

FOOD AND DRUG ADMINISTRATION (FDA)
RECALLS/ALERT NOTICES

1. FDA MEDICAL EQUIPMENT RECALLS AND ALERTS. The following recalls are reported in accordance with AFMLL 2-95, page CE-4, and should be treated as directed modifications in accordance with that AFMLL and AFI 41-201, Chapter 2, Section D. If you possess any of these items and have not received recall notification, you should contact the manufacturer for recall instructions. Suspension is only required for Class I items. (FOM, Capt David Zemkosky, DSN 343-4028)

CLASS I RECALLS: None

CLASS II RECALLS:

6530NS
MDC 13739
PRODUCT Sterilizers, Dry Heat
Operator's Manual and Front Panel Decal for the Medtronix M-300 Talc Sterilizer, dry heat sterilizer used to sterilize talc which is used by hospitals for thoracic surgeries. Recall #Z-089-7.
CODE All manuals and units in distribution.
MANUFACTURER Dentronix, Inc., Ivyland, Pennsylvania (spec. developer).
RECALLED BY Dentronix, Inc., Ivyland, Pennsylvania, by letter dated October 15, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Pennsylvania, Florida, Ohio, Hawaii, California, Tennessee, Kentucky, Washington state, Maryland, Michigan, Texas.
QUANTITY 14 units were distributed.
REASON The operators manual and the front panel of the device makes reference to instrument sterilization when the maximum temperature of the sterilizer is not sufficient to sterilize instruments.

None Present
 Action Taken _____

6530NS
MDC 15757
PRODUCT Lasers, Surgical
Aurora Diode Laser, used in dental surgery. Recall #Z-186-7.
CODE Various serial numbers.
MANUFACTURER Premier Laser Systems, Inc., Irvine, California.
RECALLED BY Manufacturer. FDA approved the firm's corrective action plan on December 12, 1996. Firm-initiated field correction ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 52 units were distributed.

REASON Noncompliance with performance standards for laser products in that the operator's manual lacked calibration procedures.

None Present

Action Taken _____

6530NS
MDC 16214
PRODUCT

Wheelchairs, Powered

Powered and manual wheelchairs:

- (a) Applause Manual Wheelchair, Product No. E20300-5XX;
- (b) Ovation Powered Wheelchair, Product No. DE20300-501;
- (c) Enabler Manual Wheelchair, Product No. E20000-5XX;
- (d) Electro-Lite Powered Wheelchair, Product Nos. DE90003A & DE90003A/L.

Recall #Z-191/194-7.

CODE All serial numbers lower than 303974 shipped prior to April 22, 1992.

MANUFACTURER Damaco, Inc., Moorpark, California.

RECALLED BY Manufacturer, by letters sent between July 2 and 5, 1996, and October 23, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY 2,665 units were distributed; firm estimated that 2,177 units remained in commerce at time of recall initiation.

REASON The rear wheel axle bolt may break when bending stress exceeds the carrying capacity.

None Present

Action Taken _____

6525NS
MDC 17801
PRODUCT

Collimators, Gamma Camera

Collimator for Multispect 2 Gamma Camera Systems; designed for SPECT acquisitions/imaging studies utilizing Technetium and Thallium radionuclides. Recall #Z-195-7.

CODE All units shipped prior to 2/18/96.

MANUFACTURER Siemens Medical Systems, Inc., Nuclear Medicine Group, Hoffman Estates, Illinois.

RECALLED BY Manufacturer, by issuing a Mandatory Next Service Call Field Modification Instruction (FMI-00174) on December 11, 1996.

Firm-initiated field correction ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY 215 units were distributed.

REASON The collimator latches intermittently fail to latch or unlatch due to high contact resistance of relays on the CLMD board inside the gantry.

None Present

Action Taken _____

6515NS
MDC 13215 Infusion Pumps
PRODUCT Sabratek Model 6060 Homerun Volumetric Infusion Pump, for the
 delivery of enteral, epidural, subcutaneous, arterial, and
 intravenous fluids to the patient. Recall #Z-204-7.
CODE All units with software version 2.0.
MANUFACTURER Sabratek Corporation, Niles, Illinois.
RECALLED BY Manufacturer, by telephone on October 15, 1996, followed by
 letter dated October 16 and 18, 1996. Firm-initiated field
 correction ongoing.
DISTRIBUTION Illinois, Massachusetts, Ohio, Florida, Texas, Missouri, North
 Carolina, Pennsylvania, Indiana, California, Washington state,
 Louisiana, Ireland, Brazil, Canada.
QUANTITY 487 units were distributed.
REASON There is a possibility that the device can bypass the delay
 delivery mode when the infusion pump is programmed in the
 Continuous, 25 Period, Intermittent or Auto-Ramp profile,
 delivering the solution as programmed without the delayed
 delivery.

