

Patient Safety Advisory

Veterans Health Administration Warning System
Published by VA Central Office

July 8, 2004

Item: **Tubing separation of Edwards Lifesciences VAMP Plus® Disposable Pressure Transducers Monitoring Kits**

General Information: Edwards Lifesciences Regulatory Affairs Department has confirmed the receipt of complaints relative to tubing disconnects on their VAMP Plus® Pressure Monitoring Kits that may result in blood leaks and potential for exsanguinations. The complaint rate is presently about 1% and disconnects have not been specific to one lot.

Specific Incident: One VA facility reported 6 failures in the past two weeks in the arterial portion of Edwards Lifesciences Pressure monitoring Kit# PXVP23X3 resulting in potential grave harm to patients.



Picture courtesy of Edwards Lifesciences

Suggestions:

- 1) Caregivers should always inspect disposable products for obvious defects before use.
- 2) Follow directions for use and, ensure all connections are secure and finger tight during set-up of pressure monitoring systems.
- 3) Be vigilant of any blood leaks or dampened blood pressure waveforms when using this transducer.
- 4) Contact your local representatives to exchange, free of charge, all defective, Edwards Lifesciences transducer devices.

Addl. Information: Edwards Lifesciences is conducting an investigation into the cause of these complaints and possible actions to improve the reliability of the tubing connections. They will keep the VA informed on their progress including any recommended actions for customers. Further communication will be provided if deemed necessary to stop using these devices.

Source: VISN 1 and Manufacturer

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