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Gastrointestinal Flexible Endoscopes: Infection Control Risks, Lessons Learned from Outbreaks, and Centers for Disease Control and Prevention Guidance

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INTRODUCTION

The Centers for Disease Control and Prevention (CDC) is the nation's health protection agency. The mission of the CDC Division of Healthcare Quality Promotion (DHQP) is to protect patients; protect health care personnel; and promote safety, quality, and value in national and international health care delivery systems. DHQP develops infection control guidelines and resources with input from the Healthcare Infection Control Practices Advisory Committee (HICPAC), a federal advisory committee appointed to provide advice and guidance to the Department of Health and Human Services and to CDC regarding the practice of infection control and strategies for surveillance, prevention, and control of health care–associated infections, antimicrobial resistance, and related events in US health care settings. DHQP assists with investigation and response to emerging health care–associated threats including those resulting in adverse events among patients and health care personnel. The DHQP also works with public and private partners to prevent the spread of antimicrobial resistance.

Flexible endoscopes are diagnostic and therapeutic instruments used to visualize the interior of hollow organs and collect tissue samples. Gastrointestinal endoscopes can acquire high levels of microbial contamination during routine use. A review of health care–associated infections linked to flexible endoscopes through July 1992 found 281 instances of pathogen transmission (ranging from asymptomatic colonization to death) transmitted by gastrointestinal endoscopy and 96 by bronchoscopy; a recent review found 130 outbreaks of infections associated with gastrointestinal endoscopes and bronchoscopes, more than any other semicritical medical devices.[1,2]

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Endoscopes must be reprocessed between each patient use to ensure they are clean and free from debris and infectious material, decreasing the risk of transmission of pathogens. Reprocessing is a multistep process consisting of cleaning followed by disinfection or sterilization. Cleaning is the physical removal of foreign material (eg, soil and organic material), typically using water under pressure, brushes, and detergents or enzymatic products. High-level disinfection is the elimination of many or all pathogenic microorganisms, except large numbers of bacterial spores, typically using liquid chemicals or wet pasteurization. Sterilization eliminates all pathogenic microorganisms, including bacterial spores, typically using a combination of heat, pressure, and time in steam-, gas-, or plasma-based systems. Medical devices are classified as critical, semicritical, or noncritical based on the intended function in a clinical procedure according to the Spaulding Classification Scheme, which also determines reprocessing requirements.[3,4] Reusable flexible endoscopes are generally classified as semicritical devices because they contact mucous membranes or nonintact skin, conferring a high risk of infection. These should be cleaned and high-level disinfected or cleaned and sterilized after each patient use: if there is an available sterilization process, cleaning and sterilization is preferred.

Device manufacturer instructions for use (IFU) outline the Food and Drug Administration (FDA)-approved methods of reprocessing. Thorough cleaning is the essential first step in reprocessing to reduce the burden of microbes and soil; failure to adequately perform cleaning and high-level disinfection has been identified in several investigations of bacterial pathogen transmission associated with these devices.[5–8] Cleaning flexible endoscopes is challenging because of their intricate designs and delicate materials. Cleaning and high-level disinfection may be automated or manual. Automated endoscope reprocessors are associated with better adherence to recommended cleaning steps.[9]

In recent years, several accessories or modifications have been introduced to reduce the bioburden on endoscopes or to improve reprocessing, including removable endcaps, cover products, single-use buttons, and other single-use components. Note that endoscope accessories that enter sterile tissue (eg, biopsy forceps) are themselves considered critical devices and should always be sterilized after each patient use. If these endoscope accessories cannot be sterilized after each use, they should be considered single-use items and discarded after use. Lubricating sprays, simethicone, and other accessories that are not approved for use on these devices may contribute to reprocessing failure.[10]

CDC resources relevant to flexible endoscopes include the Guideline for Disinfection and Sterilization in Healthcare Facilities,[3] the Essential Elements of a Reprocessing Program for Flexible Endoscopes – The Recommendations of the HICPAC,[11] and the FDA/CDC/ American Society for Microbiology Duodenoscope Surveillance Sampling & Culturing Protocols[12] (discussed in Shanil P. Haugen's article, "Reducing the Risk of Infection from Reprocessed Duodenoscopes – Recent Actions by the U. S. Food and Drug Administration," elsewhere in this issue).

