ArcRoyal uc

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

t +353 (0)46 9280100

# Field Safety Notice – FSN-24-F-001

J&J Ethicon MONOCRYL™ Plus Antibacterial (poliglecaprone 25) Suture included in Halyard CPT IR1196

**Type of Action:** Voluntary Product Recall

**Attention: This letter is to inform you of a Field Safety Notice initiated by J&J**

**ArcRoyal Identifier:** FSN-24-F-001 **J&J Ethicon Identifier:** 2364579

18 June 2024

Dear Valued Customer,

ArcRoyal received a Field Safety Notification from J&J Ethicon on the 12th of June 2024. The notification detailed that J&J is conducting a Field Safety Corrective Action to voluntary recall (remove) specific lots of J&J sutures.

**Product Impacted:** Halyard Mr.McKenna Hip Pack CPT IR1196 containing J&J Ethicon MONOCRYL™ Plus Antibacterial (poliglecaprone 25) Suture ArcRoyal Code 10-111099, Supplier Code MCP3213H

**Details:**
Ethicon identified a manufacturing issue on a specific packaging machine that resulted in a hole in the primary packaging of a small percentage of MONOCRYL™ sutures manufactured between January 27 and March 27, 2024, which have been supplied to ArcRoyal. The occurrence of this defect is rare with an estimated rate of 0.011% of product presenting the condition (99.9% of product is not impacted by this defect). When present, the hole is always and only on the first package in the horizontal box of quantity 36, and it occurs in the same location on the bottom side foil cavity of the first package towards the peelable flaps.

**Details of affected devices**
ArcRoyal supply Halyard with the affected J&J Ethicon MONOCRYL™ Plus Antibacterial (poliglecaprone 25) in the below lots of IR1196. This suture is piggybacked to the CPT. All other components within the CPT are safe to use as normal and are not impacted by this field safety notice.

ArcRoyal uc

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

t +353 (0)46 9280100

**Table 1:** Affected product

| ArcRoyal Code | J&J Ethicon Code | Description | Pack Code | Work Order/Lot |
|---|---|---|---|---|
| 10-111099 | MCP3213H | MONOCRYL™ Plus Antibacterial (poliglecaprone 25) Suture | IR1196 | 800237, 800816, |

**Clinical Risk:**

Ethicon has not received any complaints or reports of injuries related to this issue.

It is likely that this issue will be detected prior to use in surgery. If the defect is not detected, the breach in sterility could introduce pathogens to the patient and cause infection. This may necessitate medical interventions such as use of antibiotics and/or surgical intervention. The chance of systemic infection is very unlikely because of the small inoculum of bacteria that would likely be present and the use of prophylactic antibiotics prior to or after surgery. Therefore, the probability of harm to the patient is extremely rare.

A hole in the cavity also exposes the product to the environment which could potentially compromise its physical properties leading to treatment failure which may require additional surgical intervention or prolonged surgery.
The health risk is limited to those products with compromised packaging. Other products in the field with no seal issues are unaffected. Health care practitioners who have treated patients using these product lots should follow those patients post-operatively in the usual manner with no additional action required.

Ethicon has identified and corrected the manufacturing issue that led to this recall.

**Actions for customers to take:**
**Based off the instructions received from J&J Ethicon, ArcRoyal requires that the following actions are taken:**

1. Ensure the contents of this Field Safety Notice are read and understood by those within your organization who may use the affected product listed in the above table 1.

2. Inspect your inventory, locate, identify and quarantine any units of the impacted product detailed in Table 1. If you have product subject to this recall, please

**ArcRoyal uc**

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

**t +353 (0)46 9280100**

maintain a copy of this notice with the affected packs quarantined product and keep a copy for your records.

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

4. Customers are required to return unused sutures subject to this recall that are in inventory immediately. Your customer sales representative will be in contact regarding this return to ArcRoyal and providing replacement product.

5. Complete and return the Field Safety Corrective Action Response Form, Appendix I, to ArcRoyal (ArcRoyal.QARAQueries@owens-minor.com) confirming receipt of this notification. Please also return Appendix II identifying how many packs you have used and how many packs remain in your inventory.

6. On use of CPT IR1196 referenced, ArcRoyal Code 10-111099 Suture is to be removed and placed in quarantine for return. The remainder of the CPT remains safe for use.

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 18/June/2024.

Mary O'Reilly
ArcRoyal Quality Manager

ArcRoyal uc

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

t +353 (0)46 9280100

# Appendix I
# FSN-24-F-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-F-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 IR1196 containing the affected product listed in Table 1 of this FSN.

| | |
|---|---|
| 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

t +353 (0)46 9280100

# Appendix II
# FSN-24-F-001
# Field Safety Corrective Action Response Form

Please identify quantity of lots listed below which have been used and quantity of packs which still remain in your inventory. Quantity remaining should be returned to ArcRoyal via your customer representative.

| Lot Number | Quantity of packs used | Quantity of packs within Whitfield Inventory |
|---|---|---|
| 800237 | | |
| 800816 | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

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