

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 13215, 17634**  
 PRODUCT

**Infusion Pumps, Multi-Channel**

Abbott Plum XL Series Infusion Pumps, single and triple line infusion pumps utilizing I.V. administration set cassettes. Recall #Z-821/826-0.  
 All serial numbers manufactured prior to 12/1/99 of the following list numbers. 11555-04, Plum XL Infusion Pump 11781-04, Plum XL3 Multi-Line Infusion Pump, 11845-04, Plum XL3 Micro/Macro Multi-Line Infusion Pump, 11846-04, Plum XL Micro/Macro Infusion Pump, 11855-04, Plum XL3 Micro/Macro Multi-Line Infusion Pump, w/Dataport, 11859-04, Plum XL Micro/Macro Infusion Pump w/Dataport. Abbott Laboratories, Morgan Hills, California.  
 Abbott Laboratories, Hospital Products Division, Abbott Park, Illinois, by Technical Service Bulletins dated February 2000, and by letter dated May 26, 2000. Firm-initiated recall ongoing.  
 Nationwide.  
 81,159 pumps were distributed.  
 Increased number of cassette alarms.

CODE

MANUFACTURER  
 RECALLED BY

DISTRIBUTION  
 QUANTITY  
 REASON

None Present  
 Action Taken \_\_\_\_\_  
 \_\_\_\_\_

**6515 NS**  
**MDC 13215, 17634**  
 UPDATE

**Infusion Pumps, Multi-Channel**

Abbott Plum XL Series Infusion Pumps, single and triple line infusion pumps utilizing I.V. administration set cassettes, Recall #Z-821/826-0, which appeared in the July 5, 2000 Enforcement should read: Firm-initiated field correction.

None Present  
 Action Taken \_\_\_\_\_  
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**6515 NS**  
**MDC 13987**  
 PRODUCT

**Physiologic Monitoring Systems, Telemetric**

Version 6A and prior versions of software for Marquette Coherent Digital Telemetry (CDT) LAN Monitoring Systems, a patient monitoring system designed to collect and transmit ECG and other physiological data from ambulatory patients, without the patient being physically connected to a display device. Recall #Z-774-0.

CODE

All versions of the software used with CDT LAN Monitoring Systems.

MANUFACTURER  
RECALLED BY

GE Marquette Medical Systems, Inc., Milwaukee, Wisconsin.  
Manufacturer, by issuing an Urgent Patient Alarm Safety Alert  
dated May 3, 2000. Firm-initiated field correction ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide and international.  
2,254 units were distributed.  
Due to a software defect, there could be alarm failure.

None Present  
 Action Taken \_\_\_\_\_

**6525 NS**  
**MDC 18179**  
PRODUCT

**Stereotactic Systems, Neurosurgical Frameless**  
Sterostatic Neurosurgery Planning System, SteroPlan 2.0 and SteroPlan  
2.1. Recall #Z-858-0.

CODE  
MANUFACTURER  
RECALLED BY

Catalog No. STERO-SW-2.  
Radionics, Burlington, Massachusetts.  
Manufacturer, by telephone on May 30, 2000. Firm-initiated recall  
ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide and international.  
44 units were distributed.  
position errors up to 2.5 mm may be observed if the user removes a slice  
from a CT or MRI image after the image has been fused and a fusion matrix  
has been generated.

None Present  
 Action Taken \_\_\_\_\_

**6525 NS**  
**MDC 18179, MMMPA, M001**  
PRODUCT

**Stereotactic System**  
Fixer Image Scan Editing Utility, Version 3.0, intended to allow  
the user to remove suprious image slices from a scan.  
Recall #Z-784-0.

CODE  
MANUFACTURER  
RECALLED BY

Fixer Software Utility Version 3.0  
Radionics, Inc., Burlington, Massachusetts.  
Manufacturer, by telephone on March 9, 2000, followed by letter.  
Firm-initiated field correction ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide and international.  
33 installed bases.  
Fixer 3.0 may provide inconsistent results if a file is changed  
and saved twice in the same session.

None Present  
 Action Taken \_\_\_\_\_

**6530 NS**  
**MDC 12330**  
PRODUCT

**Lift, Patient**  
Sarita and Sarita 160 Patient Lift, Non-AC Powered Lift/Transfer  
System used to transfer patients/residents between beds,  
chairs and toilets: a) Model KKA0400;  
b) KKA0420-16; c) KKA0401; d) KKB3000-11US; e) KKB3020-16US.

CODE Recall #Z-785/789-0.  
 All serial numbers prior to 4899 834795-011  
 Model KKB3000-11US - Sarita; Model KKB3020-16US - Sarita 160.  
 MANUFACTURER Arjo, Inc., Roselle, Illinois.  
 RECALLED BY Manufacturer, by letter dated May 11 and 30, 2000.  
 DISTRIBUTION Firm-initiated field correction ongoing.  
 QUANTITY Nationwide.  
 REASON 967 units were distributed.  
 Premature cracking of foot support platform of the lift.

None Present  
 Action Taken \_\_\_\_\_  
 \_\_\_\_\_

**6530 NS  
 MDC 12330  
 PRODUCT**

**Lift, Patient**

Maxilift Patient Lift, Non-AC powered, used to move patients  
 in a nursing home situation. Recall #Z-790-0.  
 CODE All serial numbers preceding week 1/95, with serial number  
 prefixes preceding US0195, SE0195, GB0195, and include serial  
 numbers beginning with 93MM, 93ME, 94MM and 94ME.  
 Model 211026, Maxilift Manual Chassis with Scale  
 Model 212624, Maxilift Manual Chassis - Beige  
 Model 210024-06, Maxi Scale Std - Beige  
 Model 212000-06, Maxi Pillar Beige  
 Model KMB0810-06US, Maxilift Combi  
 Model KMB0830-06US, Maxilift Combi with Scale  
 Model KMB2351, Maxilift Electric with Scale  
 Model MA0500, Maxi Pillar  
 Model MA0510, Maxi Mast for Electric Chassis  
 Model MB0500, Maxilift Beige  
 Model MB0510, Maxilift with Battery Powered Chassis  
 Model MB0600, Maxilift with Scale - Beige  
 Model MB0610, Maxilift Battery Powered with Scale.  
 MANUFACTURER Arjo, Inc., Roselle, Illinois.  
 RECALLED BY Manufacturer, by letters dated May 11 and 30, 2000.  
 DISTRIBUTION Firm-initiated field correction ongoing.  
 QUANTITY Nationwide.  
 REASON 1,017 units were distributed.  
 Spring (roll) pin subject to shear in Maxilifts greater  
 than 5 years old.

None Present  
 Action Taken \_\_\_\_\_  
 \_\_\_\_\_

**6530 NS  
 MDC 12330  
 PRODUCT**

**Lift, Patient**

Maximove Patient Lift, Non-AC powered, used to move patients  
 in a nursing home situation: Models KRA0300, MA0510, KMA1004,  
 KMB0810-06, KMB0830-06, KMB4500-12US, KMB6950-12US, KMB6970-  
 12US,  
 KMB6980-12US. Recall #Z-791/799-0.

CODE Maximove models KRA0300 (mast Model), KMB4500-12US, KMB6950-12US, KMB6970-12US, KMB6980-12US, serial numbers GB 2097 784578 001 through GB 0899 819426 006; weeks 20/97 through 08/99  
 Model KMB4500-12US - Maximove with powered V chassis  
 Model KMB6950-12US - Maximove with powered parallel chassis & scale  
 Model KMB6970-12US - Maximove with powered parallel chassis  
 Model KMB6980-12US - Maximove with powered V chassis & scale  
 Maximove Combi models KRA0300 (Mast model) and KMA1004, serial numbers start with GB or SE; weeks 03/96 through 05/99  
 Model KMA1004 - Maximove Combi Lift Arm Assembly  
 Maxilift Combi models MA0510 (Mast Model), KMB0810-06, KMB0830-06, serial numbers GB 0596 770428 003 through GB 3496 773176 010; weeks 05/96 through 34/96  
 Model KMB0810-06US, Maxilift Combi  
 Model KMB0830-06US, Maxilift Combi with Scale.

