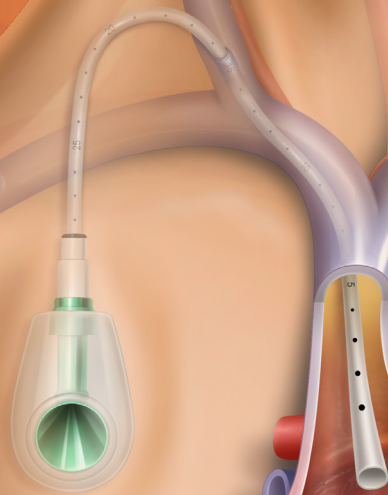


# ACCESSING TOTALLY IMPLANTED APHERESIS VASCULAR DEVICES



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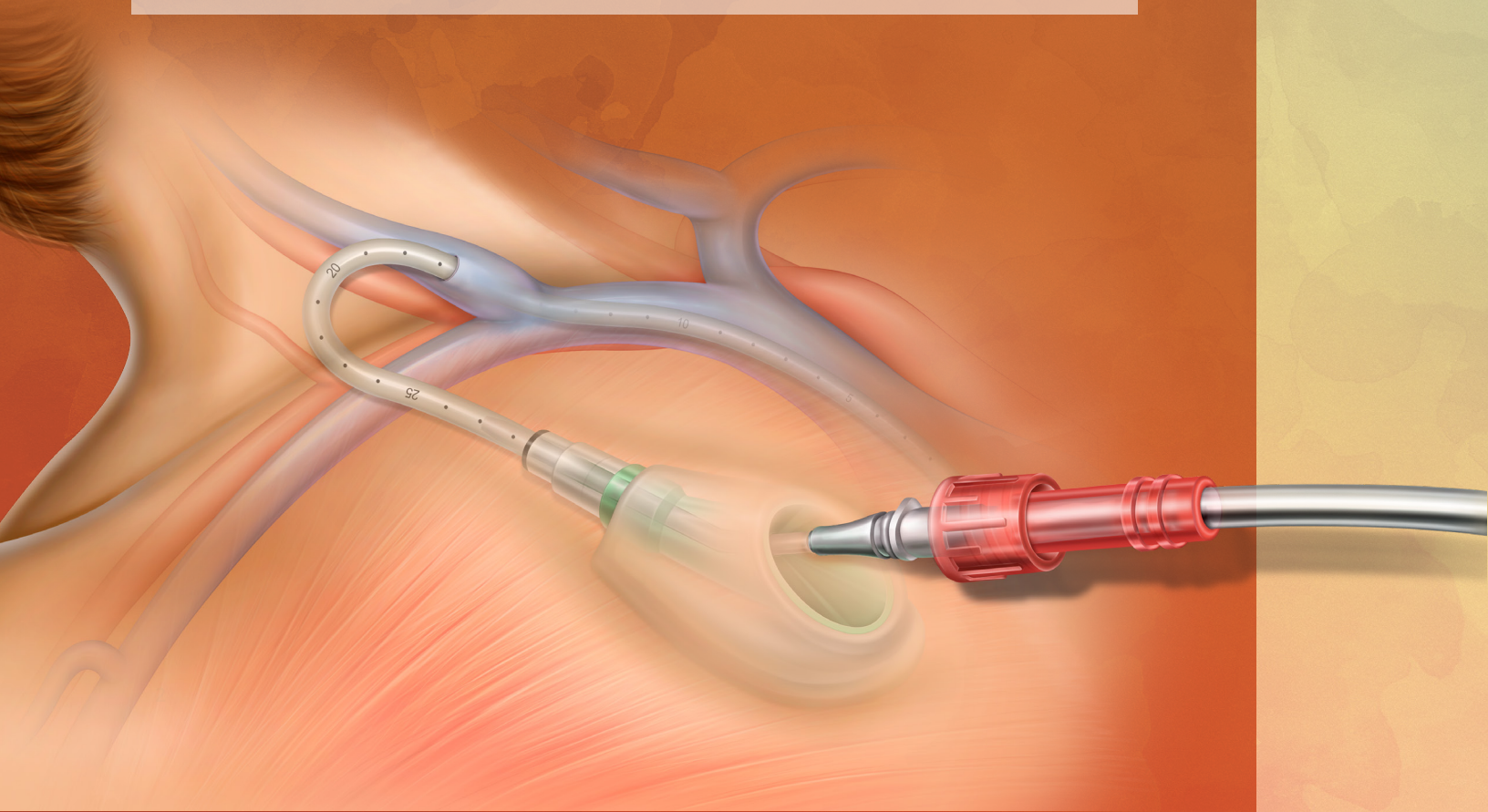


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# OVERVIEW

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The use of therapeutic apheresis (TA) is growing every year and increasing evidence shows that it's being used as a primary therapy or adjunct to other therapies for various conditions that impact neurologic, hematologic, oncologic, rheumatologic, and renal systems. Apheresis is a procedure with significant physiologic outcomes, so the care of TA patients requires knowledge and skill of leading practices and innovative devices. This educational activity will discuss the rationale for TA procedures and the nursing considerations in the delivery of apheresis care. Access methods will be reviewed along with the risks and adverse events associated with vascular access procedures.





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# INFORMATION

## ACCESSING TOTALLY IMPLANTED APHERESIS VASCULAR DEVICES

### LEARNING OBJECTIVES

After completing this continuing education activity, the participant should be able to:

1. Discuss nursing practice for the delivery of apheresis.
2. Identify diseases treated with apheresis.
3. Discuss the rationale for therapeutic apheresis procedures.
4. Recognize risks and adverse reactions associated with apheresis procedures.
5. Discuss current vascular access methods for apheresis.

### INTENDED AUDIENCE/EDUCATIONAL NEED

This continuing education activity is intended for registered nurses and healthcare professionals who want to learn more or need to gain knowledge and skills in apheresis ports in outpatient and inpatient settings such as apheresis clinics, oncology departments, intensive care units, and the emergency department (ED).

### TEACHING METHODOLOGIES

The education activity is a self-paced, independent learning activity. Course goals are presented, followed by corresponding content. Learners can evaluate attainment of objectives by completing the test questions and comparing with the answer key. References can be reviewed for additional information.

This continuing education activity is governed by principles of adult learning and consists of written content with illustrations to complement the narrative. Learner comprehension will be assessed through post-test questions following the content.

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1. Complete course content and review learner objectives.
2. Once you complete your review, the post-test will unlock in the menu. Answer questions correctly to access the evaluation.
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**The certificate of course completion issued at the conclusion of this course must be retained in the participant's records for at least four (4) years as proof of attendance.**



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# INTRODUCTION

Apheresis is a medical technique where whole blood components (eg, plasma, red cells, white cells, and platelets) are separated to isolate and remove parts that adversely contribute to a disease or condition.<sup>1</sup> The abnormal parts are removed from the body, and the normal components are returned.<sup>1</sup> There are various types of apheresis for the different conditions.

Centrifugation and membrane filtration are two conventional apheresis methods.<sup>2</sup> Filtration uses permeable membranes (columns) to separate components according to molecular weight,<sup>3</sup> and centrifugation uses centrifugal force to separate the blood components according to density.<sup>1</sup> When apheresis is performed to treat diseases, most often as an adjunct to other treatment, it is called therapeutic apheresis (TA) and can be used for more than 84 neurologic, hematologic, oncologic, rheumatologic, and renal diseases, and medical conditions that are listed and discussed in the American Society for Apheresis (ASFA) *Guidelines*.<sup>3</sup> Each condition has a corresponding indication for the use of apheresis in specific situations encountered in the disease and is assigned a category and grade (Table 1)<sup>3</sup> that is developed via rigorous application of evidence-based criteria that can be used in support of or against therapeutic apheresis (TA) intervention. Some of the conditions for which apheresis is the first-line therapy (primary or adjunct) include the following.

- Acute inflammatory demyelinating disease



- Acute liver failure
- Goodpasture syndrome
- Catastrophic antiphospholipid TPE syndrome (CAPS)
- Graft-Versus-Host Disease
- Cutaneous T cell lymphoma (CTCL)
- Familial hypercholesterolemia
- Hereditary hemochromatosis
- Hyperviscosity in hypergammaglobulinemia
- Myasthenia gravis
- Paraproteinemic demyelinating neuropathies
- Polycythemia vera
- Sickle cell disease
- Thrombotic microangiopathy
- Liver transplantation
- Renal transplantation
- Vasculitis
- Wilson disease



**TABLE 1 | ASFA 8<sup>th</sup> Edition Category Definitions and Grading Recommendations, 2019**

Category	Definition	Grade	Definition
I	Disorders for which apheresis is accepted as the first-line therapy, either as a primary standalone treatment or in conjunction with other modes of treatment.	1A	Strong recommendation, high-quality evidence.
II	Disorders for which apheresis is accepted as second-line therapy, either as a standalone treatment or in conjunction with other modes of treatment.	1B	Strong recommendation, moderate-quality evidence.
III	Optimum role of apheresis therapy is not established. Decision making should be individualized.	1C	Strong recommendation, low-quality or very low-quality evidence.
IV	Disorders in which published evidence demonstrates or suggests apheresis to be ineffective or harmful. IRB approval is desirable if apheresis treatment is undertaken in these circumstances.	2A	Weak recommendation, high-quality evidence.
		2B	Weak recommendation, moderate-quality evidence.
		2C	Weak recommendation, low-quality or very low-quality evidence.

Reference: Padmanabhan A, Connelly-Smith L, Aqui N, Balogun RA, et al. Guidelines on the use of therapeutic apheresis in clinical practice—evidence-based approach from the Writing Committee of the American Society for Apheresis: the eighth special issue. *Journal of clinical apheresis*. 2019;34(3):171-354.





