

# CUSTOMER INFORMATION BULLETIN

## Update to Copeland® Fetal Scalp Electrode IFU

Dear Customer,

We would like to bring to your attention several updates we have made to the Copeland® Fetal Scalp Electrode IFU to provide extra clarity regarding attachment and set up and warnings against reuse, reprocessing and re-sterilisation.

- We have provided a guide as to the level of rotation required to open and close the needle during attachment. The IFU now states, “ With the fingers of the other hand, rotate (C) approximately 180° ANTI-CLOCKWISE to open the needle and then approximately 180° CLOCKWISE to insert the needle into the fetal scalp.”
- We have added the text, “Firmly connect the fetal scalp electrode to the leg plate and the leg plate to the maternal attachment electrode.”
- The troubleshooting steps now read:
  1. Check that you have followed the instructions and applied the fetal scalp electrode correctly.
  2. Check that the fetal monitor and paper recorder is switched on.
  3. Check that the maternal attachment electrode is correctly applied and is connected to the leg plate.
  4. Check that the leg plate cable is correctly connected to the monitor.
  5. Check that the fetal scalp electrode is firmly and securely inserted into the leg plate.
  6. Re-position the electrode.
  7. Replace the electrode.
- We have added the following text, “For Single Use Only. Do not reuse on another person, reprocess or re-sterilise as doing so may compromise the structural integrity of the device, leading to device failure; potentially the cause of serious harm to patients and users. Reuse, reprocessing or re-sterilisation may also result in serious harm to patients and users from cross-contamination and infection with transmissible diseases. Unless opened or damaged, contents of package are sterile.



If you have any queries regarding these changes, please do not hesitate to contact your Rocket Medical representative.

Product Code	Description
R57008-00-CN	Rocket® Copeland® Fetal Scalp Electrode for Qwik Connect Cables
R57008-00-FM	Rocket® Copeland® Fetal Scalp Electrode for Philips Avalon FM30/FM50 DECG Cables

**Customer Information Bulletins** for all of our products can be found on our website at: [www.rocketmedical.com](http://www.rocketmedical.com)