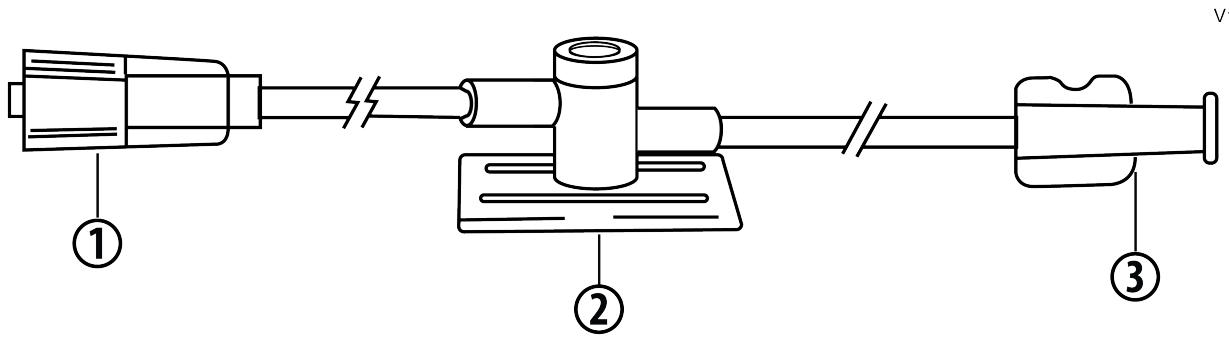
Edwards

VAMP Closed Blood Sampling System with Needleless Sampling Site



1. Proximal (To Patient)
2. Sampling Site
3. Distal

Instructions for Use

For single use only

Carefully read these instructions for use, which address the warnings, precautions, and residual risks for this medical device.

1.0 Description

The Edwards Lifesciences VAMP closed blood sampling system provides a safe and convenient method for withdrawing blood samples. The VAMP system is designed for use with all disposable and reusable pressure transducers and for connection to central line and arterial catheters. The VAMP closed blood sampling system is used for the drawing and retention of heparinized blood from the catheter or cannula within the line, allowing undiluted blood samples to be drawn from an in-line sampling site. At the completion of sample drawing, the mixed heparin and blood solution is reinfused into the patient to reduce fluid loss.

Device performance, including functional characteristics and accuracy, have been verified in a comprehensive series of testing. All acceptance criteria were appropriate and met. The device outputs directly support the safety and performance of the device for its intended use when used in accordance with the established Instructions For Use.

The device is intended to be used by medical professionals who have been trained in the safe use of hemodynamic technologies and the clinical use of blood sampling technologies as part of their respective institutional guidelines.

VAMP blood conservation technology reduces unnecessary blood loss and risk of infection. Additional risks include blood loss, blood splatter, embolus, thrombosis, adverse reaction to device materials, tissue trauma/injury, systemic infection, and/or hemolysis.

2.0 Intended Use/Purpose

To be used only for blood withdrawal.

VAMP closed blood sampling system is intended to be used only for blood withdrawal.

3.0 Indications for Use

For adult patients with medical conditions requiring periodic withdrawal of blood samples from arterial and central line catheters, including peripherally inserted central catheters and central venous catheters, which are attached to pressure monitoring lines.

4.0 Contraindications

Not to be used without an attached flush device or flow controlling device when used for arterial applications.

There are no absolute contraindications when used for venous applications.

5.0 Warnings

This device is designed, intended and distributed for SINGLE USE ONLY. DO NOT RE-STERILIZE OR REUSE this device. There are no data to support the sterility, non-pyrogenicity and functionality of the device after reprocessing. Such action could lead to illness or an adverse event as the device may not function as originally intended.

Some models may contain phthalates, specifically DEHP [Bis (2-ethylhexyl) phthalate], which may pose a risk of reproductive or developmental harm in pediatric patients, pregnant or nursing women.

Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

This device contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight: DBMC; CAS No. 119-47-1; EC No. 204-327-1. Current scientific evidence supports that medical devices manufactured from Isoprene rubber do not cause an increased risk of cancer or adverse reproductive effects.

