

Ansell Healthcare
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 United States

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 www.ansell.com



PURCHASING
 OWENS & MINOR #78
 134 INDUSTRIAL PARK ROAD, STE 1000
 GREENSBURG, PA 15601-0339

URGENT: VOLUNTARY RECALL OF ANSELL SANDEL WEIGHTED SAFETY SCALPEL

November 11, 2013

Dear PURCHASING,

Our mission at Ansell Sandel Medical Solutions LLC is to improve the safety and well-being of healthcare professionals and patients through our protective products. We are deeply committed to ensuring that our products are as safe as possible. As a result, we are writing to voluntarily inform you that we have become aware of an issue with several of our SANDEL® Weighted Safety Scalpel products.

Ansell has received a small number of complaints concerning the scalpels. A complaint was received from an end user that noted five scalpels, item 2210-N (Sterile) Lot 0563, in their supply area showed the blade was visibly exposed. A nurse retrieving a sample at the time cut her finger which required a band aid. In a separate event, sales personnel in Australia retrieved a box of scalpels, item 2211-N (Sterile) Lot 2782, from the Ansell warehouse sample area and discovered that four out of five blades had its pointed ends exposed and pierced through the inner packaging. A further check revealed that scalpel item 2210-L (Sterile) Lot 0662 had a similar issue. The shield did not cover the blade fully and movement and/or transportation could have caused scalpels inside to move and pierce the inner pouch.

A review of scalpel samples (not from the affected lot) indicates that if the safety mechanism is not fully engaged, the blade tip could be exposed 1 to 3 mm. The exposure of the tip could compromise the integrity of the package and the sterility of the scalpel. In addition, the exposure of the tip could cause injury. A picture of a scalpel with an exposed blade is attached in Figure 1. While our investigation has shown a very low incidence of this occurrence, out of caution, Ansell is issuing a voluntary recall notice to all customers who have ordered the following products with the associated lot numbers:

| Product | Lot # | Expiration Date | Distribution Date Range |
|---|-------|-----------------|-----------------------------|
| 2210-N Weighted Safety Scalpel, #3 Handle with #10 Blade, Orange Shield with TIME OUT® Sleeve (S) 12 per box; 8 boxes per case (96 total scalpels) | 0563 | Jan 2016 | Apr 30, 2013 – Sep 27, 2013 |
| | 2263 | Jul 2016 | Aug 08, 2013 – Oct 16, 2013 |
| 2210-L Weighted Safety Scalpel, #3L Handle (8.75") with #10 Blade, Orange Shield with TIME OUT® Sleeve (S) 12 per box; 2 boxes per case (24 total scalpels) | 0662 | Feb 2015 | Mar 19, 2012 – Sep 28, 2012 |
| | 2052 | Jun 2015 | Sep 11, 2012 – Aug 16, 2013 |

(Continued on next page)

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(Continued from previous page)

| Product | Lot # | Expiration Date | Distribution Date Range |
|---|-------|-----------------|-----------------------------|
| 2211-N Weighted Safety Scalpel, #3 Handle with #11 Blade, Blue Shield with TIME OUT® Sleeve (S) 12 per box; 8 boxes per case (96 total scalpels) | 1413 | Apr 2016 | Jun 17, 2013 – Jun 28, 2013 |
| | 1623 | May 2013 | Jul 2, 2013 – Oct 25, 2013 |
| | 2782 | Sep 2015 | Dec 24, 2012 – May 22, 2013 |
| 2211-L Weighted Safety Scalpel, #3L Handle (8.75") with #11 Blade, Blue Shield with TIME OUT® Sleeve (S) 12 per box; 8 boxes per case (96 total scalpels) | 2962 | Sep 2015 | Jan 29, 2013 – May 6, 2013 |
| | 0662 | Feb 2015 | Mar 19, 2012 – Jul 30, 2012 |
| 2215-N Weighted Safety Scalpel, #3 Handle with #15 Blade, Yellow Shield with TIME OUT® Sleeve (S) 12 per box; 8 boxes per case (96 total scalpels) | 1203 | Mar 2016 | May 21, 2013 – May 23, 2013 |
| | 1553 | May 2016 | Jun 19, 2013 – Oct 25, 2013 |
| 2215-L Weighted Safety Scalpel, #3L Handle (8.75") with #15 Blade, Yellow Shield with TIME OUT® Sleeve (S) 12 per box; 8 boxes per case (96 total scalpels) | 2052 | Jun 2015 | Sep 14, 2012 – Oct 21, 2013 |
| 2220-N Weighted Safety Scalpel, #4 Handle with #20 Blade, Orange Shield and TIME OUT® Sleeve (S) 12 per box; 4 boxes per case (48 total scalpels) | 1793 | May 2016 | Jul 13, 2013 – Oct 25, 2013 |