## Coordination of Care



The duration, frequency, and type of procedure varies depending on the therapeutic needs of the patient. However, whether a patient undergoes one procedure or multiple over the course of months and years, an exhaustive diagnostic work-up, collaboration of medical specialties, and experienced apheresis team of physicians and nurses is imperative. General factors to consider include rationale, impact, technology, plan of care, clinical and laboratory end-points, timing, and location.<sup>3</sup> All providers and the apheresis team should justify the rationale for the procedure with information from published studies, patient-specific risks associated with established or presumptive diagnosis and patient medical history. Potential and known effects of TA on co-morbidities and medications should be reviewed. The type of anticoagulant, replacement solution, vascular access, and volume of whole blood processed should be addressed. The total number and interval of procedures should be established with clinical and laboratory parameters to monitor the effectiveness of the treatment. There should be an agreement on the timing of initiation of

TA based on clinical considerations and any criteria that would lead to discontinuation.

The ASFA “Choosing Wisely” campaign<sup>4</sup> recommends a standard approach for planning a procedure, effective communication between apheresis providers and patients, and serves as a guide for nurses and physicians who may have limited experience in TA.<sup>3</sup> The recommendations emphasize that TA referrals should be written, and the treatment plan, therapeutic goals and follow-up visits are specified in consultation with the referring physician. Management of blood products, procedure reactions, clinical responsibilities, and documentation should be accomplished according to national guidelines, local requirements, and facility policies. It is important to document the details of each TA such as lot numbers of items and products, type and quantity of solutions, timeline, vital parameters, laboratory test results, and additional information on deviations from the plan, adverse events, and complications.



## APHERESIS PROCEDURES

TA treatment procedures outlined in the ASFA *Guidelines*<sup>3</sup> are summarized in Table 2. Those classified as cytoapheresis involve red blood cell depletion or exchange (RBE), lipoprotein apheresis (LDL-a), platelet depletion, and extracorporeal photopheresis (ECP). Plasma treatments incorporate therapeutic plasma exchange (TPE) and various secondary treatments of separated plasma comprised of adsorption, filtration, or precipitation of selective components with or without replacement fluids.

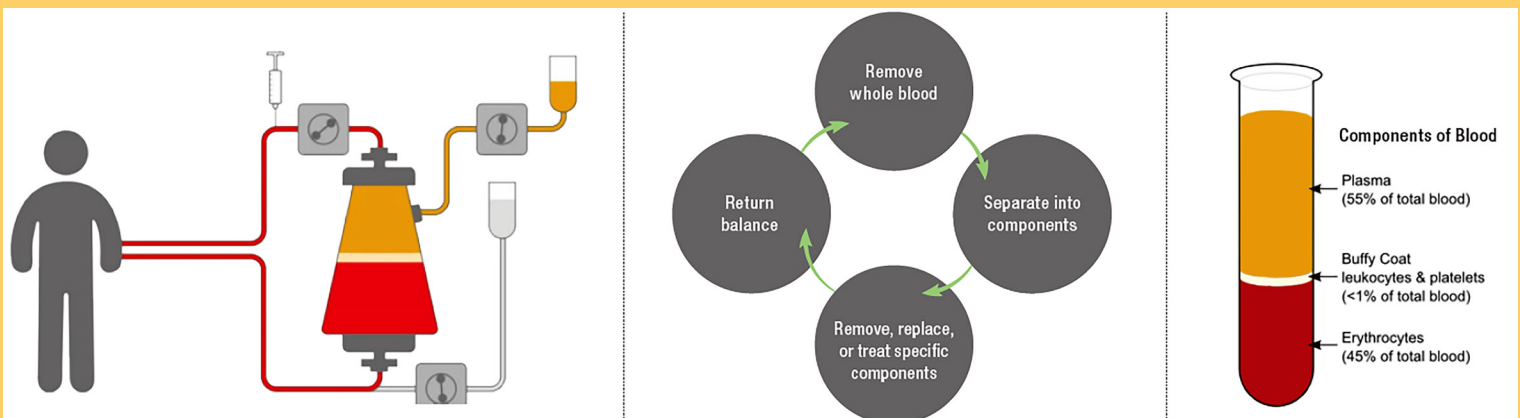
- ECP: The buffy coat is separated from the blood, treated extracorporeally with a photoactive compound and exposed to ultraviolet A (UV-A) light, and reinfused during the same procedure.<sup>3</sup>
- RBE: Red blood cells are separated from other components of blood, then removed from the patient, and

replaced with donor red blood cells and colloid solution.<sup>3</sup>

- TPE: Plasma is separated from other components of blood, removed from the patient, and replaced with a replacement solution such as colloid solution (eg, albumin and/or plasma) or a combination of crystalloid/colloid solution.<sup>3</sup>
- Lipoprotein apheresis (LDL-a): Removal of lipoprotein particles from the blood with the return of remaining components through processes such as double filtration plasmapheresis, heparin-induced extracorporeal LDL (HELP)-apheresis, polyclonal-sheep-anti-apoB-immunoabsorption, dextran-sulfate plasma adsorption, dextran-sulfate whole blood adsorption, and polyacrylate whole blood adsorption.<sup>3</sup>

## Basics of Apheresis

Apheresis refers to a family of procedures that involve removing whole blood from an individual, separating the blood into its various components by passing it through a medical device, then removing, replacing, and/or treating specific components before returning the balance of the blood to the individual. Apheresis procedures have a number of different uses ranging from blood donation to disease treatment.



References: Kalantari K. The choice of vascular access for therapeutic apheresis. *J clin apher.* 2012;27(3):153-9. DOI: 10.1002/jca.21225

YaleMedicine. Apheresis. <https://www.yalemedicine.org/conditions/apheresis>. Published October 28, 2019. Accessed November 8, 2021.



**TABLE 2 | Apheresis Procedures**

TA Modality	Extracorporeal Photopheresis (ECP)	Red Blood Cell Exchange (RBCx)	Therapeutic Plasma Exchange (TPE)	LDL Apheresis (LDL-a)
<b>Basic Action</b>	Buffy coat treated and exposed to ultraviolet A light	RBCs removed and replaced with donor RBCs alone and colloid solution	Plasma removed and replaced with a replacement solution	Selective removal of low density lipoproteins (plasma)
<b>Machine</b>	Centrifuge	Centrifuge	Centrifuge	Filtration
<b>Procedure</b>	Continuous or Discontinuous	Continuous	Continuous or discontinuous	Continuous
<b>Diseases (Short List)</b>	Cutaneous T-cell Lymphoma Graft vs. Host Disease (GVHD) Transplant Rejection	Sickle Cell Disease	Myasthenia Gravis Guillain-Barre Syndrome Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Thrombotic Thrombocytopenic Purpura (TTP)	Familial Hypercholesterolemia
<b>Target Flow Rates</b>	120-150 mL/min	80-100 mL/min	80-100 mL/min	60-120 mL/min

Adamski J. Vascular access considerations for extracorporeal photopheresis. *Transfusion*. 2018;58:590-7. DOI: <https://doi.org/10.1111/trf.14500>.

Adapted from: Padmanabhan A, Connelly-Smith L, Aqui N, Balogun RA, et al. Guidelines on the use of therapeutic apheresis in clinical practice—evidence-based approach from the Writing Committee of the American Society for Apheresis: the eighth special issue. *Journal of clinical apheresis*. 2019;34(3):1-184.

Health Augusta University. Red cell exchange procedure. <https://augustahealth.testcatalog.org/show/RBC-Exchange>. Accessed November 10, 2021.

Medical Advisory Secretariat. Low-density lipoprotein apheresis: an evidence-based analysis. *Ont Health Technol Assess Ser*. 2007;7(5):1-101.

De Simone N, Sarode R. A tale of two ports: an in vitro comparison of flow characteristics for therapeutic plasma exchange. *Transfusion*. 2018;58:605-8. DOI: <https://doi.org/10.1111/trf.14494>.

Janssens ME, Wakelin S. Centrifugal and membrane therapeutic plasma exchange—a mini-review. *Eur. Oncol*. 2018;14(2):105-09. DOI: <https://doi.org/10.17925/EOH.2018.14.2.105>.

Otrock Z, Thibodeaux S, Jackups RJr. Vascular access for blood cell exchange. *Transfusion*. 2018;58(5): 569-579. DOI: <https://doi.org/10.1111/trf.14495>.

Wendler T, Schilling R, Lennertz A et al. Efficacy and safety of DALI LDL-apheresis at high blood flow rates: A prospective multicenter study. *J. Clin. Apher*. 2003;18(4):157-166. DOI: <https://doi.org/10.1002/jca.10071>.

