# URGENT FIELD SAFETY NOTICE

## FCA #127

## VAMP OPTIMA

Model Numbers: MHD8VLTW, MHD8VRL5, VOPTIMAL
Lot Numbers: All lots for models listed

# MEDICAL DEVICE RECALL

<MM DD, YYYY>

<Customer #>
<Contact name or Dept.>
<Firm Name>
<Attention: RISK MANAGEMENT>
<Address>
<City/state/zip>

Dear Valued Customer:

As part of our strong commitment to quality, we continuously monitor our products throughout their life cycle to quickly identify and correct any potential issues. We recently identified an issue with the Vamp Optima, and the issue was confirmed after Edwards evaluated complaints received from our target market release sites. We ask that you complete the attached Acknowledgement Form and return to Edwards at the number listed. This product is being recalled by Edwards.

Details on affected devices:

The Edwards Lifesciences VAMP Optima closed blood sampling system provides a safe and convenient method for the withdrawal of blood samples from pressure monitoring lines. The blood sampling system is designed for use with disposable pressure transducers and for connection to central line, venous, and arterial catheters where the system can be flushed clear after sampling. The VAMP Optima closed blood sampling system is used for the drawing and retention of heparinized or non-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 blood or mixed heparin and blood solution is reinfused into the patient to reduce fluid loss.

To be used only for blood withdrawal. The blood sampling system is indicated for use on patients 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.

Edwards

Description of the problem and indication of product being recalled:

The instructions for use are unclear in the steps for blood sampling and the positioning of the stopcock. If the clinician were to incorrectly position the stopcock, the blood sample will be diluted with saline. This has occurred with drawing 1ml samples for blood glucose readings. The clinician immediately noted upon testing the saline in the blood sample. When this occurs, the clinician will need to obtain another pure blood sample for testing. This may cause a slight delay in treatment.

In addition, some clinicians are putting the reservoir stopcock in the incorrect position when flushing after a blood draw. This can result in not clearing blood completely from the top of the reservoir and subsequent clot forming. Clotting is an inherent risk when any device is introduced into the vascular system. Since line maintenance is a routine part of patient care, line clotting is unlikely to result in an injury. If clotting does occur, the clinician can change out the system with a minimal delay in treatment or monitoring.

There is a potential for distortion in pressure readings if the stopcock at the reservoir is in the incorrect position. This is also true for the LASS Sample Site.

At Edwards Lifesciences, we are committed to helping you advance the care and treatment of patients. This commitment extends to the products, service, education, and support we provide. We apologize for any inconvenience caused by this action and appreciate your attention in this matter.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

If you have any questions, please contact Edwards Customer Service on 0870 606 2040

Sincerely,

Vice President of Quality, Critical Care

This Urgent Field Safety Notice has been communicated by Edwards Lifesciences to the relevant competent authority.

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CUSTOMER ACKNOWLEDGEMENT

<Customer #>
<Firm Name>
<Attention: RISK MANAGEMENT>
<Address>
<City/state/zip>

Please follow all instructions below to complete the recall process.

Complete this acknowledgement form with the following information:

- Verify your inventory
- Complete all sections of the table below, indicate "0" if you have no product to return
- If you have unused product to return, call Customer Service on 0870 606 2040 to obtain a Returned Good Authorization (RGA) number
- Email the completed form to Edwards Customer Service on UK_CustomerService@Edwards.com within 10 days from receipt of this notification

| Model | Lot Number | PO# | Ship To Date | Quantity Shipped From EW | Number of units to be returned | RGA Number |
|---|---|---|---|---|---|---|
| | | | | | | |

| | |
|---|---|
| Name (Print): | |
| Title/Dept. | |
| Telephone Number: | |
| Signature: | |
| Date: | |