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PE, SIMPLIFIED

The future of PE treatment with ultimate precision, maximum efficiency, and optimal outcomes.

AVENTUS®
THROMBECTOMY & BLOOD REINFUSION SYSTEM


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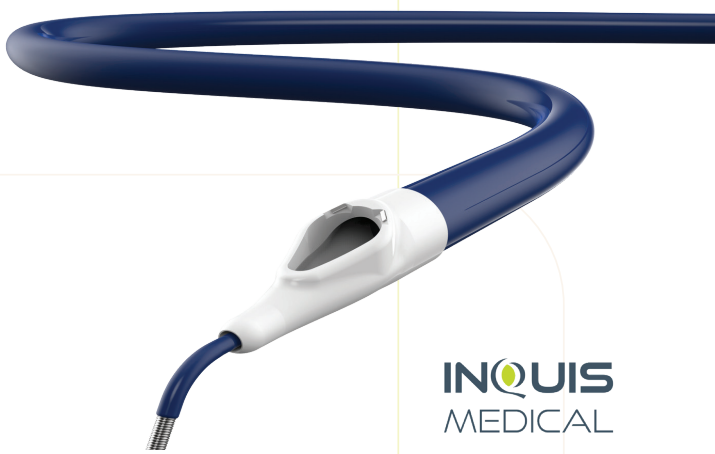

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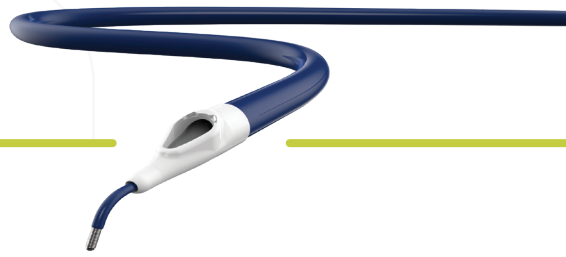


INDICATIONS FOR USE
The Aventus Thrombectomy System is indicated for:
- The non-surgical removal of emboli and thrombi from blood vessels.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The Aventus Thrombectomy System is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism.

The Aventus Clot Management System is indicated for use with the Aventus Thrombectomy System for autologous blood transfusion.

Transforming the Future of PE Care: Expanding Mechanical Thrombectomy Through Innovation

Advancing PE intervention with the AVENTUS Thrombectomy System, a streamlined solution designed for procedural efficiency, seamless workflow, and safe, reliable outcomes.

By Mehdi Shishehbor, DO, MPH, PhD

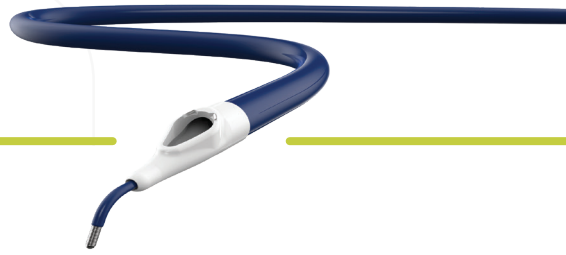
Acute pulmonary embolism (PE) is responsible for an estimated 100,000 to 180,000 deaths annually in the United States, making it the third leading cause of cardiovascular mortality and the leading preventable cause of in-hospital death.[1-3] In addition to mortality, PE is associated with significant morbidity, including the need for chronic anticoagulation (AC) therapy, oxygen therapy, rehabilitation, and development of chronic thromboembolic pulmonary hypertension. PE is also costly, requiring multiple days in the intensive care unit or hospital step-down unit for hemodynamic and respiratory stabilization. Further, these patients require multiple tests to diagnose and follow their progress, including extensive investigation to better identify the underlying cause of PE.[4]

Because of the significant morbidity and mortality associated with PE, there has been interest in improving its treatment, including improving patient quality of life and reducing overall health care costs associated with treatment. This has led to significant improvement in treatment options over the last 10 years with catheter-based interventions and the establishment of PE response team (PERT) programs.[5] The ultimate goal has been to identify intermediate-high–risk patients early, treat proactively with catheter-directed devices, and discharge in a timely fashion, collectively reducing mortality, morbidity, length of stay, and cost.

Early research showed that catheter-directed thrombolysis (CDT) can reduce right ventricular (RV) dysfunction in intermediate- and high-risk PE.[6] However, CDT does not provide an immediate therapeutic result, and contraindications to thrombolytic therapy can limit its applicability.[7] This led to the introduction of mechanical thrombectomy (MT). Recent evidence has supported the use of MT as an adjunctive therapy to AC in acute intermediate-risk PE to safely reduce clot burden and RV/LV (right ventricular/left ventricular) ratio.[8-10] A recently published randomized controlled trial showed lower hemodynamic deterioration in patients undergoing MT versus CDT but no difference in mortality or major bleeding.[11]

Although catheter-based interventions have helped treatment progress, they are not without drawbacks that have limited broad utilization. In fact, only 5% to 15% of PE patients are treated with catheter-based intervention, with a median of about 6% across all hospitals studied.[12] Studies focusing on high- and intermediate-risk PE patients show slightly higher percentages of catheter-based intervention utilization, ranging from 11.4% to 20.6%.[12] This heterogeneity of care has been shown to be highly influenced by people living in underserved or underprivileged areas of the United States, where access to catheter-based interventions or physicians experienced in these latest forms of treatment are not available.[13] Furthermore, complication rates from PE range widely across treatment centers. Although differences in patient severity seen at institutions are a contributing factor, it should be our goal to improve standardization of care and reduce heterogeneity of patient outcomes.

A number of opportunities exist with the expanding role of PERT programs and growing data supporting the use of MT to treat intermediate-high–risk PE. The next generation of PE devices must be safe, provide reproducible outcomes, and reduce procedure time without increasing overall treatment costs. Furthermore, they must empower physicians during the procedure and lower the learning



curve, which will ultimately expand this life-saving opportunity across the United States.

As we look to the future, devices that can complete the case with a single pass through the heart will have value. Removing guesswork around what is happening at the tip of the catheter in real time during clot extraction aspirations will reduce procedure time and make thrombectomy more precise. Reducing the need for operator-specific skill in catheter and wire manipulation will help broaden adoption while also reducing overall procedure time and complications. Finally, the focus should also be on improving patient outcomes and reducing procedural complications, such as bleeding risk and procedural blood loss. One simple, yet effective approach is the emergence of devices that enable clot extraction with less guidewire and catheter manipulation, and the ability to return patient blood that is lost during clot aspiration. Investigational Device Exemption (IDE) trials of new devices have already shown promise in limiting the need for postprocedure blood transfusions, which increases the complexity in providing patient care, increases hospitalization time, and increases treatment costs.

What do you see as the biggest value in broadening the adoption of MT?

Dr. Shishehbor: We want every patient with intermediate- and high-risk PE at any location in the world to have the option to be treated with MT. For these patients, MT provides faster hemodynamic and respiratory stabilization, reduces length of hospital stay and health care costs. If we can achieve that and reach zero device-related complications, the impact will be substantial. For example, in the AVENTUS IDE trial, there were zero device-related major adverse events in over 130 cases. For the right patient, MT can make treatment safer, more efficient, and more cost-effective.

How can new MT devices, such as the AVENTUS® Thrombectomy System, address challenges in PE treatment?

Dr. Shishehbor: The AVENTUS Thrombectomy System addresses key challenges in PE procedures by intelligent directional aspiration with streamlined blood reinfusion. The aspiration catheter requires less manipulation and allows treatment with a single aspiration catheter, minimizing multiple exchanges and the need for additional devices. Because of its directionality, it also can effectively aspirate clot without the need to navigate into side branches of the pulmonary arteries. In most cases, you can park the guidewire in the lower lobe and effectively aspirate clot without the need to continually manipulate the wire and catheter. Physicians are also empowered with the AVENTUS TrueClot™ Sensing technology to know what is happening at the tip of the catheter in real time, which eliminates guesswork during clot extraction aspirations. Finally, the AVENTUS System allows for simple and efficient blood return that can be done on the patient table without multiple support staff. These features improve the procedure and provide fast, efficient, and safe outcomes for patients. ■

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The AVENTUS® Thrombectomy System: Intelligent Design for Precise Pulmonary Embolism Intervention

A purpose-built mechanical thrombectomy platform combining directional aspiration, integrated navigation, TrueClot™ Sensing, and streamlined blood reinfusion for efficiency, control, and safety in PE treatment.

By David O'Connor, MD, FACS

The AVENTUS® Thrombectomy System is a mechanical thrombectomy platform engineered specifically for the unique anatomic and procedural challenges of pulmonary embolism (PE) intervention. The system consists of a 24-F directional aspiration catheter, an aspiration syringe, and an in-line blood reinfusion system (Figure 1). Together, these components are designed to simplify workflow, maximize aspiration efficiency, streamline blood return, and enhance overall procedural control.

All elements of the system are positioned on the patient bedside directly in front of the operator, improving efficiency and reducing the need for multiple support staff. The aspiration catheter incorporates directional aspiration for targeted clot engagement and includes both a built-in dilator tip and a 5-F navigation catheter to improve deliverability while eliminating device exchanges. The in-line filtration system streamlines reinfusion and minimizes blood loss by removing the need for syringe detachment and back table filtration activities.

In addition, the system features TrueClot™ Sensing, a proprietary technology that allows real-time identification of blood, clot, and vessel wall at the catheter tip. This capability helps operators distinguish wall contact from organized clot engagement, eliminating guesswork, improving efficiency, and saving time.

Figure 1. AVENTUS Thrombectomy System.

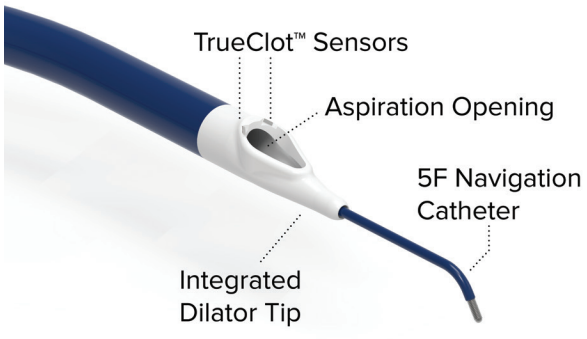
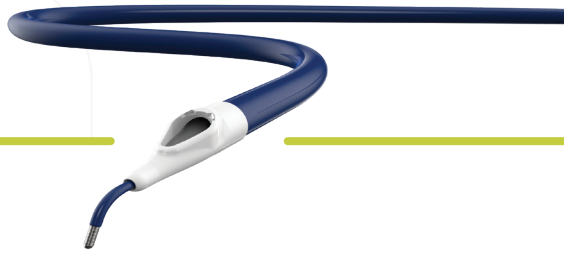


Figure 2. Catheter tip with integrated dilator and 5-F navigation catheter.

INTELLIGENT CATHETER TIP DESIGN—NAVIGATE, TARGET, ASPIRATE

The 24-F AVENTUS Aspiration Catheter incorporates several design elements aimed at maximizing clot extraction while simplifying procedural workflow. A key feature is its built-in atraumatic dilator tip (Figure 2), which eliminates the need for dilator exchanges and improves navigation efficiency compared with conventional systems. Once pulmonary access is achieved,



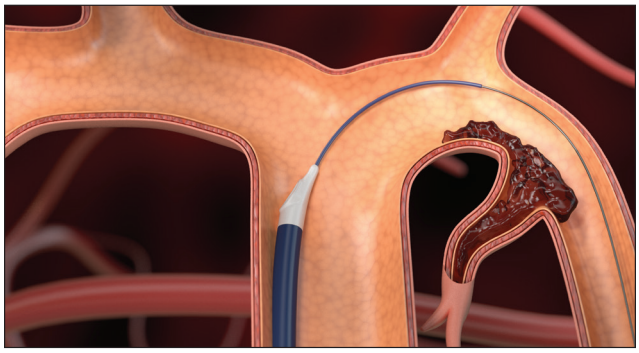


Figure 3. Integrated navigation catheter enabling simple wiring of left PA without device exchanges or need for accessory and curved catheters.

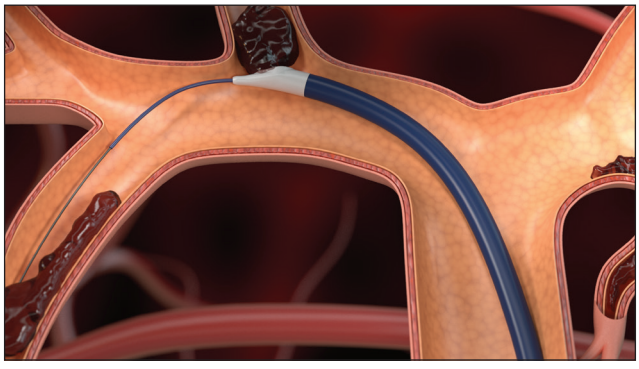


Figure 4. Directional aspiration of the truncus anterior without changing guidewire position.

the catheter is advanced over a 0.035-inch guidewire to the target vessel.