## TECHNICAL ASPECTS AND MECHANISMS OF APHERESIS

Centrifugation- and filter-based systems use negative pressure to withdraw blood from the patient and a positive pressure when returning it<sup>2</sup> and are either<sup>2</sup> via a closed or open system. A closed system incorporates functionality of collection of buffy coat, photoactivation with UV-A light, and reinfusion of treated cells into one device. The closed systems use the Latham bowl for cell separation and buffy coat collection and the photoactivation chamber is integrated to allow all three phases to occur with one device. They function by discontinuous-flow or by both discontinuous- and continuous-flow. Discontinuous-flow devices can only be used in a single-needle mode, which means that the same vascular access site is used for collection of whole blood and return of plasma, RBCs, and treated buffy coat. Only a small blood volume can be withdrawn, processed, and returned before another volume is withdrawn. With dual mode devices, the continuous double-needle mode requires separate collection and return vascular sites. If the procedure starts in double-needle mode and one of the access sites is lost the mode can then be converted to single needle mode to complete the therapy. Dual mode devices have shorter treatment times and faster processing of blood and photoactivation, therefore they are more commonly used due to their processing efficiency. The open system consists of separate instrumentation for leukapheresis and UV-A photoactivation. They are validated and approved for their separate uses only, but not together.<sup>5</sup>

## VASCULAR ACCESS

Several considerations must be evaluated before selecting a vascular access route such as type of procedure, patient's vascular anatomy, acuity, frequency and duration of treatment, and the underlying disease state.<sup>6</sup> The duration of treatment can be months to years. Often patients start with intensive, consecutive therapy at weekly or bi-weekly intervals, so establishing effective vascular access (VA) and preserving its patency is critical to the success of apheresis. Some protocols adhere to a prescribed treatment plan regarding the intervals and others allow modification of treatment intervals based on patient response. Both scenarios require patients to have long-term VA that will not collapse under the negative pressures of the procedures. Reliable VA is also necessary to achieve a wide range of flow rates. The ideal route enables safe and successful completion of therapy with negligible risk of infection, complications, or interference with the patient's quality of life. For TA, access routes include the following:<sup>2</sup>

Peripheral IV access	Acute non-tunneled central venous catheters (CVCs)	Chronic tunneled CVCs	Arteriovenous fistulae (AVF) and grafts (AVG)	Implantable access ports
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Peripheral veins and CVCs are routes most frequently used for acute administration of TA for periods of time of weeks to months. AVG and AVF are not particularly common routes for procedures, but are an option when a long course of TA, generally several months or years, is anticipated.<sup>6</sup> Protocols for vascular access should be based on such factors as the patient's health, vascular anatomy, and preference as well as the experience and comfort level of the physician.<sup>3</sup> Other examples of determinants are included in Table 3.

**TABLE 3 | Examples of Determinants for Vascular Access for Apheresis**

Determinant	Example
Type of Procedure	Cytapheresis for hyperleukocytosis or thrombocytosis often done daily in patients with cellular hyperviscosity require CVC, but peripheral access would not be appropriate
Type of TA System Used	CVC or AVF necessary when using membrane-based system, whereas peripheral access may be appropriate when using centrifugation-based system
Acuity, Number, and Frequency of Treatments	5 to 7 daily treatments best managed with temporary CVC, especially in inpatients, whereas 1 to 3 treatments over 1 to 2 weeks may be best managed with peripheral access
Anticipated Duration	If duration of treatment >3 to 4 weeks tunneled CVC is usually most appropriate whereas treatment lasting months indicates implantable ports, and treatment lasting years indicates AVF
Location of Treatment	Inpatient versus outpatient setting

Reference: Kalantari K. The choice of vascular access for therapeutic apheresis. *J clin apher.* 2012;27(3):153-9. DOI: 10.1002/jca.21225.

## Peripheral Access

Generally, peripheral catheters are preferred when vascular access is required for shorter periods, direct access to the central circulation is not necessary, and when smaller gauge catheters suffice for the procedure. Peripheral access can be relatively easy to obtain in a patient with healthy veins and less painful than other vascular access types. In patients taking anticoagulants, peripheral access allows for direct compression of puncture sites and fewer hematoma-related complications compared with the sites used for CVCs. The blood flow rate (BFR) of centrifugation-based systems, less than 100 mL/min, enables peripheral veins to be considered for TA, especially for infrequent or shorter duration treatments.<sup>2</sup> This route requires at least one vein that has the size and rigidity to accommodate negative and positive pressures of the collection and return of blood during apheresis. In general, antecubital veins can be accessed with 16- to 18-gauge dialysis needles and if the patient has adequate peripheral veins in both arms, the double-needle technique can be used with devices that accommodate this method.<sup>5</sup>



## KNOWLEDGE CHECK

**Centrifugation and filter-based systems use negative pressure to withdraw blood from the patient and a positive pressure when returning it.**

- A. True
- B. False

[\[Click Here for Answer\]](#)

The use of peripheral access for TA varies considerably within the United States (US) and globally.<sup>7</sup> Adamski<sup>5</sup> reported on a 2018 analysis of apheresis programs in two US health systems that demonstrated this variability. One health system performed approximately 800 apheresis procedures per year and reported that peripheral access was used in less than 5% of procedures. Another health system that performed approximately 3500 procedures annually reported peripheral access for 64% of apheresis procedures. The authors surmised that the difference is due, in part, to providers' degree of comfort, use of ultrasound, experience, and technical skills with vascular access for apheresis therapies.<sup>5</sup>

## AVF and AVG Access

AVF and AVG routes provide long-term access. AVF is a surgical connection established between an artery and vein to create draw and return access for apheresis. It provides access via the patient's own vessels and is most frequently used for hemodialysis. AVG is also a surgical connection of an artery and vein; however, synthetic material or live tissue is used to establish draw and return access for apheresis. It is most frequently used for hemodialysis treatments



when the patient's anatomy is not suitable for AVF. Studies performed on hemodialysis patients showed higher rates of morbidity and mortality when associated with the use of tunneled catheters compared to AVF,<sup>2</sup> and AVF has less risk of clotting compared with AVGs. Historically when TA is considered for several years, AVF and AVG have been the preferred conventional options for vascular access.<sup>2</sup> Only physicians who are experienced in apheresis and competent in fistula or graft access techniques should cannulate AVF and AVGs.<sup>5</sup>



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## CVC Access

Non-tunneled CVC systems are generally comprised of rigid, large bore, dual lumen catheters with tapered ends to accommodate high flow rates, withstand draw and return pressures, and allow simultaneous draw and return flow without recirculation. They are most appropriately considered as an option for relatively short-term treatments (ie, 1 – 2 weeks) primarily for inpatients. For long-term treatments, ports and tunneled catheters should be considered because of lower rates of infections compared with non-tunneled catheters.<sup>2</sup> Tunneled CVCs (TCVCs) can be used for treatment that is expected to last from weeks to years. Most TCVCs are dual-lumen catheters (10-13.5 Fr) that are flexible enough to minimize vascular injury, yet sufficiently rigid to preserve patency during high-flow rates.<sup>5</sup> These catheters are “tunneled” through subcutaneous tissue before central vein cannulation as a means to reduce the risks of sepsis and infection by separating the skin insertion site from the vascular access site.<sup>5</sup> Some are designed with a cuff that is located within the subcutaneous tunnel near the skin insertion site that forms a seal between the skin and venous insertion sites as it heals around the catheter, as an added measure to mitigate the risk of infection.<sup>5</sup>

## Implantable Access Devices (Ports)

TCVC with ports are called port-CVC, implantable access devices, or implantable ports. Refer to figures 1 and 2 for two examples. Their use has rapidly grown in patients that require long-term treatment such as in chemotherapy.<sup>8</sup> They may have single or double lumens, the ports and catheters are available in multiple shapes and sizes, and there are no external components. These implantable access ports are said to be a patient-focused option because it does not inhibit activities of daily living like bathing and may improve body image compared to other conventional access options.<sup>8</sup> The procedure for placing an implantable access port is similar to a TCVC; except that a pocket is created at the skin insertion site to allow for complete, subcutaneous implantation of the port. These ports have a self-sealing silicone septum where noncoring needles are passed through to access the port reservoir treatments.<sup>5</sup> Larger gauge needles increase the likelihood for sufficient blood flow. They are designed with a metal stylet inside of a metal catheter that is inserted at a 90-degree angle to the port septum.<sup>5</sup> The needle penetrates the septum of the port every time that it is accessed, therefore, the septum can potentially deteriorate with repeated use, which may necessitate premature replacement of the device.<sup>9</sup>

## Figure 1 | Conventional Port



## Figure 2 | Subcutaneous Apheresis Port



*Image provided by BD*

Providers should evaluate which implantable routes provide the desired access and achieves flow rate requirements. De Simone and Sarode<sup>8</sup> conducted an in vitro experiment to compare flow features of two single-lumen implantable access ports. One of the implantable access ports (Port A) had a round chamber that eliminates dead space and deters sludge buildup. The outlet is set tangentially and creates a spinning flow within the chamber, which is designed to prevent buildup and reduces opportunity for occlusion. The other IAD (Port B) had a spherical internal chamber with no corners and an outlet at the chamber floor. This design is also intended to decrease the likelihood of sludge and clot formation, and therefore decrease the need for tissue plasminogen activator (tPA). The researchers used expired red blood cell units and adjusted the hematocrit to 40% with normal saline (NS) in a 2-L bag. A continuous-flow centrifugation machine operated 1.0-volume TPE with 5% albumin as fluid replacement. Critical alarms were experienced with Port A. It was not able to operate at a flow rate higher than 90 mL/min and multiple alarms were triggered at flow rates of 80 to 90 mL/min. Port B achieved flow rates of up to 110 mL/min without triggering alarms, which suggests that it may be a more suitable access option when flow rates similar to CVC for TPE procedures are needed.<sup>8</sup>

Implantable access ports have the lowest risk for catheter-related bloodstream infections (CRBSIs) compared with other conventional apheresis procedures, especially when the port does not have to be accessed frequently and aseptic technique and other safety protocols are adhered to (ie, flushing and locking protocols.) Maki et al<sup>10</sup> conducted a meta-analysis of 14 prospective studies to evaluate CRBSI risk associated with conventional implantable ports. Their analysis revealed a significantly low rate of CRBSI of 0.1 per 1000 implanted days, which is almost 95% lower than the infection rates associated with TCVC.<sup>10</sup> This is especially important for patients receiving TA procedures that are at increased risk of infection due to concomitant immunosuppression (eg, ECP). Although conventional implantable access ports are effectively used for some apheresis procedures, they are not specifically designed or approved for TA. For example, these ports have the potential to achieve flow rates of 50-60 mL/min, which is suitable for ECP and RBC exchange; however, usually not sufficient for other apheresis therapies that require higher flow rates.<sup>5</sup> See Table 4 for a comparison of the various types of vascular access.