6.0 Instructions for Use

CAUTION: The use of lipids with the VAMP closed blood sampling system may compromise product integrity.

6.1 Equipment

- Flush device or flow controlling device (max 4 ml/hour flow rate).
- Disposable or reusable pressure transducer, if desired.
- VAMP closed blood sampling system with needleless sampling site.

6.2 Setup

1. Using aseptic technique, remove the VAMP kit from the sterile package.
2. Attach the distal end with the female luer-lock connector to the transducer stopcock on the disposable transducer or reusable transducer dome. Ensure that all connections are secure.
3. If a transducer is in the line, deliver flush solution first through the transducer and out through the transducer vent port according to your transducer's instructions.
4. Replace all vented caps on the sideports of the stopcocks with non-vented caps.
5. Deliver flush solution slowly to fill the VAMP kit.

   CAUTION: Remove all air bubbles to reduce the risk of air emboli.
6. If a transducer is being used, mount the transducer either on the patient's body per hospital procedure or on an IV pole using the appropriate clamp and holder.
7. Pressurize the IV solution bag. Flow rate will vary with pressure across the flush device.
8. Securely connect the proximal end of the kit with the male luer-lock connector to the pre-filled catheter (Figure 1).
9. If necessary, zero and calibrate the transducer according to the transducer manufacturer's instructions.

7.0 Drawing Blood Samples from the VAMP Needleless Sampling Site

Although a variety of techniques can be used for drawing samples, the following guidelines are provided as an aid to the clinician:

Two methods may be used to draw blood samples from the VAMP needleless sampling site. Method One uses a sampling syringe with the VAMP needleless cannula. Method Two, direct line sampling, uses a direct-draw unit with an integral VAMP needleless cannula.

7.1 Drawing Blood Samples Using Method One (Syringe and Cannula)

1. Draw a sufficient amount of blood from the distal portion of the line past the sampling site to ensure an accurate sample per hospital procedure.
2. Close the line between the IV fluid source and the sampling site by turning the appropriate stopcocks.
3. Swab the VAMP needleless sampling site with disinfectant such as alcohol or betadine, depending on hospital policy.

   Note: Do not use acetone.
4. To draw a blood sample, use a cannula (packaged separately) and syringe.

   CAUTION: Do not use a needle through the sampling site.
5. Using an individually packaged cannula (Figure 2):
   a) Using aseptic technique, open the cannula package.
   b) Attach the cannula onto a selected luer-tip syringe by aligning the cannula luer-lock to the luer-tip on the syringe, and twisting until secure.
6. Ensure that the syringe plunger is depressed to the bottom of the syringe barrel.
7. Push the cannula into the VAMP needleless sampling site and hold in place for approximately 1-2 seconds (Figure 3).
8. Draw the required volume of blood into the syringe.

   Note: If difficulties are experienced in drawing the sample, check the catheter and VAMP kit for possible occlusions or restrictions.
9. While holding the cannula, remove the syringe/cannula from the sampling site by **pulling straight out**.

   CAUTION: Do not twist the syringe out of the sampling site.
10. Once the last sample has been drawn, swab the sampling site to ensure removal of any residual blood remaining on the sampling port.

    Note: Do not use acetone.
11. Open appropriate stopcocks and flush the line clear of residual blood.
12. Discard all syringes and cannulas after use according to hospital policy.

7.2 Transferring Blood Samples

1. To transfer the blood sample from the syringe to vacuum tubes, use the blood transfer unit (BTU) (Figure 4).
   a) Using aseptic technique, peel open the pouch.
   b) Ensure that all connections are tight.

c) Hold the VAMP blood transfer unit in one hand and push the cannula on the filled sample syringe through the VAMP blood transfer unit needleless injection site.
d) Insert the selected vacuum tube into the BTU's opening until the internal needle has punctured the rubber disk on the vacuum tube.
e) Fill the vacuum tube to the desired volume.
f) Repeat steps (d) and (e) according to the requirements for the patient's blood study.