MANUFACTURER Arjo Inc., Roselle, Illinois.  
 RECALLED BY Manufacturer, by letters dated may 11 and 30, 2000.  
 Firm-initiated field correction ongoing.

DISTRIBUTION Nationwide.  
 QUANTITY 1,465 units were distributed.  
 REASON Over depression of the locking spring pin results in the lift arm not locking.

None Present  
 Action Taken \_\_\_\_\_

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**6530 NS**  
**MDC 12330**  
**PRODUCT**

**Lift, Patient**  
 Marisa Patient Lift, Non-AC Powered, used to move weak or highly dependent patients in a nursing home situation: a) Model KGB2000-US, Marisa Complete with Jib, but no Scale; b) Model KGB2100-US, Marisa Complete with Jib and with Scale ; c) Model KGA0200. Recall #Z-800/802-0. All serial numbers below GB 3298 807390 002.

CODE Arjo, Inc., Roselle, Illinois.  
 MANUFACTURER Manufacturer, by letters dated May 11 and 30, 2000. Firm-initiated field  
 RECALLED BY correction ongoing.  
 DISTRIBUTION Nationwide.  
 QUANTITY 1,331 lifts were distributed.  
 REASON Jib assembly plunger may not fully engage in the carriage receptacle.

None Present  
 Action Taken \_\_\_\_\_

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**6530 NS**  
**MDC Various**  
**PRODUCT**

**Carts**  
 Medical Graphics Cart, Part #800192, used for diagnostic equipment for checking a patient's pulmonary function, ECG, and other factors. Recall #Z-828-0. Carts with "99" stamped in their bases with 8 dots arranged in a circle around the 99 are affected.

CODE Medical Graphics Corporation, St. Paul, Minnesota.  
 MANUFACTURER Manufacturer, by product bulletin dated May 25, 2000. Firm-initiated field  
 RECALLED BY correction ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide and international.  
46 carts were distributed.  
Base of cart could crack allowing caster to come off and cart to topple over.

None Present  
 Action Taken \_\_\_\_\_

**6630 NS**  
**MDC**  
**PRODUCT**

**Coagulation Analyzers**

SYSMEX CA-1000 and SYSMEX CA-5000 Automated Coagulation Analyzer, used to the clotting times of heparinized patients to adjust their heparin treatment. Recall #Z-754/755-0.

CODE  
MANUFACTURER  
RECALLED BY

All serial numbers.  
Sysmex Corporation of America, Long Grove, Illinois.  
Manufacturer, by letter dated April 26, 2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide and international.  
1,405 CA-1000 analyzers and 132 CA-5000 analyzers were distributed.  
Incorrect aPTT (activated partial thromboplastin time) analysis of patient Samples which contain elevated levels of fibrinogen or fibrinogen-related products which are not measured by aPTT (fibrinogen monomer) could occur.

None Present  
 Action Taken \_\_\_\_\_

**6630 NS**  
**MDC 15552**  
**UPDATE**

**Colgulation Analyzers**

Several recalls which appeared in the June 28, 2000 Enforcement Report incorrectly listed the manufacturer and recalling firm as the same. The following are the correct manufacturers and recalling firms for the noted recalls:

Z-754/755-0 - SYSMEX CA-100 and SYSMEX CA-500 Automated Coagulation Analyzer

Manufacturer: Sysmex Corp., Kobe, Japan

Recalling Firm: Sysmex Corporation of America, Long Grove, IL

Z-785/789-0 - Sarita and Sarita 160 Patient Lift;

Z-790-0 - Maxilift Patient Lift;

Z-791/799-0 - Maximove Patient Lift;

Z-800/802-0 -Marisa Patient Lift

Manufacturer: Arjo Ltd., Glouster, UK

Recalling Firm: Arjo, Inc., Roselle, IL.

None Present  
 Action Taken \_\_\_\_\_

**6640 NS**  
**MDC 17740**  
**PRODUCT**

**Hematology Analyzer**

Bayer Advia 120 Automated Hematology System, Model 120, a quantitative automated hematology analyzer that provides a leukocyte, differential count and reticulocyte analysis for in vitro diagnostic use in clinical laboratories.

CODE  
MANUFACTURER  
RECALLED BY

Recall #Z-810-0.  
All serial numbers.  
Bayer Diagnostics Mfg. Ltd., Swords, Co. Dublin, Ireland.  
Bayer Corporation, Elkhart, Indiana, by letter dated May 2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide and international.  
1,800 units were distributed.  
Higher than expected percentage Reticulocyte counts were received, due to carryover from one sample to another.

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 **06 OCT 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	<b>6505 Nonstandard</b>
PRODUCT	Tricana(tm) Capsules, 1 mg, in units of 90, Rx for the treatment of obesity and reducing the problem areas of fat. Recall #D-433-0.
CODE	All lot codes.
MANUFACTURER	Thermo-Life International, San Carlos, California.
RECALLED BY	Manufacturer, by letter on April 6, 2000. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	33,203 bottles were distributed.
REASON	Unapproved new drug.

[ ] None Present  
 [ ] Action Taken \_\_\_\_\_

NSN	<b>6515 Nonstandard</b>
PRODUCT	Various kits/trays containing containing products recalled by Clinipad Corporation: Peripherally Inserted Central Catheter; MLC SLI Peripherally Inserted Central; PAT 100 Port Access Tray; CISK B. Braun IV Start Kits; CGKM Guidewire Introducer Set; CESKSD Continuous Epidural Anesthesia Tray; Spinocan Spinal Needle; Braun Percutaneous Introducer Set; Burrton Microcath Intra. Cath. Placement; Runyon Large Volume Parcentesis Kit; Double Ended Vented Transfer Device; Dressing Change Tray; Dressing Change Kits. Recall #Z-691-0.
CODE	(Note: If necessary, A complete list of devices, catalog and lot numbers can be obtained from the Philadelphia District Office Recall Coordinator).
MANUFACTURER	B. Braun Medical, Inc., Allentown, Pennsylvania.
RECALLED BY	Manufacturer, by letter on March 23, 2000, instructing the consignees to remove and destroy the Clinipad components in the kit/trays. Firm-initiated recall ongoing.

COMPONENT MFR  
DISTRIBUTION  
QUANTITY  
REASON

Clinipad Corporation, Charlotte, North Carolina.  
Nationwide.  
921,000 units.  
The products contain Clinipad products labeled as sterile for which Clinipad is unable to assure sterility and/or contain Clinipad products not labeled as sterile for which the company has no assurance that they meet microbiological release specifications.

None Present  
 Action Taken \_\_\_\_\_

**CLASS II RECALLS:**

NSN  
PRODUCT  
CODE  
MANUFACTURER  
RECALLED BY  
DISTRIBUTION  
QUANTITY  
REASON

**6505 Nonstandard**  
Sorbic Acid Preserved Saline Solution, in 16-ounce bottles, under the following labels: Fedco, Equate, London Drugs and Life. Recall #Z-849-0.  
Lot Numbers 8J101, EXP 10/00; 9C091, EXP 3/01.  
Optopics Laboratories Corporation, Fairton, New Jersey.  
Manufacturer, by letter on April 14, 2000. Firm-initiated recall ongoing.  
To direct wholesale accounts.  
10,500 bottles of Lot #8J101; 10,728 bottles of Lot #9C091 were distributed.  
Lack of sterility assurance of Sorbic Acid Preserved saline.

