

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.

**SUMMARY PAGE**

**MEDICAL DEVICES**

PRODUCT Accolade TMZF Hip Stems (various)  
MANUFACTURER Stryker Ireland, Ltd Orthopedics  
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PRODUCT Cmax 110v Surgical Table Hand Control  
MANUFACTURER Steris Corp  
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PRODUCT Flexicair MC3, model M4000, Low Airloss Therapy Units  
MANUFACTURER Hill-Rom Manufacturing, Inc  
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PRODUCT G-4 HighMag Flange  
MANUFACTURER Volk Optical, Inc  
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PRODUCT Medtronic INTREPID Spinal System SPACER & System Coverplate  
MANUFACTURER Medtronic Sofamor Danek Deggendorf GmbH  
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PRODUCT Offset Adaptor Trial  
MANUFACTURER Stryker Howmedica Osteonics Corp  
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PRODUCT **POWERSAIL Coronary Dilatation Catheters**  
MANUFACTURER Abbott Vascular-Cardiac Therapies dba Guidant Corp  
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PRODUCT Welch Allyn Vital Signs Monitor 5300 Series/Class II  
MANUFACTURER  
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PRODUCT Zimmer Alumina Ceramic Femoral Head & Kinectivo Technology Modular Neck  
MANUFACTURER Zzimmer, Inc  
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PRODUCT Zimmer Pulsavac Wound Debridement System, medullary cement plugs & Coonrad/Morrey total  
elbow cement restrictor  
MANUFACTURER Zimmer Orthopedic Surgical Products  
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**PHARMACEUTICALS**

PRODUCT Cefazolin for Injection  
MANUFACTURER Sandoz GmbH  
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PRODUCT Cefdinir for Oral Suspension  
MANUFACTURER TEVA Pharmaceuticals USA Inc  
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PRODUCT CycloSPORINE Capsules  
MANUFACTURER Apotex Corp  
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PRODUCT Hydrocodone Bitartrate and Acetaminophen Oral Solution  
MANUFACTURER KV Pharmaceutical Co Westport  
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PRODUCT KIONEX Sodium Polystyrene Sulfonate  
MANUFACTURER Paddock Laboratories, Inc  
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PRODUCT Nitrofurantoin Capsules  
MANUFACTURER Sandoz Inc  
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PRODUCT Rising Potassium Citrate Extended-Release Tablets  
MANUFACTURER Corepharma LLC  
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Route to \_\_\_\_\_ Status \_\_\_\_\_

**THE FOLLOWING IS A CLASS I RECALL. THERE IS A REASONABLE PROBABILITY THAT THE USE OF THE AFFECTED PRODUCT MAY CAUSE SERIOUS INJURY OR DEATH IF THE PROBLEM IS NOT CORRECTED.**

**This is an update to NRAC Issue #1744 Addendum date 7/30/09.**

PRODUCT 1) POWERSAIL Coronary Dilatation Catheter: 3.25x18mm (US) Part #1005524-18  
RECALL NUMBER # Z-1804-2009  
PRODUCT 2) POWERSAIL Coronary Dilatation Catheter: 4.0x8mm (CE) Part #1005726-08  
RECALL NUMBER # Z-1805-2009  
PRODUCT 3) POWERSAIL Coronary Dilatation Catheter: 2.75x18mm (US) Part #1005522-18  
RECALL NUMBER # Z-1806-2009  
PRODUCT 4) POWERSAIL Coronary Dilatation Catheter: 3.25x8mm (US) Part #1005524-08  
RECALL NUMBER # Z-1807-2009  
CODE 1) Lot 7101051, exp 09-2009  
2) Lot 7112051, exp 10-2009  
3) Lot 8012151, exp 12-2009  
4) Lot 8053061, exp 04-2010  
MANUFACTURED & RECALLED BY Abbott Vascular-Cardiac Therapies dba Guidant Corp.,  
Temecula, CA  
QUANTITY 557 units  
DISTRIBUTION Nationwide, and Internationally  
REASON Distal shaft of the POWERSAIL coronary Dilatation Catheters exhibits damage that may result in a leak of contrast material and functional failures.

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Route to \_\_\_\_\_ Status \_\_\_\_\_

PRODUCT Cmax 110v Surgical Table Hand Control. The Cmax Surgical Table is a mobile, electro-hydraulically operated surgical table designed to support all general surgical procedures, with the addition of STERIS table accessories. Tabletop positioning and articulations are controlled via the hand control.

