

**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:**

6525NS

MDC 15944

Cameras, Gamma

PRODUCT:

ICON Software Versions Less Than 6.0.2 used on the ICON A, AP, P, V, and MacICON Workstations and the Integrated Gamma Camera Systems Diacam, Orbiter, Multispect 2 and Multispect 3, Recall #Z-1097/1100-6.

CODE:

None.

MANUFACTURER: Siemens Medical Systems, Inc., Hoffman Estates, Illinois.

RECALLED BY: Manufacturer by letters February 1996, March 1996 and June 1996. Firm-initiated recall ongoing.

DISTRIBUTION: Nationwide and international.

QUANTITY: 2,240 units were distributed.

REASON: The ICON software versions less than 6.0.2 contained bugs which effect the acquisition of patient data, caused the loss of patient data, and require the re-injection of patient with radioactive isotopes in some instances.

None Present

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

6515NS

MDC 12636

Monitor Systems, Physiologic

PRODUCT:

SIRECUST 960/961/1260/1261/1280/1281 MULTI I/O; Pressure Waveform Triggering of External Devices, Software Versions up to and including VA4, Recall #Z-1103/1107-6

CODE:

Part number

Description

28 74 506 E2501

S/W UPG VA2-XMS MIOP 9+12

28 74 514 E2501

S/W UPG VA2-AXX Multi I/O 9+12

33 60 760 E2501

S/W UPG VBO-BXX Multi I/O 9+12

43 27 008 E2501

S/W UPG VA4-XXX MIOP 12/9

47 13 637 E2501

S/W UPG VBO/VA4 Multi I/O 9+12

MANUFACTURER: Siemens Medical Systems, Inc., Danvers, Massachusetts.

RECALLED BY: Manufacturer issued a device safety alert dated May 6, 1996. Firm-initiated recall ongoing.

DISTRIBUTION: Nationwide, international.

QUANTITY: Undetermined amount distributed.

REASON: Misbranded. The user manual does not address the possible potential for the loss trigger and for the balloon pump to remain in a deflated state which will produce an audible alarm when it occurs.

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

6525NS  
MDC 15944 Cameras, Gamma  
PRODUCT: Software Beta Version 4.5 with Gated 3-D EF, used to create an image of the area where the radiation emissions occurred. Recall #Z-1114-6.  
CODE: Software beta version 4.5.  
MANUFACTURER: Trionix Research Laboratory, Twinsburg, Ohio.  
RECALLED BY: Manufacturer by letter August 16, 1996. Firm-initiated recall ongoing.  
DISTRIBUTION: Nationwide and international.  
QUANTITY: 38 units were distributed.  
REASON: The manufacturer is marketing the device without a cleared premarket notification submission under section 510 (k) of the Act.

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

6525NS  
MDC 13271 X-Ray Rad Units, Fixed  
PRODUCT: Multi Diagnost 3 Radiographic Systems. Recall #Z-1120-6.  
CODE: Serial numbers: 4411881093; 4411921193, 4411931193, 4411991293, 4452120904, 4452160394, 4452270494, 4492330594, 4492370694, 44200694, 4492410694, 4492510994, 4502591094, 4502601094, 4502611094, 4502681194, 4502701194, 4502731194, 4502761294, 4502771294, 4502791294.  
MANUFACTURER: Philips Medical Systems North America Company, Shelton, Connecticut.  
RECALLED BY: Manufacturer by letter October 13, 1995. Firm-initiated recall ongoing.  
DISTRIBUTION: Nationwide.  
QUANTITY: 21 units were distributed.  
REASON: The drive shaft connecting the lateral tilt drive unit and table top could fracture at the welded joint; thus allowing the table top to rapidly and unexpectedly tilt as much as 25 degrees.

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

6530NS  
MDC 15757 Lasers, Surgical  
PRODUCT: Argon Dental Laser Systems. Recall #Z-1121/1123-6.  
CODE: Model Numbers: (a) ACL-5500; (b) ACL/PCU-5500, (c) Genesis 2000.  
MANUFACTURER: Ion Laser Technology, Salt Lake City, Utah.  
RECALLED BY: Manufacturer by telephone July 30, 1996. Firm-initiated recall ongoing.

DISTRIBUTION: Nationwide.  
QUANTITY: (a) 62 units; (b) 106 units; (c) 77 units were distributed.  
REASON: The devices failed to comply with 21 CFR 1040.11 (a)(2) in that the AL, PCU, and Genesis operator's manuals lacked calibration procedures and schedule for recalibration.

