

935 Horsham Road
Horsham, PA 19044
215-443-5424
Fax 215-672-6740

Advanced Medical Inc.

Veronica Haug
Vice President, Operations



March 21, 2008

Advanced Medical Systems
935 Horsham Road
Suite M
Horsham, PA 19044

RE: MEDEFIL, INC. HEPARIN RECALL

Dear Customer,

We have been advised that Medefil, Inc. has initiated a voluntary recall of nineteen lots of Heparin I.V. Flush syringes as a result of a recall of USP Heparin Sodium by their supplier SPL of Wisconsin.

The following Medefil product codes are included in the recall:

Product Code	Lot Number
MIH-3335	H107301 H107313 H107340 H108122
	H107305 H107317 H108111 H108127
	H107309 H107322 H108116
MIH-3333	H107332 H108106 H108118
MIH-2233	H08124
MIH-2235	H08113 HH07325
MIH-4425	H207335
MIH-3323	H108117

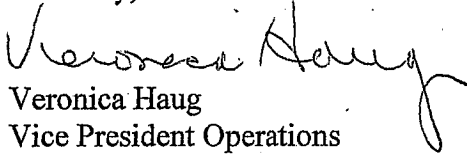
On the enclosed Attachment A is a list of Medefil Heparin Syringes shipped to your institution which fall within the category of recallable products. **Stop using these lots immediately!**

We request that you return all inventory of the lot numbers listed as soon as possible to Advanced Medical Systems at the address listed on our letterhead. Credit will be issued for returned full and partial cases of product for the listed lot numbers only. Freight charges will also be reimbursed if they are indicated on the packing slip accompanying the returned product.

If you are returning product please complete the Response Recall Form and fax to 215-672-6740. If you do not have any of the recalled product we also request that you complete the Response Recall Form.

We apologize for any inconvenience this may cause you and thank you for your cooperation in this matter.

Sincerely,


Veronica Haug
Vice President Operations

Attachment

VMH/cl

MEDEFIL, INC.



URGENT Product Recall

Voluntary Recall of Heparin I.V. Flush Syringes

Lot Numbers: H107301, H107305, H107309, H107313, H107317, H107322, H07325, H107332, H207335, H107340, H108106, H108111, H08113, H108116, H108117, H108118, H108122, H08124, and H108127
Medefil, Inc.

Active Pharmaceutical Ingredient, Heparin Sodium USP Lot Number 1035-0773
Recalled by the manufacturer Scientific Protein Laboratories LLC

March 20, 2008

Mr. Charlie Hokansen
Advanced Medical Systems / Vygon
935 Horsham Road
Horsham, PA 19044

Dear Charlie:

This letter serves as notification of Medefil, Inc.'s voluntary recall of nineteen lots of Heparin I.V. Flush Syringes produced from the Active Pharmaceutical Ingredient, ("API") Heparin Sodium USP, Lot Number 1035-0773 that has been recalled by the manufacturer, Scientific Protein Laboratories LLC.

The Medefil specific lot numbers recalled are listed below.

Lot Number	Product	Concentration	Fill Volume
H107301	Heparin I. V. Flush Syringe	100 Units/ml	5 ml fill in 12 ml Syringe
H107305	Heparin I. V. Flush Syringe	100 Units/ml	5 ml fill in 12 ml Syringe
H107309	Heparin I. V. Flush Syringe	100 Units/ml	5 ml fill in 12 ml Syringe
H107313	Heparin I. V. Flush Syringe	100 Units/ml	5 ml fill in 12 ml Syringe
H107317	Heparin I. V. Flush Syringe	100 Units/ml	5 ml fill in 12 ml Syringe
H107322	Heparin I. V. Flush Syringe	100 Units/ml	5 ml fill in 12 ml Syringe
H07325	Heparin I. V. Flush Syringe	10 Units/ml	5 ml fill in 12 ml Syringe
H107332	Heparin I. V. Flush Syringe	100 Units/ml	3 ml fill in 12 ml Syringe
H207335	Heparin I. V. Flush Syringe	1 Unit/ml	5 ml fill in 6 ml Syringe
H107340	Heparin I. V. Flush Syringe	100 Units/ml	5 ml fill in 12 ml Syringe
H108106	Heparin I. V. Flush Syringe	100 Units/ml	3 ml fill in 12 ml Syringe
H108111	Heparin I. V. Flush Syringe	100 Units/ml	5 ml fill in 12 ml Syringe
H08113	Heparin I. V. Flush Syringe	10 Units/ml	5 ml fill in 12 ml Syringe
H108116	Heparin I. V. Flush Syringe	100 Units/ml	5 ml fill in 12 ml Syringe
H108117	Heparin I. V. Flush Syringe	100 Units/ml	3 ml fill in 6 ml Syringe
H108118	Heparin I. V. Flush Syringe	100 Units/ml	3 ml fill in 12 ml Syringe

