Rocketmedical

Perinatal Care

URGENT FIELD SAFETY NOTICE

Field Safety Corrective Action

Commercial Name:	**Rocket® KCH Fetal Bladder Drain**
Affected Product Codes:	R57405
LOT:	**ALL**
Type of action:	**Advice**
Date of Notice:	30th July, 2019
Reference:	**CUST-OCC110**

Rocket® KCH Fetal Bladder Drain

Dear Valued Customer,

This Urgent Field Safety Notice (FSN) has been issued in regards to the Rocket® KCH Fetal Bladder Drain, Product Code R57405.

Description:
A complaint has been received regarding kinking of the device prior to use. Our investigation suggests that the most likely cause for this failure is handling in a way that is not in accordance with the IFU. If a device is kinked it cannot be used. If a spare device is not available this may result in a delay to the procedure. Temporary drainage can be provided via the device introducer or a needle.

In addition, we have become aware that the device has been used for pleural drainage, which is not included in the device indications. Such use is off-label. Rocket Medical has not conducted the necessary activities to demonstrate the safety or performance of the device in pleural drainage.

Rocket Medical Actions:
Updates have been made to the IFU to clarify the handling procedure and to add additional cautions regarding kinking. We will implement a change to distribution pack size to help ensure that the clinician has a spare device to hand in the event of such an occurrence.

A design change is being considered. Due to the low level of complaints vs. sales we have reduced risk by advising clinicians to take precautions now.

A contraindication against use in pleural drainage has been added.

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Customer Actions:
Rocket Medical has updated the IFU for this product. Please be aware that product already in the supply chain will not carry the new IFU. Devices may be used with note of the following information:

- This product is contraindicated for pleural drainage
- Clinicians should ensure that spare devices are available on stand-by during a procedure should kinking occur. A practice run prior to the procedure may be beneficial
- Instructions for catheter preparation:
  Prepare the catheter
  The KCH™ catheter, with its forming wire in place, (Fig.1) is unrolled gently by hand. Each coil must be unwound separately. Unroll the fetal component between forefinger and thumb. **Do NOT pull the tip of the catheter in an attempt to straighten it as this will induce twisting of the material and cause the catheter to kink.** Carefully repeat the process for the maternal component. CAREFULLY remove the forming wire and red pusher and substitute with the semi-rigid guidewire.
  Using the tapered end of guidewire holder as a support, insert the curved end of the wire through the whole length of the KCH™ catheter. Gently straighten the catheter to allow passage of the guidewire.

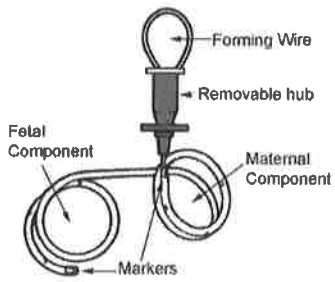

Figure 1

Communication of this FSN:

This FSN must be communicated to Hospital Supply Departments, Medical Device Safety Officers and those working within fetal medicine 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.

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02/08/19
Rocket Medical REF: CUST-OCC110

Dear Valued Customer

Please find attached a Field Safety Corrective Action (FSCA) for the R57405 which was reported by ANSM France (ANSM Reference MV-2018-00847) that damage has been sustained to 2 KCH Fetal Bladder Drainage Catheters making the devices unusable.

The damage sustained prevented the catheter from being inserted into the applicator resulting in a delay in the procedure. A 3rd unit was used without issue; no patient harm was reported.

In addition, we have become aware that the device has been used for pleural drainage, which is not included in the device indications. Such use is off-label. Rocket Medical has not conducted the necessary activities to demonstrate the safety or performance of the device in pleural drainage.

It is the intention of Rocket Medical plc to publish this FSCA to all Customers who have purchased the implicated code of R57405 within the last 5 years (shelf life of the device). The FSCA details an additional contraindication regarding pleural use and additional advice regarding the use of the device for fetal bladder drainage.

Please note that this an advisory only FSCA and not a recall, Rocket medical have not received any related reports from Singapore.

Yours Sincerely,

[redacted]

Jackie Irwin
QA Manager
Rocket Medical Plc.