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

6525NS  
MDC 13272 X-Ray Rad Units, Mobile  
PRODUCT: Mobile/Portable General Purpose Units, used in radiographic studies: (a) Model HP200; (b) HP300. Recall #Z-1101/1102-6.  
CODE: HP200 and HP300 mobile/portable general purpose systems containing the R-120 series collimators.  
MANUFACTURER: Mikasa X-Ray Co LTD., Tokyo, Japan.  
RECALLED BY: Manufacturer. FDA approved the firm's corrective action plan on September 9, 1996. Firm-initiated field correction ongoing.  
DISTRIBUTION: Nationwide.  
QUANTITY: 40 units.  
REASON: Noncompliance with performance standards for diagnostic x-ray products in that the units failed to meet light illuminance requirement at a source to image distance (SID) of 40 inches and they failed to meet edge contrast ratio requirement at an SID of 40 inches.

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

**CLASS III RECALLS:** None

**MEDICAL EQUIPMENT SAFETY ALERTS:** None

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

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

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

**CLASS III:** A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Most of these items are nonstandard, and the possibility exists that medical activities may have purchased them locally. There is also a possibility that some of these items have NSNs assigned and may have been reported in earlier Q.A. messages. Activities having quantities of [AU1]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/FOCO no later than 8 NOV 96 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 (343-7445))

CLASS I RECALLS: None

CLASS II RECALLS:

**NSN** 6505 Nonstandard  
**PRODUCT** Thiothixene HCl Capsules, USP, 1 mg, 2 mg and 5 mg strength, packed in bottles of 100, under the Schein and Rugby labels, an antipsychotic.  
Recall #D-263/265-6.  
**CODE** 1 mg, Lot numbers: C5C0227, CXB104, CXC104  
2 mg, Lot numbers: C5C0231  
5 mg, Lot numbers: C5E0809, C5E1128, C5E1129  
(Schein label)  
1 mg, Lot numbers: CXB104, CXC104  
2 mg, Lot numbers: C5C0231 (Rugby label).  
**MANUFACTURER** Danbury Pharmacal, Inc., Carmel, New York.  
**RECALLED BY** Danbury Pharmacal, Inc., Subsidiary of Schein Pharmaceutical, Inc., Brewster, New York, by letter dated July 31, 1996. Firm-initiated recall ongoing.  
**DISTRIBUTION** Nationwide.  
**QUANTITY** 28,710 bottles (1 mg); 9,513 bottles (2 mg); 26,752 bottles (5 mg) were distributed.

**REASON**      **Dissolution failure.**

[ ] None Present

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

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**NSN**          **6505 Nonstandard**

**PRODUCT:**    **Delflex brand and custom manufactured NMC**

**(National Medical Care) Rx peritoneal dialysis  
solution for home dialysis use.**

**53 lots packaged in 2, 3 and 5 liter bags,**

**Recall #D-231/252-**

**CODE:**

<b>Fresenius product code</b>	<b>Product</b>	<b>Lot #</b>
044-50501	1.5% Dextrose, Low Mg, 5 Liter	07-008-6F
	07-162-6F	
	07-175-6F	
	07-048-6G	
	07-100-6G	
044-50502	2.5% Dextrose, Low Mg, 5 Liter	07-094-6F
	07-148-6F	
	07-183-6F	
	07-203-6F	
	07-042-6G	
044-50511	1.5% Dextrose, Std Mg, 5 Liter	07-174-6F
	07-099-6G	
044-20201	1.5% Dextrose, Low Mg, 2 Liter	07-190-6F
044-20322	2.5% Dextrose, Low Mg, Low Ca, 2L/3L	07-193-6F
044-50512	2.5% Dextrose, Std Mg, 5 Liter	07-196-6F
	07-055-6G	
	07-098-6G	
	07-121-6G	
044-20211	1.5% Dextrose, Std Mg, 2 Liter	07-204-6F
044-50524	4.25% Dextrose, Low Mg, Low Ca, 5 Liter	07-079-6G
044-50522	2.5% Dextrose, Low Mg, Low Ca, 5 Liter	07-002-6G
	07-041-6G	
	07-062-6G	
	07-063-6G	
	07-086-6G	
	07-178-6G	
044-50521	1.5% Dextrose, Low Mg, Low Ca, 5 Liter	07-009-6G
044-50504	4.25% Dextrose, Low Mg, 5 Liter	07-010-6G
	07-064-6G	

07-069-6G

044-30321 1.5% Dextrose, Low Mg, Low Ca, 07-038-6G  
3 Liter

044-25321 1.5% Dextrose, Low Mg, Low Ca, 07-052-6G  
2.5L//3L

044-20202 2.5% Dextrose, Low Mg, 2 Liter 07-074-6G

044-25311 1.5% Dextrose, Std Mg, 2.5L/3L 07-087-6G

044-25314 4.25% Dextrose, Std Mg, 2.5L/3L 07-089-6G

044-15211 1.5% Dextrose, Std Mg, 1.5L/2L 07-147-6G

044-20221 2.5% Dextrose, Std Mg, 2 Liter 07-154-6G

NMC Product Code:

65-2204-9 4.25% Dextrose, Low Mg, 2 Liter 07-121-6F

65-2202-3 2.5% Dextrose, Low Mg, 2 Liter 07-189-6F

65-2221-3 1.5% Dextrose, Low Mg, Low Ca, 07-197-6F  
2 Liter

65-5502-3 2.5% Dextrose, Low Mg, 5 Liter 07-017-6G  
07-034-6G

65-5521-3 1.5% Dextrose, Low Mg, Low Ca, 07-018-6G  
5 Liter

07-078-6G

65-5504-9 4.25% Dextrose, Low Mg, 5 Liter 07-049-6G

65-2322-9 2.5% Dextrose, Low Mg, Low Ca, 07-051-6G  
2L/3/

65-5501-5 1.5% Dextrose, Low Mg, 5 Liter 07-056-6G  
07-120-6G

65-4302-9 2.5% Dextrose, Low Mg, 3 Liter 07-075-6G

65-5522-1 2.5% Dextrose, Low Mg, Low Ca, 07-085-6G  
5 Liter

65-3302-0 2.5% Dextrose, Low Mg, 2.5L/3L 07-088-6G

65-1214-9 4.25% Dextrose, Std Mg, 1.5L/2L 07-162-6G

65-3314-5 4.25% Dextrose, Std Mg, 2.5L/3L 07-163-6G

MANUFACTURER: Fresenius USA, Inc., Ogden, UT 84404

RECALLED BY: Manufacturer by telephone August 15, 1996.

Firm-initiated recall ongoing.

DISTRIBUTION: Nationwide and Canada.

QUANTITY: 672,000 liters were distributed.

REASON: Excessive endotoxin levels.

None Present

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

NSN 6505 Nonstandard

PRODUCT: Empire Airgas labeled as "Oxygen Compressed USP"  
packaged in aluminum and steel high pressure  
cylinder sizes 300, 200, 125, E and D,  
Recall #D-253-6.

CODE: All lots with 001 thru 214.

**MANUFACTURER:** Empire Airgas, Inc., Syracuse, New York.  
**RECALLED BY:** Empire Airgas, Inc., Elmira, New York by letter  
August 16, 1996. Firm-initiated recall ongoing.  
**DISTRIBUTION:** New York.  
**QUANTITY:** 31,000 units were distributed.  
**REASON:** GMP deficiencies.

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

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**NSN** 6505 Nonstandard  
**PRODUCT:** (a) Red Blood Cells; (b) Cryoprecipitated AHF;  
(c) Recovered Plasma, Recall #B-593/595-6.  
**CODE:** Unit number (a-c) 30H81550.  
**MANUFACTURER:** American Red Cross Blood Services, Ashley,  
Pennsylvania.  
**RECALLED BY:** Manufacturer by letter December 6, 1995.  
Firm-initiated recall ongoing.  
**DISTRIBUTION:** Pennsylvania, New York.  
**QUANTITY:** 1 unit was distributed.  
**REASON:** Blood products, which tested negative for the  
antibody to the human immunodeficiency virus  
type 1 (anti-HIV-1), but were collected from a  
donor who previously tested repeatedly  
reactive for anti-HIV-1, were distributed.

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

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**NSN** 6505 Nonstandard  
**PRODUCT:** (a) Red Blood Cells; (b) Platelets; (c) Recovered  
Plasma, Recall #B-603/605-6.  
**CODE:** Unit number (a-c) 3D2745.  
**MANUFACTURER:** Puget Sound Blood Center, Seattle, Washington.  
**RECALLED BY:** Manufacturer by letter July 13, 1995.  
Firm-initiated recall ongoing.  
**DISTRIBUTION:** Washington, California.  
**QUANTITY:** 3 units were distributed.  
**REASON:** Blood products, collected from a donor whose  
spouse was diagnosed with hepatitis B, were  
distributed.

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

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**NSN** 6505 Nonstandard  
**PRODUCT** Apothe'Cure brand (a) Progesterone Sr, 10 mg and 200 mg capsules; (b) Estriol/Testosterone/Progesterone (1 mg, 2 mg, and 7.5 mg respectively) capsules; (c) DHEA/Progesterone (25 mg each) capsules. Recall #D-257/260-6.  
**CODE** Lot numbers: (a) 05139687, 06089677 (200 mg); (b&c) no lot numbers.  
**MANUFACTURER** Apothe'Cure, Inc., Dallas, Texas.  
**RECALLED BY** Manufacturer by letters dated August 5, 1996. Firm-initiated recall ongoing.  
**DISTRIBUTION** Nationwide, Canada, United Kingdom.  
**QUANTITY** Undetermined.  
**REASON** FDA analysis found samples to be super and sub-potent. Current GMP deficiencies.