RECALL NUMBER # Z-1599-2009  
 CODE Serial #'s: AC0001 to AC0221  
 MANUFACTURER Steris Corp., Montgomery, AL  
 RECALLED BY Steris Corp., Mentor, OH  
 QUANTITY 217 units  
 DISTRIBUTION Nationwide and Internationally  
 REASON A limited quantity of the Cmax Hand Controls, P150832-500, were manufactured without Loctite thread locker on the screws that attach the mounting clip to the hand control case. This clip provides a means of storing the hand control on the table side rails. It is possible that screws without Loctite can work loose and the clip can become separated from the hand control. If both screws back out completely, the internal components of the hand control and/or the table control board may become damaged. This would cause a loss of hand control functionality.

Route to \_\_\_\_\_ Status \_\_\_\_\_

PRODUCT 1) Medtronic INTREPID Spinal System SPACER, 32X23, 8 DEG, Sizes: 10-24 MM in 1 mm increments, Catalog Numbers: all numbers from 7961810 to 7961824; Rx only, Sterile. The INTREPID Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease

RECALL NUMBER # Z-1796-2009  
 PRODUCT 2) Medtronic INTREPID Spinal System SPACER, 32X23, 12 DEG, Size: 10-24 MM in 1 MM increments, Catalog Numbers: all numbers from 7961210 to 7961224

RECALL NUMBER # Z-1797-2009  
 PRODUCT 3) Medtronic INTREPID Spinal System SPACER M 37X27, 8 DEG, Sizes 10-24 MM in 1 MM increments, Catalog Numbers: all numbers from 7962810 to 7962824

RECALL NUMBER # Z-1798-2009  
 PRODUCT 4) Medtronic INTREPID Spinal System SPACER M 37X27, 12 DEG, Size: 10-24 MM in 1 MM increments, Catalog Numbers: all numbers from 7962210 to 7962224

RECALL NUMBER # Z-1799-2009  
 PRODUCT 5) Medtronic INTREPID Spinal System SPACER L 42X30, 8 DEG, Size: 10 - 24 MM in 1 MM increments: Catalog Numbers: all numbers from 7963810 to 7963824

RECALL NUMBER # Z-1800-2009  
 PRODUCT 6) Medtronic INTREPID Spinal System SPACER L 42X30, 12 DEG, Size: 10 - 24 MM in 1 MM increments, Catalog Numbers: all numbers from 7963210 7963224

RECALL NUMBER # Z-1801-2009  
 PRODUCT 7) Medtronic INTREPID Spinal System Coverplate, Sizes: Small, Medium and Large; Catalog Numbers: 7961330, 7962330 and 7963330

RECALL NUMBER # Z-1802-2009  
 CODE All Lots  
 MANUFACTURER Medtronic Sofamor Danek Deggendorf GmbH, Deggendorf, Bavaria, Germany  
 RECALLED BY Medtronic Sofamor Danek USA, Inc., Memphis, TN  
 QUANTITY 8,028 units  
 DISTRIBUTION Nationwide and Internationally  
 REASON The firm received complaints regarding the use of the product in patients with poor bone quality, translational instability, and difficulty implanting the cover plate detachment.

Route to \_\_\_\_\_ Status \_\_\_\_\_

PRODUCT 1) Offset Adaptor Trial - 2MM, Triathlon Revision Instruments. Non-Sterile; Indications for use include disabling joint disease of the knee. Catalog Number 5570-T-020

RECALL NUMBER # Z-1607-2009

PRODUCT 2) Offset Adaptor Trial - 4MM, Triathlon Revision Instruments. Non-Sterile; Catalog number 5570-T-040; Indications for use include disabling joint disease of the knee.

RECALL NUMBER # Z-1608-2009

PRODUCT 3) Offset Adaptor Trial - 6MM, Triathlon Revision Instruments. Non-Sterile; Catalog number 5570-T-060; Indications for use include disabling joint disease of the knee.

RECALL NUMBER # Z-1609-2009

PRODUCT 4) Offset Adaptor Trial - 8MM, Triathlon Revision Instruments. Non-Sterile; Catalog number 5570-T-080; Indications for use include disabling joint disease of the knee.

RECALL NUMBER # Z-1610-2009

CODE All lot numbers

MANUFACTURED & RECALLED BY Stryker Howmedica Osteonics Corp., Mahwah, NJ

QUANTITY 2,986 units

DISTRIBUTION Nationwide and Internationally

REASON Triathlon Offset Adaptors may seize during surgery and the OR staff may be unable to disassemble the instrument using the removal tool.

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Route to \_\_\_\_\_ Status \_\_\_\_\_

PRODUCT Flexicair MC3, model M4000, Low Airloss Therapy Units, for the prevention of pressure sores

RECALL NUMBER # Z-1875-2009

CODE The prefix "IC" is representative of a Flexicair MC3 and a six digit number without a prefix is representative of a refurbished Flexicair MC3

MANUFACTURED & RECALLED BY Hill-Rom Manufacturing, Inc., Charleston, SC

QUANTITY 946 units

DISTRIBUTION Nationwide and Canada

REASON The devices may emit smoke from the blower box assembly.