OUTBREAKS AND REPROCESSING LAPSES ARE OPPORTUNITIES TO IDENTIFY DEVICE CONCERNS

Health care facilities are required to report potential outbreaks of infectious diseases to their local or state health department. They may also request assistance in investigating these events, which can include responding to the spread of pathogens in a patient population or evaluating infection risks associated with failure to adhere to reprocessing protocols that remove and inactivate infectious material on reusable medical devices. State and local health departments work with health care facilities to conduct outbreak investigations, coordinate patient notifications and laboratory testing, and recommend control measures. In turn, public health partners may contact CDC for technical assistance to help establish priorities, focus resources, and review findings. CDC can also provide laboratory support in the context of an investigation to confirm species identification, determine antimicrobial susceptibility patterns, identify antibiotic resistance elements, perform molecular typing of clinical samples, and analyze isolates from patient specimens and environmental samples to determine genetic relatedness. The agency can provide onsite technical assistance when requested by the state or local health department, including gathering and interpreting epidemiology, reviewing infection prevention and control practices, and providing laboratory support. CDC also collaborates with other federal agencies, notably the FDA for issues related to medical products and the Center for Medicare and Medicaid Services for issues related to facility regulations and oversight.

CDC has assisted in many outbreak investigations that highlight the transmission risks associated with duodenoscopes and other flexible endoscopes.[5] Some common themes of endoscope-related outbreaks and infection control lapses include complex device design leading to contamination and poor adherence to IFUs or recommended reprocessing practices.[5,8,13] Additionally, problems with reprocessing equipment have been implicated in outbreaks, such as internal contamination of automated endoscope reprocessors and with water of poor quality used for rinsing devices following high-level disinfection.[14]

Findings from endoscope-related outbreaks have driven manufacturer initiatives aimed to reduce the risk of pathogen transmission associated with flexible endoscope use and changes in FDA oversight of these devices, including:

- Refinements in device design
- Enhancements in the design of reprocessing equipment
- Improved environmental standards in health care settings
- Improving reprocessing instructions and protocols taking into consideration real-world performance of reprocessing staff (“human factors”)
- Increased recognition of the importance of robust training and adherence to reprocessing protocols

Following the identification in 2013 of the association between duodenoscopes and transmission of multidrug-resistant bacteria,[8] with transmission often related to identified reprocessing deficiencies, much attention has focused on duodenoscopes. Additionally,

pathogen transmission events continue to be reported in connection with these devices, including in settings without device damage or failure to adhere to recommended reprocessing instructions, suggesting that residual contamination may remain even after following all manufacturer steps for reprocessing, highlighting a need for additional solutions to reduce risks to patients.[15,16] Other types of gastrointestinal flexible endoscopes may also be susceptible to such issues.

LESSONS LEARNED IN THE LABORATORY

The CDC laboratory has supported numerous endoscope-related outbreak investigations. CDC laboratory support begins with discussion of the relevant epidemiology to inform common exposures among patients, followed by developing testing and sampling strategies in consultation with public health partners. Microbiologists have cultured duodenoscopes, colonoscopes, and endoscopic ultrasound devices for the detection of pathogens and compared recovered pathogens with patient isolates using next-generation sequencing to determine and confirm the causality of transmission from contaminated devices. Laboratory staff have also provided guidance to public health and clinical partners in assessment of endoscope damage and reprocessing practices and collection of related samples.