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

**NSN** 6515 Nonstandard  
**PRODUCT:** Becton Dickinson Control Syringe, a device that consists of a 10cc calibrated hollow plastic barrel and a movable plunger, Recall #Z-983-6  
**CODE:** Catalog number 304134, Lot #6C428, 6C429.  
**MANUFACTURER:** Becton Dickinson Division, North Canaan, Connecticut.  
**RECALLED BY:** Becton Dickinson, Franklin Lakes, New Jersey by telephone April 18, 1996, with follow-up letter of April 23, 1996. Firm-initiated recall complete.  
**DISTRIBUTION:** Connecticut  
**QUANTITY:** 40,900 units were distributed.  
**REASON:** A molding problem could result in cracked thumbing.

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

**NSN** 6515 Nonstandard  
**PRODUCT:** Biological Microroughins Latex Examination Gloves, Powder-Free in all sizes, Recall #Z-1054-6.  
**CODE:** "CM 1054 M 9403".  
**MANUFACTURER:** Tekmedic (M) SDN. BHD., Taman Tun Drismai, Mali.  
**RECALLED BY:** Intax Inc. (d/b/a Calderwood Rubber & Plastic),

Santa Barbara,  
California by letter and telephone August 4, 1994.  
Firm-initiated recall complete.

**DISTRIBUTION:** California.

**QUANTITY:** 655 cases were distributed.

**REASON:** The gloves failed the water leak test.

None Present

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

NSN 6515 Nonstandard

**PRODUCT:** Haemotronic Arterial Venous Blood Tubing Set for  
Hemodialysis Model 5M 4208, Recall #Z-1096-6.

**CODE:** Lot #B942538.

**MANUFACTURER:** Haemotronic S.p.A., Modena, Italy.

**RECALLED BY:** Haemotronic Inc., Fairfield, New Jersey by fax on  
April 3, 1996. Firm-initiated recall ongoing.

**DISTRIBUTION:** Tennessee.

**QUANTITY:** 9,984 sets were distributed.

**REASON:** The device is subject to blood leakage.

None Present

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

NSN 6515 Nonstandard

**PRODUCT** Transmucosal Implant Extensions, endosseous  
implant accessories used for dental  
restoration surgery:

(a) Second Phase Set, Catalog No. 8246S; 4.0  
mm Diameter x 4.0 mm High;

(b) Transmucosal Implant Extension (TIE)  
Catalog No. 8265A, 4.0 mm Diameter x 4.0 mm  
High. Recall #Z-1133/1134-6.

**CODE** Lot Numbers: (a) 302406, 307908, 301311,  
413002, 413704, 409106, 421206, 412908,  
407809, 417209, 404210, & 416510; (b) 305909,  
412909, 413503, 405704, 400905, 407606,  
422006, 407606, 412508.

**MANUFACTURER** Intepore International, Irvine, California.

**RECALLED BY** Manufacturer, by letters on January 31, 1995.  
and March 10, 1995. Firm-initiated recall  
complete.

**DISTRIBUTION** Nationwide, Mexico, Lebanon, Canada, Taiwan.

**QUANTITY** 1,926 units were distributed; firm estimated  
that little if any product remained on market

at time of recall initiation.

**REASON** The packaging labels were labeled as 4.0 x 1.0 mm IMC Titanium Inserts when the packages actually contained products with a 4.0 x 4.0 mm Transmucosal Implant Extension.

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

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**NSN** 6515 Nonstandard

**UPDATE** Davis-Geck Valtrac Bar Biofragmentable Anastomosis Ring, Recall #Z-1043/1051-6 which appeared in the August 28, 1996, Enforcement Report listed an incorrect product number for item (b). The correct product number is 8083-00.

**RECALLED BY** also failed to provide the following information: Sherwood Medical Company, St. Louis, Missouri, issued two letters dated May 22, 1996, to U.S. accounts and a letter dated May 23, 1996, to foreign accounts, requesting return of only Control No. 894100 of Product No. 8083-00, and that the consignees examine all other lot numbers (Control Nos.) of all Product Numbers listed for proper orientation of the device. Any device found not properly oriented was not to be used, but returned for replacement. Firm-initiated field correction ongoing.

See AFMLL 20-96.

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

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**CLASS III RECALLS:**

**NSN** 6505 Nonstandard

**PRODUCT** Oral Suspension Pepcid, 40 mg per 5ml constituted, 400 mg for constitution, product is used for the treatment of duodenal and gastric ulcers, gastroesophageal reflux and various hypersecretory conditions.  
Recall #D-255-6.

**CODE** Lot Numbers D0120, D0121, D0129, D0133, all

labeled with EXP SEP99.  
**MANUFACTURER** Merck Manufacturing Division, West Point, PA.  
**RECALLED BY** Manufacturer by letter August 29, 1996. Firm-  
initiated recall ongoing.  
**DISTRIBUTION** Nationwide.  
**QUANTITY** 3,500 packages were distributed.  
**REASON** Several lots were labeled with an incorrect  
expiry date of Sep99; the correct expiry date  
is Nov98.