Deliverability is further enhanced by an integrated 5-F navigation catheter (Figure 2). Together, the catheter tracks smoothly over a guidewire, with the navigation catheter providing additional support while enabling efficient branch selection within the pulmonary arterial tree. This is particularly advantageous when transitioning between the right and left pulmonary arteries (PAs). After completing clot removal in the right PA, the catheters can be withdrawn into the main PA, where the navigation catheter is redirected into the left PA (Figure 3). This guided transition significantly improves access to the left PA and obviates the need for accessory or curved catheters.

The catheter's directional aspiration technology also contributes to procedural efficiency. Its angled aspiration opening leverages fluid dynamics to generate a vortex effect, improving clot extraction relative to devices with end-hole designs. Operators can orient aspiration toward the clot without wiring each individual branch. Directional

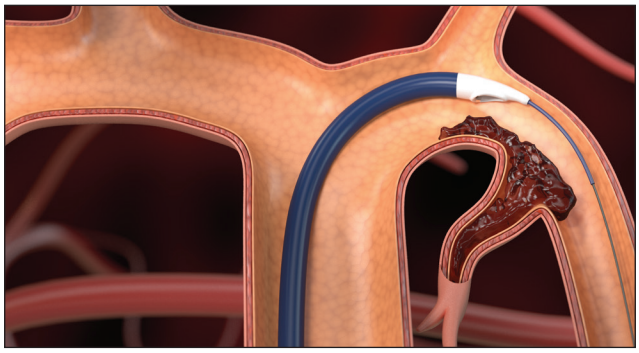


Figure 5. Directional aspiration of the left PA.

aspiration also allows operators to remove clot from segmental branches while in the main branch without changing wire position or accessing individual branches. For instance, when treating clot in the truncus anterior, the catheter can be positioned at the bifurcation while the guidewire remains parked distally. The radiopaque tip allows clear visualization under fluoroscopy, enabling the operator to rotate the opening toward the branch and extract clot without cannulation (Figure 4). Directional aspiration is particularly advantageous in the left PA, where acute angulation and posterior orientation can increase the risk of wall interaction with end-hole catheters (Figure 5).

The atraumatic dilator tip, integrated navigation catheter, and directional aspiration technology offer an intentionally engineered solution that enhances deliverability, reduces procedural steps, and supports comprehensive clot extraction across complex pulmonary anatomy.

TRUECLOT™ SENSING—KNOW WHAT'S AT THE TIP

TrueClot™ Sensing is one of the most innovative features of the AVENTUS Thrombectomy System.

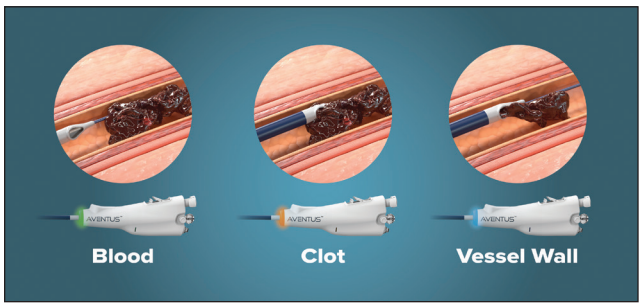


Figure 6. TrueClot™ Sensing: Green (blood), orange (clot), blue (vessel wall latch).

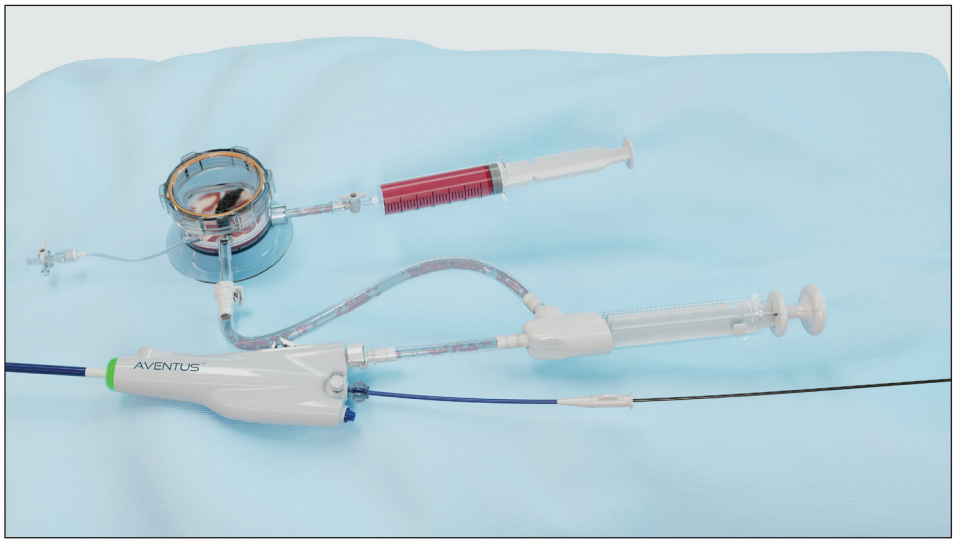


Figure 7. AVENTUS Clot Filtration and Reinfusion System.

The technology can differentiate between blood, clot, and vessel wall at the catheter tip in real time. This enables operators to distinguish wall latches from clot engagement without withdrawing the catheter to troubleshoot, saving time and reducing unnecessary passes through the right heart.

The system has integrated electrodes at the aspiration opening that continuously analyzes the material properties of anything it contacts. A proprietary algorithm is then used to interpret the data and inform the operator in real time throughout the procedure.

Real-time feedback is provided via an intuitive color-coded LED indicator on the handle, with green representing blood, orange indicating clot, and blue indicating vessel wall (Figure 6).

STREAMLINED BLOOD RETURN—REINFUSE, DON'T WASTE

The in-line blood reinfusion system is designed to minimize blood loss and simplify clot management. The aspiration syringe remains connected to the catheter throughout the procedure, reducing procedural steps and eliminating the need for syringe detachment. After each aspiration, the syringe is pushed forward, sending clot and blood into the clot canister using dual one-way valves. Within the canister, dual filters separate clot from blood, allowing immediate visualization of extracted material and confirmation of aspiration effectiveness (Figure 7).

A 60-mL return syringe attached to the canister's outflow port automatically fills with filtered blood when the aspiration syringe is pushed forward, enabling clean and simple reinfusion at the patient table.

Unlike systems that require multiple handoffs to the back table or external collection bags, the AVENTUS method provides an FDA-cleared solution for safe and efficient blood return. In the AVENTUS Pivotal Trial, there were no reinfusion-related adverse events and no allogeneic blood transfusions required.[1]

This streamlined approach represents an important advancement in blood management during PE thrombectomy, supporting safety, efficiency, and usability. ■

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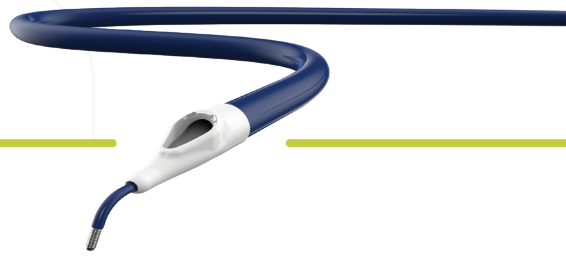

Real-World Insights From Early Adoption of the AVENTUS® Thrombectomy System

Integrated directional aspiration, navigation, and TrueClot™ Sensing technologies and streamlined blood return deliver practical benefits in pulmonary embolism cases.

By Brian Stegman, MD, FACC, FSCAI

As Director of the Pulmonary Embolism Program at CentraCare Heart and Vascular Center, I have had the pleasure of working with multiple specialties to develop a comprehensive, nationally recognized program for the treatment of acute pulmonary embolism (PE). The multidisciplinary team works closely to deliver seamless, 24/7 cardiopulmonary care from emergency intervention through recovery and follow-up of patients with PE. Our innovative, patient-centric care model helps ensure that Central Minnesotans have access to the most advanced cardiovascular treatment options close to home.

To provide patients with the most cutting-edge care, it is important for the team to have access to the latest innovations in PE treatment to provide high-quality care to all patients promptly and efficiently. As a top enroller in the AVENTUS Trial, we have developed expertise with the new AVENTUS® Thrombectomy System. This article outlines the device's features that have made an immediate impact in our PE cases through improvements in procedural efficiency and outcomes.

FAST AND EFFICIENT CLOT BURDEN REDUCTION WITH LARGE-BORE DIRECTIONAL ASPIRATION

Procedural efficiency is very important in our PE cases to optimize patient outcomes, physician time, and hospital resources. These patients are often very sick, so achieving timely hemodynamic and respiratory stability is important. Further, in a busy catheterization laboratory, the ability to complete a mechanical thrombectomy (MT) PE procedure from access to closure in under an hour can be valuable in critically ill patients. The AVENTUS Thrombectomy System enables this in several ways.

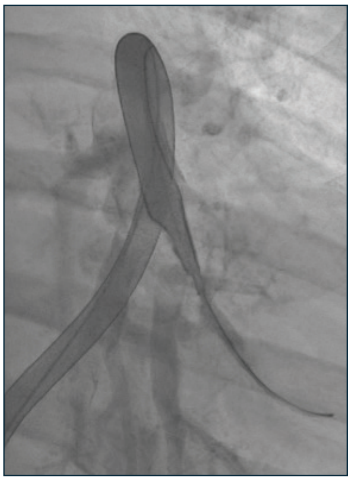

Figure 1. AVENTUS Catheter opening positioned posterior, directly at clot in the left basilar branches of the PA.

First, the directional aspiration catheter allows you to efficiently extract clot by predictably facing toward the clot and away from the vessel wall. This results in a higher rate of successful aspirations and avoiding suction on the vessel wall (wall latch), which solves one of the issues with end-hole aspiration catheters that can mimic a clot "lollipop" scenario. Taking this one step further, TrueClot™ Sensing technology allows you to immediately identify whether the catheter is approximated to vessel wall or clot, allowing for improved procedural efficiency and less uncertainty when suction is maintained after aspiration. This is especially important in the left pulmonary artery (PA) which, due to is abrupt posterior/inferior course, can lead to frequent wall-latch events with end-hole aspiration catheters. The beveled aspiration opening provides the ability to ensure the aspiration opening is appropriately positioned (Figure 1) and eliminates the need for curved or accessory catheters. This innovation addresses one of the historical issues of procedural efficiency with MT and adds predictability during clot aspiration.

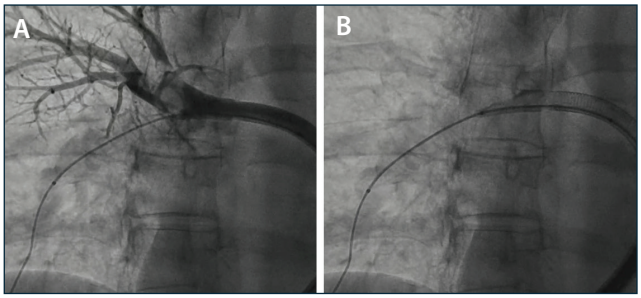

Figure 2. Residual clot in the truncus anterior. Fluoroscopic image showing the AVENTUS Catheter position without exchanging devices (A). AVENTUS Catheter aligned with the ostium of the truncus anterior while maintaining original wire position for a "drive by" aspiration (B).

Second, directional aspiration allows for targeted branch aspiration without the need to individually wire side branches. This is achieved by facing the aspiration opening toward the branch and directing suction to mobilize and remove the clot. A great example of this is residual clot in the truncus anterior (Figure 2A), which can frequently be aspirated by maintaining original wire access and appropriate catheter position without the requirement of wiring and engaging the branch. The catheter is highly torqueable and visible under fluoroscopy, making alignment with side branches simple and enabling "drive-by aspiration" as you are working either proximally or distally (Figure 2B).

Finally, the 24-F beveled catheter provides efficient aspiration in cases with high clot burden with very low rates of catheter clogs or lollipops. The beveled design of the aspiration opening not only provides directionality, but it also increases the surface area of the opening versus an end-hole design. This allows clot to easily enter the catheter, reducing the likelihood of lollipop scenarios.

REDUCING PROCEDURE TIME THROUGH EFFICIENCIES IN TRACKING AND NAVIGATION

One pain point with other aspiration systems is that they require the exchange of a dilator to safely advance the aspiration catheter through the PAs. To minimize device exchanges, many operators will choose a distal location to begin aspiration and work proximally to avoid the need to readvance the catheter. However, with end-hole catheters, if there is residual distal clot burden, you need to exchange for the dilator and readvance. With AVENTUS, the operator can start at the level of greatest clot burden and work proximally or distally as residual clot burden and anatomy dictates without additional procedural steps.

