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Rocketmedical

ROCKET MEDICAL PLC – SRN: GB-MF-000025375

Urgent Field Safety Notice NVFSN-09

R57008-00-FM Copeland® Fetal Scalp Electrode for Philips® Avalon® FM30/FM50 DECG Cables & R57008-00-CN Copeland® Fetal Scalp Electrode for Qwik Connect Cables 6Fg

07 May 2025

Dear Customer,

Rocket Medical is issuing this Field Safety Notice regarding the devices listed in Table 1. Our records indicate that you have one or more of these devices.

Affected Product Codes:

Image 1: R57008-00-CN / R57008-00-FM

Image 2: R57008-00-CN / R57008-00-FM

Figure 1: This is an image showing R57008-00-FM and R57008-00-CN

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Product Code(s)	Product Description(s)	Affected LOT(s)	Basic-UDI(s)
R57008-00-FM	Copeland® Fetal Scalp Electrode for Philips® Avalon® FM30/FM50 DECG Cables	503459 503458 503457 503329 503328 500028 499185	050552709TF30AXP
R57008-00-CN	Copeland® Fetal Scalp Electrode for Qwik Connect Cables	503557 499108	050552709TF30AXP

Table 1

Description of the problem:

Revision 16 of ZDOCK167, the Instructions For Use (IFU) of the Fetal Scalp Electrodes is missing the following Warning and Cautions. These were present in previous revisions of the IFU but were erroneously removed from Revision 16. The missing information has now been added to Revision 17 of the IFU which accompanies this FSN.

WARNING:	Chronic fetal bleeding (e.g., due to partial placental abruption) leading to loss of fetal blood volume, may compromise the fetus's ability to successfully respond to hypoxia.
CAUTION:	Do not rely on the spring tension to insert the needle into the skin.
CAUTION:	Device performance and safety has not been verified for use in water births. The device must not be immersed in water.
CAUTION:	If there is severe maternal thrombocytopaenia, any decision to use the fetal scalp electrode should be taken carefully, considering the potential risks and benefits, and taking account of clinical guidelines. In case of accidental maternal injury from the electrode, or if the fetus is affected, there may be increased bleeding, bruising or abnormal blood clotting.

Actions Required by Customers:

We understand that you received the above referenced product(s) and therefore request that you follow the steps listed below:

- Ensure a copy of this FSN and the updated IFU is available to all users or potential users of this device
- Complete the FSN acknowledgment form at the end of this document and return to: CustomerServices@rocketmedical.com

Stock Instruction:

- Stock is not affected; no action is required.

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Rocket Medical PLC. does not expect any disruption in the supply of this device as a result of this issue.

We have notified the relevant regulatory authorities of this issue and resulting Field Safety Corrective Action.

Your cooperation in this matter is greatly appreciated. We would like to sincerely apologise for the inconvenience caused by this issue and thank you for your continued custom. If you have any questions on this issue, please contact your Rocket Medical sales representative.

Yours sincerely,

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[redacted]

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Tel:
Fax:
Email:
Web:

[redacted]

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Customer Acknowledgement Form

Please complete this form *even if you have not seen this issue.*

Product Code	Product Description	Affected LOTs
R57008-00-FM	Copeland® Fetal Scalp Electrode for Philips® Avalon® FM30/FM50 DECG Cables	503459 503458 503457 503329 503328 500028 499185
R57008-00-CN	Copeland® Fetal Scalp Electrode for Qwik Connect Cables	503557 499108

On behalf of this organisation, I acknowledge that I have read and understood this FSN, completed the indicated actions and that the information will be displayed in a prominent position within the appropriate clinical environment for a minimum of one month from the date of receipt.

Number of Units in Affected LOTs:	

Organisation		**Location (Country)**	
Address			
Email		**Telephone no.**	
Name		**Position no.**	
Signature		**Date**	

Return completed forms by email to:

Name	David Ashby
Position	Regulatory Affairs Manager
Organisation	Rocket Medical PLC
Email	CustomerServices@rocketmedical.com
Subject of email	URGENT FIELD SAFETY NOTICE Fetal Scalp Electrode

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