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Route to \_\_\_\_\_ Status \_\_\_\_\_

PRODUCT 1) Zimmer Pulsavac Wound Debridement System high capacity intramedullary brush tip, sterile; Catalog Number: 00515018300. Used in conjunction with the Pulsavac Plus Wound Debridement System for pulsatile lavage/debridement

RECALL NUMBER # Z-1698-2009

PRODUCT 2) Zimmer Allen medullary cement plugs, 1 - 20 dia. flange/10 mm dia. core, 1 - 24 mm dia. flange/12 mm dia. core (polyethylene with barium sulfate) with inserter, sterile; Catalog Number: 00801102001. Total joint arthroplasty to control, restrict, or impede the flow of cement. Larger plugs are useful in revision surgery where a wide, smooth Intramedullary canal must be plugged

RECALL NUMBER # Z-1699-2009

PRODUCT 3) Zimmer Coonrad/Morrey total elbow cement restrictor with nozzle, 1 - 16 mm, 1 - 25 mm, sterile; Catalog Number: 32810503800. Total joint arthroplasty to control, restrict or impede the flow of cement. Larger plugs are useful in revision surgery where a wide, smooth Intramedullary canal must be plugged

RECALL NUMBER # Z-1700-2009

CODE 1) Lot #: 61229259  
2) Lot #: 61239672

3) Lot #'s: 61249897 and 61249899  
MANUFACTURER Zimmer Orthopedic Surgical Products, Dover, OH  
RECALLED BY Zimmer, Inc., Warsaw, IN  
QUANTITY 501 units  
DISTRIBUTION Nationwide, Canada, Japan  
REASON The seal on the sterile barrier pouch may be inadequate, resulting in lack of assurance of sterility.

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Route to \_\_\_\_\_ Status \_\_\_\_\_

PRODUCT 1) Zimmer Alumina Ceramic Femoral Head, 12/14 taper, 32 mm diameter, neck length 0 mm, sterile; Catalog Number: 6428-32-02. Orthopedic implant used in total hip arthroplasty  
RECALL NUMBER # Z-1616-2009  
PRODUCT 2) Zimmer Kinectivo Technology Modular Neck, BB, 12/14 neck taper, sterile; Catalog Number: 00-7848-022-01. Orthopedic implant used in total hip arthroplasty  
RECALL NUMBER # Z-1617-2009  
CODE 1) Lot Number: 61007046  
2) Lot Number: 60917793  
MANUFACTURED & RECALLED BY Zimmer Inc., Warsaw, IN  
QUANTITY 147 units  
DISTRIBUTION Nationwide and Internationally  
REASON The corner tab of the inner compartment lid was not folded under before the outer lid was sealed, resulting in lack of assurance of sterility.

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Route to \_\_\_\_\_ Status \_\_\_\_\_

PRODUCT Welch Allyn Vital Sign Monitor 5300 Series/Class II. (VSM 300). The VSM300 can monitor systolic and diastolic noninvasive blood pressure (NIBP), pulse rate, and mean arterial pressure (MAP). Units configured with the appropriate options can also simultaneously monitor temperature and noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2), and continuously monitor pulse rate. The monitor provides programmable audible and visual alarms and automatic NIBP measurements at selectable intervals  
RECALL NUMBER # Z-1873-2009  
CODE Please email your serial numbers to Rhoda@recallalert.org to have them checked  
MANUFACTURED & RECALLED BY Welch Allyn Protocol, Inc., Beaverton, OR  
QUANTITY 68,123 units  
DISTRIBUTION Nationwide and Internationally  
REASON The Welch Allyn VSM300 Vital Signs Monitor may experience a loss of audio that includes a loss of audio alarms.

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Route to \_\_\_\_\_ Status \_\_\_\_\_

PRODUCT G-4 HighMag Flange, Model #VG4HM. Standard Gonio Lens for High Magnification Static and Dynamic Gonioscopy  
RECALL NUMBER # Z-1710-2009  
CODE Lot #: A1050030  
MANUFACTURED & RECALLED BY Volk Optical, Inc., Mentor, OH  
QUANTITY 15 units  
DISTRIBUTION Nationwide and Internationally

REASON The ring of the Gonio lenses distributed was engraved as, 'G4 High Mag Gonio LNF'; however, the engraving should have read simply: 'G4 High Mag Gonio.'