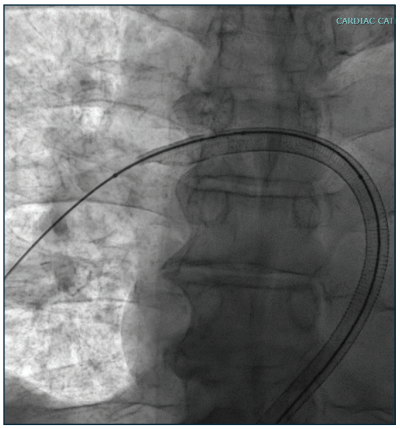

Figure 3. Guidewire positioned in the distal branches of the right lower lobe. The physician is free to work back and forth without exchanging for a dilator or moving guidewire position.

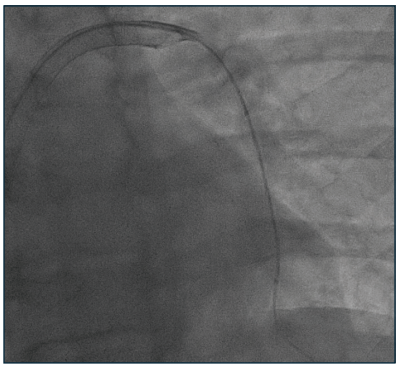

Figure 4. AVENTUS Catheter positioned in left PA with aspiration opening pointed away from wall and to the center of the lumen. Access in left is gained without guidewire and dilator exchanges.

Further, because the AVENTUS System offers directional aspiration, in the vast majority of cases, you can place your guidewire into a lower lobe of the left or right PA and leave it in one position for all aspirations on that side (Figure 3). This helps reduce procedural time and complexity by limiting guidewire manipulation and the need to advance into side branches to aspirate clot.

If you must change guidewire position, it's done very easily by pulling back the integrated navigation catheter while leaving roughly 3 cm of your soft guidewire extended distally. The shape of the navigation catheter allows you to easily select new vessels quickly and readvance the catheter if needed. The ease in this technique is highlighted when switching from the right PA to the left PA. With this method, the soft guidewire will naturally flop into the left PA when pulling the AVENTUS Aspiration Catheter back into the trunk of the main PA, enabling catheter advancement in the left PA without any additional wire or dilator exchanges (Figure 4). These features save a considerable amount of time by reducing procedural steps, enabling treatment with one catheter, and reducing time spent manipulating guidewires and catheters.

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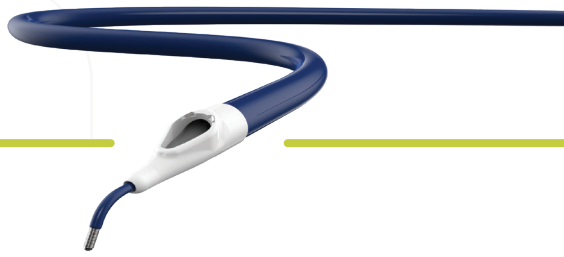

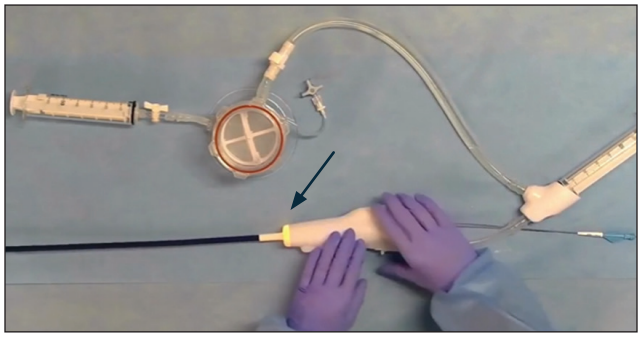

Figure 5. TrueClot™ Sensing is indicating contact with clot by showing an orange light (arrow). Green indicates contact with only blood, and blue indicates a vessel wall latch.

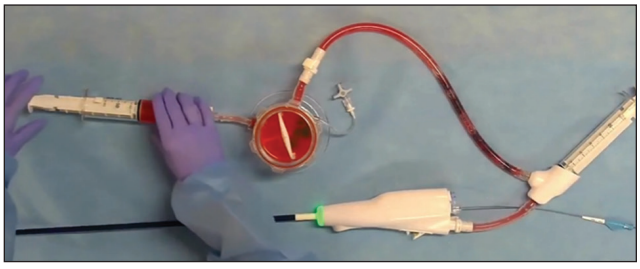

Figure 6. Blood filtration and reinfusion done at the patient bed. The contained and clean system simplifies blood reinfusion.

UTILIZING TRUECLOT™ SENSING TO ELIMINATE GUESSWORK

In our cath lab, we are always trying to limit unnecessary aspiration and contrast injections. TrueClot™ Sensing provides the ability to have confidence that the aspiration you performed mobilized clot and progress through your procedure with fewer unnecessary aspirations and procedural steps. Furthermore, while large-bore aspiration does not require direct contact with the clot to provide successful aspiration, TrueClot™ Sensing allows for awareness of clot position near the aspiration opening for prompt extraction (Figure 5).

Where TrueClot™ Sensing has shown particular clinical benefit is helping identify what is at the catheter tip during suspected wall latches versus clot lollipop scenarios. With other MT systems, when the catheter is obstructed and aspiration vacuum is maintained, it is difficult to confidently know whether you have a wall latch or a clot lollipop. This leads to additional mitigation steps that lead to procedural inefficiency. With TrueClot™ Sensing, we instantly know if the catheter is obstructed by the vessel wall or clot to act accordingly. This information is extremely valuable to complete the case as quickly and efficiently as possible.

STREAMLINED CLOT FILTRATION AND BLOOD REINFUSION

Blood loss in MT procedures is not always insignificant, which can lead to drops in hemoglobin levels, require consideration for transfusions, extend hospital length of stay, or lead to attenuation of improvement in symptoms that aspiration thrombectomy provides. In some cases, blood loss can result in suboptimal outcomes, increases in health care costs, and increased length of stay, all of which can compromise patient outcomes and increase cost of hospitalization. The integrated AVENTUS Blood Reinfusion System allows for simple, safe, and efficient blood return and is one of only two large-bore aspiration systems with FDA approval for blood reinfusion.

The AVENTUS Blood Reinfusion System is a big step forward in simplifying blood return. The aspiration syringe remains connected throughout the procedure, eliminating the need to disconnect and have an assistant independently filter blood for reinfusion. This eliminates the back-and-forth handling of blood, which is required by some blood return systems. This is accomplished by dual one-way valves in the aspiration syringe that extracts blood and clot when pulled back and sends aspirated material to the clot canister when the syringe plunger is advanced forward. Clot is filtered with dual filters, ensuring only filtered blood is collected (Figure 6).

Overall, both my staff and I appreciate how blood return is streamlined with the AVENTUS System. It allows us to feel we are doing everything in our power to optimize the outcome of each individual patient and ensure they leave the hospital in a condition that is as close as possible to how they felt prior to their PE. Sometimes, especially in our sickest patients, every drop truly matters. ■

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Proven Performance and Clinical Data That Move the Field Forward: Key Insights From the AVENTUS Trial

A Q&A with the National Principal Investigators regarding the design of the AVENTUS Trial, key outcomes and results, and unique features of the AVENTUS® Thrombectomy System.

With Jun Li, MD, FACC, FSCAI, RPVI, and Saher Sabri, MD

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Tell us more about the design of the AVENTUS Trial.

Dr. Li: The AVENTUS Trial was a pivotal Investigational Device Exemption (IDE) trial of 130 patients with acute intermediate-risk pulmonary embolism (PE) treated with the AVENTUS® Thrombectomy System. The intent-to-treat cohort included 120 patients, and 10 were treated as roll-in patients. Those procedures were performed by 49 unique operators at 22 United States sites. The trial's primary endpoints included a safety endpoint of device-related major adverse events (MAEs) within 48 hours and an efficacy endpoint of change in right ventricular/left ventricular (RV/LV) ratio at 48 hours.

What stood out to you regarding the enrollment of the AVENTUS Trial?

Dr. Li: To me, it is that we had a low number of roll-in patients and high number of unique operators, which demonstrated a low learning curve for the AVENTUS System. For these physicians, it was the first time they used the device, and the procedures went smoothly across the board. My experience is that this is due to the unique features of the AVENTUS Thrombectomy System that simplify PE treatment.

Dr. Sabri: The baseline features of the patients stood out to me, as they indicated more of a high-intermediate–risk PE population. Most patients had increases in cardiac biomarkers and a high Bova score, which together indicated high-intermediate–risk PE. The trial also had strong diversity of operator specialty, geographic location, and hospital size. Taken together, these points demonstrate that the AVENTUS System has broad real-world applicability and can be adopted across diverse users and hospital settings.

What do the 10 roll-in patients say about the device?

Dr. Sabri: It speaks to the ease of use of the device. Trial protocol allowed for up to 50 roll-in patients so the operator could gain experience with the device, but only 10 were utilized. I started with a roll-in patient, and in retrospect that patient could have been part of the IDE trial. We really didn't need extra hands-on experience to be successful. This was experienced across the board, by interventional cardiologists, interventional radiologists, and vascular surgeons. So, regardless of the realm of practice you're in, all of us found it to be very intuitive.

PE, SIMPLIFIED

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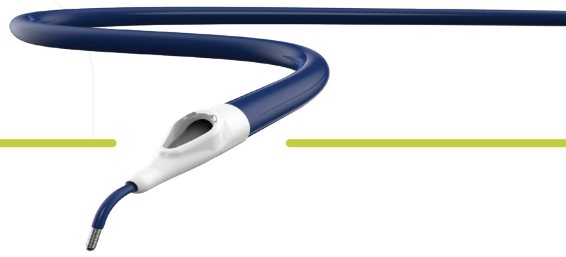


Figure 1. Results from the prospective AVENTUS Trial published in the *Journal of the Society for Cardiovascular Angiography & Interventions* (*JSCAI*) (April 2025).

What were the primary efficacy and safety results of the trial?

Dr. Li: Excitingly, the primary efficacy endpoint was met, with a mean reduction in RV/LV ratio of 0.47 from baseline to 48 hours postprocedure (Figure 1). The primary safety endpoint was met with zero device-related MAEs reported within 48 hours, far better than the performance goal of 25%. We were also able to achieve rapid clot removal, simple blood reinfusion, minimal blood loss, and short recovery times.

What stood out to you in the secondary endpoints that were studied?

Dr. Sabri: The first data point is the clot burden reduction with a modified Miller Score decrease of 35.9%, which is one of the highest recorded in IDE trials (Figure 1). That is exciting, as it demonstrates the efficiency of clot removal with this device. The other interesting data point was the low reported intensive care unit (ICU) length of stay of 0.8 days and short total hospital length of stay of 2.7 days (Figure 2). Finally, and possibly the most compelling was the improvement in patients' functional outcomes at 30 days postprocedure compared to 48 hours postprocedure. This is the first IDE trial to show improvements in patient quality of life and a 6-minute walk test (Figure 3). These are significant findings, and it's refreshing to see an IDE trial go beyond typical efficacy and safety measures.

What is the relevance of the data reporting short length of hospital stay after using AVENTUS?

