VESCO
MEDICAL

MEDICAL DEVICE RECALL – ENFit Medicine Bottle Adapters

May 09, 2025

Vesco Medical LLC
60 Collegeview Road, Suite 144
Westerville, OH 43081, USA

Dear Customer:

This is to inform you of a Class III product recall involving: Vesco Medical ENFit® Medicine Bottle Adapters (sizes 1-7) product codes VED-690 through VED-696.

Please see the representative product label below for ease in identifying the products that are packaged in 100 unit cases.

This recall has been initiated because Vesco determined that some of the male ENFit fittings of these adapters did not strictly conform to the ISO 80369-3 specification for ENFit fittings such that it is possible for enteral fluid from the bottle to leak at the fitting when the fluid is being drawn into the mating syringe. Vesco discovered the issue pursuant to one customer complaint that it received and has not received any reports of injury or adverse events associated with this issue. We have determined that the probability of risk to health associated with the use of this product is remote. Despite that, Vesco has elected to perform a market removal (recall) of all possibly affected adapters, which includes adapter sizes 1 through 7 which are consecutive part numbers VED-690 through VED-696.

Our records indicate that we shipped affected products to you as listed in the accompanying report with the lot numbers and in the quantities noted.

Please examine your inventory and quarantine any remaining product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

Please contact Vesco at the following address or phone number to inform us of the quantity of product(s) you have quarantined, and to receive a return authorization number, prepaid shipment label and instructions for your return of the product. Alternatively, you can provide a Certificate of Destruction (form attached) that specifies the number and identity of the devices that were destroyed and rendered unusable, signed by an agent of your company.

Vesco Recall Coordinator
60 Collegeview Road, Suite 144
Westerville, OH 43081, USA

Email Address: info@vescomedical.com

Phone: 614.914.5991

Please indicate your choice of either having the product replaced or being reimbursed by check or credit memo for the returned or destroyed goods.

Please also U.S. Mail the enclosed postcard, or email the completed table below, providing the requested information. If you have any questions, please call the Vesco Recall Coordinator at 614.914.5991 between 8:00 am and 5:00 pm ET.
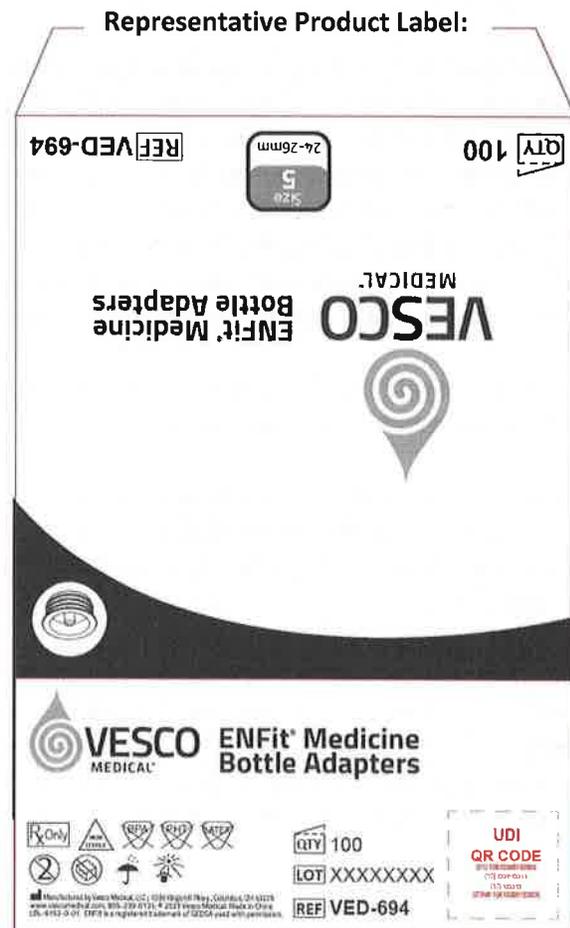
This recall is being made with the knowledge of the U.S. Food and Drug Administration. The FDA has confirmed the classification of this recall as class III.

We appreciate your assistance.

Thank you,

Tom Hancock
President & CEO
Vesco Medical, LLC
60 Collegeview Road, Suite 144
Westerville, OH 43081, USA

Representative Product Label:

ENFit® is a registered trademark of GEDSA used with permission.

INVENTORY REPORT FORM

Please use this form to report the quantity of product(s) you have quarantined for disposition if reporting by email or U.S. Mail.

CUSTOMER or CONSIGNEE:

Name:	
Address:	
Phone:	
Email:	

Product Number	Quantity On Hand (cs of 100 units)	Products to be returned or destroyed	Lot #
VED-690 – size 1			
VED-691 – size 2			
VED-692 – size 3			
VED-693 – size 4			
VED-694 – size 5			
VED-695 – size 6			
VED-696 – size 7			

Please return this completed form to:

Vesco Recall Coordinator
60 Collegeview Road, Suite 144
Westerville, OH 43081, USA

Email Address: info@vescomedical.com

Phone: 614.914.5991

Vesco ENFit® Medicine Adapter Shipment Report

Customer / Consignee: Pediatric Home Services

Inventory Item	VED-690	VED-691	VED-692	VED-693	VED-694	VED-695	VED-696	Grand Total
Pediatric Home Services					1			1

Lot Numbers Potentially Affected:	202408, 202412, 202501

(Quantities are in cases of 100 units)

ENFit is a registered Trademark of GEDSA used with permission.

VESCO MEDICAL	QUALITY MANAGEMENT SYSTEM FORM	Form Number QSF-013-02	
		Unique Document Number	
Effective Date 9/17/15	Certificate of Destruction	Template Number QST-002-02	Revision 2

This is to certify that all materials received from Vesco Medical and indicated for destruction were destroyed. We further warrant that reasonable precautions were taken to prevent any unauthorized third party from gaining access to the destroyed materials while they were in our possession to final disposition.

Items to be Destroyed:

Please complete the information below and return to Vesco Medical by email: info@vescomedical.com or fax 614-902-3275.

Method of Destruction:

Date:

Destruction witnessed by:

Total number of cases destroyed by item number:

Lot Number(s):

Notes if applicable:

Revision History:

Rev.	Description	Author	Effective Date
1	Initial Issue	Jennifer Barbosa/John Kropczynski	03/25/15
2	Update header	Jennifer Barbosa	9/17/15

This document has been approved by the following:

	Approval Required	Signature	Date	Training Required
Author	☒Yes ☐No	On File	On File	☒Yes ☐No
QA/RA	☒Yes ☐No	On File	On File	☒Yes ☐No
Marketing	☒Yes ☐No	On File	On File	☒Yes ☐No
Engineering	☒Yes ☐No	On File	On File	☒Yes ☐No
Manufacturing	☒Yes ☐No	On File	On File	☒Yes ☐No

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