

**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:

6530NS
MDC 12113 Incubators, Infant (Non-Transport)
PRODUCT Servo O2 Oxygen Control System, used to provide precise control of oxygen concentration for infants in the Care Plus Incubator or under oxygen hoods. Recall #Z-134-7.

CODE Part #6600-0236-901. All serial numbers.
MANUFACTURER BPR Medical Systems, Mansfield, Notts, United Kingdom.
RECALLED BY Ohmeda, Specialty Products Division, Columbia, Maryland, by letter dated October 14, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Tennessee, California.
QUANTITY 33 units were distributed.
REASON The low battery audible alarm may not sound prior to battery depletion and subsequent device shutdown, and the nominal time of operation remaining after activation of the visual low battery alarm is seven minutes rather than the specified nominal value of ten minutes.

[] 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 24 JAN 97 for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DPSC purchase order number, contract number, and stock record account number (SRAN). (FOM-P), Bonnie Phillips, DSN (343-7445)

CLASS I RECALLS: None

CLASS II RECALLS:

NSN	6505 Nonstandard
PRODUCT	Pseudoephedrine HCl, adrenergic bulk pharmaceutical, non-Rx, under the following labels: China Meheco Zhuhai Import & Export Company, Buckton Scott Limited, and H. Reisman Corporation. Recall #D-035-7.
CODE	Lot numbers: 940501 (Buckton Scott), PSE-02501 (H. Reisman).
MANUFACTURER	China Meheco Zhuhai Import & Export Company, China (bulk manufacturer).

RECALLED BY H. Reisman Corporation, Orange, New Jersey
(importer), by telephone May 24, 1995 followed
by letter via fax. Firm-initiated recall
complete.
DISTRIBUTION Michigan, Texas.
QUANTITY 145 kg were distributed; firm estimated that
10 percent of product remained on market at
time of recall initiation.
REASON Pseudoephedrine HCl was mistakenly mixed with
Ephedrine HCl.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Nature's Formula Herbal Espresso, in 1 fluid
ounce/30 ml plastic bottles, dietary
supplement. Recall #D-036-7.
CODE All lots distributed prior to August 30, 1996.
MANUFACTURER EFS-Herbal Drops, San Diego, California.
RECALLED BY Manufacturer, by letter sent September 18-20,
1996. Firm-initiated recall complete.
DISTRIBUTION Arizona, Arkansas, California, Florida,
Louisiana, Minnesota, Mississippi, Nevada,
Oklahoma, Tennessee, Texas, Utah, Washington
state, Wisconsin, Canada.
QUANTITY Approximately 3,609 bottles were distributed.
REASON Unapproved new drug; product labeled for use
as a bronchodilator.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT UDL Laboratories brand Amantadine HCl
Capsules, USP, 100 mg, unit dose packaged in
blister pack strips of 10, Rx indicated in the
treatment of idiopathic Parkinson's disease.
Recall #D-037-7.
CODE Lot #5V850 EXP 6/97.
MANUFACTURER Banner Pharmacaps formerly known as Chase
Laboratories, Inc., Newark, New Jersey
(responsible firm).

RECALLED BY UDL Laboratories, Inc., Rockford, Illinois
(repacker), by letter dated October 30, 1996.
Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
QUANTITY 2,093 unit cartons were distributed; firm
estimated that 20 percent of product remained
on market at time of recall initiation.

REASON Dissolution failure at 9-month stability
timepoint.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Minocycline Hydrochloride Capsules, USP, 50
mg, in bottles of 100. Recall #D-038-7.
CODE Lot #11415L EXP 1/97.
MANUFACTURER Warner-Lambert Company, Lititz, Pennsylvania
(responsible firm).

RECALLED BY Warner Chilcott, Inc., Morris Plains, New
Jersey, by letter dated October 18, 1996.
Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
QUANTITY 4,767 bottles were distributed.

REASON Lot failed content uniformity test (one
capsule was less than 67%LS, RSD of 10 is
13%).

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Clamping Adaptor, GammaMed 121 High Dose Rate
Afterloader, used with a bronchial catheter.
Recall #Z-059-7.
CODE Part #931012.
MANUFACTURER Isotopen-Technic Dr. Sauerwein GMBH, Haan,
Germany.

RECALLED BY Frank Barker Associates, Inc., Towaco, New
Jersey, by letter dated August 18, 1995.
Firm-initiated recall complete.

DISTRIBUTION Nationwide and Canada.
QUANTITY 62 units were distributed.

REASON The clamping adaptor does not allow the iridium-192 sealed source to return to its fully shielded position if the catheter becomes disconnected.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT (a) Peri-Guard Pericardium
(b) Supple Peri-Guard Pericardium. Products are prepared from bovine pericardium and are patches used primarily for pericardial closure and hernia repair.
(c) Peri-Strips Staple Line Reinforcement, intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using linear cutter surgical staplers.
Recall #Z-061/063-7.

CODE All lots.
MANUFACTURER Bio-Vascular, Inc., St. Paul, Minnesota.
RECALLED BY Manufacturer, through meetings and telephone conference calls during the period from approximately January 1996 to April 1996, and by notification sent on September 23, 1996; and by sending revision of indications for use to customers who received the product. No product was returned. Firm-initiated field correction ongoing.

DISTRIBUTION Nationwide.
QUANTITY (a) 1,783 units; (b) 832 units; (c) 166 units were distributed.