Dr. Li: We are all struggling with access and bed availability in our health care systems. If there are technologies that can shorten the length of hospital stay, that will allow us to treat more patients and prioritize

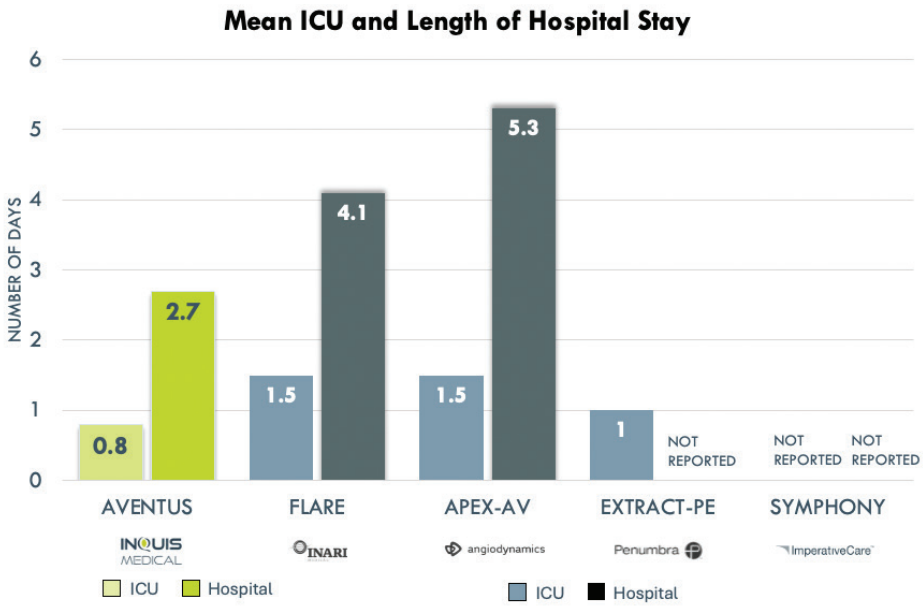
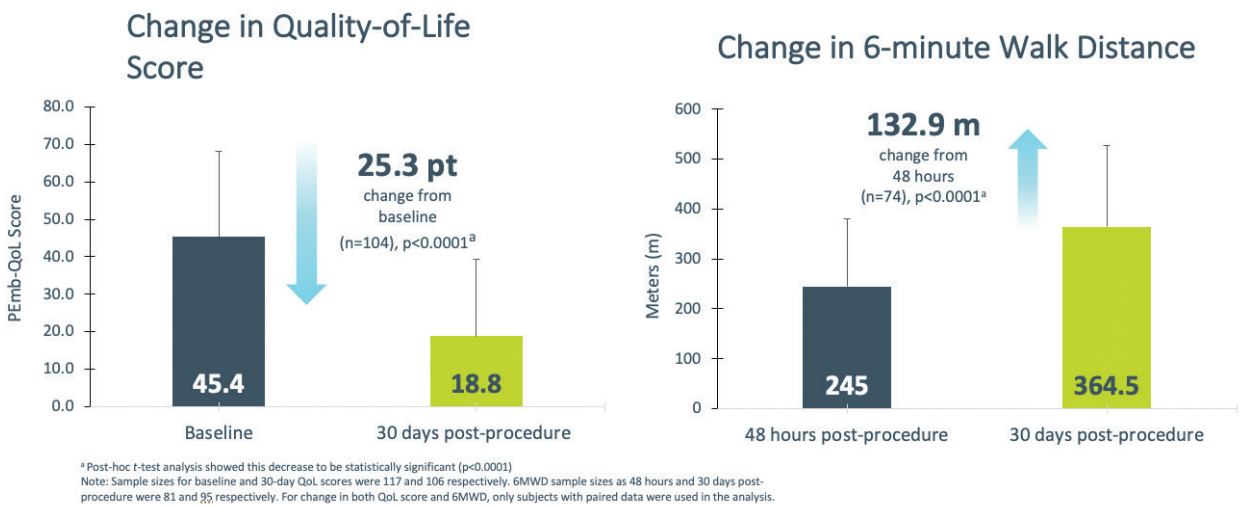


Figure 2. All IDE Trial reported ICU and total length of hospital stay.

those waiting in the emergency departments. Most emergency departments in the United States are backed up, which has been documented recently in the press and attributed to a lack of available beds. So, it's great that the AVENTUS Trial demonstrated a short ICU stay for patients treated with the AVENTUS System.

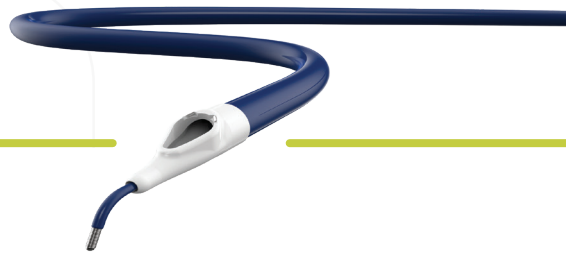
What was your experience like with the AVENTUS Thrombectomy System, and what makes it unique?

Dr. Li: The AVENTUS Thrombectomy System improves upon current mechanical thrombectomy systems, which have deficiencies in navigation between the right and left pulmonary arteries (PAs), prolonged procedure times, and blood loss. The AVENTUS System has an integrated navigation catheter that allows you to access the right and left PAs very quickly. The aspiration catheter is designed with an integrated dilator and atraumatic tip, which allows you to navigate without separate dilator exchanges, saving time and making catheter placement efficient and safe. Furthermore, because of the directional aspiration design, you can orient the catheter in different directions to aspirate clot with precision. Lastly, because the in-line blood filtration



[a] Post-hoc *t*-test analysis showed this decrease to be statistically significant (p<0.0001)
Note: Sample sizes for baseline and 30-day QoL scores were 117 and 106 respectively. 6MWD sample sizes as 48 hours and 30 days post-procedure were 81 and 95 respectively. For change in both QoL score and 6MWD, only subjects with paired data were used in the analysis.

Figure 3. Quality of life and functional status at 30 days.



and return system is localized at the patient bed, it eliminates a lot of the back-and-forth handling of blood that you see with other systems, which often involves multiple techs and slows the procedure down. With the AVENTUS System, you can quickly aspirate, filter the blood, and return it to the patient all on the bed right in front of you. This essentially allows us to perform a bloodless thrombectomy where almost no blood is lost during the procedure.

Dr. Sabri: I found the directional aspiration to be very useful, as you don't need to wire every branch to extract clot. For example, for clot in the truncus, you can park the AVENTUS Aspiration Catheter at the mouth of the branch and aspirate from the main right PA branch, improving procedural efficiency. From my experience, this may explain why we were able to achieve such great clot burden reduction in the trial. Finally, my team members were very happy with the blood return system. The patient table and back table were very clean, and the system made it easier to return the patients' blood. In the trial, blood loss was minimal, and there were no complications due to blood return. Furthermore, no blood transfusions were needed. All these features made the procedure as efficient as possible. Less exchanges, less blood loss, and a cleaner procedure. It was not a hard sell for the trial sites to use it.

How many procedures did it take for you to feel comfortable with this new device?

Dr. Li: I think it only took about two or three procedures to feel comfortable with it and see the unique differences of the device. A lot of us have already had large-bore experience in the treatment of PE, so having a few cases is sufficient to build upon that. Additionally, because there's minimal back and forth with this device, you could arguably do it with just one additional person at your table, such as a cath lab tech. That is so important to allow us to provide care for PE patients throughout the United States, even in underserved areas that don't have several fellows, nurses, and techs to support procedures.

Can you recall a patient that you enrolled in the study and what you saw from the clinical impact on the patient?

Dr. Sabri: I want to share a story of a patient who is middle-aged man and a former athlete. His activity had been impacted by his health, and he said he wanted to go back to playing basketball routinely on weekends. He was somewhat hesitant about the procedure and being in a clinical trial. However, I told him I felt confident in making him feel better, faster with this device. He decided to consent and enroll in the trial. The procedure went great, and he was emotional afterwards hearing how well it went. When he performed the 6-minute walk test at 30 days postprocedure, the difference was significant. It was amazing to see how much farther he walked than 48 hours postprocedure. He gave me a hug and told me how much better he felt after the procedure and after discharge, and that he was glad he had enrolled in the trial. Today, he is back to playing basketball, and it's great to see the direct impact on his life. ■

Disclosures
Dr. Li: Consultant to Abbott Vascular, Boston Scientific, Medtronic, and Inari Medical.
Dr. Sabri: Consultant to Medtronic and Boston Scientific; research support, Inquis Medical.

View the *JSCAI* publication and data highlights from the AVENTUS Pivotal Trial.

CASE REPORT

Rapid Treatment of High-Clot-Burden Pulmonary Embolism With the AVENTUS® Thrombectomy System

A case highlighting procedural efficiency enabled by intelligent device design.

By Jun Li, MD, FACC, FSCAI, RPVI

Pulmonary embolism (PE) remains a major cause of cardiovascular morbidity and mortality, and its management continues to evolve as clinicians confront increasingly complex presentations. Among the most challenging scenarios is the treatment of patients with significant clot burden with extensive central obstruction, impaired right ventricular (RV) function, and hemodynamic instability. Determining the optimal revascularization strategy for these patients is not always straightforward. Systemic anticoagulation alone is typically insufficient, as this approach takes time and is associated with bleeding risk that is prohibitive for many patients. Mechanical thrombectomy (MT) is often our preferred option in these patients, and advancements in catheter-based options have been welcomed to more efficiently extract clot while minimizing the risk of device-related complications.

A key priority in this patient profile is the rapid reduction of clot burden. Large central clots tend to increase pulmonary vascular resistance, driving acute RV pressure overload. This can lead to a downward spiral of RV dysfunction, systemic hypotension, and possibly cardiogenic shock. Even in intermediate-risk patients, prolonged RV strain has been associated with worse short- and long-term outcomes. Fast restoration of pulmonary perfusion not only stabilizes hemodynamics but may shorten intensive care unit stays, reduce the need for rescue therapies, and improve recovery pathway.

The following case report details a patient with high-risk PE and extensive clot burden, highlighting the clinical decision-making, endovascular strategy, and real-world challenges encountered in managing significant clot burden. Through the utilization of the new AVENTUS® Thrombectomy System, strategies can be applied to improve outcomes in a clinical landscape that is still actively defining best practices.

CASE PRESENTATION

A woman in her early 80s presented with acute dizziness, pallor, and incontinence during physical therapy. She subsequently experienced chest pain and shortness of breath, prompting emergency evaluation. Her medical history included hypertension, hyperlipidemia, and bilateral popliteal deep vein thrombosis, which led to ischemic stroke a month prior. She was prescribed dual antiplatelet therapy consisting of aspirin and clopidogrel; however, she was nonadherent, which we suspect led to additional clot formation that embolized to her pulmonary vasculature.

TABLE 1. CASE PATIENT'S BASELINE LABORATORY TESTING RESULTS

Laboratory Test	Value
Hematocrit	30.5%
Hemoglobin	9.8 g/dL
Serum creatinine	1.35 mg/dL
Platelet count	200 X 10^9/L
INR	1.2
Troponin	729 ng/L
RV/LV ratio	1.5
SpO_2	88%-90%
Cardiac index	1.98 L/min/m^2

Abbreviations: INR, international normalized ratio; RV/LV, right ventricular/left ventricular.

PE, SIMPLIFIED

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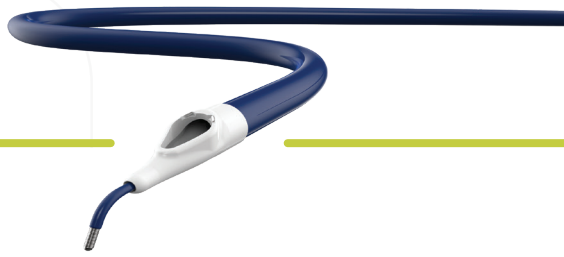

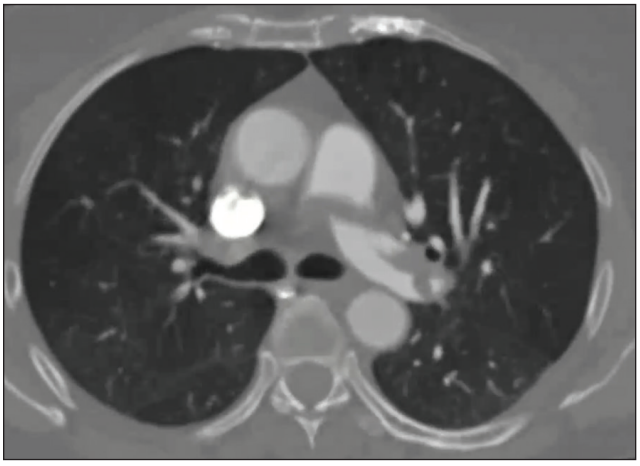

Figure 1. CT image showing saddle clot and significant clot burden extending into the right and left PAs.

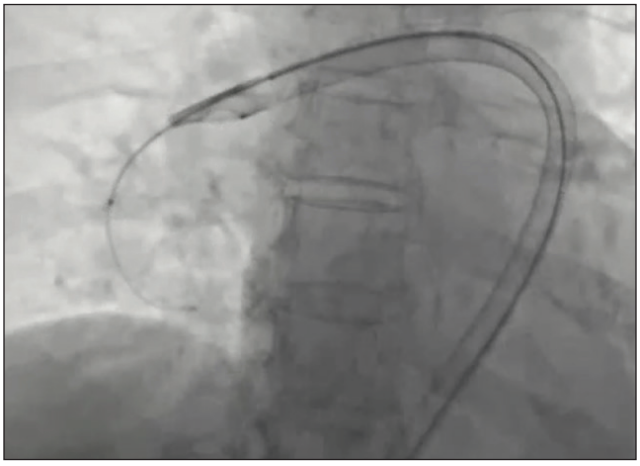

Figure 2. Directional aspiration catheter rotated to face the RLL.

Upon arrival to the emergency department, she was hypotensive, tachypneic, and hypoxic with oxygen saturation of 88% despite an 8 L/min simple mask. Vital signs included a heart rate of 84 bpm and blood pressure was 128/69 mm Hg (Table 1). Baseline CT imaging and transthoracic echocardiography demonstrated significant PE burden and evidence suggestive of right heart strain. A large saddle clot was present, with additional clot burden extending into the branches of both the left and right pulmonary arteries (PAs) (Figure 1).

