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

Guidance for Industry and Food and Drug Administration Staff

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Preface

Public Comment

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The objectives of this guidance document are to: 1) highlight the cross-contamination risk associated with specific types of irrigation valves and accessories when used with flexible gastrointestinal endoscopes; 2) clarify terminology used to describe these devices; and 3) 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. FDA uses product codes to identify devices that supply endoscopic irrigation, the most common being 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 premarket notification (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] stool,[2] or other patient fluids[3] that travel back through the endoscope channels and tubing (a phenomenon hereafter referred to as "backflow," see Figure 1). 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.

This guidance outlines 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.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database Web site at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

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

FDA provides the following definitions for terms used to describe components of flexible gastrointestinal endoscopes and accessories. We provide additional explanations for these terms in Figure 1. To help ensure consistency in the use and premarket review of these devices, FDA recommends that device manufacturers use the terms and definitions described below in both their labeling and 510(k)s.

FDA is defining both terms "single-use device" and "disposable" to refer to a device that is used on a single patient during a single procedure and then discarded. A single procedure performed on one patient, hereafter referred to as a "patient use," may include multiple insertions of an endoscope into the patient.

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[1] For a description of blood traveling back towards the water bottle, please see Report No. 09-01784-146 issued on June 16, 2009 by the Department of Veterans Affairs Office of Inspector General. The report is titled Healthcare Inspection: Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities. (www.va.gov/oig/54/reports/VAOIG-09-01784-146.pdf).

[2] For reports of stool traveling back towards the water bottle, please see these descriptions of two different events submitted to the 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

[3] For reports of unspecified patient fluids traveling back towards the water bottle, please see these descriptions of two different events submitted to the FDA MAUDE Database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=2401789 and http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=3229842

- 24 Hour Use: The use of a device within a single 24-hour period with no reprocessing between patient uses. A device labeled "24 Hour Use" implies multi-patient use.

- Backflow-Prevention Valve: The valve that is intended to prevent the proximal irrigation system from being contaminated by backflow of fluids from the patient (see Figure 1). When multiple valves are present in the irrigation system, the backflow-prevention valve is the one closest to the patient. When used in the auxiliary-water / forward-water-jet channel, this valve is frequently referred to as a "one-way valve."

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

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

- Irrigation System: All devices and device components between the patient and the water bottle (including the bottle) that convey or contact water used for irrigation. The irrigation system may be subdivided into the Distal Irrigation System and Proximal Irrigation System:

    - Distal Irrigation System: All components of the irrigation system between the patient and the backflow-prevention valve, including the backflow-prevention valve (e.g., endoscope, distal tubes/accessories, etc.).

    - Proximal Irrigation System: All components of the irrigation system between the water bottle and the backflow-prevention valve, excluding the backflow-prevention valve (e.g., water bottle, water bottle cap, proximal tubes/accessories, etc.).

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

- Reprocessing: Validated processes used to render a medical device fit for a subsequent single use after it has been previously used or contaminated. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization. For guidance regarding reprocessing of reusable medical devices, please see "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" (http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm253010.pdf).

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

- Single-Use Device (SUD): A single-use device, also referred to as a disposable device, is 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. For guidance regarding the labeling of single-use devices, please see "Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071069.pdf).

