

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:

6515NS

MDC 13215

PRODUCT

CODE

Infusion Pumps

3M Model 3000 Modular Infusion Pump. Recall #Z-147-7.

The serial numbers are arranged in columns below "Adapter Sleeve", "Interlocking Track" or "both." "Adapter Sleeve" means that a problem with the adapter sleeve needs to be corrected and "Interlocking Track" means that a problem with interlocking track needs to be corrected. Devices identified by serial numbers in the first two columns have only one of the two problems and devices with serial numbers in the third column are affected by both problems.

<u>Adapter Sleeve</u>	<u>Interlocking Track</u>	<u>Both</u>
30012897-30012980	30005706-30005755	30013194-30013293
30012894-30012991	30005756-30005767	30013294-30013393
30012966	30005844-30005955	30013394-30013493
30012918-30012993	30006020-30006129	30013494-30013593
30013012-30013089	30005768-30005800	30013595-30013693
30013002-30013093	30005801-30005810	30013609
30013004-30013091	30005811-30005843	30013602-30013672
30012937-30013061	30005956-30005961	30013613
30013023	30005962-30005986	30013623
30002306-30003100	30005987-30006019	30013694-30013717
30013094-30013193	30014619-30014678	30013719-30013723
30015078-30015175	30014714-30014720	30013734-30013748
30015082-30015172	30014679-30014713	30013749-30013848
30015076-30015167	30016130	30013849-30013853
30015095-30015162	30016131-30016151	30013854-30013953
30006472-30006474	30006272-30006291	30013955-30014053
30015276-30015295	30006153-30006268	30014054-30014153
30015296- 30015305	30006292-30006294	30014154-30014253
30006485-30006514	30006156-30006396	30014254-30014453
30015306-30015318		30014454-30014553
30015331-30015410		30014502
		30014504
		30014509
		30014515
		30014528
		30014562-30014603
		30014604-30014608
		30014554-30014602

30014555-30014601
30014721-30014889
30014821-30014825
30014721-30014781
30014876
30014882-30014925
30014876-30014924
30014874-30014920
30014926-30014975
30006397-30006416
310000046-9
30014976-30015054
30014981
30015003
30015047
30006417-30006436
30014918-30015073
30015000
30014977-30015075.

MANUFACTURER 3M Infusion Therapy (was purchased by Graseby Medical), Arden Hills, Minnesota.
RECALLED BY Graseby Medical, Inc., Arden Hills, Minnesota, by letter on October 21, 1996. Firm-initiated field correction ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 1,381 interlocking female tracks and 2,717 activator arms.
REASON The pumps can disconnect from their modular connection systems and can fall to the floor.

None Present
 Action Taken _____

6515NS
MDC 13203
PRODUCT

Pumps, Extracorporeal Perfusion

3M Sarns Perfusion System 8000 Roller Pump Power Supply Cables:
(a) 115 Volt Roller pump, Catalog #16402, Part 98-0702-0647-3;
(b) 220 Volt roller pump, Catalog #16407, Part 98-0702-0648-1.
Recall #Z-150/151-7.

CODE Serial numbers (a) 10002-10086, 10090, 10092-10096, 10098, 10099, 10100, 10110, 6231, 6248, 6251-6253, 6255-6257, 6259, 6260, 6281-6283, 6285-6291, 6296-6302, 6347-6351; (b) Serial numbers 6276-6280, 6303-6305, 6307-6318, 6324-6324-6328, 6334-6338.

MANUFACTURER Undetermined.
RECALLED BY 3M Health Care, Ann Arbor, Michigan, by letter October 29, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 186 units were distributed.
REASON The power supply cable assemblies used may contain an improperly sized resistor which may not achieve maximum specified blood flow.

None Present
 Action Taken _____

6515NS
MDC 14278

Scanners, Ultrasonic

PRODUCT Software used in Diagnostic Ultrasound Systems, Model numbers 5200B, Performa, and 5200S. Recall #Z-164-7.
 CODE All Model 5200B, 5200S and Performa Ultrasound Systems.
 MANUFACTURER Acoustic Imaging, Phoenix, Arizona.
 RECALLED BY Manufacturer, by notification for Model 5200, Model 5200s and Model Performa, sent on June 10, 1996, and by sending corrective software for Model 5200s and Model Performa on July 30, 1996. Firm-initiated field correction ongoing.
 DISTRIBUTION Nationwide and international.
 QUANTITY 635 units of Model 5200B, 672 units of Performa, and 536 units of Model 5200S.
 REASON An error in the software trace function used to measure the circumference of a 2D structure, may under certain circumstance cause perimeter measurements to be inaccurate.

