representative.

EverFlex™ self-expanding peripheral stent system

Brief Statement

Indications for Use

The EverFlex™ self-expanding peripheral stent system is intended to improve luminal diameter in the treatment of symptomatic de novo or restenotic lesions up to 180 mm in length in the native superficial femoral artery and/or proximal popliteal arteries with reference vessel diameters ranging from 4.5 mm–7.5 mm.

The EverFlex™ self-expanding peripheral stent system is indicated for improving luminal diameter in patients with atherosclerotic disease of the common and/or external iliac arteries up to and including 100 mm in length, with a reference vessel diameter of 4.5 mm–7.5 mm.

Contraindications

Use of the EverFlex™ self-expanding peripheral stent system is contraindicated in patients with known hypersensitivity to nickel titanium and in patients contraindicated for anticoagulant and/or antiplatelet therapy, patients who are judged to have a lesion that prevents complete inflation an angioplasty balloon or proper placement of the stent or stent delivery system.

Warnings

- If resistance is encountered at any time during the insertion procedure, do not force passage. Forced passage may damage the stent or the vessel. If resistance is felt, carefully withdraw the stent system without deploying the stent.
- If resistance is felt when initially pulling back on the distal grip, do not force deployment. Carefully withdraw the stent system without deploying the stent.
- If resistance is met during delivery system withdrawal, advance the outer sheath until the outer sheath marker contacts the catheter tip and withdraw the system as one unit.

Precautions

- Do not exceed 20 atm or 300 psi (2068 kPa) while flushing the delivery system.
- Always use an introducer sheath during the implant procedure to protect the vessel and the puncture site. Support from an introducer sheath is also necessary to minimize lengthening or shortening of the stent during stent deployment.
- If the lesion is not predilated, it may be difficult to properly position or remove the stent system.
- The stent system is not designed for recapturing or repositioning after establishing vessel apposition.
- Failure to hold the proximal grip in a fixed position may result in partial deployment, foreshortening, lengthening, or increased deployment force.
- The stent is not designed to be lengthened or shortened relative to its nominal length. Excessive stent lengthening or shortening may increase the risk of stent fracture.

- Use caution when crossing a deployed stent with any adjunct device.
- Do not expand the stent beyond its nominal diameter.

Potential Adverse Events

The potential complications include, but are not limited to the following: abrupt or sub-acute closure, allergic reaction to device materials or procedure medications, allergic reaction to nitinol, amputation, aneurysm, angina, arrhythmia, arterio-venous fistula, artery injury (e.g. dissection, perforation, or rupture), bleeding requiring transfusion, bruising, contract medium reaction/renal failure, death, device breakage, edema, embolism, failure to deploy stent, fever, gastrointestinal bleeding due to anticoagulation, hematoma, hypertension/hypotension, infection, inflammation, intraluminal thrombus, myocardial infarction, pain, partial stent deployment, pseudoaneurysm, renal failure, renal insufficiency, restenosis, sepsis, shock, stent collapse or fracture, stent migration, stent misplacement, stroke, surgical or endovascular intervention, thrombosis/occlusion of the stent, transient ischemic attack, venous thromboembolism, vessel spasm, worsening claudication or rest pain.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Important information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device, at www.medtronic.com/manuals or contact a Medtronic representative.

SpiderFX™ embolic protection device

Reference Statement

Indications for Use

Lower Extremity (LE) Interventions

The SpiderFX™ Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk™ Peripheral Plaque Excision System, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities. The vessel diameter at the filter basket placement site should be between 3.0 mm and 6.0 mm.

Carotid Interventions

The SpiderFX™ Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0 mm and 7.0 mm.

Saphenous Vein Graft (SVG) Interventions

The SpiderFX™ Embolic Protection Device is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/debris). The device also acts as the guidewire while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.0 mm to 6.0 mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral vasculature.

Contraindications

Do not use with patients in whom anticoagulant and antiplatelet therapy is contraindicated; Do not use in vessels with excessive tortuosity; Do not use in patients with uncorrected bleeding disorders; Do not use in the renal arteries.

