Johnson&Johnson

15 May 2024

Dear Valued Customer,

URGENT: MEDICAL DEVICE REMOVAL

PDS™ II (polydioxanone) Suture

Please distribute this information to the appropriate personnel at your facility.

To The Attention of:

Operating Room Manager / Surgeon,

Johnson & Johnson Ethicon has initiated a voluntary medical device recall (removal) of specific lots of PDS™ II (polydioxanone) Suture distributed in Malaysia.

Affected Products

The scope of this medical device recall includes the products listed below:

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT LOTS.

PRODUCT NAME	PRODUCT CODE	PRODUCT LOTS
PDS 5/0 45CM VIOLET M1 RB-2	W9101H	UAMLPS
PDS 5/0 45CM VIOLET M1 RB-2	W9101H	UAMHJS

Reason for the Voluntary Removal

Johnson & Johnson identified a manufacturing issue on a specific packaging machine that resulted in a hole in the primary packaging of a small percentage of PDS™ sutures manufactured between January 27 and March 27, 2024. 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 as shown in Figure 1 and 2.**

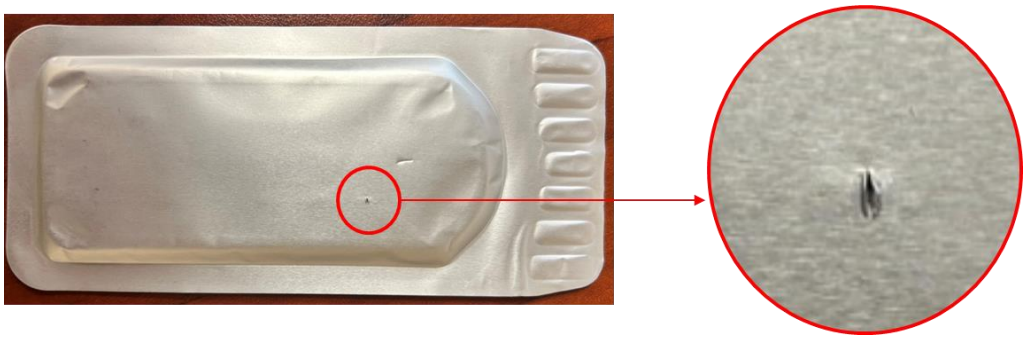

Figure 1: Foil suture package (bottom side) indicating hole location. Top side of suture package contains printed product information as shown in Attachment 1.

Figure 2: Location of first package

First package is defined as the package closest to the front of the box with the foil cavity side facing the box. The front of the box contains the labeling for the product.

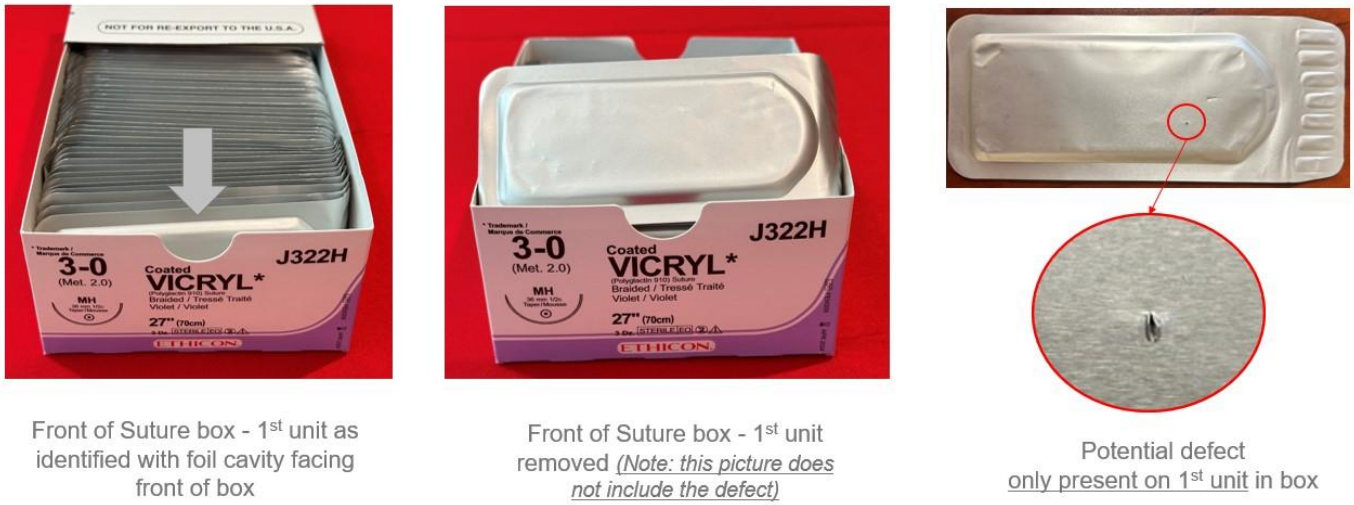

Figure 2: Sales unit box (QTY:36) indicating location of first package.