None Present
 Action Taken _____

CLASS III RECALLS: None

MEDICAL EQUIPMENT SAFETY ALERTS: None

2. DRUG/SUPPLY PRODUCT RECALLS AND MEDICAL INFORMATION. The Food and Drug Administration (FDA) advises that the drug products listed below were recalled by the manufacturers or distributors concerned. The FDA has classified these recalls as follows:

CLASS I: A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.

CLASS II: A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

CLASS III: A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. Most of these items are nonstandard, and the possibility exists that medical activities may have purchased them locally. There is also a possibility that some of these items have NSNs assigned and may have been reported in earlier Q.A. messages. Activities having quantities of [AU]these items on hand will immediately suspend the materiel from issue and use. CONUS activities will contact the nearest office of the respective manufacturer or distributor for disposition instructions. OVERSEAS activities will report quantities suspended to AFMLO/FOM-P no later than 14 MAR 97 for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity

suspended; strength size; requisition; and DPSC purchase order number, contract number, and stock record account number (SRAN). (FOM-P), Bonnie Phillips, DSN (343-4170)

CLASS I RECALLS: None

CLASS II RECALLS:

NSN 6505 Nonstandard
PRODUCT Trasyol (aprotinin injection) sterile solution for intravenous infusion, packaged in 200 ml stoppered glass vials, used during coronary artery bypass graft surgery. Recall #D-073-7.
CODE Lot 6CCY EXP 11/97, 6FAH EXP 11/97, 6HAG EXP 12/97.
MANUFACTURER Bayer A.G. Leverkusen, Germany.
RECALLED BY Bayer Corporation, West Haven, Connecticut, by letter on December 17 and 23, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 15,442 vials of lot 6CCY, 7,392 vials of lot 6FAH, and 9,882 vials of lot 6HAG were distributed.
REASON Lack of adequate assurance of sterility. Aluminum skirt holding vial may not be adequately crimped in place.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Acetabular Reamer Shell, 54mm, Catalog No. 1207-354. Recall #Z-183-7.
CODE Lot Number 00041821.
MANUFACTURER Linvatec Corporation, Division of Zimmer/Bristol-Squibb Company, Largo, Florida.
RECALLED BY Manufacturer, by letter dated October 18, 1996. Firm-initiated recall complete.
DISTRIBUTION Virginia, Texas, Pennsylvania, Wisconsin, Minnesota, North Carolina, Tennessee, Washington state, California, Maryland, Arkansas, New York.
QUANTITY 19 devices were distributed.
REASON The reamer shell is etched to identify it as a 54mm shell when in fact it may be a 55mm

[] None Present
[] Action Taken _____

NSN 6515 Nonstandard
PRODUCT MicroSeal Reusable Phacoemulsification
Needles, used during ophthalmic surgery:
(a) Catalog #DP8030, 30 Degree MicroSeal
Needle; (b) Catalog #DP8045, 45 Degree
MicroSeal Needle. Recall #Z-189/190-7.
CODE (a) Package date code 96085; (b) Package date
code 96086.
MANUFACTURER Storz Instrument Company, St. Louis, Missouri.
RECALLED BY Manufacturer, by letter dated October 28,
1996, followed by fax on December 9, 1996.
Firm-initiated recall ongoing.
DISTRIBUTION International.
QUANTITY (a) 339 boxes (6 units per box); (b) 210 boxes
(6 units per box) were distributed.
REASON The needles were packaged with the incorrect
instructions for use. "Microflow Needle
DP82XX Series Instructions for Use" were
packaged with the products and lacks a warning
statement instructing the user not to use the
needle if the brown thermoprotective sleeve is
missing or detached from the needle.