Lot Number	Product	Concentration	Fill Volume
H108122	Heparin I. V. Flush Syringe	100 Units/ml	5 ml fill in 12 ml Syringe
H08124	Heparin I. V. Flush Syringe	10 Units/ml	3 ml fill in 12 ml Syringe
H108127	Heparin I. V. Flush Syringe	100 Units/ml	5 ml fill in 12 ml Syringe

This recall has been initiated due to a presence of a contaminant in the specific lot of Heparin Sodium API. The Food and Drug Administration has received reports of serious injuries and/or deaths in patients administered finished heparin injectable products manufactured from heparin API containing this contaminant. Typical symptoms include anaphylactic-like reactions such as: low blood pressure, shortness of breath, nausea, vomiting, abdominal pain.

Please be advised that Medefil has not received any reports of adverse reactions associated with our Heparin I.V. Flush Syringes.

Our records indicate that that you have received these lots. Please confirm if you have received these lots and place them under quarantine. **Stop using these lots Immediately!** Please contact all customers to whom you have further distributed the product and tell them to place them under quarantine and to **stop using these lots Immediately.** Your customers should return all product to you.

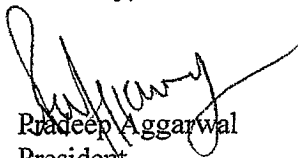
The recall is being conducted with the knowledge of the Food and Drug Administration.

Your assistance is appreciated. If you have any questions concerning this recall, please call me at (630) 682 - 4600. {7:45 am - 4:30 pm central time; Monday – Friday}

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

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

Sincerely,



Randeep Aggarwal
President
Medefil, Inc.

Attachment A

Medefil Urgent Recall Response Form

Please complete, sign and fax this response to Colleen Lynch at fax number (215) 672-6740 to confirm receipt of the Medefil Recall Letter and your intent to arrange shipment to Advanced Medical Systems, 935 Horsham Road, Ste. M, Horsham, PA 19044 for the recalled lots.

Material on Hand:

Product Number	Lot Number	Quantity on Hand
MIH-3335	H107301	
MIH-3335	H107305	
MIH-3335	H107309	
MIH-3335	H107317	
MIH-3335	H107317	
MIH-3335	H107322	
MIH-2235	H07325	
MIH-3333	H107332	
MIH-4425	H207335	
MIH-3335	H107340	
MIH-3333	H108106	
MIH-3335	H108111	
MIH-2235	H08113	
MIH-3335	H108116	
MIH-3323	H108117	
MIH-3333	H108118	
MIH-3335	H108122	
MIH-2233	H08124	
MIH-3335	H108127	

Customer Signature: _____

Signature & Title (I have knowledge of my firm's product inventory and disposition)

Telephone Number

Date

SYSTEM DATE: 032108 042921PM

Advanced Medical Systems

CUSTOMER / ITEM SALES SUMMARY LISTING

DATE 03/20/08

MARCH 20, 2008

PAGE 115

CUSTOMER: H135 - HENRY SCHEIN, INC.

INVOICE DATE RANGE: 11/01/07 TO 03/20/08

ITEM NUMBER	ITEM DESCRIPTION	QTY SOLD	U/M	AVG.PRICE	EXT.PRICE
MIH-3335	HEPARIN 100u 5ml/12ml 60/BOX	24.00	BX	21.60	518.40
			CUSTOMER TOTALS:		518.40