Updated Information for Healthcare Providers Regarding Duodenoscopes

- FDA has received inquiries from healthcare providers about whether they should cancel ERCP procedures, based on the fact that one specific model duodenoscope manufactured by Olympus (the TJF-Q180V) does not currently have a 510(k) clearance. FDA is not recommending that healthcare providers cancel ERCP procedures for their patients who need them.

- Olympus has a pending 510(k) application for this device, and the company continues to market the product while the application is under review. FDA is not taking action against Olympus regarding its device during our review of the application, because, based on the information currently available to the Agency, we believe that that removal of the device from the market could lead to an insufficient number of available duodenoscopes to meet the clinical demand in the United States of approximately 500,000 procedures per year.

- The FDA’s analysis indicates that the reported duodenoscope-associated infections have occurred in patients who have had procedures with duodenoscopes from all three manufacturers. At this time, FDA has no evidence that the lack of a 510(k) clearance was associated with the infections.

- FDA recommends the following:
  - Thoroughly clean and disinfect duodenoscopes, pursuant to the manufacturers’ instructions;
  - Have a comprehensive quality program in place for reprocessing duodenoscopes;
  - If you suspect that a duodenoscope may be associated with a patient infection, take it out of service and meticulously clean and disinfect it until it is verified to be free of pathogens;
  - Inform patients of the benefits and risks associated with ERCP procedures, including the risk of possible infection;
  - Discuss with your patients what they should expect following the ERCP procedure and what symptoms (such as fever or chills, chest pain, severe abdominal pain, trouble swallowing or breathing, nausea and vomiting, or black or tarry stools) should prompt additional follow-up;
  - Submit a report to the manufacturer and to the FDA via MedWatch if you suspect problems have led to patient infections.
Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication

Date Issued: February 19, 2015

Audience:
- Gastroenterologists
- Gastrointestinal surgeons
- Endoscopy nurses
- Staff working in endoscopy reprocessing units in health care facilities
- Infection control practitioners
- Patients considering endoscopic retrograde cholangiopancreatography (ERCP) procedures

Medical Specialties: Gastroenterology, Infection Control

Device: All ERCP endoscopes (side-viewing duodenoscopes)

Figure 1: Close-up view of an ERCP endoscope tip.

Purpose:
The FDA wants to raise awareness among health care professionals, including those
working in reprocessing units in health care facilities, that the complex design of ERCP endoscopes (also called duodenoscopes) may impede effective reprocessing. Reprocessing is a detailed, multistep process to clean and disinfect or sterilize reusable devices. Recent medical publications and adverse event reports associate multidrug-resistant bacterial infections in patients who have undergone ERCP with reprocessed duodenoscopes, even when manufacturer reprocessing instructions are followed correctly. Meticulously cleaning duodenoscopes prior to high-level disinfection should reduce the risk of transmitting infection, but may not entirely eliminate it.

Summary of Problem and Scope:

More than 500,000 ERCP procedures using duodenoscopes are performed in the United States annually. The procedure is the least invasive way of draining fluids from pancreatic and biliary ducts blocked by cancerous tumors, gallstones, or other conditions. Duodenoscopes are flexible, lighted tubes that are threaded through the mouth, throat, stomach, and into the top of the small intestine (the duodenum). They contain a hollow channel that allows the injection of contrast dye or the insertion of other instruments to obtain tissue samples for biopsy or treat certain abnormalities. Unlike most other endoscopes, duodenoscopes also have a movable “elevator” mechanism at the tip. The elevator mechanism changes the angle of the accessory exiting the accessory channel, which allows the instrument to access the ducts to treat problems with fluid drainage.

Although the complex design of duodenoscopes improves the efficiency and effectiveness of ERCP, it causes challenges for cleaning and high-level disinfection. Some parts of the scopes may be extremely difficult to access and effective cleaning of all areas of the duodenoscope may not be possible. In addition, a recent FDA engineering assessment and a growing body of literature have identified design issues in duodenoscopes that complicate reprocessing of these devices. For example, one step of the manual cleaning instructions in device labeling is to brush the elevator area. However, the moving parts of the elevator mechanism contain microscopic crevices that may not be reached with a brush. Residual body fluids and organic debris may remain in these crevices after cleaning and disinfection. If these fluids contain microbial contamination, subsequent patients may be exposed to serious infections.

The FDA is closely monitoring the association between reprocessed duodenoscopes and the transmission of infectious agents, including multidrug-resistant bacterial infections caused by Carbapenem-Resistant Enterobacteriaceae (CRE) such as Klebsiella species and Escherichia coli. In total, from January 2013 through December 2014, the FDA received 75 MDRs encompassing approximately 135 patients in the United States relating to possible microbial transmission from reprocessed duodenoscopes. It is possible that not all cases have been reported to the FDA. The agency is continuing to evaluate information about documented and potential infections from multiple sources, including Medical Device Reports (MDRs) submitted to the FDA, the medical literature, the health care community, professional medical societies, and the Centers for Disease Control and Prevention (CDC).

