

### About VasoNova

VasoNova, Inc. has created, developed and commercialized an innovative vascular navigation system. Founded in 2005, VasoNova is the leader in algorithm-based vascular navigation and measurement technology, committed to innovating high quality medical devices to help clinicians address patient needs and improve patient care. VasoNova is located in Sunnyvale, CA.

Please consult labeling for additional information.

### Indication for Use:

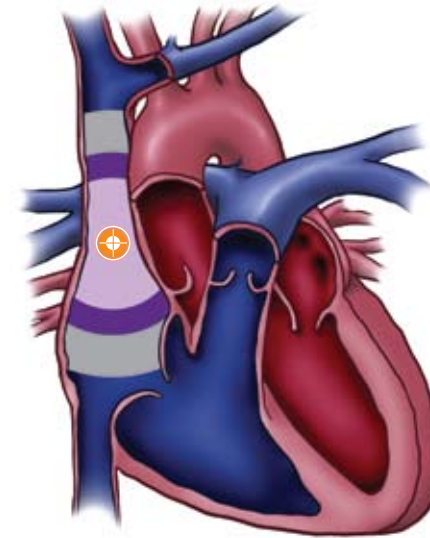
The VPS Catheter is indicated for short or long-term peripheral access to the central venous system for hyperalimentation, chemotherapy, or other intravenous therapy; for blood sampling; and for contrast studies. The maximum recommended injection rate is 2cc/sec for the 3F Catheter and 5cc/sec for the 4F and 5F catheters. The VPS Catheter is indicated for use with or without the VPS Stylet and VPS Console. The VPS Stylet and Console are indicated for use as a supplemental aid for VPS Catheter tip placement. The VPS Stylet provides stiffness for use in placement of the catheter, intravascular capability for ECG detection and recording and intravascular ultrasound for catheter guiding and positioning. The VPS Stylet used with the VPS Console provides real-time catheter tip location information by using the patient's physiological (cardiac electrical activity and blood flow) information. Pressure warning: The maximum pressure of the injection with the VPS 3F, 4F and 5F catheter may not exceed 300psi.

### Complications:

Before attempting catheter placement, ensure that you are familiar with all possible complications and their emergency treatment should any of them occur. Complications are: air embolism, bleeding, brachial plexus injury, cardiac arrhythmia, cardiac tamponade, catheter erosion through skin, catheter embolism, catheter occlusion, catheter related sepsis, endocarditis, exit site infection, exit site necrosis, extravasation, fibrin sheath formation, hematoma, intolerance reaction to implanted device, laceration of vessels or viscus, myocardial erosion, perforation of vessels or viscus, phlebitis, pneumothorax, spontaneous catheter tip malposition or retraction, venous thrombosis, ventricular thrombosis, vessel erosion, risks normally associated with local or general anesthesia, surgery, and postoperative recovery.

Use of this product should be in accordance with the instructions provided and as directed by the prescribing physician.

See package IFU and website for additional information.



Because optimal placement matters...  
**VasoNova VPS**

Smart Guidance.

Advancing the standard of  
care for PICC placement



For more information on VasoNova VPS and its accessories, please contact your VasoNova representative or visit [www.vasonova.com](http://www.vasonova.com).

**VasoNova Customer Service:** 408-738-7008, or visit us on the web at [www.vasonova.com](http://www.vasonova.com).  
VasoNova, Inc. 1368 Bordeaux Drive, Sunnyvale, CA 94089

VasoNova, Vascular Positioning System and VPS are trademarks and/or registered trademarks of VasoNova, Inc.  
Bard and Sherlock are trademarks and/or registered trademarks of C.R. Bard and its affiliates.

LBL-1035 (B)



## Advancing the Standard of Care for PICC Placement

VasoNova™ has developed an innovative vascular navigation system that is designed to revolutionize the standard of care for the placement of peripherally inserted central catheters (PICCs). Using a combination of intravascular Doppler ultrasound and ECG technology, the VasoNova Vascular Positioning System™ (VPS™) uses internal physiological parameters to achieve precise catheter positioning. The VasoNova VPS rapidly guides and accurately positions the catheter, giving you the confidence of placing the PICC line at the desired location.