TREATMENT STRATEGY

This patient presented with acute decompensation, high thrombus burden, and preexisting cardiac and cerebrovascular risk factors. Her hypoxia, hemodynamic instability, and history of recent stroke complicated systemic thrombolytic considerations.

MT with the AVENTUS Thrombectomy System was selected due to:

- Need for rapid, large-volume clot extraction with directional aspiration to stabilize cardiopulmonary function
- Ability to perform autologous blood reinfusion after aspiration
- Simplified device navigation with no dilator exchanges or accessory/curved catheters needed
- TrueClot™ Sensing, which provides real-time feedback on what's happening at the catheter tip, eliminating guesswork, improving efficiency, and saving time
- Favorable safety profile in patients with elevated bleeding risk

This strategy enabled targeted clot removal across multiple lobar and segmental branches while avoiding systemic thrombolysis.

PROCEDURAL OVERVIEW

Access was obtained using a 24-F sheath in the common femoral vein. PA access was achieved with a JR4 catheter and Hi-Torque Versacore guidewire (Abbott), which were used to traverse the right heart and enter the main PA. The Versacore guidewire was then exchanged for an Amplatz super stiff guidewire (Boston Scientific Corporation) and advanced distally into the right lower lobe PA to provide stable support.

The 24-F AVENTUS Thrombectomy Catheter was delivered over a 5-F navigation catheter into the main PA. The AVENTUS Catheter and navigation catheter are advanced coaxially over the guidewire, providing enhanced control and support when steering into targeted PA branches. This technique, combined with the catheter's integrated dilator tip, improves deliverability and reduces device exchanges compared with other MT systems. These efficiencies are particularly valuable in high-risk PE cases in which minimizing procedural time can be lifesaving.

A major advantage of the AVENTUS Thrombectomy System is its built-in dilator, which eliminates the need to plan around separate dilator exchanges and allows for a streamlined treatment strategy. Additionally, the system enables the full procedure to be performed with a single aspiration catheter, avoiding reliance on curved catheters, disks, or multiple aspiration catheter sizes (eg, 24 F, 20 F, 16 F) within the same case.

After crossing the heart with the AVENTUS Catheter, the TrueClot™ Sensing light indicated we were in contact with the saddle clot in the main PA. We performed two aspirations,

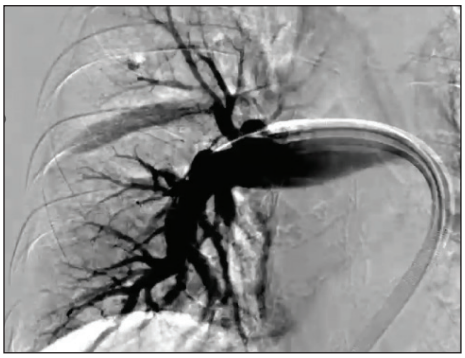

Figure 3. Angiogram showing reperfusion of the main PA and right PA.

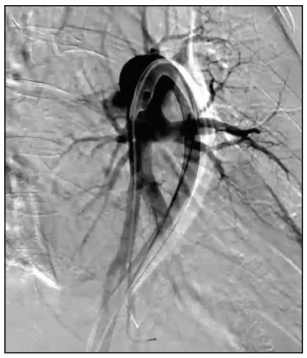

Figure 4. Catheter placement in the LLL.

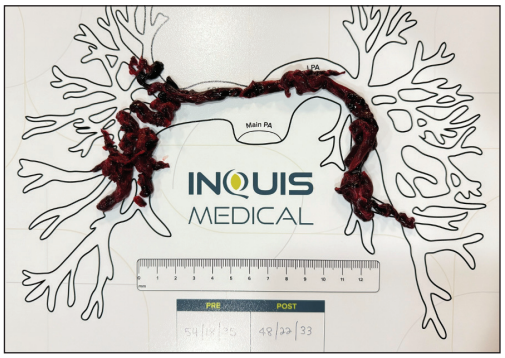

Figure 5. Clot haul diagram showing significant removal of clot burden.

which immediately cleared the saddle clot. The patient's blood was filtered via the AVENTUS Clot Filtration and Blood Reinfusion System at the patient bed by my supporting tech while I advanced the AVENTUS Catheter to the right lower lobe (RLL). After all aspirations, blood was reinfused with only one supporting tech. Using fluoroscopic guidance, the directional aspiration catheter was oriented toward the RLL (Figure 2) and was successfully cleared with two additional aspirations. At this point, we took an angiographic image by injecting 10 mL of contrast into the injection port of the AVENTUS Catheter handle. Fluoroscopy showed a clear main PA and RLL, with some clot remaining in the truncus anterior of the right upper lobe (RUL). Without changing wire position, we advanced the AVENTUS Directional Catheter to the RUL and rotated the directional aspiration opening to face the bifurcation of the truncus anterior. We successfully aspirated the remaining clot without needing to wire or advance the catheter into the branch (Figure 3). This strategy is not only effective but is a unique advantage of the AVENTUS System that saves significant time. In fact, all clot in the main PA and right PA was removed while keeping the Amplatz super stiff wire in the original position of the RLL.

To treat the left PA, we began by exchanging the Amplatz super stiff for the Versacore guidewire. Leaving roughly 3 cm of the Versacore extended from the end of the navigation catheter, we pulled the AVENTUS Catheter back until the guidewire flipped into the left PA. The guidewire was then placed distally into the left lower lobe (LLL). The AVENTUS Catheter was then advanced into the LLL over the Versacore guidewire (Figure 4). During the initial aspiration, TrueClot™ Sensing indicated that we were latched onto vessel wall. We then rotated the catheter to change orientation and successfully aspirated the remaining clot in the LLL. TrueClot™ Sensing proved to be particularly useful in the left PA, where vessel wall latches are common with end-hole catheters. Unlike other MT systems, TrueClot™ Sensing provided us with real-time feedback to understand what was at the catheter tip and resolve the issue without wasting additional time troubleshooting or exchanging for a an accessory or curved catheter. After each aspiration, filtered blood was returned immediately to the patient by utilizing the AVENTUS Clot Filtration and Blood Reinfusion System with only one supporting technician.

PROCEDURAL RESULTS

Angiography after aspiration demonstrated restored blood flow in previously obstructed segmental branches and substantial reduction of thrombus burden. In total, an estimated 30 mL of clot was removed (Figure 4), with nearly all extracted blood filtered and returned to the patient. We saw immediate hemodynamic improvements, with final PA pressures dropping from 54/18 mm Hg (mean, 35 mm Hg) to 48/23 mm Hg (mean, 33 mm Hg) and heart rate decreasing from 84 to 80 bpm. Oxygen saturation improved to 99%, and the patient left the procedure on room air. Treatment of this high-risk case was completed without any complications. ■

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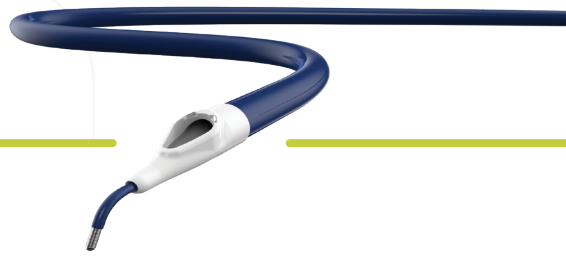


CASE REPORT

Targeted Mechanical Thrombectomy in High-Risk Pulmonary Embolism Using the AVENTUS® Precision Thrombectomy System

By Fabio Komlos, MD

Pulmonary embolism (PE) is a leading cause of cardiovascular mortality, and outcomes are closely tied to the right ventricular (RV) response to acute increases in pulmonary vascular resistance. Patients with intermediate-high–risk PE, defined by RV dysfunction and elevated biomarkers despite preserved systemic blood pressure, have a meaningful risk of clinical deterioration.

Systemic anticoagulation alone may not prevent early decompensation, while systemic thrombolysis carries significant bleeding risk. Mechanical thrombectomy (MT) allows direct, immediate reduction of clot burden without fibrinolytic therapy and is increasingly integrated into PE response protocols.

This case describes the successful use of the AVENTUS® Thrombectomy System in recurrent, intermediate-high–risk PE with large central clot burden and an active proximal venous embolic source.

CASE PRESENTATION

A male patient in his late 40s with a history of extensive bilateral PE and right leg deep vein thrombosis (DVT) presented with progressively worsening exertional dyspnea and fatigue. Two years prior, he had undergone percutaneous MT for PE using a large-bore aspiration system (FlowTriever, Inari Medical) with complete recovery. He completed 1 year of anticoagulation but discontinued therapy afterward.

On the day of presentation, the patient noted persistent tachycardia in the 130s bpm on his smartwatch, unresponsive to rest and hydration, prompting emergency evaluation. He also reported a 1-week history of right calf discomfort.

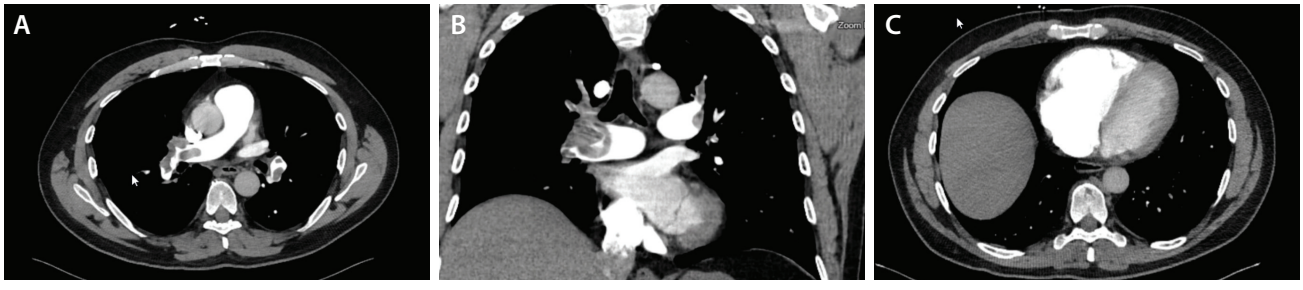


Figure 1. Pretreatment CTA demonstrating extensive bilateral PE and signs of RV pressure overload. Axial CTPA showing large, centrally located thrombi involving the right main PA with extension into the lobar and segmental branches of the right lower lobe (A). Coronal reformatted CT images confirming extensive thrombus burden in the right PA system, predominantly involving the lower lobe vasculature, with reduced distal perfusion (B). Axial cardiac CT image demonstrating marked RV dilation with septal bowing consistent with elevated RV systolic pressure; the calculated RV/LV ratio was 1.7, indicating significant right heart strain (C).

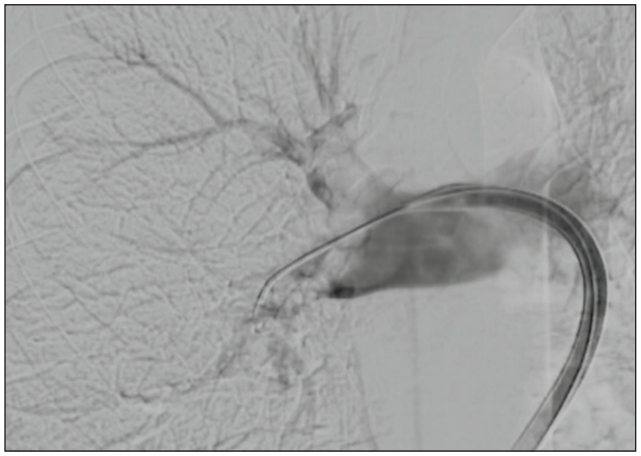


Figure 2. Minimal baseline angiography was necessary due to utilization of real-time TrueClot™ Sensing technology. A single, targeted angiographic run was obtained to confirm large central thrombus in the right main PA with near-complete obstruction of lobar and segmental branches, correlating with the findings of CTPA. Additionally, we decided not to do a pulmonary angiogram on the left side.

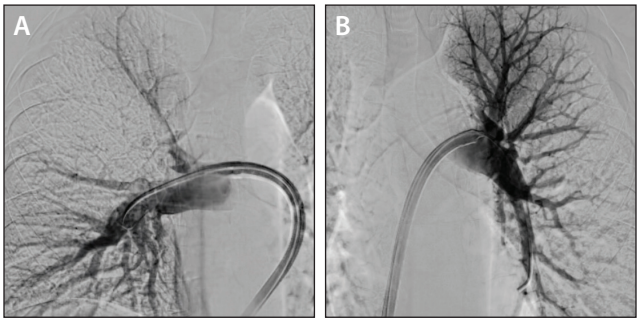


Figure 3. Post-thrombectomy pulmonary angiography demonstrating restored bilateral perfusion with minimal residual thrombus. Right PA angiogram demonstrated significantly improved opacification of segmental and subsegmental branches, with only minimal distal residual thrombus (A). Left PA angiogram showing near-complete resolution of previously occlusive thrombus, with brisk and homogeneous enhancement of the lower lobe vascular bed and restored downstream perfusion (B).