Recommendations for Facilities and Staff that Reprocess ERCP
Duodenoscopes:

- **Follow closely all manufacturer instructions for cleaning and processing.**
  - The FDA recommends adherence to general endoscope reprocessing guidelines and practices established by the infection control community and endoscopy professionals, as described in the Additional Resources section, below. In addition, it is important to follow specific reprocessing instructions in the manufacturer’s labeling for each device.
  - Even though duodenoscopes are inherently difficult to reprocess, strict adherence to the manufacturer’s reprocessing instructions will minimize the risk of infection. Deviations from the manufacturer’s instructions for reprocessing may contribute to contamination. The benefit of using cleaning accessories not specified in the manufacturer’s instructions, such as channel flushing aids, brushes, and cleaning agents, is not known.

- **Report problems with reprocessing the device to the manufacturer and to the FDA, as described below.**

- **Follow these additional general best practices:**
  - Meticulously clean the elevator mechanism and the recesses surrounding the elevator mechanism by hand, even when using an automated endoscope reprocessor (AER). Raise and lower the elevator throughout the manual cleaning process to allow brushing of both sides.
  - Implement a comprehensive quality control program for reprocessing duodenoscopes. Your reprocessing program should include written procedures for monitoring training and adherence to the program, and documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure.

**Recommendations for Health Care Providers:**

- Inform patients of the benefits and risks associated with ERCP procedures.
- Discuss with your patients what they should expect following the ERCP procedure and what symptoms (such as fever or chills, chest pain, severe abdominal pain, trouble swallowing or breathing, nausea and vomiting, or black or tarry stools) should prompt additional follow-up.
- Consider taking a duodenoscope out of service until it has been verified to be free of pathogens if a patient develops an infection with a multidrug-resistant organism following ERCP, and you suspect that there may be a link between the duodenoscope and the infection.
- Submit a report to the manufacturer and to the FDA via MedWatch.
as described below, if you suspect that problems with reprocessing a duodenoscope have led to patient infections.

**Recommendations for Patients:**

- Discuss the benefits and risks of procedures using duodenoscopes with your physician. For most patients, the benefits of ERCP outweigh the risks of infection. ERCP often treats life-threatening conditions that can lead to serious health consequences if not addressed.
- Ask your doctor what to expect following the procedure and when to seek medical attention. Following ERCP, many patients may experience mild symptoms such as a sore throat or mild abdominal discomfort. Call your doctor if, following your procedure, you have a fever or chills, or other symptoms that may be a sign of a more serious problem (such as chest pain, severe abdominal pain, trouble swallowing or breathing, nausea and vomiting, or black or tarry stools).

**FDA Activities:**

The FDA is actively engaged with other government agencies, including CDC, and the manufacturers of duodenoscopes used in the United States to identify the causes and risk factors for transmission of infectious agents and develop solutions to minimize patient exposure. Recent FDA activities include:

- Collaboration with CDC and the Environmental Protection Agency (EPA) to test the antibiotic-resistant organisms to assess their susceptibility to high-level disinfectants.
- Exploration, with CDC, of additional potential strategies to reduce the risk of infections, such as microbiological surveillance testing of duodenoscopes.
- Communication with international public health agencies to study the extent of the problem and identify possible solutions being considered outside the United States.
- Reviews of reprocessing validation data from each of the three manufacturers marketing duodenoscopes in the United States (FUJIFILM, Olympus, and Pentax).

The FDA continues to actively monitor this situation and will provide updates as appropriate.

**Reporting Problems to the FDA:**

Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations [MedicalDevice/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm). Health care personnel employed by facilities that are subject to the FDA’s user facility reporting requirements [MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm) should follow the reporting procedures established by their facilities.
Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. Health care providers should submit voluntary reports of the transmission of an infection due to an inadequately cleaned duodenoscope to the agency via the Medical Device Reporting (MDR) (/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm) process.

If, after following the manufacturer’s reprocessing instructions, a health care provider suspects bacterial contamination—either because of an increase in infections after ERCP, or because of the results of bacterial surveillance culturing of duodenoscopes—we encourage the health care provider to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/Safety/MedWatch/HowToReport/ucm2007306.htm).

Additional Resources:

- FDA: Reprocessing of Reusable Medical Devices (/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm2025268.htm)
- FDA: Preventing Cross-Contamination in Endoscope Processing: FDA Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm)

References:


Contact Information:
If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.
INTERIM CULTURE METHOD FOR THE DUODENOSCOPE – DISTAL END AND INSTRUMENT CHANNEL

CDC Disclaimer: This protocol has not been validated. The protocol is still being developed and evaluated for the major duodenoscope types. This is an interim protocol and will be updated accordingly.