[] None Present
[] Action Taken _____

NSN 6530 Nonstandard
PRODUCT Powered and manual wheelchairs:
(a) Applause Manual Wheelchair, Product No.
E20300-5XX;
(b) Ovation Powered Wheelchair, Product No.
DE20300-501;
(c) Enabler Manual Wheelchair, Product No.
E20000-5XX;
(d) Electro-Lite Powered Wheelchair, Product
Nos. DE90003A & DE90003A/L.
Recall #Z-191/194-7.
CODE All serial numbers lower than 303974 shipped
prior to April 22, 1992.
MANUFACTURER Damaco, Inc., Moorpark, California.
RECALLED BY Manufacturer, by letters sent between July 2
and 5, 1996, and October 23, 1996. Firm-
initiated recall ongoing.
DISTRIBUTION Nationwide and international.

QUANTITY 2,665 units were distributed; firm estimated that 2,177 units remained in commerce at time of recall initiation.

REASON The rear wheel axle bolt may break when bending stress exceeds the carrying capacity.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Viramune (nevirapine) Tablets, 200 mg, packaged in bottles of 100, and in unit dose blisters of 10 cards, 10 tablets per card, Rx, used in combination with other antiretroviral agents for the treatment of HIV-1 infected adults who have experienced clinical and/or immunologic deterioration. Recall #D-061-7.
CODE Lot numbers: NS816A EXP 12/98, NS816AX EXP 12/98, NS852A EXP 1/99, NS852B EXP 7/98.
MANUFACTURER Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut.
RECALLED BY Roxane Laboratories, Inc., Columbus, Ohio (distributor), by letter on November 22, 1996. Firm-initiated recall complete.
DISTRIBUTION Nationwide.
QUANTITY 13,043 bottles of 100 tablets and 380 cartons of 10x10 blister packs were distributed; firm estimated that 50 percent of product remained on market at time of recall initiation.
REASON Dissolution failure (average of 74%; SPEC is NLT 75%).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Oxygen, Compressed USP, transfilled into D or E compressed medical gas cylinders. Recall #D-062-7.

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CODE The following lot numbers were transfilled during the period of 1/4/96 through 10/16/96:
3376004 33760046 3376036 3376061
6526031 3376050 33753555 3376067

3376073	3376095	6525285	65253204
3376088	3376073	3376116	3376138
3376113	3372599	3376131	3376158
3376179	0546151	0546172	6525320
3376201	3376205	0546219	3376240
3376233	3376249	3376264	3376270.

MANUFACTURER RECALLED BY Hammer Medical Supply, Inc., Clive, Iowa.
 Hammer Medical Supply, Inc., Des Moines, Iowa,
 by visit beginning on or about October 24,
 1996. Firm-initiated recall ongoing.

DISTRIBUTION QUANTITY Iowa.
 Approximately 400 cylinders were in the field
 at time of recall initiation.

REASON Lack of complete and accurate label
 information (e.g. incorrect lot number).

[] None Present
 [] Action Taken _____

NSN 6505 Nonstandard

PRODUCT PanMist S, Guaifenesin Orange-Flavored Syrup,
 produced by Sage Laboratories, Inc. from
 December, 1995 through April, 1996, and
 packaged under the Pan American Laboratories
 Label.
 Recall #D-063-7.

CODE Lot numbers: SL410SU, SL411SU, SL412SU, S5002,
 S5106, S6015, S6031, SL413SU, S5001, S5113.

MANUFACTURER Sage Pharmaceuticals, Inc., Shreveport,
 Louisiana.

RECALLED BY Manufacturer, by fax on November 22, 1996,
 followed by letter sent on November 25, 1996.
 Firm-initiated recall ongoing.

DISTRIBUTION QUANTITY Louisiana.

Lot Number	Packaging Size	Number Bottles
SL410SU	Pint Bottles	1536
SL411SU	Pint Bottles	1512
SL412SU	Pint Bottles	1505
S5002	Pint Bottles	1554
S5106	Pint Bottles	1260
S6015	Pint Bottles	1560
S6031	Pint Bottles	1560
	10487 TOTAL	
SL413SU	15 ml Sample Bottles	42552
S5001	15 ml Sample Bottles	50544
S5113	15 ml Sample Bottles	46368
	139464 TOTAL.	

