

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-P, Capt Paul J. Toth, DSN 343-7445)**

CLASS I RECALLS: None.

CLASS II RECALLS:

6515 NS

MDC 14360

PRODUCT

CODE

MANUFACTURER

RECALLED BY

DISTRIBUTION

QUANTITY

REASON

Venturi Ventilators Part #1572. Recall #Z-505-0.
Ventilators manufactured and distributed between June 24, 1997 and February 23, 2000.

Cardiopulmonary Corporation, Milford, Connecticut.
Manufacturer, by fax/overnight mail between March 8-9, 2000.
Firm-initiated field correction ongoing.

Connecticut, Florida, New Jersey, North Carolina, South Carolina, Italy, United Kingdom, Saudi Arabia, France, Mexico.

109 units.

During extended use of the humidifier and the airway heater, the breathing bag may become soft and pliable. This condition when combined with high-pressure settings may allow the breathing bag to intermittently impede expiratory flow and lead to an interruption in exhalation and higher than expected airway pressures.

None Present

Action Taken _____

6525 NS

MDC 15966, 13469, M0001, MMMPA

PRODUCT

CODE

MANUFACTURER

RECALLED BY

DISTRIBUTION

QUANTITY

REASON

MINICAP XP Workstations, using Baseline 8.5 software, for Computed Tomography SPECT studies with gamma cameras.
Recall #Z-515-0.

All Marconi MINICAP XP workstations using the Baseline 8.5 software.

Marconi Medical Systems, Inc., Highland Heights, Ohio.
Manufacturer, by letter dated February 28, 2000.

Firm-initiated recall ongoing.

Nationwide and international.

131 units were distributed.

During 360 degree SPECT, the resulting image will appear flipped left to right.

None Present

Action Taken _____

6515 NS
MDC 12047
PRODUCT

Heat Condenser Humidifier, Catalog No. 1571.
Recall #Z-517-0.

CODE

Lot Numbers: 2-44910, 2-45910, 4-47910, 1-48910, 3-44910, 3-45910,
5-47910, 1-49910, 2-50910, 4-51910, 2-52910,3-49910, 3-50910, 3-52910,
4-49910, 6-49910.

MANUFACTURER
RECALLED BY

Hudson Respiratory Care, Inc., Temecula, California.
Manufacturer, by letter on January 10 and 11, 2000.
Firm-initiated recall ongoing.

DISTRIBUTION

Arkansas, Arizona, California, Colorado, Florida, Georgia, Hawaii,
Illinois, Indiana, Kansas, Kentucky, Louisiana, Maryland, Michigan,
Minnesota, Mississippi, Montana, North Carolina, New Mexico, Nevada,
New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, Tennessee,
Texas, Utah, Virginia, Washington, Wisconsin, West Virginia, Canada,
Japan, Thailand.

QUANTITY
REASON

70,405 units were distributed.
The product contains a chemical odor that could compromise a patient
during the device's initial use.

None Present
 Action Taken _____

6515 NS
MDC 12911, 18495
PRODUCT

Pacesetter Trilogy Pulse Generator, indicated for the treatment of
bradycardia:

- a) Trilogy(tm) SR 2250L Pulse Generator;
 - b) Trilogy(r)SR+ 2260L Pulse Generator;
 - c) Trilogy(r) SR+ 2264L Pulse Generator;
 - d) Trilogy(tm) DC 2308L Pulse Generator;
 - e) Trilogy(r) DC+ 2318L Pulse Generator;
 - f) Trilogy(tm) DR 2350L Pulse Generator;
 - g) Trilogy(tm) DR+ 2360L Pulse Generator;
 - h) Trilogy(tm) DR+ 2364L Pulse Generator.
- Recall #Z-536/543-0.

CODE

2250 ALL SERIAL NOS
2260 ALL SERIAL NOS. EXCEPT 184500 THRU 223346
2264 ALL SERIAL NOS. EXCEPT 182800 THRU 196114
2308 ALL SERIAL NOS.
2318 ALL SERIAL NOS. EXCEPT 184500 THRU 202821
2350 ALL SERIAL NOS.
2360 ALL SERIAL NOS. EXCEPT 194956 THRU 200821
2364 ALL SERIAL NOS. EXCEPT 212662 THRU 213771; 214271
THRU 215421; 216422 THRU 217346;
217847 THRU 218946;
219222 THRU 219721; AND, 219947 THRU 220545 AND
50000-159000.

