B. Braun addEASE Binary Connector: Class I Recall -Stopper Fragments May Enter Bag

U.S. Food & Drug Administration

AUDIENCE: Risk Manager

ISSUE: When the addEASE binary connector is inserted into a partial additive bag (PAB) stopper, fragments of the stopper may enter the bag, resulting in a small amount of visible particles in the solution. The particles can potentially enter a patient's body and lead to serious adverse health consequences, such as pulmonary embolism, stroke, or heart attack. These issues could result in serious injury or death.

BACKGROUND: The addEASE is used to transfer fluid between a partial additive bag (PAB) and a drug vial.

RECOMMENDATION: On June 28, 2010 B Braun sent an Urgent Medical Device Recall letter to its customers informing them of the recall and advising them to immediately stop using or distributing addEASE connectors.

Braun PAB containers can continue to be used safely with a standard syringe and needle in accordance with the Direction for Use.

Healthcare professionals are encouraged to report adverse events related to the use of this product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[11/30/2010 - Recall Notice [3] - FDA]

SOURCE [4]

Source URL (retrieved on *07/10/2014 - 5:22am*):
http://www.mdtmag.com/news/2010/11/b-braun-addease-binary-connector-class-i-recall-stopper-fragments-may-enter-bag?qt-recent_content=0

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149236.htm
[3] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm235244.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm235283.htm