Excellence in Laparoscopy

Oct 10, 2019

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Affected Device:	VHMED® Specimen Retrieval Bag
Affected Model Number(s):	SR001, SR002, SR003, SR004, SR005, SR006, SR007, SR008, SR100, SR101, SR102, SR103, SR104, SR105, SR106, SR200, SR201, SR202, SR203, SR204, SR205, SR206 5RN1, 1RN2, 1RN4, 1RN7, 5RD1, 1RD2, 1RD4, 1RD7, 0RS1, 0RS2, 0RS4, 0RS7, 0RSL, 0RSX, 0RSD, 0RST, 5RR1, 8RR2, 1RR2, 1RR4, 1RR7, 1RRL, 7RRX
Type of Action:	Field Safety Correction Action
Date:	Oct 10, 2019
Attention:	Users and Distributors of VHMED® Specimen Retrieval Bag

Dear valued VHMED® customer,

This Field Safety Notice is being issued to alert you to the release of an updated device Instructions for Use (IFU) for the product model listed above. As of Oct 10, 2019, this revised IFU has been included with all new shipments of these products. No return of product is required in response to this Field Safety Notice.
All relevant National Competent Authorities have been advised of the FSCA

DESCRIPTION OF ISSUE

In Aug 2019, VHMED received several customer complaints that the endobags were broken during surgery and has lost no time in contacting relevant customer over the incidents. VHMED became aware of the potential

VHMED (NANTONG) CO. LTD.
108 Qiantangjiang Road,
Tongzhou Bay, Jiangsu,
226332 China
Tel: +86 (0)513 8692 0166
Fax: +86 (0)513 8692 0266
Web: www.vhmed.com
Email: info@vhmed.com

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for damage of the endobag to occur as a result of inappropriate releasing of string which can result in damage of endobag and failure of closing mechanism. The revised IFU contains clear string releasing guidance that must be followed to ensure device integrity.

RISK TO PATIENT

The device with damaged bag can not meet the clinical needs any more. The medical personnel must seek for other alternatives during the surgery which may extend the operation time and increase the risk of infection.

REQUIRED ACTIONS

All customers who purchased these affected device model prior to Oct 10, 2019 should identify any affected product within their possession and refer to the affected IFU for information on string releasing. Please complete and return the attached Response Form to info@vhmed.com to acknowledge your receipt and understanding of this Field Safety Notice. **You must return a Response Form even if you no longer have affected product in your possession.** If you or your facility has distributed these affected products to other persons or facilities, please promptly forward the recipients copies of this Field Safety Notice and Response Form. No return of product is necessary; this notification is being provided for awareness only.

Sincerely,

施金燕(Jinyan Shi)
Regulatory and Compliance
VHMED (Nantong) Co. Ltd.

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URGENT FIELD SAFETY NOTICE RESPONSE FORM

VHMED® Specimen Retrieval Bag Instructions for Use (IFU) Update

Please complete this Response Form and return it to info@vhmed.com within 10 days of receipt. This form must be completed even if you no longer have affected product in your possession. No return of product is required in response to this Field Safety Notice.

☐ I have read and understand the affected Urgent Medical Device Field Safety Notice regarding the release of an updated Instructions for Use (IFU) for the VHMED® Specimen Retrieval Bag.	
Facility Name:	Facility Address:
Printed Name:	Signature:
Department:	Date:
Email:	Phone Number:

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