FDA

Class 2 Device Recall Dermacea Gauze Fluff Roll

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See Related Information[22]

Date Initiated by Firm	August 01, 2018
Create Date	October 03, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0017-2019
Recall Event ID	80924[23]
510(K)Number	K990530[24]
Product Classification	Dressing, wound, occlusive[25] - **Product Code** NAD[26]
Product	Dermacea Gauze Fluff Roll, 6 Ply, 4-1/2 x 4-1/8 yd (11.4 cm x 3.7 m), REF 441103 Product Usage: Used as both primary and secondary dressing for bandaging heads, limbs and difficult-to-dress wounds.
Code Information	Lot Numbers: 18D180662,18E070362,18E222362,18F072362
Recalling Firm/ Manufacturer	COVIDIEN LLC 15 Hampshire St Mansfield MA 02048-1113
For Additional Information Contact	508-261-8000
Manufacturer Reason for Recall	Potential for product sterility breach due to a compromised or pinched seal defect
FDA Determined Cause [2]	Nonconforming Material/Component
Action	On August 1, 2018 Cardinal Health issued Urgent Medical Device Recall notices to U.S. customers via Fed Ex and OUS customers were directly contacted by Quality & Regulatory Affair representatives supporting that country. Customers were advised to take the following actions: 1. Inspect stock and quarantine affected product. 2. Immediately stop using affected product. 3. Return the completed acknowledgment form via fax to 847-689-9101 or 614-652-9648, whether or not you have affected product, as Cardinal Health is required to confirm receipt of this notification from customers, and to prevent further notices. 4. Notify any customers to whom you may have distributed product affected by this recall. 5. Contact the appropriate Customer Service group to arrange for credit and return of any affected product you may have: ¿ Hospital 800-964-5227 ¿ Federal Government 800-444-1166 ¿ Distributors800-635-6021 ¿ All other customers 888-444-5440 Customers with any questions regarding this letter may call (800) 292-9332.
Quantity in Commerce	2,730,821 units in total
Distribution	US Nationwide Distribution
Total Product Life Cycle	TPLC Device Report[27]