

SmartPort⁺

with Vortex and Endexo Technologies

The Port Your Patient Deserves.



Vortex Technology

Reduce chamber occlusions. Increase nursing efficiency.
Reduce overall interventions.

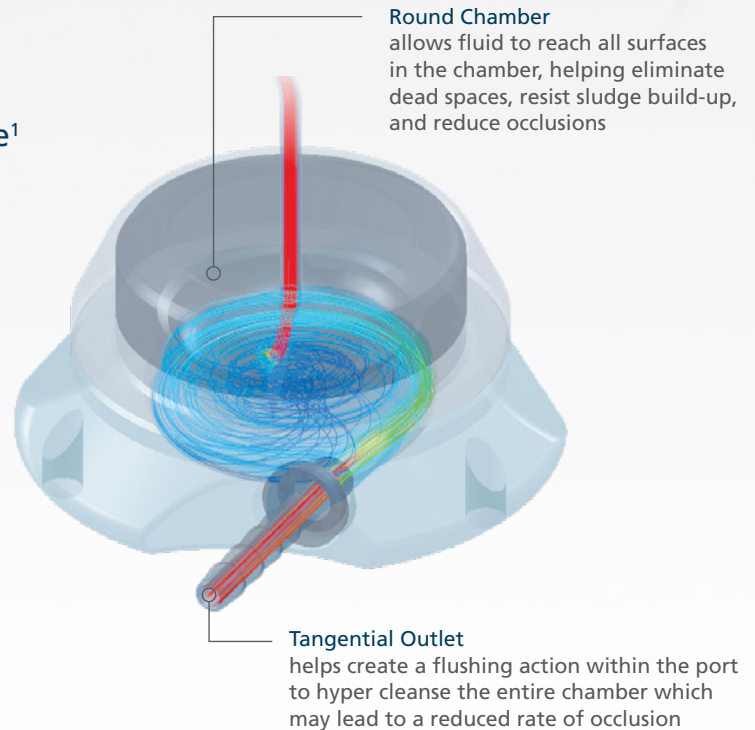
A comparison of conventional vs. Vortex chambered ports shows a clear advantage¹

Vortex Technology demonstrated

73% fewer port occlusions¹

69% fewer secondary interventions¹

Use of Vortex port technology results in
\$1,224_{USD} average savings per patient over conventional ports²



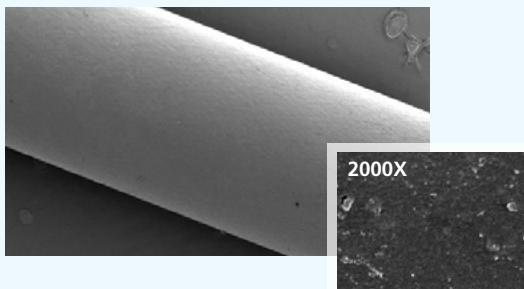
BioFlo Catheter with Endexo Technology

Proven to Reduce Thrombus Accumulation, In Vitro³

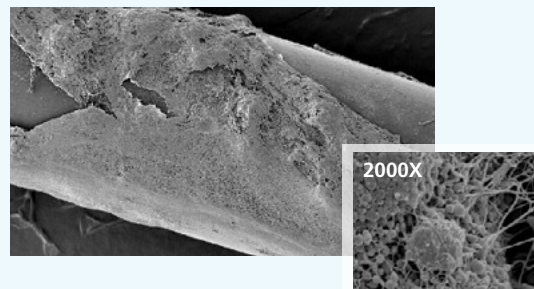
Endexo Technology is a permanent and non-eluting polymer that is "blended" into the polyurethane from which the catheter is made and is present throughout the entire catheter. Endexo Technology remains present for the life of the catheter and provides a catheter material more resistant to thrombus accumulation³

SEM (Scanning Electron Microscopy) Images

BioFlo Port at 15X magnification
Catheter has no visible thrombus, fibrin sheath, or clot.