Purpose

This method is to culture bacteria from reprocessed duodenoscopes (after drying) specifically from the distal end and instrument channel. A laboratory will need to decide whether to process the samples with a Culture Method A - Presence/ Absence by Enrichment method or Culture Method B - Quantitative. The quantitative method also incorporates enriching the remainder of the sample to capture lower levels of contamination.

Sample Types:
- Instrument channel flush (50 ml)
- Distal end and elevator mechanism, sampled by a channel-opening brush (submerged in 50 ml)

Materials and Reagents

- Vortex
- Incubator 35°C to 37°C
- Conical/ centrifugation tubes of various sizes tubes (50-cc, 1.5-cc)
- Sterile 0.01M phosphate buffered saline (PBS) with 0.02% Tween®-80 solution (PBST) (one example - Teknova, #P3875)
- Blood agar plates
- Selective agar (suggest MacConkey II agar plates for the detection of enteric pathogens)
- Tryptic soy broth (5 mL) (one example – Hardy Diagnostics, K89)
- Pipets and pipette tips
Culture Method A – Presence/ Absence by Enrichment

Note: Process irrigation water and PBST negative controls using the same protocol as the samples

1. Vortex the sample for 2 minutes in 10 second bursts  
2. Aseptically, remove the channel-opening brush  
3. Transfer the fluid samples (instrument channel flush, channel-opening brush fluid) to 50-cc conical tubes  
4. Concentrate by centrifugation on a benchtop centrifuge equipped for high volume suspensions (range: 3,500 - 5,000 x g for 10 - 15 min).  
5. Remove supernatant for a final volume of 1 mL without disrupting the pellet, or re-suspend the pellet to a final volume of 1 mL using PBST  
6. Transfer the 1 mL sample to TSB (5 mL)  
7. Incubate at 35°C to 37°C for 48 hrs  
8. Check and record turbidity at 18 to 24 hrs (overnight) and 48 hrs  
9. If the sample is turbid, streak broth for isolation onto blood agar and MacConkey II agar plates  
10. Incubate at 35°C to 37°C; MacConkey II agar for 18- 24 hrs (overnight) and blood agar for 48 hrs  
11. Observe plates for suspect colonies  
12. Streak suspect colonies for isolation  
13. Work up pure isolates for characterization of “low- concern” bacteria, which represent flora from skin and the environment, and species identification of “high-concern” bacteria.  
   a. “Low-concern” bacteria include, but are not limited to, coagulase-negative staphylococci, micrococci, diptheroids, *Bacillus* spp. and other gram-positive rods  
   b. “High-concern” bacteria include, but are not limited to, *Staphylococcus aureus*, *Enterococcus* spp., *Streptococcus* sp. viridians group, *Pseudomonas aeruginosa*, *Klebsiella* spp., *Salmonella* spp., *Shigella* spp. and other enteric gram-negative bacilli.

Culture Method B - Quantitative

Note: Process the irrigation water and PBST negative controls using the same protocol as the samples

1. Vortex the sample for 2 minutes in 10 second bursts  
2. Aseptically, remove the channel-opening brush
3. Transfer the fluid samples (instrument channel flush, channel-opening brush fluid) to 50-cc conical tubes

4. Concentrate by centrifugation on a benchtop centrifuge equipped for high volume suspensions (range: 3,500 - 5,000 x g for 10 - 15 min)

5. Remove supernatant without disrupting the pellet to a final volume of 1 mL. If needed, add PBST to a final volume of 1 mL and re-suspend.

6. Prepare a 1:10 dilution by adding 100 µl of sample to 900 µl of PBST

7. Vortex the sample for 10 sec

8. Pipet the following on to blood agar and MacConkey II agar plates in triplicate and spread evenly to allow for counting colonies
   a. 100 µl of the undiluted sample (final dilution 10^{-1})
   b. 100 µl 1:10 dilution (final dilution 10^{-2})

9. Add remainder of sample to TSB (5 mL) for enrichment in order to capture contamination below the detection limit

10. Incubate at 35°C to 37°C; MacConkey II agar for 18- 24 hrs (overnight), blood agar for 48 hrs, and TSB for 48 hrs

11. For agar plates: check and record growth at 18 to 24 hrs (overnight; MacConkey II and blood agar plates) and approximately 48 hrs (blood agar)
   a. Count and record number of colonies from plates
   b. Calculate CFU/sample duodenoscope, accounting for the dilution of the sample

12. For TSB: check and record turbidity at 18 to 24 hrs (overnight) and approximately 48 hrs (two days)
   a. If the sample is turbid, streak broth for isolation on blood agar and MacConkey II agar plates
   b. Incubate at 35°C to 37°C; MacConkey agar for 18- 24 hrs (overnight) and blood agar for 48 hrs (two days)
   c. Observe plates for suspect colonies