MANUFACTURER
RECALLED BY

St. Jude Medical, Cardiac Rhythm Management Division, Sylmar, California.
Manufacturer, by letter on July 19, 1999. Firm-initiated recall ongoing.

QUANTITY Approximately 163,000 affected pulse generators have been implanted since their introduction to commerce in 1995. the firm states that there are about 3200 affected devices in field inventories.

REASON The devices may exhibit premature battery depletion caused by a current leakage path that could be created during the laser welding process to attach the battery to the device hybrid.

None Present
 Action Taken _____

**6515 NS
MDC 12911, 18495
PRODUCT**

Pacesetter Affinity Dual Chamber Pulse Generators, also known as cardiac pacemaker:
a) Model No. 5130L; b) Model No. 5130R;
c) Model No. 5230R; d) Model No. 5330R;
e) Model No. 5330L. Recall #Z-544/548-0.

CODE
Affected products all have a "use before" date of December 2000. They were produced in June 1999.

MANUFACTURER St. Jude, Inc., Cardiac Rhythm Management Division, Sylmar, California.
RECALLED BY Manufacturer, by notification material distributed on February 11, 2000.
Firm-initiated recall ongoing.

DISTRIBUTION Nationwide, Canada, Sweden.

QUANTITY 850 were implanted
41 have been explanted
plus 18 non-implanted units were returned.

REASON Decreased reliability has been observed in a limited, very specific, and well-defined group of Affinity pulse generators. Testing has revealed that conductive material used to secure a resistor to the hybrid circuitry may not provide continuous and proper electrical connection to the underlying circuitry. This resistor is used to measure the battery operating current of the pulse generator and is reported to the clinician through the programmer. The battery itself is not affected.

None Present
 Action Taken _____

**6515 NS
MDC 13203
PRODUCT**

Sarns 8K Safety Monitor and 9K Perfusion System, indicated for use in extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures:
a) 8000 Perfusion System Safety Monitor,
Part No. 98-0702-06606;
b) Reconditioned 8K Safety Monitor,
Part No. 78-8067-7278-2;
c) Trial 8K Safety Monitor, Part No. 78-8067-6878-0;
d) Loaner 8K Safety Monitor, Part No. 78-8067-6053-0;
e) 9000 Perfusion System 110V, Part No. 98-0702-0270-4;
f) 9000 Perfusion System 220V, Part No. 98-0702-0269-6;
g) 9000 Perfusion System 100V, Part No. 98-0702-0268-8;

h) Reconditioned 9K Perfusion System,
 Part No. 78-8066-6922-8;
 i) Trial 9K Perfusion System, Part No. 78-8066-8934-1.
 Recall #Z-552/560-0.
 See above.
 Terumo Cardiovascular Systems Corporation, Ann Arbor, Michigan.
 Manufacturer, by mail or E-mail starting on February 16, 2000, followed by
 telephone and fax. Firm-initiated recall ongoing.
 Nationwide and international.
 1,688 units were distributed.
 The level sensor system malfunctions. The malfunctions have been related to
 false alarms when there was an adequate fluid level in the reservoir and
 failure to alarm when the blood level fell below the position of the sensor.

None Present
 Action Taken _____

CLASS III RECALLS:

6525 NS
MDC 15944
 PRODUCT

Series II Compact Video Imager Multi Format Camera; used with
 gamma cameras, nuclear, C-Arm, and digital radiography.
 Recall #Z-509-0.

CODE
 MANUFACTURER
 RECALLED BY

Model MP4600-2A-X, serial numbers 3162B, 3163B, 3164B.
 International Imaging Electronics, Bolingbrook, Illinois.
 Manufacturer, by telephone followed by letter on March 9, 2000.
 Firm-initiated recall ongoing.

DISTRIBUTION
 QUANTITY
 REASON

California.
 3 units were distributed.
 The video imagers had been shipped without final testing
 and final inspection.