None Present
 Action Taken _____

6515NS
 MDC15592
 PRODUCT Oxygenators
 Centrifugal Battery Pack with Battery Cables and Battery Cable Assembly:
 (a) Catalog # 9490, Part No. 98-0702-0485-8, 110/115 Volt Centrifugal Battery Pack with Battery Cables;
 (b) Catalog #9491, Part No. 98-0702-0486-6, 220/224 Volt Centrifugal Battery Pack with Battery Cables;
 (c) Part No. 78-7066-9180-0, Battery Cable Assembly.
 Recall #Z-170/172-7.
 CODE Includes all units distributed between March 1995 and October 18, 1996.
 MANUFACTURER 3M Health Care, Ann Arbor, Michigan.
 RECALLED BY Manufacturer, by letter on November 8, 1996. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide and international.
 QUANTITY Approximaely 240 cables were distributed.
 REASON The battery cables used with the 3M Sarns Delphin I and II Control modules were incorrectly assembled.

None Present
 Action Taken _____

CLASS III RECALLS:

PRODUCT Software Versions 4.0 and 4.6, Part Nos. 469800, 471005, 471177, 471009, Used in Synctron CX7 and CX3/CX7 Delta Clinical Systems, in-vitro diagnostic analyzer. Recall #Z-163-7.
 CODE No codes. All Synchron CX Quantum IV Version 4.0 and 4.6 software.
 MANUFACTURER Beckman Instruments, Brea, California.
 RECALLED BY Manufacturer, by letter on September 25, 1996. Firm-initiated field correction ongoing.
 DISTRIBUTION Nationwide and international.
 QUANTITY 2,071 units were distributed.
 REASON The device has a software malfunction that can cause false low test results for glucose and BUN.

[] None Present
[] Action Taken _____

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 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 28 FEB 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:

NSN	6505 Nonstandard
PRODUCT	Albumin (Human) 5%. Recall #B-003-7.
CODE	Lot #6.231.026.0 EXP 3-8-99.
MANUFACTURER	Central Laboratory Blood Transfusion Service, Swiss Red Cross, Bern, Switzerland.
RECALLED BY	Alpine Biologics, Inc., Blauvelt, New York, by letters of September 30, 1996, October 1 and 24, 1996. Firm-initiated recall ongoing.
DISTRIBUTION	New York, Pennsylvania, Virginia, Florida, Indiana, South Dakota, Colorado, Washington state, Arizona, California.
QUANTITY	4,468 vials were distributed.

REASON Parke-Davis Fluogen showed a decrease in potency of one component of the vaccine after distribution.
See Q. A. Messages 6353-0034 and 6309-0031.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT UDL brand Albuterol Sulfate Syrup:
(a) Albuterol Sulfate Syrup 1 mg/2.5 mL, Oral Syringe; (b) Albuterol Sulfate Syrup 2 mg/5 mL, Oral Syringe; (c) Albuterol Sulfate Syrup 2 mg/5mL, UD50. Recall #D-048/050-7.
CODE Lot numbers: (a) 506004; (b) 506005; (c) 508023.
MANUFACTURER Nova Laboratories, Caguas, Puerto Rico (responsible firm).
RECALLED BY UDL Laboratories, Inc., Largo, Florida, by letter on October 15, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 355 cases of Lot #508023, 54 cases of Lot #506004 and 47 cases of Lot #506005 were distributed.
REASON Microbial contamination.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Abbott brand Ultane (sevoflurane) Inhalation Anesthetic, Rx halogenated general inhalation anesthetic drug, in 250 ml bottles.
Recall #D-054-7.
CODE Lot #10-590-DK EXP 10/97.
MANUFACTURER Maruishi Pharmaceutical Company, Ltd., Osaka, Japan.
RECALLED BY Abbott Laboratories, Hospital Products Division, Abbott Park, Illinois, by letter dated November 18, 1996, followed by telephone. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.

QUANTITY 7,700 bottles were distributed; firm estimated that 500 bottles remained on market at time of recall initiation.