IMMEDIATE ACTION REQUESTED

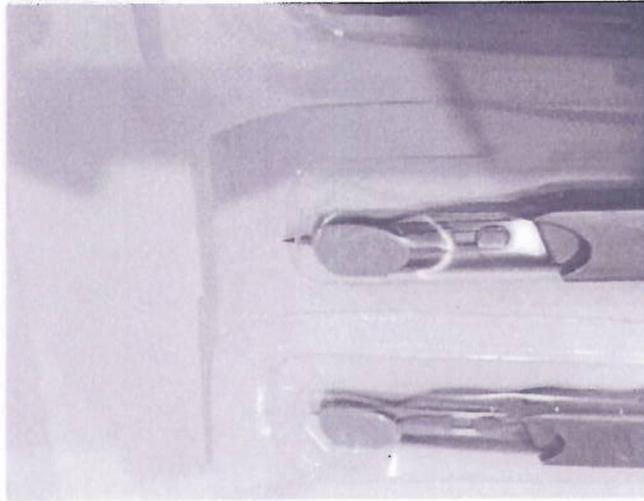
1. Do not ship SANDEL Weighted Safety Scalpel products 2210-L, 2210-N, 2211-L, 2211-N, 2215-L, 2215-N, or 2220-N to a hospital or end user with the above lot numbers. The product reference number can be located in the upper right corner of the dispenser box and the lot number can be found in the lower left corner of the dispenser box (see Figure 2 attached).
2. Please quarantine SANDEL Weighted Safety Scalpel products 2210-L, 2210-N, 2211-L, 2211-N, 2215-L, 2215-N, or 2220-N with the above lot numbers in your inventory.
3. Please complete the attached response form and return it to our attention (return information is noted on the form). Additionally, if you have distributed this product to other accounts, please notify them of the voluntary recall and instruct them to return any outstanding stock to you as indicated in the attachment. You will be provided with return materials authorization (RMA) information from Customer Service. All returned product will either be replaced or credited without delay.

This voluntary recall is being made with the full knowledge of the United States Food and Drug Administration. We sincerely apologize for this inconvenience and appreciate your help in supporting this action. If you have any questions or need additional information, please contact Customer Service by calling **866-764-3327 (6:00 am – 5:00 pm PST/9:00 am – 8:00 pm EST)** or email sandel-cs@ansell.com.

Sincerely,

Adam Weintraub
 Director, Healthcare Safety Devices
 Ansell Sandel Medical Solutions LLC

Figure 1:



Product
REF #

Figure 2:

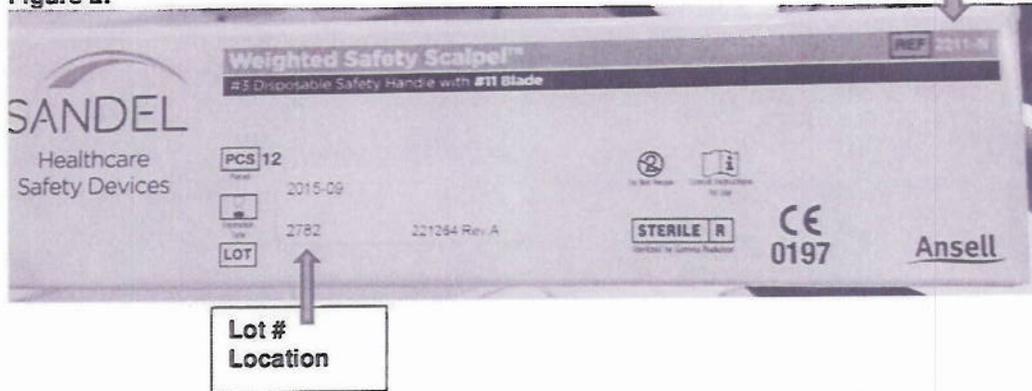


Figure 3:

