



URGENT PRODUCT RECALL

November 2, 2010

Attention: Pharmacy / Materials manager

RE: Medefil Prefill Heparin Lock Flush Syringe

Medefil, Inc. is conducting a voluntary recall of specific lots of Medefil Prefilled syringes which contain heparin. This recall is being conducted due to a notification Medefil received from its supplier, Scientific Protein laboratories (SPL), of a recall of Heparin Sodium, USP Lot Number 1035-0780 Active Pharmaceutical Ingredient (API).

Scientific Protein laboratories LLC initiated the recall because of additional testing of retained samples of crude Heparin contained in this APL Lot (0135-0780) indicated a trace amount (0.15% to 0.38%) of Oversulfated Chondroitin Sulfate (OSCS). As indicated by the supplier SPL, typical symptoms may include anaphylactic-like reactions such as low blood pressure, shortness of breath, nausea, vomiting, diarrhea and abdominal pain. Medefil, Inc. tested the affected lot during routine incoming inspection and found no evidence or presence of OSCS when tested using then current USP Monograph methods – Nuclear magnetic Resonance (NMR) and Capillary Electrophoresis (CE).

Medefil has not received any complaints and/or reports of adverse reactions associated with this recalled lots of Heparin I.V. Flush Syringes.

This recall applies ONLY to heparin reorder numbers and lot numbers listed on the attached page, no other lot numbers or product codes are affected by this action.

Our records indicate that you may have received product affected by the recall. Please examine your inventory and in-use stock immediately to determine if you have any units of the affected product on hand. **Should any recalled product be found, please remove it from inventory and place in quarantine immediately.** Please refer to the instructions on the attached sheet for product return.

This recall is being conducted with the knowledge of the Food and Drug Administration. We apologize for any inconvenience this action may cause.



PRODUCT REMOVAL ACKNOWLEDGEMENT FORM
Medefil, Inc

It is important that MSD receives the necessary information on the amount of affected products in your possession.

Complete the information below and fax this form as soon as possible by faxing to:

MSD Customer Service at 781-344-8320 Attn: Medefil Recall.

You will be contacted with return instructions within 24 hours.

Please return this form even if the quantity is zero.

Item code	Description	Lot	Qty in cases	Qty in eaches
MIH-2221	HEPARIN 10U 1/6ML	H10228		
MIH-2235	HEPARIN 10U 5/12ML	H10190		
		H10229		
		H10278		
MIH-3333	HEPARIN 100U 3/12ML	H109298		
MIH-3335	HEPARIN 100U 5/12ML	H109291		
		H109293		
		H109295		
		H109297		
		H109299		
		H109300		
MIH-4425	HEPARIN 1U 5/6ML	H210210		

MSD acct # _____

Company Name _____

Address _____

City _____

State _____ Zip _____

Signature _____

Title _____

Date _____

Phone # _____