Damaged or Worn Covers for Medical Bed Mattresses Pose Risk of Contamination and Patient Infection: FDA Safety Communication

Date Issued: April 19, 2013

Audience: Nurses, Caregivers, Infection Control Professional Staff, Risk Managers, Materials Managers, Housekeepers, Biomedical Engineers, Directors of Purchasing, and other health care providers and staff responsible for the purchase, inspection, use, or maintenance of medical bed mattress covers

Medical Areas: Any patient care setting where medical bed mattress covers are used. These include Intensive Care, Diagnostic Care, Emergent or Urgent Care, Ambulatory Care, Specialty Care, General Care, Long Term Care, and Home Care.

Purpose: The Food and Drug Administration (FDA) is alerting health care providers, health care facility staff, and caregivers that damaged or worn covers for medical bed mattresses can allow blood and body fluids to penetrate medical bed mattresses, posing a risk of infection to patients. The FDA is providing recommendations for reducing this risk, clarifying terms used to describe medical bed mattress covers, and encouraging health care providers, health care facility staff and caregivers to report problems related to medical bed mattress covers.

Medical Bed Mattress Covers:
A medical bed mattress cover provides outer protection to a medical bed mattress by preventing blood and body fluids from entering the inside (inner core) of the mattress. Types of mattresses may include **alternating pressure (ac-powered) air flotation mattresses (https://wayback.archive-it.org/7993/20170722215739/http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=2319)**, **non-powered flotation mattresses (https://wayback.archive-it.org/7993/20170722215739/http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?ID=2367)**, and other mattresses that are part of **hospital beds (https://wayback.archive-it.org/7993/20170722215739/http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=2318)**. Medical bed mattress covers may be coated with or contain a substance that kills germs (viruses or bacteria) or prevents bacterial growth. There are multiple terms used to describe medical bed mattress covers: water-resistant (keeps liquid away from the material), water-proof (prevents liquid from entering inside the material), or water-repellent (keeps liquid away from the material and prevents liquid from entering inside the material).

Medical bed mattress covers, whether water-resistant, water-proof, or water-repellent, may lose their effectiveness over time. The duration of time that a medical bed mattress cover is expected to last (expected life) varies from manufacturer to manufacturer. In addition, the expected life of a medical bed cover may differ from that of the mattress itself. For example, a medical bed mattress may have a longer expected life than the mattress cover.

Summary of Problem and Scope:
From January 2011 to January 2013, the FDA received 458 reports associated with medical bed mattress covers failing to prevent blood and body fluids from leaking into the mattress (fluid ingress). Fluid ingress may occur if mattress covers become worn or damaged from small holes or rips in the fabric or from incorrect cleaning, disinfecting and laundering procedures. The zipper on the cover may also allow fluid to penetrate the mattress. Some reports indicate that if blood and body fluids from one patient penetrate a mattress, they can later leak out from the mattress when another patient is placed on the bed. Patients are at risk for infection if they come into contact with blood and body fluids from other patients.

Medical literature shows that damaged and wet (soiled) mattresses can be a source of contamination during infection outbreaks. The FDA is concerned that fluid ingress from worn or damaged medical bed mattress covers may be widespread and largely under-recognized by health care providers, health care facility staff, and caregivers.

Recommendations:
Inspect

- Regularly check each medical bed mattress cover for any visible signs of damage or wear such as cuts, tears, cracks, pinholes, snags or stains.
- Routinely remove the medical bed mattress cover and check its inside surface. Once the mattress cover is removed, inspect the mattress for wet spots, staining, or signs of damage or wear. Check all sides and the bottom of the mattress.
- Be aware that it may be difficult to identify damaged or soiled mattresses because mattress covers tend to be dark in color.

Remove and Replace

- Remove any damaged, worn or visibly stained medical bed mattress according to the healthcare facility's procedures and manufacturer's instructions.
- Immediately replace any medical bed mattress cover with visible signs of damage or wear to reduce the risk of infection to patients.

Maintain

- Clean and disinfect undamaged medical bed mattress covers according to the manufacturer's guidelines.
- DO NOT stick needles into a medical bed mattress through the mattress cover.

Develop an Inspection Plan

- Check the expected life of the medical bed mattress and the mattress cover.
- Create an inspection plan for all medical bed mattresses in your facility.
- Contact the medical bed mattress cover manufacturer for any additional questions.

FDA Activities:
The FDA will continue to monitor this issue and keep the public informed if new information becomes available.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect a problem with medical bed mattress covers, we encourage you to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (https://wayback.archive-it.org/7993/20170722215739/http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm)**.

Health care personnel employed by facilities that are subject to **FDA's user facility reporting requirements (https://wayback.archive-it.org/7993/20170722215739/http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)** should follow the reporting procedures established by their facilities.

To help the FDA learn as much as possible about the adverse events associated with medical mattress covers, please include the following information in your reports, if available:

- Manufacturer's Name
- Device Name (Brand Name)
- Date Device was Manufactured and/or Obtained by the Facility
- Distributor's Name
- Details of Adverse Event and Medical and/or Surgical Interventions (if required)

Contact Information:

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at **INDUSTRY.DEVICES@FDA.HHS.GOV (https://wayback.archive-it.org/7993/20170722215739/mailto:INDUSTRY.DEVICES@FDA.HHS.GOV)**, 800-638-2041 or 301-796-7100.

Helpful Links:

- **Guidelines for Environmental Infection Control in Health Care Facilities: Recommendations of CDC and Healthcare Infection Control Practices Advisory Committee (https://wayback.archive-it.org/7993/20170722215739/http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_hcf_03.pdf)**

More in Safety Communications (/7993/20170722215739/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/default.htm)

2017 Safety Communications (/7993/20170722215739/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm)

2016 Safety Communications (/7993/20170722215739/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm553855.htm)