California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Medline Industries Proxima Drapes Sterile Surgical Drapes

Recall Date	Product Description	Recalling Firm	Recall Reason
03/14/2025	Proxima Drape labeled as DRAPE C-SECTION W/ WINDOW SHEET, DRAPE, SPLIT, ST,10/CS DRAPE, LAPROSCOPY, CHOLE, W/TROUGH, ST, 8/ CS DRAPE, LAPROSCOPY, CHOLE, W/TROUGH, ST, 8/ CS DRAPE, ABDOMINAL, MAJOR, ST, 8/CS DRAPE, ABDOMINAL, MAJOR, ST, 8/CS DRAPE, SPLIT, CVMAX, 6/CS DRAPE, ORTHOMAX, BAR, 6/ CS DRAPE, FEMORAL, RADIAL, 5/CS DRAPE, C-SECTION, FEN, CLR SCREEN, WIRE, 7/CS DRAPE, HAND, ULTRAGARD, 18/CS DRAPE, HAND, ULTRAGARD, 18/CS DRAPE, U, ORTHOMAX, 6/CS DRAPE, SPLIT, 77X120", 10/ CS DRAPE, ROBOTIC,	MEDLINE INDUSTRIES, LP – Northfield	Potential breach in pouch packaging which could lead to loss of sterility.

	W/LEGGING, W/POUCH, 5/CS - DRAPE, ROBOTIC, W/LEGGING, W/POUCH, 5/CS Sterile surgical drape. Proxima Drape labeled as: PACK, BASIC, SIRUS, V, 5/CS PACK, BASIC IV, SIRUS, 5/CS PACK, SET UP, NO DRAPE, 12/CS PACK, SET UP, NO DRAPE, 12/CS PACK, SET UP, NO DRAPE, 12/CS PACK, SET UP, NO DRAPE, 12/CS PACK, SET UP, NO DRAPE, 12/CS PACK, UNIVERSAL II, SIRUS, 7/CS PACK, LAPAROTOMY, NO GOWN, 10/CS PACK, CYSTOSCOPY, PK VI, 14/CS PACK, CYSTOSCOPY, PK VI, 14/CS PACK, OB III, GRADUATED UNDERBUTTOCK, 6/CS PACK, LAVH, AURORA, 4/CS Sterile surgical drape. Proxima Drape labeled as: ENT-PLASTICS PACK Sterile surgical drape. Proxima Drape labeled: MINOR PACK LAPAROSCOPY Sterile surgical drape.		

	Proxima Drape labeled as: FACE surgical drape. Proxima Drape labeled as: HEAD AND NECK OSIS WILLIS SHOULDER PACK EXTREMITY PACK-LF TOTAL HIP PACK-LF SHOULDER W/POUCH- LFVEIN PACK Sterile surgical drape. Proxima Drape labeled as: UNIVERSAL DAVINCI ROBOTIC P Sterile surgical drape. Proxima Drape labeled as: ORTHO TRAUMA CDS TOTAL KNEE AUX PACK TOTAL HIP PACK TOTAL HIP TOTAL KNEE SPINE Sterile surgical drape.		

Recall Class	Product Identification	Distribution	Affected Dates
II	Item No.: DYNJCDCSEC01 UDI (case): 40888277367679 UDI (each): 10888277367678 Item No.: DYNJP2498 UDI (case): 40080196739494 UDI (each): 10080196739493 Item No.: DYNJP3102A UDI (case): 40080196778363 UDI (each): 10080196778362 Item No.: DYNJP3103 UDI (case): 40080196744221 UDI (each): 10080196744220 Item No.: DYNJP4014	402 units in California	February and prior

