Class I Medical Device Recall: B. Braun addEASE Binary Connector

U.S. Food & Drug Administration

B. Braun addEASE Binary Connector

Recall Class: Class I

Date Recall Initiated: June 24, 2010

Product:
addEASE Binary Connectors
Catalog numbers N7990 and N7933

Manufactured and distributed from April 4, 2004 to June 4, 2010

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

Recalling Firm: B. Braun

Reason for Recall: 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.

Public Contact:

For questions about the affected product or information on returning unused addEASE binary connectors, contact:

B. Braun Customer Support Department
800-227-2862
Monday - Friday, 8:00am - 7:00pm EST
FDA District: Los Angeles

If you have experienced a problem with particulates in the PAB after use of an addEASE binary connector and wish to report the problem, contact:

Braun Clinical and Technical support at 1-800-854-6851

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to FDA's MedWatch Program [1] either on line, by regular, mail, phone or fax.

FDA Comments:

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.**

B. Braun requested that its customers contact the Customer Support Department to arrange for return of any full or partial cases of addEASE. A Customer Support Representative will provide customers with instructions for handling the affected product. The firm will arrange for unopened cases to be returned to B. Braun Medical, Inc. for proper disposal. Individual units (out of shipping cases) may be destroyed at the customer’s facility.

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

Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Useful Links:

- MedWatch: The FDA Safety Information and Adverse Event Reporting Program [1]

SOURCE [2]

Source URL (retrieved on *01/31/2015 - 12:07pm*):
http://www.mdtmag.com/news/2010/11/class-i-medical-device-recall-b-braun-addease-binary-connector

Links:
[1] http://www.fda.gov/Safety/MedWatch/default.htm
[2] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm235244.htm