SmartPort+

with Vortex and Endexo Technologies

The Port Your Patient Deserves.

angiodynamics

Vortex Technology

Reduce chamber occlusions. Increase nursing efficiency. Reduce overall interventions

A comparison of conventional vs. Vortex* chambered ports shows a clear advantage[1]

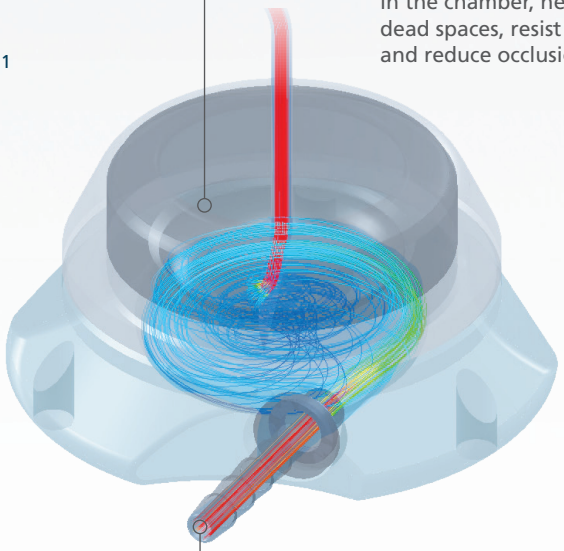
Vortex Technology demonstrated

73% fewer port occlusions[1]

69% fewer secondary interventions[1]

Use of Vortex port technology results in

$1,224 average savings per patient over conventional ports[2]



Round Chamber
allows fluid to reach all surfaces in the chamber, helping eliminate dead spaces, resist sludge build-up, and reduce occlusions

Tangential Outlet
helps create a flushing action within the port to hyper cleanse the entire chamber leading to a reduced rate of occlusions

BioFlo Catheter with Endexo Technology

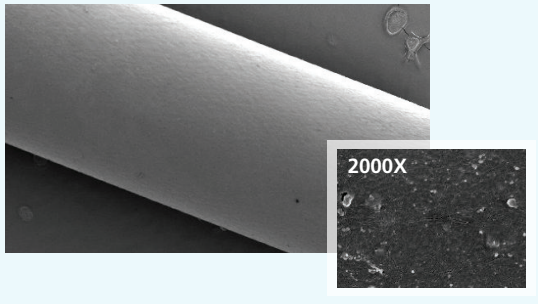
Proven to Reduce Thrombus Accumulation, In Vitro[3]

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 accumulation[3]

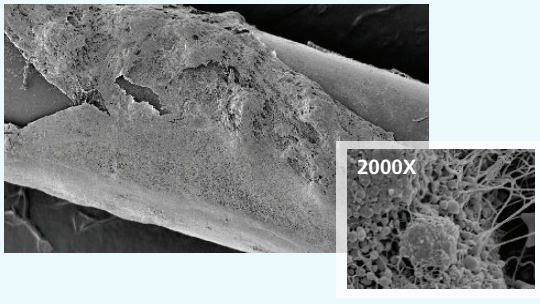
BIOFLO PORT
1.29%
UEDVT RATE
VS
4.5%
BARD
X-PORT ISP[4†]