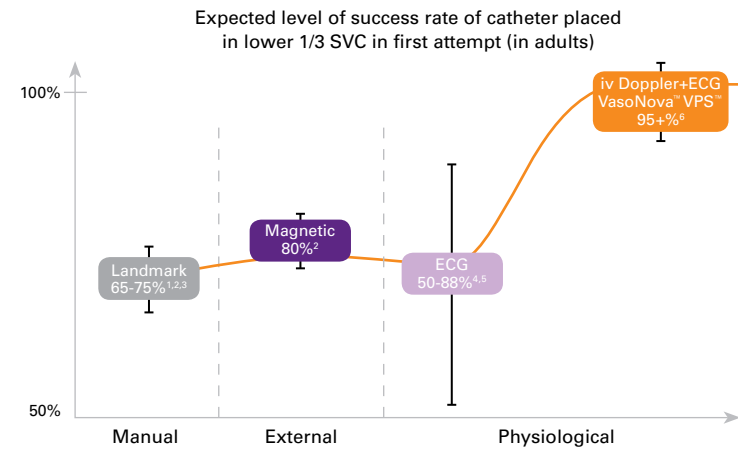


## Precise Placement: Vital to the Patient's Health

Placing the catheter tip in the lower third of the superior vena cava (SVC) and specifically at the caval-atrial junction (CAJ) is important for patient safety when using the catheter. Even minor malposition of the catheter tip within the SVC can increase catheter malfunction rates and thrombotic complications<sup>1</sup>. Current PICC placement technologies allow for a large variation of tip location relative to the lower 1/3 of the SVC, which may undermine the effectiveness of patient therapy and clinicians' efficiency.

## Why is the caval-atrial junction so important?

Certain medications, due to their vesicant nature, have the potential to severely damage vessels if they are not quickly diluted by the patient's blood. The turbulent flow characteristics of the CAJ allow the drug to mix quickly with and be diluted by the blood and hence allow the drug's rapid transport to the rest of the body.



- Landmark**  
(± 6.25cm from CAJ or lower 1/3 SVC)
- Magnetic**  
(Unknown)
- ECG**  
(± 3.5cm from CAJ or lower 1/3 SVC)
- VPS**  
(- 1.0cm to 0cm from CAJ or lower 1/3 SVC)<sup>7</sup>



## Evolution of Catheter Placement Technology

### Landmark: “Blind” placement with confirmation X-ray

The current “landmark” technique for PICC placement has not changed significantly in more than three decades. Clinicians routinely place the PICC using external landmarks and approximate measurement at the bedside. The location of the catheter tip must be confirmed by chest X-ray. When using the landmark technique, clinicians have a 65-75%<sup>1,2,3</sup> success rate of placing the catheter tip within the lower third of the SVC in the first attempt, with a tolerance of ± 6.25cm<sup>8</sup> from the CAJ.

### Magnetic: External system for locating catheter tip

Some systems use external devices to approximate the location of the magnet tip of a preloaded stylet. Based on the literature, clinicians have a first attempt success rate of up to 80%<sup>2</sup>. However, the external magnetic systems can only provide an approximate location of the catheter tip relative to the lower 1/3 of the SVC, and cannot provide real-time feedback when the catheter is at the vessel

wall. Operation of these systems may be affected by electromagnetic interference. Certain patient types present challenges, including obese patients or patients with pacemakers<sup>9</sup>. Additionally, the patient must be able to tolerate the external location device being on their chest and must remain motionless throughout the procedure. This may create a significant amount of discomfort to the patient.