*Image provided by BD*



**TABLE 4 | Comparison of Advantages and Disadvantages Associated with VA Used in TA**

Vascular Access Type	Indications for Use	Advantage	Complications
Peripheral Veins	<ul style="list-style-type: none"> <li>Centrifugal based TA</li> <li>Acute or discontinuous TA</li> </ul>	<ul style="list-style-type: none"> <li>Low rate of infection</li> <li>Immediate use</li> </ul>	<ul style="list-style-type: none"> <li>Patient discomfort</li> <li>Infiltration and sclerosis of veins</li> </ul>
Nontunneled CVC	<ul style="list-style-type: none"> <li>Short term use (&lt;2 weeks)</li> <li>Acute or discontinuous TA</li> <li>Centrifugal or filter-based TA</li> </ul>	<ul style="list-style-type: none"> <li>Can be placed at bedside</li> <li>Blood flow rate high</li> </ul>	<ul style="list-style-type: none"> <li>Risks inherent to catheter insertion</li> <li>Infection</li> <li>Central vein stenosis</li> </ul>
Tunneled CVC	<ul style="list-style-type: none"> <li>Short- or long-term use</li> <li>Centrifugal or filter-based TA</li> </ul>	<ul style="list-style-type: none"> <li>Reduced infection rate compared to nontunneled catheters</li> <li>Blood flow rate high</li> </ul>	<ul style="list-style-type: none"> <li>Risks inherent to catheter insertion</li> <li>Infection, dysfunction</li> <li>Central vein stenosis</li> </ul>
AVF	<ul style="list-style-type: none"> <li>Chronic TA &gt;3 months</li> <li>Centrifugal or filter-based TA</li> </ul>	<ul style="list-style-type: none"> <li>Lowest infection rates and dysfunction compared to other conventional VA</li> </ul>	<ul style="list-style-type: none"> <li>Requires surgery and adequate patient vascular anatomy</li> <li>Requires a approx. 6 to 8 week maturation period prior to use</li> <li>May be associated with primary maturation failure and subsequent need for additional procedure(s)</li> <li>Requires trained staff for cannulation</li> </ul>
AVG	<ul style="list-style-type: none"> <li>Chronic TA &gt;3 months</li> <li>Centrifugal or filter-based TA</li> </ul>	<ul style="list-style-type: none"> <li>Lower infection rates and dysfunction compared to catheters</li> <li>Most may be used within 2 weeks of placement</li> </ul>	<ul style="list-style-type: none"> <li>Requires surgery</li> <li>Requires trained staff for cannulation</li> <li>Higher infection and thrombosis rates compared to AVF</li> </ul>
Totally implantable ports	<ul style="list-style-type: none"> <li>Long-term use (years)</li> </ul>	<ul style="list-style-type: none"> <li>Lower infection rates compared to tunneled CVC, patients able to bathe, swim, and exercise</li> </ul>	<ul style="list-style-type: none"> <li>Infection and thrombosis</li> </ul>

Adapted from Golestaneh L, Mokrzycki MH. Vascular access in therapeutic apheresis. Updated 2013. *J clin apher.* 2013;28(1):64-72. doi: 10.1002/jca.21267.

Kalantari K. The choice of vascular access for therapeutic apheresis. *J clin apher.* 2012;27(3):153-9. DOI: 10.1002/jca.21225

# TOTALLY IMPLANTED VASCULAR ACCESS DEVICES FOR LONG- TERM APHERESIS

## **Novel Design and Functionality of Totally Subcutaneous Apheresis Port**

The number of TA procedures and chronic apheresis patient population is rising and there has been a need for advancements in long-term access options. In 2017, the Food and Drug Administration (FDA) cleared the first totally subcutaneous apheresis port that was specifically designed for long-term apheresis treatment.<sup>11</sup> The innovative design and functionality are substantially different from conventional implantable access ports. Unlike conventional implantable access ports that are cylindrical or round with a septum to penetrate,<sup>12</sup> this novel device is a titanium funnel-shaped port (see Figure 3).

## **Figure 3 | Funnel-Shaped Subcutaneous Apheresis Port**



It is coated in silicone for patient comfort, and the tunnel-shape guides a 14- or 16-gauge IV catheter to an angled needle stop design. The catheter is advanced through a silicone valve that keeps the device closed when not in use and a seal that keeps the device closed while the catheter accessed in the port.<sup>5</sup>

*Image provided by BD*



Conventional implantable access ports are accessed at a 90 degrees angle, but the totally subcutaneous apheresis port can be accessed at 30 degrees,<sup>5</sup> which is an advantage because it alleviates chaotic flow and inefficient flushing often experienced with perpendicular outlets and sludge in dead space often observed with ports with squared corners (see Figure 4).

**Figure 4 | 30-Degree Access of Implantable Port**

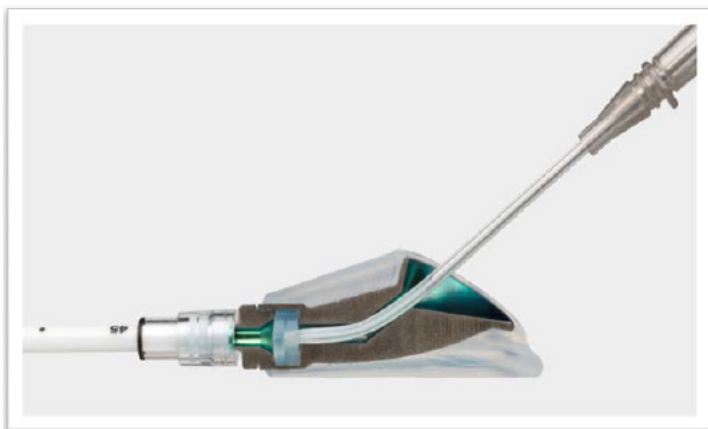


Image provided by BD

The needle can be advanced until it encounters a needle stop, which prevents the needle from being advanced beyond the acceptable seating position, unless excessive force or a smaller gauge catheter is used, which can result in damage or harm to the patient.<sup>13</sup> Refer to Table 5 for the differences between subcutaneous apheresis ports and conventional ports.

**Table 5 | Device Identifiers for Subcutaneous Apheresis Ports and Conventional Ports**

	Subcutaneous Apheresis Port	Conventional Port
Access Angle	30°	90°
Access Needle	14G or 16G catheter-over-needle IV	Huber needle
Entry Method	Catheter opens a valve	Needle pierces septum
Port Shape and Palpation	Funnel shape, palpate funnel top	Triangle shape, palpate for bumps
X-ray Identifier	Round bottom flask	Triangle
Flow Rate	Up to 100 mL/min	Up to 50-60 mL/min

Source: Gill JC, Oakley DJ, Onwuemene OA. Strategies to aid identification of apheresis PowerFlow ports: a case report. *J Emerg Nurs.* 2021;47(1):21-7. DOI: 10.1016/j.jen.2020.10.004

The totally subcutaneous apheresis port is bench tested to withstand at least 1000 accesses and has blood flow rate capability up to 150 mL/min at low system pressure<sup>13</sup> depending on the size of the catheter. Adamski<sup>5</sup> performed more than 70 ECP procedures using the totally subcutaneous apheresis port on five patients with chronic graft-versus-host disease (GVHD) or steroid resistant cutaneous T-cell lymphoma (CTCL). Flow rates of 30 to 50 mL/min were maintained without activating pressure alarms and flow rates up to 100 mL/min during therapeutic plasma exchange procedures were achieved.<sup>5</sup>

Another advantage of the specially designed apheresis port is that it can be used for treatment immediately after placement with options that include:<sup>14</sup>

- two-port placement (one as the access and the other for return), or
- single-port placement (serving as the access and using peripheral cannulation for return, or as part of a discontinuous procedure).

The effect that totally subcutaneous apheresis ports can have on the patients' quality of life should also be carefully evaluated in the coordination of care. When possible, the care team should consider that patients with subcutaneous access report a higher quality of life when compared to patients that have exterior devices. This is largely because subcutaneous devices allow the patient to participate in activities of daily living without much modification from the norm (eg, swimming without covering the site) and maintenance of the totally subcutaneous is simpler. Patients may also feel less self-conscious because subcutaneous devices have minimal visibility on aesthetic appearance. These factors combined with, higher flow rates and reduced infections and complications should be considered.



## COMPLICATIONS AND ADVERSE EFFECTS OF APHERESIS

Vascular access complications vary depending on the type and can occur suddenly or be delayed in their presentation. Complications related to peripheral access include venous infiltration, pain at cannulation sites, thrombosis or sclerosis of veins, infection, and scarring that impedes ongoing or future access. CVC complications are often more serious and include hemothorax, pneumothorax, pneumopericardium, arterial puncture, cardiac arrhythmia, and hematomas. Although all reactions or complications are important for the patient, most are mild and moderate, and severe events are rare. Henriksson et al<sup>15</sup> evaluated the data entered by the apheresis centers that participated in the World Apheresis Association (WAA) apheresis registry. Of the 50846 procedures involving 7142 patients, it was found that more adverse events occurred during initial procedures versus subsequent (8.4 and 5.5%, respectively). AEs were mild in 2.4% (access 54%, device 7%, hypotension 15%, tingling 8%), moderate in 3% (tingling 58%, urticaria 15%, hypotension 10%, nausea 3%), and severe in 0.4% of procedures (syncope/hypotension 32%, urticaria 17%, chills/fever 8%, arrhythmia/asystole 4.5%, nausea/vomiting 4%).<sup>15</sup> This section discusses some of the more common complications. Any changes in condition or new symptoms at the access site should be evaluated by a physician promptly.