SEM (Scanning Electron Microscopy) Images

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



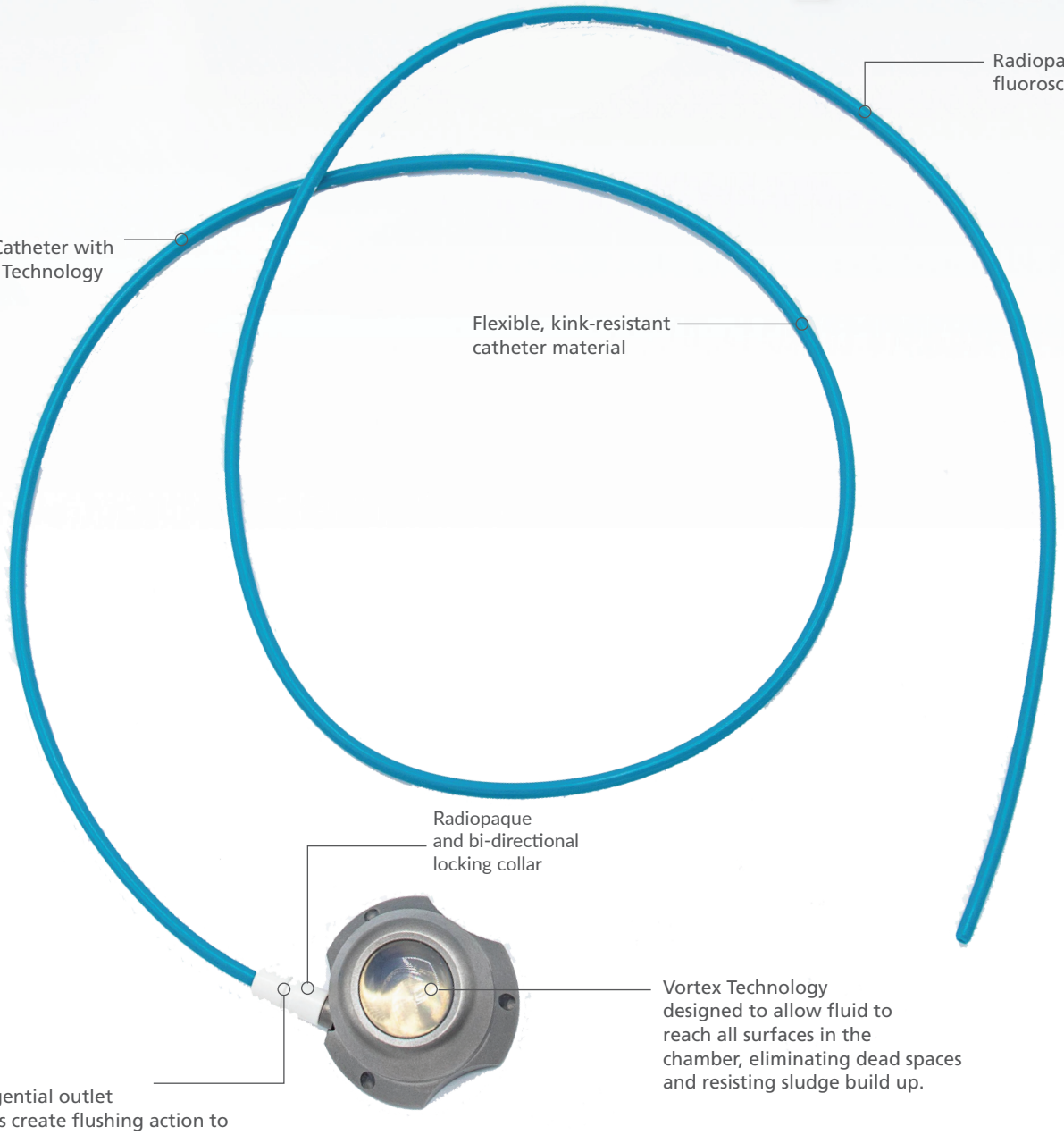
Bard PowerPort with ChronoFlex catheter at 15X magnification
Catheter has significant thrombus, fibrin sheath, or clot.



† 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, Bard Access Systems Inc, Salt Lake City, US)

