

16 April 2014

Field Safety Notice – Return of Instrument

Dear Clinician,

This letter is to inform you that Cochlear has initiated a field corrective action for the Cochlear™ Baha® Soft Tissue Gauge 6 mm, part # 95070.

This item may have a manufacturing imperfection in the smooth surface of the metal. While this imperfection is minimal, our risk analysis has indicated that it could potentially leave residual metal on the patient's skin. To date there have been no adverse events reported to Cochlear associated with the use of this instrument. We advise you to no longer use the instrument and return it to Cochlear. We are notifying the appropriate authorities in the affected markets regarding this action.

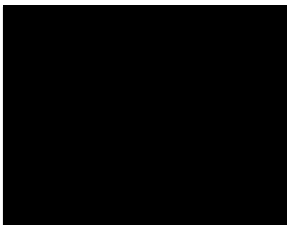
We will replace the Soft Tissue Gauge as quickly as possible. The instructions on how to return the product and how to get a replacement product in order to minimize any impact on scheduled surgeries are provided in Annex 1 of this letter. The log sheet to track the items returned by the clinics is provided in Annex 2 of this letter.

PLEASE COMPLETE, SIGN AND RETURN THE LOG SHEET WITHOUT DELAY.

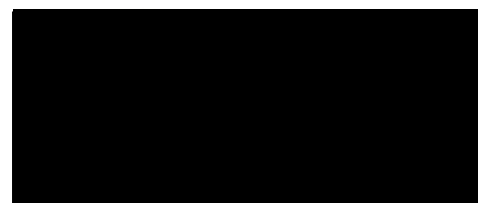
We apologize for any inconvenience and would like to express our sincere thanks for your support in this process.

If you have any questions regarding this letter please do not hesitate to get in touch with your Cochlear representative.

Sincerely,



President EMEA & Latin America



Head – Clinical, Technical,
Research & Regulatory, EMEA

**Annex 1 – Return and replacement instructions for the Cochlear™ Baha® Soft Tissue
Gauge 6mm, part # 95070.**

**FSCA Baha Soft Tissue Gauge 6mm - Part 95070
Return Instructions**

1. Please forward the enclosed letter and Inventory Log sheet to those staff in your organisation who will be able to locate any affected product, both clinic stock and any 'in use' stocks in your possession.
2. Fill in the enclosed Inventory Log Sheet with the affected quantity and LOT numbers. If you have none of the above mentioned stocks, please also confirm this on the Inventory Sheet.
3. Please liaise with your Cochlear representative to receive a Return Material Authorisation. This will help facilitate the return of the products.
4. Scan the Inventory Log Sheet, e-mail it immediately to FSCA@Cochlear.com and keep a copy for your own records.
5. A courier will be arranged by your Cochlear representative to pick up the affected products and the Inventory Log Sheet. Both shall be returned to:

**Cochlear Europe Ltd
Attn: FSCA Baha Soft Tissue Gauge - Part 95070
6 Dashwood Lang Road
Bourne Business Park
Addlestone
Surrey KT15 2HJ
United Kingdom**

We are asking you to complete the above actions without delay.

Our Customer Service will be in contact with your department to discuss the replacement product to minimise any impact on scheduled surgeries.

Annex 2 – Log Sheet for the returned Cochlear™ Baha® Soft Tissue Gauge 6mm, part # 95070.



**PLEASE COMPLETE THIS SHEET, SCAN IT AND SEND IT IMMEDIATELY TO:
FSCA@cochlear.com**

PLACE ANOTHER COPY INSIDE THE PACKAGE WITH THE RETURNED PRODUCT. ADDRESS THE COURIER TO:

Cochlear Europe Ltd
Attn: FSCA Baha Soft Tissue Gauge - Part 95070
6 Dashwood Lang Road
Bourne Business Park
Addlestone
Surrey KT15 2HJ
United Kingdom

For pick-up by courier please call your local Customer Service person. Cochlear will cover the costs for the shipment.

RMA Number(s) provided by Cochlear:

**INVENTORY LOG SHEET
FSCA Baha Soft Tissue Gauge 6mm - Part 95070**

I confirm that the records below are correct:

<u>Clinic Name</u> (CAPITAL LETTERS)	<u>Your Name and Phone</u> (CAPITAL LETTERS)	<u>Date and Signature</u>

Please return all your Baha Soft Tissue Gauge 6mm - Part 95070

Please fill in the quantity and the LOT numbers (if possible). If none are on stock, please write "0" into the "Quantity returned". Thank you for your cooperation.

**IF PRODUCT HAS BEEN USED,
IT MUST BE STERILISED BEFORE IT IS RETURNED.**

<u>Baha Soft Tissue Gauge 6mm – Part Number 95070</u>			
		<u>Quantity</u>	<u>Security Seal Broken</u>
1. LOT number			Yes / No
2. LOT number			Yes / No
3. LOT number			Yes / No
4. LOT number			Yes / No
5. LOT number			Yes / No
6. LOT number			Yes / No
7. LOT number			Yes / No
8. LOT number			Yes / No

If more than 8 different LOT numbers of Baha Soft Tissues Gauge 6mm are returned, please attach as many copies of this sheet as needed or provide a separate list of LOT numbers.