

13th January 2017

URGENT FIELD SAFETY NOTICE

Product Name:

- Adson Disposable Bipolar Force110mm Straight with 1mm tip
- McPherson Disposable Bipolar Forceps 110mm Straight with straight 0.5mm tip
- 110mm Straight Micro Jeweller with Straight 0.5mm tip
- Disposable Bipolar Forceps 200mm Straight with 1mm Tip

Affected Product Codes and Lot Numbers:

Product Description	Product Code	Lot Number
Adson Disposable Bipolar Force110mm Straight with 1mm tip	100-115-13100	300915/AH, 301115/AH and 30115/AH
McPherson Disposable Bipolar Forceps 110mm Straight with straight 0.5mm tip	100-005-11050	310815, 300915/AH, 301115/HA, 301115/AH and 301115AH
110mm Straight Micro Jeweller with Straight 0.5mm tip	100-085-11050	AV310815, 300915/AH, 301115/AH
Disposable Bipolar Forceps 200mm Straight with 1mm Tip	100-255-20100	AV300915, 311015AH, AV300915, 311115AH and 301115/AH

Please note this Field Safety Notice **supersedes** the previous Field Safety Notice issued by Accuscience Ireland Limited on 23rd December 2016.

Dear Valued Customer,

Bipolar Forceps are used for different applications in surgical procedures.

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

Problem Statement

There were 4 products (Table 1) placed on the market, the authenticity of the products in the pack were not verified and labelling inconsistencies exist in relation to these 4 products. Verification of the information contained on the labels was incomplete.

The incorrect and unverified information placed on these labels by Accuscience include:

- Device Name and Description
- Manufacturer Details
- Sterilisation Method
- CE Mark
- Date of manufacture
- Expiration date

3 lots of McPherson Disposable Bipolar Forceps 110mm Straight with straight 0.5mm tip were incorrectly labelled as 110mm Straight Micro Jeweller with Straight 0.5mm tip.

In the case of the Adson Disposable Bipolar Forceps 110mm Straight with 1mm tip (Ref 100-115-13100) product, we are unable to confirm any details of the actual product supplied in the packaging. As such we do not have any information in relation to the performance or safety of the product supplied to users.

Table 1

Product Description	Product Code	Lot Number
Adson Disposable Bipolar Forceps 110mm Straight with 1mm tip	100-115-13100	300915/AH, 301115/AH and 30115/AH
McPherson Disposable Bipolar Forceps 110mm Straight with straight 0.5mm tip	100-005-11050	310815, 300915/AH, 301115/HA, 301115/AH and 301115AH
110mm Straight Micro Jeweller with Straight 0.5mm tip	100-085-11050	AV310815, 300915/AH, 301115/AH
Disposable Bipolar Forceps 200mm Straight with 1mm Tip	100-255-20100	AV300915, 311015AH, AV300915, 311115AH and 301115/AH

Risk to Health

As the information on the label was not verified and the incorrect product was placed on the market, the quality and performance of the product cannot be guaranteed.

This is an electrical item and if there was an issue with the quality of product this may have implications for user and patient safety.

Actions Required

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

- Discontinue immediately 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:

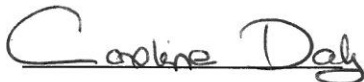
Post: Unit C3, M7 Business Park, Newhall, Naas, Co. Kildare

Telephone: +353 (0)45 882 600

Fax: +353 (0) 45 873 799

E-mail: caroline.daly@pharmed-group.com

Yours sincerely,



Caroline Daly
Quality Representative
Accuscience Ireland Ltd.