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2008 Safety Alert: Heparin and Normal Saline Pre-Filled Flushes

The following information is from AM2 PAT, Inc. Contact the company for a copy of any referenced enclosures.

NATIONWIDE URGENT DEVICE RECALL RECALL EXPANSION 2nd Notice

FOR IMMEDIATE RELEASE

DATE 01/18/08

AM2PAT, INC. (doing business as Sierra Pre-Filled Inc)
455 W. DEPOT STREET
ANGIER, NC 27501
919-552-9689

AM2 PAT, Inc. Issues Nationwide Recall of All Lots and All Sizes of Pre-Filled Heparin and Normal Saline Flushes

AM2 PAT, Inc., Angier, North Carolina, is initiating a Nationwide recall of all lots of both **Heparin** and **Saline** pre-filled flushes manufactured by AM2 PAT. These products are distributed under two brand names, Sierra Pre-Filled Inc. and B. Braun. These products are sold in 3ml, 5ml sizes for Heparin and 3ml, 5ml and 10ml sizes for Normal Saline. Both products are sold as pre-filled syringes.

One lot under recall of this product 1003-02, Lot 070926H, Heparin IV flush syringes has been found to be contaminated with *Serratia marcescens*, which has resulted in patient infections. CDC has confirmed growth of *Serratia marcescens* from several unopened syringes of this product.

This type of bacterial infection could present a serious adverse health consequence that could lead to life-threatening injuries and/or death.

Consumers and user facilities who have any of these recalled pre-filled syringes, Heparin or Saline Lock Flush Solution USP, should **stop using the product immediately**. These products should be immediately quarantined in your inventory and returned to your distributor immediately.

The following information for this recall includes:

MANUFACTURER: Sierra Pre-Filled, Inc., Angier, North Carolina

PRODUCT DESCRIPTION: Heparin Lock Flush Solution USP, All Strengths and Sizes

Saline Lock Flush Solution USP, All Strengths and Sizes

LOT #	NDC #	CATALOG #	Product Brand Name
All	64054-1003-02	1003-02	Heparin Lock Flush 100units/ml 5ml
	64054-1003-01	1003-01	Heparin Lock Flush 100units/ml 3ml
	64054-3005-02	3005-02	Heparin Lock Flush 10units/ml 5ml
	64054-3003-02	3003-02	Heparin Lock Flush 10units/ml 3ml
	64054-3003-06	3003-06	Heparin Lock Flush 10units/mL 3ml (6ml syringe)
	64054-3005-06	3005-06	Heparin Lock Flush 10units/mL 5ml (6ml syringe)
	64054-0910-2	0910-12	Normal Saline Flush 10ml
	64054-0905-2	0905-12	Normal Saline Flush 5ml
	64054-0903-2	0903-12	Normal Saline Flush 3ml

The firm voluntarily recalled these products after confirming bacterial contamination in some end user samples of product code 1003-02, Lot 070926H.

These products have been distributed nationwide.

It appears from an ongoing Food and Drug Administration (FDA) inspection of AM2 PAT, Inc.'s facility that the firm is not in compliance with the Quality System regulation and failed to have adequate controls to ensure necessary sterility of its pre-filled syringes.

Consumers with questions may contact Sierra Pre-Filled at 919-552-9689, Monday through Friday, 10am-5pm Eastern Standard Time.

This recall is being conducted with the knowledge of the Food and Drug Administration.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

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