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT  
CODE  
MANUFACTURER  
RECALLED BY  
DISTRIBUTION  
QUANTITY

**6505 Nonstandard**  
a) UriTAB(tm) Caplets (Phenazopyridine HCL 95 mg), 30 caplet box, OTC, for urinary pain relief; b) PremeTAB(tm) Tablets (Acetaminophen 500 mg, Pamabrom 25mg, Pyrilamine Maleate 15 mg) 15 tablet units, OTC, for use I n premenstrual discomfort;  
c) PrevenTAC(tm) Caplets (Aspirin 81 mg), 30 caplets, OTC, to help in the prevention of heart disease and heart attacks;  
d) SomaTAC(tm) Caplets (Diphenhydramine Hydrochloride 50 mg), 15 caplets, OTC, helps relieve occasional sleeplessness due to stress, anxiety, restlessness, and irritability. Recall #D-413/416-0.  
a) Lot #J15460; b) Lot #J15466; c) Lot #J16148;  
d) Lot #J15548.  
Formulex Canada, Inc., Villemont-Royal, Quebec, Canada (contract manufacturer).  
Olus Laboratories, Farmingdale, New York (responsible firm), by fax on February 21, 2000, and by telephone on March 22, 2000. Firm-initiated recall ongoing.  
a) Connecticut, New Jersey, Oregon; b) Connecticut, New Jersey, New York, Oregon;  
c) Connecticut, Florida, Georgia, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Texas; d) Connecticut, New Jersey, Oregon.  
a) 77 cases, 24 blister packs of 30 caplets each per case; b) 89 cases, 24 blister packs of 15 tablets each per case; c) 593 cases, 24 blister packs of 30 caplets each per case; d) 97 cases, 24 blister packs of

REASON 15 caplets each per case were distributed.  
Products are unapproved new drugs.

None Present  
 Action Taken \_\_\_\_\_

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**NSN** **6505 Nonstandard**  
**PRODUCT** Glyburide Tablets, USP, (micronized), 6 mg, in 100-tablet bottles, Rx indicated as an adjunct to diet to lower the blood glucose in patients with non-insulin-dependent diabetes mellitus (type II) whose hyperglycemia cannot be satisfactorily controlled alone. NDC #55370-506-07. Recall #D-421-0.

**CODE** Lot #ST2343A EXP 9/00.  
**MANUFACTURER** MOVA Pharmaceuticals Corporation, Caguas, Puerto Rico.  
**RECALLED BY** Manufacturer, by letter on June 12, 2000. Firm-initiated recall ongoing.  
**DISTRIBUTION** Nationwide.  
**QUANTITY** 8,407 bottles were distributed.  
**REASON** Blend uniformity failure.

None Present  
 Action Taken \_\_\_\_\_

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**NSN** **6505 Nonstandard**  
**PRODUCT** Meperidine HCl Injection, USP, 75 mg/mL, 1 mL fill in 2 mL tubex(r), Rx. Recall #D-431-0.

**CODE** Lot #2001276 EXP 1/02.  
**MANUFACTURER** Wyeth Ayerst Laboratories, West Chester, Pennsylvania.  
**RECALLED BY** Manufacturer, by telephone on or about June 12, 2000. Firm-initiated recall ongoing.  
**DISTRIBUTION** Tennessee.  
**QUANTITY** 343,124 units were distributed.  
**REASON** Lack of assurance of sterility.

None Present  
 Action Taken \_\_\_\_\_

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**NSN** **6515 Nonstandard**  
**PRODUCT** The Becton Dickinson (Bard Parker) ABG Kits, containing recalled Clinipad products. Recall #Z-819-0.

**CODE** Catalog Numbers 305089, 375280, 305306, 375310, 375315, 375320, 375325, 305326, 305342, 375381, 375385, 375392, 375395, 375410, 375420, 305421.  
(A complete list of devices, catalog and lot numbers can be obtained from the New Jersey District Office Recall Coordinator).

**MANUFACTURER** Becton Dickinson & Company, Franklin Lakes, New Jersey.  
**RECALLED BY** Manufacturer, by recall communications dated April 17, 2000. Firm-initiated recall ongoing.

**COMPONENT MFR** Clinipad Corporation, Rocky Hill, Connecticut.  
**DISTRIBUTION** Nationwide.  
**QUANTITY** 956,850 kits were distributed.  
**REASON** Kits contain Clinipad products labeled as sterile for which Clinipad is unable

to assure the sterility.

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6515 Nonstandard**

Kits/Trays containing recalled Clinipad products, 86 different Cook catalog order numbers. (Note: If necessary, a complete list of devices, catalog and lot numbers can be obtained from the Detroit District Office Recall Coordinator). Recall #Z-829-0.

CODE

All catalog order numbers containing one of the following five prefixes: J-CHSGY, J-MHSGY, J-SBHS, J-TCY, AND J-DANY.

MANUFACTURER  
RECALLED BY

Cook Urological, Spencer, Indiana.  
Manufacturer, by letter on March 17, 2000. Firm-initiated recall ongoing.

COMPONENT MFR  
DISTRIBUTION

Clinipad Corporation, Rocky Hill, Connecticut.  
Nationwide and international.

QUANTITY

13,812 kits.

REASON

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

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6515 Nonstandard**

Sterile Procedural Trays/Kits packaged by Orion Medical Products, Wheeling, IL; the trays are packaged in cases of 10, 20, or 30 trays each under the Orion, Managed Care, Rusch, Lifenet, ProMed, Grace, Manheim, Starline, and Intermed labels. Recall #Z-820-0.

CODE

All Orion kit lot numbers shipped since 1/1/97 of the listed reorder numbers.

MANUFACTURER  
RECALLED BY

Orion Life Systems, Inc., Wheeling, Illinois.

COMPONENT MFR  
DISTRIBUTION

Manufacturer, by letter dated March 22, 2000. Firm-initiated recall ongoing.  
Clinipad Corporation, Rocky Hill, Connecticut.  
Nationwide.

QUANTITY

70,000 cases were distributed.

REASON

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**

Bard/Vas-Cath, Modified Vas-Cath Catheter Repair Kit, Catalog Number 5586000. Recall #Z-841-0.

CODE

Lot Numbers 22AK1493, 22AK1495, 22LJX028.

MANUFACTURER  
RECALLED BY

Bard Access Systems, Inc., Salt Lake City, Utah.

DISTRIBUTION

Manufacturer, by letters mailed April 4-5, 2000. Firm-initiated recall ongoing.

QUANTITY

1,008 units were distributed.

REASON

Catheter repair kit connector may detach from repaired catheter extension legs.

None Present  
 Action Taken \_\_\_\_\_

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**NSN** **6515 Nonstandard**  
**PRODUCT** a) VA Medical Center, Seattle Cardiac Pack; b) Lawrence Memorial Hospital  
Pericardiocentesis Pack. Recall #Z-846/847-0.  
**CODE** Lot Numbers M0899291, M0999201.  
**MANUFACTURER** Cordis Corporation, Miami, Florida (component manufacturer/responsible firm).  
**RECALLED BY** Maxxim Medical, Inc., (formerly Cordis Medical Products), Asheville, North  
Carolina, by telephone on May 5, 2000 and April 27, 2000. Firm-initiated recall  
ongoing.  
**DISTRIBUTION** Washington state, Kansas.  
**QUANTITY** a) 27 kits; b) 5 packs were distributed.  
**REASON** Kits/packs contain catheters recalled by Cordis Corporation for possible  
unexpected fibers.

None Present  
 Action Taken \_\_\_\_\_

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**NSN** **6515 Nonstandard**  
**PRODUCT** T-9 Scoop Transtracheal Procedure Tray. Recall #Z-743-0.  
**CODE** Lot Numbers: 0339, 1409, 2749.  
**MANUFACTURER** Transtracheal Systems, Englewood, Colorado.  
**RECALLED BY** Manufacturer, by mail on June 9, 2000, followed by telephone.  
Firm-initiated recall ongoing.  
**COMPONENT MFR** Clinipad Corporation, Rocky Hill, Connecticut.  
**DISTRIBUTION** Nationwide and international.  
**QUANTITY** 643 trays.  
**REASON** Trays contain Clinipad products labeled as sterile for which Clinipad  
is unable to assure the sterility.