Route to \_\_\_\_\_ Status \_\_\_\_\_

- PRODUCT 1) Accolade TMZF Hip Stem; Hydroxylapatite Coated, Titanium Plasma Spray, V40 Taper, Sterile. 132 degree neck angle. Accolade 132 Size 1, Item Number: 6020-0130. Hip stems are single use devices intended for cementless fixation. The products are intended for use in primary reconstruction of the proximal femur or revision of a previous total hip arthroplasty, # Z-1354-2009
- RECALL NUMBER PRODUCT 2) Accolade TMZF Hip Stem; Hydroxylapatite Coated, Titanium Plasma Spray, V40 Taper, Sterile. 132 degree neck angle. Item Number: 6020-0230 ACCOLADE 132 SIZE 2 # Z-1355-2009
- RECALL NUMBER PRODUCT 3) Accolade TMZF Hip Stem; Hydroxylapatite Coated, Titanium Plasma Spray, V40 Taper, Sterile. 132 degree neck angle. Item # 6020-0335 ACCOLADE 132 SIZE 3 # Z-1356-2009
- RECALL NUMBER PRODUCT 4) Accolade TMZF Hip Stem; Hydroxylapatite Coated, Titanium Plasma Spray, V40 Taper, Sterile. 132 degree neck angle. Item Number: 6020-0335, ACCOLADE 132 SIZE 3 # Z-1357-2009
- RECALL NUMBER PRODUCT 5) Accolade TMZF Hip Stem; Hydroxylapatite Coated, Titanium Plasma Spray, V40 Taper, Sterile. 132 degree neck angle. Item Number: 6020-0537 ACCOLADE 132 SIZE 5 # Z-1358-2009
- RECALL NUMBER PRODUCT 6) Sterile. 132 degree neck angle. Item Number: 6020-0637 ACCOLADE 132 SIZE 6. Accolade TMZF Hip Stem; Hydroxylapatite Coated, Titanium Plasma Spray, V40 Taper # Z-1359-2009
- RECALL NUMBER PRODUCT 7) Accolade TMZF Hip Stem; Hydroxylapatite Coated, Titanium Plasma Spray, V40 Taper, Sterile. 132 degree neck angle. Item #: 6020-0740 ACCOLADE 132 SIZE 7 # Z-1360-2009
- RECALL NUMBER PRODUCT 8) Accolade TMZF Hip Stem; Hydroxylapatite Coated, Titanium Plasma Spray, V40 Taper, Sterile. 132 degree neck angle. Item #: 6020-2530 ACCOLADE 132 SIZE 2.5 # Z-1361-2009
- RECALL NUMBER PRODUCT 9) Accolade TMZF Hip Stem; Hydroxylapatite Coated, Titanium Plasma Spray, V40 Taper, Sterile. 132 degree neck angle. Item # 6020-3535 ACCOLADE 132 SIZE 3.5 # Z-1362-2009
- RECALL NUMBER PRODUCT 10) Accolade TMZF Hip Stem; Hydroxylapatite Coated, Titanium Plasma Spray, V40 Taper, Sterile. 132 degree neck angle. Item #: 6020-4535 ACCOLADE 132 SIZE 4.5 # Z-1363-2009
- RECALL NUMBER PRODUCT 11) Accolade TMZF Plus Hip Stem; Hydroxylapatite coated, Titanium Plasma Spray; V40 taper Longitudinal Grooves, Stem Length 120mm, Head Offset - 43mm, 127 degree neck angle. Item #: 6021-0230 ACCOLADE (127 DEG) SIZE 2 # Z-1364-2009
- RECALL NUMBER PRODUCT 12) Accolade TMZF Plus Hip Stem; Hydroxylapatite coated, Titanium Plasma Spray; V40 taper Longitudinal Grooves, Stem Length 120mm, Head Offset - 43mm, 127 degree neck angle. Item #: 6021-0335 ACCOLADE (127 DEG) SIZE 3 # Z-1365-2009
- RECALL NUMBER PRODUCT 13) Accolade TMZF Plus Hip Stem; Hydroxylapatite coated, Titanium Plasma Spray; V40 taper Longitudinal Grooves, Stem Length 120mm, Head Offset - 43mm, 127 degree neck angle. Item #: 6021-0435 ACCOLADE (127 DEG) SIZE 4. Hip stems are single use devices intended for cementless fixation. The products are intended for use in primary reconstruction of the proximal femur or revision of a previous total hip arthroplasty. # Z-1366-2009;
- RECALL NUMBER PRODUCT 14) Accolade TMZF Plus Hip Stem; Hydroxylapatite coated, Titanium Plasma Spray; V40 taper Longitudinal Grooves, Stem Length 120mm, Head Offset - 43mm, 127 degree neck angle. Item #: 6021-0537 ACCOLADE (127 DEG) SIZE 5

RECALL NUMBER # Z-1367-2009  
 PRODUCT 15) Accolade TMZF Plus Hip Stem; Hydroxylapatite coated, Titanium Plasma Spray; V40 taper Longitudinal Grooves, Stem Length 120mm, Head Offset - 43mm, 127 degree neck angle. Item #: 6021-0637 ACCOLADE (127 DEG) SIZE 6