Product REF #
Lot #
Expiry date



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ANSELL SANDEL WEIGHTED SAFETY SCALPEL VOLUNTARY RECALL
RESPONSE FORM

Please complete this form and return it as soon as possible via fax at 818-534-2510 or email sandel-cs@ansell.com.

CONTACT INFORMATION:

Company: _____

Your Name: _____

Title: _____

Address: _____

City, State, Zip, Country: _____

Telephone: _____

E-Mail Address: _____

Signature: _____

Date: _____

HyFlex

GAMMEX

SKYN

ACTIVARMR

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RESPONSE REQUIRED:

1. Do you have any of the following products with the associated lot numbers in inventory? (Please check inventory levels before answering.) YES _____ NO _____

| Product | Lot # | Expiration Date | Distribution Date Range |
|---|-------|-----------------|-----------------------------|
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2. [If you answered 'Yes' to #1] Please list the number of cases and boxes you currently have in inventory for each affected product.

| Product | Lot # | No. of Cases | No. of Boxes |
|-----------------------------|-------|--------------|--------------|
| 2210-N Inventory Remaining: | 0563 | | |
| | 2263 | | |
| 2210-L Inventory Remaining: | 0662 | | |
| | 2052 | | |
| 2211-N Inventory Remaining: | 1413 | | |
| | 1623 | | |
| | 2782 | | |
| 2211-L Inventory Remaining: | 2962 | | |
| | 0662 | | |
| 2215-N Inventory Remaining: | 1203 | | |
| | 1553 | | |
| 2215-L Inventory Remaining: | 2052 | | |
| 2220-N Inventory Remaining: | 1793 | | |

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NEXT STEPS:

1. Please return this completed form to Customer Service via fax at 818-534-2510 or email sandel-cs@ansell.com.
2. Upon receipt of this form, Customer Service will contact you with a return materials authorization (RMA) number and will provide you with specific instructions on how to return the product.
3. If you have distributed this product to other locations or accounts, please forward a copy of the enclosed **notification letter** for their review and action. They should return the product directly to you. Upon receipt of the product, please complete this form and submit it to Customer Service via fax at 818-534-2510 or email sandel-cs@ansell.com.

Thank you for your assistance in supporting this action. If you have any questions, please contact Customer Service at 866-764-3327 (6:00 am – 5:00 pm PST/9:00 am – 8:00 pm EST).

HyFlex

GAMMEX

SKYN

ACTIVARMR

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Figure 1:

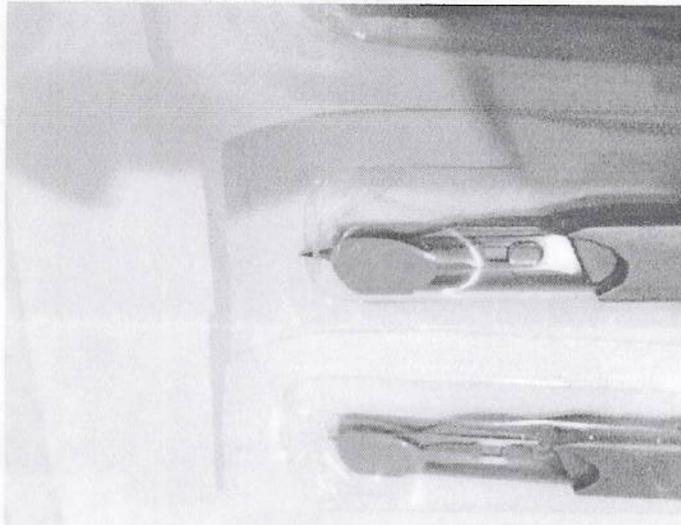


Figure 2:

