

NATIONAL RECALL ALERT CENTER - IMMEDIATE WARNING ALERT NOTIFICATION
THE FOLLOWING HAVE BEEN RECALLED OR ARE SUBJECT TO FIELD CORRECTION
THIS LISTING IS ISSUED BY - NATIONAL RECALL ALERT CENTER, WASHINGTON, D.C.

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MANUFACTURER Medtronic Sofamor Danek Deggendorf GmbH
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MANUFACTURER Covidien
PAGE 2

PRODUCT Respironics Esprit Ventilator System
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BIOLOGICALS

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PRODUCT Donor Management System (DMS Blood Management Computer System
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PRODUCT Haemonetics LN620 PCS2 Plasma Harness Set Model # LN620
MANUFACTURER Haemonetics Corp
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Route to _____ Status _____

PRODUCT **PediCap End-Tidal CO2 Detector (PediCap and PediCap6)**
RECALL NUMBER Not available at the time of this publication
CODE The following 80 lot numbers apply:
8294199 8301112 8301113 8315189 8315190 8319262 8319263 8322181 8322182
8326251 8326252 8326253 8326254 8329072 8329073 8330001 8333183 8350018
8350019 8354221 8354224 8357021 8357022 8361153 9005011 9005012 9012058
9012059 9026042 9026043 9033128 9033129 9040067 9040068 9047127 9047128
9054110 9054111 9061066 9061067 9065209 9068061 9068062 9072281 9075059
9075060 9079160 9082376 9082377 9086312 9089126 9089127 9103038 9103039
9110481 9110482 9117039 9117040 9124134 9124135 9131188 9131189 9138084
9138085 9138266 9145088 9145089 9152238 9152239 9159128 9159129 9170191
9170192 9170197 9176471 9176477 9184145 9191233 9191234 9204128
MANUFACTURED & RECALLED BY Covidien, formerly known as Tyco Healthcare, Boulder, CO
QUANTITY Limited to the 80 lot numbers listed above
DISTRIBUTION Nationwide
REASON A reported difficulty in manually ventilating an intubated patient through the PediCap. There is a possibility that a recent modification to the PediCap End-Tidal CO2 Detector may result in increased resistance to airflow through the PediCap. This could result in ineffective ventilation of the patient and/or inadequate detection of CO2 levels, so that the indicator paper will not change color.
CONTACT Technical services group can be reached at 1-800-635-5267, option 3, then option 1

Route to _____ Status _____

PRODUCT 1) Hospira Phoenix Infusion System with MedNet Software, Symbiq One-Channel Infusion System, Software versions v2.1 & v3.0
RECALL NUMBER # Z-1815-2009
PRODUCT 2) Hospira Phoenix Infusion System with MedNet Software, Symbiq Two-Channel Infusion System, Software versions v2.1 & v3.0
RECALL NUMBER # Z-1816-2009
CODE 1) List number 16026-04-83/84 and 87/88, software versions 2.1 and 3.0 only
2) List number 16027-04-83/84 and 87/88, software versions 2.1 and 3.0 only
MANUFACTURED & RECALLED BY Hospira, Inc., Morgan Hill, CA
QUANTITY 12,222 Units
DISTRIBUTION Nationwide
REASON Potential delay/under infusion of critical therapy-- Devices experience increased frequency of alarms that result in temporary pump stoppage.

Route to _____ Status _____

PRODUCT 1) Medtronic INTREPID Spinal System SPACER, 32X23, 8 DEG, Size: 10MM, Part Number: REF 7961810; 12MM, REF 7961812; 14MM, REF 7961814; 16MM, REF 7961816; 18MM, REF 7961818; 20MM, REF 7961820; Rx only, STERILE R. The

INTREPID Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease.