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

**NSN** 6505 Nonstandard  
**PRODUCT** Apothe'Cure brand 4-Aminopyridine Sr. 17.5 mg  
capsules. Recall #D-261-6.  
**CODE** Not coded.  
**MANUFACTURER** Apothe'Cure, Inc., Dallas, Texas.  
**RECALLED BY** Manufacturer by letters mailed and hand  
delivered on August 5, 1996. Firm-initiated  
recall ongoing.  
**DISTRIBUTION** Nationwide, Canada, United Kingdom.  
**QUANTITY** Undetermined.  
**REASON** FDA analysis found samples to be super and  
subpotent. Current GMP deficiencies.

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

**NSN** 6505 Nonstandard  
**PRODUCT** Zeneca brand Elavil (Amitriptyline HCl) 50 mg  
tablets in bottles of 100, product is an  
antidepressant with sedative effects.  
Recall #D-262-6.  
**CODE** Lot number 4404W, EXP March 2000.  
**MANUFACTURER** Merck & Company, Inc., West Point,  
Pennsylvania.  
**RECALLED BY** Zeneca Pharmaceuticals Inc., Wilmington,  
Delaware, by telephone August 28, 1996,  
followed by letter August 29, 1996. Firm-  
initiated recall ongoing.  
**DISTRIBUTION** Massachusetts, New Jersey, Ohio, Pennsylvania,  
Tennessee, Virginia, and Puerto Rico.  
**QUANTITY** 50 cases (600 bottles per case) were  
distributed between August 14 and 22, 1996.

**REASON** Some shipping cases for one Elavil lot were mislabeled to indicate the contents were another product, Sorbitrae 5 mg Chewable Tablets.

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

**NSN** 6515 Nonstandard

**PRODUCT:** Linvatec brand, SPIKED WASHER, Catalog Number 8631S, 17mm X 2.5, Sterile, Single used in conjunction with Linvatec soft tissue anchoring screws to attach ligaments, tendons and other soft tissues to long bone, Recall #Z-1095-6

**CODE:** Lot Number 33747

**MANUFACTURER:** Linvatec, Largo, FL 34643

**RECALLED BY:** Manufacturer, by letter July 12, 1996.  
Firm-initiated recall ongoing.

**DISTRIBUTION:** Nationwide.

**QUANTITY:** 26 devices were distributed.

**REASON:** Both the package and etching on the washer was labeled as 17mm x 2.5 instead of the correct dimension of 17mm x 1.3.

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

**NSN** 6515 Nonstandard

**PRODUCT** Vacutainer Brand Safety-Lok Needle Holder, Catalog #366213, used during blood collection, Recall #Z-1108-6.

**CODE** Lot numbers: 6A255, 6A256, 6B250, 6B251, 6B252, 6C250, 6C251, 6C252, 6C253, Lots recalled in Europe: 5L251/55, 5M251, 6A250/53, 6A259.

**MANUFACTURER** Becton Dickinson Vacutainer Systems, Sumter, South Carolina.

**RECALLED BY** Becton Dickinson Vacutainer Systems, Franklin Lakes, New Jersey, by telephone April 22, 1996, followed by letter on May 13, 1996.  
Firm-initiated recall ongoing.

**DISTRIBUTION** Nationwide and Europe.

**QUANTITY** 526,500 estimated amount remain on market.

**REASON** Improper assembly lock mechanism.

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

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**NSN** 6515 Nonstandard  
**PRODUCT** Exeter Broach, a handheld, reusable orthopedic device made of stainless steel used to prepare (ream) the femoral canal for implantation of the femoral stem during reconstructive hip surgery. Recall #Z-1112/1113-6.  
**CODE** All units.  
**MANUFACTURER** Howmedica International, Inc., Herouville, France.  
**RECALLED BY** Pfizer Hospital Products Group, Rutherford, New Jersey, by letter April 18, 1996. Firm-initiated recall complete.  
**DISTRIBUTION** Nationwide.  
**QUANTITY** 6 units were distributed.  
**REASON** The distal tip of the broach may break off during use.

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

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**NSN** 6515 Nonstandard  
**PRODUCT** Vacutainer Brand Plus SST Test Tubes, used by health care professionals to collect patient blood at health care facilities packaged in a paperboard box, 100 units per box. Recall #Z-1109-6.  
**CODE** Lot number 5L 305.  
**MANUFACTURER** Becton Dickinson Vacutainer Systems, Sumter, South Carolina.  
**RECALLED BY** Becton Dickinson, Franklin Lakes, New Jersey by telephone April 3, 1996. Firm-initiated recall ongoing.  
**DISTRIBUTION** New Jersey, South Carolina.  
**QUANTITY** 51,000 units were distributed.  
**REASON** An incorrect tube dimension was printed on the shelf cartons.