REASON Product is degrading into hydrogen fluoride and failing pH specification (pH of 1 or below; SPEC is 5.5-6).

[] None Present
[] Action Taken _____

NSN 6515 Nonstandard
PRODUCT Gesco brand Per-Q-Kit catheter kits:
(a) Per-Q-Kit 3 Fr. Single Lumen PICC Insertion Kit with Guidewire Reorder Number 4133107 ;
(b) Per-Q-Kit 4 Fr. Single-Lumen PICC Insertion Kit with Guidewire Reorder Number 4134107. Recall #Z-173/174-6.

CODE Lot Numbers (a) 51EG1023; (b) 51EG1024.
MANUFACTURER Gesco International, Inc., San Antonio, Texas.
RECALLED BY Bard Access Systems, Inc., Salt lake City, Utah, by letter dated November 11, 1996; firm-initiated field correction ongoing.

DISTRIBUTION Nationwide.
QUANTITY 984 kits were distributed.
REASON The expiration date is incorrectly labeled.

[] None Present
[] Action Taken _____

NSN 6515 Nonstandard
PRODUCT Gent-L-Kare Sterile Procedure Trays, sterile, single-use disposable trays packaged with gloves and Tyvek lids:
(a) Urethral Catherization Trays, Catalog nos. 2498, 2499, 2502, 2503;
(b) Foley Catherization Trays, Catalog nos. 2510, 2512, 2513, 2524, 2526;
(c) I.V. Start Kits, Catalog No. 2608, reorder nos. 51-2592, 3108033, 3008050, 3108044, 3108060, 3108031, 3108016, 51-2591;
(d) Tracheostomy Care Trays, Catalog Nos. 4118 (reorder no. RW031), 4120 (reorder nos. 3010028 & 3010037), 4128.
Recall #Z-177/180-7.

CODE All lots beginning with "J", "K", "L" and "M".
MANUFACTURER Sterling Disposable Products, Inc., Chicago,

RECALLED BY Illinois (tray assembler).
Premium Plastics, Inc., Chicago, Illinois
(distributor), by letter dated October 11,
1996, and by telephone on October 16, 17, 23,
24, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
QUANTITY 89,682 cases were distributed; firm estimated
that 3,000 cases remained on market at time of
recall initiation.

REASON Some of the trays may have part of the glove
sealed between the Tyvek lid and the tray,
therefore compromising the package integrity,
resulting in a lack of assurance of sterility.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT VENTAK MINI AICD Automatic Implantable
Cardioverter Defibrillators, Model 1746.
Recall #Z-182-7.

CODE Serial numbers 602154, 602157, and 602164.
MANUFACTURER Guidant Corporation, Cardiac Pacemakers, Inc.,
St. Paul, Minnesota.

RECALLED BY Manufacturer, by telephone on November 21,
1996, and by letter dated November 22, 1996.
Firm-initiated recall complete.

DISTRIBUTION Florida, New Jersey, New York.
QUANTITY 3 units were distributed.

REASON Devices do not have the required medical
adhesive applied in the device's lead
connector block.

None Present
 Action Taken _____

NSN 6540 Nonstandard
PRODUCT Intraocular Lens, AMO Model PS-53ANB.
Recall #Z-181-7.

CODE Serial numbers 9408416245 through 9408416252.
MANUFACTURER Allergan Medical Optics Puerto Rico, Anasco,
Puerto Rico.

RECALLED BY Allergan, Inc., Irvine, California, by fax on
July 30, 1996, followed by letter dated
September 5, 1996. Firm-initiated recall
complete.

QUANTITY 17 lenses from two production lots.

DISTRIBUTION Washington state, Canada, England, Germany.
REASON The 16.0 diopter lenses are labeled as 11.0 diopter lenses which would result in a refractive error if implanted.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Quinine Sulfate Tablets, used for the prophylaxis and treatment of patients with malaria: (a) 200 mg; (b) 260 mg; (c) 325 mg. Recall #D-051/053-7.
CODE USP 260 MG Tablets:
LOT NUMBER: 3001-860V, EXP DATE 01/97
3001-861V, EXP DATE 01/97
3001-862V, EXP DATE 01/97
USP 200MG & 325 MG Tablets:
LOT NUMBER: 2184-055162V, EXP DATE 12/96
2184-065122V, EXP DATE 02/97
2359-761, EXP DATE 10/97.
MANUFACTURER Zenith laboratories Caribe, Inc., Cidra, Puerto Rico.
RECALLED BY Manufacturer, by letter September 1996. Firm-initiated recall complete.
DISTRIBUTION Nationwide.
QUANTITY 260 mg -- 9,251 bottles of 100, 1,092 bottles of; 200 mg -- 4,651 bottles of 100, 1,092 bottles of 500; 325 mg -- 5,241 bottles of 100 and 600 bottles of 1,000 were distributed.
REASON Product fails USP purity test (more than 2% of Cinchonidine Sulfate).

