COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

May 09, 2017

URGENT: MEDICAL DEVICE CORRECTION

ATTENTION:
Risk Management/Recall Administration
Our records indicate that you may have received some of the affected products listed below.

Details on affected devices:

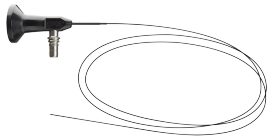
Product Brand Name	Catalog Identifier	Part Number	Lot Number
VueOptic Visualization Source	FVO-150	G25343	All lots
Flexor Vue Deflecting Endoscopic System	FV-090075-150	G50972	
	FV-090045-150	G34306	

Description of the problem:
Cook Medical is initiating a voluntary correction of the products listed above. We have identified that the reprocessing instructions do not provide sufficiently detailed information for the cleaning, disinfection, and sterilization of these products. Our preliminary investigation indicates that the validation data related to the reprocessing of these devices do not meet the current guidance.

There have been no reports of adverse reactions related to inadequate cleaning, disinfection, or sterilization associated with these devices to date.

Potential adverse events that may occur if the products are not adequately reprocessed include urological infections and systemic infections from a urological origin as well as adverse events resulting from chemical residual exposure.

Intended use for affected products:

Product Family	Intended Use	Product Image
VueOptic Visualization Source	Used during endoscopic procedures for direct visualization of body cavities or organs.	
Flexor Vue Deflecting Endoscopic System*	The Flexor 180 Deflecting Ureteral Access Sheath is intended for use during endoscopic procedures to provide working access to body cavities or organs, as well as protection for the VueOptic Visualization Source. The VueOptic Visualization Source is intended for use during endoscopic procedures for direct visualization of body cavities or organs.	

*The Flexor Vue Deflecting Endoscopic System consists of a Flexor 180 Deflecting Ureteral Access Sheath and a VueOptic Visualization Source. The Flexor 180 is intended for one-time use only. The reprocessing instructions apply to the VueOptic Visualization Source.

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Distribution of the VueOptic Visualization Source and Flexor Vue Deflecting Endoscopic System products will not occur until the reprocessing instructions in the Instructions for Use have been corrected.

You can continue to use the VueOptic Visualization Source and Flexor Vue Deflecting Endoscopic System by following the attached document for Reprocessing Instructions.

Action to be taken:

1. Examine your inventory immediately to identify and quarantine those affected products.
2. Implement the provided updated Reprocessing Instructions.
3. Return the required *Acknowledgement and Receipt Form* within 30 days.
4. **Even if you do not have affected products**, you must still complete the *Acknowledgement and Receipt Form* and send it via fax (812.339.7316) or email (fieldactionsna@cookmedical.com).
5. Immediately report any adverse events to Cook Medical Customer Relations at 800.457.4500 or 812.339.2235, Monday through Friday between 7:30 am and 5:00 pm (Eastern Time), or by email at customerrelationsna@cookmedical.com.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA:
Online at: http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail)
Call the FDA at: 1-800-FDA-1088

Transmission of this notice:

This notice must be shared with appropriate personnel, including down to the user level, within your organization or to any organization where the potentially affected devices have been transferred.

This action is being taken with the knowledge of the Food and Drug Administration.

We recognize this situation is a disruption to your normal operations and we sincerely apologize. Thank you again for your immediate assistance in this matter. Should you have any medical questions or concerns, please contact Cook Medical Customer Relations at 800.457.4500 or 812.339.2235. We look forward to your response.

Cook Medical

[redacted]

Rita A. Harden
Director, Customer Relations & Regulatory Reporting

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URGENT: PLEASE RETURN THIS FORM

Acknowledgement and receipt form
Response is required.

RE: Correction on the Vue Optic Visualization Source, and Flexor Vue Deflecting Endoscopic System:

Customer Account Number:	Customer Name:	
Street Address:	City:	
State, Postal Code:	Department:	Phone Number:
Form Completed By (Printed Name, Signature):		Date:

Actions Taken:
This Medical Device Correction should be shared with appropriate personnel within your organization or to any organization where the potentially affected devices have been transferred or relocated.

