

FDA U. S. Food & Drug Administration
MAUDE Adverse Event Report

STRYKER MEDICAL STRYKER PATIENT MATTRESSES MATTRESS, AIR FLOTATION, ALTERNATING PRESSURE

Event Date 10/19/2018

Event Type Malfunction

Event Description

Neuro science intensive care unit (icu) & trauma icu - 19 patient bed mattresses found to be compromised with fluid ingress. Mattresses removed by environmental services with biomed support. Mattresses will be evaluated and cultured by infection control. Stryker rep coming on site to assess for warranty. Environmental services will be trained to inspect and identify compromised mattresses going forward. 24 stryker iso gels were affected. 14 out of 16 of hillrom accumax were affected. No patient identifiers are available. No known injuries at this time, voluntary.

MEDLINE INDUSTRIES, INC. MEDLINE GURNEY MATTRESS MATTRESS, FLOTATION THERAPY, NON-POWERED

Catalog Number MDTS2676H4C

Event Date 10/05/2018

Event Type Malfunction

Event Description

Ed gurney mattress was cleaned according to policy following the care of a pt. During normal cleaning, there was no fluid leakage, punctures, breaks in the integrity of the mattress being cleaned. However, due to the history of previous mattress issues, the staff completed an add'l step to ensure the integrity of the mattress. That step involves taking a clean, dry white paper towel and placing on the mattress with pressure applied by the staff member's hand palm. When this step was taken, the mattress leaked urine looking fluid onto the paper towel. The mattress was bagged and taken out of use.

MEDLINE INDUSTRIES INC. MEDLINE GURNEY MATTRESS MATTRESS, FLOTATION THERAPY

Catalog Number MDTS2676H4C

Event Date 08/06/2018

Event Type Malfunction

Event Description

Two events involving medline gurney mattress (b)(6) 2018: pt had intravenous fluid catheter inserted, which returned blood upon insertion. Blood pooled on mattress through sheet. On (b)(6) 2018: trauma pt with multiple injuries bled on gurney. Both mattresses were being cleaned per mfr guidelines following the use on the above mentioned pts. Routine cleaning process did not find any blood. Breaks, pokes visible to the eye on the mattress. However, when a white towel was placed on the individual mattress and pressure applied, bright red blood was seen on the white towel. Mattresses were removed from use and placed in biohazard bags. Kept for mfr's rep to pickup for investigation.