RECALL NUMBER
PRODUCT

Z-1796-2009
2) Medtronic INTREPID Spinal System SPACER, 32X23, 12 DEG, Size: 10MM, Part Number: REF 7961210; 12MM, REF 7961212; 14MM, REF 7961214; 16MM, REF 7961216; 18MM, REF 7961218; 20MM, REF 7961220; Rx only, STERILE R

RECALL NUMBER
PRODUCT

Z-1797-2009
3) Medtronic INTREPID Spinal System SPACER M 37X27, 8 DEG, Size 10MM, Part Number: REF 7962810; 12MM, REF 7962812; 14MM, REF 7962814; 16MM, REF 7962816; 18MM, REF 7962818; 20MM, REF 7962820; USA, Rx only, STERILE R

RECALL NUMBER
PRODUCT

Z-1798-2009
4) Medtronic INTREPID Spinal System SPACER M 37X27, 12 DEG, Size: 10MM, Part Number: REF 7962210; 12MM, REF 7962212; 14MM, REF 7962214; 16MM, REF 7962216; 18MM, REF 7962218; 20MM, REF 7962220; USA, Rx only, STERILE R

RECALL NUMBER
PRODUCT

Z-1799-2009
5) Medtronic INTREPID Spinal System SPACER L 42X30, 8 DEG, Size: 10MM: Part Number: REF 7963810; 12MM, REF 7963812; 14MM, REF 7963814; 16MM, REF 7963816; 18MM, REF 7963818; 20MM, REF 7963820; USA, Rx only, STERILE R

RECALL NUMBER
PRODUCT

Z-1800-2009
6) Medtronic INTREPID Spinal System SPACER L 42X30, 12 DEG, Size: 10MM, Part Number: REF 7963210; 12MM, REF 7963212, 14MM, REF 7963214; 16MM, REF 7963216; 18MM, REF 7963218; 20MM, REF 7963220; USA, Rx only, STERILE R

RECALL NUMBER
PRODUCT

Z-1801-200
7) Medtronic INTREPID Spinal System Coverplate, size: Small, Part Number: REF 7961330; medium, REF 7962330; large, REF 7963330; STERILE R

RECALL NUMBER
PRODUCT

Z-1802-2009
8) Medtronic SOFAMOR DANEK INTREPID SPINAL SYSTEM, 5.5MM TAPERED SCREW, Length: 20MM, , Part Number: REF 7960020; 25MM, REF 7960025, 30MM, REF 7960030; and 35MM, REF 7960035; QTY: 1 EA, NON-STERILE, Rx only

RECALL NUMBER
CODE

Z-1803-2009

MANUFACTURER
RECALLED BY
QUANTITY
DISTRIBUTION
REASON

All lots
Medtronic Sofamor Danek Deggendorf GmbH, Deggendorf, Bavaria, Germany
Medtronic Sofamor Danek USA Inc, Memphis, TN
8,028 units
Nationwide and Internationally
The firm received complaints regarding the use of the product in patients with poor bone quality, translational instability, difficulty implanting the cover plate and case of cover plate detachment.

Route to _____ Status _____

PRODUCT
RECALL NUMBER
CODE
MANUFACTURER
RECALLED BY
QUANTITY
DISTRIBUTION
REASON

BD 60ml Syringe Luer-Lok tip, Sterile, Product Number: 309653
Z-1811-2009
Lot Number: 819101A
Becton Dickinson & Company, Columbus, NE
Becton Dickinson & Company, Franklin Lakes, NJ
133,600 units
Nationwide
Insufficient Seal

Route to _____ Status _____

PRODUCT

Respironics Esprit Ventilator System, Model Number V1000 with Optional External Battery; Product Number: 1001456