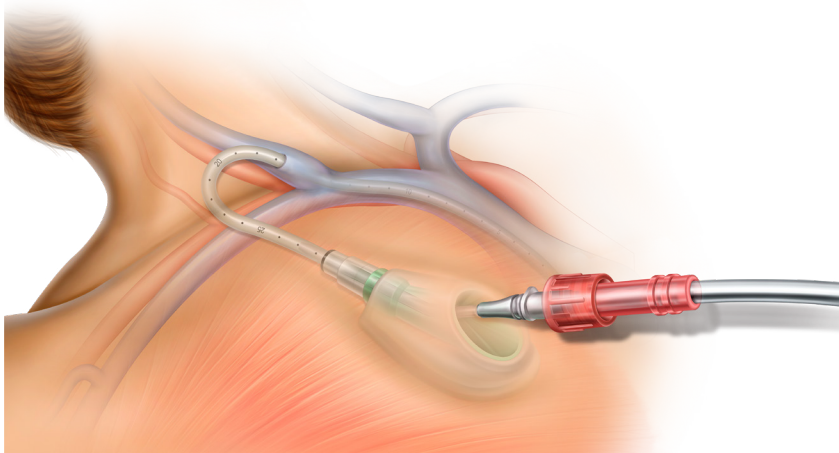


Image provided by BD



## INFECTION

Infection can present within the blood stream or at the access site. Infection at the site or along the subcutaneous tunnel is characterized by erythema, swelling, pain, and/or purulent drainage. Two of the most well-known bloodstream infections are catheter-related bloodstream infections (CRBSI) and central-line blood stream infection (CLABSI). CRBSI is a bloodstream infection that is undeniably associated with the central line, where the patient exhibits the clinical symptoms of infection, and the same organism is identified in the blood and through a culture of the catheter. CLABSI is a bacteremia with at least one positive blood culture, clinical manifestations of infection, and with no identifiable source of infection except the catheter. Treatment of either bloodstream infection is removal of the catheter and administration of antibiotics.<sup>5</sup>

## CATHETER DYSFUNCTION

Catheter dysfunction is failure to achieve sufficient blood flow between the catheter and the apheresis device. Dysfunction early in the process is often due to a mechanical malfunction. (eg, a bend in the catheter or incorrect catheter tip positioning). Using fluoroscopy during venous access placement can mitigate these types of dysfunctions.<sup>5</sup>

Catheter-related sheath (CRS) formation is another common cause of catheter dysfunction that results from a physiologic reaction between the catheter, vein wall, and blood components.<sup>5</sup> When this type of dysfunction occurs, the patient can be referred for radiographic or fluoroscopy evaluation to document catheter tip position. Contrast injection of a normal, functioning catheter should show contrast exiting the end-holes and filling a substantial portion of the vein lumen distal to the tip of the catheter. However, when a sheath has formed, contrast will track in a retrograde fashion along the catheter and leak out into the vein lumen through holes or tears in the sheath.

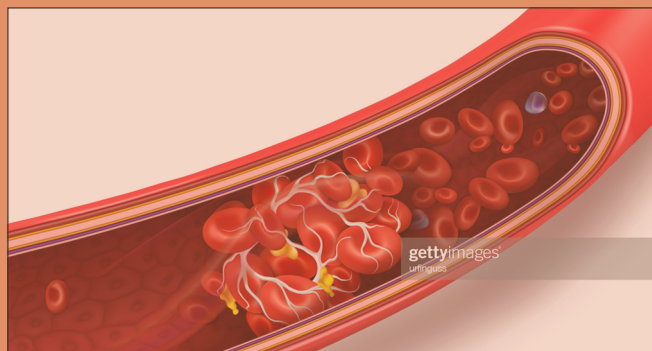
Adamski<sup>5</sup> reports that more than 80% of long-term catheters form a sheath that may extend to the catheter tip that enables infusion, but inhibits withdrawal of blood. Thrombolysis is an initial step that can restore blood flow when a CRS obstructs the catheter tip and may be repeated if adequate flow is not established following the first attempt. If thrombolysis ultimately fails to restore blood flow the catheter should be replaced.<sup>5</sup>

## THROMBUS

A catheter-related venous thrombosis (CRT) is when the thrombus extends into the vessel outside of the access route and compresses an adjacent vein. The reported incidence of CRTs in long-term TCVC or implantable access ports procedures is 7% to 62% and highly dependent on the varied patient populations and devices studied. Underlying hyper-coagulable states, large catheter lumen diameters, and tip positioning are factors that can contribute to CRT. Pulmonary embolism is a life-threatening complication that is estimated to occur in 10% to 15% of patients with CRT and patients are at risk for ischemic stroke if emboli are shunted through the patent foramen ovale into left atrium and brain.<sup>5</sup> Routine catheter flushes and use of anticoagulant locking solutions (eg, heparin) are traditionally used in hopes of preventing this complication.<sup>5</sup> If the vascular access is functional and still required for therapy, it can remain in place if there is no evidence of infection, the tip is in the correct position, and the patient is asymptomatic on systemic anticoagulation therapy.<sup>5</sup>

## CENTRAL VENOUS STENOSIS

Central venous stenosis occurs when there is trauma related to TCVC or implantable access ports access routes where inflamed endothelium produces intimal hyperplasia and fibrosis generating a stenosed scar in the vein. Signs and symptoms often present as swelling, erythema, and pain. In severe cases it can lead to superior vena cava syndrome (SVCS) in and require emergency intervention. The syndrome is characterized by bilateral edema of upper extremities, head, and neck. The risk of venous stenosis can be reduced by selecting implantable access ports with the smallest lumen size to support apheresis flow rates and rotating CVC access sites to minimize venous trauma.<sup>5</sup>



## CLINICAL EVIDENCE

Ipe et al,<sup>16</sup> evaluated the safety and efficacy of a cylindrical conventional implantable access ports compared to the specially designed subcutaneous apheresis port (funnel shaped) in apheresis patients at a 2000-bed community and tertiary care health system. This health system performed an estimated 3400 TA procedures annually. For this study, four patients were implanted with the conventional IAD and four patients were implanted with the totally subcutaneous apheresis port between 2016 and 2017. Researchers found that all patients with the conventional implantable access port experienced an interruption at the beginning of the procedure related to poor flow rates or catheter occlusions (classified as grade III adverse event) (Table 6), which triggered several insufficient flow alarms. Of the four patients with the totally subcutaneous apheresis port, three experienced a grade I adverse event (Table 6) and tolerated the procedure without medication. One of the four patients experienced a grade III adverse event, which required removal of the port. Infection was not noted in any of the patients with the totally subcutaneous apheresis port. The researchers concluded that overall, ports are a preferred option for long-term TA with fewer and less severe complications noted with the totally subcutaneous apheresis port.<sup>16</sup>

**TABLE 6 | Grading of Adverse Events (AEs) Based on Patient Experience and Outcome**

Grading	Measures and Consequences
I - Mild	Tolerated without medication
II - Moderate	Need of medication due to AE
III - Severe	Interruption due to AE
IV - Death	Due to AE

Reference: Henriksson MM, Newman E, Witt V, Derfler K, Leitner G, Eloit S, Dhondt A, Deeren D, Rock G, Ptak J, Blaha M. Adverse events in apheresis: an update of the WAA registry data. *Transfusion and apheresis science*. 2016;54(1):2-15. doi: 10.1016/j.transci.2016.01.003.

Garritty et al<sup>17</sup> conducted a prospective evaluation of the totally subcutaneous apheresis port in four patients undergoing outpatient therapeutic plasma exchange via jugular access over 18 to 97 days. Two patients received albumin as replacement fluid and achieved peak inlet flow of  $99 \pm 5$  mL/min and  $101 \pm 6$  mL/min, and peak plasma flow of  $53 \pm 6$  and  $47 \pm 6$  mL/min. Two patients received plasma as replacement fluid and achieved peak inlet flow of  $46 \pm 7$  and  $85 \pm 4$  mL/min and peak plasma flow of  $27 \pm 3$  and  $35 \pm 4$  mL/min. Although pressure alarms occurred in 6 of the 47 procedures, 5 were resolved quickly by lowering the inlet rate by 10%.<sup>17</sup>

### KNOWLEDGE CHECK

**Which of the following is an advantage of a totally subcutaneous apheresis port?**

- A. It is coated in silicone for patient comfort
- B. It contains a needle stop to prevent damage to the port.
- C. Its funnel shape decreases chance of sludge formation.
- D. All of the above

[\[Click Here for Answer\]](#)



Grenier-Harris and Christen<sup>18</sup> found that their experience with conventional implantable access ports led to discomfort for patient when accessed, repeated needle sticks, no stabilizing device/dressing during treatment, and blood flow was positional, which led to frequent and substantial amounts of alteplase/cathflo needed to establish brisk blood flow to perform the procedure. They sought to evaluate the impact of the totally subcutaneous apheresis port on apheresis nurses, physicians, and patients for ECP procedures. Training and education tools were provided to apheresis nurses and interventional radiology providers who cared for apheresis patients. Practice was completed and competency verified on patient port access. Patients who already had conventional long-term vascular access were switched to totally subcutaneous apheresis ports with more than 85% of active ECP patients implanted with the totally subcutaneous apheresis port. Alteplase/cathflo use decreased from 6.8% in conventional vascular access to less than 1% necessity when the totally subcutaneous apheresis port is used, which has the added benefit of decreased risk of infection and fibrin accumulation in the patient. Fully completed collection without any interruptions (ie, early buffy coat collections) decreased from 15.9% with conventional methods to 7.2% in totally subcutaneous apheresis ports, which suggests that patients are getting more effective treatments. Early buffy coat collections that resulted in  $\leq 1,000$  mL whole blood processed decreased from 3.6 % in conventional vascular access to 1.1%. They also found that the use of an occlusive dressing with the totally subcutaneous apheresis port combined with its flat position on the body of the patient make it more comfortable, safe, and stable. A lower incidence of infection was seen compared to a CVC with external exposure.<sup>18</sup>