None Present
 Action Taken _____

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 **23 JUN 00** for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DSCP purchase order number, contract number, and stock record account number (SRAN). (FOM-P), **Bonnie Phillips DSN (343-4170)**

CLASS I RECALLS:

NSN	6550 Nonstandard
PRODUCT	ProCide NS Reusable Activated Dialdehyde Sterilizing and Disinfecting Solution, in 2.5-gallon, 1-gallon and 1-quart units, a re-usable activated dialdehyde sterilizing and disinfecting solution. Recall #Z-283-0.
CODE	All lots. Expiration dates range from September 2000 through December 2001.
MANUFACTURER	Metrex Research Corporation, Parker, Colorado.
RECALLED BY	Sybron Dental Specialties, Inc., Orange, California, by letter dated March 17, 2000. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	2,057 cases (1-quart size), 143,409 (1-gallon size), and 356 cases (2.5-gallon size) were distributed.
REASON	Failure of the product to achieve sterilization or high level disinfection may result in patients being exposed to the risk of infection.

None Present
 Action Taken _____

CLASS II RECALLS

NSN	6505 Nonstandard
PRODUCT	Human Tissue for Transplant: Various Musculoskeletal Tissues, Skin, and Blood Vessels. Recall #B-541-0.
CODE	Each graft is uniquely identified with a nine or ten digit graft number.
MANUFACTURER	LifeNet, Virginia Beach, Virginia.
RECALLED BY	Manufacturer, by letter dated January 24, 2000. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide, Canada, Puerto Rico, Israel.
QUANTITY	1,434 allografts.

REASON Various tissues for transplant were collected from twenty donors who had not been properly evaluated.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Platelets, Pheresis, Leukocytes Reduced. Recall #B-571-0.
CODE Unit Numbers: 24204-3038-01 and 24204-3038-02.
MANUFACTURER Blood Systems, Inc., Rapid City, South Dakota.
RECALLED BY Blood Systems, Inc., Scottsdale, Arizona, by telephone on August 4, 1999,
and by letter dated August 16, 1999.
DISTRIBUTION Nevada.
QUANTITY 2 units were distributed.
REASON Blood products had unacceptable platelet counts.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT First Aid kits containing recalled Clinipad products:
a) Blister Kit containing, in part, 5 sterile alcohol prep pads
b) Pocket First Aid Kit containing, in part, 4 sterile alcohol prep pads
c) Weekend Warrior First Aid Kit containing, in part, 3 sterile alcohol prep pads
d) Cramer Personal First Aid Kit containing, in part, 6 sterile alcohol prep pads
e) Retail First Aid Kit containing, in part, 15 sterile alcohol prep pads. Recall #Z-507-0.
CODE a) Blister Kit - No lot number
b) Pocket First Aid Kit - LKE169, LKK391
c) Weekend Warrior First Aid Kit - LKK400
d) Cramer Personal First Aid Kit - LKB061, LKC111, LKD112 LKG250, LKH308, LKK397
e) Retail First Aid Kit - LKC102, LKE160, LKF180, LKI313, LKK382.
MANUFACTURER Cramer Products, Inc., Gardner, Kansas.
RECALLED BY Manufacturer, by letter dated March 15, 2000, advising all consignees to remove and destroy the Clinipad Alcohol Prep Pads. Firm-initiated recall ongoing.
Component Manufacturer
Clinipad Corporation, Charlotte, North Carolina.
DISTRIBUTION Nationwide.
QUANTITY a) Blister Kits - 1,152; b) Pocket First Aid Kits - 1,217;
c) Weekend Warrior First Aid Kits - 100; d) Cramer Personal First Aid Kits - 5,315; e) Retail First Aid Kits - 4,444.

