# Health Alert Network

**Tri-County Health Department**
**Serving Adams, Arapahoe and Douglas Counties**
**Phone 303/220-9200 • Fax 303/741-4173 • www.tchd.org**
**Follow us on Twitter @TCHDHealth and @TCHDEmergency**
**John M. Douglas, Jr., M.D. Executive Director**

**The pages that follow contain information critical to protecting the health of your patients and the citizens of Colorado.**

## HAN ADVISORY

Number of pages including cover: 4

Subject: **Advisory - Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices**

Message ID: 9/15/2015 10:45:00 AM
Recipients: HAN Community Members.
From: TRI-COUNTY HEALTH DEPARTMENT
Adams, Arapahoe and Douglas County, Colorado

Recipient Instructions: **Tri-County Health Department is forwarding you the attached HAN. You may have already received this broadcast if you are on the CDPHE distribution list, however, we wanted to ensure you did not miss this important information. No response is required.**

==========

You have received this message based upon the information contained within our Health Alert Network Notification System. If you have a different or additional e-mail or fax address that you would like us to use, or if you have additional questions, call 720-200-1477.

**Categories of Health Alert Network Messages:**

**Health Alert:** Conveys the highest level of importance; warrants immediate action or attention.
**Health Advisory:** Provides important information for a specific incident or situation; may not require immediate action.
**Health Update:** Provides updated information regarding an incident or situation; unlikely to require immediate action.
**Info Service/Public Health Brief:** Provides general information that is not necessarily considered to be of an emergent nature.

**You may download a copy of this HAN from the TCHD website at http://www.tchd.org/259/Health-Alert-Network**

Tri-County Health Department

This is an official

# CDC HEALTH ADVISORY

HEALTH ALERT NETWORK BROADCST
FROM: CO_CDPHE
CDCHAN-00382

Subject: HAN Advisory – Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices
RECIPIENTS: Local Public Health Agencies, Infection Preventionists, Infectious Disease Physicians – fax and email for all
RECIPIENT INSTRUCTIONS: LPHAs – Please forward to health care providers in your jurisdiction. This HAN will be posted on the CDPHE Health Facilities Portal; therefore, long-term care facilities and other regulated health care facilities can access it.

## Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices


**Summary**
*The Centers for Disease Control and Prevention (CDC), other health departments, and U.S. Food and Drug Administration (FDA) investigate outbreaks of health care associated infections and other adverse events that are caused by contaminated devices and drugs or breaches in infection prevention and control practices - including outbreaks involving reusable medical devices such as endoscopes or other surgical instruments. These events occurred in a variety of outpatient settings including primary care clinics, pediatric offices, cosmetic surgery centers, pain remediation clinics, imaging facilities, cancer (oncology) clinics, dental clinics, and health fairs. The outbreaks serve as a reminder of the serious consequences that can result when healthcare personnel fail to follow basic principles of infection control. Such consequences include: infection transmission to patients, notification of thousands of patients of possible exposure to bloodborne pathogens, referral of providers to licensing boards for disciplinary action, and malpractice suits filed by patients.*

*Please review this Health Advisory regarding proper cleaning, disinfection, and sterilization of reusable medical devices.*


The CDC and FDA are alerting healthcare providers and facilities about the public health need to properly maintain, clean, and disinfect or sterilize reusable medical devices. Recent infection control lapses due to non-compliance with recommended reprocessing procedures highlight a critical gap in patient safety**.**

[1] **Critical items** (e.g., surgical instruments) are objects used to enter sterile tissue or the vascular system and must be cleaned and sterilized prior to reuse.

[2] **Semi-critical items** (e.g., endoscopes for upper endoscopy and colonoscopy, laryngoscope blades) are objects that contact mucous membranes or non-intact skin and require, at a minimum, cleaning and high-level disinfection prior to reuse.

Healthcare facilities (e.g., hospitals, ambulatory surgical centers, clinics, and doctors' offices) that utilize reusable medical devices are urged to immediately review current reprocessing practices at their facility to ensure they (1) are complying with all steps as directed by the device manufacturers, and (2) have in place appropriate policies and procedures that are consistent with current standards and guidelines.

**Background**

Recent media reports describe instances of patients being notified that they may be at increased risk for infection due to lapses in basic cleaning, disinfection, and sterilization of medical devices. These events involved failures to follow manufacturers' reprocessing instructions for critical[1] and semi-critical[2] items and highlight the need for healthcare facilities to review policies and procedures that protect patients.