**TABLE 7 | Comparison of Cost, Length of Procedure, and Flow Rate Between Conventional and Totally Subcutaneous Apheresis Ports in Two Patients**

	Average Cost of Procedure	Average Time of Procedure (min)	Average Flow Rate (mL/min)
Patient A-conventional x2	\$1059.34	92	62
Patient A-subcutaneous x2	\$306.00	77	81
Patient B-conventional x1	\$179.78	133	45
Patient B-subcutaneous x1	\$89.51	119	50

Adapted from Williams III LA, Arnesen C, Gunn C, Boshell MN, Pham HP, Guillory B, Adamski J, Marques MB. New subcutaneous PowerFlow port results in cost and time savings in a busy outpatient apheresis clinic. *J clin apher*. 2019;34(4):482-6. DOI: <https://doi.org/10.1002/jca.21678>

Williams et al<sup>19</sup> compared the cost and time necessary to complete apheresis procedures using conventional implantable access ports and the totally subcutaneous apheresis port on two long-term TA patients undergoing at least 10 procedures with each type of port. The cost of needles, thrombolytic therapy, staff time, procedure length, and the total time the patient was in the apheresis unit was examined in addition to flow rates, and alarm rates between the two ports (see Table 7). The totally subcutaneous apheresis port resulted in substantial cost and time savings related to a decreased need for thrombolytic agents prior to procedures and the time savings from faster inlet flow rates, fewer pressure alarms, and less time waiting for thrombolytic agents to dissolve existing clots. In one patient switching vascular access device types to the totally subcutaneous apheresis port reduced the average procedure cost from \$1059.34 to \$306.00.<sup>19,20</sup>

## Reported Complications and Limitations

In general, ports can be relatively easy to maintain after placement with periodic flushing. In a study of 700 port placements in the surgical literature, 18% had complications.<sup>14</sup>

In 2019 Gray et al<sup>21</sup> evaluated the performance and adverse events with totally subcutaneous apheresis ports used in 18 TA patients from 2017 through 2019. Flow rates up to 90 mL/min were achieved and impeded only by patient tolerance. Infection was observed with an estimated risk of associated bloodstream infection of 0.18 per 1000 intra-vascular device days in the population studies. Other complications included obstruction due to fibroblastic sleeve and migration of the vascular device.<sup>21</sup>



In another study, Williams et al<sup>20</sup> reported on potential initial limitations and barriers to implementing the totally subcutaneous apheresis port. Their facility is the only major apheresis center for many surrounding states, where they perform TA for patients from five states covering a 260-mile radius. They found that using totally subcutaneous apheresis ports in all referred patients undergoing chronic outpatient apheresis procedures was not reasonable because their patients also received other infusions and treatments via their ports closer to where they live. The geographic location of the facility, access to devices, and the patients' specific needs are factors that may impact the decision for health care facilities to use this new technology. Therefore, some facilities may need to have a plan for addressing referred patients, stocking the device, and facilitating widespread training.<sup>20</sup>

## APHERESIS QUICK FACTS



**The American Society for Apheresis (ASFA) issues guidelines and recommendations on the use of TA in clinical practice**



**Apheresis patient settings vary from outpatients to inpatients, ranging from scheduled procedures to emergencies**



**Duration of apheresis procedures is often < 3 hours**



**Depending on disease state, frequency of treatment ranges from weekly to every 3 months**



**In centrifuge procedures, citrate or heparin-based anticoagulation solutions are used to prevent clotting**

## COMPETENCIES, POLICY AND PROCEDURES

Apheresis is a medical procedure that can have significant physiologic consequences for patients. It is performed in a range of inpatient and outpatient settings (ie, intensive care units (ICUs), oncology units, general patient care units) by physicians and nurses who may specialize in apheresis. Some nurses perform apheresis a limited amount of time as part of a wider role (ie, ICU nurses) or a specialty clinical setting where they only perform apheresis procedures.<sup>22</sup>

As discussed earlier in the content, physicians and nurses may observe similarities and differences between totally subcutaneous apheresis ports and conventional ports, so facilities need to have training available to help with correct port identification and use. Gill et al<sup>23</sup> illustrates this need through a case study where a patient with a history of apheresis procedures and bilateral totally subcutaneous apheresis ports was evaluated in the emergency department (ED) for an acute exacerbation of neuromyelitis optica. The totally subcutaneous apheresis ports were mistaken for conventional ports, and one was accessed with a Huber needle rather than an appropriate over-the-needle catheter. The patient experienced pain and swelling during infusion of fluids and the port malfunctioned causing a need to be replaced.<sup>23</sup>

In another example, Johnson and Li<sup>24</sup> describe a case where a TA patient received the incorrect port despite numerous communications with the patient and their health provider's office about the importance of specifically ordering the totally subcutaneous apheresis port. Ultimately a conventional port with a similar name was placed. The error was recognized during the initial apheresis treatment where numerous access alarms occurred despite multiple needle adjustments, patient repositioning, and decreasing the inlet flow rate. The procedure was terminated, and the patient was transferred to interventional radiology for port replacement. It was discovered that the physician's office placed the correct order for the totally subcutaneous



apheresis port, but the interventional radiology team inadvertently selected a conventional port. There was additional delay in discovery of this error because apheresis nurses were not proficient in how to distinguish between the ports. This type of error can lead to delay in treatment, additional unanticipated procedures, increased cost and time, and patient discomfort and dissatisfaction. This case study serves as a cautionary tale that correct identification of the port through manufacturer's labeling and manual palpation can decrease the incidence of incorrect port placement.<sup>24</sup>

It is vital that physicians and nurses who care for apheresis patients have the education and aids to improve port identification and access. Furthermore, health care facilities should have policies and procedures, qualified apheresis physicians and nurses, validated machine and devices, and a mechanism to report and investigate adverse events.

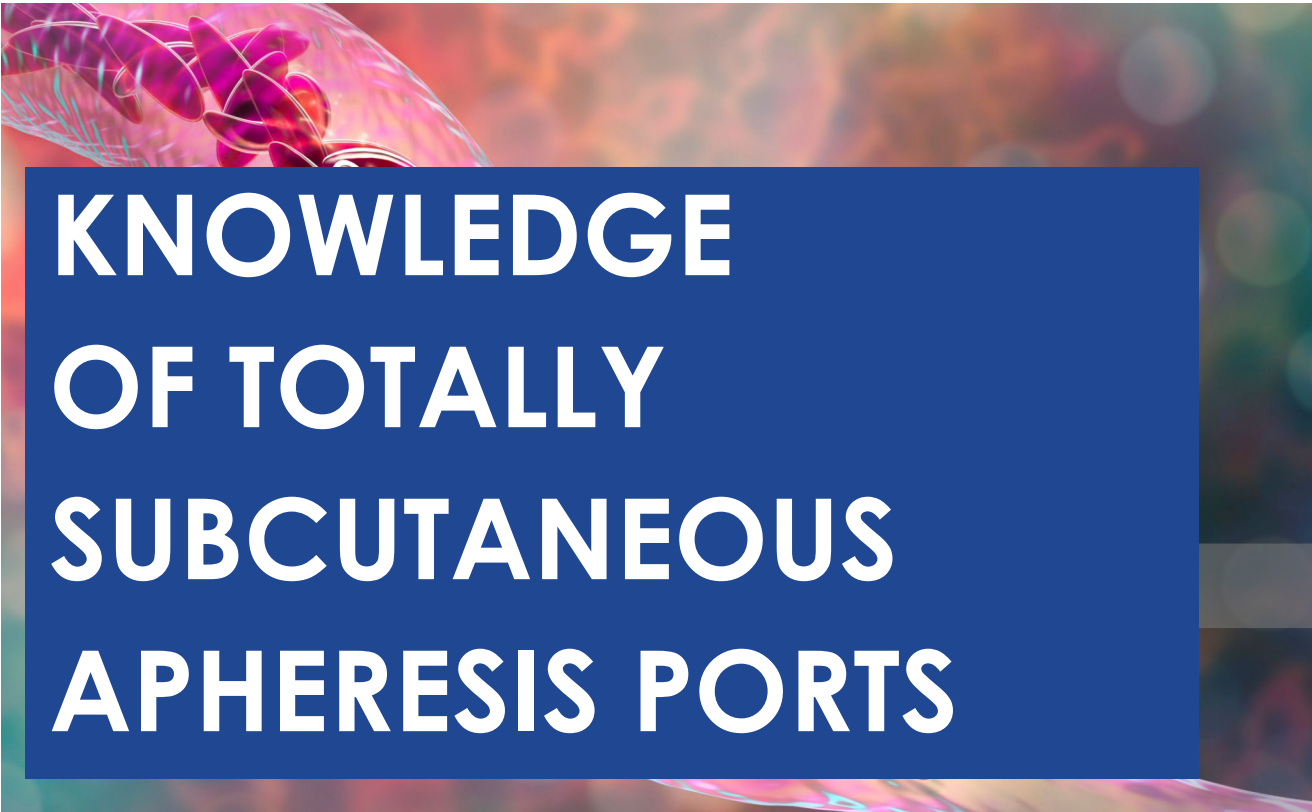
### KNOWLEDGE CHECK

**Which of the following NOT a complication associated with central venous catheters?**

- A. Deep vein thrombosis
- B. Arterial puncture
- C. Hemothorax
- D. Cardiac arrhythmia

[\[Click Here for Answer\]](#)

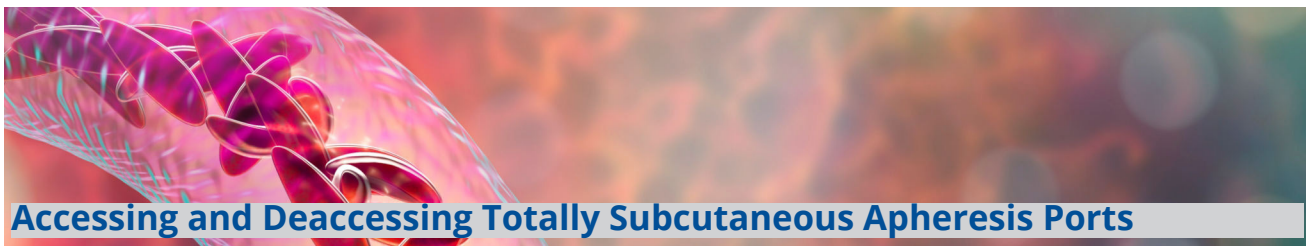




# KNOWLEDGE OF TOTALLY SUBCUTANEOUS APHERESIS PORTS

Knowledge of TA encompasses patient experience factors such as social, emotional, and ethical aspects as well as technical competency regarding the equipment. Nurses should be able to verbalize and demonstrate the necessary skills of the process and how to perform them successfully.