	UDI (case): 40080196287308 UDI (each): 10080196287307 Item No.: DYNJP4015 UDI (case): 40080196770039 UDI (each): 10080196770038 Item No.: DYNJP4124 UDI (case): 40080196164944 UDI (each): 10080196164943 Item No.: DYNJP6108 UDI (case): 20888277668840 UDI (each): 10080196574124 Item No.: DYNJP8005UG UDI (case): 40080196574125 Item No.: DYNJP8303 UDI (case): 40080196771111 UDI (each): 10080196771110 Item No.: DYNJP8304A UDI (case): 40080196292432 UDI (each): 10080196292431 Item No.: DYNJP9108 UDI (case): 40080196152576 UDI (each): 10080196152575 Lot No.: 45024100168 - 45024100185 Item No.: DYNJP1020S UDI (case): 40080196308126 UDI (each): 10080196308125 Item No.: DYNJP1025S UDI (case): 40080196308133 UDI (each): 10080196308132 Item No.: DYNJP1040 UDI (case): 40080196722892 UDI (each): 10080196722891 Item No.: DYNJP1055S UDI (case): 40080196308195 UDI (each): 10080196308194 Item No.: DYNJP3000 UDI (case): 40080196722946 UDI (each): 10080196722945 Item No.: DYNJP5050 UDI (case): 40080196753391 UDI (each): 10080196753390 Item No.: DYNJP6060S UDI (case): 40884389110295 UDI (each): 10884389110294 Item No.: DYNJP9120A UDI (case): 40080196915416		

	UDI (each): 10080196915415 Lot No.: 31124090044H - 31124100007F Item No.: DYNJ84258A UDI (case): 40195327650743 UDI (each): 10195327650742 Item No.: DYNJ84258B UDI (case): 40198459117986 UDI (each): 10198459117985 Lot No. (Shelf Life): 24HBK264 (12/31/26), 24IBD271 (7/31/26) Item No.: DYNJ34603F UDI (case): 40198459143596 UDI (each): 10198459143595 Item No.: DYNJ903916I UDI (case): 40195327580118 UDI (each): 10195327580117 Lot No. (Shelf Life): 25AMD464(11/30/2029) - 24IBM203(02/28/2026) Item No.: DYNJ910462 UDI (case): 40195327695638 UDI (each): 10195327695637 Lot No. (Shelf Life): 24JMD608 (06/30/2026) Item No.: DYNJ35520B UDI (case): 40198459106904 UDI (each): 10198459106903 Item No.: DYNJ38529F UDI (case): 40195327693870 UDI (each): 10195327693879 Item No.: DYNJ43406F UDI (case): 40198459074005 UDI (each): 10198459074004 Item No.: DYNJ43421D UDI (case): 40198459074784 UDI (each): 10198459074783 Item No.: DYNJ69185A UDI (case): 40195327582839 UDI (each): 10195327582838 Item No.: DYNJ69340B UDI (case): 40198459026127 UDI (each): 10198459026126		

	Item No.: DYNJ88923 UDI (case): 40198459216856 UDI (each): 10198459216855 Lot No. (Shelf Life): 24KMB843(05/31/2027) - 25ABB569(02/10/2026) Item No.: DYNJ53968P UDI (case): 40195327532759 UDI (each): 10195327532758 Lot No. (Shelf Life): 24KMC372 (3/31/2026) - 24HMK377 (4/30/2026) Item No.: CDS985210G UDI (case): 40195327553310 UDI (each): 10195327553319 Item No.: DYNJ65826A UDI (case): 40195327516193 UDI (each): 10195327516192 Item No.: DYNJ87398 UDI (case): 40198459034405 UDI (each): 10198459034404 Item No.: DYNJ908743C UDI (case): 40195327636297 UDI (each): 10195327636296 Item No.: DYNJ908744C UDI (case): 40195327636280 UDI (each): 10195327636289 Item No.: DYNJ910326B UDI (case): 40198459075002 UDI (each): 10198459075001 Lot No. (Shelf Life): 24LBK011 (04/30/2026) - 24KBQ357(12/31/2025)		

For additional information, please visit: FDA Website (1), FDA Website (2), FDA Website (ENT-Plastics), FDA Website (Minor and Laparoscopy), FDA Website (Face Lift), FDA Website (Head and Neck, Willis Shoulder, etc.), FDA Website (Universal Davinci), and FDA Website (Orthopedics).