REASON Guaifenesin may precipitate.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Intal Inhalers, cromolyn sodium, 200 metered dose size and 112 metered dose size, Rx, used for management of bronchial asthma.
Recall #D-064-7.
CODE DT6G EXP 5/97 (200 metered size); CK9G EXP 5/97 EXP 5/97, CK10G EXP 6/97 (112 metered size).
MANUFACTURER 3M Health Care (Riker Labs), Loughborough, England.
RECALLED BY Rhone Poulenc Rorer, Collegeville, Pennsylvania, by letter followed by telephone. Firm-initiated recall complete.
DISTRIBUTION Nationwide and international.
QUANTITY 197,835 units were distributed.
REASON Product failed leakage rate test at the 12-month stability testpoint due to faulty stem diaphragm in valve.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Rhone-Poulenc Rorer's (a) Regroton Tablets (Chlorthalidone, 50 mg and Reserpine, 0.25 mg); Demi-Regroton Tablets (Chlorthalidone 25 mg and Reserpine 0.125 mg), used for the management of hypertension.
Recall #D-065/066-7.
CODE

Lot numbers	EXP Date
(a) MN 1399	6/30/00
MN 0845	4/30/99
MN 0653	11/30/98
MN 0489	6/30/98
MN 0179	3/31/97
MN 0178	3/31/97
MN 0084	3/31/97
MN 1611	6/30/97
(b) MN 1286	3/31/00
MN 0654	6/30/98
MN 0490	6/30/98
MN 0249	2/28/97
MN 0082	2/28/97.

MANUFACTURER Rhone Poulenc Rorer Pharmaceutical, Inc.,

RECALLED BY Manati, Puerto Rico.
Rhone Poulenc Rorer Pharmaceuticals, Inc.,
Collegetown, Pennsylvania., by letter,
followed by telephone. Firm-initiated recall
ongoing.
DISTRIBUTION Nationwide.
QUANTITY 192,932 bottles were distributed.
REASON Reserpine is from an unapproved supplier.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Cimetidine Tablets, USP, 800 mg, an oral Rx
drug used in the short-term treatment of
active duodenal ulcers or active benign
gastric ulcers, maintenance therapy for
duodenal ulcer patients at reduced dosage
after healing of active ulcers, erosive
gastroesophageal reflux disease, and the
treatment of pathological hypersecretory
conditions, packaged under the following
labels and package sizes:
i) Novopharm, in 100, 500, and 1000 tablet
bottles;
ii) Warrick Pharmaceuticals, in 100, 500, and
1000 tablet bottles. Recall #D-067-7.
CODE Lot #101981 EXP 7/98 (Note: the lot number has
various suffixes, dependent on the bottle
size).
MANUFACTURER Novopharm Ltd., Scarborough, Ontario, Canada.
RECALLED BY Novopharm USA, Inc., Schaumburg, Illinois, by
letter dated November 22, 1996. Firm-
initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 5,549 bottles of 100 tablets, 519 bottles of
500 tablets and 91 bottles of 1000 tablets
were distributed; firm estimated that very
little, if any product remained on market at
time of recall initiation.
REASON Product fails dissolution at the 3-month
stability timepoint.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Cytovene (Ganciclovir) Capsules, 250 mg, in 180 count bottles, used for management treatment of cytomegalovirus virus. Recall #D-068-7.
CODE Lot #B0088 (packaged lot B0418).
MANUFACTURER Syntex Puerto Rico, Inc., Humacao, Puerto Rico.
RECALLED BY Hoffmann-La Roche, Inc., Nutley, New Jersey, by telephone on July 29, 1996, followed by letter August 1996, and telephone. Firm-initiated recall complete.
DISTRIBUTION Nationwide.
QUANTITY 8,000 bottles were distributed; firm estimates none remains on the market.
REASON Product fails dissolution at the 6-month stability timepoint (64%; SPEC is NLT 70%).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT 0.15% Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP, in 1000 ml infusion bags, used for the prevention or treatment of potassium depletion. Recall #D-069-7.
CODE J6D410 and J6D414 EXP dates 10/98.
MANUFACTURER McGaw, Inc., Irvine, California.
RECALLED BY Manufacturer, by letter dated June 18, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 44,364 units were distributed.
REASON Container label may not bear the following red-boxed information which highlights the concentration of potassium: "20 mEq K+/liter".

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Zestoretic (Lisinopril & Hydrochlorothiazide) 12.5 mg Tablets, used for the management of hypertension. Recall #D-070-7.