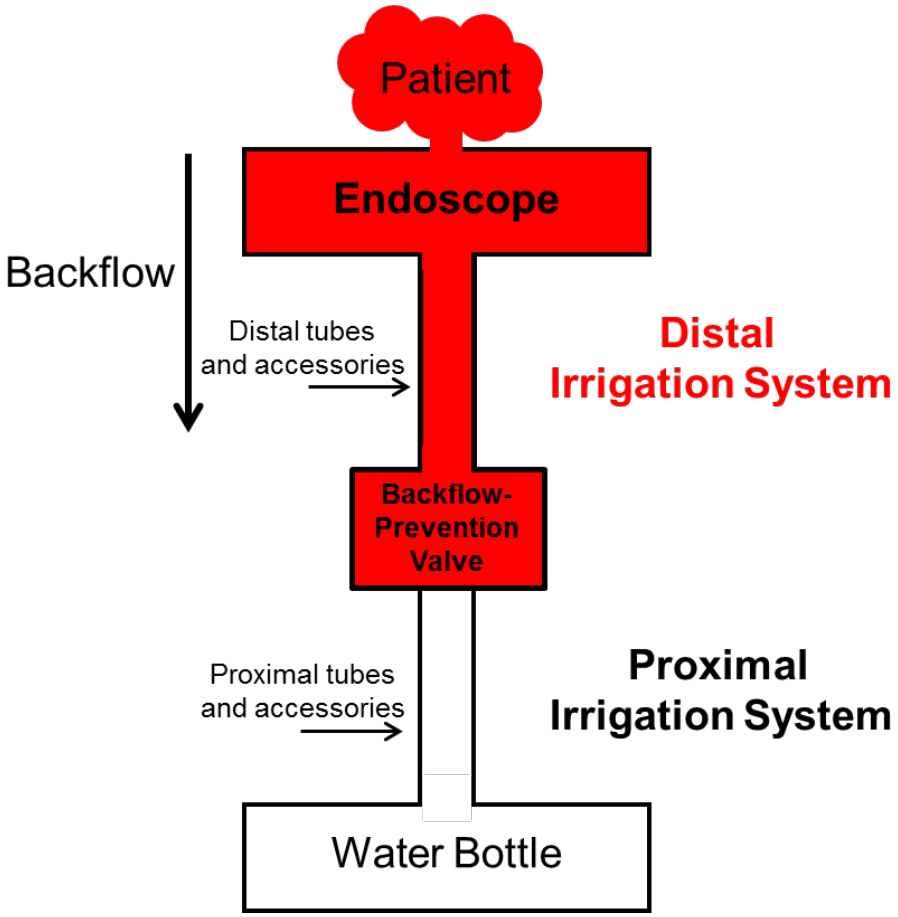

Figure 1. Illustration of critical terms defined in this guidance document.
A backflow-prevention valve divides the irrigation system into distal and proximal components. The backflow-prevention valve is designed to prevent backflow of contaminated fluid (colored red here) from the patient into the proximal irrigation system so that the water bottle and proximal tubes/accessories may be used safely for multiple patients.

III. Irrigation Channels

Channels used for irrigation are a potential source of contamination of the proximal 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 backflow-prevention valve in this channel is called the air/water valve or the air/water button. This backflow-prevention valve is located on the endoscope control handle, and should be labeled for reprocessing or replacement after every patient use because of the potential for contamination of the valve.

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 backflow-prevention valve 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 backflow-prevention valve, patient fluids such as blood and stool can travel back through the auxiliary water channel and into the auxiliary water inlet and other parts of the irrigation system. Therefore, the length and narrow diameters of channels in gastrointestinal endoscopes alone 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 below in Section IV.

For auxiliary water channels with external valves, any device that is *directly* connected to the auxiliary water inlet (up to and including the backflow-prevention valve in the fluid pathway) should be considered part of the distal irrigation system and thus contaminated, and should be reprocessed or replaced after every patient use. For those endoscopes with an internal backflow-prevention valve in the auxiliary water channel, the backflow-prevention 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 or device component that is directly connected to the biopsy channel during an endoscopic procedure 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. If the irrigation system does not include a backflow-prevention valve or other feature demonstrated to prevent backflow of contaminated fluids into the proximal irrigation system, then all components of the irrigation system should be reprocessed or discarded after being used during a procedure in one patient and before starting one in the next patient.

A. Device Design

(1) Prevention of Backflow to the Proximal Irrigation System

When irrigating through flexible gastrointestinal endoscopes, FDA recommends there be at least one device component within the irrigation system that has a backflow-prevention valve or other feature to prevent the backflow of fluids contaminated with microorganisms into the proximal irrigation system. FDA recommends this backflow-prevention valve or other feature be tested with quantitative chemical and/or microbiological assays to demonstrate prevention of the backward flow of fluids under simulated use conditions.

Performance testing of the device system incorporating backflow-prevention valves or other features for reducing the risk of cross-contamination between patients should utilize worst case conditions, including worst case backpressure, pressure cycling to simulate periodic changes in fluid pressure and flow, duration, and concentration of chemical and/or microbiological markers. The test protocol should identify relevant conditions including pressures, fluid volumes and flow conditions, type and purpose of connections within the flow path, tubing lengths, and time of relevant procedures that may influence backflow of fluid into the system. The test report should include relevant descriptive information on the system, including a description of the backflow-prevention valve function and its critical operational characteristics such as cracking pressure and maximum back pressure, identification of the potential for regurgitation on valve closing, and the volume of fluid that may backflow upon regurgitation from back pressure. In addition, the test method should include appropriate positive and negative controls and be of sufficient sensitivity for the study objectives.

