Excelsior Medical 5 ml Fill in 6 cc Prefilled Saline Flush Syringes: Recall - Potential Loss of Sterility

U.S. Food & Drug Administration

AUDIENCE: Risk Manager

ISSUE: Routine internal testing conducted on this product found that some of these syringes may leak and lose sterility. This recall pertains only to syringes with the following product code numbers: E0100-50, 10056-1000, 10056-240, 14056-240, 910056-1000, and S5. Exposure to syringes with a sterility issue could result in systemic infection, which may lead to serious injury and/or death.

BACKGROUND: The Excelsior Disposable 5ml fill in 6 cc prefilled saline flush syringes are intended for the flushing of venous access devices and IV tubing.

RECOMMENDATION: Consumers who have 5ml fill in 6 cc saline pre-filled syringes manufactured by Excelsior Medical should immediately discontinue using these syringes and return them to the point of purchase.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products 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

[10/15/2010 - Press Release [3] - Excelsior Medical]

SOURCE [4]

Source URL (retrieved on *12/12/2013 - 9:53pm*):
http://www.mdtmag.com/news/2010/10/excelsior-medical-5-ml-fill-6-cc-prefilled-saline-flush-syringes-recall-potential-loss-sterility

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm

[3] http://www.fda.gov/Safety/Recalls/ucm229531.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm229781.htm