None Present  
 Action Taken \_\_\_\_\_

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**NSN** **6515 Nonstandard**  
**PRODUCT** Alcohol Prep Antiseptic Pad in Lovenox(r) ContinuCare(tm) Program AT HOME  
KITS. (NDC for Clinipad Alcohol Prep is 19154-1254-3). Recall #D-430-0.  
**CODE** All lot numbers.  
**MANUFACTURER** Aventis Pharmaceutical Products, Collegeville, Pennsylvania.  
**RECALLED BY** Manufacturer, by letter dated April 21, 2000, stating that if the  
individual preferred to keep the kits they need to remove and destroy the  
Clinipad Alcohol Preps. Firm-initiated recall ongoing.  
**COMPONENT MFR** Clinipad Corporation, Rocky Hill, Connecticut.  
**DISTRIBUTION** Canada, Brazil, France, United Kingdom, Puerto Rico.  
**QUANTITY** Firm estimated that 300 kits remained on market at time of recall  
initiation.  
**REASON** Lack of assurance of sterility for the Clinipad Corporation manufactured  
alcohol prep pads.

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6515 Nonstandard**

Walkmed Administration Sets for WalkMed Infusion Pumps:  
a) Catalog #PS-400/300; b) Catalog #EFV-101S; c) Catalog #EFV-101B;  
d) Catalog #FPS-560. Recall #Z-756/759-0.  
Lot Numbers: a) Lot 9I112, 9I113, 9J115, 9K103;  
b) D991020-B; c) D991027-A; d) D991202-A.  
McKinley Medical, LLLP, Wheat Ridge, Colorado.  
Manufacturer, by mail on May 5, 2000. Firm-initiated recall ongoing.  
Nationwide and international.  
41,720 sets were distributed.  
Defective plastic elbow connector could allow leak or air introduction.

CODE

MANUFACTURER  
RECALLED BY  
DISTRIBUTION  
QUANTITY  
REASON

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6515 Nonstandard**

Vasoview Dissection/Vessel Harvesting System:  
a) VasoView, Part #09331; b) Vasoview Uniport, Part #11344;  
c) Vasoview Uniport Plus, Part #11346. The VasoView Uniport dissection  
cannula has applications in minimally invasive surgery allowing access  
for vessel harvesting, and is primarily indicated for patients undergoing  
endoscopic vessel harvesting surgery for arterial bypass. Recall #Z-  
771/773-0.  
All codes.  
Guidant Corporation, Menlo Park, California.  
Manufacturer, by letter on May 11, 2000, followed by telephone.  
Firm-initiated recall ongoing.  
Nationwide and international.  
5,730 units were distributed.  
Sterility may be compromised as evidenced by a loss of package integrity.

CODE  
MANUFACTURER  
RECALLED BY  
DISTRIBUTION  
QUANTITY  
REASON

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6515 Nonstandard**

Howmedica Ostenonics System 12 Crossfire P4 10 polyethylene insert, Catalog  
number 6352-5-074. Recall #Z-818-0.  
Case Code TC3021.  
Howmedica Ostenonics Corp., Allendale, New Jersey.  
Manufacturer, by letter, dated April 3, 2000, and faxed on April 4, 2000. Firm-  
initiated recall ongoing.  
Nationwide.  
151 units were distributed.  
Size improperly stamped.

CODE  
MANUFACTURER  
RECALLED BY  
DISTRIBUTION  
QUANTITY  
REASON

None Present  
 Action Taken \_\_\_\_\_

NSN

PRODUCT

CODE

MANUFACTURER

RECALLED BY

DISTRIBUTION

QUANTITY

REASON

**6515 Nonstandard**

a) Bard Button Device Decompression Tubes; b) Bard Replacement Gastrostomy Device Kit. Recall #Z-855/856-0.

All lot numbers.

C.R. Bard, Inc., Mentor, Ohio.

C.R. Bard, Inc., Billerica, Massachusetts, by letter on May 16, 2000.

Firm-initiated recall ongoing.

Nationwide.

63,345 units were distributed.

The device may be partially occluded (due to mold flash) causing narrowing in the through-hole.

[ ] None Present

[ ] Action Taken \_\_\_\_\_

NSN

PRODUCT

CODE

MANUFACTURER

RECALLED BY

DISTRIBUTION

QUANTITY

REASON

**6515 Nonstandard**

Valleylab LS1000 Ligasure Vessel Sealing System, for use in general and plastic surgery. Recall #Z-804-0.

Lot Numbers: ANH000330, ANH000404, ANH000407, ANH000410 thru ANH000414, ANH000417 thru ANH000420.

Valleylab, Inc., Boulder, Colorado.

Manufacturer, by letter on April 12, 2000, and April 15, 2000. Firm-initiated recall ongoing.

Alabama, Arizona, California, Colorado, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Maryland, Michigan, North Carolina, New Jersey, New York, Oklahoma, Pennsylvania, Tennessee, Texas, Wyoming, Australia, Canada, France, Israel and Lebanon.

155 cases, 6 units per case were distributed.

Grasping ability of device may decrease and, with continued use, come apart.

[ ] None Present

[ ] Action Taken \_\_\_\_\_

NSN

PRODUCT

CODE

**6515 Nonstandard**

Curity Spinal Anesthesia Tray; Safe Tap Spinal Anesthesia Tray; Spinal Anesthesia; Saddle Block and Customer Special Spinal Tray. Recall #Z-766/770-0.

Note: This recall only applies to alpha numeric lot numbers beginning with "FE83", "HE83", "JE83" and "GE83"; numerical lot numbers beginning with "0",

"4", "5" and "9".

Part # Description

470 CURITY Spinal Anesthesia Tray

4716 CURITY Spinal Anesthesia Tray

4720 CURITY Spinal Anesthesia Tray

4722 CURITY Spinal Anesthesia Tray

4724 CURITY Spinal Anesthesia Tray

4727 CURITY Spinal Anesthesia Tray

4730 CURITY Spinal Anesthesia Tray

4731 CURITY Spinal Anesthesia Tray  
 4747 Safe Tap Spinal Anesthesia Tray  
 4748 Safe Tap Spinal Anesthesia Tray  
 4749 Safe Tap Spinal Anesthesia Tray  
 4760 CURITY Spinal Anesthesia Tray/Saddle Block  
 4761 CURITY Spinal Anesthesia Tray  
 4762 CURITY Spinal Anesthesia Tray  
 4763 CURITY Spinal Anesthesia Tray/Saddle Block  
 4764 CURITY Spinal Anesthesia Tray/Saddle Block  
 4765 CURITY Spinal Anesthesia Tray  
 4766 CURITY Spinal Anesthesia Tray  
 4767 CURITY Spinal Anesthesia Tray/Saddle Block  
 4768 CURITY Spinal Anesthesia Tray  
 4769 CURITY Spinal Anesthesia Tray  
 4770 CURITY Spinal Anesthesia Tray  
 4787 CURITY Spinal Anesthesia Tray/Saddle Block  
 4795 CURITY Spinal Anesthesia Tray/Saddle Block  
 4815 CURITY Spinal Anesthesia Tray  
 4920 CURITY Spinal Anesthesia Tray  
 5171 Continuous Epidural Anesthesia Tray  
 10569 Customer Special: Spinal Tray  
 10584 Customer Special: Spinal Tray  
 10590 Customer Special: Spinal Tray  
 10614 Customer Special: Spinal Tray  
 10616 Customer Special: Spinal Tray  
 10617 Customer Special: Spinal Tray  
 10618 Customer Special: Spinal Tray  
 10641 Customer Special: Spinal Tray  
 10702 Customer Special: Spinal Tray  
 10705 Customer Special: Spinal Tray  
 10708 Customer Special: Spinal Tray  
 472867 Customer Special: Spinal Tray  
 476827 Customer Special: Spinal Tray.