Risk to Health

Johnson & Johnson 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.

Johnson & Johnson has identified and corrected the root cause of the manufacturing issue that led to this recall.

Action Required

Our records indicate that your facility has received the products(s) subject to this medical device recall. Please take the following actions:

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1. Determine whether you have inventory of the lots listed in Attachment 2.
2. Quarantine all product(s) in scope and return all inventory for credit.
3. Complete the Customer Acknowledgement Letter (Attachment 2) and return the affected product to the local Johnson & Johnson sales organization. Please return the Customer Acknowledgement Letter even if you do not have product subject to this recall.
4. If any of the affected product(s) have been forwarded to another facility, contact that facility to arrange for return and provide them with the Customer Notification Letter.
5. Please share this information with all the appropriate staff at your facility.
6. Please keep a copy of this notice for your awareness and records.

At Johnson & Johnson, our first priority is to our customers and their patients, and that includes the safe and effective use of our products. We recognize the recall of this product may be disruptive to your facility and we appreciate your assistance in this matter.

Thank you for being a Johnson & Johnson Customer.

Kind Regards,

Kay Lee Haema Ng

Digitally signed by Kay Lee Haema Ng
DN: c=US, o=JNJ, ou=Subscribers, cn=Kay Lee Haema Ng, 0.9.2342.19200300.100.1.1=152026419
Reason: I am approving this document.
Date: 2024.05.15 18:29:54 +08'00'
Adobe Acrobat version: 2020.013.20064

Ng Kay Lee Haema
Johnson & Johnson Sdn. Bhd.,
Commercial Quality Manager,
MedTech Singapore, Malaysia and Philippines

ATTACHMENTS:

Attachment 1: Product Identification Tool
Attachment 2: Customer Acknowledgement Form