### ECG Only: Physiological system with limited capability

This method uses limited physiological information. Studies report that clinicians have a first attempt success rate ranging from 50 - 88%<sup>4,5</sup> with a tolerance of ± 3.5cm from the CAJ<sup>8</sup>. However, since a normal sinus rhythm is required for this method to work, patients who had an abnormal P-wave were excluded from these studies. Therefore, patients with AF, pacemakers, heart failure or myocardial pathology — approximately 1 out of 11 people in the U.S.<sup>10</sup> – may not be able to benefit from this technology.

## Smart Guidance Means Accurate Placement for Patients

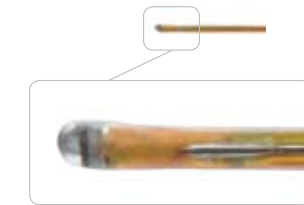
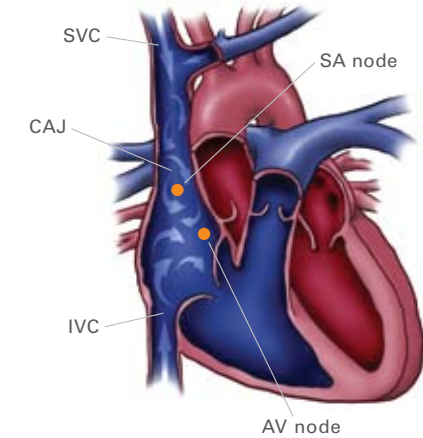
### The VasoNova™ VPS™: intravascular ultrasound and ECG combined

The area from the lower third of the SVC to CAJ has a distinctive signature due to unique blood flow characteristics and close proximity to the heart’s electrical network. Using a proprietary algorithm that combines intravascular Doppler and ECG technologies, the VasoNova VPS starts analyzing physiological information at the point of insertion and provides real-time, continuous guidance to the user. By combining multiple vectors, the system identifies the unique signature of the area, informing the clinician when the catheter tip is ideally placed. The VasoNova VPS is designed to provide high accuracy in placement (± 0.5cm)<sup>7</sup> without limitations from the pathophysiology of the heart. The VasoNova VPS can be used in normal patients and those with AF and pacemakers who are unable to benefit from other PICC placement technologies.

### Smart Guidance: the Road Map to Successful Catheter Placement

The VasoNova VPS consists of several components: the VPS Stylet, the VPS Power Injectable PICC catheter and the VPS Console. The VPS Stylet contains two sensors at its tip: a Doppler Ultrasound sensor and an intravascular ECG lead. Due to the ingenuity of our R&D group, VasoNova was able to miniaturize the two sensors and construct a highly technical and flexible stylet that can fit into the lumen of the VPS Power Injectable PICC line with comparable dimensions to other market available PICC lines<sup>11</sup>. Once the VPS stylet is loaded into the VPS catheter and connected to the VPS console per the Instruction for Use, the VPS Stylet is able to detect the patient’s physiological data, such as blood flow characteristics and ECG waveform. From the point of insertion, patient data are sent to the VPS console for real-time analysis. Using the highly advanced hardware and complex algorithm, the VPS console analyzes multiple vectors derived from these data and determines the location of the catheter tip while it is advanced through the patient’s vasculature. Using the data gathered by the sensor and analysis done by the console, the VasoNova VPS console displays visual indicators. These indicators guide the clinician in real-time as the catheter is advanced through the vasculature.

The VasoNova VPS Console is designed to allow clinicians to record patient information and up to 5 hours of procedural data. Data collected by the VPS Console during the procedure can be retrieved using a memory stick (not supplied) through a USB port or printed out with a printer (optional), allowing the clinician to attach the results of the placement procedure to the patient’s medical record. The VPS Console is light weight (less than 9 pounds) and can be mounted on conventional poles and stands for ease of transportation or use. Furthermore, all of the VPS catheters are power injectable and are available in common sizes. Due to the unique combination of all of the components, the VasoNova VPS is able to provide a comprehensive solution to help clinicians place the catheter tip at the lower third of the SVC, specifically at the CAJ.



