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12 November 2013

**ATTN: Chief Executive Officer
Procurement Manager**

**URGENT MEDICAL DEVICE RECALL
RC-2103-RN-01152-1**

Manufacturer Initiated Recall of Ansell Sandel Weighted Safety Scalpels

Dear Valued Customer,

We are writing to inform you that we have become aware of an issue with some of our Ansell Sandel Weighted Safety Scalpel products and we are recalling affected lots of scalpels from the market.

We have received notice that select lots of Ansell Sandel Weighted Safety Scalpels are packaged with the scalpel blade exposed beyond the safety shield. 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 manufacturer initiated recall notice to all customers who have ordered products from the following lots:

Product	Lot #	Expiry	Region
2211-N Weighted Safety Scalpel #3 Handle with #11 Blade, (Sterile), Blue Shield with TIME OUT® Sleeve	2782	March 2015	Australia
2210-L Weighted Safety Scalpel, #3L Handle (8.75") with #10 Blade, (Sterile), Orange Shield with TIME OUT® Sleeve	0662	September 2015	Australia
2211-L, Weighted Safety Scalpel #3 Long Handle with #11 Blade, (Sterile), Blue Shield with TIME OUT® Sleeve	0662	March 2015	Australia

Some Ansell Sandel Safety Scalpels were provided to customers as samples for product evaluation. If any of the samples in your possession come from any of the lot numbers listed above, we ask you to follow the actions in the request outlined below

Immediate action requested by Ansell

Ansell requests that you undertake the following immediate actions to assist with its manufacturer initiated recall procedure:

1. Do not ship any Ansell Sandel Weighted Safety Scalpel products with the lot numbers identified in the table above to a hospital or end user. 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).

If you have product samples, check the scalpel/s in your possession to see if they came from one of the lot numbers identified above. 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 attached).

2. Please quarantine any Ansell Sandel Weighted Safety Scalpels with the lot numbers set out in the above table in your stock inventory.
3. Please complete the attached response form and return it to us (return information is set out in the **attached** form).

4. In addition, if you have distributed this product to other distributors or users, please notify them of this manufacturer initiated recall and instruct them to return any outstanding stock to you as indicated in the **attachment**.
5. You will be provided with return authorisation information from Ansell's customer service team. All returned products will either be replaced or credited as soon as practicable.

This manufacturer initiated recall is made with the full knowledge and cooperation of the Therapeutic Goods Administration.

Our mission at Ansell Limited is to improve the safety and wellbeing of healthcare professionals and patients through use of our protective products. We are deeply committed to ensuring that our products are as safe as possible and sincerely apologise for this inconvenience and appreciate your help in supporting this action. If you have any questions or need further information, please call our Customer Service Department on 1800 337 041 or email anzcustomerservice@ap.ansell.com.