BD PowerPort with ChronoFlex catheter at 15X magnification
Catheter has significant thrombus, fibrin sheath, or clot.



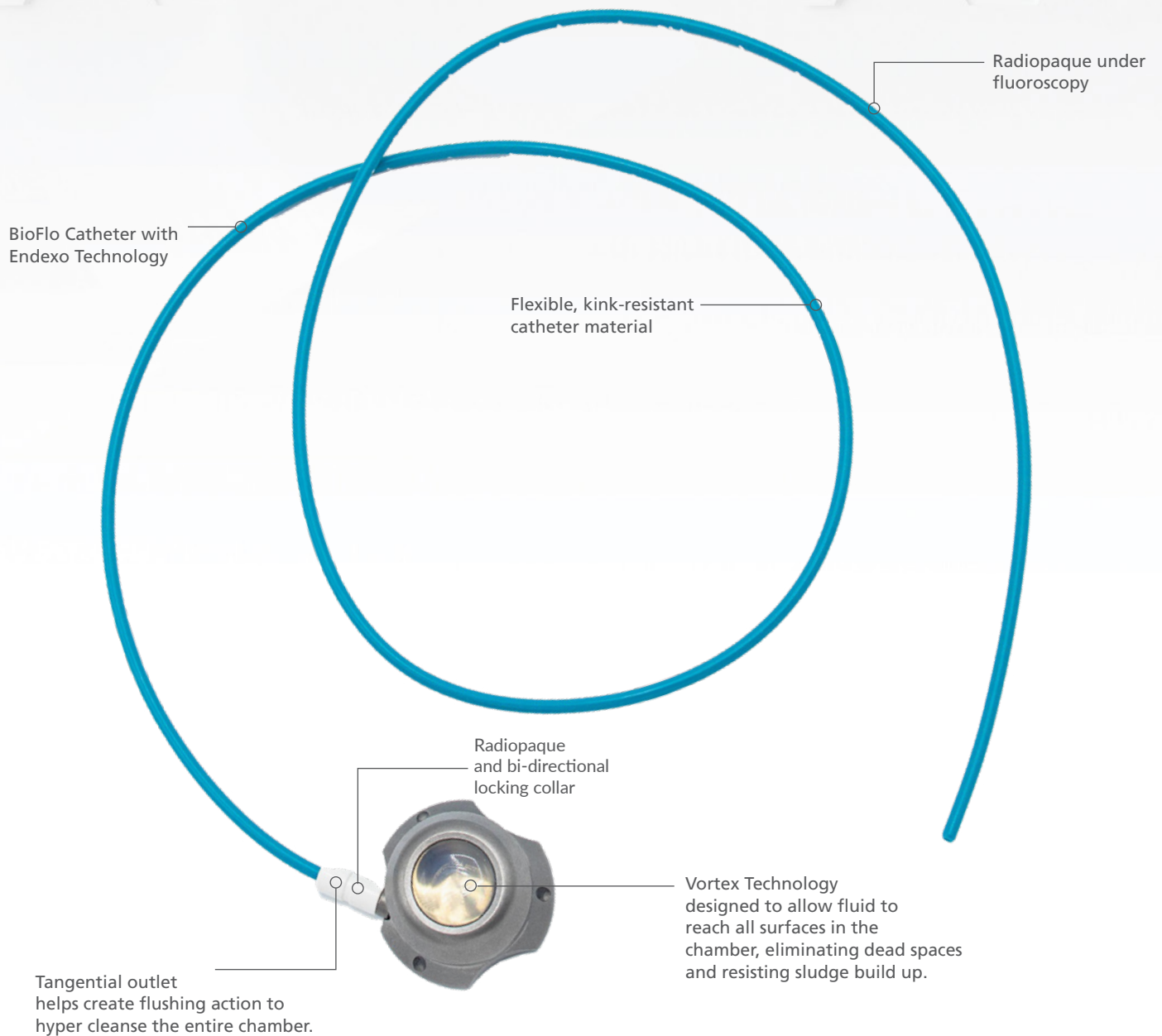
BIOFLO PORT
1.29%
UEDVT RATE
VS
4.5%
BD
X-PORT ISP^{4†}

[†] Results from individual site experience may not be indicative of clinical evidence at other institutions.