The VPS Stylet contains two miniature-sized sensors to detect physiological information: the Doppler Ultrasound sensor at the tip and the intravascular ECG lead.



The green arrow indicates the catheter tip is moving with the blood flow towards the heart, as appropriate.

The orange “do-not-enter” sign indicates the catheter is moving against blood flow, such as into the internal jugular vein and away from the heart, or has passed the lower third of the SVC and going into the right atrium.

The yellow triangle indicates there is not enough information available, which may occur if the catheter tip is against the vessel wall.

The blue bull’s eye indicates the tip has arrived in the lower 1/3 of the SVC or at the caval-atrial junction.

1. Trerotola et al. J Vasc Interv Radiol 2007; 18:513-518  
 2. Naylor JAVA 2007; 12:1:29-31  
 3. VSN Market Research  
 4. Starr et al, Ann Surg, 1986; 673-676  
 5. Salmela et al. Acta Anaesthesiol Scand 1993; 37:26-28

6. Estimated  
 7. Designed to achieve -1.0 to 0cm from CAJ or lower 1/3 of SVC  
 8. McGee et al. Critical Care Medicine, 21:8:1118-1123  
 9. Bard “ Sherlock” II IFU  
 10. Calculated from American Heart Association 2009 statistics

11. Test results on file at VasoNova  
 12. The National Nosocomial Infections Surveillance system estimates the average cost of this type of infection is \$45,000 per patient. According to the CDC, bloodstream infections have an estimated mortality of 12-25%.