None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Coly-Mycin S Otic with Neomycin and Hydrocortisone (Colistin Sulfate-Neomycin Sulfate-Thonzonium Bromide-Hydrocortisone Acetate Otic Suspension, Sterile), Rx drug intended for use in the treatment of superficial bacterial infections of the external auditory canal and for the treatment of infections of mastoidectomy and fenestration cavities caused by organisms susceptible to the antibiotics.
 Recall #D-056-7.

CODE Lot 02885P (10mL vials) EXP 12/96, and lot 028D5P (5mL vials) EXP 4/97.

MANUFACTURER Warner-Lambert Company, Parke-Davis Sterile Products Division, Rochester, Michigan.

RECALLED BY The Parke-Davis Division of Warner-Lambert Co. Morris Plains, New Jersey, by letter dated October 31, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 31,392 vials of lot 02885P were distributed between September 1995 and December 1995. 60,108 vials of lot 028D5P were distributed between January 1996 and June 1996. At the time of the recall, there was no remaining inventory at the distribution centers.

REASON Product fails potency for hydrocortisone acetate (stability samples stored at 30 degrees C inverted, assayed as high as 133%).

[] None Present
 [] Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Prednisone Tablets, USP, 10 mg, in bottles of 1000, Rx corticosteroid, under the Schein label.
 Recall #D-057-7.

CODE Lot #CBA114 EXP 11/30/96.

MANUFACTURER Danbury Pharmacal, Inc., Carmel, New York.

RECALLED BY Danbury Pharmacal, Inc., Brewster, New York, by letter dated November 6, 1996. Firm-initiated recall complete.

DISTRIBUTION Nationwide.

QUANTITY 4,871 bottles were distributed; firm estimated that little product remained on market at time of recall initiation.

REASON Product failed content assay on stability at 22 months (114%; limit is 110%).

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Cefotan (Cefotetan Disodium), 1 gm/10 ml vial, sterile injectable antibiotic.
Recall #D-058-7.

CODE Lot #3256W EXP 2/98.

MANUFACTURER Smith Kline Beecham, Conshohocken, Pennsylvania (responsible firm).

RECALLED BY Zeneca Pharmaceuticals, Inc., Wilmington, Delaware, by letter dated November 20, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY Firm estimated that 150,000 vials remained on market at time of recall initiation.

REASON Product fails moisture specification at the six month stability timepoint (1.65%; limit is 1.5%).

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Guaifenesin/Codeine Phosphate Cough Syrup, 100 mg/10 mg per 5 ml; an OTC schedule V narcotic expectorant cough suppressant: (a) Regular Formula, Product Code 8023, packaged in 4 ounce and 1 pint bottles, labeled under the following labels:
i) MGP Mytussin AC Cough Syrup, Manufactured by: Morton Grove Pharmaceuticals, Inc., Morton Grove, Illinois
ii) GG Glydeine Cough Syrup, Distributed by Geneva Pharmaceuticals, Inc., Broomfield, Colorado
iii) Robafen AC Cough Syrup, Distributed by Major Pharmaceuticals, Inc., Chicago, Illinois

(b) Sugar Free Formula, Product Code 8045, packaged in 1 pint and 1 gallon bottles, labeled under the following labels:
 i) MGP Mytussin AC Cough Syrup, Sugar Free, Manufactured by: Morton Grove Pharmaceuticals, Inc., Morton Grove, Illinois
 ii) GG Glydeine Cough Syrup, Sugar Free, Distributed by Geneva Pharmaceuticals, Inc., Broomfield, Colorado
 iii) Robafen AC Cough Syrup, Sugar Free, Distributed by Major Pharmaceuticals, Inc., Chicago, Illinois. Recall #D-059/060-7.
 Lot 20547, EXP 07/31/97 and 20643, EXP 10/31/97.