RECALL NUMBER
CODE

Z-1813-2009

Serial Numbers: VS2700460, VS2700540, VS2700542, VS2700557, VS2700564, VS2700581, VS2700584, VS2700585, VS2700134, VS2700140, VS2700547, VS2700573, VS2700127, VS2700632, VS2700633, VS2700634, VS2700676, VS2700690, VS2700693, VS2700647, VS2700641, VS2700678, VS2700679, VS2700517, VS2500580, VS2700596, VS2700599, VS2700606, VS2700910, VS2701416, VS2700536, VS2700550, VS2700551, VS2700553, VS2700561, VS2700122, VS2700123, VS2700124, VS2700125, VS2700201, VS2700399, VS2700409, VS2700410, VS2700411, VS2700414, VS2700417, VS2700662, VS2700923, VS2700927, VS2700432, VS2700438, VS2700440, VS2700441, VS2700442, VS2700331, VS2700332, VS2700336, VS2700359, VS2700390, VS2700556, VS2700563, VS2700459, VS2700318, VS2700319, VS2700320, VS2700321, VS2700119, VS2700209, VS2700610, VS2700646A, VS2700691, VS2700630, VS2700360, VS2700412, VS2700200, VS2700463, VS2700464, VS2700466, VS2700467, VS2700468, VS2700469, VS2700470, VS2700473, VS2700474, VS2700476, VS2700477, VS2700478, VS2700479, VS2700480, VS2700481, VS2700431, VS2700433, VS2700434, VS2700435, VS2700436, VS2700437, VS2700439, VS2700471, VS2700472, VS2700475, VS2700355, VS2700392, VS2700102, VS2700138, VS2700141, VS2700206, VS2700207, VS2700356, VS2700358, VS2700368, VS2700383, VS2700384, VS2700385, VS2700386, VS2700387, VS2700388, VS2700391, VS2700613, VS2700619, VS2700621, VS2700622, VS2700623, VS2700346, VS2700348, VS2700349, VS2700350, VS2700351, VS2700352, VS2700353, VS2700354, VS2700361, VS2700362, VS2700363, VS2700365, VS2700366, VS2700367, VS2700370, VS2700375, VS2700377, VS2700380, VS2700381, VS2700382, VS2700508, VS2700512, VS2700526, VS2700528, VS2700529, VS2700322, VS2700328, VS2700329, VS2700330, VS2700403, VS2700405, VS2700407, VS2700408, VS2700506, VS2700515, VS2700516, VS2700393, VS2700394, VS2700395, VS2700413, VS2700415, VS2700418, VS2700419, VS2700424, VS2700426, VS2700427, VS2700428, VS2700430, VS2700698, VS2700920, VS2701403, VS2701407, VS2700333, VS2700334, VS2700335, VS2700337, VS2700338, VS2700339, VS2700340, VS2700342, VS2700343, VS2700443, VS2700444, VS2700445, VS2700448, VS2700450, VS2700451, VS2700452, VS2700454, VS2700672, VS2700692, VS2700906, VS2700908, VS2700915, VS2701401, VS2701405, VS2701404, VS2700208, VS2700211, VS2700213, VS2700232, VS2700236, VS2700396, VS2700397, VS2700398, VS2700615, VS2700629, VS2700530, VS2700611, VS2700453, VS2700525, VS2700531, VS2700105, VS2700142, VS2700143, VS2700909, VS2700913, VS2700914, VS2700132, VS2700456, VS2700644, VS2700685, VS2700696, VS2700701, VS2700325, VS2700327, VS2700715, VS2700916, VS2700369, VS2700371, VS2700372, VS2700373, VS2700374, VS2700376, VS2700378, VS2700379, VS2700583, VS2700635, VS2700640, VS2700643, VS2700646, VS2700713, VS2700937, VS2701417, VS2700677, VS2700549, VS2700558, VS2700578, VS2700543, VS2700577, VS2700121, VS2700567, VS2700919, VS2700237, VS2700300, VS2700502, VS2700505, VS2700513, VS2700518, VS2700519, VS2700520, VS2700680, VS2700700, VS2700710, VS2700712, VS2700911, VS2700912, VS2700918, VS2700921, VS2700922, VS2700924, VS2700625, VS2700628, VS2700651, VS2700652, VS2700608, VS2700447, VS2700210, VS2700212, VS2700216,, VS2700217, VS2700218, VS2700219, VS2700220, VS2700221, VS2700222, VS2700223, VS2700224, VS2700225, VS2700227, VS2700228, VS2700229, VS2700230, VS2700120, VS2700130, VS2700131, VS2700133, VS2700111, VS2700113, VS2700115, VS2700202, VS2700203, VS2700234, VS2700235, VS2700301, VS2700302, VS2700303, VS2700304, VS2700305, VS2700306, VS2700307, VS2700308, VS2700309, VS2700310, VS2700311, VS2700312, VS2700313, VS2700314, VS2700315, VS2700316, VS2700317, VS2700657, VS2700658, VS2700659, VS2700667, VS2700668, VS2700687, VS2700901, VS2700902, VS2700903, VS2700904, VS2700907, VS2700527, VS2700539, VS2700541, VS2700554, VS2700555, VS2700589, VS2700590, VS2700597, VS2700600, VS2700601, VS2700602, VS2700603, VS2700604, VS2700598, VS2700609, VS2700612, VS2700586, VS2700587, VS2700588, VS2700595, VS2700716,, VS2700455, VS2700503, VS2700504, VS2700509, VS2700511, VS2700534, VS2700535, VS2700545, VS2700552, VS2700559, VS2700571, VS2700572, VS2700620,

