

ArcRoyal uc
 Virginia Road,
 Kells,
 Co. Meath
 A82 R862, Ireland

p +353 (0) 46 928 0100

30 Nov 2022

Field Safety Notice
 Ophthalmic Drape
Type of Action: Product Recall
 FSN-22-K-001

Commercial Name: Custom Procedure Trays 44-108443 containing Halyard Ophthalmic Drape 183x292 ArcRoyal Code 10-010962, Supplier Code 79356, containing 3M Incise Drape 1021NS.

Type of Action: Recall of 3M Ophthalmic Drape ArcRoyal Code 10-007953, Supplier Code 2070600 containing defective 3M Incise Drape 1021NS contained within Custom Procedure Tray 44-108443.

Attention: This letter is to inform you of a Field Safety Notice initiated by 3M via Halyard

ArcRoyal received a Field Safety Notification from Halyard on the 28th of Nov 2022. The notification detailed that 3M, supplier of the Incise 1021NS which Halyard include in their Ophthalmic Drape (ArcRoyal Code 10-010962, Halyard Code 79356-80), is conducting a recall on specific lots. ArcRoyal product impacted by this recall is ArcRoyal Code 10-010962, Halyard Code 79356-80, Lot number AC22042203. ArcRoyal have placed this drape into CPT 44-108443, Work Orders (Lot,) 765744 and 758780.

Details:

The recall notice was issued by 3M due to a recent investigation where they confirmed the liner of the adhesive component of the affected drapes is difficult to remove without damaging the product and may render the product unusable. Additionally, 3M has observed an increase in reported adhesive related skin injuries for these affected lots. Although the acceptance criteria for the device was met upon product release, the adhesive component may not meet 3M's performance criteria throughout product shelf life. Refer to enclosed 3M Recall Notice for additional information concerning recall details. The affected 3M Incise Drape component is contained within Ophthalmic Drape manufactured by O&M Halyard, Inc which is contained within an ArcRoyal CPT as listed below. This recall only affects the 3M Incise Drape due to its strong adhesiveness. The Ophthalmic Drape and the remainder of the CPT is still safe to use.

Details of affected devices:

ArcRoyal Code	Halyard Code	3M code	Description	Pack Code	Work Order/Lot
10-010962	79356-80	1021NS	CPT 44-108443 containing Halyard Ophthalmic Drape containing the affected 3M Incise Drape	44-108443	765744, 758780

ArcRoyal uc

Virginia Road,
Kells,
Co. Meath
A82 R862, Ireland

p +353 (0) 46 928 0100

Actions for customers to take

Based off the instructions received from 3M via Halyard, ArcRoyal requires that the following actions are taken:

1. Complete and return the completed Field Safety Notification Response Form, Appendix I, to ArcRoyal at ArcRoyal.QARAQueries@owens-minor.com confirming receipt of this notification. ***This should be done even if you have no affected product***
2. Please identify and immediately cease use of any affected Incise Drape within the Ophthalmic drape and quarantine it for destruction/disposal per facility policy. The Ophthalmic drape and the remainder of the CPT remains safe to use.
3. If you have further distributed the product, identify those facilities, notify them at once of this product recall and have them remove and destroy/dispose of the affected product.
4. If / when the affected 3M Incise Drape is disposed of at the end users facility, Appendix II must be completed and returned to ArcRoyal at ArcRoyal.QARAQueries@owens-minor.com
5. Ensure a copy of this notification is included in each case of CPTs before sending to the end users facility.

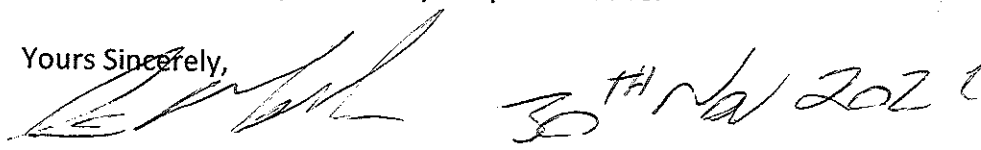
NOTE: If you no longer use the product or it is no longer in your inventory, it is still important that you return the Customer Response Form for our reconciliation purposes.

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. Attached is the Field safety notice issued by 3M to our supplier Halyard with the instructions to notify all end users affected by this notification.

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,



Ciarán McCurtin - General Manager, ArcRoyal

ArcRoyal uc

Virginia Road,
Kells,
Co. Meath
A82 R862, Ireland

p +353 (0) 46 928 0100

Appendix I
FSN-22-K-001
Field Safety Notice Response Form

Please complete this form as acknowledgement that you have received, read and understood the actions to be taken in relation to FSN-22-K-001 and product below:

ArcRoyal Code	Halyard Code	3M code	Description	Pack Code	Work Order/Lot
10-010962	79356-80	1021NS	CPT 44-108443 containing Halyard Ophthalmic Drape containing the affected 3M Incise Drape	44-108443	765744 758780

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

- We have received the notice and have stock to destroy.

Units to return:

Pack Code	Work Order/Lot Number	Quantity left in stock of affected packs

- We have received the notice and all stock has been used.

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

ArcRoyal uc

Virginia Road,
Kells,
Co. Meath
A82 R862, Ireland

p +353 (0) 46 928 0100

Appendix II
FSN-22-K-001
Certificate of Destruction

Company name:**Country:****Address:****Telephone:**

I certify that the product listed in the table below has been removed and destroyed as a result of product Field Safety Notice FSN-22-K-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):**