Please complete the following:

☐Yes ☐No I have read and understood the instructions in the Medical Device Correction letter.

☐Yes ☐No I understand that the Reprocessing Instructions as provided in the letter should be implemented immediately.

☐Yes ☐No I am a Distributor and I have notified customers of this Medical Device Correction.

Other Information:

- Upon completing this Acknowledgement and Receipt Form, please send it to Cook Medical Customer Relations Department via fax (812.339.7316) or email (fieldactionsna@cookmedical.com).
- For information regarding this correction, contact Cook Medical Customer Relations at 800.457.4500 or 812.339.2235.

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Suggested Vue Optic Reprocessing Instructions

Step 1: Clean the Vue Optic Visualization Source

1. Remove all residual organic matter, blood and irrigation solution to allow the sterilization or disinfection medium to contact the surface of the device.
   NOTE: Disinfection solutions do not effectively penetrate residual organic matter.
2. Prepare a cleaning solution using Steris Prolystica 2X Concentrate Enzymatic Cleaner using a minimum effective concentration (1/8 oz. per gallon) and warm (30-43°C) tap or Deionized (DI) water. Immerse the device and soak for 20 minutes.
3. Using a soft nylon-bristled brush, remove any remaining residual organic matter, blood and irrigation solution from the device by brushing each device for 30 seconds while immersed in the solution.
4. Rinse the device thoroughly with clean running tap or DI water for 30 seconds each.
5. Dry the device thoroughly using a soft, lint-free cloth.
6. Prior to disinfection/sterilization and reuse, inspect the device to verify that it functions properly and that no visible soil remains. All surfaces should be smooth and free of abrasions.

NOTE: Automated cleaning methods are not compatible with the Vue Optic Visualization Source.

Step 2: Disinfect or Sterilize the Vue Optic Visualization Source

NOTE: The device has been validated for both disinfection and sterilization. Both are not required.

Disinfection

NOTE: Before disinfecting the Vue Optic Visualization Source, complete cleaning of the device must be performed.

NOTE: Remove all removable components from the Vue Optic Visualization Source (i.e., camera head, light source adapter) before disinfecting the device.

NOTE: Cidex® Activated glutaraldehyde HLD Solution is a high-level disinfection solution that has been found to be compatible with the Vue Optic Visualization Source.

1. Activate Cidex Activated glutaraldehyde HLD Solution per the manufacturer's instructions. Test the activated solution prior to use with CIDEX Solution Test Strips.
2. Immerse the device completely, filling all hard-to-reach areas and eliminating air pockets, in Cidex Activated glutaraldehyde HLD Solution for a minimum of 25 minutes at 25°C.
3. Rinse the device thoroughly in a room-temperature Sterile Water for Injection (SWFI) water bath. Rinse by immersing the device completely for a minimum of one minute. Manually flush all hard-to-reach areas with SWFI water.
4. Agitate the device under SWFI water, bring it above water level, and then re-immerse it.
5. Repeat steps 3 and 4 two additional times, using fresh SWFI for each of the three rinses.

NOTE: Automated disinfection methods are not compatible with the Vue Optic Visualization Source.

Sterilization

NOTE: Before sterilizing the Vue Optic Visualization Source, complete cleaning of the device must be performed.

NOTE: Remove all removable components from the Vue Optic Visualization Source (i.e., camera head, light source adapter) prior to sterilizing the device.

Sterrad Sterilizers

The Vue Optic Visualization Source may also be re-sterilized using hydrogen peroxide sterilization with Sterrad® Sterilizers. The following table illustrates the cycles validated with the VueOptic:

ASP STERRAD® cycles	
STERRAD® 100NX	Standard Cycle
STERRAD® 100NX	Express Cycle
STERRAD® 100NX	Flex Cycle
STERRAD® 100NX	Duo Cycle
STERRAD® NX	Standard Cycle
STERRAD® NX	Advanced Cycle

NOTE: Thoroughly inspect the Vue Optic Visualization Source and components after cleaning, disinfection, and sterilization functions have been performed.