REASON First aid kits contain Clinipad Alcohol Prep Pads labeled as sterile for which Clinipad is unable to assure the sterility.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Sterile Procedure Kits/Trays containing recalled Clinipad products. Recall #Z-518-0.
CODE i) Central Line Tray, catalog #470, lots 668, 669
ii) Dressing Change Tray, catalog #478, lots 668, 669
iii) Subclavian Dressing Change Tray, catalog #755, lot 669
iv) Hyperal Tray, catalog #580A, lots 667, 669
v) Cambridge Marketing I.V. Start Kit, catalog # SW4000, lot 667
vi) Subclavian Tray, catalog #359, lot 663
MANUFACTURER Sterling Medical-Products International, Inc., Prophetstown, Illinois.
RECALLED BY Manufacturer, by letter on March 30, 2000, requesting all accounts and sub-accounts to destroy the Clinipad products. Firm-initiated recall ongoing.
COMPONENT MFR Clinipad Corporation, Rocky Hill, Connecticut.
DISTRIBUTION Illinois, South Carolina, Tennessee.
QUANTITY 2,280 kits.
REASON The kits and trays contain Clinipad products labeled as sterile for which Clinipad is unable to assure sterility.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Medline Sterile Procedure Kits/Trays containing recalled Clinipad Products. Recall Z-519-0.
CODE Kit Catalog # Kit Description
DMCHLDCT0 Central Line Dressing Change Tray
DMGTPN01 TPN Tray
DMHHCLDCT0 Central Line Dressing Change Tray
DMHVPICCC01 Fill Dressing Tray
DYNDC1001 Central Line Dressing Change Tray
DYNDC1002 Dressing Change Tray
DYNDC1003 Central Line Dressing Tray
DYNDC1005 Dressing Change Tray
DYNDC1007 Dressing Change Tray
DYNDC1009 Central Line Dressing Change Tray
DYNDM1002 TPN Tray
DYND74560 Central Line Dressing Change Tray
DYND74561 Dressing Change Tray - Tegaderm
DYND74562 Dressing Change Tray - Sureste
DYND74565 Central Line Dressing Change Tray
DYND74566 Dressing Change Tray - Tegaderm
DYND30210 Midstream w/Funnel/PVP, 4oz Cup

DYND30226	Midstream w/PVP, 4oz ECO
DYNJ07141C	Subclavian Tray
DYND12110	Cath Care Tray
DYND20100	Sterile Irrigation Tray
DYND20105	Sterile Bulb Irrigation Tray
DYND20300	Sterile Irrigation Tray
DYND20305	Irrigation Tray
DYND70900	Suture Removal Tray
DYND71030	Suture Removal Tray
DYND74000	IV Start Kit
DYND74003	IV Start Kit
DYND74015	IV Start Kit
DYND74053	IV Start Kit
DYND74081	IV Start Kit
DYND74100	Subclavian On Pack
DYND74101	Subclavian Off Pack
DYND74102	Fistula Pack
DYND74226G	On/Off Kit
DYND74601	Blood Withdrawal Tray
DYNJC2047D	Port Starter Kit
DYNJC2741	HYP Subclavian Dressing Tray
DYNJC2777	Dressing Removal Tray
DYNJ04000A	IV Start Kit Flexigrid
DYNJ04001	IV Start Kit
DYNJ04014C	IV Start Kit
DYNJ04060	Skin Staple Removal Kit
DYNJ04060	Skin Staple Removal Kit
DYNJ04081	IV Start Kit
DYNJ04156	IV Start Kit
DYNJ04205A	IV Start Kit
DYNJ04208A	IV Start Kit
DYND04216	On/Off Tray
DYNJ04242A	Suture Removal Tray
DYNJ04244	IV Start Kit
DYNJ05611	IV Start Kit
DYNJ05712B	IV Start Kit
DYNJ05877A	IV Start Kit
DYNJ07147	Incision & Drainage Tray
DYNJ07179A	Suture Removal Kit
DYNJ07267B	Subclavian Dressing Tray
DYNJ07293	Wound Closure
DYNJ07450	Dialysis Tray
DYNJ15384	Suture Removal Tray
MDS701550	Suture Removal Tray
MDS706551	Suture Removal Tray
MDS70815	Incision & Drainage Tray
MDS708550	Suture Removal Tray

Note 1: Home Care kits will be the same part numbers as listed above except there is an "H" suffix.

Note 2: Single packs will be the same part numbers as listed above except there is a "Z" suffix.

MANUFACTURER
RECALLED BY

Medline Industries, Inc., Mundelein, Illinois.
Manufacturer, by letter dated March 16, 2000, requesting accounts not to use and destroy the Clinipad products when using the kits. The firm's sales representatives are to visit each account and attach to individual kits an orange

COMPONENT MFR
DISTRIBUTION
QUANTITY
REASON

sticker stating "RECALL DO Not Use The Clinipad Product Within This Kit Destroy The Clinipad Product". Firm-initiated recall ongoing.
Clinipad Corporation, Rocky Hill, Connecticut.
Nationwide.
Approximately 230,000 kits.
Kits and trays contain Clinipad products labeled as sterile for which Clinipad is unable to assure sterility.