Anatomy of the Smart Port+

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



Smart Port+ Power Injectable Ports

UPN	CATHETER SIZE	CATHETER MATERIAL	SUTURE HOLE
SINGLE LUMEN STANDARD TITANIUM PORT			
H787CT50STBANFRVI0	5FR	ATTACHED BIOFLO	NON-FILLED
H787CT50STBARVI0	5FR	ATTACHED BIOFLO	FILLED
H787CT50STBDNFRVI0	5FR	DETACHED BIOFLO	NON-FILLED
H787CT50STBDRVI0	5FR	DETACHED BIOFLO	FILLED
H787CT60STBANFRVI0	6FR	ATTACHED BIOFLO	NON-FILLED
H787CT60STBARVI0	6FR	ATTACHED BIOFLO	FILLED
H787CT60STBDNFRVI0	6FR	DETACHED BIOFLO	NON-FILLED
H787CT60STBDRVI0	6FR	DETACHED BIOFLO	FILLED
H787CT80STBANFRVI0	8FR	ATTACHED BIOFLO	NON-FILLED
H787CT80STBARVI0	8FR	ATTACHED BIOFLO	FILLED
H787CT80STBDNFRVI0	8FR	DETACHED BIOFLO	NON-FILLED
H787CT80STBDRVI0	8FR	DETACHED BIOFLO	FILLED
SINGLE LUMEN MINI TITANIUM PORT			
H787CT50PTBANFRVI0	5F	ATTACHED BIOFLO	NON-FILLED
H787CT50PTBARVI0	5F	ATTACHED BIOFLO	FILLED
H787CT50PTBDNFRVI0	5F	DETACHED BIOFLO	NON-FILLED
H787CT50PTBDRVI0	5F	DETACHED BIOFLO	FILLED
H787CT60PTBANFRVI0	6F	ATTACHED BIOFLO	NON-FILLED
H787CT60PTBARVI0	6F	ATTACHED BIOFLO	FILLED
H787CT60PTBDNFRVI0	6F	DETACHED BIOFLO	NON-FILLED
H787CT60PTBDRVI0	6F	DETACHED BIOFLO	FILLED

UPN	CATHETER SIZE	CATHETER MATERIAL	SUTURE HOLE
SINGLE LUMEN LOW PROFILE TITANIUM PORT			
H787CT50LTBANFRVI0	5FR	ATTACHED BIOFLO	NON-FILLED
H787CT50LTBARVI0	5FR	ATTACHED BIOFLO	FILLED
H787CT50LTBDNFRVI0	5FR	DETACHED BIOFLO	NON-FILLED
H787CT50LTBDRVI0	5FR	DETACHED BIOFLO	FILLED
H787CT60LTBANFRVI0	6FR	ATTACHED BIOFLO	NON-FILLED
H787CT60LTBARVI0	6FR	ATTACHED BIOFLO	FILLED
H787CT60LTBDNFRVI0	6FR	DETACHED BIOFLO	NON-FILLED
H787CT60LTBDRVI0	6FR	DETACHED BIOFLO	FILLED
H787CT80LTBANFRVI0	8FR	ATTACHED BIOFLO	NON-FILLED
H787CT80LTBARVI0	8FR	ATTACHED BIOFLO	FILLED
H787CT80LTBDNFRVI0	8FR	DETACHED BIOFLO	NON-FILLED
H787CT80LTBDRVI0	8FR	DETACHED BIOFLO	FILLED
SINGLE LUMEN PLASTIC PORT			
H787CT50LPBANFRVI0	5FR	ATTACHED BIOFLO	NON-FILLED
H787CT50LPBARVI0	5FR	ATTACHED BIOFLO	FILLED
H787CT50LPBDNFRVI0	5FR	DETACHED BIOFLO	NON-FILLED
H787CT50LPBDRVI0	5FR	DETACHED BIOFLO	FILLED
H787CT60LPBANFRVI0	6FR	ATTACHED BIOFLO	NON-FILLED
H787CT60LPBARVI0	6FR	ATTACHED BIOFLO	FILLED
H787CT60LPBDNFRVI0	6FR	DETACHED BIOFLO	NON-FILLED
H787CT60LPBDRVI0	6FR	DETACHED BIOFLO	FILLED
H787CT80LPBANFRVI0	8FR	ATTACHED BIOFLO	NON-FILLED
H787CT80LPBARVI0	8FR	ATTACHED BIOFLO	FILLED
H787CT80LPBDNFRVI0	8FR	DETACHED BIOFLO	NON-FILLED
H787CT80LPBDRVI0	8FR	DETACHED BIOFLO	FILLED

SMART PORT VALVED INTRODUCER CONFIGURATIONS

Catheter French	Introducer Size
5F	6F
6F	6F
8F	8F

KIT COMPONENTS

Port Body
(1) Locking Collar
Single Lumen Catheter
18G Introducer Needle
0.038x 50cm J-tipped Guidewire
Peelable Sheath Introducer
(Valved or Non-Valved)
Tunneler
Plastic Blunt Needle
(1) 22G straight huber needle
(1) 22G 90 degree huber needle
(1) Vein Pick

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.

CONTRAINDICATIONS

- Catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates for 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. Hinke, D.H.; Zandt-Stastny, 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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