Potential Adverse Events

The potential complications include, but are not limited to the following: Access site adverse event (e.g., av fistula, hematoma, hemorrhage, pseudoaneurysm, puncture site infection); Adjunct device entanglement (LE only); Adverse reaction to antiplatelet/anticoagulation agents or contrast media; Allergic reaction to device materials; Amaurosis fugax (carotid only); Amputation (LE only); Aneurysm (LE and SVG); Angina (carotid and SVG only); Arterial dissection; Cerebral hemorrhage (carotid only); Congestive heart failure (carotid only); Cardiac tamponade (SVG only); Coronary ischemia (SVG only); Death; Device(s) deformation, collapse, fracture, or rupture; Device(s) thrombosis (acute and subacute); Dissection (LE and carotid only); Embolization of air, debris, plaque or thrombus (evidenced by slow or no-flow) from mechanical disruption by the intervention resulting in TIA or stroke; Embolization or migration of the interventional device(s); Emergency surgery; Failure to deliver stent to the intended site (SVG only); GI bleeding due to anticoagulation (LE and carotid only); Hemodynamic compromise (e.g., prolonged hypotension requiring treatment with intravenous medications) (LE and carotid only); Hyperperfusion syndrome (carotid only); Hypotension or hypertension; Infection; Intimal flap (SVG only); Intracerebral bleed (carotid only); Ischemia (LE and SVG only); Myocardial infarction; Occlusion (SVG only); Renal insufficiency (LE and carotid only); Renal failure requiring dialysis; Repeat intervention to treatment site (LE only); Restenosis of stented segment (greater than 50% obstruction) (SVG only); Seizure (carotid only); Sepsis; Significant cardiac arrhythmia requiring treatment with medications and/or transvenous pacing; Stent entanglement; Stroke (LE and carotid only); Thrombosis (acute and subacute); Transient Ischemia Attack (TIA) (LE and carotid only); Vasospasm; Vessel dissection, perforation, rupture or intimal flap; Vessel/filter occlusion

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Important information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device, at www.medtronic.com/manuals or contact a Medtronic representative

IN.PACT™ 018 Paclitaxel-coated percutaneous transluminal angioplasty balloon catheter

Brief Statement

Indications for Use

The IN.PACT™ 018 paclitaxel-coated PTA balloon catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions with lengths up to 360 mm in superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.

Contraindications

- The IN.PACT™ 018 DCB is contraindicated for use in:
 - Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
 - Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
 - Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
 - Patients with known allergies or sensitivities to paclitaxel

- Women who are breastfeeding, pregnant, or are intending to become pregnant, or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure.

Warnings

Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution). Do not move the guidewire during inflation of the IN.PACT™ 018 DCB. Do not exceed the rated burst pressure (RBP). The RBP is 10 atm (1013 kPa) and is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection. The safety and effectiveness of using multiple IN.PACT™ 018 DCBs with a total drug dosage exceeding 34,854 µg of paclitaxel in a patient has not been clinically evaluated.

Precautions

- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents.
- Administer appropriate drug therapy to the patient according to standard protocols for PTA before insertion of the dilatation catheter.

- Take precautions to prevent or reduce clotting when any catheter is used. Flush and rinse all products entering the vascular system with heparinized normal saline or a similar solution. For the IN.PACT™ 018 DCB catheter, flush the guidewire lumen through the guidewire port with heparinized normal saline until the fluid exits the distal tip. Do not rinse or wipe the IN.PACT™ 018 DCB catheter.
- Identify allergic reactions to contrast media and antiplatelet therapy before treatment and consider alternatives for appropriate management prior to the procedure.
- This product is not intended for the expansion or delivery of a stent.
- This product is not intended for pre-dilation or post-dilation
- Do not expose the product to organic solvents such as alcohol.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximately match the diameter of the vessel just distal to the lesion.

Potential Adverse Events

The potential adverse events associated with use of the device include but are not limited to: Abrupt vessel closure, access site pain, allergic reaction to contrast medium, antiplatelet therapy, or catheter system components (materials, drugs, and excipients), amputation/loss of limb, arrhythmias, arterial aneurysm, arterial thrombosis, arteriovenous (AV) fistula, death, dissection, embolization, fever, hematoma, hemorrhage, hypotension/hypertension, inflammation, ischemia or infarction of tissue/organ, local infection at access site, local or distal embolic events, perforation or rupture of the artery, pseudoaneurysm, renal insufficiency or failure, restenosis of the dilated artery, sepsis or systemic infection, shock, stroke, systemic embolization, vessel spasms or recoil, and vessel trauma which requires surgical repair.