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

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**NSN** 6515 Nonstandard  
**PRODUCT** Total Knee Flat Tibial Wedge. Recall #Z-1125-6.

**CODE** AWWZA, AXOVA, AXPVB. Lot code written on the outside of the box.

**MANUFACTURER** Howmedica, Inc., Rutherford, New Jersey.

**RECALLED BY** Manufacturer by a market withdrawal letter dated December 5, 1995. Firm-initiated recall complete.

**DISTRIBUTION** Nationwide, Australia, Ireland, Canada, New Zealand.

**QUANTITY** 72 units were distributed.

**REASON** Instead of product containing a small right component as labeled, it may contain a small left component.

None Present  
 Action Taken \_\_\_\_\_  
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**NSN** 6515 Nonstandard

**PRODUCT** Total Knee Flat Tibial Wedge, a small, vitallium alloy, kidney shaped device used in conjunction with the tibial baseplate during reconstructive knee surgery.  
Recall #Z-1126-6.

**CODE** Catalog # 6630-6-110; lot number BPGEC.

**MANUFACTURER** Howmedica, Incorporated, Rutherford, New Jersey.

**RECALLED BY** Manufacturer by letter April 19, 1996. Firm-initiated recall complete.

**DISTRIBUTION** New Jersey.

**QUANTITY** 25 devices were manufactured; firm estimates none remain on market.

**REASON** Product misbranded, instead of containing a Right, Small -1 component as labeled, it may contain a Left, Small - 1 component.

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

**NSN** 6515 Nonstandard

**PRODUCT** Hip Stem Endoprosthesis:  
(a) Sentry, Catalog No. 6258-5-008, 5 Right, 250mm Length, 15.5mm Diameter;  
(b) Sentry, Catalog No. 6258-5-005, 4 Right, 250mm Length, 15.5mm Diameter;  
(c) Sentry, Catalog No. 6258-4-012, 5 Left, 250mm Length, 21.5mm Diameter;  
(d) Austin Moore, Catalog No. 6940-9-400, Labeled 9" in Length. Recall #Z-1127/1130-6.

**CODE** Lot Codes: (a) ATMNB; (b) CHXZA; (c) CHTZA; (d) OKYVA.

**MANUFACTURER** Howmedica, Inc., Rutherford, New Jersey.

**RECALLED BY** Manufacturer, (a) by fax on November 17, 1995; (b) by fax on January 10, 1996; (d) by fax on December 7, 1995. Firm-initiated recall complete.

**DISTRIBUTION** (a) Massachusetts, New Jersey, Virginia; (b) Minnesota, California, (c) Virginia; (d) Minnesota.

**QUANTITY** Amount shipped: (a) Lot code: ATMNB - 4

units, CCKFA - 0 units, (b) Lot code: CHXZA - 2 units; (c) Lot code: CHTZA - 1 unit; (d) Lot code: OKYVA - 2 units.

**REASON** Packaging, labeling, and sizing mix-ups led to packages with incorrect labeling or product.

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

**NSN** 6515 Nonstandard

**PRODUCT** Head and Neck Replacement (HNR) Log Stem, Catalog #6257-2-300. Recall #Z-1131-6.

**CODE** Lot Code COGSC.

**MANUFACTURER** Howmedica, Inc., Rutherford, New Jersey.

**RECALLED BY** Manufacturer, by fax on February 21, 1996. Firm-initiated recall complete.

**DISTRIBUTION** Pennsylvania, West Virginia, Georgia, Michigan, Washington state, Ohio.

**QUANTITY** 8 units were distributed.

**REASON** Instead of containing a 200 mm x 43 mm long stem as labeled, the package may contain a 225 mm x 43 mm long stem.

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

**NSN** 6515 Nonstandard

**PRODUCT** Osteonics Omnifit Cup Insert series, sterile, implantable, non-critical Rx devices:

(a) Osteonic Omnifit 10 Degree cup Insert

Series I, 28 mm, Catalog #2002-2854; (b)

Osteonics Omnifit 20 Degree Cup Insert Series

II, 26 mm, Catalog #2042-2654.

Recall #Z-1153/1154-6.

**CODE** (a) Case # 1NCGW; (b) Case #1NCGM.

**MANUFACTURER** Osteonics Corporation, Allendale, New Jersey.

**RECALLED BY** Manufacturer, by telephone on April 22, 1996, followed by letter on April 30, 1996. Firm-initiated recall complete.