2. According to hospital policy, discard the VAMP blood transfer unit, syringes, and cannulas after transferring the blood sample from the syringe into the vacuum tubes.

7.3 Drawing Blood Samples Using Method Two (Direct-Draw Method)

1. Draw a sufficient amount of blood from the distal portion of the line past the sampling site to ensure an accurate sample per hospital procedure.
2. Close the line between the IV fluid source and the sampling site by turning the appropriate stopcocks.
3. Swab the sampling site with disinfectant such as alcohol or betadine, depending upon hospital policy.

   Note: Do not use acetone.
4. To draw a blood sample, use the direct-draw unit.

   CAUTION: Do not use a needle through the sampling site.

   a) Using aseptic technique, peel open the pouch.
   b) Ensure that the cannula is securely tightened to the direct-draw housing.
   c) Position the sampling site so that it faces upward.
   d) Push the cannula of the direct-draw unit into the sampling site (Figure 5).
   e) Insert the selected vacuum tube into the open end of the direct-draw unit and push until the internal needle of the direct-draw unit has punctured the rubber disk on the vacuum tube.

      CAUTION: To prevent backflow of vacuum tube contents (including air) from entering fluid path, remove vacuum tube before reaching maximum fill capacity.
   f) Fill the vacuum tube to the desired volume.

      Note: If difficulties are experienced in drawing the sample, check the catheter and VAMP kit for possible occlusions or restrictions.
   g) Repeat steps (e) and (f) according to the requirements of the patient's blood study.
   h) When the last sample has been drawn, remove the vacuum tube first and then grasp the direct-draw unit by the cannula and **pull straight out**.

      CAUTION: Do not twist the direct-draw unit housing or remove it with the vacuum tube still attached.
5. Discard the direct-draw unit after use according to hospital policy.
6. Once the last sample has been drawn, swab the sampling site to ensure removal of any excess blood remaining on the sampling port.

   Note: Do not use acetone.
7. Flush the line clear of residual blood.
8. Discard all syringes and cannulas after use according to hospital policy.

   WARNING: Laboratory values should correlate with patient's clinical manifestations. Verify accuracy of laboratory values before instituting therapy.

8.0 Routine Maintenance

Since kit configurations and procedures vary according to hospital preferences, it is the responsibility of the hospital to determine exact policies and procedures.

9.0 MRI Safety Information

MR **MR Safe**

The VAMP closed blood sampling system is MR Safe.

Precaution:
Follow the conditions for safe scanning for any accessory devices (e.g., disposable transducers or reusable transducers) that are connected to the VAMP closed blood sampling system. If the MR safety status for the accessory devices is not known, assume they are MR Unsafe and do not allow them to enter the MR environment.

10.0 How Supplied

Contents sterile and fluid path nonpyrogenic if package is undamaged or unopened. Do not use if package is opened or damaged. Do not resterilize. Visually inspect for breaches of packaging integrity prior to use.

11.0 Storage

Store in a cool, dry place.

12.0 Shelf Life

The shelf life is as marked on each package. Storage or usage beyond the expiration date may result in product deterioration and could lead to illness or an adverse event as the device may not function as originally intended.

13.0 Technical Assistance

For technical assistance, please call Edwards Technical Support at the following telephone numbers:

Inside the U.S. and Canada
(24 hours): 800.822.9837
Outside the U.S. and Canada

(24 hours): 949.250.2222
In the UK: . . . . . 0870 606 2040 - Option 4
In Ireland: . . . . . 01 8211012 - Option 4

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

14.0 Disposal

After patient contact, treat the device as biohazardous waste. Dispose of in accordance with hospital policy and local regulations.

Prices, specifications, and model availability are subject to change without notice.

Refer to the symbol legend at the end of this document.