None Present
 Action Taken _____

NSN
PRODUCT

6515 Nonstandard
Sterile Catheter Irrigation Trays and Wound Dressing Trays;
20 trays per case containing recalled Clinipad Products:
a) Visiting Health Professionals Catheter Irrigation Tray, Premium Custom Concepts, a Division of Premium Plastics, Inc., Chicago, IL 60616; reorder #3022016
b) Unicare Deluxe Facial Wound Closure Instrument Pack, reorder #2663
c) Unicare Wound Closure Tray, reorder #2665
Recall #Z-520-0.

CODE

a)Lots PE0038 and PG0063; b) Lot RF0020;
c) Lots RF0025 and SH2156.

MANUFACTURER
RECALLED BY

Premium Plastics, Inc., Chicago, Illinois.
Manufacturer, by telephone on March 29, 2000, instructing the accounts to destroy the remaining entire kits for credit.
Firm-initiated recall ongoing.

COMPONENT MFR
DISTRIBUTION
QUANTITY
REASON

Clinipad Corporation, Rocky Hill, Connecticut.
North Carolina and Puerto Rico.
5,820 trays.
Kits and trays contain Clinipad products labeled as sterile for which Clinipad is unable to assure sterility.

None Present
 Action Taken _____

NSN
PRODUCT

6515 Nonstandard
On/Off dialysis kits containing recalled Clinipad products as follows:
a) MPC-595; b) MPC-590; c) MPC-685. Recall #Z-521-0.

MANUFACTURER
RECALLED BY

CODE
a) MPC-595 - Lot #804917, 900975, 902649, 6L786, and 916129
b) MPC-590 - Lot #97G10B, 802258, 817819, 910665, VA0625, and AK982
c) MPC-685 - Lot #712084, 716073, 805046, 900984, and 914327
Molded Products, Harlan, Iowa.
Manufacturer, by telephone on March 20, 2000, followed by letter dated March 21, 2000, requesting accounts to destroy any recalled Clinipad product in the kits.
Firm-initiated recall ongoing.

COMPONENT MFR
DISTRIBUTION

Clinipad Corporation, Rocky Hill, Connecticut.
Wisconsin and California.

QUANTITY

MPC-590 - 6,550 kits; MPC-595 - 3,650 kits; and MPC-685 - 41,450 kits.

REASON

Kits contain Clinipad products labeled as sterile for which Clinipad is unable to assure the sterility.

[] None Present

[] Action Taken _____

NSN

6515 Nonstandard

PRODUCT

Medical PEG kits containing recalled Clinipad products: Surgitek Surgi-PEG, Initial Placement Gastrostomy Tray - Pullwire System 15FR, Cat #110115; Surgitek Surgi-PEG, Initial Placement Gastrostomy Tray - Pullwire System 20FR, Cat #1101120; Surgitek Surgi-PEG, Initial Placement Gastrostomy Tray - Pullwire System 24FR, Cat #1101124; Surgitek Surgi-PEG, Initial Placement Gastrostomy Tray - Guidewire System 15FR, Cat #1101215; Surgitek Surgi-PEG, Initial Placement Gastrostomy Tray - Guidewire System 20FR, Cat #1102120; Surgitek Surgi-PEG, Initial Placement Gastrostomy Tray - Guidewire System 24FR, Cat #1102124; Surgitek S.O.S., One-Step Button with Percutaneous Stoma Measuring Device - Guidewire Method 24FR 1.7cm, Cat #4018170; Surgitek S.O.S., One-Step Button with Percutaneous Stoma Measuring Device - Guidewire Method 24FR 2.4cm, Cat #4018240; Surgitek S.O.S., One-Step Button with Percutaneous Stoma Measuring Device - Guidewire Method 24FR 3.4cm, Cat #4018340; Surgitek S.O.S., One-Step Button with Percutaneous Stoma Measuring Device - Guidewire Method 24FR 4.4cm, Cat #4018440; Surgitek S.O.S., One-Step Button with Percutaneous Stoma Measuring Device - Guidewire Method 18FR 1.2cm, Cat #4118120; Surgitek S.O.S., One-Step Button with Percutaneous Stoma Measuring Device - Guidewire Method 18FR 1.7cm, Cat #4118170; Surgitek S.O.S., One-Step Button with Percutaneous Stoma Measuring Device - Guidewire Method 18FR 2.4cm, Cat #4118240; Surgitek S.O.S., One-Step Button with Percutaneous Stoma Measuring Device - Guidewire Method 18FR 3.4cm, Cat #4118340; Surgitek S.O.S., One-Step Button with Percutaneous Stoma Measuring Device - Guidewire Method 18FR 4.4cm, Cat #4118440; Percutaneous Stoma Measuring Device - Guidewire, Cat #PSMD-GW; Percutaneous Stoma Measuring Device - Pullwire, Cat #PSMD-PW.
Recall #Z-526-0.