The Kendall Company LP, Mansfield, Massachusetts.  
 Manufacturer, by mail on May 10, 2000. Firm-initiated recall ongoing.  
 Nationwide, Japan, Panama, Bahamas, Saudi Arabia.  
 Approximately 14,570 cases.  
 Spinal anesthesia trays contain recalled Epinephrine Injection USP, 1 ml  
 ampule.

MANUFACTURER  
 RECALLED BY  
 DISTRIBUTION  
 QUANTITY  
 REASON

None Present  
 Action Taken \_\_\_\_\_  
 -----

**NSN**  
**PRODUCT**

**6515 Nonstandard**  
 Medtronic AneuRx Stent Graft System, designed to treat infrarenal  
 abdominal aortic or aorto-iliac aneurysms using an endovascular approach.  
 Recall #Z-862-0.

CODE

Catalog Number Tapered Tip Reusable Handle  
 YREC1855 NA  
 YREC20375 PD03140-20  
 YREC22375 PD03140-22  
 YREC24375 PD03140-24  
 YREC26375 PD03140-26  
 YREC28375 PD03140-28

YREC31375 NA  
 YRBR2012135 PD03138-20  
 YRBR2213135 PD03138-22  
 YRBR2414135 PD03138-24  
 YRBR2615135 PD03138-26  
 YRBR2816135 PD03138-28  
 YRBR3116135 NA  
 YRBR2012165 PD03139-20  
 YRBR2213165 PD03139-22  
 YRBR2414165 PD03139-24  
 YRBR2615165 PD03139-26  
 YRBR2816165 PD03139-28  
 YRBR3116165 NA  
 Catalog Number IDS  
 YRDEC1855 PD02457-18  
 YRDEC20375 PD02457-20  
 YRDEC22375 PD02457-22  
 YRDEC24375 PD02457-24  
 YRDEC26375 PD02457-26  
 YRDEC28375 PD02457-28  
 YRDEC31375 PD02457-31  
 YRDBR2012135 PD02087-20  
 YRDBR2213135 PD02087-22  
 YRDBR2414135 PD02087-24  
 YRDBR2615135 PD02087-26  
 YRDBR2816135 PD02087-28  
 YRDBR3116135 PD02087-31  
 YRDBR2012165 PD02086-20  
 YRDBR2213165 PD02086-22  
 YRDBR2414165 PD02086-24  
 YRDBR2615165 PD02086-26  
 YRDBR2816165 PD02086-28  
 YRDBR3116165 PD02086-31

MANUFACTURER  
 RECALLED BY

Medtronic, Inc., Minneapolis, Indiana.  
 Medtronic AVE, Santa Rosa, California, by letter on June 13, 2000, and by  
 visit. Firm-initiated recall ongoing.

DISTRIBUTION  
 QUANTITY  
 REASON

Nationwide.  
 230 units were distributed.  
 Product has the potential for detachment of a 21F-tapered tip nosecone  
 from the catheter.

None Present  
 Action Taken \_\_\_\_\_

NSN  
 PRODUCT  
 CODE  
 MANUFACTURER  
 RECALLED BY  
 DISTRIBUTION

**6520 Nonstandard**  
 Replace/Steri-Oss brand of 4.3 mm Diameter Dental Healing Abutment. Recall  
 #Z-831- 0.  
 Lot #307893, Part #61027, EXP 2/05.  
 Nobel Biocare USA, Inc., Yorba Linda, California.  
 Manufacturer, by letter on May 3, 2000. Firm-initiated recall ongoing.  
 California, Colorado, Connecticut, Florida, Idaho, Indiana, Michigan, Minnesota,  
 Missouri, North Carolina, New Jersey, New York, Ohio, Pennsylvania, Texas,  
 Virginia, Washington state.

QUANTITY

110 units were distributed.

REASON The wrong size, 4.5 mm D x 3 mm H, endosseous dental implant (healing abutment) was placed into the device packaging labeled for a 4.5 mm D x 5 mm H healing abutment.

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6540 Nonstandard**  
MemoryLens Ultraviolet-Absorbing, Hydrophilic, Posterior Chamber Lens: a) Model No. U940A, MemoryLens Ultraviolet-Absorbing, Hydrophilic, Posterior Chamber Intraocular;  
b) Model No. U940S, MemoryLens Ultra violet-Absorbing, Hydrophilic, Posterior Chamber Intraocular Lens.  
Recall #Z-741/742-0.

CODE  
MANUFACTURER  
RECALLED BY

All Lot Numbers manufactured on or before 3/24/2000.  
Ciba Vision Corporation, Duluth, Georgia.  
Manufacturer, by letter dated April 10, 2000. Firm-initiated recall ongoing.

QUANTITY  
REASON

263,000 units were distributed.  
Implantation of this lens may cause postoperative inflammation.

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6545 Nonstandard**  
Atwater Carey Ltd. First Aid Kits having the following particular names identifying the uses of the kits: Blister Doc, Pocket Doc, Travel Doc, Cycle Doc, Personal (First Aid), Dayhiker, Backpacker, After The Fall, Walkabout, Family (First Aid), International, Expedition, EMT First Aid, Mountain Rescue, 25 Person, EMT WMI, Sport Pak, Whitewater, Pocket Watertight, Swiftwater Paddler, Wilderness Canoe, Marine Life Pak, Athletes Kit, Athletes Replace Module, Coaches Kit, Coaches Replace Module, Team, American Challenge Team, Team Replace Module, Wound Management Module, First Aid Refill of Antiseptic Towelettes, First Aid Refill - Tincture of Benzoin, Blister Kit, and Marine Waterproof. These kits are labeled as assembled by Wisconsin Pharmacal, Inc., Jackson, WI; Wilderness Medicine Pro 0.5, 1.0, 2.0, and 3.0 First Aid Systems. These first aid kits have the firm name and address of Atwater Carey, Ltd., Salida, CO 81201 on the labels.

CODE

The following private label first aid kits were included in the recall: Eagle Creek Traveler, Kwik Tek, Safeway 25 Person Refill, Campmor Hiker, Campmor Guide, and Campmor Advanced. Recall #Z-827-0.  
Code Information: There are no lot numbers on the kits. The kits have part numbers, as follows: Atwater Carey Ltd. first aid kits: 153-156, 158-163, 165, 166, 168, 169, 171-173, 175, 177, 177CO, 178, 180-184, 182RM-184RM, 184AC, 208, 217, 220, 221, and 299.

MANUFACTURER  
RECALLED BY  
COMPONENT MFR

Wilderness Medicine Pro first aid kits: 260-263 Eagle Creek Traveler Kits: 268 and 268C Kwik Tek Kit: 277; Safeway 25 Person Refill: 282 Campmor first aid kits: 294-296.  
WPC Brands/Wisconsin Pharmacal Company, Jackson, Wisconsin.  
Manufacturer, by letter dated March 28, 2000. Firm-initiated recall ongoing.  
Clinipad Corporation, Rocky Hill, Connecticut.

DISTRIBUTION Nationwide, Canada, Belgium.  
 QUANTITY 219,000 kits were distributed; firm estimated that 70,000 kits remained on market at time of recall initiation.  
 REASON Kits contain Clinipad products labeled as sterile for which Clinipad is unable to assure the sterility.