In the emergency department, he was tachycardic to 123 bpm, blood pressure was 135/99 mm Hg, and he required 2 L/min nasal cannula oxygen to maintain an oxygen saturation at 97%. High-sensitivity troponin-I was 389 ng/L and B-type natriuretic peptide was 218 pg/mL, consistent with myocardial strain.

CT pulmonary angiography (CTPA) demonstrated large, multilobar, occlusive (Figure 1A) and near-occlusive emboli (Figure 1B), most prominently in the right lower lobe, with RV dilation (RV/LV [right ventricular/left ventricular] ratio, 1.79) (Figure 1C) and reflux of contrast into the inferior vena cava. Duplex ultrasound confirmed acute DVT in the right popliteal, posterior tibial, and peroneal veins.

Transthoracic echocardiography demonstrated moderate RV dilation and dysfunction with McConnell's sign. His sPESI (simplified PE Severity Index) score was 2 and Bova score was 4 (stage II), consistent with intermediate-high–risk PE. The PE response team recommended urgent endovascular intervention.

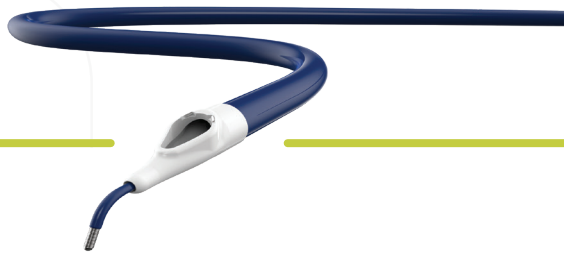
PROCEDURAL OVERVIEW

Moderate conscious sedation was used. Right common femoral venous access was obtained, and a 24-F introducer sheath was placed after dual ProGlide preclosure (Abbott). A Swan-Ganz catheter was advanced into the main pulmonary artery (PA) and baseline PA pressures measured 44/21 mm Hg.

The AVENTUS Thrombectomy Catheter was advanced over the integrated 5-F navigation catheter on an Amplatz wire into the PA (Figure 2). Its soft, atraumatic tip enabled smooth advancement without a dilator. A right pulmonary angiogram was performed directly through the system. Upon engaging clot, the catheter's real-time TrueClot™ Sensing indicator changed color, confirming optimal alignment for aspiration. A single, targeted angiographic run was obtained to confirm large central thrombus in the right main PA with near-complete obstruction of lobar and segmental branches, correlating with the findings of CTPA.

Three aspirations were performed in the right lower lobe, and three aspirations in the left lower lobe, each time rotating the directional aspiration opening toward a different branch. No catheter removal or exchanges were required during the entire procedure.

While navigating the catheter within the PAs, the AVENTUS TrueClot™ Sensing indicator showed a green light to confirm that the device tip is positioned freely within the bloodstream and not in contact with thrombus, allowing safe advancement into the target branch. The indicator then changed to orange when the catheter was engaging directly with thrombus, signaling optimal alignment for aspiration. This real-time feedback enables precise clot targeting, reduces the need for



multiple angiographic contrast injections, and enhances procedural efficiency.

The in-line blood return system allowed real-time visualization of aspirated thrombus (Figure 3) and delivered negligible blood loss. Total contrast volume was approximately 50 mL. Completion angiography showed near-complete restoration of bilateral perfusion (Figure 4). Postprocedure PA pressures were 21/11 mm Hg. Total device time was 22 minutes with no arrhythmia, vascular injury, or hemodynamic instability.

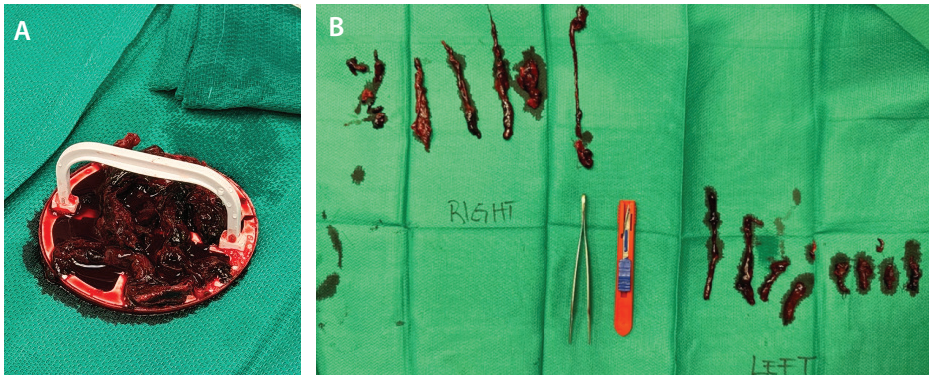


Figure 4. Visible thrombus retrieval with a closed-loop aspiration and reinfusion system. AVENTUS Clot Filter demonstrating collected thrombus segments readily visible during aspiration. This visual feedback confirms device effectiveness in real time and allows immediate assessment of clot burden removed (A). Organized display of extracted thrombus from the right (left side of image) and left (right side of image) PA systems, demonstrating removal of large, centrally located embolic casts consistent with the patient's angiographic findings (B).

POSTPROCEDURAL COURSE

The patient experienced immediate improvement in dyspnea and was weaned to room air the same day. He remained hemodynamically stable without complications and was discharged home the following morning on therapeutic anticoagulation. A predischarge CTA demonstrated minimal residual distal thrombus and improved branch perfusion. He reported full resolution of symptoms at follow-up.

DISCUSSION

MT offers a treatment strategy that rapidly reduces RV afterload while avoiding the bleeding risk of thrombolytics. In this case, several design features of the AVENTUS Thrombectomy System supported efficient and effective clot removal:

- Single-system approach allowed transition across branches without catheter exchange
- Large-bore aspiration with seamless blood reinfusion enabled rapid clot removal with minimal blood loss
- Directional control enabled precise targeting of occluded branches
- TrueClot™ Sensing technology reduced contrast exposure and expedited aspiration alignment
- Real-time visualization of retrieved thrombus confirmed procedural progress

These combined advantages resulted in rapid hemodynamic normalization, restored bilateral perfusion, and next-day discharge.

CONCLUSION

Percutaneous MT using the AVENTUS Thrombectomy System achieved rapid and complete reperfusion in this patient with recurrent intermediate-high risk PE, leading to immediate improvement in cardiopulmonary function and expedited hospital discharge. Device innovations that streamline workflow and improve targeting efficiency may support expanding adoption of catheter-based therapy in appropriate PE populations. ■

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CASE REPORT

Rapid RV Recovery and Clinical Improvement After Use of the AVENTUS® Thrombectomy System for Saddle PE

By Saba Lahsaei, MD, FACC, RPVI

Pulmonary embolism (PE) remains a major cause of cardiovascular morbidity and mortality worldwide. It occurs when thrombotic material—most often from a deep vein thrombosis in the lower extremities or pelvis—embolizes to the pulmonary arterial circulation, obstructing blood flow, increasing right ventricular (RV) afterload, reducing effective lung perfusion, causing hypoxia, and leading to RV dysfunction or failure.

Management of PE traditionally centers on risk stratification. Low-risk patients may be managed with anticoagulation alone, while intermediate- and high-risk patients (with RV dysfunction, elevated cardiac biomarkers, or hemodynamic instability) may require systemic thrombolysis, catheter-directed therapy, or surgical embolectomy. However, systemic thrombolysis carries a substantial bleeding risk, and surgical embolectomy is invasive and resource intensive.

Recent advances in catheter-based thrombectomy devices have provided an important alternative—mechanical removal of thrombus without systemic fibrinolysis. Among these, the AVENTUS® Thrombectomy System represents a new frontier in percutaneous treatment of PE, offering efficient clot extraction with simultaneous blood reinfusion and safety enhancements through TrueClot™ Sensing technology.

CASE PRESENTATION

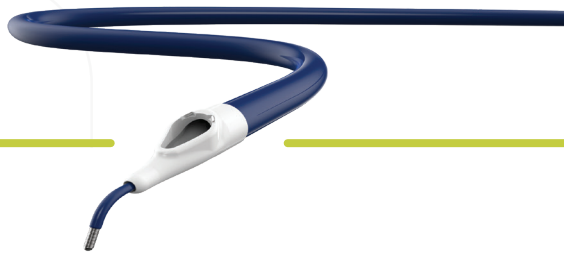
A male patient in his mid-70s presented to the emergency department with acute shortness of breath and chest discomfort that had developed suddenly while at rest. His past medical history included hypertension and hyperlipidemia. On arrival, his oxygen saturation was 86% on room air, respiratory rate was 28 breaths/min, heart rate was 112 bpm, and blood pressure was 118/70 mm Hg. Physical examination revealed jugular venous distension and mild respiratory distress.

Laboratory evaluation showed elevated D-dimer (4.8 µg/mL) and mildly increased troponin I. CT pulmonary angiography (CTPA) demonstrated a saddle PE extending into both main pulmonary arteries (PAs) (Figure 1). Echocardiography revealed marked RV dilation with a RV/LV (right ventricular/left ventricular) ratio of 1.4, consistent with RV strain (Figure 2).

Given the large clot burden and RV dysfunction but without hemodynamic collapse, the patient was classified as intermediate-high–risk PE. After multidisciplinary discussion with the PE response team (PERT), he was selected for mechanical thrombectomy (MT) using the AVENTUS Thrombectomy System.

PROCEDURAL OVERVIEW

Under fluoroscopic guidance via right femoral venous access, the AVENTUS Catheter was advanced into the PAs. The catheter tracked into the right PA smoothly, aided by the integrated navigation catheter and guidewire. As the AVENTUS Catheter was advanced into the distal right PA, TrueClot™ Sensing indicated that we were in contact with a large clot burden. We performed an aspiration, and a large volume of clot was extracted. The AVENTUS Catheter was then pulled back to the mid-right PA, and an additional aspiration removed more clot from the mid and upper branches. The directional aspiration catheter was then



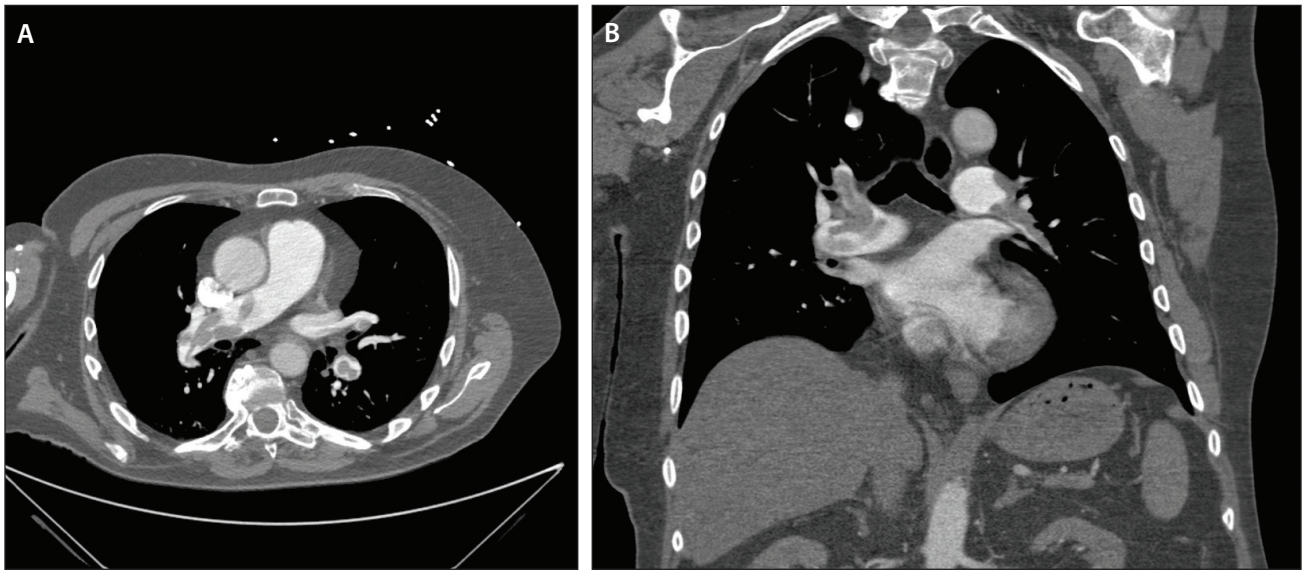


Figure 1. Transverse plane CTPA demonstrating a saddle PE extending into both main PAs (A). Coronal plane CTPA demonstrating a saddle PE extending into both main PAs (B).

rotated to face the truncus anterior, and remaining clot was aspirated without needing to adjust guidewire position or advance the AVENTUS Catheter into the branch, making the procedure on the right PA fast and efficient.