CODE 3657W EXP 11/1/97, 3604W EXP 11/1/97, 4135 EXP 5/1/98, 4136W EXP 11/1/98.
MANUFACTURER IPR Pharmaceuticals, Carolina, Puerto Rico.
RECALLED BY Zeneca Pharmaceuticals, Wilmington, Delaware, by letter. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and Puerto Rico.
QUANTITY Firm estimated that 3,200 cases (307,200 blisters) remained on market at time of recall initiation.
REASON The rear blister pack label incorrectly states the hydrochlorothiazide potency as 25 mg. The correct potency of 12.5 mg is also stated in several other spots on the label.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Nitrostat Sublingual Tablets (Nitroglycerin Tablets USP), Rx, indicated for the acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease: (a) 0.4 mg bottles of 25; (b) 0.3 mg bottles of 100. Recall #D-071/072-7.
CODE Lot numbers: 00645F EXP 3/97 (bottles of 25); 10325F EXP 1/97 (bottles of 100).
MANUFACTURER Warner Lambert Company, Fajardo, Puerto Rico.
RECALLED BY Parke-Davis, Division of Warner Lambert Company, Morris Plains, New Jersey, letter dated December 6, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 23,369 bottles of 25 tablets and 22,413 bottles of 100 tablets were distributed.
REASON Lot 00645F failed content assay at the 18-month stability timepoint. Lot 10325F may not meet assay specifications through its shelf-life.

None Present
 Action Taken _____

NSN 6520 Nonstandard
 PRODUCT Extrude Putty Polyvinylsiloxant Dental Impression Material, sold under the following three configurations and part numbers:
 Extrude Putty Refill, Part No.# 18919: Putty packed in cardboard, package Contains:1-Jar Putty Base 280 ml 1-Jar Putty Catalyst 28 ml ***; Extrude Deluxe Introductory Kit, Part No.# 20229: Each kit contains one set of Extrude Putty Refill Part No. 18919. The introductory kit comes in a cardboard box labeled in part: "Extrude KERR Deluxe-Intro Kit ***"; Case Extrude Putty Package, Part No.# 25079: This box contains 12 sets of Extrude Putty Refill Part No. 18919.
 Recall #Z-187-7.

CODE All lot numbers with an expiration date of 9/96 through 7/97. This recall covers any Extrude Putty made within the past twelve months. The lot number and expiration date can be found printed on the bar code label affixed to the outer package.

MANUFACTURER KERR Corporation, Romulus, Michigan.
 RECALLED BY Sybron Dental Specialties, Orange, California (responsible firm), by letter dated July 1, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.
 QUANTITY 16,950 sets were distributed; firm estimated that 1,200 sets remained on market at time of recall initiation.

REASON The device fails to set within the specified time frame.

[] None Present
 [] Action Taken _____

NSN 6550 Nonstandard
 PRODUCT Seprafilm Bioresorbable Membrane, Part #4301-03, indicated for use in patients undergoing abdominal or pelvic laparotomy as an adjunct to reduce incidence of post-operative adhesions. Recall #Z-025-7.

CODE Lot #N5043B.
 MANUFACTURER Genzyme Corporation, Framingham, Massachusetts.

RECALLED BY Genzyme Corporation, Cambridge, Massachusetts,
by letter on August 21, 1996. Firm-initiated
recall complete.
DISTRIBUTION Georgia, Florida, Pennsylvania.
QUANTITY 4 boxes (10 units per box) were distributed.
REASON Product was distributed without approved
labeling for marketing in the United States.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Vitros DT NH3 Slides, for use with Vitros DT
Chemistry Systems to quantitatively measure
ammonia on the Ektachem (Vitros) DT60/DT60II
analyzer. NOTE: The NH3 slides are also used
in conjunction with Ektachem DT slides for
CREATININE where NH3 slides serve only as
a blank. Recall #Z-197-7.

CODE Catalog #153 2589; Lot numbers:
1051-0123-2067; 1051-0123-3756;
1051-0123-5162; 1051-0123-5163;
1051-0124-2065; 1051-0124-3055;
1051-0124-3855; 1051-0167-1911;
1051-0167-3672; 1051-0167-6801;
1051-0167-6802; 1051-0168-1723.

MANUFACTURER Johnson & Johnson Clinical Diagnostics,
Rochester, New York.

RECALLED BY Manufacturer, by letter dated October 15,
1996. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.
QUANTITY 37,092 boxes were distributed; firm estimated
that 4,000 boxes remained on market at time of
recall initiation.