None Present  
 Action Taken \_\_\_\_\_

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**CLASS III RECALLS:**

**NSN 6505 Nonstandard**  
**PRODUCT** a) Glyburide Tablets (micronized), USP, 1.5 mg, 100 tablets, unit dose, Rx;  
 b) Glyburide Tablets (micronized), USP, 3 mg, 100 tablets, unit dose,.  
 Products are indicated as an adjunct to diet to lower the blood glucose I n patients with non-insulin dependent diabetes mellitus (type II) whose hyperglycemia cannot be satisfactorily controlled alone. NDC Numbers: 55953-034-41 and 55953-035-41. Recall #D-411/412-0.  
**CODE** Lot Numbers: a) 114058B EXP 10/00, 114059B EXP 10/00, 114060B EXP 10/00, and 116884A EXP 4/01; b) 114061D EXP 4/01, 114062D EXP 4/01, 114063D EXP 4/01, 114517B EXP 5/01, and 116893A EXP 12/01.  
**MANUFACTURER** Novopharm, Ltd., Toronto, Canada.  
**RECALLED BY** Teva Pharmaceuticals USA, Sellersville, Pennsylvania, by letter on June 5, 2000. Firm-initiated recall ongoing.  
**DISTRIBUTION** Nationwide.  
**QUANTITY** 1,386 units were distributed; firm estimated that 5 percent of product remained on market at time of recall initiation.  
**REASON** Impurity failure (12 month stability testing).

None Present  
 Action Taken \_\_\_\_\_

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**NSN 6505 Nonstandard**  
**PRODUCT** Humegon(r) Vial lyophilized powder (memotropins for injection, USP), 2 mL vial, 75 IU, Rx infertility drug. NDC #0052-0300-02. Recall #D-417-0.  
**CODE** Lot Numbers: 0990199300, 1000299300, 10103993000, 1020499300, 103599300, 1040699300, and 1050799300.  
**MANUFACTURER** Organon, Inc., West Orange, New Jersey.  
**RECALLED BY** Manufacturer, by letter dated May 17, 2000. Firm-initiated field correction ongoing.  
**DISTRIBUTION** Nationwide and Puerto Rico.  
**QUANTITY**

Lot #	Amount Shipped
0990199300	16,796 units
1000299300	16,524 units
1010399300	16,220 units
1020499300	16,661 units
1030599300	16,638 units
1040699300	16,827 units

1050799300 11,276 units.  
Note: Each unit consists of five Humegon vials and five 2 mL Sodium Chloride Injection, USP vials.

[ ] None Present  
[ ] Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6505 Nonstandard**  
Triazolam Tablets, USP, 0.125 mg and 0.25 mg, Rx product taken orally as sleeping aid, under the following labels:  
Par NDC: 49884-453-62 (10x10), 0.125 mg Tablets  
49884-453-05 (500), 0.125 mg Tablets  
Par NDC: 49884-454-62 (10x10), 0.25 mg Tablets  
49884-454-05 (500), 0.25 mg Tablets  
Qualitest NDC: 0603-6186-10 (10x10), 0.125 mg Tablets  
Qualitest NDC: 0603-6187-10 (10x10), 0.25 mg Tablets.  
Recall #D-422/423-0.

CODE

0.125 mg Tablets:  
Mfr. Lot# Par Lot# Control# Size EXP Label  
TE030 013635 014152 10x10 5/2000 Par  
014153 10x10 5/2000 Qualitest  
014154 500s 5/2000 Par  
015617 10x10 5/2000 Par  
9B126 017499 017587 500s 2/2001 Par  
017589 10x10 2/2001 Par  
017590 10x10 2/2001 Par  
017591 10x10 2/2001 Par

0.25 mg Tablets:  
TF064 013730 013871 10x10 6/2000 Par  
013872 10x10 6/2000 Qualitest  
013874 500s 6/2000 Par  
9F200 018698 019113 500s 6/2001 Par.

MANUFACTURER  
RECALLED BY

Alphapharm Pty Ltd., Carole Park, Old, Australia (bulk tablets).  
Par Pharmaceutical, Inc., Spring Valley, New York, by letters on March 14 and 24, 2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY

Nationwide.  
0.125 mg:  
10x10s total shipped: 4689 units  
500s total shipped : 2661 units  
0.25 mg:  
10x10s total shipped: 6961 units  
500s total shipped : 1385 units.

REASON

Individual impurity specification failure.

[ ] None Present  
[ ] Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6505 Nonstandard**  
a) Rubratope(r)-57 Diagnostic Kit (Cyanocobalamin Co 57), Rx, 4 capsules (NDC #0270-3868-10); b) Rubratope(r) Cyanocobalamin Co 57 Capsules, UPS, Rx, 5 and 10 capsules, intended for the diagnosis of pernicious anemia and as a diagnostic adjunct in other defects of intestinal vitamin B12

absorption. NDC #0270-3866-10 and 0270-3866-20.

Recall #D-424/425-0.

CODE

Lot Numbers and EXP dates: UW408681 10/1/99, UW308661 10/1/99, UW308662 10/1/99, UX408681 10/20/99, UX308661 10/20/99, UX308662 10/20/99, UZ408681 1/6/00, UZ408661 1/6/00, UZ408662 1/6/00, WA408681 1/22/00, WA408661 1/22/00, WA418661 1/22/00, WA408662 1/22/00, WD408681 6/5/00, WD418681 6/5/00, WD408661 6/5/00, WD408662 6/5/00, WD508662 6/5/00, WE108681 5/12/00, WE408661 5/12/00, WE308662 5/12/00, WE408662 5/12/00, WG408681 6/19/00, WG408661 6/19/00, WG408662 6/19/00.

MANUFACTURER  
RECALLED BY

Bristol-Myers Squibb Company, New Brunswick, New Jersey.  
Bracco Diagnostics, Inc., Princeton, New Jersey (responsible firm), by field alert letter on May 5, 2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY

Nationwide.  
10 kits, 10 bottles of 5 capsules, and 20 bottles of 10 capsules were distributed.

REASON

Incorrect capsule release assay which could lead to a false negative calculation.

None Present

Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6505 Nonstandard**

Vasosulf(r) Ophthalmic Solution (sulfacetamide sodium 15% -Phenylephrine Hydrochloride 0.125%), Rx indicated for the treatment of conjunctivitis, corneal ulcer, and other superficial ocular infections due to susceptible microorganisms, and an adjunctive in systemic sulfonamide therapy of trachoma. NDC # 58768-883-05 (5 mL);

NDC #58768-883-15 (15 mL). Recall #D-420-0.

CODE

X1095 EXP 1/01, Y1104 EXP 7/00, X1105 EXP 2/01.

MANUFACTURER  
RECALLED BY

OMJ Pharmaceuticals, San German, Puerto Rico (finished product).  
CIBA Vision Corporation, San German, Puerto Rico, by letter on May 30, 2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY

Nationwide.  
19,872 units were distributed; firm estimated that 9,300 units remained on market at time of recall initiation.

REASON

Failure to revalidate new manufacturing specifications.

None Present

Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6505 Nonstandard**

Atropisol(r) Atropine Sulfate) Ophthalmic Solution 1%, 1 mL, Rx indicated for the treatment of inflammatory conditions of the iris or uveal tract and also as a cyclopegic or mydriatic for refraction. Recall #D-419-0.

CODE

Lot Numbers and EXP dates:W102 4/00, W103 4/00, W104 5/00, W105 5/00, W106 8/00, X2091 2/00, X2092 3/01, X2093 8/01, X2094 8/01, X2095 8/01, X2096 9/01, X2097 9/01 X2098 9/01 X2099 9/01.

MANUFACTURER  
RECALLED BY

OMJ Pharmaceuticals, San German, Puerto Rico (finished product).  
CIBA Vision Corporation, San German, Puerto Rico, by letter on May 30, 2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY

Nationwide.  
14,665 units were distributed; firm estimated that 3,300 units remained on

REASON market at time of recall initiation.  
Product labeled with incorrect expiration date.

[ ] None Present  
[ ] Action Taken \_\_\_\_\_

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NSN **6505 Nonstandard**  
PRODUCT Lanoxin Tablets, 0.125 mg, in bottles of 30 and 100, Rx oral cardiotoxic indicated for the treatment of mild to moderate heart failure and for the control of ventricular response rate in patients with chronic atrial fibrillation. Recall #D-418-0.