RECALL NUMBER # Z-1368-2009  
 PRODUCT 16) Accolade TMZF Plus Hip Stem; Hydroxylapatite coated, Titanium Plasma Spray; V40 taper Longitudinal Grooves, Stem Length 120mm, Head Offset - 43mm, 127 degree neck angle. Item Number: 6021-0740 ACCOLADE PLUS TMZF HIP STEM #7

RECALL NUMBER # Z-1369-2009  
 PRODUCT 17) Accolade TMZF Plus Hip Stem; Hydroxylapatite coated, Titanium Plasma Spray; V40 taper Longitudinal Grooves, Stem Length 120mm, Head Offset - 43mm, 127 degree neck angle. Item #: 6021-2530 ACCOLADE (127 DEG) SIZE 2.5

RECALL NUMBER # Z-1370-2009  
 PRODUCT 18) Accolade TMZF Plus Hip Stem; Hydroxylapatite coated, Titanium Plasma Spray; V40 taper Longitudinal Grooves, Stem Length 120mm, Head Offset - 43mm, 127 degree neck angle. Hip stems are single use devices intended for cementless fixation. The products are intended for use in primary reconstruction of the proximal femur or revision of a previous total hip arthroplasty. Item #: 6021-3535 ACCOLADE (127 DEG) SIZE 3.5

RECALL NUMBER # Z-1371-2009  
 PRODUCT 19) Accolade TMZF Plus Hip Stem; Hydroxylapatite coated, Titanium Plasma Spray; V40 taper Longitudinal Grooves, Stem Length 120mm, Head Offset - 43mm, 127 degree neck angle. Item #'s: 6021-4535 ACCOLADE (127 DEG) SIZE 4.5

RECALL NUMBER # Z-1372-2009  
 PRODUCT 20) Accolade TMZF Plus Hip Stem; Hydroxylapatite coated, Titanium Plasma Spray; V40 taper Longitudinal Grooves, Stem Length 120mm, Head Offset - 43mm, 127 degree neck angle. Item # 6021-5537 ACCOLADE (127 DEG) SIZE 5.5

RECALL NUMBER # Z-1373-2009  
 PRODUCT 21) Citation TMZF HA Hip Stem. Item #'s: 6265-5103 CITATION TMZF SIZE 3 LEFT

RECALL NUMBER # Z-1374-2009  
 PRODUCT 22) Citation TMZF HA Hip Stem. Item #'s: 6265-5105 CITATION TMZF SIZE 5 LEFT

RECALL NUMBER # Z-1375-2009  
 PRODUCT 23) Citation TMZF HA Hip Stem. 6265-5106 CITATION TMZF SIZE 6 LEFT

RECALL NUMBER # Z-1376-2009  
 PRODUCT 24) Citation TMZF HA Hip Stem - RT. Item #: 6265-5112 CITATION TMZF SIZE 2 RIGHT

RECALL NUMBER # Z-1377-2009  
 PRODUCT 25) Citation TMZF HA Hip Stem - RT. Item #: 6265-5113 CITATION TMZF SIZE 3 RIGHT

RECALL NUMBER # Z-1378-2009  
 PRODUCT 26) Citation TMZF HA Hip Stem - RT. Item #: 6265-5114 CITATION TMZF SIZE 4 RIGHT

RECALL NUMBER # Z-1379-2009  
 PRODUCT 27) Citation TMZF HA Hip Stem - RT. Item #: 6265-5115 CITATION TMZF SIZE 5 RIGHT

RECALL NUMBER # Z-1380-2009  
 PRODUCT 28) Citation TMZF HA Hip Stem. Item # 6265-5116 CITATION TMZF SIZE 6 RIGHT

RECALL NUMBER # Z-1381-2009  
 PRODUCT 29) Short Citation TMZF HA Hip Stem - Right; Hydroxylapatite Coated, Titanium Plasma Spray; V40 Taper, 132 degree neck angle: Stem Length - 102mm; Head Offset - 52mm, Distal Diameter - 16mm. Item #: 6265-5217 Citation TMZF HA Short Size#7R

RECALL NUMBER # Z-1382-2009  
 PRODUCT 30) Super Secur Fit Plus. Item # J6054-0610 #6-10 Super Secur-Fit Plus

RECALL NUMBER # Z-1383-2009  
 PRODUCT 31) Super Secur Fit Plus. Item #: J6054-0612 #6-12 Super Secur-Fit Plus

RECALL NUMBER # Z-1384-2009  
 PRODUCT 32) Super Secur Fit Plus. Item #: J6054-0711 #7-11 Super Secur-Fit Plus