CODE

A total of 68 lot numbers are as follows:
97070353, 97070713, 97070714, 97070863, 97090709, 97070066, 97080305, 97080615, 97100463, 97100464, 97070581, 97080616, 97100471, 97040072, 97080304, 97100010, 97040511, 97040536, 97040787, 97050435, 97090008, 97100229, 97100472, 97110609, 97080303, 97110045, 97080589, 97090043, 97100486, 97070704, 97080069, 97080285, 97080597, 97090021, 97090882, 97100489, 97100631, 97050675, 97050901, 97070566, 97070702, 97080068, 97080289, 97080587, 97080592, 97080863, 97090041, 97090459, 97080288, 97080595, 97090039, 97090458, 97090702, 97100642, 97110603, 97080287, 97080596, 97090681, 97070570, 97080286, 97090683, 97090700, 97090457, 97090460, 97100112, 97100788, 97100804, and 97100787.

MANUFACTURER

Applied Medical Technology, Inc., Cleveland, Ohio.

RECALLED BY

Manufacturer, by letter on March 29, 2000, requesting that all accounts to remove and destroy the Clinipad products in the kits and to attached a warning sticker labeled, "WARNING: When this PEG kit is opened, please remove and destroy the enclosed Clinipad component", on any remaining kits in inventory. Firm-initiated recall ongoing.

COMPONENT MFR
DISTRIBUTION
QUANTITY
REASON

Clinipad Corporation, Rocky Hill, Connecticut.
Wisconsin.
1,982 kits were distributed.
Kits contain Clinipad products labeled as sterile, for which Clinipad cannot assure the sterility.

None Present
 Action Taken _____

NSN
PRODUCT

6515 Nonstandard
Custom Procedure Ready Trays containing recalled Clinipad Products:
1) Part No. 16-01029, Custom Angio Card Cath Pack
2) Part No. 16-02130, Custom Adult Cardiac Cath Tray
3) Part No. 16-02355, Custom Cardiac Cath Lab Pack
4) Part No. 16-02451, Custom Angio Card Cath Pack
5) Part No. 18-02510, Custom Biopsy Tray
Recall #Z-527-0.

CODE

1) Lots MFG5994, MFG5955, MFG6086, MFG6098
2) Lots MFG5921, MFG6157
3) Lot MFG5978
4) Lot MFG6051
5) Lots MFG5848, MFG5917, MFG5927, MFG5937.

MANUFACTURER
RECALLED BY

Medical Techniques, In., North Salt Lake, Utah.
Manufacturer, by telephone and mail on March 17, 2000, instructing all accounts and sub-accounts to remove and destroy the Clinipad product inside the kits before using the kits. Replacement product was being sent for use in each kit. Firm-initiated recall ongoing.

COMPONENT MFR
DISTRIBUTION
QUANTITY
REASON

Clinipad Corporation, Rocky Hill, Connecticut.
New Jersey, Texas, Saudi Arabia.
450 trays were distributed.
The trays contained Clinipad products that lacked assurance of sterility.

None Present
 Action Taken _____

NSN
PRODUCT

6515 Nonstandard
First Aid Kits containing Clinipad Product:
Model Numbers:
11000 12318 12600 12702 12703 12704 12988
12989 13300 13126 14302 14303 25001 26000
30500 33000 38000 40001 50000 51019 60002
60003. Recall #Z-528-0.