CODE Lot Numbers: 9355140, 0006075, and 9354174.  
MANUFACTURER Glaxo Wellcome, Inc., Zebulon, North Carolina.  
RECALLED BY Allscripts, Inc., Libertyville, Illinois, by letters dated April 17, 2000, and June 7, 2000. Firm-initiated recall ongoing.

DISTRIBUTION California, Illinois, Iowa, Wisconsin, Pennsylvania, Arizona, Indiana, Louisiana, Florida, Idaho, Michigan, Hawaii, Maine.

QUANTITY 86 bottles of 30 and 19 bottles of 100 tablets were distributed; firm estimated that 30 percent of the product remained on market at time of recall initiation.

REASON Tablets do not meet thickness specification and therefore may be subpotent.

[ ] None Present  
[ ] Action Taken \_\_\_\_\_

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NSN **6505 Nonstandard**  
PRODUCT MediGel H (Topical Hydrocortisone Hydrogel), 1% Hydrocortisone, in 4-ounce plastic bottles, OTC.NDC #57437-7777-04. Recall #D-426-0.

CODE Lot No. LMQ.  
MANUFACTURER Henley Healthcare, Inc., Sugarland, Texas.  
RECALLED BY Manufacturer, by telephone on or about May 1 to 6, 2000. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 228 bottles were distributed.

REASON Super-potent.

[ ] None Present  
[ ] Action Taken \_\_\_\_\_

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NSN **6505 Nonstandard**  
PRODUCT Vicoprofen(r) Tablets (hydrocodone bitartrate 7.5 mg and ibuprofen 200 mg), in 500-count bottles, Rx. NDC #0044-723-03. Recall #D-428-0.

CODE Lot #0000060685 EXP 10/01.  
MANUFACTURER Knoll Pharmaceutical Company, Whippahy, New Jersey.  
RECALLED BY Knoll Pharmaceutical Company, Mt. Olive, New Jersey, by letter on April 28, 2000. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 3,475 bottles were distributed.

REASON Misbranded - Some bottles have partially illegible lot numbers and/or

None Present  
 Action Taken \_\_\_\_\_

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NSN  
PRODUCT

**6505 Nonstandard**

IBU(r) Tablets (Ibuprofen), 800 mg, in 500-count bottles, Rx non-steroidal anti-inflammatory agent.

Par NDC #49884-469-05. Recall #D-429-0.

CODE  
MANUFACTURER  
RECALLED BY

Lot #20692 EXP 11/00.

BASF Corporation, Shreveport, Louisiana.

Manufacturer, by telephone on May 19, 2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide.

9,279 bottles were distributed.

Product exceeds impurity specification at 18-month stability (4-isobutylacetophenone).

None Present  
 Action Taken \_\_\_\_\_

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NSN  
PRODUCT

**6505 Nonstandard**

Aspirin Tablets, 325 mg, in units of 2, 100, and 300, Rx under the following labels: Pharmacist Formula (2 tablets); Albertson (100 count); and Target (300 count).

Recall #D-432-0.

CODE  
MANUFACTURER  
RECALLED BY

Lot #8M00476 EXP 10/01.

Leiner Health Products, Inc., Kalamazoo, Michigan.

Leiner Health Products, Inc., Carson, California, by letter faxed on May 2, 2000, followed by mail on May 3, 2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY

California, Florida, Idaho, Hawaii, Illinois, Maryland, Minnesota, Texas, Virginia.

47,832 10-tablet bottles; 9,276 300-count bottles and 5,424 boxes 100 tablet blisters were distributed.

REASON

Dissolution failure (24 month stability).

None Present  
 Action Taken \_\_\_\_\_

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NSN  
PRODUCT  
CODE

**6515 Nonstandard**

Cemented Hip Stem, Catalog #6098-0940. Recall #Z-760-0.

Case Code: 46364801

Serial Numbers: 20458S, 20459D, 20461S, 20462S, 20463S, and 38086P.

MANUFACTURER  
RECALLED BY

Stryker Howmedica Osteonics, Allendale, New Jersey.

Manufacturer, by telephone on March 21, 2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Illinois, Minnesota, Oklahoma and Canada.

5 units were distributed.

Mislabeling - The device is labeled having a 127 degree neck angle when in fact the hip stem actually have a 132 degree neck angle.

None Present

Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6515 Nonstandard**

Pentalumen Thermodilution Catheter, Heparin Coated, Flow-Directed Thermodilution Pulmonary Artery Catheter, Rx device for rapid and accurate measurement of hemodynamic pressure and determination of cardiac output using a cardiac output computer. Z-762-0.

CODE  
MANUFACTURER  
RECALLED BY

List #412320401, Lot #59-249-SN.  
Abbott Laboratories, Hospital Products Division, Abbott Park, Illinois.  
Manufacturer, by letter dated May 10, 2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide, Canada, Chile.  
960 catheters were distributed.  
One or more of the lumens in the catheter may be occluded.

None Present  
 Action Taken \_\_\_\_\_

NSN  
UPDATE

**6515 Nonstandard**

Several recalls which appeared in the June 28, 2000 Enforcement Report incorrectly listed the manufacturer and recalling firm as the same. The following is the correct manufacturer and recalling firm for the noted recall:  
Z-762-0 - Pentalumen Thermodilution Catheter, Heparin Coated: Manufacturer: Abbott Laboratories, Salt Lake City, UT Recalling Firm: Abbott Laboratories, Abbott Park, IL.

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6515 Nonstandard**

Genesis II and Profix Porous Femoral Components, sterile product, packaged one per container for use by an orthopaedic surgeon:

Z-763-0 - Genesis II Femoral Components:

Description	Part Number	Lot
Sz 3 LT	71420036	00111302
Sz 4 LT	71420038	91106643
Sz 5 LT	71420040	00111462
Sz 5 LT	71420040	00111463
Sz 5 LT	71420040	00304339
Sz 5 LT	71420040	00304340
Sz 6 LT	71420042	91103882
Sz 6 LT	71420042	91103883
Sz 6 LT	71420042	91107062
Sz 6 LT	71420042	91107063
Sz 6 LT	71420042	91107064
Sz 6 LT	71420042	00101454
Sz 6 LT	71420042	00101457
Sz 7 LT	71420044	00206821
Sz 7 LT	71420044	00206822
Sz 4 RT	71420054	91201372

Sz 4 RT	71420054	91201373
Sz 4 RT	71420054	91201371
Sz 4 RT	71420054	91204594
Sz 4 RT	71420054	00101463
Sz 4 RT	71420054	00101464
Sz 4 RT	71420054	00111306
Sz 4 RT	71420054	00111307
Sz 4 RT	71420054	00111308
Sz 5 RT	71420056	91107068
Sz 5 RT	71420056	91107069
Sz 5 RT	71420056	91107070
Sz 5 RT	71420056	91106158
Sz 5 RT	71420056	90016159
Sz 5 RT	71420056	91106160
Sz 5 RT	71420056	91107067
Sz 5 RT	71420056	00111304
Sz 5 RT	71420056	00111304A
Sz 5 RT	71420056	00404566
Sz 5 RT	71420056	00404567
Sz 5 RT	71420056	00404563
Sz 5 RT	71420056	00404564
Sz 5 RT	71420056	00404565
Sz 7 RT	71420060	91204591
Sz 7 RT	71420060	91204592
Sz 7 RT	71420060	00206823
Sz 7 RT	71420060	00206824
Sz 7 RT	71420060	00406018
Sz 7 RT	71420060	00406017
Sz 7 RT	71420060	00103496

Z-764-0

Prefix Femoral Components:

