

Vortex® Ports vs. Conventional Ports



RESIDUAL DEPOSITS

Residual deposits consist of blood solids, precipitates and other materials that may accumulate in the port chamber during and between



Sludge formation

procedural fluid exchanges. These deposits, also commonly referred to as *sludge*, are harmful in that

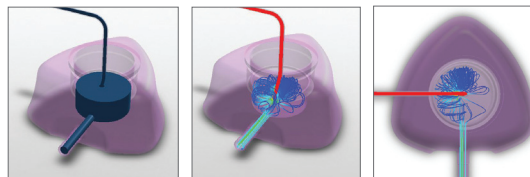
they restrict or occlude flow and are a locus site for infection. Often, the deposits cannot be safely cleared and additional surgical procedures are required.

As sludge forms, the rate of formation increases rapidly. The initial deposits act as a filter that grows in size and efficiency as more and more solids are collected.

The improvement of the Vortex design over conventional ports has been demonstrated clinically in a number of studies, most notably in **"A Randomized, Prospective Trial of Conventional Vascular Ports vs. The Vortex "Clear-Flow" Reservoir Port in Adult Oncology Patients"** which was first published in the *Journal of Vascular Access Devices (JVAD)* – The official publication of the Association for Vascular Access (AVA).

FACTORS AFFECTING THE FORMATION OF RESIDUAL DEPOSITS IN CONVENTIONAL PORTS^{1,2,3,4}

A primary factor impacting the propensity of a port system to develop deposits is the internal geometry of the port itself. Conventional ports have cylindrical geometry with square corners at the base and septum and an exit stem placed perpendicularly to the chamber.



Conventional port velocity streamlines

Fluid flow studies confirm that this design results in dead spaces behind the needle and in corners where solids may collect and adhere. Laboratory studies validate this.



Before 5ml flush

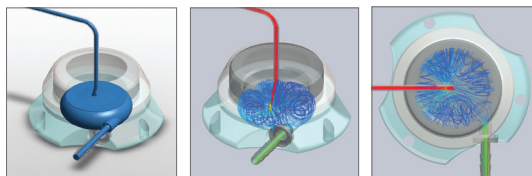


After 5ml flush

Laboratory studies conducted under simulated clinical conditions (5 ml flush at 1 ml/s). Residual solids are clearly visible in the region behind the needle exit.

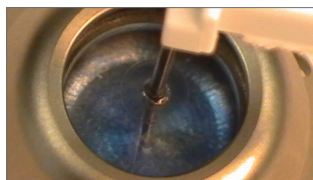
HOW RESIDUAL DEPOSITS ARE MINIMIZED THROUGH THE VORTEX PORT DESIGN

The internal geometry of AngioDynamics' Vortex ports differs substantially from conventional ports. The Vortex ports have elliptical geometry with no internal corners and the exit placed tangentially to the chamber.

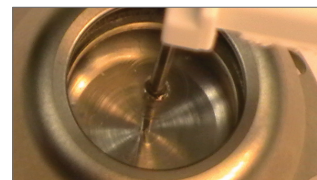


Vortex port velocity streamlines

Fluid flow develops into a toroidal vortex, that hyper-cleanses the chamber by removing small solids before they accumulate into residual deposits.



Before 5ml flush



After 5ml flush

Laboratory studies conducted under simulated clinical conditions (5 ml flush at 1 ml/s) confirm the fluid dynamics and verify that solids are completely removed.

PROPER CARE AND MAINTENANCE OF VASCULAR ACCESS PORTS

The following guidelines for implanted port maintenance and site care are a combination of the most current recommendations from the foremost organizations, including:

- Oncology Nursing Society 2004 Access Device Guidelines⁶
- Infusion Nurses Society 2006 Standard of Practice⁷
- Centers For Disease Control 2002 Guidelines for Infection Prevention⁸
- Additional guidelines can be found in the AngioDynamics Smart Port[®] CT Instructions For Use

DRESSINGS

The Oncology Nursing Society (ONS) recommends the following for Implanted Port dressings⁶:

- For continuous access, change non-coring needle and transparent dressing every week if non-occlusive
- Gauze dressing change every other day or immediately if dressing is wet, soiled or non-occlusive

FLUSHING

Oncology Nursing Society (ONS) recommendations for Venous Ports⁶:

- 10–20 mL of normal saline after infusion or withdrawal
- Heparin 100 units/mL, 5 mL every month or every six weeks and after each use
- Normal saline flush before and after use

NEEDLE CHANGE

- ONS recommends needle changes every week for continuous access⁶

1. Swerdlow P.S., "Red Cell Exchange in Sickle Cell Disease", Hematology, Jan 2006; 2006: 48–53
2. McCabe. L.M., Smith. J.C. Unit Operations of Chemical Engineering, McGraw-Hill, 1976 52–53
3. Deen,W.M. Analysis of Transport Phenomena. Oxford University Press, New York, 1998.
4. Solidworks Flow Simulation 2009 Technical Reference
5. Stevens B., Barton, S. E., Brechbill M., Moenter S., Piel A. L., Shankle D. A Randomized, Prospective Trial of Conventional Vascular Ports vs. The Vortex "Clear-Flow" Reservoir Port in Adult Oncology Patient. JVAD, 2000.
6. Camp-Sorrell, D., ed. Access Device Guidelines: Recommendations for Nursing Practice and Education. 2nd ed. Pittsburgh: Oncology Nursing Society; 2004.
7. Infusion Nurses Society. January/February 2006. Infusion Nursing Standards of Practice. Journal of Infusion Nursing. Volume 29, Number 15.
8. Centers for Disease Control and Prevention (CDC). August 9, 2002. Guidelines for the Prevention of Intravascular Catheter-Related Infections. Morbidity and Mortality Weekly Report (MMWR). Volume 51, Number RR-10.

IMPORTANT RISK INFORMATION

The following is a brief summary of important risk information for the Smart Port[®] power-injectable port line. For detailed information on the categories referenced, please consult the instructions for use packaged with each device. Observe all instructions prior to use. Failure to do so may result in patient complications.

INDICATION FOR USE: The Smart Port[®] CT power injectable port line is indicated for any patient requiring repeated access of the vascular system for delivery of

medications, nutritional supplementation, fluids, blood, blood products, sampling of blood and power injection of contrast media for imaging. **MP and LP models:** Use of non Y site LifeGuard[™] Safety Infusion Set (size = 20Ga or 19Ga) is indicated for power injection of contrast media. For power injection of contrast media, maximum recommended infusion rate is 5ml/sec.

CONTRAINDICATIONS: Smart Port[®] CT should not be implanted in the presence of known or suspected infections, bacteremia, septicemia and peritonitis, or in patients who have exhibited prior intolerance to the

materials of construction, or patients whose body size or tissue is insufficient to accommodate the size of the port or catheter.

WARNINGS AND PRECAUTIONS: Please see package insert for complete list of warnings and precautions.

POTENTIAL COMPLICATIONS: Consult package insert for a complete list of potential complications.

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

ANGIODYNAMICS[®]

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