

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 13457, 13462,  
15175, N1509**

PRODUCT  
CODE  
MANUFACTURER  
RECALLED BY  
DISTRIBUTION  
QUANTITY  
REASON

**Scales (General)**

Model 1200 Mini Digital Hanging Scale Recall # Z-1237-9  
FRW 1424423  
Integrated Measurement Systems, Inc., Elk Grove Village, IL.  
Manufacturer, by letter on 8/7-10/99. Firm-initiated recall ongoing.  
Nationwide.  
113 scales.  
The scale may disconnect fro the lifter boom.  
 None Present  
 Action Taken \_\_\_\_\_

**6520 NS**

**MDC 11232**

PRODUCT  
CODE  
MANUFACTURER  
RECALLED BY  
DISTRIBUTION  
QUANTITY  
REASON

**Dialyzer, Hemodialysis**

Hemodialysers. Recall # Z-1238-9.  
Lot: 757980911A.  
Althin Medical, Inc., Miami Lakes, FL.  
Manufacturer, on August 26, 1999 by letter via courier.  
Senko Medical Instrument Mfr., Toyko Japan.  
3876 units.  
Crack blood ports which may compormise the sterility barrier and  
cause leakage.  
 None Present  
 Action Taken \_\_\_\_\_

**6525 NS**

**MDC 13281**

PRODUCT  
CODE  
MANUFACTURER  
RECALLED BY  
DISTRIBUTION  
QUANTITY  
REASON

**Computers, Radiotherapy Planning System**

3-D Imgcomp Utility User Manual Update, Z-1223-9  
All Versions (2.72b & 3.07d)  
Precision Therapy International, Inc., Norcross, GA  
Manufacturer, by letters faxed on February 10, 1999. Field  
correction ongoing.  
Nationwide and international.  
190 Manuals  
A design error may lead to a serious miscalculation of radiation  
dose.  
 None Present  
 Action Taken \_\_\_\_\_

**CLASS III RECALLS:**

**6520 NS**

**MDC 11156**

PRODUCT

**Dental Engines**

STRAUMANN INTRAsurg 500, an AC powered drilling device intended

	to supply power to and serve as a base for other dental devices such as a dental handpiece during dental and maxillofacial surgery. Z-1215-9.
CODE	Serial #s: 824-828, 830, and 831.
MANUFACTURER	KAVO DENTAL GmbH Biberach-Riss, Germany
RECALLED BY	The Straumann Co., Waltham Massachusetts, by _____ on June 30, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Arizona, California, Delaware, Massachusetts, Montana, Texas.
QUANTITY	7 Units were distributed.
REASON	Software error may cause unit to shutdown prior to reaching preset torque limit. [ ] 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 **5 November 99** 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>6515 Nonstandard</b>
PRODUCT	Indigo Bare-Tip fiberoptic. Recall #Z-1224-9
CODE	LF020
MANUFACTURER	Ethicon Endo-Surgery, Inc. Albuquerque, NM
RECALLED BY	Indigo Medical, Inc., Cincinnati, Oh, on August 6, 1999 by telephone and letter dated August 6, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	TN, PA, AR, KY and NY.
QUANTITY	9 units
REASON	I fiberoptic tip is contaminated. [ ] None Present [ ] Action Taken _____

**CLASS II RECALLS:**

NSN

PRODUCT  
CODE

MANUFACTURER  
RECALLED BY

DISTRIBUTION  
QUANTITY  
REASON

**6505 Nonstandard**

Fresh Frozen Plazma. B-1172-9.

Unit Numbers:

20LY15001, 20LY15002, 20LY15006, 20LY14986, 20LY14987, 20LY14988,  
20LY14989, 20LY14990, 20LY14991, 20LY14992,  
20LY14993, 20LY14994, 20LY14995, 20LY14996, 20LY14997,  
20LY14998, 20LY14999, 20LY15000.

American Red Cross (Lewis and Clark Region), Boise, Idaho  
Manufacturer, by telephone on July 23, 1998 and September 15,  
1998 and letters dated September 15, 1998, and October 20, 1998.