REASON The DT NH3 results were biased up to 40%
higher than the reference method.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Staphytest-OD Latex Staphylococcus Aureus
Test, for in-vitro diagnostic use,
Stock #50050. Recall #Z-196-7.

CODE Lot #103006 EXP 8/31/97.

MANUFACTURER Unipath Limited, Basingstoke, Hants, England.

RECALLED BY Orion Diagnostica, Inc., Somerset, New Jersey,

by telephone from October 18-22, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Illinois, Indiana, Missouri, Maryland, New York, Pennsylvania, Texas, Washington state, Wisconsin.

QUANTITY 48 kits were distributed.

REASON The reagents in the kit are deteriorating, leading to false positive reactions with Staphylococcus epidermidis, ATC 12228 and some auto-agglutination.

None Present
 Action Taken _____

NSN 6550 Nonstandard

PRODUCT Vitros Lipase Slides, for use with Vitros Chemistry Systems to quantitatively measure lipase activity in serum and plasma, for in-vitro diagnostic use. Recall #Z-198-7.

CODE Catalog #1668409, lot numbers: 5919-0082-6895 through 6897.

MANUFACTURER Johnson & Johnson Clinical Diagnostics, Inc., Rochester, New York.

RECALLED BY Manufacturer, by letter dated November 15, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 4,355 cartridges (15 slides each) were distributed; firm estimated that 3,500 cartridges remained on market at time of recall initiation.

REASON Some cartridges within affected lots may contain slides that exhibit significant biases in lipase results.

None Present
 Action Taken _____

TYPE I SUSPENSION:

SUBJ Q.A. MESSAGE 7028-0002
TYPE I SUSPENSION OF MEDICAL MATERIEL
DELIVER IMMEDIATELY TO DIRECTOR OF MEDICAL LOGISTICS
IMMEDIATE ACTION IS REQUIRED TO REMOVE SUSPENDED MATERIEL FROM USING ACTIVITIES (WARDS, PHARMACIES, CLINICS, EMERGENCY ROOMS, ETC.) AND SERVICEABLE INVENTORIES IN MEDICAL LOGISTICS. SEE AFMAN 23-110, VOL 5, CHAP 19, PARA 19.7.3 FOR REQUIRED ACTIONS.

1. A TYPE I MEDICAL MATERIEL COMPLAINT WAS RECEIVED ON THE FOLLOWING MATERIEL:

NSN: 6515-01-337-8987

PRODUCT: BAND, TUBAL LITIGATION, DISP, PLASTIC, STERILE
MANUFACTURER: CIRCON CABOT, LANGHORN, PA

PART NUMBER: 000719-250

LOT NUMBER: 1305004

REASON: A TYPE I COMPLAINT REPORTS REFERENCED BAND BROKE DURING PLACEMENT ON LEFT FALLOPIAN TUBE, CAUSING AN EXPANDING HEMATOMA. THE BLEEDING WAS NOT CONTROLLED WITH APPLICATION OF AN ADDITIONAL FALOPE RING AND REQUIRED EXCISION OF THE LEFT TUBE AND OVARY TO COMPLETELY CONTROL THE BLEEDING. SEVERAL OTHER FALOPE RINGS FROM REF., LOT NUMBER 1305004 HAD SMALL CRACKS IN THEM.

2. PLEASE EXAMINE YOUR INVENTORIES OF THE TUBAL LITIGATION BAND, 6515-01-337-8987, MFG: CIRCON CABOT, LANGHORN, PA, P/N 000719-250, LOT NUMBER 1305004 AND SUSPEND IMMEDIATELY.

3. SUSPENDED QUANTITIES ARE TO BE REPORTED TO DPSC, ATTN: DPSC-MSCBA, J. JOHANSON, DSN 444-7224, COM 215-737-7224, FAX DSN 444-2058, COM 215-737-2058. SUSPENSE DATE IS 30 DAYS (CONUS) AND 45 DAYS (OCONUS) AFTER RECEIPT OF THIS MESSAGE.

4. DISPOSITION AND CREDIT WILL BE COORDINATED WITH THE MANUFACTURER. THERE ARE NO DEPOT STOCKS.

5. THIS INFORMATION WILL BE PUBLISHED IN AFMLL 02-97.

6. POC AT AFMLO/FOM-P IS BONNIE PHILLIS, DSN 343-4170.

7. FOR MAJCOMS & NGB: THIS MESSAGE HAS BEEN TRANSMITTED TO ALL DESIGNATED SUBORDINATE MEDICAL ACTIVITIES IAW AFMAN 23-110, VOL 5, CHAPTER 19.

