ROCKET MEDICAL PLC
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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
Destroy Device

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

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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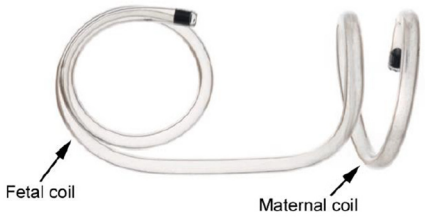
Rocket KCH™ Fetal Bladder Drain R57405
Destroy Device
Non-medical grade material used

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. 
1	**2. Commercial name(s)**
	Rocket KCH™ Fetal Bladder Drain 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**
	000000000475024, 000000000479735, 000000000482145, 000000000488912.
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 on the part of our supplier in which non-medical grade material was provided and used in manufacture instead of the medical grade material ordered.
2	**2. Hazard giving rise to the FSCA**
	Following discovery of the mistake, sales of the product were suspended and biological safety testing (cytotoxicity) was undertaken on a device made with the incorrect material. The results of this testing demonstrated that an extract of the non-medical grade material gives a positive

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	result in an *in vitro* cytotoxicity test. Whilst not demonstrated, this means that we cannot rule out the risk of *in vivo* toxicity.
2	**3. Probability of problem arising**
	A positive cytotoxicity test is not, on its own, indicative of a toxic effect in clinical use. Rather, it is an indication of the need for further evaluation. To date, no incidents have been reported because of this issue.
2	**4. Predicted risk to patient/users**
	The results of *in vitro* cytotoxicity tests cannot be interpreted directly in terms of clinical risk until further information is obtained. It is therefore not possible to estimate the risk to patients.
2	**5. Further information to help characterise the problem**
	Cytotoxicity tests are routinely used as screening tests in the biological evaluation of medical devices. A positive result means that an extract of the device led to a toxic response in a proportion of cultured mammalian cells. This does not necessarily mean that a toxic effect will occur upon clinical use, but this possibility cannot be ruled out. Therefore, a decision to destroy all devices that have not yet been implanted has been made.
2	**6. Background on Issue**
	No incidents have been reported as a consequence of this issue. An error has been made on the part of our supplier in which non-medical grade material was provided and used instead of the medical grade material ordered. Sales of the product were suspended whilst testing was undertaken, which has since revealed a positive result for *in vitro* cytotoxicity. Whilst not demonstrated, this means that we cannot rule out the risk of *in vivo* toxicity. Medical grade material has now been procured, but further testing is being undertaken to confirm conformity before this device is returned to the market.
2	**7. Other information relevant to FSCA**
	Sales of the device continue to be suspended. Upon the advice of the German Regulatory Body, BfArM, this field safety corrective action is being implemented to destroy any unused product on the market. The Rocket KCH™ Fetal Bladder Drain has a five-year shelf life but is commonly used within one year of manufacture. The total number of devices considered to have been affected by this issue is 2474 units, although it is likely that the majority have been used and we estimate only 854 to remain on the global market.

	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 ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Without delay, identify any KCH™ Fetal Bladder Drains / KCH Fetal Bladder Catheters (REF R57405) in stock. Note: all devices within shelf life are affected by this issue. Destroy

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	all devices not yet implanted. Rocket Medical will replace or reimburse all destroyed devices. Please confirm that you have received this communication and undertaken the required actions by completing and returning the attached "Customer Response" form. 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. No action is recommended for devices already implanted (please see justification below). If users are concerned about the impact of the non-availability of the device for the treatment of a particular patient, they should inform Rocket Medical who will put them in touch with the appropriate regulatory authority. All questions 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 **Is follow-up of patients or review of patients' previous results recommended?** No. Justification: 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.	
3	**4. Is Customer Reply Required?** (Please complete and return applicable form(s).)	Yes
3	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Further actions, including additional testing, are being undertaken to allow return of the device to the market. It is anticipated that compliant devices will become available from 23 November 2020.	
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.	

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	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.	
4	**4. Further advice or information already expected in follow-up FSN?**	N/A – Follow-up FSN not expected.
4	**5. If follow-up FSN expected, what is the further advice expected to relate to:**	
	N/A – Follow-up FSN not expected.	
4	**6. Anticipated timescale for follow-up FSN**	N/A – Follow-up FSN not expected.
4	**7. Manufacturer information** (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**	
		Ruth Sharples Head of Quality and Regulatory Affairs 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) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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)	000000000475024, 000000000479735, 000000000482145, 000000000488912.

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		

4. Return acknowledgement to:	
Email	regulatoryaffairs@rocketmedical.com
Subject of e-mail	"INTCOMP131-FSN Response"

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Deadline for returning the Customer Response form	Immediately / As soon as possible.

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