ROCKET MEDICAL PLC
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www.rocketmedical.com

[Date]

[Name and title of the customer]

[Address]

URGENT PRODUCT DEFECT CORRECTION

Product name: Rocket FBS Kit for Lactate with Sampling Wand, R57028-00-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 code: R57028-00-SW

LOT Numbers affected: 000000000483581 and 000000000486235

Expiry dates: Various, ranging from (oldest to newest) 24-Feb-2022 and 15-Sep-2022

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

Problem / Issue

The device is indicated for use in lactate analysis of fetal blood, 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 kit (a copy of which is provided) 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.

This action affects all LOTs of Rocket FBS Kit for Lactate with Sampling Wand, R57028-00-SW, as listed above, which are still within shelf-life. No other Rocket Medical devices are affected.

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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 12 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

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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

Rocket FBS Lactate Kits
INSTRUCTIONS FOR USE

Indications: These instructions apply to Rocket Fetal Blood Sampling Kits for Lactate measurement, product code R57028-00-SW. Procedure kit for single patient use, to obtain up to 5 fetal blood lactate samples in cases of suspected fetal distress during labour. If additional sampling is necessary or if labour is protracted, a further pack may be required. This device should only be used by or under the supervision of trained personnel and in conjunction with current local clinical practice guidelines.

This kit is indicated for use with handheld lactate analysers that are compatible with the collection of blood in capillary tubes containing Na/Li unbalanced heparin in high concentration (240USP/ml).

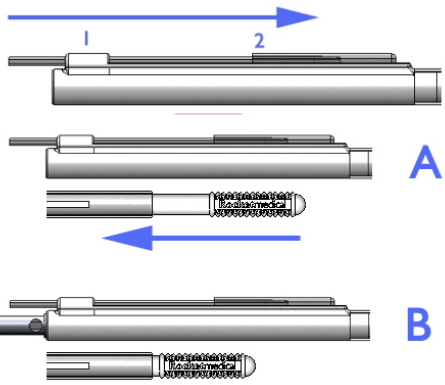
Contraindications: This procedure is contraindicated with placenta previa, when identification of the presenting part is uncertain, in the presence of genital infections (e.g. herpes, Group B streptococcus, gonorrhoea, HIV/AIDS and Hepatitis B) or where the mother is a confirmed carrier of haemophilia and the fetus is either affected or of unknown status, or acute fetal compromise with associated fetal bradycardia of >3 mins.

WARNING: Do not use this kit without prior verification that it is suitable for use with the analyser.

CAUTION: Avoid fetal face, fontanels and genitalia.
CAUTION: DO NOT USE ETHYL CHLORIDE SPRAY – this may adversely affect the internal surface of the plastic amnioscope.
CAUTION: Do NOT use the sample if the blood clots
CAUTION: Do not shake the filled collection tube or use wires and magnets to mix heparin. Use of these techniques may cause air entrainment into the sample. Samples containing air bubbles may be rejected by the analyser.

Preparation:

1. Using aseptic technique, remove the kit from outer bag and unfold outer drape to form a sterile field.
2. Follow local hospital procedure to prepare the perineum and vagina using antibacterial solution.
3. Select a capillary tube from the kit and load into the holder. Locate the end of the tube into the holder at ❶ and then gently advance into the rear tube grip at ❷. Ensure the tube is secure before sampling.
4. The sampling wand comes pre-fitted with an FBS blade. Lightly holding the shaft and rear finger grip (A), push the grip forward to expose the blade (B). **Ensure the blade is locked forward before use.**
5. Locate the Amnilume over the slot in the endoscope and push gently to engage. The light will activate when the light source is correctly fitted. Remove by pushing off with the thumb.
6. Insert endoscope complete with obturator into the vagina against the fetal presentation. Remove obturator. Position the bevelled end by rotating endoscope to obtain the best possible seal against the fetal presentation.
7. Clean the puncture area with the x-ray detectable gauze swabs and forceps provided.
8. With a clean swab stick, apply a *thin* layer of petroleum jelly (supplied) to the puncture area to promote blood aggregation.
9. **IMPORTANT:** Remove excess petroleum jelly with a new dry swab stick before skin puncture.
10. Perform skin puncture through the endoscope using the FBS blade holder or Sampling Wand. Either ❶ make a vertical stab, rotate the blade 90° and make a second stab to form a cross or ❷ make a vertical stab, then angle the blade upwards and extend using the front edge of the blade to produce a single incision 4-5mm long. Always wait for a good sized (3-4mm) bead to form on the surface before collection. Never slash at the scalp and avoid multiple small stabs. Rocket® FBS blades have a maximum depth of penetration of 2.2mm.
11. Collect the blood sample using the capillary tube. Typically, handheld lactate analysers require up to 10µl of blood, which can be obtained by filling the distal 1-2cm of the sampling tube only.
12. Attach a Rocket Capillary Tube Dispenser to the proximal end of the tube.
13. Following the analyser manufacturer's instructions, insert a test strip into the analyser and squeeze the bulb to dispense a suitable bead of blood onto the test strip. Complete the analysis.



Post sampling:

14. Haemostasis is accomplished by applying pressure to fetal puncture site with a swab for one full contraction.
15. If test results and local clinical guidance so indicate, repeat procedure.

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.

Disposal:
This device should be handled and disposed of in accordance with local hospital policy and with regard to all applicable regulations, including but without limitation to, those pertaining to human health & safety and care of the environment.

NATURAL LATEX **This device is not manufactured with natural rubber latex**

℞ ONLY

STERILE EO

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EC REP **Rocket Medical GmbH**
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Germany

DO NOT RESTERILISE
Unless opened or damaged, contents of package are sterile.
Store at room temperature. Avoid prolonged exposure to elevated temperatures.

CE 1639