The FDA, CDC, and the American Society for Microbiology, together with duodenoscope manufacturers and other experts, developed standardized protocols for duodenoscope surveillance sampling and culturing. The protocol is intended for surveillance sampling and quality assurance testing of reprocessed duodenoscopes, and not necessarily for outbreak investigations; however, it can be adapted to maximize the recovery of causative outbreak pathogens at the discretion and capacity of the health care facility.[12] The protocol provides sample collection methods for the instrument channel from biopsy port to distal end using a flush/brush/flush method (FBF) and from the elevator recess by flushing and brushing. Options for culturing endoscope samples are also provided and are limited to detection of high-concern pathogens for surveillance and causative agent of infection. Portions of those protocols can also be used for other devices at the discretion of the health care facility. Based on the culturing methods used (quantitative or presence/absence), the protocol also provides examples of microbial limits, interpretations and response guidance for different levels and presence of high-concern organisms and low/moderate-concern organisms. Selective media and differential media may also be used to detect causative or high-concern agents. Examples of high-concern organisms include gram-negative rods (eg, *Escherichia coli*, *Klebsiella pneumoniae*, other Enterobacteriaceae, and *Pseudomonas aeruginosa*), gram-positive organisms (eg, *Staphylococcus aureus*, b-hemolytic *Streptococcus*, and *Enterococcus* species), and yeasts. In one study, high-concern organisms were identified on 15% of reprocessed duodenoscopes.[17] As of December 2018, FDA had identified upwards of a 6% reprocessing failure rate.[18]

Recovery of an organism by culture methods is highly variable. Flushing alone is not adequate to remove organisms attached to the interior surfaces of duodenoscopes or other flexible endoscopes with ports or channels. Two-thirds of all CDC-processed duodenoscopes, all sampled by FBF, yielded high-concern organisms undetected by prior sampling. In one investigation, high-concern bacteria were detected on a duodenoscope with

a total microbial count of 18 colony-forming units (CFU); reprocessing failure is indicated by greater than or equal to one high-concern organism, or 100 CFU for low/moderate-concern organisms. In another instance, the target organism was detected only when total counts exceeded 470 CFU. The FBF method does not guarantee recovery of the target organism but it may reveal another pathogen, which may also suggest that reprocessing failure occurred.[15] Microbial growth should be identified to differentiate high-concern organisms from low/moderate-concern organisms. One or more colonies of a high-concern organism exceeds the microbial limit and indicates a reprocessing failure requiring removal of the endoscope from use.

For duodenoscopes not meant to return to service, destructive processing yields greater recovery of total microbial counts and target organisms, such as in the recovery of New Delhi metallo-b-lactamase-producing carbapenem-resistant *E coli* from a duodenoscope.[8] In one investigation, three duodenoscopes were sampled using the FBF method, then destructively sampled using bath sonication of the distal tip submerged in a specimen cup containing saline. The total number of recovered organisms from sonication was either equal to or nearly three orders of magnitude greater than the FBF, despite being performed after FBF. Neither method identified the target organism, carbapenem-resistant *P aeruginosa*, at the lowest microbial burden: it was detected only by sonication at a microbial burden of 10^4 CFU; detection by FBF and sonication occurred at the greatest detected burden of 10^6 CFU.

The distal tip of all submitted endoscopes may also be examined for any damage that may retain organic matter and microbes. Using a lens with a × 10 magnification can reveal flaws that would be missed by unaided visual examination, such as chips on the edges of glass lenses (Fig. 1). Borescopes may be required to identify kinks or damage within endoscope channels. These flaws can interfere with high-level disinfection and may cause false-negative culture results.

ACTIONS TO REDUCE ENDOSCOPE-RELATED PATHOGEN TRANSMISSION RISKS

Duodenoscopes are an important source of device-related transmission events, and other reusable gastrointestinal flexible endoscopes may also be susceptible to contamination and subsequent pathogen transmission. Despite recent improvements in device design, reprocessing methods and equipment, and staff training and oversight, pathogen transmission from persistent contamination of flexible gastrointestinal endoscopes continues to occur.[15,16,19] Several factors can contribute to persistent contamination, including intricate device designs that are difficult to clean and disinfect, highly complex reprocessing instructions that are difficult to follow, rapid turnover of endoscopes between procedures leading to reduced time for reprocessing, contamination of the health care environment (including water distribution systems and reprocessing equipment), frequent staff turnover, and inadequate staff training.

Health care facilities can take steps to reduce the risks of transmission events through protocols and training that support adherence to guidelines and manufacturer instructions. In addition, tracking and logging of device use and reprocessing, regular maintenance, and staff

training and oversight can support better device maintenance practices, ensure adequate reprocessing of all devices (including loaned devices, which are often not tracked as well as owned devices), and facilitate investigations in the event of pathogen transmission or an infection control lapse. If pathogen transmission might be linked to use of a flexible endoscope, a comprehensive response is warranted to evaluate the device handling and reprocessing to detect lapses in infection control or other issues that contribute to persistent contamination and transmission of infections.

