

FDA Consumer

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Enema Tip Recall.

Severe allergic reactions in patients undergoing barium enemas prompted the manufacturer last October to voluntarily recall the type of enema tip used in the procedures. The 150 adverse reaction reports included nine deaths.

Up to 10 million barium enema x-ray procedures are performed each year in the United States to diagnose disorders of the lower digestive tract.

The exact cause of the adverse reactions is unclear. The manufacturer, E-Z-Em, Inc., of Westbury, N.Y., asked physicians to stop using enema tips with inflatable latex cuffs. The firm also stated in recall letters to health professionals and purchasers that water-soluble proteins in products with latex may trigger severe allergic reactions, especially in patients who have a history of allergies. The recalled E-Z-Em tips have inflatable cuffs (used to prevent barium leakage from the rectum during the procedure) that contain latex.

Through the October 1990 FDA Drug Bulletin, the agency also alerted U.S. physicians to the problem, requesting reports of allergic reactions to barium enemas or to products containing latex.