Utah

18 Units were distributed.

Blood products, for which freeze time was as not documented, were  
distributed.

None Present

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

NSN

PRODUCT  
CODE

MANUFACTURER  
RECALLED BY

DISTRIBUTION  
QUANTITY  
REASON

**6505 Nonstandard**

Platelets, Pheresis

Units 40P68486, 40P68040, 40P673000, 40P67158.

American Red Cross.

American Red Cross Blood Services Heart of America Region on July 2, 1999 by  
letter.

Illinois and Missouri.

4 units.

Blood Products collected from a donor who reported travel to an  
area designated as endemic for malaria, were distributed.

None Present

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

NSN

PRODUCT

CODE

MANUFACTURER  
RECALLED BY  
DISTRIBUTION  
QUANTITY  
REASON

**6515 Nonstandard**

a)Rotablator RotaLink Plus Pre-connected Exchangeable  
Rotational Atherectomy System Z-1220-9

b)Rotational RotaLink Coronary Advancer Z-1221-9

c)Rotablator RotaLink Peripheral Advancer Z-1222-9

Cat NOS.a) 23631-002-23631-007, 23631-015, 23631-016,

b) 22782-001A0, 22782-0010

c) 11381-90

Boston Scientific Corporation, Redmond, WA

Manufacturer, by . Firm-initiated recall ongoing.

Nationwide.

Braking mechanism may fail to secure guidewire during use.

None Present

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

NSN

PRODUCT

CODE

MANUFACTURER  
RECALLED BY

**6515 Nonstandard**

Mimi-Acutack 1.5 mm Cannulated Hex Driver Tip, Part #HAD-L-0815.

Recall #Z-1225-9

HWC

ACUMED, INC., Beaverton, OR.

Manufacturer, on July 6 and 12, 1999 by faxed Recall notice.

DISTRIBUTION Firm-initiated recall on-going.  
QUANTITY Nationwide.  
REASON 4 each.  
The Hex driver tips may prevent the Mini-Acutrak Bone Screw from seating properly.  
[ ] None Present  
[ ] Action Taken \_\_\_\_\_

**NSN**  
PRODUCT **6515 Nonstandard**  
CODE Tracheostomy Care Trays. Recall # Z-1232/1235-9  
MANUFACTURER Catalog #4118  
RECALLED BY Sterling Disposable Products, Inc., Chicago, Ill.  
DISTRIBUTION Premium Plastics, Chicago, Ill., August 30, 1999 by letter.  
QUANTITY Nationwide.  
REASON 122,840 trays.  
Trays were contaminated with ETO resistant mold.  
[ ] None Present  
[ ] Action Taken \_\_\_\_\_

**CLASS III RECALLS:**

**NSN**  
PRODUCT **6550 Nonstandard**  
CODE APLIGRAF (GRAFTSKIN), indicated for use with standard therapeutic compression for the treatment of non-infected partial and full thickness skin ulcers due to venous insufficiency of greater than 1-month duration which has not responded to conventional therapy.  
RECALL #Z-1219-9.  
LOT NUMBER: LOT NUMBER:  
GS9906.22.03.1A  
Unit Numbers: 42, 43,45, 46, 47, 50, 52-74, and 76  
LOT NUMBER: GS9906.22.03.2A  
Unit Numbers: 1, 3, 5, 6, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19, 21, 22, 23, 24, 25, 26,28, 29, 30, 31, 32, 34, EXP July 22, 1999.  
MANUFACTURER ORGANOGENESIS INC.  
CANTON,Massachussets  
RECALLED BY Novartis Pharmaceuticals Corp. (Global Distributor), East Hanover, New Jersey by  
Telephone on on July 21, 1999, followed by letter on July 22, 1999. Firm-initiated recall ongoing.  
DISTRIBUTION Alabama, Arizona, California, Georgia, Illinois, Indiana, New York, Massachusetts, Maryland, Maine, Michigan, Missouri, North Carolina, Ohio, Pennsylvania, South Carolina, Texas.  
QUANTITY 58 units were distributed.  
REASON products ph may be out of specification due to packaging error.  
[ ] None Present  
[ ] Action Taken \_\_\_\_\_