13. Streak suspect colonies for isolation

14. Work up pure isolates for characterization of “low-concern” bacteria, which represent flora from skin and the environment, and species identification of “high-concern” bacteria.
   a. “Low-concern” bacteria include, but are not limited to, coagulase-negative staphylococci, micrococci, diptheroids, Bacillus spp. and other gram-positive rods
   b. “High-concern” bacteria include, but are not limited to, Staphylococcus aureus, Enterococcus spp., Streptococcus sp. viridians group, Pseudomonas aeruginosa, Klebsiella spp., Salmonella spp., Shigella spp. and other enteric gram-negative bacilli.
**Screening colonies for focused identification of “high-concern” bacteria**

In this procedure, it is suggested that laboratories focus their efforts on species identification of “high-concern” bacteria to reduce workload. Characterize colonies with morphology consistent with those species using local clinical laboratory procedures. Facilities should consider using a rapid identification system (e.g. MALDI-TOF) for shortening turn-around times of results.

- **MacConkey agar:** Perform species identification of recovered GNR.
- **Blood Agar:** Characterize by hemolysis and perform preliminary tests (gram-stain, coagulase and other screening biochemicals) to rule out “low-concern” bacteria. Further species identification is required for “high-concern” bacteria.

**Limitations**

The sensitivity, specificity and limits on quantitation or detection are not established for all organisms with the specified processing methods.

This procedure focuses on the growth of “high-concern” organisms versus overall bioburden. To capture the overall bioburden, facilities may consider requiring lower temperatures of 30°C (±2) with an extended incubation time of 5-7 days for samples on additional blood agar plates.
INTERIM SAMPLING METHOD FOR THE
DUODENOSCOPE – DISTAL END AND INSTRUMENT CHANNEL

CDC Disclaimer: This protocol has not been validated. The protocol is still being developed and evaluated for the major duodenoscope types; however, a version of this protocol has been used with Olympus, small intestinal videoscopes, models TJF-160VF and TJF-Q180V. This is an interim protocol and will be updated accordingly.

Purpose

This method is for use in the field to sample reprocessed duodenoscopes (after drying) for bacteria specifically located on the distal end; and for collecting samples from the instrument channel (via the instrument port to the distal end). Ideally, two personnel should perform this protocol, where one will hold the duodenoscope (facilitator) and the other person samples (sampler) accordingly. It is important to sample gently, while thoroughly, in order for optimal sampling and maintaining the integrity of the duodenoscope.

Materials and Reagents

- Sterile channel-opening brush, specific to the duodenoscope model manufacturer recommendations (one example - Olympus, #MH-507)
  - Note: Facility may choose to use the non-sterile disposable channel-opening brush but interpretations of positive cultures may be difficult
- Sterile 0.01M phosphate buffered saline (PBS) with 0.02% Tween®-80 solution (PBST) (one example - Teknova, #P3875)
- Sterile leak-proof specimen cups (120 mL) (one example - Fisher Scientific, #14-375-462)
- Sterile irrigation water (50 mL per duodenoscope)
- Sterile 60-cc syringes
- Additional materials: Parafilm®, Sterile alcohol pads, Sterile gloves, Permanent marker, Sterile diaper pads, Hair coverings, Labels, Face masks/ shields, Sterile gowns, Tray with sterile liner
**Definitions**

*Distal end* – Includes the elevator mechanism (e.g. forceps elevator or elevator) and elevator recess for duodenoscopes with sealed elevator wire channel; and elevator mechanism, elevator recess, and elevator channel for duodenoscopes with unsealed elevator wire channel.

*Lowered/ closed position* - Notes the position of the elevator mechanism being parallel or within the elevator recess relative to the distal end of the duodenoscope, Figure 1a.

*Raised/ open position* - Notes the position of the elevator mechanism being perpendicular to the distal end of the duodenoscope, Figure 1b.

Figure 1. Distal end, Model TJF-Q180V (Olympus) – Illustrating the orientation of forceps elevator in the (a) ‘lowered/ closed’ position and (b) ‘raised/ opened’ position (photos taken by CDC DHQP).
Method – Preparation of Materials

_In Laboratory: Aseptically prepare specimen containers with PBST and sterile irrigation water if these reagents are not commercially available or already prepared_

1.) Prepare autoclavable channel-opening brushes: Gather and wrap one channel-opening cleaning brush for use on each duodenoscope in appropriately-sized autoclave pouches; autoclave using approved sterilization cycles available in healthcare laboratories (132°C for 4 minutes or 135°C at 3 minutes)

2.) In a biological safety cabinet, aseptically prepare the following:
   a. Fill sterile leak-proof specimen containers with 50 mL PBST; label for brush samples with sample ID/ date
   b. Sterile irrigation water: aliquot 50 mL into sterile leak proof specimen containers; label for instrument channel flush with sample ID/ date

