



COVIDIEN

URGENT DEVICE RECALL
Handi-Fil Disposable Syringe Fill Tube

DATE February 1, 2010

RE: Handi-Fil Disposable Syringe Fill Tube
Catalog Number: 302050
Lot Number: 7159027
Expiration Date: June 2010

Dear Handi-Fil Disposable Syringe Fill Tube Customer:

Covidien is sending this communication to provide you with important information regarding our Handi-Fil Disposable Syringe Fill Tube, catalog number 302050, lot number 7159027. We have received reports of sterilized packages of this product that are unsealed. We are therefore initiating a voluntary recall of this product and lot.

Lot number 7159027 of the Handi-Fil Disposable Syringe Fill Tube was released for distribution on June 8, 2007. The recall involves only the Handi-Fil Disposable Syringe Fill Tube, lot number 7159027, expiration date June-2010.

The lot number for this product is located on the lower right hand corner of the single use sterilized package. Additionally, the product label on the shipping case contains the lot number in the upper right hand corner.

According to our records, you have received the Handi-Fil Disposable Syringe Fill Tube, catalog number 302050. Please check your inventory of this product. If lot 7159027 is in your inventory, please discontinue use of this product immediately.

Using the attached business response form, please report the quantity of lot 7159027 that is currently in your stock. If you do not have any of this lot in stock, please indicate by checking the appropriate box on the business response form. When completed, fax the completed form to (314) 654-8206. It is important we receive a fax from each customer notified, even if you have no product in stock.

All product, lot number 7159027, is to be returned to Covidien. Once the business notification form is received, an RGA for the quantity of product you have reported will be sent to you for the return. You will receive credit for all returned product; lot number 7159027.

If this product has been distributed by you to other consignees, we request that you notify these consignees of this recall.

If you have questions about this recall, please contact our Product Monitoring department at 800-778-7898. For questions about credit for the product, please call Customer Service at 888-744-1414, menu option 1, then menu option 2.

This voluntary recall is being performed by Covidien with the full knowledge of the U.S. Food and Drug Administration.

Please complete the enclosed business notification form by Friday, February 12, 2010. It is very important that we receive the information from you so we can expedite the return and credit process. We greatly appreciate your cooperation in this matter.

COVIDIEN

675 McDONNELL BOULEVARD.
HAZELWOOD, MO
63042

800-778-7898 [T]
314-654-8206 [F]



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Regards,



Vice President
Quality and Regulatory Compliance

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BUSINESS RESPONSE FORM

RE: Handi-Fil Disposable Syringe Fill Tube
Catalog number 302050
Lot number 7159027

Please use this form to acknowledge receipt of the Handi-Fil Disposable Syringe Fill Tube Recall Letter.

Name of Institution:

Address:

Telephone:

Fax:

CHECK ONE:

We have the following quantities of the recalled product in stock:

Product	Lot number	Quantity-Full cases (100 units per case)	Quantity-Individual units
Handi-Fil Disposable Syringe Fill Tube	7159027		

We have none of the recalled product in stock

Name and title of person completing this form:

Please fax this completed form to Covidien Product Monitoring at **314-654-8206** by February 12, 2010.

If you have any questions, you may contact Covidien Product Monitoring at 800-778-7898 or by email: productmonitoringhazelwood@covidien.com

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