Recently, CDC asked the HICPAC to provide guidance on ways to improve facility-level training and ensure competency for reprocessing of flexible endoscopes. The Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC, freely available on the Internet, provides minimum expectations for a reprocessing program.[11]

The HICPAC recommendations review essential steps for flexible endoscope reprocessing:

1. *Precleaning* of flexible endoscopes and accessories immediately after finishing a procedure
2. *Leak testing* after each use, and before manual cleaning, which can help identify damage to external surfaces or channels that can lead to persistent contamination or to further damage
3. *Manual cleaning*, including brushing and flushing channels and ports, before performing high-level disinfection or sterilization
4. *Visual inspection* of the endoscope and accessories to ensure these are clean and free of defects: lighted magnification or other methods may be needed for this step
5. *Disinfection or sterilization* with close attention to the manufacturer IFU
6. *Storage* of the endoscope and accessories in a manner that prevents recontamination, protects these items from damage, and promotes drying, either vertically in a cabinet that prevents coiling and touching of the bottom, or horizontally in a unit designed for this purpose
7. *Documentation* of adherence to essential steps each time the endoscope is reprocessed

The HICPAC recommendations also describe key elements for a reprocessing program:

1. *Administrative*, including roles and responsibilities of facility leadership and management and topics to address in policies, including the selection, use, transport, reprocessing, and storage of endoscopes and accessory devices and the management of “loaner” endoscopes
2. *Documentation* of endoscope and patient identifiers, procedure end time, manual cleaning start time, effectiveness of cleaning and disinfection products, preventive maintenance and repair of endoscopes and reprocessing equipment, and investigation of critical or potential critical events

3. *Inventory* of all endoscopes and their reprocessing methods, including each device's unique identifier, manufacturer and model, locations of use, number of procedures, IFU, reprocessing locations and reprocessing equipment used, and current device status

4. *Physical setting* of the reprocessing areas, including a work flow that facilitates separation of clean and dirty; appropriate directional airflow, heating, ventilation, and air conditioning; access to a dedicated handwashing sink, eyewash stations, available IFU; and space to access hardcopy or electronic documentation

5. *Education and training* covering the rationale for the seven essential steps described previously; decontamination, cleaning, and sterilization of certain accessories; training and competency assessment based on each device's IFU and its associated reprocessing equipment and chemicals; and *competency assessment* of trainers, managers, and staff

6. *Risk assessment* or comprehensive gap analysis covering precleaning and transport, reprocessing, staff competencies, sufficient reprocessing personnel for routine and emergency situations, documentation that any automated endoscope reprocessors in use are validated for the endoscopes that they reprocess, and periodic audits of protocols and documentation to monitor compliance

7. Review of every *disinfection/sterilization breach or failure* to determine the risk of transmission of infection to patients and determine the need for notification of patients, in consultation with an infection preventionist and state and local health departments, and to determine the need to report an increase in infections or device contamination to MedWatch, the FDA Safety Information and Adverse Event Reporting program

The HICPAC document also reviews several unresolved issues related to supplemental reprocessing measures, storage interval, storage space, and replacement of endoscopes. Other accompanying materials, all freely available on the CDC Web site, include a policy template, audit tool, competency verification tool, inventory and repair and maintenance log, gap analysis tool, and root cause analysis template, which can be modified for facility use.

Facilities that identify problems with devices or reprocessing instructions should contact the manufacturer and FDA because these findings may have implications for other users and could indicate the need for changes in device design or instructions. Health care facilities should ensure adherence to applicable state and local regulations. Industry guidance for maintaining the safety of the water supply used for reprocessing is found in Association for the Advancement of Medical Instrumentation TIR 34: water quality for the reprocessing of medical devices.[20] Industry guidance and guidelines related to flexible endoscope reprocessing include American National Standards Institute/Association for the Advancement of Medical Instrumentation ST91: comprehensive guide to flexible and semirigid endoscope processing in health care facilities[21] and the 2011 multisociety guideline on reprocessing flexible gastrointestinal endoscopes.[22]

If transmission of a pathogen is suspected to be linked to a flexible endoscope, or an infection control lapse is identified, the health care facility should investigate to identify other potentially affected patients and review device reprocessing IFU, policies, protocols, and practices to ensure adherence to the IFU and other best practices (Box 1). Health care facilities may consider culturing the endoscope to determine whether contamination is persistent and, if so, may consider sending the device to the manufacturer to evaluate for damage or defects that could predispose to ongoing contamination. If a reprocessing deficiency is identified, health care facilities should strongly consider notifying the affected patients.[23] Health care facilities should be aware of state requirements for reporting outbreaks to public health authorities and should be familiar with the resources from public health partners for the investigation and control of infections and infection control deficiencies.

