Recall -- Firm Press Release

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AM2 PAT, Inc. Issues Nationwide Recall of Pre-Filled Heparin Lock Flush Solution USP (5 mL in 12 mL Syringes)

Contact:
AM2PAT, INC.
919-552-9689

FOR IMMEDIATE RELEASE --ANGIER, NC -- December 20, 2007 --- AM2 PAT, Inc., Angier, North Carolina, is initiating a nationwide recall of one lot of Pre-Filled Heparin Lock Flush Solution USP (5 mL in 12 mL Syringes), Lot # 070926H. The heparin IV flush syringes have been found to be contaminated with *Serratia marcescens*, which have 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 these recalled pre-filled syringes, Heparin Lock Flush Solution USP, should **stop using the product immediately**. Please quarantine the affected product in your inventory and return it 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, 100 units/ml, 5ml in pre-filled syringes.

LOT#	NDC#	CATALOG #
070926H	64054-1003-02	1003-02

The firm voluntarily recalled this product after confirming bacterial contamination in some end user samples.

This product was distributed nationwide including the following states: Florida, Texas, Illinois, Colorado, and Pennsylvania.

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.
The firm is continuing to work with FDA and CDC on monitoring this situation and FDA will provide continuing updates.

Consumers with questions may contact the company at **1-919-552-9689 or 847-691-6500 { MONDAY THROUGH FRIDAY 9AM EASTERN TILL 5PM EASTERN}**

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, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

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