

Ansell Sandel Weighted Safety Scalpel / Cardinal Health / Ansell / Owens & Minor / Update (2/14)

Reason/Information:

This recall contains additional nomenclatures and lot numbers from previously published MMQC-13-2125. Reason: Due to a complaint that 5 scalpels showed the blade was visibly exposed.

Disposition/Instructions:

Ansell requests the following immediate actions to assist with the manufacturer initiated recall procedure:

- Do not ship any Ansell Sandel Weighted Safety Scalpel products with affected lot numbers. The product reference number can be located in the upper right corner of the dispenser box and the lot number can be found in the lower left corner of the dispenser box (see Figure 2) (See Image on Message under Additional Documentation/Attachment).
- If you have product samples, check the scalpel/s in your possession to see if they came from one of the lot numbers identified. For individual scalpels still in their sterile packaging, the product reference number and lot number can be found in the upper right hand corner of the product label. (See Figure 3) (See Image on Message under Additional Documentation/Attachment).
- Quarantine any affected Ansell Sandel Weighted Safety Scalpels.
- Complete the response form (See Image on Message under Additional Documentation/Attachment) and fax it to Cardinal Health at 847-689-9101 or email it to anzcustomerservice@ap.ansell.com.
- In addition, if product has been distributed to other distributors or users, notify them of this manufacturer initiated recall, with instructions to return any outstanding stock.
- Upon receipt of the response form, Ansell Customer Service will provide a return goods authorization number and will provide specific instructions on how to return the materiel.
- All returned products will either be replaced or credited as soon as practicable.

For questions call Cardinal Health at 800-444-1166, 614-757-5000, or email Ansell Customer Service at anzcustomerservice@ap.ansell.com.

Note:

Product Identification # - CAT No(s): 2210-N; 2215-L; 2215-N; 2220-N; 2210-L; 2211-L; 2211-N.

Cardinal CAT # - SL2210-LA; SL2210-N; SL2211-LA; SL2211-N; SL2215-LA; SL2215-N; SL2220-N.

Item Information:

NSN (FSC-NIIN): 6515-NS1
Part Number: 2211-N
Nomenclature: WEIGHTED SAFETY SCALPEL; #3 HANDLE W/ #11 BLADE; BLUE SHIELD W/ TIME OUT SLEEVE
UI: EA
Manufacturer: ANSELL
Distributor: OWENS & MINOR

LOT / SN:
1413
1623

NOTES:

NOTE 1:

Lot# 1413 Expiration Date: April 2016; Distribution Date Range: 17 June 2013 - 28 June 2013.

Lot# 1623 Expiration Date: May 2013; Distribution Date Range: 2 July 2013 - 25 October 2013.

NOTE 2:

Additional Nomenclature - 12 per box; 8 boxes per case (96 total scalpels). O&M SKU#: 69060221N.

NSN (FSC-NIIN): 6515-NS2
Part Number: 2210-L
Nomenclature: WEIGHTED SAFETY SCALPEL; #3L HANDLE (8.75) W/ #10 BLADE; ORANGE SHIELD W/ TIME OUT SLEEVE
UI: EA
Manufacturer: ANSELL
Distributor: OWENS & MINOR

LOT / SN:
2052
NOTES:

NOTE 1:

Additional Nomenclature - 12 per box; 2 boxes per case (24 total scalpels). O&M SKU#: 690602210L.

NOTE 2:

Lot# 2052 Expiration Date: June 2015; Distribution Date Range: 11 September 2012 - 16 August 2013.

NSN (FSC-NIIN): 6515-NS3
Part Number: 2211-L
Nomenclature: WEIGHTED SAFETY SCALPEL; #3 L HANDLE (8.75) W/ #11 BLADE; BLUE SHIELD W/ TIME OUT SLEEVE
UI: EA
Manufacturer: ANSELL
Distributor: OWENS & MINOR

LOT / SN:

2962

NOTES:

NOTE 1:

Additional Nomenclature - 12 per box; 8 boxes per case (96 total scalpels).

NOTE 2:

Lot# 2962 Expiration Date: September 2015; Distribution Date Range: 29 January 2013 - 6 May 2013.