3.) Repeat step (2) for the total number of duodenoscopes to be sampled

4.) Save the remainder of stock PBST and irrigation water as negative controls

_In the area where the duodenoscope(s) will be sampled:_

1.) Clean and disinfect the counter where sampling of the duodenoscope(s) will be performed with an EPA approved disinfectant for hard, non-porous surfaces observing manufacturer’s instructions on contact time and disinfection procedure

2.) **Sampler and Facilitator:** Don sterile gowns, face masks/shields, hair coverings and gloves

3.) Prepare the sampling materials by laying out the sterile diaper pad; placing respectively labeled sampling containers, pre-moistening PBST tubes in a rack, as well as other needed items (e.g. 60-cc syringes)

4.) Gather sterile cleaning and channel-opening brushes for sampling of the duodenoscopes

Method – Elevator mechanism and channel

1.) **Sampler and Facilitator:** Don sterile gloves

2.) **Facilitator:** Sanitize the outer surface of the duodenoscope tip with a sterile alcohol pad, but use caution to not wipe the elevator mechanism and lens face at the distal end that will be sampled with the channel-opening brush (Figure 2); allow to air dry prior to sampling. Place duodenoscope in tray with sterile liner until sampling

3.) **Facilitator:** Obtain the channel-opening brush and open the pouch for sampler to access brush

4.) **Facilitator:** Using the controller, set the elevator mechanism in the lowered/ closed position (Figure 1a) and orient the distal end (relative to the Sampler) for optimal sampling

5.) **Sampler:** Dip the channel-opening brush into the labeled PBST specimen container to pre-moisten the brush and press excess fluid from the brush inside the inner walls of the container
6.) **Sampler**: Using the pre-moistened channel-opening brush, with twisting motion of the brush, sample the inside of the elevator mechanism, recess, and channel in the lowered/closed position (Figure 3a)

7.) **Facilitator**: Using the controller, set the elevator mechanism in the raised/open position (Figure 1b) and then orient the distal end (relative to the **Sampler**) for optimal sampling inside the mouth of the specimen container

Figure 2. Clean the outer surface of the duodenoscope tip with a sterile alcohol pad but take care to not wipe the elevator mechanism and lens face (photo taken by CDC DHQP).

8.) **Sampler**: Using the channel-opening brush, firmly brush under the elevator mechanism in the raised/open position (Figure 3b) and scrub the face of the lens (Figure 3c)

9.) **Sampler**: Drop the channel-opening brush portion inside the mouth of the corresponding labeled (i.e. sample ID, date) specimen container.

10.) **Facilitator**: Tighten the lid, and secure with Parafilm®
Figure 3. Sampling the elevator mechanism in the (a) ‘lowered/ closed’ position, (b) ‘raised/ opened’ position, and (c) sampling the elevator mechanism and lens face (photos taken by CDC DHQP).

Method – Instrument Channel

1.) **Sampler and Facilitator**: Replace and don sterile gloves if needed
2.) **Facilitator**: Obtain a sterile 60-cc syringe for the instrument channel sample, fill syringe with 50 mL sterile irrigation water from pre-filled and labeled specimen container, and hand to the **Sampler**
3.) **Facilitator** and **Sampler**: Coordinate how to hold the duodenoscope at the optimal angle for the **Sampler** to flush the instrument channel via the instrument port and the **Facilitator** to collect the sample in the specimen container
4.) **Sampler:** Flush the instrument channel with 50 mL of sterile irrigation water, specifically from the biopsy valve to the distal end to collect sample in sterile, labelled specimen container

5.) **Sampler:** Remove the 60-cc syringe and fill with air, then re-attach it to the instrument port and flush the air through the channel to flush out any remaining fluid into the sterile specimen container

6.) **Facilitator:** Tighten the lid, and secure with Parafilm®

---

**Storage and Shipping Considerations**

1.) Samples should be placed at 4ºC or on cold-paks for storage until further processing or shipping. Samples should not be stored beyond 24 hours after sampling.

2.) Save and send remainder of unused irrigation water and PBST for testing (negative controls)

3.) When packaging for overnight shipping:
   - Seal lids with Parafilm®;
   - Place each specimen container in its own ziplock bag;
   - Remainder of unused stock PBST and sterile irrigation water (negative control) in their own ziplock bags;
   - All bags with tubes may be placed in several large outer bags

---

**Duodenscope handling after sampling**

After sampling is complete, we recommend reprocessing the duodenoscope according to manufacturer’s specifications while holding the scope until the microbial results are available.

**Limitations**

Environmental sampling and processing methods are to be used for investigational or research purposes. The sampling efficiency of this method has not been established.
Interim Protocol for Healthcare Facilities Regarding Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing

Outbreaks of bacterial infection associated with endoscopes are often attributed to improperly reprocessed endoscopes. However, recent reports have identified carbapenem-resistant Enterobacteriaceae (CRE) transmission associated with persistently contaminated duodenoscopes for which no breaches in reprocessing were identified (1).

