Mitigating the Risk of Cross-Contamination from Valves and Accessories Used for Irrigation through Flexible Gastrointestinal Endoscopes

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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Preface

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

This draft guidance document, when finalized, will: highlight the cross-contamination risk associated with specific types of irrigation valves and accessories when used with flexible gastrointestinal endoscopes; clarify terminology used to describe these devices; and outline strategies to mitigate the risk of cross-contamination between patients. Flexible gastrointestinal endoscopes and accessories (including valves and other devices used for irrigation) are Class II devices, as described in 21 CFR 876.1500. There are many product codes for devices that supply endoscopic irrigation, but the most common include, but are not limited to, FDF (colonoscope and accessories, flexible/rigid), FDS (gastroscope and accessories, flexible/rigid), and OCX (endoscopic irrigation/suction system). These irrigation devices may be submitted to FDA in 510(k) applications as part of a flexible gastrointestinal endoscope system or separately as accessories to flexible gastrointestinal endoscopes.

During colonoscopy or esophagogastroduodenoscopy (EGD), clinicians often use a water bottle to supply irrigation for the procedure. Clinicians typically use a single water bottle for multiple patients without reprocessing the water bottle between patients. This practice raises the risk of

cross-contamination between patients, because the water bottle and associated tubing/connectors can become contaminated with blood[1] or stool[2] that travels up through the endoscope channels and tubing (a phenomenon referred to as "backflow"). FDA has received reports of backflow from irrigation channels into the water bottle and tubing when the irrigation channel did not have a backflow-prevention mechanism in place.

When finalized, this draft guidance will outline the recommended mitigation strategies to reduce the risk of cross-contamination from connectors and irrigation accessories, including device design and appropriate labeling. The recommendations regarding the device design are limited to irrigation systems for flexible gastrointestinal endoscopy, because irrigation systems for other devices, such as arthroscopes, may require different risk mitigation strategies due to the need to aseptically handle those irrigation systems.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Definitions

For the purposes of this guidance, FDA provides the following definitions regarding the terminology associated with the use of flexible gastrointestinal endoscopes and accessories. We recommend that, for consistency, manufacturers of these devices adopt similar definitions in both the labeling and in premarket notifications to ensure consistency in the use and review of these devices.

- 24 Hour Use: The use of a device for 24 hours with no reprocessing between patient uses. A device labeled "24 Hour Use" implies multi-patient use.

- Consumable: A device that is intended to be discarded or replaced after use, with no reprocessing. Consumable devices include all single-use devices and the subset of 24-hour multi-patient use devices that are discarded after use (see also Table 1 below).

- Cross-contamination: The transfer of potentially harmful substances or disease-causing microorganisms from one patient to another patient.

[1] Department of Veterans Affairs Office of Inspector General. Healthcare Inspection: Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities. Report No. 09-01784-146. June 16, 2009. (www.va.gov/oig/54/reports/VAOIG-09-01784-146.pdf)

[2] FDA MAUDE Database http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=964104 and http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=1474183

- Distal End: The distal end of the endoscope is located farthest from the control section of the endoscope, and is the portion of the endoscope that is inserted into the patient.

- Irrigation System: The water bottle, water bottle cap, and associated tubing, valves, and connectors used with water for irrigation during endoscopy. For the purposes of this guidance, the "irrigation system" excludes the most distal valve, but assumes that a distal one-way valve is in place.

- Multiple Patient Use (Multi-Patient Use) Device: A device that is intended to be used on multiple patients, either with reprocessing (for reusable devices) or without reprocessing (for consumable devices) between patient uses.

- Reprocessing: Validated processes used to render a medical device that has been previously used or contaminated, fit for a subsequent single use on another patient. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization.[3]

- Reusable Medical Device: A device intended for repeated use, either on the same or different patients, with appropriate cleaning and other reprocessing between uses (see also Table 1 below).

- Single-Use Device (SUD): A single-use device, also referred to as a disposable device, intended for use on one patient during a single procedure. It is not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient.[4]

Table 1

	Consumable		**Reusable**	
Labeled:	**"Single-use"**	**"24-hour multi-patient use"**	**"Reusable"***	
Action described in labeling:	Discard after single use (a single patient or procedure)	Discard after 24-hour multi-patient use	Reprocess after every patient or procedure	Reprocess after 24-hour multi-patient use

[3] See FDA's draft guidance, "Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf). FDA's draft guidance represents FDA's proposed approach to this issue.

[4] See the FDA guidance, "Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals," (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071058.htm).

*As described in Section IV.B.4.ii., devices labeled as "Reusable" can refer to devices reprocessed after either every patient use or after multi-patient use, and the reprocessing instructions should clearly indicate which is applicable for a given device.

Previous use of the terms in medical device labeling notwithstanding, to be consistent with use of these terms in other guidance documents, FDA is defining the terms "single-use device" and "disposable" to both refer to a device that is used on a single patient during a single procedure, ("every patient use,") and then discarded. A single procedure may include multiple insertions of an endoscope into a single patient.

III. Irrigation Channels

Channels used for irrigation are a potential source for cross-contamination of the irrigation system during the use of flexible gastrointestinal endoscopes. These channels include:

- Air / Water Channel
- Auxiliary Water / Forward Water Jet Channel
- Instrument / Working / Biopsy Channel

A. Air / Water Channel

An Air / Water Channel is present on most flexible gastrointestinal endoscopes. The water in this channel is directed towards the endoscope lens to wash debris from the lens. The valve to prevent backflow of fluids is called the air/water valve or the air/water button. This one-way valve is located on the endoscope control handle, and should be labeled for reprocessing or replacement after every patient use. The air / water valve is the most distal valve in this fluid pathway.