Suleman et. al (2019) reported a port-associated DVT rate of 1.29% with the BioFlo port. In a previous study at the same institution with similar sample size and patient population, the port-associated DVT rate was 4.5% (X-port ISP, BD Access Systems Inc, Salt Lake City, US)

Anatomy of the SmartPort+

SmartPort+ – Combining the Two Best in Class Technologies, Vortex Technology and Endexo Technology



SmartPort+ Power Injectable Ports

UPN	CATHETER SIZE	CATHETER MATERIAL	SUTURE HOLE
SINGLE LUMEN STANDARD TITANIUM PORT			
H787CT50STBANFV10	5FR	ATTACHED BIOFLO	NON-FILLED
H787CT50STBAV10	5FR	ATTACHED BIOFLO	FILLED
H787CT50STBDNFV10	5FR	DETACHED BIOFLO	NON-FILLED
H787CT50STBDV10	5FR	DETACHED BIOFLO	FILLED
H787CT60STBANFV10	6FR	ATTACHED BIOFLO	NON-FILLED
H787CT60STBAV10	6FR	ATTACHED BIOFLO	FILLED
H787CT60STBDNFV10	6FR	DETACHED BIOFLO	NON-FILLED
H787CT60STBDV10	6FR	DETACHED BIOFLO	FILLED
H787CT80STBANFV10	8FR	ATTACHED BIOFLO	NON-FILLED
H787CT80STBAV10	8FR	ATTACHED BIOFLO	FILLED
H787CT80STBDNFV10	8FR	DETACHED BIOFLO	NON-FILLED
H787CT80STBDV10	8FR	DETACHED BIOFLO	FILLED
SINGLE LUMEN MINI TITANIUM PORT			
H787CT50PTBANFV10	5FR	ATTACHED BIOFLO	NON-FILLED
H787CT50PTBAV10	5FR	ATTACHED BIOFLO	FILLED
H787CT50PTBDNFV10	5FR	DETACHED BIOFLO	NON-FILLED
H787CT50PTBDV10	5FR	DETACHED BIOFLO	FILLED
H787CT60PTBANFV10	6FR	ATTACHED BIOFLO	NON-FILLED
H787CT60PTBAV10	6FR	ATTACHED BIOFLO	FILLED
H787CT60PTBDNFV10	6FR	DETACHED BIOFLO	NON-FILLED
H787CT60PTBDV10	6FR	DETACHED BIOFLO	FILLED

SMARTPORT VALVED INTRODUCER CONFIGURATIONS		KIT COMPONENTS	Tunneler
Catheter French	Introducer Size	Port Body	Plastic Blunt Needle
5F	6F	(1) Locking Collar	(1) 10 mL Luer Lock Syringe
6F	6F	Single Lumen Catheter	(1) 10 mL Slip Lock Syringe
8F	8F	18G Introducer Needle	(1) 22G straight huber needle
		0.038x 50cm J-tipped Guidewire	(1) 22G 90 degree huber needle
		Peelable Sheath Introducer	(1) Vein Pick
		(Valved or Non-Valved)	