MANUFACTURER Morton Grove Pharmaceuticals, Inc., Morton Grove, Illinois.

RECALLED BY Manufacturer, by letters dated November 20 and 21, 1996. Firm-initiated recall ongoing.

DISTRIBUTION QUANTITY Nationwide.
 1,741 - 40 oz. and 5,615 pints of regular formula and 12,596 pints and 296 gallons of sugar free formula were distributed, firm estimated that 25% of the product remained on the market at time of recall initiation.

REASON Potency of codeine phosphate cannot be assured through the expiration date due to content assay failures of routine stability samples (87%; SPEC is 90-110%).

None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Amantadine Hydrochloride Capsules, USP, 100 mg, in bottles of 100 and 500, Rx indicated in the treatment of idiopathic Parkinson's disease. Recall #D-055-7.
 CODE Lot #824959.
 MANUFACTURER Chase Laboratories, Newark, New Jersey (responsible firm).
 RECALLED BY Banner Pharmacaps, High Point, North Carolina, by letters on or about October 21, 1996. Firm-initiated recall complete.
 DISTRIBUTION Nationwide.

QUANTITY 5,584 bottles were distributed.
REASON Product fails dissolution at 9 month stability
timepoint.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Intertech/SIMS single use resuscitator (Adult)
With Mask, Filter, and One-Way Valve, Catalog
No. 008010, a portable, single patient use,
mouth-to-mouth device for treatment of adult
victims suffering from respiratory failure.
Recall #Z-167-7.

CODE Lot Numbers 6H0257 and 6H0258.
MANUFACTURER Sims Medical System (also known as Intertech)
Fort Myers, Florida.

RECALLED BY Manufacturer, by letter on October 29, 1996.
Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.
QUANTITY 283 cases (10 units per case) were
distributed.

REASON Resuscitators may be assembled with the flex
tube on the patient end of the valve housing
which makes the device inoperable.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT 3M Sarns Disposable Centrifugal Pumps,
indicated for use as an extracorporeal blood
pump: (a) Part No. 98-0702-0266-2, Delphin
7850 Centrifugal Pump Heads 8 Pack;
(b) Part No. 98-0702-1027-7, Delphin 7850
Disposable Pump Bulk Pkg.
Recall #Z-168/169-7.

CODE (a) Catalog # 164275, Lot Numbers: W347844,
W347845, W346707, W347211, W346708, W347209,
W347210; (b) Lot Number: W346816.

MANUFACTURER 3M Health Care, Ann Arbor, Michigan.

RECALLED BY Manufacturer, by telephone, fax, and letter on
November 8, 1996. Firm-initiated recall
ongoing.

DISTRIBUTION Nationwide and international.
QUANTITY Approximately 6,500 pumps.

REASON Products may contain plastic particulate

levels that exceed the firm's particulate specification.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Centrifugal Battery Pack with Battery Cables and Battery Cable Assembly:
(a) Catalog # 9490, Part No. 98-0702-0485-8, 110/115 Volt Centrifugal Battery Pack with Battery Cables;
(b) Catalog #9491, Part No. 98-0702-0486-6, 220/224 Volt Centrifugal Battery Pack with Battery Cables;
(c) Part No. 78-7066-9180-0, Battery Cable Assembly. Recall #Z-170/172-7.
CODE Includes all units distributed between March 1995 and October 18, 1996.
MANUFACTURER 3M Health Care, Ann Arbor, Michigan.
RECALLED BY Manufacturer, by letter on November 8, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY Approximately 240 cables were distributed.
REASON The battery cables used with the 3M Sarns Delphin I and II Control modules were incorrectly assembled.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Valves for oxygen cylinders tapped to accept CGA 870 valves in cartons labeled with either "ATI U.S.A." or "ATI MADE IN POLAND."
Recall #Z-175-7.
CODE All ATI OXM CGA 870 Valves Unless They are also Stamped with "Laing International" on the Body of the Valve.
MANUFACTURER Mr. Andrew Niemczyk, also known as Armo Trading, Troy, Michigan (importer).