**DISTRIBUTION** Nationwide and international.

**QUANTITY** (a) 24 units; (b) 11 units were distributed.

**REASON** The 20 degree labeled package may contain the 10 degree unit, and vice-versa.

None Present

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

**NSN** 6515 Nonstandard  
**PRODUCT** EP Medical Electrophysiology Catheters 2mm and 2, 5, 2mm electrode spacing intended for ECG recording, intercardiac pacing, stimulation and sensing in sterile form:  
(a) Model EPM-64-SC-252; (b) Model EPM-64-HD-2; (c) Model EPM-64-SC-2.  
Recall #Z-1150/1152-6.  
**CODE** Lot #95117, use before 6/97.  
**MANUFACTURER** ProCath Corporation Subsidiary of EP Medical, Inc., Berlin, New Jersey.  
**RECALLED BY** Manufacturer, by letter on October 17, 1995, and January 19, 1996. Firm-initiated recall complete.  
**DISTRIBUTION** Nationwide.  
**QUANTITY** 21 catheters were distributed.  
**REASON** The tubing weld joints may separate if handled forcefully prior to insertion. The separation of the tubing weld joint can result in a loss of torque of the distal tip curve. A loss of torque would render the catheter ineffective.

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

**NSN** 6550 Nonstandard  
**PRODUCT** Coat-A-Count Total Testosterone Kits, use in measurement of testosterone antibody.  
Recall #Z-1115-6.  
**CODE** Lot numbers: TTT1 544, TKTT5 679; TKTT2 789.  
**MANUFACTURER** Diagnostic Products Corporation, Los Angeles, California.  
**RECALLED BY** Manufacturer by notice November 11, 1993.  
Firm-initiated recall complete.  
**DISTRIBUTION** Nationwide, international.  
**QUANTITY** 3,802 bags were distributed.  
**REASON** The device was not coated, and therefore will not perform accurately in the assay.

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

**NSN** 6550 Nonstandard  
**PRODUCT** Columbia Calibre Liquid Spinal Fluid Control Assayed Level 1, used as a clinical chemistry

control in spinal fluid assays.

Recall #Z-1116-6.

**CODE** Lot number 4001740.

**MANUFACTURER** Biocell Laboratories, Inc., Rancho Dominguez,  
California.

**RECALLED BY** Manufacturer, by telephone June 15, 1993.

Firm-initiated recall ongoing.

**DISTRIBUTION** Nationwide.

**QUANTITY** 5,910 vials were distributed.

**REASON** The device contains a fungal contamination and  
is subject to leakage around the cap.

None Present

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

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**NSN** 6550 Nonstandard

**PRODUCT** STACLOT Protein S Kit, 20 test/kit, used for  
quantitative determination of functional  
protein S based on the inhibition of factor  
Va, for in vitro diagnostic use only.

Recall #Z-1117-6.

**CODE** Lot number 953124; EXP May 1997.

**MANUFACTURER** Diagonostica-Stago, France.

**RECALLED BY** American BioProducts Company (ABC),  
Parsippany, New Jersey by letter December 6,  
1995. Firm-initiated recall complete.

**DISTRIBUTION** Nationwide.

**QUANTITY** 1,519 kits were distributed, approximately  
1,000 remain on market.

**REASON** An over estimation of the Protein S activity  
level.

None Present

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

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**NSN** 6550 Nonstandard

**PRODUCT** DELFIA LH-Spec Time-Resolved Fluoroimmunoassay  
Kit, used for the quantitative determination  
of human luteinizing hormone in serum and  
plasma for ovulation detection in urine.

Recall #Z-1118-6.

**CODE** Lot numbers: 651552, 651553, 651555, 653872,  
655741, 656511.

**MANUFACTURER** Wallac Oy, Turku, Finland.

**RECALLED BY** Wallac, Inc., Gaithersburg, Maryland, by

telephone July 2, 1996. Firm-initiated recall ongoing.

**DISTRIBUTION** Pennsylvania, Massachusetts, Missouri, Georgia, Washington, New Jersey, Michigan, Texas, California.

**QUANTITY** 396 kits were distributed.

**REASON** The stability testing of the device revealed that within-plate variation increased over time.

None Present

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

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**NSN** 6550 Nonstandard

**PRODUCT** Drug of Abuse Control CON-DOA Level 1, used in the measurement of the level of drugs in individuals. Recall #Z-1119-6.

**CODE** Lot numbers: DOAC1 008.

**MANUFACTURER** Diagnostic Products Corporation, United Kingdom.

**RECALLED BY** Diagnostic Products Corporation, Los Angeles, California by telephone and fax January 19, 1994. Firm-initiated recall complete.

**DISTRIBUTION** Nationwide, Sweden, United Kingdom.

**QUANTITY** 2,374 vials were distributed.

**REASON** The level of THC in a single vial of DOAC1 008 was 2-3 times the targeted values.

None Present

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

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**NSN** 6550 Nonstandard

**PRODUCT** Package insert associated with Dade Immunoassay Control Comprehensive Tri-Level Kit, in-vitro diagnostic kit used to assist in monitoring accuracy and precision in clinical assays: (a) Catalog Nos. B5700-05, B5700-S; (b) Catalog No. B5700-06; (c) Catalog No. B5700-07; (d) Catalog No. B5700-08. Recall #Z-1135/1138-6.