Product bearing the symbol:

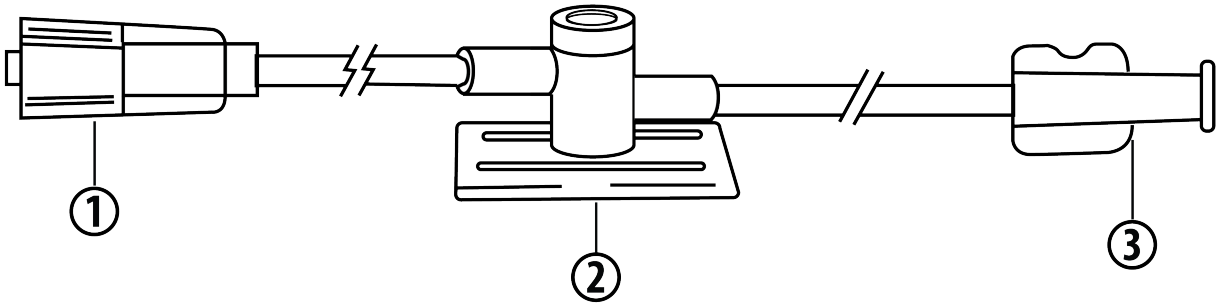
has been sterilized using Ethylene Oxide.

Alternatively, product bearing the symbol:

has been sterilized using Irradiation.

Figures

V1037



1. Proximal (To Patient)
2. Sampling Site
3. Distal

Figure 1

V1004-1

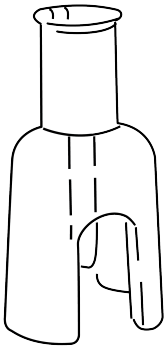
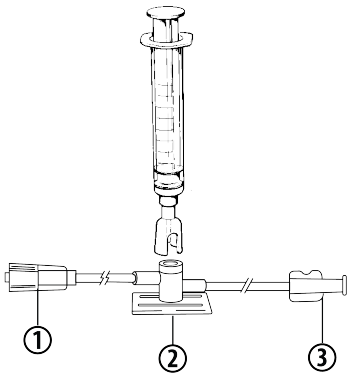


Figure 2: Vamp Needleless Cannula

V1002
V1037



1. Proximal (To Patient)
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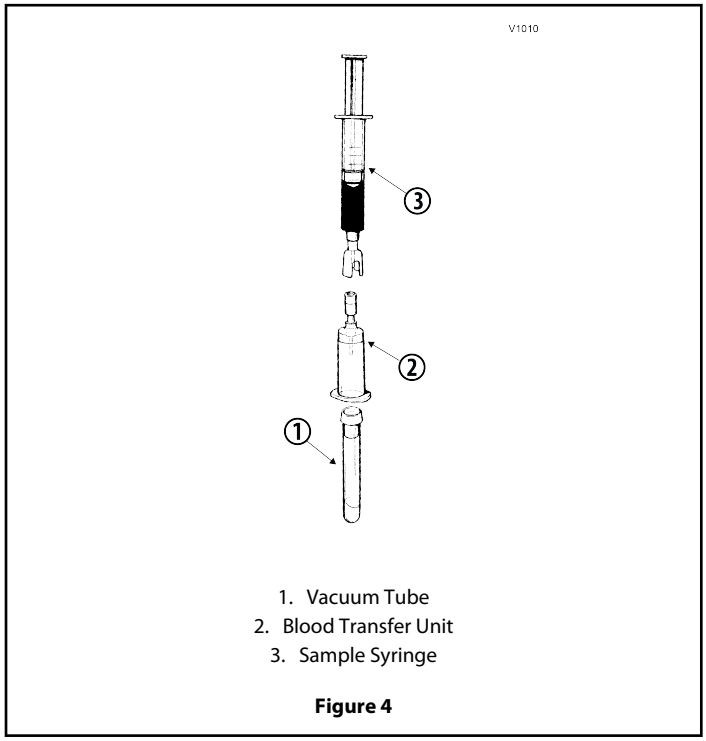
Figure 3