THE CONTAINMENT STRATEGY TO IDENTIFY AND CONTAIN NOVEL MULTIDRUG-RESISTANT ORGANISMS

Several transmission events associated with flexible endoscopes were initially detected because of identification of rare, multidrug-resistant organisms. In 2017, CDC outlined an effort to respond rapidly to novel multidrug-resistant organisms; this approach encourages health care facilities and public health authorities to respond to single isolates of an emerging antibiotic-resistant pathogen. That strategy, known as containment, is a systematic response to identify and contain novel multidrug-resistant organisms.[24]

If patients with highly antibiotic-resistant pathogens are identified and endoscopy is determined to be a possible route of transmission, health care personnel and public health authorities should review and enforce adherence to cleaning and disinfection of the endoscope and should review other infection control measures. Repeat assessment should be performed to ensure that infection control gaps are fully addressed. In consultation with public health authorities, health care facility personnel could consider microbiologic culturing of the reprocessed endoscope, depending on the procedure and the duration and type of endoscope. Additionally, a close inspection of the endoscope is warranted. If pathogens are identified from a reprocessed endoscope, the endoscope should be reprocessed and cultured again. Persistently positive endoscopes should be evaluated for damage by the manufacturer. Patients exposed to endoscopes contaminated with highly resistant pathogens should be notified and considered for screening.[12] Culturing of endoscopes to identify contamination with resistant pathogens could also be considered for endoscopes used within 30 days for patients found to be colonized or infected with a highly resistant pathogen for whom exposure to endoscopy is their only health care exposure.

SUMMARY

Gastrointestinal flexible endoscopes are complex devices used to perform essential diagnostic and therapeutic functions in health care settings. These devices are often exposed to high microbial burdens, are reused for many patients, and are difficult to reprocess adequately between patients because of their complex designs, increasing the risk of transmitting pathogens to patients. Research continues to demonstrate the presence of

biologic material on reprocessed duodenoscopes and other flexible endoscopes and transmission of pathogens in settings without observed deficiencies in reprocessing, highlighting the continued need to improve the current state of flexible endoscope design and reprocessing.

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KEY POINTS

- Gastrointestinal flexible endoscopes are essential diagnostic and therapeutic instruments that also carry risks of transmitting pathogens to patients related to problems with device design or damage and inadequate adherence to reprocessing instructions.
- These devices should be cleaned and high-level disinfected after each patient use, or cleaned and sterilized after each patient use if there is an available sterilization method, according to the manufacturer's instructions for use.
- Possible endoscope-related transmission events and outbreaks and instances of failure to adhere to recommended reprocessing practices should be reported promptly to public health authorities; investigations can help identify opportunities to improve device design, use, and reprocessing.
- CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, the Essential Elements of a Reprocessing Program for Flexible Endoscopes – The Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC), and the FDA/ CDC/American Society for Microbiology Duodenoscope Surveillance Sampling & Culturing Protocols are free resources that contain guidance on flexible endoscope reprocessing, minimal expectations for a reprocessing program, and sampling and culturing of duodenoscopes and other endoscopes.