UPN	CATHETER SIZE	CATHETER MATERIAL	SUTURE HOLE
SINGLE LUMEN LOW PROFILE TITANIUM PORT			
H787CT50LTBANFV10	5FR	ATTACHED BIOFLO	NON-FILLED
H787CT50LTBAV10	5FR	ATTACHED BIOFLO	FILLED
H787CT50LTBDNFV10	5FR	DETACHED BIOFLO	NON-FILLED
H787CT50LTBDV10	5FR	DETACHED BIOFLO	FILLED
H787CT60LTBANFV10	6FR	ATTACHED BIOFLO	NON-FILLED
H787CT60LTBAV10	6FR	ATTACHED BIOFLO	FILLED
H787CT60LTBDNFV10	6FR	DETACHED BIOFLO	NON-FILLED
H787CT60LTBDV10	6FR	DETACHED BIOFLO	FILLED
H787CT80LTBANFV10	8FR	ATTACHED BIOFLO	NON-FILLED
H787CT80LTBAV10	8FR	ATTACHED BIOFLO	FILLED
H787CT80LTBDNFV10	8FR	DETACHED BIOFLO	NON-FILLED
H787CT80LTBDV10	8FR	DETACHED BIOFLO	FILLED
SINGLE LUMEN PLASTIC PORT			
H787CT50LPBANFV10	5FR	ATTACHED BIOFLO	NON-FILLED
H787CT50LPBAV10	5FR	ATTACHED BIOFLO	FILLED
H787CT50LPBDNFV10	5FR	DETACHED BIOFLO	NON-FILLED
H787CT50LPBDV10	5FR	DETACHED BIOFLO	FILLED
H787CT60LPBANFV10	6FR	ATTACHED BIOFLO	NON-FILLED
H787CT60LPBAV10	6FR	ATTACHED BIOFLO	FILLED
H787CT60LPBDNFV10	6FR	DETACHED BIOFLO	NON-FILLED
H787CT60LPBDV10	6FR	DETACHED BIOFLO	FILLED
H787CT80LPBANFV10	8FR	ATTACHED BIOFLO	NON-FILLED
H787CT80LPBAV10	8FR	ATTACHED BIOFLO	FILLED
H787CT80LPBDNFV10	8FR	DETACHED BIOFLO	NON-FILLED
H787CT80LPBDV10	8FR	DETACHED BIOFLO	FILLED

RISK INFORMATION

INDICATIONS FOR USE

The ports are indicated for patients who require long-term access to the central venous system for blood specimen withdrawal and administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products, as well as the administration and adequate removal of nuclear medicine. When used with power injectable needles, the ports are indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s with 19G or 20G non-coring power injectable needles or 2 mL/s with a 22G non-coring power injectable needle.

Needle Size (G), non-coring power injectable	Catheter Size (F)	Maximum Recommended Flow Rate Setting (mL/s)	Maximum Recommended Pressure Setting (psi)
19/20	5, 6, and 8	5	300
22	5, 6, and 8	2	300

CONTRAINDICATIONS

- Catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates of pinch-off.⁵

- Presence of infection, bacteremia, or septicemia.
- Past irradiation of prospective insertion site.
- Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.
- Local tissue factors to prevent proper device stabilization and/or access.
- Hypercoagulopathy unless considerations are made to place the patient on anticoagulation therapy.
- Presence or suspicion of allergic reaction to materials contained in this device.
- Anatomy is insufficient to accommodate size of the port or the catheter.
- Demonstrated intolerance for an implanted device.

Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications prior to use of the product.

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

REFERENCES

1. Stevens, Barbara, et al. "A Randomized, Prospective Trial of Conventional Vascular Ports vs. the Vortex 'Clear-Flow' Reservoir Port in Adult Oncology Patients." Journal of Vascular Access Devices, vol. 5, no. 2, 2000, pp. 37-40.

2. Third party verification by Pinnacle Healthcare Management.

3. The reduction in thrombus accumulation (based on platelet count) is supported by acute in-vitro testing. Pre-clinical in-vitro evaluations do not necessarily predict clinical performance with respect to thrombus formation. Data on file.

4. Suleman A, Jarvis V, Hadziomerovic A, et al., Implanted vascular access device related deep vein thrombosis in oncology patients: A prospective cohort study, Thrombosis Research, Vol 177, 2019; P117-121

5. Hinkle, D.H.; Zandt-Stashny, D.A.; Goodman, L.R.' et al. Pinch-off Syndrome: A Complication of Implantable Subclavian Venous Access Devices, Radiology 177: 353-356, 1990.



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