Before placing totally subcutaneous apheresis ports, be sure to know the indications for using the device, verify whether the device is a power port or nonpower port, and be able to differentiate it from other devices.<sup>25</sup> Provide procedural education to the patient and discuss their pain tolerance and preference for local anesthetic should be understood. The site and surrounding area should be assessed for the signs and symptoms of infection, thrombus, infiltration, or extravasation prior to apply anesthetic. Be aware of the correct catheter tip placement for insertion and document it correctly in the patient's medical record. Verbalize every step of the technique to aseptically set up the sterile field, locate and identify the port via palpation, and how to scrub the site. Familiarity with the type of IV needle, angle to access the port, and method required for inserting the needle while advancing the catheter is paramount. Be able to describe how the device is stabilized as the funnel-shaped entrance of the port is palpated and the method for engaging the needle safety mechanism, being mindful of the risk of air embolus. Know the method of aspiration to confirm correct placement of the catheter after insertion within the port prior to connecting it to the apheresis machine. Understand the method for securing and dressing the IV catheter after insertion into the port as well as the steps for deaccessing it while continuously flushing with locking solution to maintain positive pressure to prevent backflow and clotting.<sup>26</sup> Flushing with locking solution helps prevent clot formation and catheter blockage. The type of locking solution and volume depends on how the device is used. The port's open-ended catheter should be filled with sterile locking solution after each use and if the port is unused for long periods of time, the solution should be changed at least once every four weeks.<sup>26</sup>



## Accessing and Deaccessing Totally Subcutaneous Apheresis Ports

Before beginning the procedure, always perform hand hygiene. Verify the correct patient using two identifiers. Explain the procedure to the patient and confirm consent for treatment. The patient should be in a comfortable position with privacy. The procedure site and surrounding area over and around the port should be free of signs and symptoms of infection, infiltration, thrombus, or extravasation before applying anesthetic. If any signs are present, notify the patient's provider before proceeding.<sup>25</sup>

Palpate the subcutaneous tissue over and surround the implanted port to establish borders and locate the port funnel. Performed hand hygiene, don a mask, and assist the patient with their mask. Open the sterile dressing kit (maintaining sterility of inside of wrapper sterile to be used as sterile field), additional supply packages, and appropriate needle and drop them onto sterile field maintaining sterility.<sup>25</sup>

Perform hand hygiene, don sterile gloves, and cleanse insertion area with greater than 0.5% chlorhexidine in alcohol solution using back-and-forth motion for at least 30 seconds and allow the area to dry completely. If chlorhexidine contraindicated, used betadine scrub or 70% alcohol instead. Stabilize the port with the sterile gloved nondominant hand and palpate funnel-shaped port entrance and use a shallow angle of accesses (approximately 30 degrees) to insert a 14- or 16-gauge over-the-needle IV catheter into the funnel. Slide the needle to the stop when resistance is felt. Slightly separate the needle from the catheter hub, pull the needle away from the stop, advance the catheter completely through the value withdrawing the needle while the patient performs the Valsalva maneuver.<sup>25</sup> This maneuver is a physiological technique used to reduce venipuncture pain and anxiety by a somatic and distraction process. The patient performs the maneuver by keeping the mouth closed and pinching the nose, while exhaling forcefully for a period of 20 seconds.<sup>27</sup> Immediately attach the saline primed extension wet with the 10 mL syringe to the IV catheter hub to prevent air from entering the port. Check the patency of the port by aspirating for blood return and flush the port with 0.9% sodium chloride. Be careful to not apply too much force or use the port if unable to obtain blood return.<sup>25</sup>

## Deaccessing Totally Subcutaneous Apheresis Ports

Perform hand hygiene. Choose the appropriate flush solutions of 20 mL saline followed by 500 units of heparin. Flush with saline and perform locking solution procedure by instilling heparin while withdrawing IV catheter to maintain positive pressure. Once the catheter is removed, apply pressure with a 2x2 gauze and assess the site for bleeding. Dress the catheter port site with new 2x2 dressing secured with band aid and perform hand hygiene.<sup>25</sup> See Table 8 for a summary of these procedures.

**TABLE 8 | Sample Standard Operating Procedure (SOP) for Totally Subcutaneous Apheresis Port**

<b>Access Materials</b>	<ul style="list-style-type: none"> <li>a. Shielded IV catheters 16G or 14G. 1.75 inches or longer should be used. Do NOT use non-coring needles</li> <li>b. Extension set with clamps</li> <li>c. 10mL or larger syringe filled with sterile normal saline</li> <li>d. Gloves, masks, and other items for cleaning and dressing the access site</li> </ul>
<b>Identify</b>	<ul style="list-style-type: none"> <li>a. Use palpation to locate the port</li> <li>b. Place finger on the high point of the port to identify the top of the funnel</li> <li>c. The funnel should feel concave and hollow</li> </ul>
<b>Prep</b>	<ul style="list-style-type: none"> <li>a. Prime the extension set and prepare other access materials</li> <li>b. Clean the access site per manufacturer's instructions, or per institute policy</li> </ul>
<b>Accessing the Port</b>	<ul style="list-style-type: none"> <li>a. Stabilize port with nondominant, sterile gloved hand and palpate funnel</li> <li>b. Use a shallow angle of access, insert the needle into the funnel, and slide it to the stop</li> <li>c. Pull the needle away slightly to separate it from the IV catheter hub</li> <li>d. Advance the catheter completely while continuing to pull the needle slightly away</li> <li>e. The catheter should advance a minimum of 1.5 cm to assure adequate passage through the valves</li> <li>f. If the patient can perform the Valsalva maneuver, the risk of air aspiration can be reduced</li> <li>g. Withdraw the needle and engage the safety feature</li> <li>h. Immediately attach the primed extension set</li> <li>i. Aspirate for blood return and flush with sterile saline solution</li> <li>j. Securely dress the site per hospital protocol</li> </ul>
<b>Deaccessing the Port</b>	<ul style="list-style-type: none"> <li>a. Flush port with sterile saline solution</li> <li>b. Perform locking procedure and withdraw the IV catheter while flushing continuously with locking solution. This will reduce the chance of blood backflow back into the catheter tip</li> <li>c. Apply pressure as needed if bleeding occurs at the site, and apply a dressing per hospital protocol</li> <li>d. Folded gauze may be used to support the catheter to optimize flow.</li> <li>e. For continuous access, change the IV catheter and transparent dressings every 72-96 hours, or as needed</li> <li>f. CAUTION: Some patients are hyper-sensitive to heparin or may have heparin-induced thrombocytopenia (HIT). Do not lock the port with heparin on these patients.</li> </ul>

Adapted from Bard. PowerFlow Implantable Apheresis IV Port Access Instructions for Use. <https://www.bd.com/assets/documents/pdh/initial/0744428-1705R-PowerFlow.pdf>. Accessed October 28, 2021.



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## SUMMARY

Apheresis therapies have an important and growing role in the treatment of many diseases. A stable, functioning vascular access site helps to minimize complications and maximize the efficiency of the procedure. Access methods, device types, and flow rates are critical decisions for TA of which physicians and nurses should have a fundamental understanding. The apheresis team should work together to assess the indication for therapy, treatment schedule, appropriate fluid replacement, therapeutic goal, and efficacy of therapy for each patient.

TA cannot be performed without adequate vascular access and the ability to achieve inlet flow rates of approximately 50 to 100 mL/min. Conventional CVCs are capable of such performance; however, their use has several associated risks, some of which can be mitigated if peripheral venous access can be established. However, in some patients, peripheral vascular access is not an option for long-term apheresis treatments. In these situations, totally subcutaneous apheresis ports are increasingly used because they offer advantages such as low rates of infection, long-term usage, patient comfort, and improved quality of life.

## KNOWLEDGE CHECK

**Before placing totally subcutaneous apheresis ports be sure to \_\_\_\_.**

- A. know the indications for using the device
- B. confirm consent for treatment
- C. be able to differentiate it from other devices
- D. all of the above

[\[Click Here for Answer\]](#)

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## GLOSSARY

**Adverse Event(s):** Any untoward occurrence associated with the collection, testing, processing, storage, and distribution of blood or blood components that might lead to death or life-threatening, disabling, or incapacitating conditions for patients or which results in, or prolongs, hospitalization, or morbidity.

**Apheresis:** A process in which whole blood is collected from a donor and separated into components. Some of these are retained and the remainder is returned to the donor.

**Blood Component(s):** A therapeutic constituent of human blood (red cells, white cells, platelets, plasma, cryoprecipitate).

