ArcRoyal uc

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Field Safety Notice

10-012138 Gauze included in Vingmed Custom Procedure Tray DV5078

Type of Action: Removal

FSN-24-C-001

06 March 2024

Dear Valued Customer,

Commercial Name: Vingmed DV5078 rev 06 Capio Laparoskopi Kit Gyn/Gas containing 10-012138 Gauze

ArcRoyal Identifier: FSN-24-C-001

Type of Action: Removal of 10-012138 Gauze contained within Custom Procedure Tray (CPT) DV5078

Attention: This letter is to inform you of a Field Safety Corrective Action initiated by ArcRoyal

Description of the Problem: On 08-Feb-2024, ArcRoyal received CC-24-B-006 customer complaint regarding 10-012138 gauze within CPT DV5078. Upon investigation, it was confirmed that the gauze was not fit for purpose within DV5078 Capio Laparoskopi Kit Gyn/Gas as it should not to be used as a laparoscopic swab. Therefore, ArcRoyal are initiating a field safety corrective action to remove 10-012138 from CPTs DV5078 that are on the market.

Details:
ArcRoyal have placed 10-012138 Gauze within CPT DV5078 Capio Laparoskopi Kit Gyn/Gas. However, the legal manufacturer of the gauze had a restriction on the intended use that it is not be used as a laparscopic swab. ArcRoyal did not follow this instruction resulting in the 10-012138 Gauze being placed in a pack outside the scope of its intended use and hence not fit for purpose. ArcRoyal have initiated a CAPA within the Quality Management System for this issue.

Details of affected devices

ArcRoyal supply Vingmed with the affected 10-012138 Gauze in the below work orders of DV5078;

Table 1: Affected product

ArcRoyal Vingmed CPT and Product Code	Product Description	Procedure Pack Producer	CPT Code	Work Order/Lot

Directors: A. Long, H. Galloway | ***Secretary:*** G. Rea | **Registered Office:** 38 Upper Mount Street, Dublin 2, D02 PR89, Ireland | **Company Registration Number:** 138763

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CPT DV5078 containing 10-012138 Gauze	DV5078 Capio Laparoskopu Kit Gyn/Gas containing 10-012138 10 x 10 cm non woven gauze	ArcRoyal	DV5078	795326, 792407, 792939, 794171

The affected listed 10-012138 is contained within Vingmed CPT DV5078. All other components within the CPT are safe to use as normal and are not impacted by this field safety notice.

Clinical Risk:
The possibility of serious health hazard to the patient/user is very low because the device is used in a medical institution under the supervision of health care professionals who should follow local hospital policy. The health hazard to the patient/user is also very low because as a count card is included in the pack and the process should be adhered to whereby all gauze will be reconciled before and after surgery. It may lead to a short interruption or delay of surgical procedures.

Advice on actions to be taken by the user:
To minimize disruption and ensure continuous patient care, ArcRoyal is recommending the following:

1. Ensure the contents of this Field Safety Notice are read and understood by those within your organization who may use DV5078 containing 10-012138 listed in the above Table 1.

2. Inspect your inventory, locate and identify any units of the impacted work orders as per those detailed in Table 1.

3. If you have further distributed the product, identify those facilities, notify them at once of this product removal and have them remove and destroy the affected product.

4. Complete and return the Field Safety Corrective Action Response Form, Appendix I, to ArcRoyal (ArcRoyal.QARAQueries@owens-minor.com) confirming receipt of this notification.

5. On use of CPT DV5078 referenced, 10-012138 Gauze is to be removed and destroyed. The affected 10-012138 Gauze shall be disposed of at the end users

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facility in accordance with national requirements. The remainder of the CPT remains safe for use.

6. If / when the affected 10-012138 Gauze is disposed of at the end users facility, Certificate of Destruction Appendix II must be completed and returned to ArcRoyal (ArcRoyal.QARAQueries@owens-minor.com)

7. Ensure a copy of this notification is included with each case of CPT's before sending to the end users facility

NOTE: If you no longer use the product or it is no longer in your inventory, it is still important that you return the Customer Response Form for our reconciliation purposes.

Transmission of this Advisory
ArcRoyal are committed to patient safety and would appreciate your immediate attention and cooperation to this matter. Please immediately forward this information to all departments within your organisation. Additionally, please ensure that a copy of this information is provided to any other organisations to which the affected CPTs have been transferred. Please maintain awareness on this notice and resulting corrective action for an appropriate period to ensure effectiveness of the corrective action.

We sincerely apologize for any inconvenience that this may cause and thank you for your business and continued support. If you have any questions or concerns, please do not hesitate to contact your ArcRoyal representative.

Yours Sincerely,

Mary O'Reilly
ArcRoyal Quality Manager

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Appendix I
FSN-24-C-001
Field Safety Corrective Action Response Form

Please complete this form as acknowledgement that you have received, read and understood the actions to be taken in relation to FSN-24-C-001.

The completed response form should be immediately returned via email to: ArcRoyal.QARAQueries@owens-minor.com

This facility has read and understood the information supplied to us through the Field Safety Notice issued by ArcRoyal in relation to CPT DV5078 containing the affected 10-012138 Gauze.

Facility Name	
Facility Address	
Printed name and Title	
Signature and Title	
Phone Number/Fax Number	

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Appendix II
FSN-24-C-001
Certificate of Destruction

Company name:
Country:
Address:
Telephone:

I certify that the product(s) listed in the table below have been removed and destroyed as a result of product Field Safety Notice FSN-24-C-001 instructions received from ArcRoyal.

Pack Code	Lot Number	Quantity Destroyed

additional pages may be added to detail all products

Authorized Signature:

Name:

Position:

Date:

Destruction of all affected medical devices listed was completed on (date):