



Field Safety Notice

CONMED Corporation

Buffalo Filter® LaparoVue® Visibility System

May 24, 2021

Dear Risk Manager/Purchasing Agent:

CONMED Corporation is sending this communication to provide you with important information concerning the Instructions for Use (IFU) for the Buffalo Filter® LaparoVue® Visibility System. This Correction affects the catalog numbers listed below, manufactured from April 1, 2020, to April 14, 2021:

Catalog Number	Lot Codes	Device Name
LAPVUE10	See Attachment I	LaparoVue® Visibility System, 10 per case
VUETIP10	See Attachment I	VueTip® Trocar Swab Accessory Kit, 10 per case

The Buffalo Filter® LaparoVue® Visibility System Kits are sold as single use, sterile devices. CONMED determined that the Microfiber Cloth included in each of the above kits is missing the radiopaque thread, which would render the cloth invisible under examination by X-Ray. During normal use, the Microfiber cloth sits on a back table, outside of the sterile field, and is used for wiping the scope when it is outside of the patient. It is not intended to be used within the surgical site and is actually too large to be inserted into the laparoscopic surgical site through a 12mm trocar. However, the prior Instructions for Use included with product manufactured between April 1, 2020 to April 14, 2021, state that this Microfiber Cloth is radiopaque. CONMED has received no complaints or reports of any patient or user injury or death associated with this issue.

Based on this information, CONMED has decided to correct the current Instruction for Use documents to remove the reference to the Microfiber Cloth as radiopaque. Please review your inventory of LaparoVue® Visibility System Kits for the following catalog numbers: LAPVUE10 and VUETIP10. Place a copy of the enclosed Instructions for Use, Part No. P000024914, Rev. B (LAPVUE10) and P000024924, Rev. B, with any inventory in your possession with an active expiration date. **Please dispose of any other instructions for use in your possession.**

A copy of the corrected Instructions for Use (IFU) is also available for each of the LaparoVue® Visibility System Kits at www.conmed.com. If you have provided these devices to other facilities or distributors, or you are a distributor, please forward this information as appropriate. It is imperative that all end users of these devices receive this notice.



The IFU changes are as follows:

1. LaparoVue® Visibility System IFU, P000024914, Rev. B: Step 16 now reads “**VueTip® Trocar Swabs are radiopaque.**” The prior IFU read “*VueTip® Trocar Swabs and microfiber cloth are radiopaque.*”
2. VueTip® Trocar Swab Accessory Kit IFU, P000024924, Rev. B: Step 16 now reads “**VueTip® Trocar Swabs are radiopaque.**” The prior IFU read “*VueTip® Trocar Swabs and microfiber cloth are radiopaque.*”

The affected products were distributed between April 1, 2020, and April 14, 2021.

If you have any questions or requests, please don't hesitate to contact the Field Action Support Team at +1-800-448-6506 (8:00am to 7:00pm EST Monday through Friday), fax to +1 315-624-3225, or email lapvue21@conmed.com.

CONMED is dedicated to providing safe and reliable products to our customers and their patients. We are committed to manufacturing product of the highest quality and sincerely apologize for any inconvenience this may cause you or your staff.

Sincerely,



Attachments:

LaparoVue® Visibility System IFU, P000024914, Rev. C

VueTip® Trocar Swab Accessory Kit IFU, P000024924, Rev. C



**ATTACHMENT I
PRODUCT LOT CODES
Field Safety Notice**

Affected catalog numbers and lot codes:

Lot codes for product manufactured to and including the dates listed below, for each catalog number, representing product distributed between April 1, 2020, and April 2, 2021:

Beginning Manufacture Date	Beginning Lot Code	Ending Manufacture Date	Ending Lot Code
5//9/2020	202005094	3/19/2021	202103171

This product has an active shelf life of 1 year (12 months).

CONMED lot codes on boxes and packaging contain a numeric lot code in the following form:

2014 10 01 X