There is currently very limited information to guide the use of surveillance cultures to assess endoscope reprocessing outside of recognized outbreak settings. Surveillance cultures are not a replacement for appropriate training and oversight of endoscope reprocessing practices. Before initiating surveillance cultures, facilities considering their use should involve key facility staff, including the clinical laboratory director, clinical staff, infection prevention staff, hospital epidemiologists, and risk management staff to develop a plan for implementation, and response (e.g., patient notification) to surveillance culture results.

The following considerations are intended for facilities that perform procedures using duodenoscopes to assess the adequacy of reprocessing. While these measures apply primarily for duodenoscopes, they can also be implemented for other flexible endoscopes that have an elevator mechanism (e.g., used to perform endoscopic ultrasound). This document is intended to supplement and not replace or modify manufacturer recommended reprocessing procedures. This is an interim protocol and measures outlined below may change as new information becomes available.

- **Duodenoscope Reprocessing:** Facilities should review all steps in duodenoscope reprocessing several times a year (e.g., quarterly) and ensure strict adherence to the manufacturer’s instructions, paying particular attention to the following:
  - **Inspection and manual cleaning:** Ensure that the elevator mechanism located at the distal tip of the duodenoscope is thoroughly cleaned and free of all visible debris. The visible inspection is to be done with the elevator in the “open/raised” position as well as with the elevator in the “closed/lowered” position to ensure there is no visible debris above or below the elevator mechanism. Consideration should be given to use of a magnifying glass (e.g., 10x) to improve detection of residual debris around the elevator mechanism.
  - **Drying:** Ensure that the channels of the duodenoscope and elevator mechanism are thoroughly dried prior to storage. This should include an alcohol flush followed by forced air drying if these procedures are compatible with the duodenoscope per the manufacturer’s instructions. If channels and the elevator mechanism are not completely dry, bacterial growth can occur, forming a biofilm that is difficult to remove and could result in persistent contamination.

- **Use of Duodenoscope Culturing**
  - **Surveillance:** Although routine culturing of endoscopes is not part of current U.S. guidelines, recent outbreaks associated with duodenoscopes have led some facilities to consider regular monitoring to assess the adequacy of duodenoscope reprocessing (see algorithm).
    - The optimal frequency of surveillance cultures has not been established. International guidelines have recommended intervals ranging from every 4 weeks to annually (2, 3). A facility choosing to perform surveillance cultures can consider performing post-reprocessing cultures periodically, e.g., monthly or after every 60 procedures for each duodenoscope. Some facilities could choose to perform duodenoscope cultures weekly (e.g., after procedures on Friday to allow cultures to incubate over the weekend). Alternatively, facilities can choose to perform cultures, after reprocessing, following each use.
    - Cultures should be obtained after the duodenoscope has been reprocessed (after drying) and should include at least the instrument channel and the distal end of the duodenoscope (i.e., elevator mechanism and elevator recess for duodenoscopes with sealed elevator wire channel; and elevator mechanism, elevator recess, and elevator channel for duodenoscopes with unsealed elevator wire channels). An interim sampling protocol developed by CDC that represents one approach to culturing of duodenoscopes is available at the following link ([Interim Duodenoscope Sampling Method](#) and [Interim Duodenoscope Culture Method](#)). Facilities may choose other sampling methods (e.g., flush-brush-flush method), or choose to sample additional channels beyond those specified in this approach. The sensitivity of the interim protocol has not been determined. A negative culture does not completely exclude the possibility of a contaminated duodenoscope. However, positive culture results should lead to some action as described below.
Post-reprocessing cultures of duodenoscopes should be assessed for two types of microbial growth: high- and low-concern organisms. If successfully disinfected, culturing should not detect any high-concern organisms (i.e., organisms more often associated with disease), such as Gram-negative bacteria (e.g., *Escherichia coli*, *Klebsiella pneumoniae* or other Enterobacteriaceae, as well as *Pseudomonas aeruginosa*), *Staphylococcus aureus*, and *Enterococcus*. Small numbers of low-concern organisms (i.e., organism less often associated with disease and potentially a result of contamination of cultures during collection) might occasionally be detected (e.g., coagulase-negative staphylococci excluding *Staphylococcus lugdunensis*, *Bacillus* species, diphtheroids). The levels of these low-concern contaminants on a duodenoscope can vary depending on the reprocessing, handling, and culturing practices in a facility; levels of such organisms detectable after reprocessing will therefore vary. Facilities can monitor the levels of these bacteria within the first month of surveillance testing to develop an expected baseline for those organisms. Typically, fewer than 10 colony forming unit (CFU) of low-concern microbes does not require intervention; interpretation of culture results with ≥ 10 CFU of low-concern microbes should be considered in the context of typical culture results at the facility. Any quantity of high-concern organism (i.e., one colony or greater) warrants further remedial actions as described below. This is consistent with previous recommendations (2, 4).