RECALL NUMBER # Z-1385-2009  
 PRODUCT 33) Super Secur Fit Plus. Item #: J6054-0812 #8-12 Super Secur-Fit Plus  
 RECALL NUMBER # Z-1386-2009  
 PRODUCT 34) Super Secur Fit Plus. Item #: J6054-0913 #9-13 Super Secur-Fit Plus  
 RECALL NUMBER # Z-1387-2009  
 PRODUCT 35) Omniflex-HA Hip Stem W/C Taper. Item #: 6046-0425, and Item #: 6046-0830  
 RECALL NUMBER # Z-1388-2009  
 PRODUCT 36) Super Secur Fit Plus. Item #: J6054-1014 Primary Super Secur-Fit Plus  
 RECALL NUMBER # Z-1680-2009  
 PRODUCT 37) Accolade TMZF Plus Hip Stem; Hydroxylapatite coated, Titanium Plasma Spray. Item #: W6021-0335 Accolade (127 deg) Sample  
 RECALL NUMBER # Z-1681-2009  
 PRODUCT 38) Accolade TMZF Plus Hip Stem; Hydroxylapatite coated, Titanium Plasma Spray. Item #: 6021-0030 Accolade (127 deg) Size 0  
 RECALL NUMBER # Z-1682-2009  
 PRODUCT 39) Accolade TMZF Plus Hip Stem; Hydroxylapatite coated, Titanium Plasma Spray. Item #'s: 6021-0130 Accolade (127 deg) Size 1  
 RECALL NUMBER # Z-1683-2009  
 PRODUCT 40) Accolade TMZF Hip Stem; Hydroxylapatite Coated, Titanium Plasma Spray, V40 Taper, Sterile. 132 degree neck angle. Item #'s: 6020-5537 Accolade 132 Size 5.5  
 RECALL NUMBER # Z-1684-2009  
 CODE 1) Lot #'s: 25107601, 25370101 and 25370103  
 2) Lot #'s: 24990805, 25079801, 25107701, 25187502, 25187503, 25187505 and 25335502  
 3) Lot #'s: 24972401, 25004402, 25045302, 25045303, 25107804, 25178601, 25230801, 25230802, 25245503, 25255101, 25274002, 25348901 and 25386101  
 4) Lot #'s: 24972401, 25004402, 25045302, 25045303, 25107804, 25178601, 25230801, 25230802, 25245502, 25245503, 25255101, 25274002, 25348901 and 25386101  
 5) Lot #'s: 25189704 and 25189705  
 6) Lot Numbers: 25080301 and 25189901  
 7) Lot #'s: 24883801 and 25190002  
 8) Lot #'s: 24797101, 25138701, 25138702 and 25231601;  
 9) Lot #'s: 25046001, 25095402, 25138901, 25138902, 25211802, 25387301, 25387303 and 25387304  
 10) Lot #'s: 24884902, 24955901, 25008201, 25095501, 25387501, 25387502 and 25387504  
 11) Lot #'s: 24395205, 24955101, 25006102, 25080402, 25108201, 25169401, 25231102 and 25371202  
 12) Lot #'s: 24295205, 24319601, 24859104, 24991703, 25006601, 25022201, 25045503, 25069901, 25069902, 25069904, 25108801, 25108802, 25169501, 25169502, 25190102, 25211202, 25231203, 25245201, 25245202, 25245203, 25245204, 25255401, 25255402, 25255403, 25255404, 25309704, 25348701, 25400905, 25400906, 25428401, 25428402, 25428403, 25428404, 25459601 and 25467303  
 13) Lot #'s: 24884802, 24918803, 25045801, 25045802, 25069801, 25080502, 25094901, 25108901, 25138302, 25179401, 25211501, 25231401, 25255902, 25311401, 25311402, 25337801, 25400803 and 25515602  
 14) Lot #'s: 24992703, 24992704, 25007601, 25080702, 25138501, 25138503, 25231501 and 25296301  
 15) Lot #'s: 24955501, 25109001 and 25337903  
 16) Lot #: 25138602  
 17) Lot #'s: 24860501, 24993701, 25024701, 25179501, 25231902, 25274801, 25274803, 25296702 and 25401103  
 18) Lot #'s: 24956202, 25025001, 25025003, 25025004, 25046901, 25080901, 25080902, 25095701, 25169903, 25190601, 25212102, 25232001, 25243801, 25256201, 25275701, 25275702 and 25275703  
 19) Lot #'s: 24956301, 24973501, 25025502, 25025503, 25109103, 25169701, 25190701, 25244401, 25338602, 25372501, 25427901 and 25445501

