GBS
Group Benefit Services

Compliance Alert

November 4, 2010

RECALL COMMUNICATION

On October 15, 2010, Excelsior Medical announced a recall of certain product code numbers of it's pre-filled 5ml saline (0.9% sodium chloride) flush syringes. Routine internal testing found that some of these syringes may leak and lose sterility. Exposure to syringes with a sterility issue could result in systemic infections, which may lead to serious injury and/or death. The table below contains the recalled product code numbers, which can be found in the barcode on each syringe and on the carton label. No other product codes are affected by this recall.

Recalled Product Code Numbers	
E0100-50	14056-240
10056-1000	910056-1000
10056-240	S5

Excelsior Medical recommends the following:

- Saline flush syringes with a recalled product code numbers (above) should not be used.
- Product with a recalled product code number should be returned to its point of purchase.
- Adverse events should be reported to FDA's MedWatch reporting system online (www.accessdata.fda.gov/scripts/medwatch/), by phone (1-800-FDA-1088), by facsimile (1-800-FDA-0178) or by mail using the MedWatch Form FDA 3500 (FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787).

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