REASON Devices have caused or contributed to infections and/or foreign body reactions when used as transvaginal urethral sling implants for incontinence, as labeled.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Torcon NB Advantage Selective Angiographic Catheters:
(a) Torcon NB Advantage Angiographic Catheter H1 Headhunter Cerebral with Beacon Enhanced Radiopaque Tip, French Size 4.1, Product HNBR4.1-35-100-P-NS-H1;

(b) Torcon NB Advantage Angiographic Catheter H1 Headhunter Cerebral with Beacon Enhanced Radiopaque Tip, French Size 5.0, Product HNBR5.0-38-100-P-NS-H1;

(c) Torcon NB Advantage Angiographic Catheter H1 Headhunter Cerebral with Beacon Enhanced Radiopaque Tip, French Size 6.0, Product HNBR6.0-38-100-P-NS-H1;

(d) Torcon NB Advantage Angiographic Catheter H1 Headhunter Cerebral with Beacon Enhanced Radiopaque Tip, French Size 7.0, Product HNBR6.0-35-100-P-NS-H1;

(e) Judkins Coronary Catheter Set, Reorder No. JCS-502;

(f) Judkins Coronary Catheter Set with Check Flo Performer Introducer Set, Reorder No. JCS-600-MM-090695;

(g) Judkins Coronary Catheter Set, Reorder No. JCS-601-MM-072795;

(h) Judkins Coronary Catheter Set with Micropuncture Check-Flo Performer Introducer Set, Reorder No. JCS-600-SA-090695;

(i) Marx-Cope Pediatric Gastrojejunostomy Set, Reorder No. GJS-1400-MCGJ;

(j) Gastrojejunostomy Set, Reorder No. GJS-1400-HIETTE-022895;

(k) Gastrojejunostomy Set, Reorder No. GJS-1400-HIETTE-072795;

(l) D'agostino Access Set, Reorder No. NPAS-100-D'AGOSTINO-A-050393;

(m) Colapinto Transjugular Cholangiography/Liver Biopsy Set, Reorder No. TJC-101-UPSTATE-092094;

(n) Mewissen Transfemoral Liver Biopsy Set, Reorder No. TLBS-100-MWSN.
Recall #Z-064/077-7.

CODE	All lots.
MANUFACTURER	Cook, Inc., Bloomington, Indiana.
RECALLED BY	Manufacturer, by letter dated September 24, 1996. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	207,288 units were distributed.

REASON Markers were made of stainless steel rather than platinum that resulted in reduced fluoroscope visibility.

[] None Present
[] Action Taken _____

NSN 6515 Nonstandard
PRODUCT Cordis brand PTA Balloon Catheter, "Powerflex" used for percutaneous transluminal angioplasty procedures:

- (a) Catalog No. 411-544T
- (b) Catalog No. 411-552T
- (c) Catalog No. 411-554T
- (d) Catalog No. 411-562T
- (e) Catalog No. 411-564T
- (f) Catalog No. 411-572T
- (g) Catalog No. 411-574T
- (h) Catalog No. 411-582T
- (i) Catalog No. 411-584T.

Recall #Z-079/087-7.

CODE Lot numbers: (a) S0196359
(b) R0396987, S0196448, S0196449, S0196450, S0196618
(c) R0596272, S0496555, S0496757
(d) R0496487, S0196451, S0196549, S0396130, S0496286, S0596258
(e) R0496656, R0596892, S0196554, S0396369, S0496623, S0596589
(f) R0296133, R0396721, R0496939, S0396440, W0196113
(g) R0296327, R0396719, R0496377, R0696682, S0596430, S0596718, S0596983, W0196089, W0696202
(h) R0296282, S0296115
(i) R0296332, R0396472, R0396437, R0696229, R0696427, R0696727, R0896371, S0196997, S0596100, S0796451, S0796927.

MANUFACTURER Cordis Europa, Roden, Netherlands.
RECALLED BY Cordis Corporation, Miami Lakes, Florida, by visit beginning on September 20, 1996 and completed on October 4, 1996. Firm-initiated recall complete.

DISTRIBUTION Nationwide.
QUANTITY 512 catheters were distributed.

NSN 6550 Nonstandard
PRODUCT SPORTROL Growth Promotion Test Suspensions,
containing Clostridium sporogenes, 10 ml of
suspension distributed in plastic vials, one
(1) vial per package, for USP growth promotion
testing. Recall #Z-130-7.
CODE Catalog #GP-02, Lot #GCS003-19.
MANUFACTURER North American Science Associates, Inc.,
NAmSA), Northwood, Ohio.
RECALLED BY Manufacturer, by telephone beginning on
October 29, 1996, followed by letter. Firm-
initiated recall ongoing.
DISTRIBUTION Nationwide, Ireland, Singapore, Japan.
QUANTITY 53 vials were distributed.
REASON There was reduction in the spore population
counts below the labeled range.

[] None Present
[] Action Taken _____

MEDICAL DEVICE SAFETY ALERTS:

NSN 6515 Nonstandard
PRODUCT Atrial Bipolar Pacing Leads:
(a) Model No. 4504 Capsure, Bipolar,
Implantable, Tined, Atrial Transvenous Lead
(b) Model No. 4504M Capsure, Steroid Eluting,
Bipolar, Implantable, Atrial Transvenous Lead
(c) Model No. 4582 Bipolar Atrial Pacemaker
Lead. Safety Alert #N-001/003-7.
CODE All serial numbers.
MANUFACTURER Medtronic Puerto Rico, Villalba, Puerto Rico.
ALERTED BY Medtronic, Inc., Minneapolis, Minnesota, by
letter October 4, 1996.
DISTRIBUTION Nationwide and international.
QUANTITY 26,806 leads were distributed.
REASON The devices may fail sooner than expected due
to insulation degradation (metal induced
oxidation (MIO), causing intermittent over-
and undersensing and possible intermittent
loss of capture.

[] None Present
[] Action Taken _____