(2) Reprocessing or Disposal of the Distal Irrigation System

Any device component in the distal irrigation system should be designed to be either reprocessed or discarded at the conclusion of a procedure in one patient and before starting one in the next patient.

a. Reprocessing Reusable Devices

Reusable devices should be designed to withstand multiple cleanings and high-level disinfection or sterilization cycles. Manufacturers should validate their reprocessing instructions as recommended in the FDA guidance document entitled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" (http://www.fda.gov/ucm/groups/fdagov-

public/@fdagov-meddev-gen/documents/document/ucm253010.pdf) and inform users that the reusable device should be reprocessed after every patient use.

b. Disposal of Consumable Devices

Consumable devices in the distal irrigation system should be discarded or replaced after every patient use. To mitigate the risk of cross-contamination, you should not use devices in the distal irrigation system with multiple patients unless you reprocess the devices between patients. Currently, there are no accepted scientific methods to determine whether any amount of patient material can be unintentionally transferred from one patient to another patient without harm. Therefore, FDA does not recommend using 24-hour multi-patient use connectors in the distal irrigation system unless these connectors are reprocessed between patients.

(3) Reprocessing or Disposal of the Proximal Irrigation System

Manufacturers may wish to indicate the use of proximal irrigation systems with a backflow-prevention valve and for use in multiple patients over a certain time period (e.g., 24 hours or less), and then to be reprocessed or discarded. FDA recommends device manufacturers provide performance data to support use in multiple patients and over the proposed time frame to demonstrate that the backflow-prevention valve or other feature in the distal irrigation system 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 of this guidance document. Instructions for use should address the following points:

1. Clear instructions for installing irrigation devices, including valves, connectors, and tubing, to the irrigation system of the endoscope;
2. Identification of the channel/inlet to which each device component connects;
3. Identification of compatible endoscopes and accessories (or criteria to determine compatibility);
4. Clear identification of the device or component that includes a backflow-prevention valve or other backflow prevention feature;
5. Identification of each device or component that is part of the proximal irrigation system or the distal irrigation system; and
6. Identification of the device as consumable or reusable.
    a. Consumable Device
        i. You should identify the device as a "single-use device" or a "24-hour multi-patient use device." [Note that 24-hour multi-patient use devices should not be labeled "single-use" or "disposable."]
        ii. Consumable devices should not include reprocessing instructions.
        iii. Labeling should include disposal instructions.

iv. For single-use devices, labeling should specify that the device should be discarded after being used on one patient and should not be used on multiple patients.

v. For 24-hour multi-patient use devices, labeling should recommend a maximum number of patient uses as well as a maximum duration of use, up to 24 hours, prior to discarding the device.

b. Reusable Device

i. You should identify the device as "reusable" or "reusable, after 24-hour multi-patient use."

ii. The validated reprocessing instructions should indicate whether the device is reprocessed after every patient use or after 24-hour multi-patient use. Reprocessing instructions should be consistent with the recommendations described in the FDA guidance document entitled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." We recommend you refer to the current version of ANSI/AAMI ST91: *Flexible and semi-rigid endoscope processing in health care facilities*, for consensus recommendations regarding the reprocessing of flexible endoscopes and accessories.

iii. For 24-hour multi-patient use devices, labeling should recommend a maximum number of patient uses as well as a maximum duration of use, up to 24 hours, prior to reprocessing the device.

Table 1 describes the recommended disposal/reprocessing actions for devices in the proximal and distal irrigation system labeled as consumable or reusable. The table describes the minimum recommended action that should be implemented to minimize risk, assuming that the irrigation system includes a backflow-prevention valve and performance data as described above has been provided. Reprocessing or replacing the entire irrigation system at the conclusion of the procedure in each patient is also acceptable and is recommended if the irrigation system does not include a backflow-prevention valve or other backflow-prevention feature.

Table 1. Irrigation Systems with a Backflow-Prevention Valve: Recommended Labeling and Actions for System Components

Device	Frequency of Action	Labeling and Action for Consumable Device	Labeling and Action for Reusable Device
Distal Irrigation System	After every patient use	Label as "single-use device" Discard	Label as "reusable device" Reprocess
Proximal Irrigation system	After 24 hours (reprocessing not necessary between patient uses)	Label as "24-hour multi-patient use device" Discard	Label as "reusable, after 24-hour multi-patient use" Reprocess

Manufacturers of flexible gastrointestinal endoscopes and accessories (including valves and other devices used for irrigation) must establish and maintain procedures for validating the design of their device, which shall ensure that the device conforms to defined user needs and intended uses (21 CFR 820.30(g)). FDA interprets this to require manufacturers to validate the design, including instructions for use and associated claims, of such devices to ensure that the device can be safely and effectively used as intended. This data should be kept and maintained at the manufacturer's facility. The data should be made available for review at the request of FDA or made available during an FDA inspection.