



Missouri Department of Health and Senior Services Recall Alert

The Missouri Department of Health and Senior Services has received this recall from the FDA regarding the Triton Pole Mount Infusion Pumps. Please see below for further details.

WalkMed Infusion Issues Nationwide Recall of Triton Pole Mount Infusion Pumps

Contact:

WalkMed Infusion LLC
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303-420-9569

FOR IMMEDIATE RELEASE - November 24, 2010 - This is an update to a previously announced recall. WalkMed Infusion LLC, Englewood, Colorado, is conducting a nationwide recall of Triton Pole Mount Infusion Pumps. The reason for this recall is that the pump door open alarm does not always work on all pumps to alert the user that the pump door is open. In this state, the pump can still run even though the pump door may be open and could result in a free flow perfusion, and may cause serious injury or death.

Consumers who have Triton Pole Mount Infusion Pumps which are being recalled should return the pump to the manufacturer to be refurbished either by contacting the firm directly or by contacting their distributor. WalkMed can make pumps available that have been upgraded to address this issue to swap out for affected pumps.

If the user must continue using these pumps, they should manually and visually confirm that the pump door is completely closed and latched prior to use by tugging on the pump door and follow the instructions in the operator manual to check that there is no flow through the tube set before starting the pump. If the pump door is correctly closed and latched, the user will not experience a free flow condition from this issue.

The recall includes the serial numbers 001 through 500 and serial numbers TR1401 through TR 2559 manufactured and sold before the end of June 2010.

The firm voluntarily recalled the products after learning of the potential that the door open alarm might not function in certain door open positions. FDA has been apprised of this action.

No injuries have been reported to date and no reports of this issue have been received from field use. The issue was found internally by WalkMed Infusion. The condition has been found on 40% of pumps tested. The pump door may not be effectively closed, even when latched; and the pump door open alarm may also fail and not alert the user to this condition. If the pump is then started, it is possible for the pump mechanism not to be engaged and gravity feed flow condition to exist. Free flow will not occur if the pump door is firmly latched and closed.

The Triton Pole Mount Infusion Pump was distributed nationwide to eight customers or distributors. WalkMed Infusion has notified its distributors and customers by phone and e-mail and has begun the upgrade of all recalled products. Five of these eight distributors and customers have had their pumps upgraded.

Consumers with questions may contact the company at 1-303-420-9569 between the hours of 8:00 AM and 4:00 PM Mountain Time.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm⁹
- Regular Mail: use postage-paid FDA form 3500 available at:
www.fda.gov/MedWatch/getforms.htm¹⁰.
Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

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