1. Vacuum Tube
2. Blood Transfer Unit
3. Sample Syringe

Figure 4

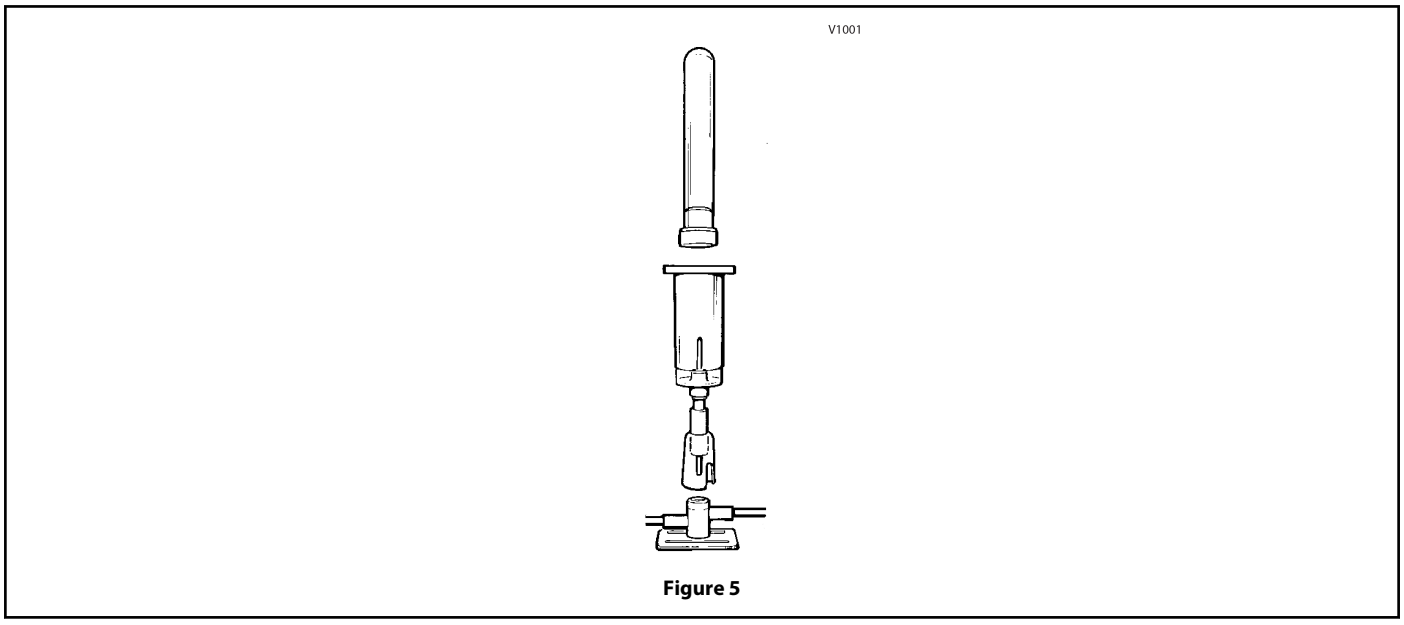
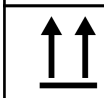
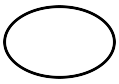


Figure 5

Symbol Legend

	English
	Single use
Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
MD	Medical device
	Importer
	Manufacturer
	Date of manufacture
LOT	Lot Number
QTY	Quantity

	English
	Caution
	Consult instructions for use on the website
	Do not use if package is damaged and consult instructions for use
	Do not resterilize
STERILE EO	Sterilized using ethylene oxide
	Contains hazardous substances
	Use-by date
	Non-pyrogenic

	English
MR	MR Safe
	Fragile, handle with care
	This way up
	Single sterile barrier system
	Store in a cool, dry place
#	Model Number
UDI	Unique device identifier

Note: Not all symbols may be included in the labeling of this product.

Made in Dominican Republic
CCT Critical Care Technologies S.R.L.
Parque Industrial Itabo
Km 18.5 Carr. Sanchez
Haina, San Cristobal, Dominican Republic

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60061214001 A / DOC-0581720 A

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA

Edwards Lifesciences B.V.
Verlengde Poolseweg 16
4818 CL Breda, Netherlands

Telephone 949.250.2500
800.424.3278
FAX 949.250.2525

Web IFU