VS2700669, VS2700682, VS2700707, VS2700905, VS2700917, VS2700457, VS2700501, VS2700507, VS2700510, VS2700521, VS2700522, VS2700523, VS2700666, VS2700705, VS2700706, VS2700708, VS2700649, VS2700650, VS2700661, VS2700703, VS2700704, VS2700686, VS2700544, VS2700565, VS2700566, VS2700568, VS2700592, VS2700593, VS2700594, VS2700458, VS2700537, VS2700548, VS2700576, VS2700607, VS2700591, VS2700617, VS2700538, VS2700546, VS2700574, VS2700579, VS2700688, VS2700695, VS2700697, VS2700699, VS2700673, VS2700532, VS2700533, VS2700560, VS2700562, VS2700569, VS2700570, VS2700582, VS2700616, VS2700618, VS2700935, VS2700943, VS2700925, VS2700926, VS2700928, VS2700929, VS2700930, VS2700931, VS2700932, VS2700933, VS2700934, VS2700936, VS2700446, VS2700449, VS2700461, VS2700462, VS2700465, VS2701402, VS2701406, VS2700341, VS2700357, VS2700345, VS2700347, VS2700344, VS2700655, VS2700656, VS2700660, VS2700663, VS2700664, VS2700665, VS2700670, VS2700674, VS2700675, VS2700683, VS2701653, VS2701655, VS2700204, VS2700205, VS2700214, VS2700215, VS2700684, VS2700694, VS2700118, VS2700714, VS2700231, VS2700233, VS2700401, VS2700402, VS2700404, VS2700406, VS2700420, VS2700421, VS2700422, VS2700423, VS2700702, VS2700938, VS2700109, VS2700126, VS2700129, VS2700135, VS2700136, VS2700137, VS2700139, VS2700654, VS2700671, VS2700719, VS2700108, VS2700389, VS2700614, VS2700626, VS2700627, VS2700128, VS2700689, VS2700717, VS2700718, VS2700709, VS2700711, VS2700939, VS2700940, VS2700941, VS2700942, VS2700636, VS2700637, VS2700638, VS2700639, VS2700631

MANUFACTURED & RECALLED BY Respironics California, Inc, Carlsbad, CA
 QUANTITY 508 units
 DISTRIBUTION Nationwide and Internationally
 REASON Through routine product monitoring Respironics discovered that under certain conditions, when operating on AC line power, a portion of the current from the External Battery charger is erroneously diverted to the ventilator. When this occurs, the External Battery charger may not transition correctly. Prolonged operation in this condition results in overcharging and accelerated aging of the battery cells. Using batteries beyond their useful life may lead to a ventilator restart and Vent Inop condition. Should a Vent Inop condition occur the ventilator will alarm both audibly and visually, and will cease to operate creating the potential for patient injury.

Route to _____ Status _____

PRODUCT Haemonetics LN620 PCS2 Plasma Harness Set Model Number: LN620
RECALL NUMBER # B-1434-09
CODE Lot Numbers: 081219511, 081219512, 081222510, 081222511, 081223510, 081223511, 081224510, 081224511, 081224512
 MANUFACTURED & RECALLED BY Haemonetics Corp., Braintree, MA
 QUANTITY 179,000 units
 DISTRIBUTION Nationwide and Canada
 REASON Plasma harness collection sets with potential leaks at the blood filter were distributed

Route to _____ Status _____

PRODUCT Donor Management System (DMS) Blood Management Computer System
RECALL NUMBER # B-1382-09
CODE Software versions 1.7.1, 1.8.0, 1.8.1, 1.9.0, 1.9.1
MANUFACTURER Haemonetics Software Solutions, Edmonton, Canada
RECALLED BY Haemonetics Corp., Braintree, MA
QUANTITY 11 systems
DISTRIBUTION CA, FL, GA, OH, NC, and Canada

REASON Software with a defect or glitch was distributed.

Route to _____ Status _____

PRODUCT Donor Management System (DMS) Blood Establishment Computer System
RECALL NUMBER # B-1381-09
CODE DMS versions 1.7.1, 1.8.0, 1.9.0, 1.9.1
MANUFACTURER Haemonetics Software Solutions, Edmonton, Canada
RECALLED BY Haemonetics Corp., Braintree, MA
QUANTITY 26 systems
DISTRIBUTION CA, FL, LA, GA, OH, NC, and Canada
REASON Software with a defect or glitch was distributed.

