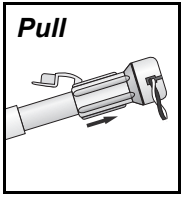
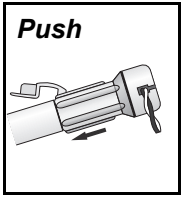
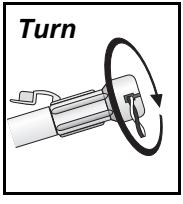
Fetal Spiral Electrode

Instructions for Use







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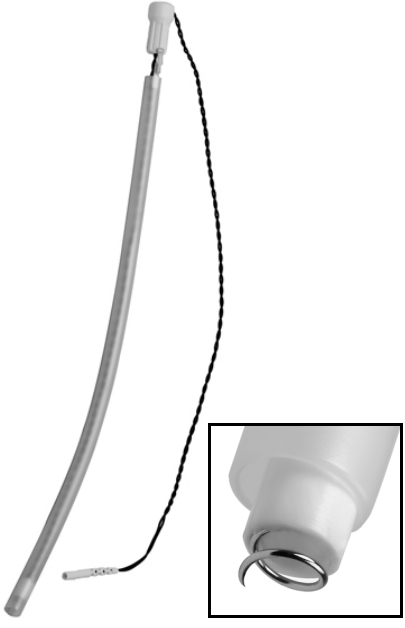

PHILIPS

About This Edition

Notice

Printing History

Current Edition:

Part Number: 4535 640 65231
July, 2007

Previous Editions:

Part Number: 4535 640 14561
November, 2004

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R_x only United States law restricts this device to sale by or on the order of a physician.

Instructions for Use

Indications

The Fetal Spiral Electrode (FSE) is for use on patients requiring fetal heart rate monitoring by way of fetal scalp during labor and delivery.

Contraindications

Do not apply to fetal face, fontanels, or genitalia, or when placenta previa is present or suspected, or in the presence of active herpes lesions, hepatitis C or HIV infection. Do not apply when woman is a confirmed carrier of hemophilia and fetus is affected or status is unknown, or when it is not possible to identify fetal presenting part where application is being considered.

Use caution and refer to your own institution's policies and procedures when fetus is premature, or woman is positive for Group B streptococcus, hepatitis A, hepatitis B, syphilis, or gonorrhea.

Definition of Product Symbols

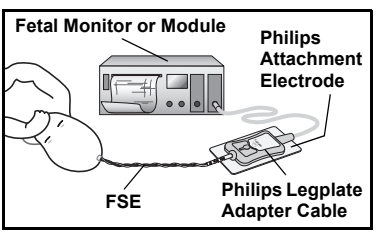
 Do Not Reuse	 Do Not Use If Seal Is Broken	 Contains No Latex	 Caution Consult Instructions	 Sterilized Via Irradiation

Warnings

- Due to design of the FSE, penetration of fetal epidermis may possibly cause trauma, hemorrhage and/or infection. Thus, the FSE must be used under conditions of aseptic technique.
- Amniotic membranes must be ruptured prior to attachment of the FSE.
- This FSE is intended for fetal monitoring only. Any other use may damage the device and result in difficulty attaching it to a fetus, or adversely affect its ability to aquire and maintain an accurate fetal signal.
- Remove the FSE from patient before performing any electro-surgical procedures.
- Do not pull the Spiral Tip from the fetal skin. Do not pull the FSE wires apart.
- Do not over-rotate Spiral Tip during attachment.

Additional Required Components

The FSE requires the following additional components (see the inside back cover for more information):



- Fetal Monitor or Module
- Philips Attachment Electrode
- Philips DECG Reusable Legplate Adapter Cable (commonly called the Legplate Adapter Cable)

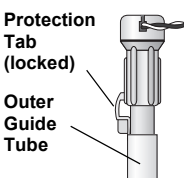
Caution

Verify that additional required components used for the monitoring procedure are fully compatible with this FSE. Look for yellow color code on cable.