- 20) Lot #'s: 24337504, 24973701, 25338702, 25372601 and 25387802
- 21) Lot #'s: 24640201, 25109201
- 22) Lot #'s: 24706601, 25044901, 25044902 and 25068301
- 23) Lot #'s: 24861701 and 25068401
- 24) Lot #'s: 24479801, 24612901, 24883101 and 25068501
- 25) Lot #'s: 23811304, 24495804 and 25068601
- 26) Lot #'s: 24356001, 24765301 and 24861901
- 27) Lot #'s: 24562402, 24729101, 24765402, 24765402 and 24796401
- 28) Lot #: 24404102
- 29) Lot #: 24480401
- 30) Lot #: 24709601
- 31) Lot #: 24709801
- 32) Lot #: 24727502
- 33) Lot #: 25076902
- 34) Lot #'s: 24475001 and 24534601
- 35) Lot #'s: 24897301 and 24352201
- 36) Lot #: 24577501
- 37) Lot #: 25309501
- 38) Lot #: 24917301
- 39) Lot #'s: 25108101, 25179201 and 25456402
- 40) Lot #'s: 25046701, 25169601 and 25190501

MANUFACTURER Stryker Ireland, Ltd., Orthopedics, Carrigtohill, County Cork, Ireland  
 RECALLED BY Stryker Howmedica Osteonics Corp., Mahwah, NJ  
 QUANTITY 1,628 units  
 DISTRIBUTION Nationwide  
 REASON Product deviation: Specific lots of sprayed HA hip stems did not meet Stryker's Internal Material Specification for tensile bond strength and crystallinity.

Route to \_\_\_\_\_ Status \_\_\_\_\_

PRODUCT KIONEX Sodium Polystyrene Sulfonate, USP, NDC 0574-2004-16, Rx Only, Net Weight 454 grams (1 lb)  
 RECALL NUMBER # D-1879-2009  
 CODE Lot #'s: 2008454787, 2008454788, 2008495106, 2008495107, 2008495108, 2008495109, 2008515297, 2009025493  
 MANUFACTURED & RECALLED BY Paddock Laboratories, Inc., Minneapolis, MN  
 QUANTITY 20,554 jars  
 DISTRIBUTION Nationwide  
 REASON Impurity (ketones); causing odor

Route to \_\_\_\_\_ Status \_\_\_\_\_

PRODUCT Hydrocodone Bitartrate and Acetaminophen Oral Solution 7.5mg/500mg/15mL; 50 x 15mL unit dose cups per case; Rx only; 15mL NDC 66689-021-01  
 RECALL NUMBER # D-1883-2009  
 CODE Lot # 150300, Exp 11/09  
 MANUFACTURER KV Pharmaceutical Co Westport, Saint Louis, MO  
 RECALLED BY VistaPharm, Inc., Largo, FL  
 QUANTITY 399 cases  
 DISTRIBUTION Nationwide  
 REASON cGMP Deviations: This product was not manufactured under Current Good Manufacturing Practices.

Route to \_\_\_\_\_ Status \_\_\_\_\_

PRODUCT 1) Cefdinir for Oral Suspension 125 mg/5 ml in a) 60 mL (NDC 0093-4136-64) and b) 100 mL (NDC 0093-4136-73) bottles, Rx only  
RECALL NUMBER # D-1876-2009  
PRODUCT 2) Cefdinir for Oral Suspension 250 mg/5 ml in a) 60 mL (NDC 0093-4137-64) and b) 100 mL (NDC 0093-4137-73) bottles, Rx only  
RECALL NUMBER # D-1877-2009  
CODE 1) a) Lot numbers: 72540 exp Jul-09; 30300365A exp Aug-10; 30300469A exp Sep-10; 72678 exp Dec-09; 30300470A exp Sep-10; 72679 exp Dec-09; 30300684A exp Oct-10; 72862 exp Sep-09; 30300777A exp Oct-10; 72863 exp Sep-09; 30301031A exp Dec-10; 72864 exp Nov-09; 30301032A exp Dec-10; 72865 exp Nov-09; 30301065A exp Jan-11; 74053 exp Mar-10; 30301066A exp Jan-11; 74054 exp Mar-10; 30301067A exp Jan-11; and 74405 exp Mar-10. b) Lot numbers: 72871 exp May-10; 74055 exp May-10; 30300106A exp Jun-10; 30300107A exp Jun-10; 72586 exp Aug-09; 30300366A exp Aug-10; 72680 exp Aug-09; 30300775A exp Oct-10; 72681 exp Jan-10; 30300776A exp Oct-10; 72867 exp Mar-10; 30300778A exp Oct-10; 72868 exp Mar-10; 30301068A exp Dec-10; 72869 exp Nov-09; 30301069A exp Dec-10; 72870 exp Nov-09; and 30301070A exp Dec-10  
2) a) Lot numbers: 74060 exp Apr-10; 30300563A exp Oct-10; 74408 exp Apr-10; 30300564A exp Oct-10; 74409 exp Apr-10; 30300758A exp Oct-10; 30300110A exp Jun-10; 30300759A exp Oct-10; 30300111A exp Jun-10; 30300791A exp Nov-10; 30300112A exp Jun-10; 30300792A exp Nov-10; 30300269A exp Jun-10; 30300793A exp Nov-10; 30300270A exp Jun-10; 30300794A exp Nov-10; 30300271A exp Jun-10; 30301023A exp Oct-10; 30300299A exp Jun-10; 30301024A exp Dec-10; 30300353A exp Aug-10; 30301071A exp Jan-11; 30300354A exp Aug-10; 30301072A exp Jan-11; 30300355A exp Aug-10; 30301073A exp Jan-11; 30300356A exp Aug-10; and 30301074A exp Jan-11. b) Lot numbers: 74058 exp Mar-10; 30300565A exp Oct-10; 74059 exp Mar-10; 30300566A exp Oct-10; 74407 exp Mar-10; 30300756A exp Oct-10; 74411 exp Mar-10; 30300757A exp Oct-10; 74412 exp May-10; 30300795A exp Oct-10; 74413 exp May-10; 30300796A exp Oct-10; 30300108A exp Jun-10; 30301025A exp Dec-10; 30300109A exp Jun-10; 30301026A exp Dec-10; 30300357A exp Aug-10; 30301075A exp Dec-10; and 30300358A exp Aug-10  
MANUFACTURER TEVA Pharmaceuticals USA, Inc., Fairfield, NJ  
RECALLED BY Teva Pharmaceuticals USA, Inc., Sellersville  
QUANTITY 1,903,193 bottles  
DISTRIBUTION Nationwide  
REASON Labeling: Incorrect or missing package insert: The pediatric dosing information is incorrect.