B. Auxiliary Water / Forward Water Jet Channel

An Auxiliary Water / Forward Water Jet Channel is present on a subset of flexible gastrointestinal endoscopes. The auxiliary water inlet is located on either the control handle or on the light guide connector. The water in this channel is forward-directing and is used to wash the gastrointestinal mucosa. The channel diameter is often wider than the diameter of the air/water channel, resulting in a powerful stream of water. For most endoscopes, the valve to prevent backflow of fluids is located outside of the endoscope body and may be part of the endoscope irrigation connector, or may be located within tubing that is attached to the water bottle.

FDA has received reports that, in the absence of a valve to prevent backflow, patient fluids such as blood[1] and stool[2] can travel through the auxiliary water channel and into the auxiliary water inlet and irrigation system. Therefore, the length and narrow diameters of channels in gastrointestinal endoscopes may not be sufficient to prevent contamination of the irrigation system. Although FDA has not yet received reports of infection that can be attributed to backflow, the risk of cross-contamination should be mitigated by following the measures recommended in Section IV, below.

For auxiliary water channels with external valves, any device that is directly connected to the auxiliary water inlet (up to and including the distal valve in the fluid pathway) should be considered contaminated, and should be reprocessed or replaced after every patient use. For those endoscopes with an internal one-way valve in the auxiliary water channel, the one-way valve should be labeled for reprocessing or replacement after every patient use.

C. Instrument / Working / Biopsy Channel

An Instrument / Working / Biopsy Channel is present on most flexible gastrointestinal endoscopes. The primary purpose of this channel is to allow instrument access through the endoscope, however specialized connectors allow irrigation through this channel. The channel diameter is wide compared to other channels; therefore, irrigation through this channel has the potential to provide a powerful stream of water that can be used to wash the gastrointestinal mucosa. Any device that is directly connected to the biopsy channel (up to and including the distal one-way valve in the fluid path) should be considered contaminated. As such, those devices should be labeled for reprocessing or replacement after every patient use.

IV. Mitigation of Cross-contamination Risk

The risk of cross-contamination from endoscope connectors during the use of flexible gastrointestinal endoscopes can be mitigated by a combination of device design, labeling, and proper device handling, as described below.

A. Device Design

1. Prevention of Backflow

When irrigating through flexible gastrointestinal endoscopes, there should be at least one device component within the fluid pathway that has a one-way valve or other feature that prevents the backflow of fluids into the irrigation system. This valve or other feature should be tested with chemical and/or microbiological assays to demonstrate that it is capable of preventing the backward flow of fluids and contamination of the water bottle by microorganisms. In the absence of a one-way valve or other feature demonstrated to prevent backflow and contamination, the water bottle and associated tubing should be designed to be reprocessed or discarded after every patient use to reduce the risk of patient infection.

2. Reprocessing or Discarding of Devices Containing the Distal One-Way Valve

Any device component between the patient and the distal valve (including the valve itself) should be designed to be either reprocessed or discarded after every patient use.

i. Reprocessing Reusable Devices

Reusable devices should be designed to withstand multiple cleanings and high-level disinfection or sterilization cycles. Manufacturers should provide performance data to support the validation of the reprocessing protocol, and inform users that the reusable device should be reprocessed after every patient use.

OR

ii. Replacing Consumable Devices

Currently, there are no accepted scientific methods to determine whether any amount of patient material can be unintentionally transferred to other patients without harm; therefore, there is no recommended testing to evaluate the safety of a 24-hour multi-patient use connector with no reprocessing between patient uses.

3. Reprocessing or Disposal of the Irrigation System

Manufacturers may wish to indicate irrigation systems with a distal one-way valve for use in multiple patients over a certain time period (e.g., 24 hours), and then to be reprocessed or discarded. Performance data to support use in multiple patients and over the proposed time duration should be provided to demonstrate that the one-way valve provides adequate mitigation against the risk of cross-contamination between patients.

B. Labeling

Labeling should be clear and specific regarding the proper use of the device. We recommend that terminology be consistent with the definitions provided in Section II, above. Instructions for use should address the following points:

1. Identification of the channel/inlet to which each device component connects;
2. Identification of compatible endoscopes and accessories (or criteria to determine compatibility);
3. Clear identification of the device or component that includes a one-way valve or other backflow prevention feature;
4. Identification of the device as consumable or reusable;

i. Consumable Device

- Identify the device as "single-use device" or "24-hour multi-patient use device."
  - Note that 24-hour multi-patient use devices should not be labeled "single-use" or "disposable."
- Consumable devices should not include reprocessing instructions.
- Labeling should include disposal instructions and should specify that the device should be discarded after every patient use for single-use devices, or after 24 hours for 24-hour multi-patient use devices.

ii. Reusable Device

- Identify the device as "reusable."
- The validated reprocessing instructions should indicate whether the device is reprocessed after every patient use or after 24-hour multi-patient use.

Table 2, below, describes the appropriate disposal/reprocessing actions for the irrigation system and devices between the patient and the distal valve (including the valve) for consumable devices or reusable devices. The table describes the minimum recommended action that should be implemented to minimize risk, assuming that the irrigation system includes a one-way valve and performance data as described above has been provided; reprocessing or replacing the irrigation system after every patient use is also acceptable.

Table 2

Device	Frequency of Action	Action for Consumable Device	Action for Reusable Device
Devices between the patient and the distal valve (including the valve)	After every patient use	Discard after every patient use	Reprocess after every patient use
Irrigation system	After 24 hours	Discard after 24 hours (multi-patient use without reprocessing between patient uses)	Reprocess after 24 hours (multi-patient use without reprocessing between patient uses)