



## Recall -- Firm Press Release

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### Covidien Initiates Voluntary Recall of Pre-Filled Syringes Containing Heparin

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**FOR IMMEDIATE RELEASE -- MANSFIELD, Massachusetts – March 28, 2008** - Covidien, formerly Tyco Healthcare, was recently notified by its supplier, Scientific Protein Laboratories LLC (SPL), of a nation-wide recall of Heparin Sodium USP active pharmaceutical ingredient. The voluntary recall affects the following 32 lots manufactured and distributed by Covidien in the United States.

Product	Lot Numbers
REF # 8881580121 Monoject PreFill™ 10U/mL Heparin Lock Flush Syringe, 10mL	7082274 7113214
REF # 8881580123 Monoject PreFill™ 10U/mL Heparin Lock Flush Syringe, 3mL	7051524 7113214
REF # 8881580125 Monoject PreFill™ 10U/mL Heparin Lock Flush Syringe 5mL	7051524 7082274 7113164 7113174
REF # 8881580300 Monoject PreFill™ 10U/mL Heparin Lock Flush Syringe 2.5mL in 3mL syringe	7051444
REF # 8881581125 Monoject PreFill™ 10U/mL Heparin Lock Flush Syringe 5mL, with BLUNTIP plastic cannula	7082274

REF # 8881590121 Monoject PreFill™ 100U/mL Heparin Lock Flush Syringe 10mL	7113064
REF # 8881590123 Monoject PreFill™ 100U/mL Heparin Lock Flush Syringe 3mL	7041194 7072154 7113034 8010194
REF # 8881590125 Monoject PreFill™ 100U/mL Heparin Lock Flush Syringe 5mL	7041194 7102804 7041204 7113034 7051534 7113044 7051544 7113054 7051554 7113104 7071924 7113114 7072034 7113154 7072044 8010064 7072054 8010114 7072064 8010134 7072154 8010174 7082284
REF # 8881591125 Monoject PreFill™ 100U/mL Heparin Lock Flush Syringe 5mL, with BLUNTIP plastic cannula	7082284

Covidien began recalling the lots today as a precautionary measure. This product recall was initiated due to a notification received from the supplier, SPL, disclosing that two lots of Heparin Sodium USP Active Pharmaceutical Ingredient acquired by Covidien had a heparin-like contaminant. To date, Covidien has not received any adverse event reports related to this issue. Although a very small product line for Covidien, the Company is committed to following the direction of the Food and Drug Administration (FDA) regarding this matter.

The FDA has received reports of serious injuries and/or deaths in patients who have been administered Heparin injectable products of other companies containing this contaminant. As indicated in the notification issued by the supplier SPL, typical symptoms include anaphylactic-like reactions such as low blood pressure, shortness of breath, nausea, vomiting, diarrhea and abdominal pain.

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

- Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)

- Regular Mail: use postage-paid FDA form 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm). Mail to: MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

Customers who have product in their possession from the recalled product lots should discontinue use immediately. Patients reporting any problems that may be related to the use of this product should be advised to contact a physician. Customers with questions about the return of recalled product should contact the Return Coordinator at 1-800-346-7197, ext. 8677, between 8:30am – 5:00pm (ET), Monday through Friday.

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