

URGENT FIELD SAFETY NOTICE

Field Safety Corrective Action:

| | |
|--------------------------------|--------------------------------|
| Commercial Name: | Rocket® FBS Amnioscopes |
| Affected Product Codes: | See table |
| LOT: | ALL |
| Type of action: | Advice |
| Date of Notice: | 16th August, 2019 |
| Reference: | CUST-OCC144 |

Use of Ethyl Chloride with Rocket Medical and NuSurgix Fetal Blood Sampling (FBS) Amnioscopes

Dear Valued Customer,

This Urgent Field Safety Notice (FSN) has been issued in regards to the use of ethyl chloride spray with Rocket Medical and NuSurgix single use amnioscopes, supplied individually and as part of Rocket® and NuSurgix FBS Kits.

Description:

Rocket Medical has received a complaint regarding the use of AXONGESIC ethyl chloride spray with Rocket FBS Amnioscopes. On contact with the spray, a white deposit was observed on the surface of the amnioscope and on the fetal scalp. This suggests an incompatibility between ethyl chloride and ABS.

ABS is a common plastic material with established biocompatibility and is widely used in similar medical devices for fetal blood sampling. ABS is the material used for both Rocket® and NuSurgix amnioscopes.

Rocket Medical Actions:

As a precautionary measure, we are investigating a change of material for the amnioscope body material across all Rocket® and NuSurgix branded amnioscopes.

Customer Actions:

Until such time as a new material is introduced, we advise that ethyl chloride spray should NOT be used with Rocket Medical or NuSurgix amnioscopes. We have updated product Instructions for Use to reflect this. Please be aware that product already in the supply chain will not carry this warning.

Communication of this FSN:

This FSN must be communicated to Hospital Supply Departments, Medical Device Safety Offices and all those responsible for conducting Fetal Blood Sampling within your facility.

For any devices that have been transferred to other organisation(s), please ensure that details of these devices are returned to Rocket Medical and that a copy of the FSN is provided to the organisation(s) to which the device has been transferred.

Awareness of this FSN should be ensured for the duration of the product lifespan (limited by expiry date), which is a maximum of 5 years for this product.

We confirm that the appropriate regulatory agencies have been advised of these actions.

PRODUCT CODES**Rocket® Fetal Blood Sampling Kits**

R57012
R57012-00-SW
R57013
R57013-00-SW
R57018
R57018-00-SW
R57024
R57024-00-SW
R57026
R57026-00-SW
R57026-NI-SW
R57027
R57028
R57028-00-SW
R57029-NUSX

Rocket® Amnioscopes

R57016
R57016-NS
R57016-NS-BULK
R57016-PLUS
R57016-PLUS-NS
R57016-LUME-NS
R57016-LUME
R57017

ACKNOWLEDGEMENT OF URGENT FIELD SAFETY NOTICE**Field Safety Corrective Action:**

Commercial Name: Rocket® FBS Amnioscopes
Affected Product Codes: See table
LOT: ALL
Type of action: Advice
Date of Notice: 16th August, 2019
Reference: CUST-OCC144

Please complete, scan and return this form, or email your responses, as soon as possible and no later than 16th September to cust-occ144@rocketmedical.com

We confirm that we have read and understood the Field Safety Notice: **“Use of Ethyl Chloride with Rocket Medical and NuSurgix Fetal Blood Sampling (FBS) Amnioscopes”** and have implemented the recommended actions.

Hospital/Account: _____

Department: _____

Address: _____

Form Completed by:

Name: _____

Role: _____

Email Address: _____

Telephone Number: _____

Signature: _____

Date: _____

Rocket Medical plc sincerely apologises for the inconvenience this may cause and are working to resolve the situation as rapidly as possible.

For further information please contact our QA Manager: Jackie Irwin at cust-occ144@rocketmedical.com