ROCKET MEDICAL PLC
SEDLING ROAD
WASHINGTON
TYNE & WEAR NE38 9BZ
ENGLAND

TEL: +44 191 419 4488
FAX: +44 191 419 5693
Email: sales@rocketmedical.com
www.rocketmedical.com

[Date]

[Name and title of the customer]

[Address]

URGENT PRODUCT DEFECT CORRECTION

Product names: Rocket FBS Sampling Wand (R57021-55-SW)

Description of items: Rocket Fetal Blood Sampling Kits for Lactate measurement and derivatives. Procedure kit for single patient use, to obtain up to 5 fetal blood lactate samples in cases of suspected fetal distress during labour.

Product codes Affected: 57021-55-SW

LOT Numbers affected (R57021-55-SW): 000000000479346, 000000000481342, 000000000485931, 000000000486822, 000000000488905, 000000000489722

Expiry dates: Various, ranging from (oldest to newest) 15-May-2021 to 12-May-2023

Rocket Medical is conducting a product correction safety alert concerning the above product names and descriptions. We are contacting you as the potentially affected product has been supplied to your organisation.

Problem / Issue

Product code R57028-00-SW is indicated for use in lactate analysis of fetal blood (IFU reference ZDOCK256), but we have become aware that the tubes within the kit are not of the required specification for lactate analysis using some analysers. Rocket Medical cannot rule out that this may result in an incorrect / misleading reading from which a clinical decision is made.

The tubes contained within the kit are of Na/Li unbalanced heparin in high concentration (240USP/ml). Rocket Medical has updated the IFU for the kits to make clear the tube specification. It is important that users verify the tube specification required by the analyser prior to use. If this verification is undertaken for all analysers used in lactate analysis at your facility and the Rocket kit only used where compatibility is confirmed, then there is no potential for harm from this issue. Future kits will include the updated IFU.

In addition, Rocket Medical has updated the intended use for these kits to reference use with handheld lactate analysers only. Users who wish to perform lactate analysis using blood gas analysers should contact their analyser manufacturer for advice regarding compatible tubes.

Product codes R57021-55-SW and R57021-85-SW (IFU reference ZDOCK185) consist of a sampling wand and capillary tubes and are indicated for the puncture of the fetal scalp and collection of fetal blood for analysis during labour. The analyte is not stated in the IFU. The IFU has been updated to indicate use for the puncture of the fetal scalp and collection of fetal blood for the determination of pH/blood gas. Future kits will include the updated IFU.

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This action affects all LOTs of Rocket FBS Kit for Lactate with Sampling Wand, R57028-00-SW, Rocket FBS Sampling Wand (R57021-55-SW) & FBS Sampling Wand (R57021-58-SW) as listed above, which are still within shelf-life.

Action

Ensure relevant staff members are informed of this action, including locums. Verify that any tubes you have are suitable for the analysers in use at your facility.

If you have supplied or transferred any potentially affected product to another facility or organisation, let that facility know of the non-recall action **immediately** by providing a copy of this letter.

Complete the attached acknowledgement form **immediately** and by 19 August 2020, **even if you do not have any affected stock remaining** and return it to Intcomp127@rocketmedical.com to reconcile this process.

Place this letter in a prominent position for at least one month.

If you have any product that is incompatible with your analysers, please contact Rocket Medical for further guidance.

For further information please contact me, Tracy Charlton, at Intcomp127@rocketmedical.com.

Thank you for your assistance in helping us to manage this situation. Rocket Medical Pty Ltd sincerely regrets any inconvenience caused to your organisation.

T. Charlton

Tracy Charlton

Regulatory Affairs Manager
Rocket Medical Plc

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Customer acknowledgement form

Please complete this form *even if you do not have any affected stock.*

URGENT PRODUCT DEFECT CORRECTION

Description of items: Rocket Fetal Blood Sampling Kits for Lactate measurement and derivatives. Procedure kit for single patient use, to obtain up to 5 fetal blood lactate samples in cases of suspected fetal distress during labour.

Product code: R57021-55-SW

LOT Numbers affected (R57021-55-SW): 000000000479346, 000000000481342, 000000000485931, 000000000486822, 000000000488905, 000000000489722

Expiry dates: Various, ranging from (oldest to newest) 15-May-2021 to 12-May-2023

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

FROM:

Organisation	
Position	
Name	
Email	
Telephone no.	
Date	
Signature	

Return completed forms by email to:

Name	Tracy Charlton
Position	RA Manager
Organisation	Rocket Medical PLC
Email	Intcomp127@rocketmedical.com
Subject of email	Action Response