**CODE** Lot Numbers: (a) IACK-28; (b) IAC1-128; (c) IAC2-228; (d) IAC3-328. All kits expire on March 26, 1998.

**MANUFACTURER** Dade International, Inc., Miami, Florida.

**RECALLED BY** Manufacturer, by letter dated June 1996

containing corrected package insert. Firm-initiated field correction complete.

**DISTRIBUTION** Nationwide and Italy.

**QUANTITY** 10,776 kits were distributed.

**REASON** The package insert had multiple inconsistencies that included an incorrect assay range.

None Present

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

**NSN** 6550 Nonstandard

**PRODUCT** Incstar FTA-ABS Fluoro Test Kit, in-vitro diagnostic for detecting antibodies in human serum to syphilis: (a) - Catalog No. 1910; (b) Catalog No. 1910G; (c) Catalog No. 6910; (d) Incstar FTA-ABS Test Sorbent, Catalog No. 1866. Recall #Z-1139/1142-6.

**CODE** Lot Numbers: (a) 115516, 115606A, 175436, 175446, 195796, 215126, 195796B, 142016, 142016A, 205356, 205356A, 265356, 265376, 295196, 265366;  
(b) 142016, 142016A, 205356, 205356A;  
(c) 115506, 175426A, 175436A, 175416, 195796A, 215216A, 265376A, 295196A;  
(d) 122156, 122156A, 122156B.

**MANUFACTURER** Incstar Corporation, Stillwater, Minnesota.

**RECALLED BY** Manufacturer, by letter on August 12, 1996.  
Firm-initiated recall complete.

**DISTRIBUTION** Nationwide and international.

**QUANTITY** Incstar FTA-ABS Fluoro Test Kits, product numbers 1910, 1910G and 6910: 587 of the test kits were distributed. Incstar FTA-ABS Test Sorbent, product number 1866: 30 of the test kits were distributed.

**REASON** Some negative samples may yield a positive assay response.

None Present

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

**NSN** 6550 Nonstandard

**PRODUCT** C. Albicans Growth Promotion Test Suspension, Catalog #GP-03, used for USP growth promotion testing. Recall #Z-1149-6.

**CODE** Lot numbers: GCA010-010, GCA010-012.  
**MANUFACTURER** North American Science Associates (NAMSA),  
Northwood, Ohio.  
**RECALLED BY** Manufacturer, by letter August 28, 1996.  
Firm-initiated recall ongoing.  
**DISTRIBUTION** Nationwide, Ireland, Japan, Singapore.  
**QUANTITY** 110 vials were distributed.  
**REASON** There was a reduction in spore population  
below the labeled range.

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

**NSN** 6550 Nonstandard  
**PRODUCT** VAI Cultureset Herpes Simplex Virus (HSV)  
Identification Kit 501020, Immunoperoxidase  
Staining Kit for use with Viral Tissue Culture  
Isolation, for in-vitro diagnostic use.  
Recall #Z-1145-6.

**CODE** Lot 106, EXP 26 MAY 97.  
**MANUFACTURER** VAI Diagnostic, Memphis, Tennessee.  
**RECALLED BY** Manufacturer, by telephone or letter on June  
21, 1996. Firm-initiated recall complete.  
**DISTRIBUTION** Nationwide.  
**QUANTITY** 224 kits were distributed.  
**REASON** The device has exhibited an unexpected drop in  
the reactivity of the labeling reagent,  
included in the kit. As a result, the  
intensity of staining in positive samples may  
reduced.

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

**MEDICAL INFORMATION:**

Reference Q. A. message 6185-0015 which Suspended/Recalled Immune Globulin and Q. A. message 6229-0021 which provided Policy/Guidelines and Disposition. DPSC has advised that activities having depot stock materiel shall return all units via U S. Mail or other carrier to the following:

Rhone-Poulenc Rorer (RPR)  
Distribution Center  
Attn: Returned Goods Processing

18504 West Creek Drive  
Tinley Park, IL 60477 USA

Enclose a letter with name and address of your activity citing quantity of each affected lot number being returned. Request that credit for returned goods and associated shipping charges be given to DPSC Financial Office (DFAS), Columbus, Ohio. Activities may apply for credit on return of materiel procured from a DLA depot by submitting a SF380 marked "credit requested" (in block 19) to DPSC, citing lot numbers and quantity returned. A copy of return document indicating quantity of materiel returned confirmation of the return. Credit requests received without the required evidence of return to Centeon will not be considered for credit.  
This confirms Q. A. message 6264-0023.

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