CODE

Lot Numbers: 299135, 299139, 299162, 299329, 299385, 299077, 299143, 299075, 298693, 299131, 299176, 299177, 299382, 299249, 299275, 299092, 299258, 299271, 299136, 299188, 299213, 299116, 299186, 299187, 299289,

299261, 299286, 298685, 299091, 299130, 299178, 299191, 299248, 299278, 299292, 299193, 299129, 299179, 299220, 299268, 299041, 299104, 299148, 299321, 299064, 299194, 299203, 299244, 299282, 298702, 299114, 299245, 299269, 299190, 299256, 299352, 298650, 298683, 298698, 298710, 299034, 299105, 299158, 299209, 299274, 298668, 299093, 299227, 299285, 299293, 299100, 299113, 299257, 299279, 299294, AND 299322.

MANUFACTURER RECALLED BY Acme United Corp., Fremont, North Carolina.
Acme United Corporation, Fairfield, Connecticut, by letter dated March 30, 2000, requesting all accounts and sub-accounts to call the firm's toll free hotline for instructions. Firm-initiated recall ongoing.

COMPONENT MFR DISTRIBUTION QUANTITY Clinipad Corporation, Charlotte, North Carolina.
Nationwide.
2,228,697 products were repackaged into kits of 22 different configurations (models).

REASON The kits contain Clinipad Alcohol Prep which have been recalled by the Clinipad Corporation for possible microbiological contamination.

None Present
 Action Taken _____

NSN PRODUCT 6515 Nonstandard
Puritan-Bennett Reusable Coupling Temperature Probe, component of the Reusable Volume Ventilator Circuits:

- a) Reusable Coupling Temperature Probe (Coupler), Catalog No. 4-007897-00;
- b) Patient Tubing Circuit with Nebulizer, Catalog No. 4-018062-00;
- c) Simplified Circuit with Vial, Catalog No. 4-018744-00;
- d) Simplified Circuit without Collector Vial and Adapter, Catalog No. 4-020740-00;
- e) Simplified Circuit with Traps, Catalog No. 4-015254-00;
- f) Simplified Circuit with Nebulizer, Catalog No. 4-018052-00;
- g) Simplified Patient Circuit, Catalog No. 4-018011-00;
- h) Patient Tubing Circuit - Conventional, Catalog No. 4-019348-00;
 - i) Simplified Patient Circuit, Catalog No. 4-007170-00;
 - ii) Simplified Circuit w/o Vial, Catalog No. 4-018743-00.

Recall #Z-561/569-0.

CODE All product with lot numbers K00902 or lower, and all lots with a numeric lot number only (no letter "K" prefix).

MANUFACTURER RECALLED BY Avenida Reforma S/N, Local A-3, Tijuana B.C., Mexico.
Puritan Bennett Corporation, a subsidiary of Mallinckrodt, Inc., Carlsbad, California, by letter dated February 11, 2000. Firm-initiated recall ongoing.

DISTRIBUTION QUANTITY Nationwide and international.
4,381 couplers domestically, and 8,170 couplers internationally were distributed.

REASON The flashing in the area of the temperature probe port was not removed.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Percutaneous Catheter Introducer Kits containing recalled Clinipad products.
Recall #Z-572-0.
CODE Abbott Kits:
Part #KIT-015-00 Lots F53699 and F40968
Part #KIT-016-00 Lot F40958
Becton Dickinson Kits:
Part #KIT-012-00 Lot F52529
Part #KIT-009-01 Lot F51169
Part #KIT-010-00 Lot F51209
Part #KIT-012-01 Lot F52539
Part #KIT-009-00 Lot F51159.
MANUFACTURER Thomas Medical Products, Inc., Malvern, Pennsylvania.
RECALLED BY Manufacturer, by letter dated March 15, 2000. Firm-initiated recall
ongoing. End users were instructed to remove and destroy the Clinipad
products included in the kits.
COMPONENT MFR Clinipad Corporation, Charlotte, North Carolina.
DISTRIBUTION California and Utah
QUANTITY 3,090 kits.
REASON Kits contain Clinipad products labeled as sterile for which Clinipad is
unable to assure the sterility.