- Holding duodenoscopes out of use while surveillance culture results are pending could be considered, especially if performing surveillance cultures after each use. Any duodenoscope found to be contaminated should not be returned to use until steps outlined in remedial actions section (below) are addressed.
- Facilities should ensure that each endoscopic procedure is appropriately documented with regard to the specific endoscope used in order to allow identification of exposed patients should microbial growth be detected as described above. Furthermore, results of post-reprocessing duodenoscope cultures should be logged and tracked for each duodenoscope.
- Non-culture methods (e.g., adenosine triphosphate (ATP) bioluminescence assays) have been used to assess duodenoscope reprocessing by detecting residual organic material after cleaning. While individual facilities might choose to use such non-culture assays, more work is needed to interpret their results since non-culture methods lack consistent correlation to bacterial concentrations. They might, however, provide insight regarding the quality of duodenoscope reprocessing if systematically validated (5, 6).

- **During outbreaks**
  - Surveillance cultures have been used during outbreaks to identify contaminated duodenoscopes and to ensure that ongoing contamination is not occurring.
  - Until the limits of detection are defined, negative surveillance cultures alone should not be used to rule out duodenoscopes as a source of cross-transmission.
  - Following documented transmission of bacteria via a duodenoscope, facilities should consider performing a series (e.g. 3 to 5) of duodenoscope surveillance cultures after reprocessing to ensure that the interventions employed to address the issue have eliminated contamination and are preventing further contamination that could lead to transmission.
  - An interim sampling protocol developed by CDC is available at the following link ([Interim Duodenoscope Sampling Method](https://www.cdc.gov/dpd/health/dsd/dsduodenoscope.html) and [Interim Duodenoscope Culture Method](https://www.cdc.gov/dpd/health/dsd/dsduodenoscope.html)).

**Remedial Actions:** Any duodenoscope found to be contaminated with any high-concern organisms or unacceptable CFU of low-concern organisms should be reprocessed again with repeat post-reprocessing cultures obtained. The duodenoscope should not be used again until it has been demonstrated to be free of high-concern organisms and has an acceptable level of low-concern organisms. Positive cultures should prompt a procedure review to ensure adherence to the manufacturer’s reprocessing instructions and to ensure cultures are being performed correctly. If a reprocessing breach is identified, appropriate facility personnel (e.g., infection prevention staff) should be notified and corrective actions should be immediately implemented. Refer to the manufacturer’s instructions for evaluating the duodenoscope for defects when bacteria are persistently recovered by duodenoscope cultures (including repeated cultures positive for low-concern organisms). In this situation, the facility can consider having the duodenoscope evaluated by the manufacturer. In addition, when unsuccessful reprocessing is suspected based on surveillance cultures, it might be helpful to review positive cultures among affected patients to determine whether other clusters of relevant pathogens could have been transmitted.
Patient Information and Notification: Patients undergoing procedures using duodenoscopes should be informed during the consenting process that there is a risk of patient-to-patient bacterial transmission associated with the procedure, including uncommon transmission of a multidrug-resistant organism. Facilities should document the specific duodenoscope used for each patient to facilitate identification of the exposed patients if needed. If high-concern organisms are recovered from a reprocessed duodenoscope (as described above), the decision to notify patients of their potential exposure should be made in consultation with key facility staff, including involved healthcare providers, infection prevention staff, hospital epidemiologists, and risk management. In instances where a multidrug-resistant organism (e.g., CRE) is cultured from a reprocessed duodenoscope, screening of exposed patients for the organism should be considered (a laboratory protocol for rectal CRE screening is available in the CDC CRE toolkit: http://www.cdc.gov/HAI/pdfs/labSettings/Klebsiella_or_Ecoli.pdf). This allows for appropriate infection control precautions to be implemented during future admissions to a healthcare facility for any exposed patient with positive screening cultures for the multidrug-resistant organism. Detailed information on patient notifications is available at: http://www.cdc.gov/injectionsafety/pntoolkit/index.html.

Staff Training and Competency: Ensure personnel performing reprocessing of duodenoscopes have received appropriate training with competency verification for reprocessing procedures. Competencies should be assessed at initiation of employee duties and at least annually and anytime a breach is identified or when a new technique or equipment is introduced. Competency verification should include direct observation in addition to other assessments per facility policy (e.g., written tests). Personnel responsible for reprocessing endoscopes are encouraged to seek certification in flexible endoscope reprocessing.