[] None Present

[] Action Taken _____

FDA PUBLIC HEALTH ADVISORY/SAFETY ALERT:

SUBJ Q. A. MESSAGE 7021-0001

FDA PUBLIC HEALTH ADVISORY/MEDICAL SAFETY ALERT FOR NON-STERILE, POWDER-FREE, CHLORINATED, LATEX PATIENT EXAMINATION GLOVES DELIVER IMMEDIATELY TO THE DIRECTOR OF MEDICAL LOGISTICS.

1. PLEASE BE ADVISED OF THE FOLLOWING FDA PUBLIC HEALTH ADVISORY/SAFETY ALERT:

NSN: 6515NS **ALSO MAY BE LISTED UNDER NUMEROUS STOCK NUMBERS

PRODUCT: GLOVE, LATEX PATIENT EXAM, NON-STERILE, POWDER-FREE, CHLORINATED

MFR: ALL

LOT/SERIAL NO: ALL

2. THE REASON IS THAT THERE ARE CONCERNS OF SPONTANEOUS

COMBUSTION CAUSED BY HIGH TEMPERATURE STORAGE. REQUEST THAT YOU INSPECT YOUR STOCK FOR THIS MATERIEL. IF FOUND FOLLOW DIRECTIONS ON BOX TO STORE GLOVES IN A COOL, DRY PLACE. LARGE QUANTITIES (ONE PALLET OR MORE) OF GLOVES ARE MORE SUSCEPTIBLE TO HAVE CHEMICAL REACTION CAUSING SPONTANEOUS COMBUSTION RESULTING IN A FIRE.

3. THE FDA RECOMMENDS THE FOLLOWING PRECAUTIONS:
 - A. AVOID LARGE INVENTORY OF POWDER-FREE LATEX GLOVES.
 - B. REMOVE SHRINK-WRAP FROM PALLETS OF STACKED CARTONS.
 - C. BREAK THE STACKED CARTONS ON EACH PALLET APART AND RESTACK OR RECONFIGURE CARTON TO FACILITATE COOLING VENTILATION.
 - D. CHECK POWDER-FREE LATEX GLOVES FOR CHARACTERISTICS SUGGESTING DETERIORATION, SUCH AS BRITTLINESS, TACKINESS, OR AN ACRID CHEMICAL ODOR OR STENCH.
 - E. ROTATE YOUR POWDER-FREE LATEX GLOVE STOCK USING "FIRST-IN-FIRST-OUT" PRACTICES.
4. IF GLOVES EXHIBIT ANY CHARACTERISTICS SUGGESTING DETERIORATION, THEY SHOULD NOT BE USED. IT IS DOUBTFUL THEY WILL PROVIDE ADEQUATE PROTECTIVE BARRIER. SHOULD THESE CHARACTERISTICS BE NOTED, OR IF EVIDENCE OF COMBUSTION IS OBSERVED PLEASE DO THE FOLLOWING:
 - A. IMMEDIATELY BREAK APART THE STACKS TO DISSIPATE HEAT
 - B. IDENTIFY GLOVES AS HAZARDOUS AND QUARANTINE OR REMOVE
 - C. CONTACT YOUR DISTRICT FDA OFFICE OR CALL FDA EMERGENCY OPERATIONS AT (301)443-1240 AND/OR CONTACT YOUR BIOENVIRONMENTAL SECTION REGARDING THE PROPER DISPOSITION OF HAZARDOUS MATERIELS.
5. THIS INFORMATION WILL BE PUBLISHED IN AFMLL 2-97.
6. POC AT AFMLO/FOM-P IS BONNIE PHILLIPS, DSN 343-4170.
7. FOR MAJCOMS & NGB: THIS MESSAGE HAS BEEN TRANSMITTED TO ALL DESIGNATED SUBORDINATE MEDICAL ACTIVITIES IAW AFMAN 23-110, VOL 5, CHAPTER 19.
8. THE LAST Q. A. MESSAGE FOR CALENDAR YEAR 1996 WAS 6353-0034.

[] None Present
[] Action Taken _____