**Recommendations**

Healthcare facilities should arrange for a healthcare professional with expertise in device reprocessing to immediately assess their reprocessing procedures. This assessment should ensure that reprocessing is done correctly, including allowing enough time for reprocessing personnel to follow all steps recommended by the device manufacturer. The following actions should be performed:

***Training***

- Healthcare facilities should provide training to all personnel who reprocess medical devices.
  - Training should be required and provided:
    - Upon hire or prior to provision of services at the facility
    - At least once a year
    - When new devices or protocols are introduced, including changes in the manufacturer's instructions for use during the device's life cycle
  - Personnel should be required to demonstrate competency with device reprocessing (i.e., trainer observes correct technique) prior to being allowed to perform reprocessing independently.
  - Healthcare facilities should maintain current documentation of trainings and competencies.
  - If the healthcare facility hires a contractor for device reprocessing, the facility should verify that the contractor has an appropriate training program and that the training program includes the specific devices the healthcare facility uses.
  - Copies of manufacturers' instructions for operating and reprocessing each type of reusable device should be readily available to staff and inspectors. This file should include instructions for use of chemical disinfectants.

***Audit and Feedback***

- Healthcare facilities should regularly audit (monitor and document) adherence to cleaning, disinfection, sterilization, and device storage procedures. Audits should assess all reprocessing steps, including:
  - Performing prompt cleaning after use, prior to disinfection or sterilization procedures
  - Using disinfectants in accordance with manufacturers' instructions (e.g., dilution, contact time, storage, shelf-life)
  - Monitoring sterilizer performance (e.g., use of chemical and biological indicators, read-outs of sterilizer cycle parameters, appropriate record keeping)
  - Monitoring automated endoscope reprocessor performance (e.g., print out of flow rate, time, and e of chemical indicators for monitoring high-level disinfectant concentration)
- Audits should be conducted in all areas of the facility where reprocessing occurs.
- Healthcare facilities should provide feedback from audits to personnel regarding their adherence to cleaning, disinfection, and sterilization procedures.

***Infection Control Policies and Procedures***

- Healthcare facilities should allow adequate time for reprocessing to ensure adherence to all steps

recommended by the device manufacturer, including drying, proper storage, and transport of reprocessed devices.

- Considerations should be made regarding scheduling of procedures and supply of devices to ensure adequate time is allotted for reprocessing.

Healthcare facilities should have protocols to ensure that healthcare personnel can readily identify devices that have been properly reprocessed and are ready for patient use (e.g., tagging system, storage in a designated area).

- Healthcare facilities should have policies and procedures outlining facility response in the event of a recognized reprocessing error or failure. Healthcare personnel should assess the cause of the error or failure and the exposure event in order to determine the potential risk of infection. The procedure should include how patients who might have been exposed to an improperly reprocessed medical device would be identified, notified, and followed.
- Individuals responsible for infection prevention and reprocessing at the healthcare facility should be consulted whenever new devices will be purchased or introduced to ensure that infection control considerations are included in the purchasing decision as well as subsequent implementation of appropriate reprocessing policies and procedures and to ensure that the recommended reprocessing equipment is available at the healthcare facility.
- Healthcare facilities should maintain documentation of reprocessing activities, including maintenance records for reprocessing equipment (e.g., autoclaves, automated endoscope reprocessors, medical washers and washer-disinfectors, water treatment systems), sterilization records (physical, chemical, and biological indicator results), and records verifying high-level disinfectants were tested and replaced appropriately.
- Healthcare facilities should follow manufacturer recommendations for maintenance and repair of medical devices that are used to perform reprocessing functions as well as medical devices that are reprocessed. If healthcare facilities contract maintenance and repair of these devices to third-party vendors, healthcare facilities should verify that these vendors are approved or certified by the manufacturer to provide those services.

**Additional Information**

Examples of relevant guidance include CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 available at http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf; and guidance from the Association for the Advancement of Medical Instrumentation (AAMI), available at http://www.aami.org/standards/index.aspx. Health care administrators should work with their infection prevention personnel and accreditation organizations to ensure that all recommendations are properly implemented to protect patients and personnel.

Problems with medical device processing should be reported to the FDA's MedWatch Adverse Event Reporting program either on line at https://www.accessdata.fda.gov/scripts/medwatch/, by regular mail, or by fax. Download the form at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm or call 1-800-332-1088 to request a reporting form, then complete he mail to address on the pre-addressed form, or submit by fax to 1-800-FDA-0178. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (see:http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm) should follow the reporting procedures established by their facilities.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Categories of Health Alert Messages: Health Alert conveys the highest level of importance; warrants immediate action or attention. Health Advisory provides important information for a specific incident or situation; may not require immediate action. Health Update provides updated information regarding an incident or situation; unlikely to require immediate action.

##This Message was distributed to State and Local Health Officers, Public Information Officers, Epidemiologists and HAN Coordinators as well as Clinician organizations##