Route to _____ Status _____

NOTE **Only products repacked by Advantage Dose are being recalled. Products from the manufacturer or other sources are not affected by this recall.**

PRODUCT 1) Tussionex CIII, Hydrocodone/Chlorphin, 5ML, 1/8mg/5ml, ER SUSP, Mfg. UCB
RECALL NUMBER # D-1900-2009
PRODUCT 2) Midazolam HCl, Oral Syrup, 5ML, 2MG/ML CIV, Mfg. ROX
RECALL NUMBER # D-1901-2009
PRODUCT 3) NOVOLIN, 70/30 U-100, HUM NPH/REG INSULIN 70-30 U/ML VIAL 10ML, Mfg NPH NDC 00169-1837-11
RECALL NUMBER # D-1942-2009
PRODUCT 4) NOVOLOG, INSULIN ASPART INJ., 100U/ML VIAL 10 ML, Mtg. NPH, NDC 00169-7501-11
RECALL NUMBER # D-1943-2009
PRODUCT 5) LANOXIN PED DIGOXIN QTY 1 ML 100MCG/ML AMP
RECALL NUMBER # D-1946-2009
PRODUCT 6) GAS FREE SIMETHICONE 125MG SOFTGEL
RECALL NUMBER # D-1947-2009
PRODUCT 7) GLYCERIN CHILD SUP SANI-SUPP Glycer. Suppos PEDIATRIC SUP
RECALL NUMBER # D-1948-2009
CODE 1) Mfg. Lot 46997, Exp. 11/14/09
2) Mfg. Lot 856964A, Exp. 11/10/09
3) Mtg. Lot V2FOO53, Exp. 06/01/10
4) Mtg. Lot VZFO216, Exp. 11/30/10
5) Mfg. Lot A26517, Exp. 04/01/10
6) Mtg. Lot S959, Exp. 07/01/10
7) Mfg. Lot 210208004, Exp. 06/01/11
MANUFACTURED & RECALLED BY Advantage Dose LLC, Shreveport LA
QUANTITY Total 2,635,663 unit doses
DISTRIBUTION Nationwide
REASON Not in conformance with cGMPs

Route to _____ Status _____

PRODUCT 1) Atenolol Tablets USP, 25 mg, 1000 count bottles (NDC 0093-0787-10) and 100 count bottles (NDC 0093-0787-01), Rx only

RECALL NUMBER # D-1897-2009
PRODUCT 2) Atenolol Tablets USP, 50 mg, 1000 count bottles, Rx only, NDC 0093-0752-10
RECALL NUMBER #D-1898-2009
CODE 1) Lot numbers: BER28A, Exp 01/2011; Lot # BER29A, Exp 02/2011; Lot # BER30B, Exp 02/2011
2) Lot number: BER34A, Exp 02/2011
MANUFACTURER Ivax Pharmaceuticals Ireland, Waterford, Ireland
RECALLED BY Teva Pharmaceuticals USA, Sellersville, PA
QUANTITY 91,161 bottles
DISTRIBUTION Nationwide
REASON Failed Content Uniformity Specification

Route to _____ Status _____

PRODUCT Actavis Twice a Day buPROPion Hydrochloride Extended-Release Tablets, USP (SR) 150 mg, 60 Tablets NDC 67767-133-60
RECALL NUMBER # D-1896-2009
CODE Lot number: 0805699A
MANUFACTURER Catalent Pharma Solutions LLC, Winchester, KY
RECALLED BY Actavis South Atlantic LLC, Sunrise FL
QUANTITY 13,236 bottles
DISTRIBUTION Nationwide
REASON Failed Impurity Specification: m-chlorobenzoic acid

Route to _____ Status _____

PRODUCT Cytomel, Liothyronine Sodium Tablets, 100 Tablets, Rx only 25 mcg, NDC 60793-116-01
RECALL NUMBER # D-1895-2009
CODE Lot numbers: 52215, exp 09/2009 and 52216, exp 09/2009
MANUFACTURED & RECALLED BY King Pharmaceuticals, Inc., Bristol, TN
QUANTITY 47,400 units
DISTRIBUTION Nationwide
REASON Subpotent 12 month stability time point