RECALLED BY Laing International, Ft. Lauderdale, Florida,
by letter on July 1, 1996. Firm-initiated
recall ongoing.
DISTRIBUTION Michigan, Florida.
QUANTITY 47,050 valves were distributed.
REASON The valves may break off with little or no
external force with the potential of causing
serious patient or health professional injury.

[] None Present
[] Action Taken _____

NSN 6515 Nonstandard
PRODUCT Storz Tanne Disposable Trepine Blades:
(a) E3050[Size]NS - Tanne Disposable Trepine
Blades - Sizes: 6.ONS, 6.25NS, 6.5NS, 6.75NS,
7.ONS, 7.25NS, 7.5NS, 7.75NS, 8.ONS, 8.25NS,
8.5NS, 8.75NS, 9.ONS, 9.25NS, 9.5NS;
(b) E3096[Size]NS - Disposable Trepine Blades
- Sizes: 6.OLNS, 6.25LNS, 6.5LNS, 6.75LNS,
7.0LNS, 7.25LNS, 7.5LNS, 7.75LNS, 8.OLNS,
8.25LNS, 8.5LNS, 8.75LNS, 9.OLNS, 9.25LNS,
9.5LNS. Recall #Z-165/166-7.
CODE All lot numbers except those beginning with
"CW".
MANUFACTURER Storz Instrument Company, Manchester, Missouri
(blades).
RECALLED BY Storz Instrument Company, St. Louis, Missouri,
by letter dated October 11, 1996. Firm-
initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 8,712 blades were distributed.
REASON Some of the packages may contain trephine
blades of the wrong size or style.

[] None Present
[] Action Taken _____

NSN 6550 Nonstandard
PRODUCT Immulite brand Progesterone Kits, a diagnostic
device test kit:
(a) Catalog No. LKPG1, 100 Test Kit
(b) Catalog No. LKPG5, 500 Test Kit.
Recall #Z-157/158-7.

CODE Lot Numbers: (a) 131, 132, 133;
(b) 131, 132, 133.
MANUFACTURER Diagnostic Products Corporation, Los Angeles,
California.
RECALLED BY Manufacturer, through publication of technical
bulletin #1083 for domestic customers and
#2098 for international customers, followed by
letters. Firm-initiated recall complete.
DISTRIBUTION Nationwide and international.
QUANTITY 1,999 kits were sold; firm estimates none
remains on the market.
REASON The device had a low bias on patient samples,
and was found to be unstable after 30 days of
the 6 month labeled expiration date.

[] None Present
[] Action Taken _____

NSN 6550 Nonstandard
PRODUCT Diamedix Corp. brand of Anti-RNP Microassay,
Catalog No. 783-270, Catalog No. 783-270, for
in-vitro diagnostic use, 96 Test Set.
Recall #Z-159-7.

CODE Lot No. 31126, EXP Dec 96.
MANUFACTURER Diamedix Corporation, Miami, Florida.
RECALLED BY Manufacturer, by letter on August 5, 1996.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 166 kits were distributed.
REASON The test results for the positive control are
above the assigned control range.

[] None Present
[] Action Taken _____

NSN 6550 Nonstandard
PRODUCT Liquid Sodium Bicarbonate-Chloride Concentrate
for Hemodialysis Item No. OLB-1-01, Not For
Parenteral Use Non pyrogenic 1 US Gal./ 4 Gal.
per case, labeled as distributed by Fresenius
USA Walnut Creek, California, Manufactured
for: BDH Inc. Toronto, Canada.
Recall #Z-176-7.

CODE Lot numbers: 6046, 6052, 6057, 6050, 6051,
6067, 6073, 6074, 6080, 6079, 6079A, 6081,
6099, 6100, 6101, 6102, 6086, 6087, 6107,
6108, 6108A, 6109, 6131, 6134, 6135, 6137,
6121, 6138, 6150, 6151, 6152, 6144, 6156,
6162, 6163, 6169, 6170, 6171, 6177, 6178,
6184. These lots have EXP dates ranging from
8/24/96 to 1/3/97.

MANUFACTURER EM Science a Division of EM Industries, Inc.,
Gibbstown, New Jersey.

RECALLED BY Manufacturer, by telephone and letter on
August 22, 23, 1996. Firm-initiated recall
ongoing.

DISTRIBUTION Nationwide.

QUANTITY 47,928 cases were distributed.

REASON The device is contaminated with
microbiological growth.

None Present
 Action Taken _____