**Blood Product:** Any therapeutic product derived from human whole blood or plasma donations.

**Buffy Coat:** The granulocyte and platelet layer that forms between red cells and plasma when a pack of whole blood is centrifuged under suitable conditions.

**Catheter-Related Bloodstream Infection (CRBSI):** The presence of bacteremia originating from an intravenous catheter.

**Catheter-Related Sheath:** A common complication of central venous catheters where infection occurs due to bacteria harboring within the fibrin sheath.

**Central Line-Associated Blood Stream Infection (CLABSI):** A laboratory-confirmed bloodstream infection not related to an infection at another site that develops within 48 hours of a central line placement.

**Central Venous Catheter (CVC):** An indwelling device that is peripherally inserted into a large, central vein (most commonly the internal jugular, subclavian, or femoral), and advanced until the terminal lumen resides within the inferior vena cava, superior vena cava, or right atrium.

**Centrifugation:** In apheresis it is the use of centrifugal force to separate components according to specific gravity.

**Colloid Solutions:** Gelatin, dextran, starch preparations (artificial colloids) that are used as plasma expanders.

**Extracorporeal Photopheresis (ECP):** A therapeutic procedure in which buffy coat, separated from patient's blood, is treated extracorporeally with a photoactive compound and exposed to ultraviolet A light and subsequently reinfused to the patient during the same procedure.

**Filtration:** In apheresis it is the use of permeable membranes to separate components of blood according to molecular weight.

**Implantable Access Device:** A subcutaneously implanted central venous access device that provides quick venous access for patients with inadequate peripheral veins.

Also referred to as port-CVC or conventional implanted ports in this educational activity.

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**LDL Apheresis:** The selective removal of low-density lipoproteins from the blood with the return of the remaining components.

**Plasma:** The liquid portion of the blood in which the cells are suspended. Plasma may be separated from the cellular portion of a whole blood collection for therapeutic use as fresh frozen plasma or further processed to cryoprecipitate and cryoprecipitate-depleted plasma for transfusion.

**RBC Exchange:** A therapeutic procedure in which blood of the patient is passed through a medical device, which separates red blood cells from other components of blood, the red blood cells are removed and replaced with donor red blood cells alone and colloid solution.

**Superior Vena Cava Syndrome (SVCS):** A condition caused when the superior vena cava is partially blocked or compressed and blood flow through the superior vena cava is slowed down.

**Therapeutic Apheresis (TA):** A therapeutic procedure in which a blood of the patient is passed through an extracorporeal medical device, which separates components of blood to treat a disease.

**Therapeutic Plasma Exchange (TPE):** A therapeutic procedure in which blood of the patient is passed through a medical device, which separates out plasma from other components of blood, the plasma is removed and replaced with a replacement solution such as colloid solution or combination of crystalloid/colloid solution.

**Thrombolytics:** A group of medications in the plasminogen activator class of drugs used in the management and treatment of dissolving intravascular clots.

**Tunneled Central Venous Catheter (TCVC):** CVC access where the external portion of the catheter is tunneled under the skin and secured for long-term therapy.

**Valsalva Maneuver:** Forced expiration against a closed glottis that causes an increase in intrathoracic pressure, leading to a reduction in preload to the heart. It is a proven method of attenuating pain and anxiety caused by venipuncture.

**Vascular Access:** A direct method of introducing or removing components from the bloodstream.

**Whole Blood:** Blood collected from a donor before separation into red cells, platelets, and plasma.



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## REFERENCES

1. YaleMedicine. Apheresis. <https://www.yalemedicine.org/conditions/apheresis>. Published October 28, 2019. Accessed November 8, 2021.
2. Kalantari K. The choice of vascular access for therapeutic apheresis. *J clin apher*. 2012;27(3):153-9. doi: 10.1002/jca.21225.
3. Padmanabhan A, Connelly-Smith L, Aqui N, Balogun RA, et al. Guidelines on the use of therapeutic apheresis in clinical practice—evidence-based approach from the Writing Committee of the American Society for Apheresis: the eighth special issue. *Journal of clinical apheresis*. 2019;34(3):171-354.
4. American Society for Apheresis. Five Things Physicians and Patients Should Question. Updated 2019. <https://www.choosingwisely.org/societies/american-society-for-apheresis/>. Accessed October 26, 2021.
5. Adamski J. Vascular access considerations for extracorporeal photopheresis. *Transfusion*. 2018;58:590-7. doi: 10.1111/trf.14500.
6. Golestaneh L, Mokrzycki MH. Vascular access in therapeutic apheresis: update 2013. *J clin apher*. 2013;28(1):64-72. doi: <https://doi.org/10.1002/jca.21267>.
7. Malchesky PS, Koo AP, Skibinski CI, et al. Apheresis technologies and clinical applications: the 2007 international apheresis registry. *Ther Apher Dial*. 2010;14:52-73. doi: 10.1111/j.1744-9987.2009.00716.x.
8. De Simone N, Sarode R. A tale of two ports: an in vitro comparison of flow characteristics for therapeutic plasma exchange. *Transfusion*. 2018;58:605-8. doi: 10.1111/trf.14494.
9. Tanhehco YC, Zantek ND, Alsammak M, Chhibber V, Li Y, Becker J, Wu DW, Foster T, Wehrli G. Vascular access practices for therapeutic apheresis: results of a survey. *J clin apher*. 2019;34(5):571-8. doi: 10.1002/jca.21726.
10. Maki DG, Kluger DM, Crnich CJ. The risk of bloodstream infection in adults with different intravascular devices: a systematic review of 200 published prospective studies. In: *Mayo Clinic Proceedings*. 2006;81(9):1159-1171. Elsevier. doi: 10.4065/81.9.1159.
11. Ryan MJ. Food and Drug Administration. Approval letter: PowerFlow™ implantable apheresis IV port. Silver Spring (MD). 2017. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf16/K163001.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf16/K163001.pdf). Accessed on October 27, 2021.
12. Lin DM, Wu Y. Implantable vascular access devices—past, present, and future. *Transfusion*. 2018;58:545-8. doi: 10.1111/trf.14485.
13. Blanco-Guzman MO. Implanted vascular access device options: a focused review on safety and outcomes. *Transfusion*. 2018;58:558-68. doi: 10.1111/trf.14503.
14. Ipe TS, Marques MB. Vascular access for therapeutic plasma exchange. *Transfusion*. 2018;58:580-9. doi: 10.1111/trf.14479.
15. Henriksson MM, Newman E, Witt V, et al. Adverse events in apheresis: an update of the WAA registry data. *Transfusion and apheresis science*. 2016;54(1):2-15. doi: <https://doi.org/10.1016/j.transci.2016.01.003>.

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16. Ipe T, Leveque C, Salazar E. Apheresis Ports: The Houston Methodist Experience. *Am J Clin Path*. 2018;150:S167-8. doi: 10.1093/ajcp/aqy112.386.
  17. Garrity D, Graves M, Linden J, St. Pierre P, Ducharme P, Zhao Y, Greene M, Vauthrin M, Weinstein R. Performance characteristics of the PowerFlow apheresis port: early experience. *J clin apher*. 2019;34(6):661-5. doi: 10.1002/jca.21743.
  18. Grenier-Harris AM, Christen ME. Improving Efficiency in Extracorporeal Photopheresis (ECP) Treatment with Use of Specially Designed Implanted Apheresis Port. *Biology of Blood and Marrow Transplantation*. 2020;26(3):S352. doi: 10.1016/j.bbmt.2019.12.176.
  19. Williams III LA, Arnesen C, Gunn C, Boshell MN, Pham HP, Guillory B, Adamski J, Marques MB. New subcutaneous PowerFlow port results in cost and time-savings in a busy outpatient apheresis clinic. *J clin apher*. 2019;34(4):482-6. doi: 10.1002/jca.21678.
  20. Williams 3rd, L. A., et al. Exclusive use of PowerFlow ports may not be appropriate for all patients. *J clin apher*. 2020;35(1):66-68. doi: 10.1002/jca.21749.
  21. Gray KL, Steidley IG, Benson HL, Pearce CL, Bachman AM, Adamski J. Implementation and 2-year outcomes of the first FDA-approved implantable apheresis vascular access device. *Transfusion*. 2019;59(11):3461-7. doi: <https://doi.org/10.1111/trf.15512>.
  22. Potok D et al. The nurse's role in therapeutic apheresis. *Nursing Times*; 2016;112(2)online;4-6. <https://www.nursingtimes.net/clinical-archive/haematology/the-nurses-role-in-therapeutic-apheresis-07-06-2016/>. Accessed October 27, 2021.
  23. Gill JC, Oakley DJ, Onwuemene OA. Strategies to aid identification of apheresis PowerFlow ports: a case report. *J Emerg Nurs*. 2021;47(1):21-7. doi: 10.1016/j.jen.2020.10.004.
  24. Johnson M, Li M. Implant- able ports for therapeutic apheresis: A cautionary tale. *J Clin Apher*. 2019;34:613–614. doi: 10.1002/jca.21702.
  25. SSM Health, St. Louis University Hospital. Apheresis PowerFlow access training/competency. PDF.
  26. C. R. Bard, Inc. The Powerflow™ IV port – CT guide. <https://www.bd.com/assets/documents/pdh/initial/BPV-PRT3-0117-0013-v1.1-PowerFlow-CT-Guide.pdf>. Accessed October 5, 2021.
  27. Srivastava A, Kumar S, Agarwal A, et al. Evaluation of efficacy of Valsalva for attenuating needle puncture pain in first time nonremunerated voluntary plateletpheresis donors: A prospective, randomized controlled trial. *Asian J Transfus Sci*. 2021;15(1):68. doi: 10.4103/ajts.AJTS\_95\_20.



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