The AVENTUS Catheter was then pulled back into the main PA, and the navigation catheter and wire seamlessly flipped into the left PA. TrueClot™ Sensing was utilized to ensure we had proper alignment and directed toward the clot and away from the vessel wall. One final aspiration cleared all the clot in the left PA. The real-time feedback of TrueClot™ Sensing was very helpful to gain proper alignment and aided in efficient clot removal in the left PA.

After each aspiration, the AVENTUS Clot Filtration and Blood Reinfusion System was used to immediately return blood to the patient without use of the back table. This helped to minimize blood loss during the procedure. Ancillary staff found the procedure to be simple and required less back-and-forth maneuvers than other MT systems.

Within minutes of thrombectomy, the patient's heart rate dropped from 92 bpm (preprocedure) to 79 bpm (postprocedure), and PA pressure dropped from 69/21 mm Hg (mean, 38 mm Hg) (preprocedure) to 41/17 mm Hg (mean, 27 mm Hg) (postprocedure).

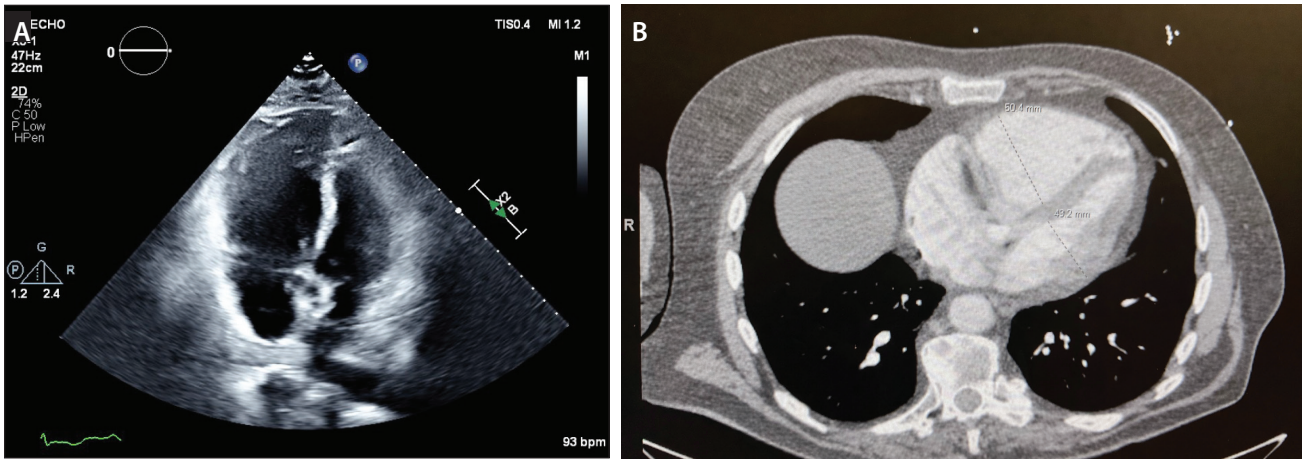


Figure 2. Echocardiogram (A) and CT image (B) showing RV dilation with an RV/LV ratio of 1.4.

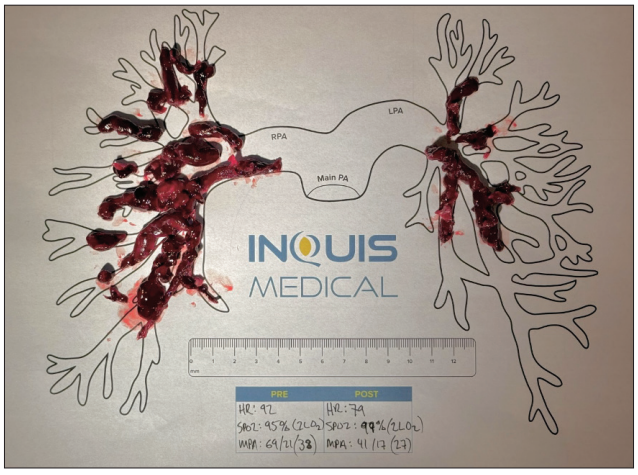


Figure 3. Aspirated clot diagram showing thrombus removed during the procedure.

Oxygen saturation improved to 99% on nasal cannula, and follow-up echocardiography 24 hours later demonstrated significant reduction in RV size and normalization of septal motion. He was transitioned to oral anticoagulation and discharged home without complications. This procedure highlights the procedural efficiencies of the AVENTUS System in a patient with high clot burden. The case required a total device time of only 35 minutes with four aspirations. There was notably less fluoroscopy and overall procedure time than other MT systems. More importantly, the patient had an immediate improvement in symptoms.

DISCUSSION

This case underscores the evolving paradigm in PE management, where rapid identification of RV strain guides timely intervention. Although anticoagulation remains the cornerstone of therapy, MT offers immediate hemodynamic relief in patients with significant clot burden, without exposing them to the bleeding risks of systemic thrombolysis.

The AVENTUS Thrombectomy System represents a next-generation approach, combining high-efficiency aspiration, autologous blood reinfusion, and intelligent catheter design that differentiate between thrombus and native vessel tissue in real time. This innovation enhances safety and procedural efficiency, particularly in distal or branching pulmonary vasculature.

Clinical Evidence and Advances

The AVENTUS Investigational Device Exemption (IDE) trial demonstrated robust safety and efficacy outcomes:[1]

- Mean RV/LV ratio reduction of −0.47 at 48 hours (P <.0001)
- 35.9% mean reduction in clot burden
- Zero device-related major adverse events within 48 hours
- Mean intensive care unit stay of 0.8 days and hospital stay of 2.6 days

In June 2025, the AVENTUS Thrombectomy System received FDA 510(k) clearance for the treatment of PE, following strong multicenter data supporting its safety and performance. As an early user and investigator in the AVENTUS Trial, I found the device easily adoptable into my clinical practice due to its simplicity and intelligent design. My staff has even commented on the improved workflow and overall cleanliness of the sterile field compared to other thrombectomy devices. The streamlined reinfusion healthy blood also limits anemia and transfusion requirements, an important consideration in elderly patients or those with comorbidities.

FUTURE DIRECTIONS

As PERT programs expand globally, integration of rapid imaging, hemodynamic evaluation, and next-generation thrombectomy platforms like AVENTUS are redefining PE management. Ongoing research aims to clarify long-term outcomes, prevention of chronic thromboembolic pulmonary hypertension, and comparative cost-effectiveness against thrombolysis and surgical embolectomy.

MT with the AVENTUS Thrombectomy System provides a safe and effective alternative for patients with intermediate- or high-risk PE. In the presented case, prompt recognition and device-assisted clot removal led to rapid RV recovery and clinical improvement without major complications. As evidence continues to expand, devices like the AVENTUS System with intelligent thrombectomy technology are poised to become integral components of advanced PE care. ■

1. Sabri S, Horr S, Stegman B, et al. Novel aspiration thrombectomy and blood reinfusion system for acute intermediate-risk pulmonary embolism: AVENTUS trial results. J Soc Cardiovasc Angiogr Interv. 2025;4:103661. doi: 10.1016/j.jscai.2025.103661

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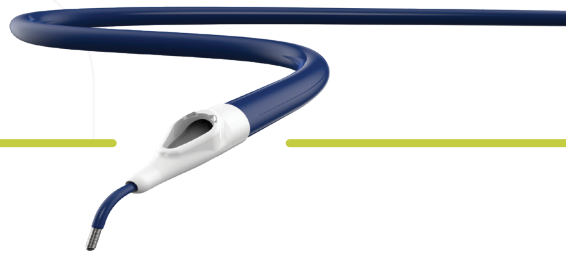


CASE REPORT

Bailout Treatment of Occluded Left PA With the AVENTUS® Thrombectomy System

By Ilan Rzadkowolsky-Raoli, MD

As an interventional radiologist at Palmetto General Hospital, I have over 15 years of experience treating venous thromboembolic disease and have completed over 750 cases. In that time, our care team has acquired extensive experience with all the commercially available treatment options. These devices have proven to be effective, but they are not without drawbacks that have limited utilization due to complexity and length of the procedure. We recently have gained experience with the new AVENTUS® Thrombectomy System, which solves many of these problems and simplifies the pulmonary embolism (PE) procedure in meaningful ways.

CASE PRESENTATION

A female patient in her early 70s was admitted to the hospital with right lower leg pain and swelling. She had severe shortness of breath and pain on inspiration. Her medical history was significant for hypertension, dyslipidemia, osteoporosis, and recent displaced fibular fracture for which she had been scheduled for surgery in 4 days. She was tachycardic (> 150 bpm) and had sustained hypotension as low as 78/53 mm Hg. A "Code PERT" (PE response team) was immediately called, which in our system triggers a power plan with all necessary labs, imaging, admissions, and consults automatically preordered. This also serves to notify CT to leave a suite open for immediate patient imaging. A call also goes out to the PERT physician on call. A CTA for PE was performed within 20 minutes and demonstrated bilateral PE involving the right and left main pulmonary arteries (PAs) and the lobar and segmental branches (Figure 1). There was right heart strain with a RV/LV (right ventricular/left ventricular) ratio of 2.0 (Figure 2). Laboratory results were significant for elevated lactate of 3.7 mmol/L, troponin of 5.7 ng/L, B-type natriuretic peptide of 2,360 pg/mL, and signs of respiratory alkalosis. As the Code PERT physician on call, I immediately identified this as a massive PE per risk stratification guidelines, and the team was called in for emergent thrombectomy. Meanwhile, an intravenous heparin drip was started as per PE protocol with bolus.

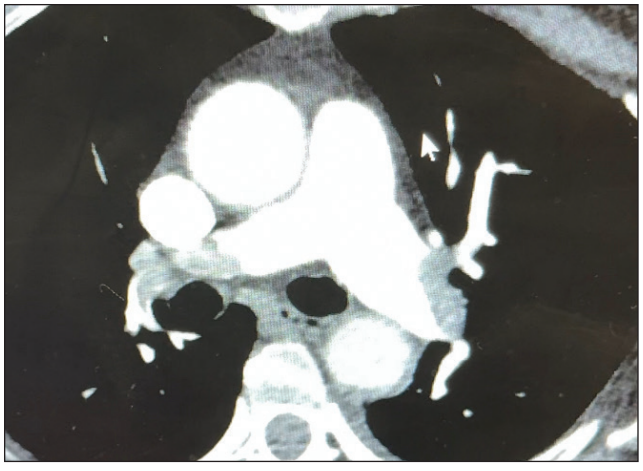


Figure 1. CT scan showing bilateral clot without a saddle, with both the right and left PA occluded with thrombus.

INDEX PROCEDURE OVERVIEW

Given the patient's hemodynamic instability and contraindications for systemic thrombolysis, large-bore mechanical thrombectomy was chosen. This has become our first-line procedure of choice due to its efficacy, speed, and safety profile.

We made the decision to use a 24-F mechanical thrombectomy device from a different manufacturer for the index procedure due to our staff being most familiar with it and the severity of the presenting patient symptoms. We achieved common femoral access, inserted the 24-F thrombectomy catheter, and delivered it to the right PA. Due to the emergent nature of the case, we did not measure PA pressures. An angiogram of the right PA showed complete occlusion of the right upper lobe branch and multiple incomplete emboli in the middle and lower lobe branches.

After completing aspirations in the right PA but prior to obtaining a right-sided angiogram, the 24-F catheter "flopped" to the left PA, dragging with it the tip of the 0.035-inch super stiff Amplatz wire with 1 cm tip. The patient felt immediate discomfort and became slightly agitated.

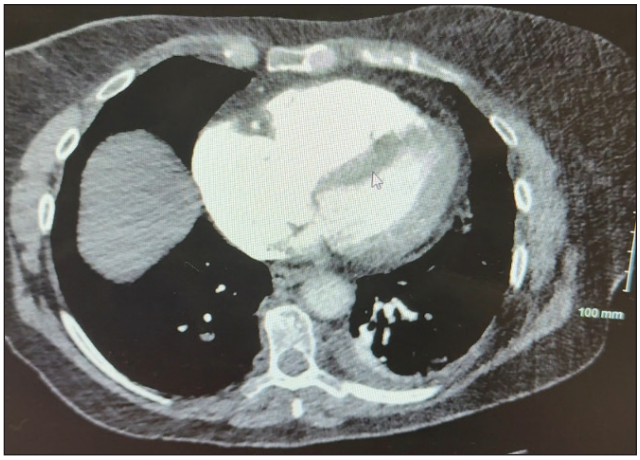


Figure 2. CT scan showing a dilated right ventricle and significant right heart strain (RV/LV ratio, 2.0).