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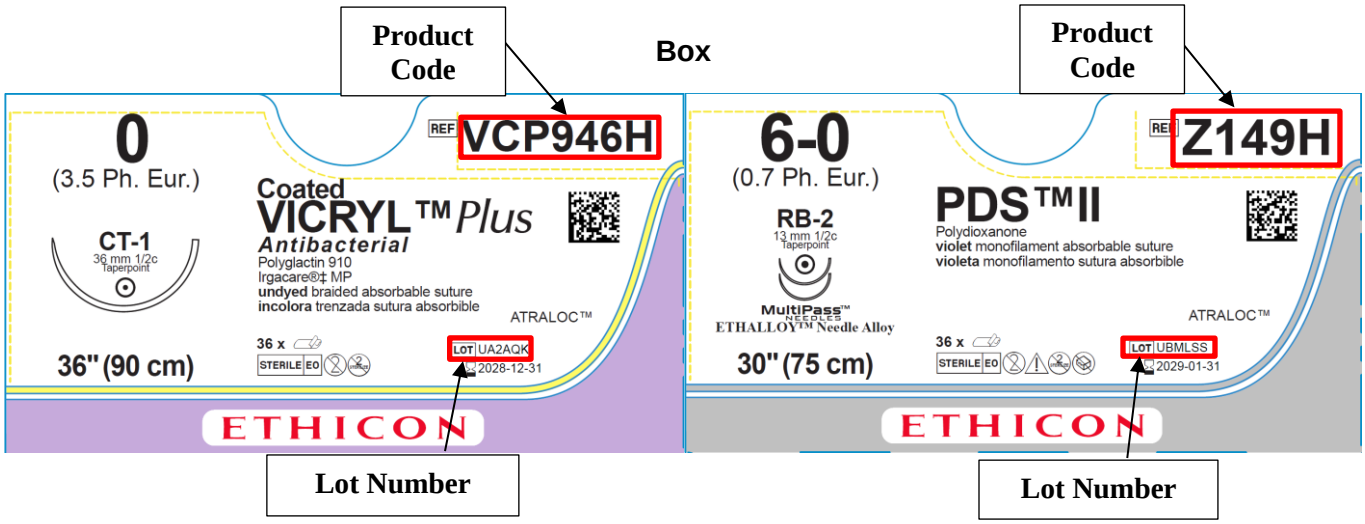
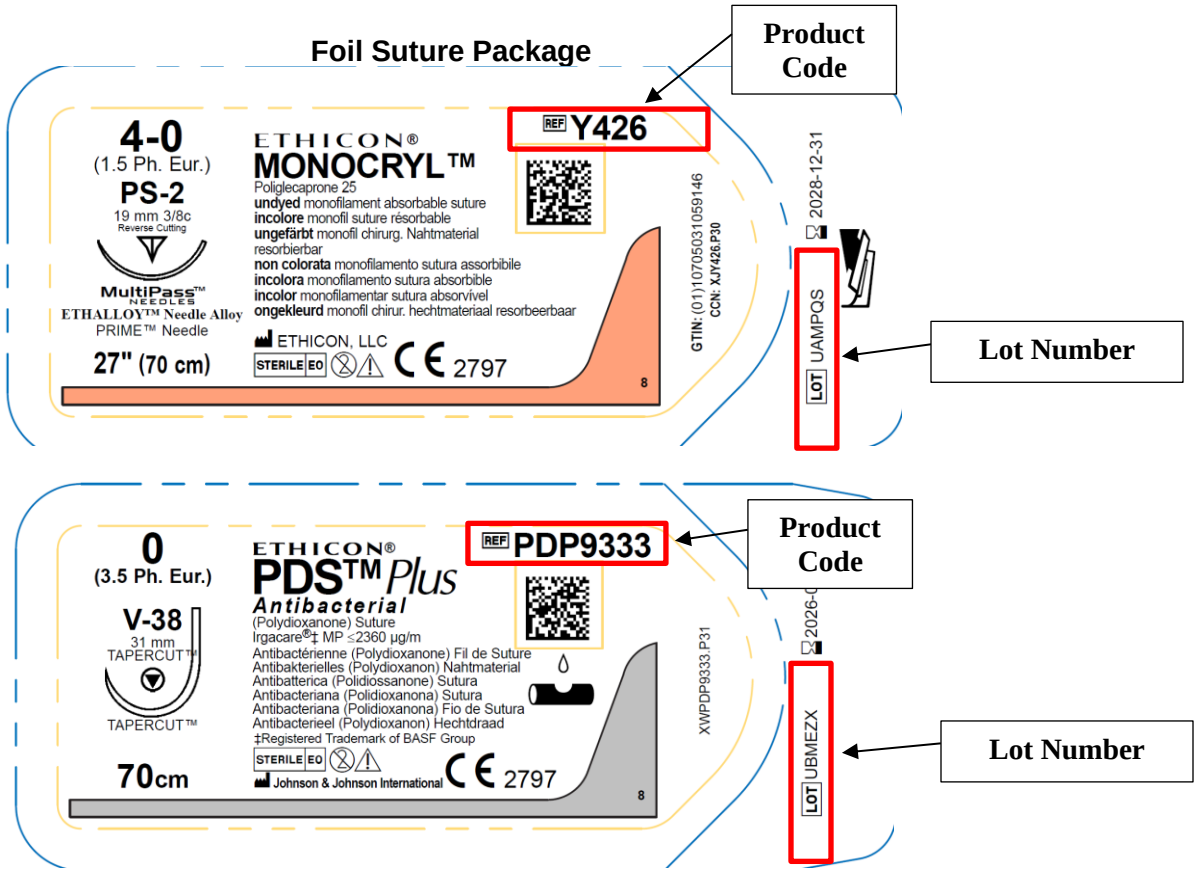
Attachment 1: Product Identification Tool

Please refer to the representative sample pictures below to identify the location of the subject product code and lots for impacted products by using the packaging labels.





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Attachment 2: Customer Acknowledgement Letter

Customer Acknowledgement Letter

Please complete the following information: Please check the checkbox

☐ We hereby acknowledge receipt of this medical device recall letter from Johnson & Johnson regarding PDS™ II (polydioxanone) Suture. We will distribute this information to all staff within our facility that use the impacted products and will maintain a copy of this notice with the identified product(s).

Product Receipts – please check one:

☐ We have NO inventory of product subject to this recall (removal).

☐ We have product subject to this recall (removal). We will quarantine all impacted lots and return for credit.

If you have product subject to this recall to return, please make a photocopy of your completed Customer Acknowledgement Letter and enclose with your return. Thank you for your cooperation.

PRODUCT NAME	PRODUCT CODE	PRODUCT LOTS	QUANTITY RETURNING (EACHES)
PDS 5/0 45CM VIOLET M1 RB-2	W9101H	UAMLPS	
PDS 5/0 45CM VIOLET M1 RB-2	W9101H	UAMHJS	

Hospital Name : _____

Name / Title : _____

Phone Number : _____

Signature & Date : _____

Hospital Stamp : _____

Note: If the verification section is answered on behalf of more than one facility and/or individual, please clearly indicated the name and address of the facility and/or individual on this page of the notification.

Please complete and return this page to our local Johnson and Johnson sales organization.