



[Home](#) > [News & Events](#) > [Newsroom](#) > [Press Announcements](#)

News & Events

FDA NEWS RELEASE

FOR IMMEDIATE RELEASE

January 25, 2008

Media Inquiries:

Peper Long, 301-827-6242

Consumer Inquiries:

888-INFO-FDA

FDA Warns Public of Contaminated Syringes *AM2 PAT, Inc., issues nationwide recall of all pre-filled syringe flushes*

The U.S. Food and Drug Administration (FDA) today announced a nationwide recall of all lots of heparin and saline pre-filled flush syringes manufactured by AM2 PAT, Inc., of Angier, N.C. Two lots have been found to be contaminated with *Serratia marcescens*, a bacterium that can cause serious injury or death.

These syringes are manufactured by AM2 PAT under the brand names Sierra Pre-filled, Inc. and B. Braun. They are sold in fill sizes of 3mL, 5mL and 10mL and syringe sizes of 6mL and 12mL.

Consumers and health care facilities with any of the recalled, pre-filled Heparin Lock or Normal Saline IV Flush syringes should **stop using the product immediately**. Health care facilities should immediately quarantine the products in their inventory and return them to their distributor. Individual consumers should return them to the location from which they were received, such as a pharmacy or hospital. They should also let their health care providers know that they have been exposed to syringes recalled by FDA.

The recall affects all lots of these products. The FDA received information that Heparin Lock Flush syringes from Lot 070926H and Normal Saline IV syringes from Lot 070917A have been found to be contaminated with *Serratia marcescens*, and have resulted in patient infections. The U.S. Centers for Disease Control and Prevention has confirmed growth of *Serratia marcescens* from unopened heparin syringes.

Traditionally, *Serratia marcescens*, a bacterium found in water and soil has been linked to pneumonia, blood infections, and urinary tract and wound infections. Some patients exposed to the recalled syringes have developed blood infections.

The company voluntarily recalled these products on Jan. 18 after confirming bacterial contamination in some user samples.

Consumers with questions may contact Sierra Pre-Filled at 919-552-9689, Monday through Friday, 10 a.m. to 5 p.m. EST.

Any adverse reactions experienced with the use of the products, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 800-FDA-1088, by fax at 800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, M.D. 20852-9787, or on the MedWatch Web site at www.fda.gov/medwatch.

MANUFACTURER: Sierra Pre-Filled, Inc., Angier, N.C.

PRODUCT DESCRIPTION:

Heparin Lock Flush Solution USP, All Strengths and Sizes

Normal Saline IV Flush Solution USP, All Strengths and Sizes

Sierra Pre-Filled Inc. Products:

NDC#	CATALOG #	Product
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 IV Flush 10mL
64054-0905-2	0905-12	Normal Saline IV Flush 5mL
64054-0903-2	0903-12	Normal Saline IV Flush 3mL

B. Braun Products:

NDC#	CATALOG #	Product
64054-3005-02	513610	Heparin Lock Flush 10units/mL 5mL
64054-1003-01	513611	Heparin Lock Flush 100units/mL 3mL
64054-1003-02	513612	Heparin Lock Flush 100units/mL 5mL
64054-0903-2	513584	Normal Saline IV Flush 3mL
64054-0905-2	513586	Normal Saline IV Flush 5mL
64054-0910-2	513587	Normal Saline IV Flush 10mL

#

[RSS Feed for FDA News Releases](#) ¹ [[what is RSS?](#) ²]

Links on this page:

1. </AboutFDA/ContactFDA/StayInformed/RSSFeeds/PressReleases/rss.xml>
2. </AboutFDA/ContactFDA/StayInformed/RSSFeeds/ucm144575.htm>