Because I was already in the left PA, I thought it prudent to proceed with left thrombectomy, but when I advanced the guidewire, it took a cephalad course and then wrapped around the superior mediastinum, eventually descending the right-side lateral to the superior vena cava. I immediately injected a little contrast through the 24-F catheter, which confirmed pericardial leak. Although the patient complained of some pain, her vital signs were strong. I placed an ultrasound probe on her heart and confirmed the hemopericardium. I placed an 8-F pigtail catheter in the caudal pericardial space and evacuated 1 L of blood, by which time we had ordered two units of packed red blood cells for transfusion. I then pulled out the groin access and sealed it with dual Perclose® devices (Abbott) using preclose technique. The pericardial drain was sutured in place.

The patient was transferred to the intensive care unit for observation. She improved overnight and expressed a desire for us to complete the embolectomy procedure. Her vital signs still showed tachycardia in the 130s bpm and her systolic blood pressure was in the 110 to 120 mm Hg. She still had positive biomarkers, and the cardiac two-dimensional echocardiogram showed RV dilatation and tricuspid regurgitation, surrogates for elevated PA pressure, which could not be measured.

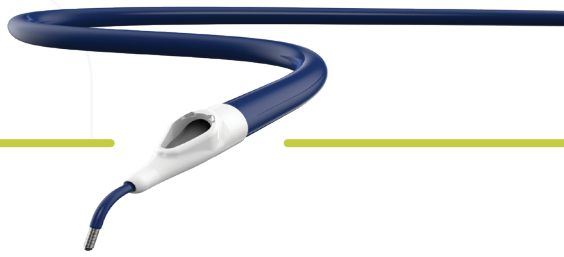
BAILOUT PROCEDURE WITH THE AVENTUS SYSTEM: LEFT PA THROMBECTOMY

After extensive multidisciplinary discussion, we decided to proceed with treatment. With the benefit of time and freedom for choice, I decided to use the AVENTUS Thrombectomy System to treat her left PA. Given the clinical context, I selected the AVENTUS Thrombectomy System based on several procedural considerations: (1) I would be able to cross the left PA apex with a softer wire due to its flexibility, negating risk of worsening pericardial damage; (2) the left upper lobe and lingular thrombus were eccentric, and I thought that the directional aspiration would help target this thrombus; (3) I wanted to do the procedure as quickly as possible, minimizing wire and catheter exchanges and need for adjunctive devices yet ensuring a good result; (4) her hemoglobin had since dropped to 8.0 g/dL (from initial of 10.3 g/dL), so I was wary of blood loss and the proprietary TrueClot™ Sensing would help identify what was at the tip of the catheter for more precise and targeted aspiration to reduce the procedure time and limit blood loss from unnecessary aspirations, and (5) the AVENTUS Clot Filtration and Blood Reinfusion System would return healthy blood to avoid wasting valuable hemoglobin.

Standard common femoral access was obtained and the access site was preclosed. The AVENTUS 24-F Catheter was then advanced through the right heart and main PA pressure was assessed, which was 34/14 mm Hg (mean, 21 mm Hg). I easily entered the right PA and obtained an angiogram to ensure that we had cleared the thrombus from the index procedure, which we had. I then carefully navigated to the left PA using a floppy-tip wire placed in the left lower lobe. Although clot was present in the upper lobe, I decided to start by treating in the left lower lobe.

After delivering the AVENTUS Catheter to the left lower lobe, we performed one aspiration, and TrueClot™ Sensing indicated we had latched on the vessel wall with a blue indicator light, and no clot was being sensed in that location. I realized that the bulk of the clot must be in the posterior segment. With other devices, this would mean pulling back the catheter, exchanging for a curved catheter or hydrophilic wire or replacing with the stiff wire, then reengaging the dilator to advance the catheter distally. Although not unmanageable, it is frustrating and usually results in a loss of 5 to 10 minutes. However, with the AVENTUS System, I simply pulled back the catheter and used the integrated guiding catheter to select the appropriate vessel. I advanced the AVENTUS Catheter until the TrueClot™ Sensing indicated an orange light signaling the presence of clot. I then performed an aspiration while slowly pulling the catheter back with the aspiration orifice directed toward the lateral side as I retracted past the lingula and left upper lobe branches. As we passed the left apical branch, the syringe filled with clot and blood. I then advanced the aspiration syringe forward, which sent the extracted blood to the AVENTUS Clot Filtration and Blood Reinfusion System.

I was not expecting much after one aspiration, but when I looked at the clot filter, I was shocked that there was a very



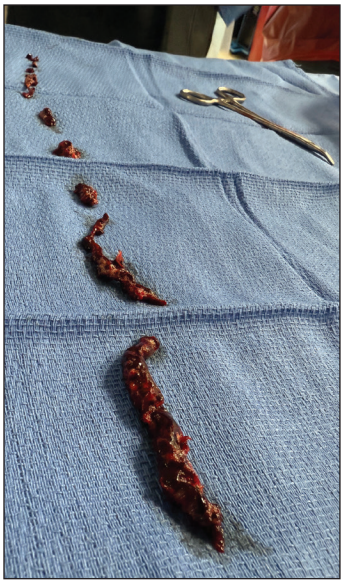


Figure 3. Extracted clot of mixed morphology from left PA using the AVENTUS Thrombectomy System.

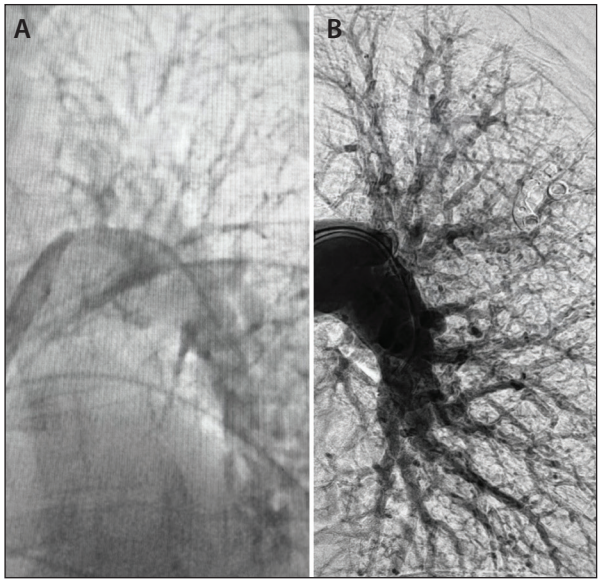


Figure 4. Preprocedure angiogram showing an occluded left PA (A). Postprocedure angiogram showing 100% clot removal and reperfusion (B).

large amount of evenly mixed morphology clot (Figure 3). I performed left pulmonary angiography through the AVENTUS Catheter and was impressed when I saw that we achieved 100% clot resolution on one single aspiration and from the historically difficult-to-treat left PA (Figure 4).

Prior to completing the procedure, PA pressures were 26/5 mm Hg (mean, 14 mm Hg), demonstrating a significant reduction especially for unilobar treatment. We successfully closed the patient using the preclose technique, and she was transferred in stable condition to the intensive care unit.

POSTPROCEDURE OUTCOME AND FOLLOW-UP

The patient demonstrated significant clinical improvement after treatment. By the third postoperative day (hospital day 6), she was eligible for discharge. However, she elected to remain in the hospital to undergo surgical repair of her broken fibula. During her extended stay, her vital signs showed continued improvement; her heart rate stabilized in the low 100s bpm, and her blood pressure normalized to 130/60 mm Hg.

To ensure complete resolution of the PE, a follow-up CTA was ordered on hospital day 9. The CTA results were negative for any residual PE, and the patient's RV/LV ratio had normalized to 0.8, indicating resolution of the right heart strain that was present on admission.

DISCUSSION

The AVENTUS Thrombectomy System solves the particularly laborious and redundant steps inherent with other devices. With the AVENTUS System, there are no catheter and dilator exchanges, as the procedure is done with one aspiration catheter and no separate dilator. In some cases, you can complete the procedure over one guidewire because the 24-F AVENTUS Aspiration Catheter is extremely torqueable and deliverable. The integrated 5-F navigation catheter and built-in dilator tip simplify catheter repositioning, reducing procedural steps and saving time. With directional aspiration, there is no longer a need for extra aspiration catheters with different angulations and curves. You can use the beveled, directional aspiration tip to address eccentric thrombus with complete control in 360° of rotation. TrueClot™ Sensing technology provides useful information to know what is at the catheter tip, eliminating guesswork, improving efficiency, and saving time. Finally, we can maximize treatment efficacy by allowing filtered blood to be returned to the patient immediately, giving you the freedom to remove as much clot as possible.

These procedural improvements allow clinicians to be more successful than previously believed, yet optimally efficient. Procedures with the AVENTUS System can be accomplished safely, successfully, and often in approximately 30 minutes. This means that mechanical thrombectomy can be adopted more widely, which the latest data are consistently showing to be more beneficial to patients than current standard of care. ■

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Disclosures: Consultant to Inari Medical, Argon Medical, and Inquis Medical.

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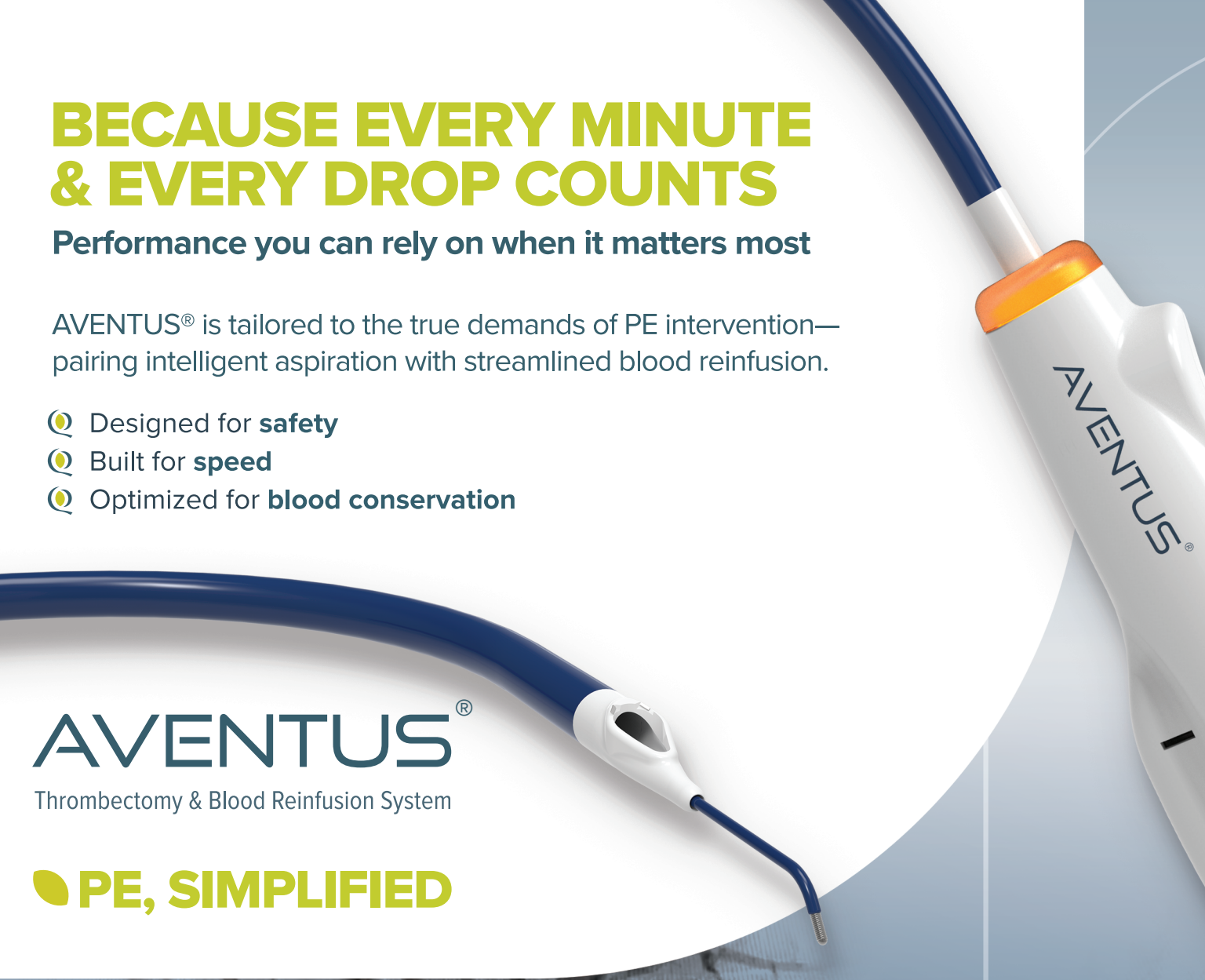

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INDICATIONS FOR USE

The AVENTUS Thrombectomy System is indicated for:
- The non-surgical removal of emboli and thrombi from blood vessels.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The AVENTUS Thrombectomy System is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism.

The AVENTUS Clot Management System is indicated for use with the AVENTUS Thrombectomy System for autologous blood transfusion.