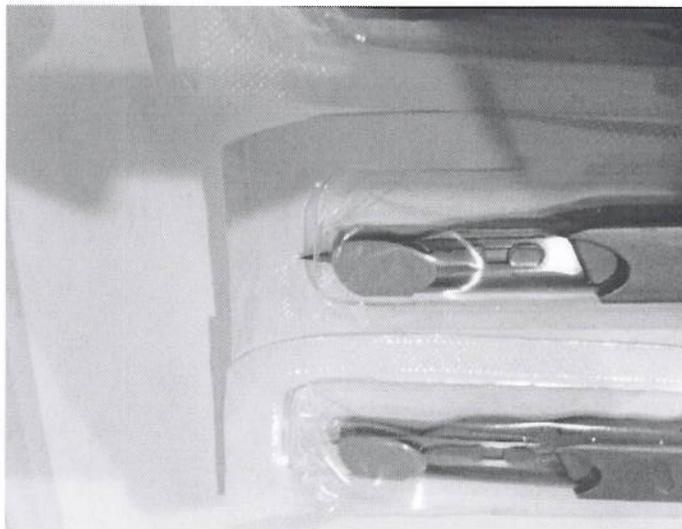
Sincerely,



Peter McCann
Vice President, Regional Sales

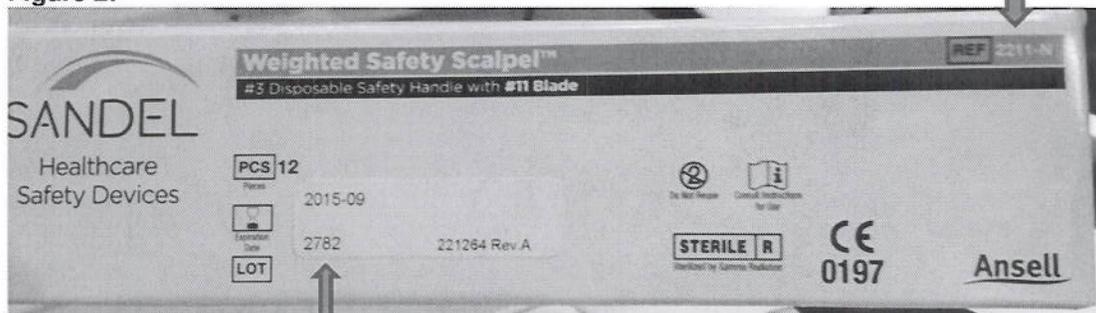
Ansell Limited

Figure 1:



Product REF #

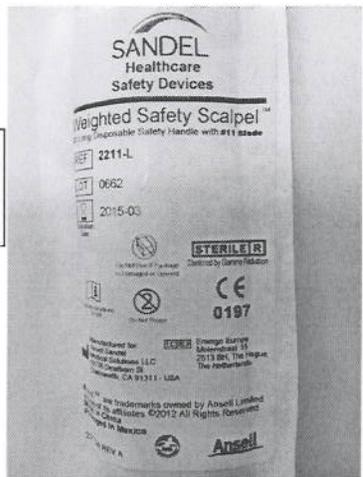
Figure 2:



Lot # Location

Figure 3:

Product REF #
Lot #
Expiry date



**ANSELL SANDEL WEIGHTED SAFETY SCALPEL
MANUFACTURER INITIATED RECALL RESPONSE FORM**

Please complete this form and return it as soon as possible via fax at 1800 803 578 or email at anzcustomerservice@ap.ansell.com

CONTACT INFORMATION:

Company: _____

Your Name: _____

Title: _____

Address: _____

City, State, Postcode, Country: _____

Telephone: _____

E-Mail Address: _____

Signature: _____

Date: _____

RESPONSE REQUIRED:

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

Product	Lot #	Expiry	Region
2211-N Weighted Safety Scalpel #3 Handle with #11 Blade, (Sterile), Blue Shield with TIME OUT® Sleeve	2782	March 2015	Australia
2210-L Weighted Safety Scalpel, #3L Handle (8.75") with #10 Blade, (Sterile), Orange Shield with TIME OUT® Sleeve	0662	September 2015	Australia
2211-L, Weighted Safety Scalpel #3 Long Handle with #11 Blade, (Sterile), Blue Shield with TIME OUT® Sleeve	0662	March 2015	Australia

- 2) [If you answered 'Yes' to #1:] Please list the number of cases, boxes or pieces you currently have either in inventory or as samples in your possession for each affected product.

2211-N, Lot number 2782: Cases: _____ Boxes: _____ Pieces: _____

2210-L Lot number 0662: Cases: _____ Boxes: _____ Pieces: _____

2211-L Lot number 0662: Cases: _____ Boxes: _____ Pieces: _____

NEXT STEPS:

- 1) Please return this completed form to Ansell Customer Service **via fax at 1800 803 578 or email at anzcustomerservice@ap.ansell.com**
- 2) Upon receipt of this form, Ansell Customer Service will contact you with a return goods authorisation 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 Ansell Customer Service **via fax at 1800 803 578 or email at anzcustomerservice@ap.ansell.com**

Thank you for your assistance in supporting this action. If you have any questions, please contact our Customer Service team at 1800 337 041.