Smiths Medical Bivona Neonatal, Pediatric and Flextend Tracheostomy Tubes: Class 1 Recall - Inadvertent Dislodgement

U.S. Food & Drug Administration

ISSUE: FDA notified healthcare professionals and medical care organizations about the Class 1 recall of certain lots of these tracheostomy tubes. Difficulty arising from disconnecting accessories from the connectors of the affected tubes may result in excessive force to detach the accessory and the tracheostomy tube may dislodge from the patient. This could lead to serious patient injury or death, especially if no replacement tube is immediately available.

BACKGROUND: The Bivona Pediatric, Neonatal and Flextend tracheostomy tube is intended to provide direct airway access for a tracheostomized patient for up to 29 days. This product is used in health care facilities and home care environment. Lot Numbers 1631477 through 1923406 are being recalled. The recalled products were manufactured from August 29, 2009 to January 29, 2011.

RECOMMENDATIONS: Consumers who have the affected tubes should identify all affected, unused product in inventory and segregate it to a quarantine location. Contact Smiths Medical Customer Service (Monday – Friday 8am-8pm CST): 1-800-258-5361 for further recall instructions. Smiths Medical mailed all U.S. consignees an Urgent Field Safety Notice on November 28, 2011 and an updated Urgent Field Safety Notice on January 9, 2012. A copy of the customer notification letter, along with pictures to distinguish the affected tubes, is posted on the Smiths Medical website at http://www.smiths-medical.com [1]

SOURCE [2]

Links:
[1] http://www.smiths-medical.com/
[2] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm293125.htm