Box 1

Suggested steps before use of a flexible endoscope after possible pathogen transmission or identification of infection control lapse

1. Review device reprocessing instructions, policies, protocols, and practices
    - **a.** Ensure facility has updated manufacturer IFU, including any manufacturer letters that supplement the IFU
    - **b.** Identify other applicable industry or professional society guidelines and applicable state and local regulations
    - **c.** Review facility protocol for reprocessing (cleaning and disinfection, or cleaning and sterilization) to ensure it adheres to manufacturer IFU
        - **i.** If the device is reprocessed using high-level disinfection and there is an available sterilization option, consider a change to sterilization
    - **d.** Device reprocessing should be observed and audited by an individual with working knowledge of reprocessing practices to ensure these adhere to facility protocols
    - **e.** If an automated endoscope reprocessor is used, ensure it is maintained according to manufacturer IFU, including changing enzymatic solution and high-level disinfectant at recommended intervals, checking disinfectant concentration, and logging results
    - **f.** Ensure water for reprocessing adheres to applicable state and local regulations and industry recommendations
    - **g.** Address gaps between policies and practices; report concerns related to IFU to the manufacturer and FDA
2. If device is suspected to have transmitted a pathogen, consider culturing endoscope to determine if contamination is still present
    - **a.** Develop a sampling plan, recognizing that ports, channels, caps, lenses, and moving parts (eg, elevator mechanism, removable caps) are among the most likely areas of damage and microbial colonization
    - **b.** Use flush-brush-flush sampling of ports and channels to maximize opportunities to recover organisms (for duodenoscopes, refer to FDA/CDC/American Society for Microbiology Duodenoscope Surveillance Sampling & Culturing Protocols12); if device will not be placed back in use, consider destructive sampling methods for greater recovery of organisms

c. Await the results of cultures of the devices before placing the devices back into use

3. If contamination persists after reviewing policies and practices, consider sending endoscope to manufacturer for maintenance and to evaluate for damage or defects

   a. Manufacturer evaluation may identify areas of the device, such as kinks or tears to interior channels, that could become colonized and lead to transmission

   b. Ensure manufacturer is aware of possible transmission and concern about device damage and any specific concerns regarding device functionality possibly related to colonization or transmission

   c. Ensure any damage is repaired before placing the device back into use

   d. Consider a review of device handling and storage practices to identify possible sources of damage and opportunities to prevent further damage in the future

4. Consider the role of patient notification and follow-up related to transmission of infection or a lapse in infection control, and the role of reporting information to FDA

   a. Facility personnel and public health authorities should review findings to determine whether there was a deviation from expected practice or persistent contamination that might have placed patients at risk

   b. Strongly consider notifying exposed patients when there is a potential risk of harm, including the possibility of transmission of bloodborne pathogens (human immunodeficiency virus, hepatitis B virus, and hepatitis C virus)23

   c. In transmission events involving multidrug-resistant organisms, facility personnel and public health authorities may choose to notify a subset of patients for the purpose of multidrug-resistant organism screening

   d. If a health care provider suspects persistent bacterial contamination of an endoscope following reprocessing, either because of an increase in infections after endoscopic procedures or because of the results of microbiologic culturing of endoscopes, the health care provider should file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program

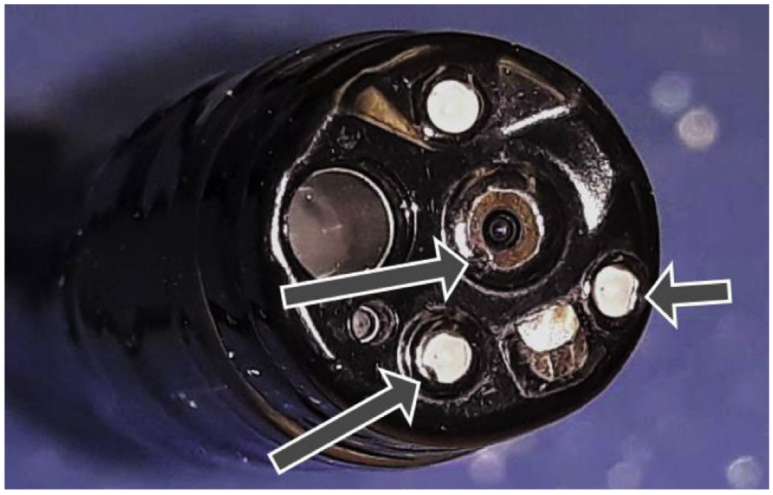

Fig. 1.

Distal end of a colonoscope. *Arrows* indicate chips on the edges of glass lenses, which may contribute to reprocessing failure. Using a lens with a × 10 magnification can reveal flaws that would be missed by unaided visual examination.