



April 2022

Medical device recall on certain Karl Storz flexible endoscopes for urological use



In April 2021, the Food and Drug Administration (FDA) reported patient infections and potential contamination issues with reprocessed urological endoscopes. FDA requested that Karl Storz conduct reprocessing validation testing on sample of flexible urological endoscopes and identified reprocessing failures following high-level disinfection.

On April 1, 2022, Karl Storz **issued a voluntary recall** and issued an urgent field safety notice to instruct users to discontinue all high-level disinfection methods for all affected urological endoscopes and discontinue liquid chemical sterilization for most of the affected urological endoscopes. The affected urological endoscopes should be sterilized after each use by an appropriate sterilization method recommended in the instructions for use.

FDA recommendations:

- Review the recall notice from Karl Storz.

Deficiencies and citations

A-0133 Patient's rights

In the first quarter of federal fiscal year 2022 (Oct. 1, 2021–Dec. 31, 2021), deficiencies related to A-0133 patient's rights (admission status notification) were cited one time in Iowa, two times in CMS Region 7 (Iowa, Nebraska, Missouri, and Kansas), and five times nationally.

Below are the details of the citation in Iowa in first quarter of FFY 2022:

- The hospital's administrative staff failed to ensure that hospital staff contacted the patient's guardian to provide them with an opportunity to make decisions regarding the patient's care.
- A review of patient's medical record revealed that the patient presented to the emergency department (ED) with their guardian. The guardian needed to leave the hospital and informed the hospital staff to contact them with any changes to the patient's status or to make any medical decisions.
- The hospital staff evaluated the patient, provided medical treatment and discharged the patient from the hospital without contacting the guardian.
- The patient fell in the hospital's parking lot and had to borrow a phone from a passerby to call their guardian. The guardian ensured that the patient returned to the ED.

Source: CMS' **Quality, Certification, and Oversight Reports (QCOR)**

Employee spotlight

- Do not use high-level disinfection methods or liquid chemical sterilization to reprocess affected urological endoscopes.
- Sterilize affected urological endoscopes after each use by using sterilization methods recommended in the instructions for use specific to each device.
- Do not use affected urological endoscopes if you do not have access to an appropriate sterilization method recommended in the instructions for use. Karl Storz will provide instructions for returning the affected endoscopes.
- Karl Storz will provide updated instructions for use for affected urological endoscopes.
- Do not use damaged devices or those that have failed a leak test, as they could be a potential source of contamination.
- Develop schedules for routine inspection and regular maintenance as specified in the manufacturer's instructions.
- Discuss the benefits and risks associated with procedures involving reprocessed urological endoscopes with your patients.

The FDA will continue to work with Karl Storz to evaluate the cause of reprocessing failures, and ensure that an adequate supply of urological endoscopes are available for users and patient care. Additionally, the FDA will continue to keep health care providers and the public informed if new or additional information becomes available.

Health Facilities Division website application

In May 2021, DIA's Health Facilities Division launched a new web application. The new application features a user-friendly interface not only for accessing records for health facilities,



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Kathy enjoys reading, gardening, and spending time with family – which includes five grandchildren – and weekends on the Mississippi River. She lives on an acreage outside of Hawkeye, Iowa, with her husband and their dog, Drake.

Contact us

If you have any questions or concerns, or if there are topics you would like to see covered in this newsletter or at a future lunch-and-learn, please contact **Megan Montalvo** at megan.montalvo@dia.iowa.gov or 515.249.9648.



but also for the Iowa Direct Care Worker Registry for certified nursing assistants (CNAs).

Entity administrators will need to request access to the new application to access facility information, self-reports, CNA information, etc. Once the administrator's access is approved, the administrator will be able to approve any other authorized facility users (i.e., entity delegate, entity HR) who request access for their facility.

Health facility employees, CNAs, and community college users are able to manage their own accounts, including making changes to their contact information.

Please note:

- Each facility is allowed to have **one** assigned entity administrator.
- Each user should be assigned only **one** role. If a user is assigned to multiple roles, the system may not work properly.
- Users should use the email address associated with their place of employment to create their Google or Microsoft account, **not a personal email account** (see PDF guide below).

The website for the new application is dia-hfd.iowa.gov.

Additional resources

- [DIA Health Facilities Database User Guide \(PDF\)](#)
- [DIA's Health Facilities Database: Entity Sign-In](#)
(YouTube video)
- [DIA's Health Facilities Database: Approving Entity Users](#)
(YouTube video for administrators)

The DIA HFD application has been upgraded and the URL has changed. Please update your bookmarks to the new URL: <https://dia.iad.iowa.gov>
NOTE: For the best user experience, DIA recommends using the application in Chrome, Edge, or Safari browsers.

Direct Care Worker Registry & Health Facility Database



DCW SEARCH

Look up eligibility status of Direct Care Workers

Identification Number

First Name

Last Name

City

Counties

Choose Counties

SEARCH



ENTITY SEARCH

Look up contact details for care facilities

Name

City

Counties

Choose Counties

Entity Types

Choose types

Designation Types

Choose types

Advanced Search

SEARCH

CLEAR

Iowa Department of Inspections and Appeals

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[Click here to access the Health Facilities Database and the Iowa Direct Care Worker Registry.](#)

[Click here to access DIA's main website.](#)