**ROCKET MEDICAL PLC**
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www.rocketmedical.com

FSN Ref: INTCOMP131-FSN FSCA Ref: INTCOMP131-FSCA

Date: DD MM YYYY

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

# Urgent Field Safety Notice
# Rocket KCH™ Fetal Bladder Drain R57405
# Device Destruction

For Attention of: Persons responsible for medical device vigilance / risk management
Clinicians in the fetal medicine department
Distributors of the device

| **Contact details of local representative:** |
|---|
| For further information, please contact: Regulatoryaffairs@rocketmedical.com |



**REGISTERED OFFICE**
**IMPERIAL WAY**
**WATFORD WD24 4XX**

**REGISTERED IN ENGLAND**
**NO. 03276608**

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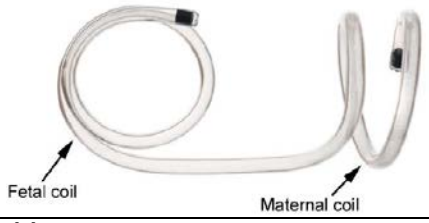
# Urgent Field Safety Notice
# Rocket KCH™ Fetal Bladder Drain R57405
# Device Destruction
# Material Non-Conformance

| 1. Information on Affected Devices | |
|---|---|
| 1 | **1. Device Type(s)** |
| | Rocket KCH™ Fetal Bladder Drain Procedure kit is a sterile, single-use device intended to create a fetal-amniotic shunt to treat fetal lower urinary tract outflow obstruction by allowing the urine to flow from the baby's bladder into the amniotic sac, bypassing the urinary tract. The device contains a double pigtail stent with an outer tube diameter of 2.1mm and inner tube diameter of 1.5mm.<br>  <br> |
| 1 | **2. Commercial name(s)** |
| | Rocket KCH™ Fetal Bladder Drain<br>Rocket KCH™ Fetal Bladder Catheter |
| 1 | **3. Unique Device Identifier(s) (UDI-DI)** |
| | R57405 |
| 1 | **4. Primary clinical purpose of device(s)** |
| | The device is indicated for use in fetal bladder decompression following the diagnosis of fetal post-vesicular obstructive uropathy in fetuses of 18-32 weeks gestation. |
| 1 | **5. Device Model/Catalogue/part number(s)** |
| | R57405 |
| 1 | **6. Software version** |
| | N/A – This device is not software and nor does it incorporate software. |
| 1 | **7. Affected serial or lot number range** |
| | 00000000468148, 00000000469156, 00000000475024, 00000000475494, 00000000477211, 00000000479414, 00000000479735, 00000000480062, 00000000480196, 00000000482145, 00000000484317, 00000000485443. |
| 1 | **8. Associated devices** |
| | N/A – There are no other devices associated with this FSN. |

| 2. Reason for Field Safety Corrective Action (FSCA) | |
|---|---|
| 2 | **1. Description of the product problem** |
| | An error has been made in which material of an inferior quality was provided and used in the manufacture of the device. It is understood that the difference in the quality of the materials is limited to Quality Controls around their manufacture, the material used in manufacture having lower controls. |
| 2 | **2. Hazard giving rise to the FSCA** |

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| | |
|---|---|
| | Sales of the device have been suspended whilst we investigate the impact of the use of this material. |
| 2 | **3. Probability of problem arising** |
| | Further evaluation is required. To date, no incidents have been reported as a consequence of this issue. |
| 2 | **4. Predicted risk to patient/users** |
| | It is not possible to estimate the risk to patients until further evaluation of this issue has been completed. |
| 2 | **5. Further information to help characterise the problem** |
| | N/A – No further information. |
| 2 | **6. Background on Issue** |
| | No incidents have been reported as a consequence of this issue.<br>An error has been made in which material of an inferior quality was used in the manufacture of the device. It is understood that the difference in the quality of the materials is limited to Quality Controls around their manufacture, the material used in manufacture having lower controls. We do not know the impact of the use of the incorrect material; a review is underway. In the meantime, we have suspended product sales and we are issuing this FSN to address product in the field. |
| 2 | **7. Other information relevant to FSCA** |
| | Sales of the device continue to be suspended. This field safety corrective action is being implemented to destroy any unused product on the market. At this time, no action is considered justified for patients with an implanted device. |

| | |
|---|---|
| | **3. Type of Action to mitigate the risk** |
| 3 | **1. Action To Be Taken by the User** |
| | ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☒ Destroy Device<br>☐ On-site device modification/inspection<br>☐ Follow patient management recommendations<br>☐ Take note of amendment/reinforcement of Instructions For Use (IFU)<br>☐ Other ☐ None<br><br>Without delay, identify any KCH™ Fetal Bladder Drains / KCH Fetal Bladder Catheters (REF R57405) in stock. Destroy all devices not yet implanted. Rocket Medical will replace or reimburse all destroyed devices.<br><br>Please confirm that you have received this communication and undertaken the required actions by completing and returning the attached "Customer Response" form.<br><br>Ensure relevant staff members are informed of this action, including locums. If this device has been transferred/supplied to another facility or organisation, please let them know of the action immediately by providing a copy of this FSN. |