Potential adverse events not captured above that may be unique to the paclitaxel drug coating include, but are not limited to: allergic/immunologic reaction, alopecia, anemia, gastrointestinal symptoms, hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia), hepatic enzyme changes, histologic changes in vessel wall, including inflammation, cellular damage, or necrosis, myalgia/arthritis, myelosuppression, and peripheral neuropathy. Refer to the Physician's Desk Reference for more information on the potential adverse effects observed with paclitaxel.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Important information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device, at www.medtronic.com/manuals or contact a Medtronic representative.

Abre™ venous self-expanding stent system

Brief Statement

Indications for Use

The Abre™ venous self-expanding stent system is indicated for use in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction.

Contraindications

Do not use the Abre™ stent system with patients with known hypersensitivity to nickel titanium (nitinol), with patients who are judged to have a lesion that prevents complete inflation of a balloon dilatation catheter or proper placement of the stent or the stent delivery system, and with patients in whom anticoagulant or antiplatelet therapy is contraindicated.

Warnings

- If unusually high resistance is encountered when advancing the Abre delivery system over the guidewire, assess the cause of the resistance before proceeding.
- If high resistance is felt when initially rotating the thumbwheel, do not force deployment. Carefully withdraw the system and do not use it.
- Do not use in patients with a total venous occlusion that cannot be dilated to allow passage of the guidewire.
- Do not use the device with contralateral access.

Precautions

- Avoid placing the cranial end or caudal end of the stent within the common iliac vein at the transition curve to the external iliac vein and internal iliac confluence. Improper placement of the stent may result in tenting or kinking of the vessel. Extending the stent length beyond the transition curve is recommended to minimize risk of migration. Stent migration can potentially lead to vessel occlusion, thrombus formation, vessel damage, embolism, and/or the need for surgical intervention, including open surgical removal from the heart.
- Selection of the appropriate stent diameter and length is crucial. An undersized stent can result in stent migration and suboptimal luminal diameter. Stents with a diameter of ≤14 mm and/or lengths of ≤80 mm should be assessed for applicability as a stand-alone stent because of migration risk, particularly in non-thrombotic iliac vein lesions and in patients that have had a previous DVT, but otherwise have normal veins with an iliac vein compression.
- Ensure that there is appropriate stent apposition to the vessel wall to secure sustained fixation through changing vessel size and shape during the procedure and post-procedural patient movement. Options to ensure appropriate stent apposition include visualization with IVUS during the procedure, confirming that the stent is extended around a curve, that the stent diameter is constrained by the vessel below the stent's nominal diameter, or that the stent is anchored by a second stent.
- Always use an introducer sheath during the implant procedure to protect both the vessel and puncture site
- If the retractable sheath (silver) is exposed beyond the hemostatic valve when the stent is positioned for deployment, pull the introducer sheath back so that the hemostatic valve covers the end of the isolation sheath (blue) and is not in direct contact with the retractable sheath. Friction from direct contact between the retractable sheath and the hemostatic valve can cause difficult stent deployment or inaccurate stent placement.
- Do not reposition the Abre stent after establishing apposition against the vessel wall. Repositioning the stent may cause stent elongation, stent fracture, or vessel damage.
- The Abre stent is not designed to be lengthened or shortened from its nominal length. Excessive stent lengthening or shortening can increase the risk of stent fracture.
- If resistance is felt when withdrawing the system, do not force withdrawal. Forcing withdrawal can cause catheter separation and embolism.
- Use care when crossing a deployed Abre stent with any adjunct device to avoid stent dislodgement or damage to the adjunct device.

Potential Adverse Events

The potential complications include, but are not limited to the following: access failure, access site infection, allergic reaction to contrast medium or procedure medications; aneurysm; AV fistula; bleeding; bruising; death; device breakage; device maldeployment; edema; embolization; fever; hematoma; hypertension; hypotension, nausea, or other vasovagal response; infection; myocardial infarction, arrhythmia, or other cardiovascular insufficiency; open surgical repair; pain; pseudoaneurysm; renal insufficiency or renal failure (new or worsening); respiratory distress or pulmonary embolism; sepsis; stent fracture; stent malapposition; stent malposition; stent migration; stroke, paradoxical embolism, transient ischemic attack, or intracerebral hemorrhage; tissue necrosis; venous occlusion, restenosis, or thrombosis, within or outside of stented segment; and vessel damage, including intimal injury, dissection, perforation, or rupture.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Important information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device, at www.medtronic.com/manuals or contact a Medtronic representative.

Treating the clot and the cause: A portfolio approach to peripheral thrombectomy

Liberant™
thrombectomy system

Excipio™*
thrombectomy
devices

Abre™
venous self-expanding
stent system