Route to \_\_\_\_\_ Status \_\_\_\_\_

PRODUCT CycloSPORINE Capsules USP, 100 mg. 30 (3 x 10) UD blister pack, Rx only, NDC # 62584-827-21  
RECALL NUMBER # D-1882-2009  
CODE Lot # 081488, Exp 01/10  
MANUFACTURER Apotex Corp., Weston, FL.  
RECALLED BY American Health Packaging, Columbus, OH  
QUANTITY 377 units (3 x 10 count blister packs per unit)  
DISTRIBUTION Nationwide  
REASON This recall was initiated because ongoing monitoring has determined that the lot has a level of related compound marginally in excess of the specification limit.

Route to \_\_\_\_\_ Status \_\_\_\_\_

PRODUCT Nitrofurantoin Capsules, 100mg, 1000 count plastic bottle, Rx only, Catalog number: 01122-10  
RECALL NUMBER # D-1878-2009  
CODE Lot #175835, Expiration 5/2010  
MANUFACTURER Sandoz Inc., Wilson, NC  
RECALLED BY Sandoz, Inc., Princeton, NJ  
QUANTITY 920 bottles/1000 tablets per bottle  
DISTRIBUTION Nationwide  
REASON Exceeded Dissolution Specification; 1 hour timepoint.

Route to \_\_\_\_\_ Status \_\_\_\_\_

PRODUCT Cefazolin for Injection, USP, 1 gram, packaged in packs of 25/1 gram vials, Rx only, For I.M. or I.V. use, Sterile, NDC 00781-3451-96  
RECALL NUMBER # D-1881-2009  
CODE Batch numbers: 155846, 155848, 155849, 155879, 155880, 155881, 156043, 156046, 156047, 156138, 156437, 156661, 156662, 156663, 156664, 156665, 157241, 157242, 157243, 157244, 157245, 157246, 157247, 157248, 157249, 157250, 157763, 157764, 157765, 157766, 157767, 157768, 157769, 157770, 157771, 157772, 158751, 158752, 158860, 159420, 160243, 160244, 160246, 160253, 160926  
MANUFACTURER Sandoz GmbH, Kundl, Austria  
RECALLED BY Sandoz, Inc., Princeton, NJ  
QUANTITY 45 batches (153,166 units)  
DISTRIBUTION Nationwide  
REASON Misbranded; product carton incorrectly states reconstitute with 2mL sterile water but should correctly state reconstitute with 2.5mL sterile water. Both immediate vial label and insert are correct.

Route to \_\_\_\_\_ Status \_\_\_\_\_

PRODUCT Rising Potassium Citrate Extended-Release Tablets, USP 10 mEq (1080 mg per tablet), Rx only, 100 Tablets, NDC 64980-138-01  
RECALL NUMBER # D-1880-2009  
CODE Lot CPF846, Exp: June 2010  
MANUFACTURED & RECALLED BY Corepharma LLC, Middlesex, NJ  
QUANTITY 3502 bottles of 100  
DISTRIBUTION NJ  
REASON Failed Dissolution Specification; 9 months stability