Rocketmedical

OPD Colposcopy

URGENT FIELD SAFETY NOTICE

Field Safety Corrective Action	**Ref: CUST-OCC145**
Commercial Name:	**Rocket® LLETZ Loop Extensions**
Affected Product Codes:	**R57818**
LOT:	See table
Type of action:	**RECALL**
Date of Notice:	Thursday 10th July 2019
Reference:	**Connection Issues Between Rocket® LLETZ Loop Extensions and LLETZ Loops.**

AFFECTED LOTS R57818 Rocket® LLETZ Loop Extensions	
455922	474008
461854	478180
466204	480891
467087	483816
472805	484439

Dear Valued Customer,

This Field Safety Notice has been issued in regards to Rocket® LLETZ Loop Extensions, Product Code R57818. We are contacting you as our records indicate that you have received this product.

Description of the Problem:

We have identified an intermittent issue, which can occur during the manufacture of Rocket® LLETZ Loop Extensions. Affected devices cannot be correctly connected to LLETZ loops.

When a connection to the LLETZ loop cannot be made, the extension cannot be used. In this situation, the worst case would result in a delay to patient treatment.

However, when a partial connection is made, an area of bare metal may be observed. In this situation, the worst case would result in a diathermy burn to the patient during a procedure. No patient injuries have been reported as a result of this issue.

Rocket Medical Actions:

As a precautionary measure, we have taken the decision to recall all unexpired lot numbers (goods manufactured over the last 5 years). Following a review, Rocket Medical will discontinue R57818 LLETZ Loop Extensions with immediate effect.

IMPORTANT: Rocket® UltraFine™ LLETZ Loops are NOT affected by this recall.

Customer Actions:

Identify any inventory with the lot numbers listed above, quarantine and return to Rocket Medical for a full refund.

To arrange return please contact Rocket Medical Customer Services on 0191 419 6988. Please complete and return the acknowledgement form overleaf.

Communication of this FSN:

This FSN must be communicated to Hospital Supply Departments, Medical Device Safety Officers, those responsible for the management of colposcopy clinics and those performing such procedures within your facility.

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

We apologise for any inconvenience that this may cause.

If you have any queries please contact us at cust-occ145@rocketmedical.com or at the address below.

Contact Details for further information:

Jackie Irwin - QA
Sedling Road,
Washington,
Tyne and Wear
NE38 9BZ
E: cust-occ145@rocketmedical.com

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ACKNOWLEDGEMENT OF URGENT FIELD SAFETY NOTICE

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Please complete, scan and return this form as soon as possible to cust-occ145@rocketmedical.com

We confirm that we have read and understood the Field Safety Notice: **"Connection issues between Rocket® LLETZ Loop Extensions and LLETZ Loops"** and have implemented the recommended actions.

Please tick the appropriate box below:

☐ We do not have any of the affected product as identified in the Field Safety Notice.

OR

☐ We have identified that we have the following stock of the affected product, as identified in the Field Safety Notice.

The following units have been returned:

R57818 Lot Number	Number of Units Returned

Hospital/Account: _____

Department: _____

Address: _____

Form Completed by:

Name: _____

Role: _____

Email Address: _____

Telephone Number: _____

Signature: _____

Date: _____

Rocket Medical plc
Sedling Road. WASHINGTON, Tyne & Wear, NE38 9BZ
T: +44 (0) 191 419 6988 E: customerservices@rocketmedical.com W: www.rocketmedical.com

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