Description	Part Number	Lot
Sz 3 RT	71502130	00105665
Sz 4 RT	71502140	91100703
Sz 4 RT	71502150	91100704
Sz 4 RT	71502140	91107043
Sz 4 RT	71502150	91107044
Sz 4 RT	71502140	91107045
Sz 4 RT	71502150	91203073
Sz 5 RT	71502150	91101207
Sz 5 RT	71502150	91106635
Sz 5 RT	71502150	91106636
Sz 5 RT	71502150	91106146
Sz 5 RT	71502150	91106147
Sz 5 RT	71502150	91106634
Sz 5 RT	71502150	91107801
Sz 5 RT	71502150	91107802
Sz 5 RT	71502150	91107724
Sz 5 RT	71502150	91107725
Sz 5 RT	71502150	91107803
Sz 5 RT	71502150	91200417
Sz 5 RT	71502150	91200418
Sz 5 RT	71502150	91100419
Sz 5 RT	71502150	91200420
Sz 5 RT	71502150	92100416
Sz 6 RT	71502160	91101209

Sz 6 RT	71502160	91107805
Sz 6 RT	71502160	91107806
Sz 6 RT	71502160	91100706
Sz 6 RT	71502160	00209183
Sz 6 RT	71502160	00209184
Sz 6 RT	71502160	00301458
Sz 6 RT	71502160	00301457
Sz 6 RT	71502160	00301456
Sz 6 RT	71502160	00305645
Sz 2 LT	71502220	00405819
Sz 2 LT	71502220	91203766
Sz 2 LT	71502220	91204891
Sz 3 LT	71502230	91106628
Sz 3 LT	71500230	91106629
Sz 3 LT	71502230	91106630
Sz 3 LT	71500230	91106149
Sz 3 LT	71502230	91106150
Sz 3 LT	71500230	00109524
Sz 4 LT	71590001	91203525
Sz 4 LT	71590001	91203526
Sz 4 LT	71502240	91101931
Sz 4 LT	71502240	91101932
Sz 4 LT	71502240	91101933
Sz 4 LT	71502240	00104672
Sz 4 LT	71502240	00109525
Sz 4 LT	71502240	00301453
Sz 4 LT	71502240	00301454
Sz 4 LT	71502240	00310670
Sz 5 LT	71502250	91102580
Sz 5 LT	71502250	91102582
Sz 5 LT	71502250	91109920
Sz 5 LT	71502250	91109921
Sz 5 LT	71502250	91110383
Sz 5 LT	71502250	91204253
Sz 5 LT	71502250	91204254
Sz 5 LT	71502250	00109527
Sz 5 LT	71502250	00109528
Sz 5 LT	71502250	00111459
Sz 5 LT	71502250	00111461
Sz 5 LT	71502250	00200116
Sz 5 LT	71502250	00200337
Sz 5 LT	71502250	00200338
Sz 5 LT	71502250	00200339
Sz 6 LT	71502260	91107049
Sz 6 LT	71502260	91107050
Sz 6 LT	71502260	91107051
Sz 6 LT	71502260	00104674
Sz 6 LT	71502260	91108859
Sz 7 LT	71502270	91106148
Sz 7 LT	71502270	91200414
Sz 7 LT	71502270	00111298.

MANUFACTURER  
RECALLED BY

Smith and Nephew, Inc., Orthopaedic Division, Memphis, Tennessee.  
Manufacturer, by letters on May 19 and 26, 2000, and by fax on May 20,  
2000.

DISTRIBUTION

Firm-initiated recall ongoing.  
Nationwide and international.

QUANTITY 945 units were distributed.  
REASON The bead sintering process temperature was insufficient for proper bead/substrate adhesion.

None Present  
 Action Taken \_\_\_\_\_

**NSN** **6515 Nonstandard**  
**PRODUCT** Cordis Smart Nitinol Stent Transhepatic Biliary System. Recall #Z-775/776-0.

**CODE** Catalog number 1440BB, Lot number X0200019;  
Catalog number 1420BB, Lot number 40200246.

**MANUFACTURER** Cordis Corporation, Miami Lakes, Florida.  
**RECALLED BY** Manufacturer, by letter on April 25, 2000. Firm-initiated recall ongoing.

**DISTRIBUTION** Tennessee, West Virginia, California, Louisiana, and Florida.  
**QUANTITY** 12 units were distributed.  
**REASON** Misabeled guidewire size and mislabeled indication for use.

None Present  
 Action Taken \_\_\_\_\_

**NSN** **6515 Nonstandard**  
**PRODUCT** Zimmer NexGen Knee Option Femoral Size D, Right, Catalog 00-5996-0114-02. Recall #Z- 834-0.

**CODE** Lot # 62813700.  
**MANUFACTURER** Zimmer, Inc., Warsaw, Indiana.

**RECALLED BY** Manufacturer, by letter on May 31, 2000. Firm-initiated recall ongoing.

**DISTRIBUTION** Nationwide and international.  
**QUANTITY** 77 units were distributed.

**REASON** The buffing residue was left affixed to the underside of the femoral knee component.

None Present  
 Action Taken \_\_\_\_\_

**NSN** **6540 Nonstandard**  
**PRODUCT** FreshLook Toric Soft Hydrophilic Contact Lenses for Astigmatism. Recall #Z-765-0.

**CODE** Lot numbers: 101297 EXP 2003-01, 101296, EXP 2003-01.

**MANUFACTURER** Wesley Jessen Corporation, Des Plaines, Illinois.

**RECALLED BY** Manufacturer, by letters dated May 12, 2000. Firm-initiated recall ongoing.

**DISTRIBUTION** Nationwide.

**QUANTITY** 564 single blister trials and 246 6-packs were distributed.

**REASON** Mislabeled for corrective power, cylinder and axis.

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6550 Nonstandard**

Lactate Membrane Kit Stat Profile M Series, for use with the Stat Profile M Analyzer. The Stat M. Analyzer is intended for in vitro diagnostic use by health care professionals and for Point-of-Care usage in the quantitative determination of sodium, potassium, ionized calcium, ionized magnesium, glucose, lactate, and BUN in serum, plasma, and whole blood to evaluate the acid-base status of patients suspected of having lactic acidosis. Recall #Z-817-0.

CODE  
MANUFACTURER  
RECALLED BY

Lot numbers: 901129 and 801129.  
Nova Biomedical Corporation, Waltham, Massachusetts.  
Manufacturer, by telephone on March 8, 2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Arizona, Massachusetts, Florida, Wisconsin and Germany.  
41 kits (6 membranes/kit) were distributed.  
Extended expiration date.

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6550 Nonstandard**

IMx hCG Calibrators, for in Vitro Diagnostic use. The Imx hCG Calibrators are for the calibration of the Imx Analyzer when used for the quantitative/qualitative determination of human chorionic gonadotropin (hCG) for the early detection of pregnancy. Recall #Z-761-0.  
List #3A63-01, Lot #55552Q100 EXP 5/13/00.

CODE  
MANUFACTURER  
RECALLED BY

Abbott Health Products, Inc., Barceloneta, Puerto Rico.  
Manufacturer, by telephone or fax on April 27, 2000, and by letter dated April 26, 2000. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide, Australia, Canada, Germany, Italy, Japan, and Mexico.  
234 kits were distributed.  
The IMx hCG Calibrator lot 55552Q100 rates have decreased over time which may result in elevated control values.

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6550 Nonstandard**

Immulate 2000 Rapid TSH L2KRT Kits, a solid-phase, competitive chemiluminescent enzyme immunometric assay designed for the detection of thyrotropin (thyroid stimulating hormone, TSH) in human serum and as an aid in the clinical assessment of thyroid status. Recall #Z-830-0.

CODE  
MANUFACTURER  
RECALLED BY

Lot Numbers 114, 114A, 115, and 116.  
Diagnostic Products Corporation, Los Angeles, California.  
Manufacturer, by telephone, fax or E-mail on April 20, 2000. Firm-initiated recall ongoing.

DISTRIBUTION

Arizona, California, Colorado, Georgia, Indiana, Kansas, Massachusetts, Maine, Missouri, New Jersey, New Mexico, New York, Pennsylvania, Rhode Island, South Carolina, Washington, and international.

QUANTITY  
REASON

845 units were distributed.  
The product can yield falsely elevated test results.

None Present  
 Action Taken \_\_\_\_\_

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