 None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Trinity IV Start Kits containing recalled Clinipad Products. Recall
#Z-574-0.
CODE Item #1067-01-03-R1, Lot Numbers: 99236, 99247, 99248.
MANUFACTURER Trinity Laboratories, Inc., Salisbury, Maryland.
RECALLED BY Manufacturer, by telephone on March 16, 2000. Firm-initiated recall
ongoing.
COMPONENT MFR Clinipad Corporation, Rocky Hill, Connecticut.
DISTRIBUTION New York.
QUANTITY 432 cases (50 pads per case) were distributed.
REASON Kits contain Clinipad products labeled as sterile for which Clinipad is
unable to assure the sterility.

 None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT IMMUNOCARD MYCOPLASMA, an ELISA diagnostic test kit for detection
of IgM to Mycoplasma pneumoniae in human serum.
Recall #Z-485-0.
CODE Catalog #709030, Lot Numbers: 709030.091 through 709030.094;
and 709030.097 through 709030.102.
MANUFACTURER Meridian Diagnostics, Inc., Cincinnati, Ohio.
RECALLED BY Manufacturer, by letter dated March 13, 2000.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 3,694 units were distributed.

REASON Test results and control results exhibit a high level of variability.

None Present
 Action Taken _____

CLASS III RECALLS

NSN 6505 Nonstandard
PRODUCT Capture-R Ready-Screen (Pooled Cells) - 96 Wells containing Polled Screening Cells; Capture-R Ready-Screen (I and II) 48 Wells containing Screening Cell I and 48 Wells containing screening Cell II; and Capture-R Ready-ID for the identification of unexpected IgG Antibodies to Red Cells. Recall #B-548-0.
CODE Kit Lot Numbers 43895, 43896, 43897, 43898, 43902, 43893, 43899.
MANUFACTURER Immucor, Inc., Norcross, Georgia.
RECALLED BY Manufacturer, by telephone on November 5, 1999, and by E-mail. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 1,624 kits were distributed.
REASON When certain lots of the Capture-R Ready plates are read using an automated reading device, a high rate of equivocal or positive test reactions were obtained.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Circon Surgitek Double J Silicone Ureteral Stents, Part Numbers 5202100 and 5202600, can be used to provide drainage from the kidneys to the bladder, and stenting of the ureter without external catheters. Recall #Z-516-0.
CODE Product number 5202100, lots 631289H and 631299H
MANUFACTURER Product number 5202600, lot 633359H.
RECALLED BY Circon Surgitek, Racine, Wisconsin.
DISTRIBUTION Manufacturer, by letter dated March 10, 2000. Firm-initiated recall ongoing.
QUANTITY Nationwide, Austria, Canada, France, Ireland, The Netherlands.
REASON 360 stents.
Inner diameters of stents are too small to allow passage of guidewires.

None Present
 Action Taken _____

NSN 6515 Nonstandard
UPDATES ALYCON Sample Syringe, 50uL, List #05D49-02, recalled by Abbott Laboratories, Inc., Diagnostics Division, Irving, Texas, which appeared in the April 12, 2000 Enforcement Report should read Recall #Z-534-0.
Roche Reagent for AST, Catalog #42381, recalled by Roche Diagnostics Corp., Indianapolis, Indiana, which appeared in the April 12, 2000 Enforcement

Report should read
Recall #Z-535-0.

None Present
 Action Taken _____

NSN 6540 Nonstandard
PRODUCT CSI Daily Wear Clear Contact Lenses. Recall #Z-508-0.
CODE Sub lot # 700022570404
Master lot #60300195.
MANUFACTURER Wesley Jessen Corporation, Cidra, Puerto Rico.
RECALLED BY Manufacturer, by letter dated March 13, 2000.
Firm-initiated recall ongoing.
DISTRIBUTION California, Illinois, Maryland, Massachusetts, Michigan,
Minnesota, Missouri, North Carolina, Virginia.
QUANTITY 27 lenses were distributed.
REASON Mislabeled for corrective power. The label indicates sphere
power of +8.00. The lenses are actually -20.00.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT AXSYM Total B-HCG, for in vitro diagnostic use.
CODE Recall #Z-484-0.
List no.9C21-10,
Lot # 57210Q100, EXP date 4/5/00
Lot # 59236Q100, EXP date 6/1/00.
MANUFACTURER Abbott Health Products, Inc., Barceltoneta, Puerto Rico.
RECALLED BY Manufacturer, by letter dated February 28, 2000.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 5,412 units were distributed.
REASON Control values are greater than the package insert ranges.

None Present
 Action Taken _____
