Infusion Set Needles [Manufactured by Nipro for Exelint]: Recall

FDA MedWatch
FDA notified healthcare professionals of a Class I recall of Exel/Exelint Huber needles, Exel/Exelint Huber Infusion Sets and Exel/Exelint "Securetouch+" Safety Huber Infusion Sets, manufactured by Nipro Medical Corporation for Exelint International Corporation due to 'coring', the cutting or dislodging of silicone cores or slivers from the ports into which they are inserted. Huber needles are used to access ports implanted under the skin of chronically ill patients for repeated access to veins for the withdrawal of blood and infusion of medication, nutritional solutions, blood products, and imaging solutions.
Inspections conducted in October 2009 of Nipro facilities found that their needles "cored" in 60 to 72 percent of tests. The reason for this coring is related to design and manufacturing processes, which the FDA continues to investigate and will update the public if there are new developments.

Hospitals, clinics and patients who have needles from these lists should immediately stop using these affected products and return any unused products to Exelint International Corporation.

There are more than 2 million units impacted by this recall in distribution nationwide. Recalled needles were manufactured from January 2007 to August 2009. Units subject to recall have a lot number that begins with "07," "08," "09," and one of the product codes or catalog numbers noted in the FDA news release.

SOURCE [1]

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http://www.ecnmag.com/news/2010/01/infusion-set-needles-manufactured-nipro-exelint-recall

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[1] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm198728.htm