NSN (FSC-NIIN): 6515-NS4

Part Number: 2210-N

Nomenclature: WEIGHTED SAFETY SCALPEL; #3 HANDLE W/ #10 BLADE ORANGE SHIELD W/ TIME OUT SLEEVE

UI: EA

Manufacturer: ANSELL

Distributor: OWENS & MINOR

LOT / SN:

0563

2263

NOTES:

NOTE 1:

Lot# 0563 Expiration Date: January 2016; Distribution Date Range: 30 April 2013 - 27 September 2013.

Lot# 2263 Expiration Date: July 2016; Distribution Date Range: 8 August 2013 - 16 October 2013.

NOTE 2:

Additional Nomenclature - 12 per box; 8 boxes per case (96 total scalpels). O&M SKU#:690602210N.

NSN (FSC-NIIN): 6515-NS5

Part Number: 2215-N

Nomenclature: WEIGHTED SAFETY SCALPEL; #3 HANDLE W/ #15 BLADE; YELLOW SHIELD W/ TIME OUT SLEEVE

UI: EA

Manufacturer: ANSELL

Distributor: OWENS & MINOR

LOT / SN:

1203

1553

NOTES:

NOTE 1:

Additional Nomenclature - 12 per box; 8 boxes per case (96 total scalpels). O&M SKU#: 690602215N.

NOTE 2:

Lot# 1203 Expiration Date: May 2016; Distribution Date Range: 21 May 2013 - 23 May 2013.

Lot# 1553 Expiration Date: May 2016; Distribution Date Range: 19 June 2013 - 25 October 2013.

NSN (FSC-NIIN): 6515-NS6
Part Number: 2215-L
Nomenclature: WEIGHTED SAFETY SCALPEL; #3L HANDLE (8.75") W/ #15 BLADE;
YELLOW SHIELD W/ TIME OUT SLEEVE
UI: EA
Manufacturer: ANSELL
Distributor: OWENS & MINOR

LOT / SN:

2052

NOTES:

NOTE 1:

Lot# 2052 Expiration Date: June 2015; Distribution Date Range: 14 September 2012 - 21 October 2013.

NOTE 2:

Additional Nomenclature - 12 per box; 8 boxes per case (96 total scalpels). O&M SKU#: 690602215L.

NSN (FSC-NIIN): 6515-NS7
Part Number: 2220-N
Nomenclature: WEIGHTED SAFETY SCALPEL; #4 HANDLE W/ #20 BLADE; ORANGE
SHIELD AND TIME OUT SLEEVE
UI: EA
Manufacturer: ANSELL
Distributor: OWENS & MINOR

LOT / SN:

1793

NOTES:

NOTE 1:

Lot# 1793 Expiration Date: May 2016; Distribution Date Range: 13 July 2013 - 25 October 2013.

NOTE 2:

Additional Nomenclature - 12 per box; 4 boxes per case (48 total scalpels). O&M SKU#: 690602220N.

Service/Additional Instructions:

CONSIGNEES: Eglin AFB, 307 Boatner RD, Eglin AFB, FL; 51ST Medical GRP Osan, Unit 2060
BLDG 777 HDQTRS RD, Osan AB;
RAF Lakenheath 48 MDSS SG, Unit 5210 BOX 230 APO, AE;
USNH Cherry Point Beaufort RD BLDG 4389, Cherry Point, NC;
Fort Belvoir MATL BR WHSE, BLDG 1414 BAY F Jackson Loop, Fort Belvoir, VA

POC Contact Information:

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Additional Message Recipients:

Please ensure widest dissemination of information to all interested entities.

Message Dissemination Authorization:

US AIR FORCE

AF Activities Will Take Action As Prescribed In AFI 41-209, Medical Logistics Support, Chapters 3 And 9. For MAJCOMS & NGB--This Msg Has Been Transmitted To All Designated Subordinate Medical Activities.

US ARMY

See Army Regulation (Ar) 40-61, 28 January 2005, Chapter 4, And The Department Of The Army Supply Bulletin (Sb 8-75-11) For Applicable Policies And Procedures.

Additional Documentation/Attachment located [here](#).