5. Alfa MJ, Fatima I, Olson N. The adenosine triphosphate test is a rapid and reliable audit tool to assess manual cleaning adequacy of flexible endoscope channels. Am J Infect Control 2013;41:294-53
Testing duodenoscope after 60 ERCP procedures or once a month

Test duodenoscope and consider holding the instrument until culture results available. Culture method options: (A) Presence/Absence by Enrichment or (B) Quantitative

Positive

Low-concern organisms
Examples: coagulase-negative staphylococci, micrococci, diphtheroids, Bacillus spp. and other gram-positive rods

Culture Method: Enrichment
1. Reprocess and culture again
2. Do not return to circulation until cultures are negative or are below acceptable levels of low-concern organisms †

OR

Culture Method: Quantitative
1. Quantify colonies, if <10 CFU/duodenoscope †, reprocess to remove PBST and return to circulation
2. If not <10CFU/duodenoscope, review facility-specific acceptable levels †, reprocess and culture again if not below acceptable levels
3. Do not return to circulation until cultures are negative or are below acceptable levels of low-concern organisms †

Negative
Reprocess again to remove PBST and return to circulation

Any high-concern organisms
Examples: Staphylococcus aureus, Enterococcus spp., Streptococcus sp. viridans group, Pseudomonas aeruginosa, Klebsiella spp., Salmonella spp., Shigella spp. and other enteric gram-negative bacilli

1. Reprocess and culture again
2. Do not return to circulation until cultures are negative or are below acceptable levels of low-concern organisms †
3. Consider notification of patients exposed to duodenoscope since last negative cultures

If cultures are repeatedly positive (3 times or more) for either any high-concern organism or >10 CFU/duodenoscope of low-concern organisms, facilities should consider re-evaluating their culture technique and/or sending the duodenoscope to the manufacturer for evaluation

† The levels of low-concern organisms on a duodenoscope may vary depending on the reprocessing, handling, and culturing practices in a facility. Therefore, the acceptable level of these organisms can vary. Facilities can monitor the levels of low-concern organisms during the first month of surveillance testing to develop an appropriate baseline for those organisms. Typically, fewer than 10 CFU of these microbes does not require intervention. Interpretation of culture results with ≥ 10 CFU of non-pathogenic microbes should be considered in the context of expected culture results at the facility.

Definitions
- Negative – A liquid enriched culture is not turbid
- Positive – A liquid enriched culture is turbid
- CFU – colony forming units
- PBST – Phosphate buffered saline with Tween®-80 solution
Testing after every duodenoscope reprocessing*

Test duodenoscope and hold the instrument until culture results available.
Culture method options:
(A) Presence/Absence by Enrichment or (B) Quantitative

Positive
Choose not to identify organism

Negative
Reprocess again to remove PBST and return to circulation

Positive
Reprocess again and re-culture

Choose to identify organism

Low-concern organisms
Examples: coagulase-negative staphylococci, micrococci, diptheroids, Bacillus spp. and other gram-positive rods

Culture Method: Enrichment
1. Reprocess and culture again
2. Do not return to circulation until cultures are negative or are below acceptable levels of low-concern organisms†

OR

Culture Method: Quantitative
1. Quantify colonies; if <10 CFU/duodenoscope†, reprocess to remove PBST and return to circulation
2. If ≥10 CFU/duodenoscope, review facility-specific acceptable levels†, reprocess and culture again if not below acceptable levels
3. Do not return to circulation until cultures are negative or are below acceptable levels of low-concern organisms†

Any high-concern organisms
Examples: Staphylococcus aureus, Enterococcus spp., Streptococcus sp., viridians group, Pseudomonas aeruginosa, Klebsiella spp., Salmonella spp., Shigella spp. and other enteric gram-negative bacilli

1. Reprocess and culture again
2. Do not return to circulation until cultures are negative or are below acceptable levels of low-concern organisms†

If cultures are repeatedly positive (3 times or more) for either any high-concern organism or >10 CFU/duodenoscope of low-concern organisms, facilities should consider re-evaluating their culture technique and/or sending the duodenoscope to the manufacturer for evaluation

*This approach could be reserved specifically for patients known to be colonized or infected with or felt to be at high risk for multidrug-resistant organisms (e.g., carbapenem-resistant Enterobacteriaceae)
†The levels of low-concern organisms on a duodenoscope may vary depending on the reprocessing, handling, and culturing practices in a facility. Therefore, the acceptable level of those organisms present after reprocessing can vary. Facilities can monitor the levels of low-concern organisms during the first month of surveillance testing to develop an appropriate baseline for those organisms. Typically, fewer than 10 CFU of these microbes does not require intervention; interpretation of culture results with ≥ 10 CFU of low-concern organisms should be considered in the context of expected culture results at the facility

Definitions
Negative – A liquid enriched culture is not turbid
Positive – A liquid enriched culture is turbid
CFU – colony forming units
PBST – Phosphate buffered saline with Tween®-80 solution