PHILIPS

URGENT Field Safety Notice

Philips Fetal Spiral Electrode
Needle Tip Breaking

Date of letter deployment: 18-NOV-2022

To: Customer Name: NHS SUPPLY CHAIN

Customer Response ID: 4436

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain this letter for your records.

Dear Customer,

Philips has become aware of a potential safety issue with the Fetal Spiral Electrode (FSE) based on complaints related to the spiral tip of the FSE breaking off during use and requiring surgical intervention to remove the broken tip from the neonate patient. As a result, Philips has decided to discontinue the distribution of this product.

The Fetal Spiral Electrode is intended for patients requiring fetal heart rate monitoring during labor. FSEs are only used when traditional/external fetal monitoring is inadequate such as with high BMI patients or when external monitoring indicates that the fetus may be in distress. The device consists of a stainless-steel spiral needle electrode. It is fixed to the fetal scalp by penetration of the skin by the spiral needle and thereby obtains the fetal ECG signal.

This *URGENT Field Safety Notice* *is* intended to inform you about:

1. What the problem is and under what circumstances it can occur

- Philips has found that the spiral tip of the FSE may break off during use, potentially requiring surgical intervention to remove the broken tip from the patient. Based on Philips investigation, this can occur due to over rotation during attachment or pulling the tip from the fetal scalp.
- The FSE may also break off if the user **pulls** the spiral tip from the fetal skin, increasing the risk of the spiral tip detaching from the FSE during removal.

To date, our investigations have been unable to identify a product defect contributing to the observed issue; however, this result does not ensure that the above are the only root causes for the reported complaints. Due to inconclusive root cause investigation results and the increased rate of reported adverse events, Philips has decided to discontinue distributing the FSEs.

2. Hazard/harm associated with the issue

The hazardous situation that exposes the patient to harm is the spiral tip of the FSE breaking off in the patient's scalp requiring an additional procedure to remove the broken segment of the FSE from the patient. The hazardous situation can occur under various circumstances, as described above. See a picture of the FSE tip magnified in section 3 below.

- Immediate and Long-Term Consequences:

The tip of the FSE detaching in situ could result in a retained foreign body in the scalp of the fetus. Consequently, medical intervention may be required to remove the FSE tip (or tip fragments). Additionally, an infection, abscess, and wound/tissue damage may also occur and could require antibiotic treatment in the vulnerable neonate population. An x-ray, which would expose a neonate to radiation, may also be required to aid health care professionals locate the detached FSE tip/fragments.

3. Affected products and how to identify them

Philips Fetal Spiral Electrode: Model # 989803137631 UDI# 20884838007431

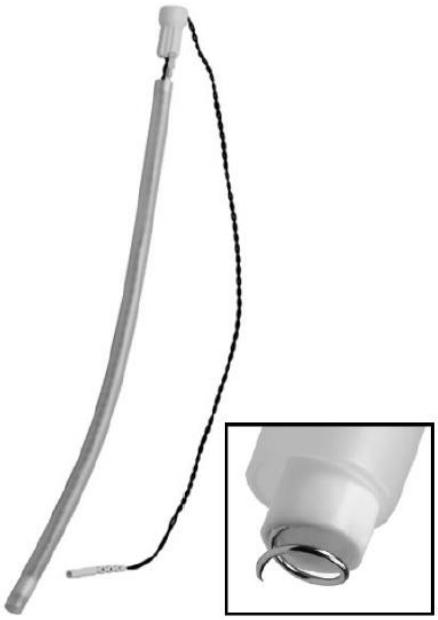


Figure 1. Fetal Spiral Electrode

4. Actions that should be taken by the customer / user in order to prevent risks for patients or users

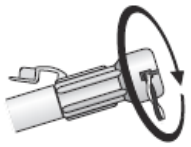
Important actions to follow in the Instructions for Use (IFU) state the following:

- Do not over-rotate Spiral Tip during attachment.
- Do not pull the Spiral Tip from the fetal skin. Do not pull the FSE wires apart.

Figure 2. Warnings – Fetal Spiral Electrode IFU (page. 2)

Turn

Turn the Grip clockwise—typically 1 full turn using the Protection Tab as a visual guide—until mild resistance indicates full attachment.



WARNING: Do not over-rotate.

Figure 3 in the IFU, page 4 and warning below: Applying FSE

Grasp the FSE electrode wires as close as possible to the fetal presenting part, turning them counterclockwise until the Spiral Tip comes free from the fetal skin.

Figure 4 in the IFU, page 5: Removing the FSE

WARNING: Do not pull the Spiral Tip from the fetal skin. Do not pull the FSE wires apart.

Inspect the Spiral Tip to ensure that it is still attached to the FSE Hub. If the tip has separated from the hub and remains embedded in the presenting part, remove it using aseptic technique. Remove the Attachment Electrode from the Legplate Adapter Cable.

Figure 5 in the IFU, page 5: Removing the FSE

In addition to the above:

- Customer should complete the Urgent Field Safety Notice Response Form online to submit both their acknowledgement of this recall **(mandatory)** and actions taken, as well as request for credit (*optional*). To request credit go to URL: https://forms.office.com/r/GsLVh2gYZi

- Pass this notice to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (If appropriate).

If you choose, discard all FSEs sold by Philips and source from an alternative supplier available in your country. If you choose to discard the FSEs, we will issue a credit after you complete the online response form.

Important! When completing the online response form and to receive credit, please provide the information listed below:

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1. The Customer Response ID provided on the top of this letter.
2. Quantity (counted by each or individual) of Philips Fetal Spiral Electrode to be credited.

5. Actions planned by Philips Hospital Patient Monitoring to correct the problem

- Philips is continuing to investigate additional root causes with FSE supplier
- Philips will immediately discontinue selling the FSEs
- Philips will reimburse for any discarded FSEs

If you need any further information or support concerning this issue, please contact your local Philips representative UK Philips Customer Care Service Centre on 0870 532 9741 or Ireland Philips Customer Care Service Centre on +353 1 7640229

This notice has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product may be reported to the event to authority UK Medicines and Healthcare products Regulatory Agency or Ireland Health Products Regulatory Authority. Philips regrets any inconvenience caused by this problem.

Sincerely,

Jeffrey Hoebelheinrich
Head of Quality
Medical Consumables & Supplies
Philips Healthcare

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URGENT Field Safety Notice Response Form

Reference: Philips Fetal Spiral Electrode Needle Breaking Off During Use

Instructions: Please complete and return this form to safetynoticeuki@philips.com promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

_____

_____

Customer Actions:
To ensure safe use of the product, all clinicians should:

- Review Important actions listed in the Instructions for Use (IFU) and Urgent Field Safety Notice Letter.
- Pass this notice to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (If appropriate).

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice Letter and confirm that the information from this Letter has been properly distributed to all users that handle the Philips Fetal Spiral Electrode.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

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Date (DD / MMM / YYYY): _____

Please email this completed form to safetynoticeuki@philips.com