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| | | |
|---|---|---|
| | At this time and based on the information available, no action is recommended for devices already implanted. The device is critical for the pre-natal survival of the fetus already implanted with this device. Any potential remedial action, such as replacing the device with an alternative or expediting delivery, is considered to carry greater risk than leaving implanted devices in situ.<br><br>All queries regarding this FSN should be directed to Rocket Medical PLC through the email address Regulatoryaffairs@rocketmedical.com. | |
| 3 | **2. By when should the action be completed?** | Immediately and without delay. |
| 3 | **3. Particular considerations for:** implantable device<br><br>**Is follow-up of patients or review of patients' previous results recommended?**<br>Not at this time. Once further testing has been undertaken to help quantify the risk to patients who have had this device implanted, Rocket Medical will issue further advice regarding appropriate follow-up of those patients. | |
| 3 | **4. Is Customer Reply Required?**<br>(Please complete and return applicable form(s).) | Yes |
| 3 | **5. Action Being Taken by the Manufacturer**<br><br>☒ Product Removal ☐ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☐ Other ☐ None<br><br>Further actions, including additional testing, are being undertaken to allow return of the device to the market. | |
| 3 | **6. By when should the action be completed?** | As soon as possible. |
| 3 | **7. Is the FSN required to be communicated to the patient /lay user?** | No |
| 3 | **8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?** | |
| | N/A. | |

| | | |
|---|---|---|
| | **4. General Information** | |
| 4 | **1. FSN Type** | New |
| 4 | **2. For updated FSN, reference number and date of previous FSN** | N/A – This is a new FSN. |
| 4 | **3. For Updated FSN, key new information as follows:** | |
| | N/A – This is a new FSN. | |

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| | | |
|---|---|---|
| 4 | **4. Further advice or information already expected in follow-up FSN?** | Yes. |
| 4 | **5. If follow-up FSN expected, what is the further advice expected to relate to:** | |
| | The follow-up FSN is expected to provide information regarding appropriate follow-up of patients previously implanted with this device. | |
| 4 | **6. Anticipated timescale for follow-up FSN** | May 2021 |
| 4 | **7. Manufacturer information**<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Rocket Medical PLC |
| | b. Address | Sedling Road, Washington, Tyne & Wear, NE38 9BZ, England |
| | c. Website address | www.rocketmedical.com |
| 4 | **8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.** | |
| 4 | **9. List of attachments/appendices:** | - Customer Response Form |
| 4. | **10. Name/Signature** | |
| | | .....<br>.....<br>**Rocket Medical PLC** |

| | |
|---|---|
| | **Transmission of this Field Safety Notice** |
| | This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. |



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# Customer Response Form

| **1. Field Safety Notice (FSN) information** | |
|---|---|
| FSN Reference number | INTCOMP131-FSN |
| FSN Date | DD MM YYYY |
| Product/ Device name | Rocket KCH™ Fetal Bladder Drain |
| Product Code(s) | R57405 |
| Batch/Serial Number (s) | 0000000000468148, 000000000469156, 000000000475024, 000000000475494, 000000000477211, 000000000479414, 000000000479735, 000000000480062, 000000000480196, 000000000482145, 000000000484317, 000000000485443. |

| **2. Customer Details** | |
|---|---|
| Healthcare Organisation Name | |
| Organisation Address | |
| Department/Unit | |
| Contact Name | |
| Title or Function | |
| Telephone number | |
| Email | |

| **3. Customer action undertaken on behalf of Healthcare Organisation** | | |
|---|---|---|
| ☐ | I confirm receipt of the Field Safety Notice and that I read and understood its content. | *Comment* |
| ☐ | I have/will perform all actions requested by the FSN. | *Comment* |
| ☐ | The information and required actions have been brought to the attention of all relevant users. | *Comment* |
| | I have destroyed the following number of devices: | *Number of devices:* |
| | The Batch/Serial Number (SN or LOT) for devices destroyed are: | *Serial / LOT number (required for replacement / reimbursement):* |
| ☐ | I do not have any affected devices. | *Comment* |
| Print Name | | |
| Signature | | |
| Date | | |



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| **4. Return acknowledgement to:** | |
|---|---|
| Email | regulatoryaffairs@rocketmedical.com |
| Subject of e-mail | "INTCOMP131-FSN Response" |
| Deadline for returning the Customer Response form | Immediately / As soon as possible. |



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