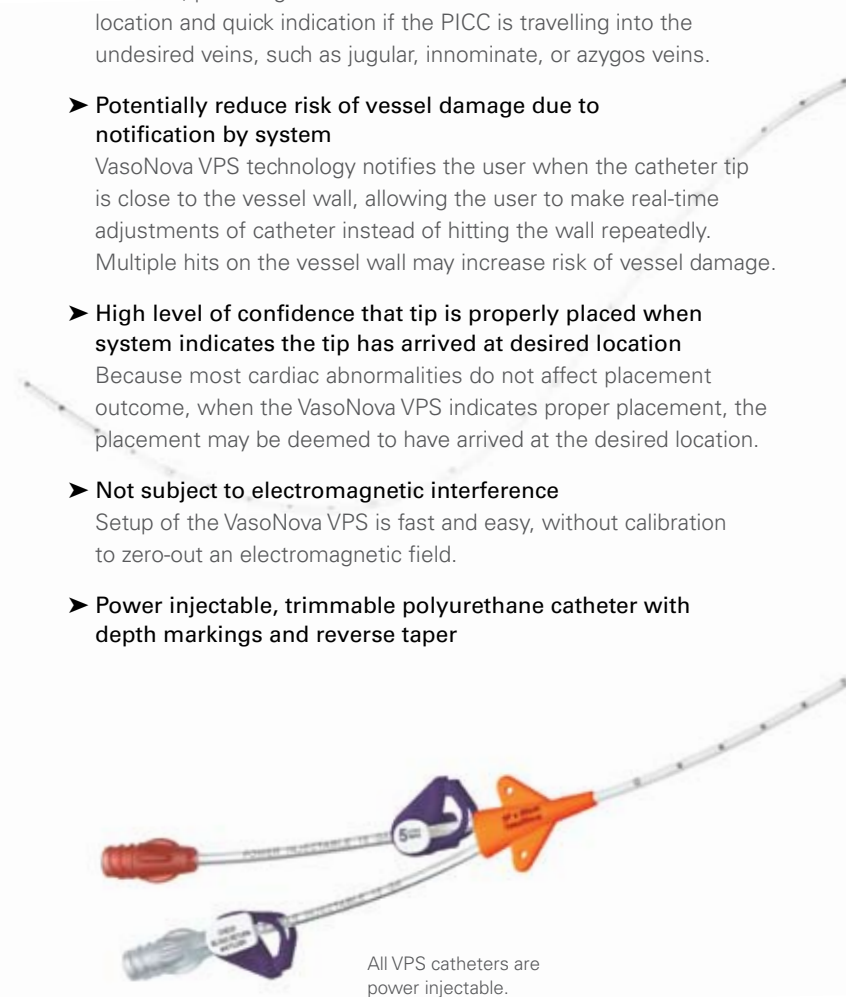
## VasoNova VPS Features and Benefits

### Expected Benefits to the Patient

- ▶ **VPS is designed to enable placement of the catheter correctly the first time**  
Since the VPS™ uses the patient's physiological characteristics to determine the catheter's location, clinicians know when the catheter is placed at the desired location. This reduces the need for adjustments and subsequent X-ray exposure, potentially reducing the patient's exposure to X-rays and related adverse outcomes from X-rays.
- ▶ **Improved likelihood of continuity of care**  
Use of the VPS may minimize disruption of care for the patient and increase timeliness of medication administration.
- ▶ **No external device on chest to induce potential discomfort**  
Without the nuisance of an external device placed on the patient's chest, the VasoNova VPS allows the patient to remain comfortable and breathe normally during the procedure.
- ▶ **Optimal placement improves infusion efficiency**  
Precise placement with the VasoNova VPS at the lower 1/3 of SVC, specially at the CAJ allows the turbulent blood flow at CAJ to quickly mix and dilute infused fluids, such as drugs, by the patient's blood, ensuring rapid transportation to the rest of the body.
- ▶ **Effective in many\* patients, including those with AF, pacemakers, myocardial pathology, obesity or challenges with body habitus**  
Unlike other catheter placement technologies, the VasoNova VPS is not limited by the size of the patient or the pathophysiology of the heart.
- ▶ **Latex-free components to maximize comfort and safety**  
Increase safety for patients who are allergic to latex.

### Expected Benefits to the Clinician

- ▶ **Easy to use**  
VasoNova VPS can contribute to faster and more confident insertion, providing a clear indication of arrival at the desired location and quick indication if the PICC is travelling into the undesired veins, such as jugular, innominate, or azygos veins.
- ▶ **Potentially reduce risk of vessel damage due to notification by system**  
VasoNova VPS technology notifies the user when the catheter tip is close to the vessel wall, allowing the user to make real-time adjustments of catheter instead of hitting the wall repeatedly. Multiple hits on the vessel wall may increase risk of vessel damage.
- ▶ **High level of confidence that tip is properly placed when system indicates the tip has arrived at desired location**  
Because most cardiac abnormalities do not affect placement outcome, when the VasoNova VPS indicates proper placement, the placement may be deemed to have arrived at the desired location.
- ▶ **Not subject to electromagnetic interference**  
Setup of the VasoNova VPS is fast and easy, without calibration to zero-out an electromagnetic field.
- ▶ **Power injectable, trimmable polyurethane catheter with depth markings and reverse taper**



### Expected Benefits to the Healthcare Facility

Fewer catheter re-positionings may contribute to:

- ▶ **Reduced risk of infection**  
Hospital-acquired infections (HAI) cost an estimated \$45,000 per incident<sup>12</sup>. With less need for repositioning, the VasoNova VPS for PICC placement may reduce the risk of catheter-related infection. Full body drapes in Full kits also provide maximum barrier to aid in infection control.
- ▶ **Minimizing X-ray requirements**  
The VasoNova VPS may require only a single confirming X-ray post placement. This reduces X-ray cost and eliminates infusion delays, thereby increasing efficiency and throughput which saves valuable nursing time.

- ▶ **Reduced labor costs**  
Optimizing first attempt success rates may reduce overall labor costs for the facility, including extra nursing time, transportation time, overtime association with confirmation and overflow due to delay.
- ▶ **Increase throughput**  
Rapid placement may minimize disruption of patient care, increase timeliness of medication administration and contribute to overall increase in throughput.



▶ *Easy to Use*

\* Contraindicated for certain patients. See IFU for contraindications.