

23rd of December 2016

URGENT FIELD SAFETY NOTICE

Product Name: Adson Bipolar Forceps
Product code: 100-115-13100
Lot Number: 301115/AH

Dear Valued Customer,

Adson Bipolar Forceps are used for different applications in surgical procedures.

Our records indicate that you may have purchased at least one of the above products and we would like to share the following information with you.

Problem Statement

Accuscience has identified issues with the product labelling for this product code with this particular lot number.

Table 1

| Product Description | Product Code | Lot Number |
|-----------------------|---------------|------------|
| Adson Bipolar Forceps | 100-115-13100 | 301115/AH |

Risk to Health

There may be a discrepancy between the product labelling description and the physical product resulting in an incorrect size of forceps being used.

Actions Required

Due to our investigation findings, customers and end-users are asked to comply with the following actions with immediate effect:

- Discontinue the use of lots in Table 1.
- Quarantine any remaining product.
- Notify all end-users of this notifications.
- Complete the attached Fax Back Form.

Your Accuscience Account Manager will be in contact to discuss this issue, address any concerns that you may have and arrange for any quarantined stock to be collected and credited to your account.

A thorough investigation into the root cause has been initiated and any corrective/preventive actions will be implemented as appropriate.

Accuscience is committed to offering quality products and superior customer service. Accuscience wishes to sincerely apologise for the inconvenience caused as a result of this Urgent Field Safety Notice. If you have any questions or comments arising from the Urgent Field Safety Notice and for information regarding replacement product should please contact:

Post: Unit C3, M7 Business Park, Newhall, Naas, Co. Kildare

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Yours sincerely,



Caroline Daly
Quality Representative
Accuscience Ireland Ltd.