Before Applying the FSE

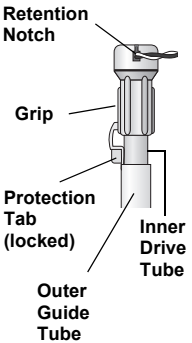
- Always follow the ***Instructions for Use*** for this product and any components with which it operates. Failure to do so may compromise the ability to obtain accurate measurements.
- Be sure to read and fully understand application precautions as explained under ***Contraindications*** and ***Warnings***.
- The FSE is for use only with previously defined ***Additional Required Components***.
- If the fetal presenting part cannot be clearly identified, do not attach the FSE to the fetus.
- During the procedure, keep the FSE electrical connector free of body fluids and liquids.
- To become familiar with the operation and feel of the FSE, it is recommended that users practice the procedures in the sections, ***Applying the FSE*** and ***Removing the FSE***, under simulated conditions prior to actual use during delivery.

NOTE: Leave the FSE Protection Tab in its 'locked' position. The Spiral Tip should remain retracted within the Outer Guide Tube until you are ready to attach the FSE to the fetus.



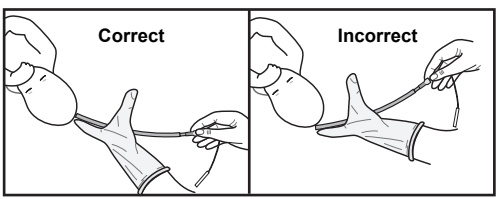
Applying the FSE

Using aseptic technique, remove the FSE from its package (leave wires locked in the Retention Notch at the top of the FSE). If necessary, gently shape the Outer Guide Tube to accomodate the anatomy of the mother.



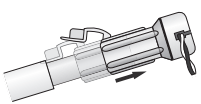
Insert

Insert the FSE until presenting part is contacted. Be sure the Guide Tube end is held flat against presenting part while performing the following steps.



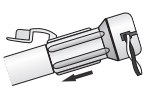
Pull

Pull the Grip out from the Outer Guide Tube enough to release the Protection Tab from the Guide Tube.



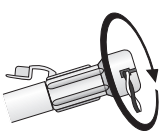
Push

With Protection Tab released, push the Grip back in until the spiral tip contacts the presenting part.



Turn

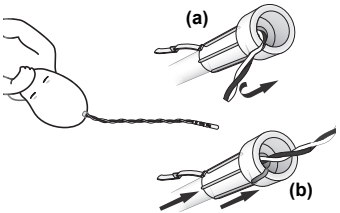
Turn the Grip clockwise—typically 1 full turn using the Protection Tab as a visual guide—until mild resistance indicates full attachment.



WARNING: Do not over-rotate.

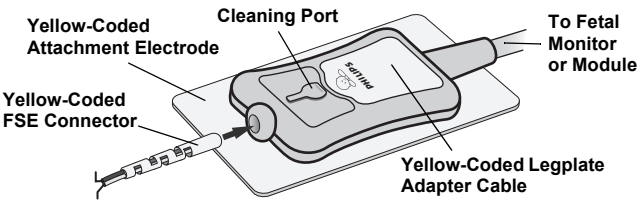
Release

Release wires from Retention Notch (a). Grasp Guide Tube, slide both Guide and Drive tubes off wires (b).



Connect

Snap the Attachment Electrode to the bottom of the Legplate Adapter Cable. Apply the Attachment Electrode (adhesive side) to the mother. Verify the FSE Connector is clean and dry, then insert it securely into the end of the Legplate Adapter Cable. Do not insert the connector into the cleaning port.



Removing the FSE

Pull the FSE connector out of the Legplate Adapter Cable. Grasp the FSE electrode wires as close as possible to the fetal presenting part, turning them counter-clockwise until the Spiral Tip comes free from the fetal skin.

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.