ETHICON
Johnson & Johnson SURGICAL TECHNOLOGIES

04-Aug-2023

URGENT: FIELD SAFETY NOTICE

PDS™ II (polydioxanone) Suture
PDS™ Plus Antibacterial (polydioxanone) Suture
– Voluntary Product Recall (Removal) –

Dear Operating Room Supervisors, Materials Management Personnel, and Chief of Surgery,

Records indicate that you have ordered or received product subject to this recall.
PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE PDS™ Sutures

Purpose of this Letter

Ethicon, Inc. ("Ethicon") has initiated a voluntary medical device recall (removal) of specific lots of undyed PDS™ II (polydioxanone) Sutures and undyed PDS™ Plus Antibacterial (polydioxanone) Sutures distributed in Switzerland.

Reason for the Voluntary Removal

Ethicon received seven complaints for one lot of undyed PDS™ II (polydioxanone) Sutures regarding low tensile strength. Internal testing on returned product from this lot confirmed that some PDS™ II (polydioxanone) Sutures from this lot did not meet Ethicon's tensile strength requirement. An investigation identified additional lots across the PDS™ Plus Antibacterial (polydioxanone) and PDS™ II (polydioxanone) Suture families that have the potential to be affected by the same root cause as the lot that received the complaints.

Risk to Health

Failure in suture tensile strength could potentially result in poor performance of the impacted product because the intended benefit of tissue approximation and/or ligation may not be achieved. In such an instance the potential harms would include bleeding/hemorrhage, treatment failure/wound dehiscence, surgery prolonged and surgery intervention. However, none of these potential harms have been reported to occur and none of the complaints received reported patient consequences to date. Health care practitioners who have treated patients using this product should follow those patients post-operatively in the usual manner with no additional action required.

ACTION REQUIRED

1. Examine your inventory immediately to determine if you have product subject to this recall on hand and quarantine such product(s). If you have product subject to this recall, please maintain a copy of this notice with the quarantined product and keep a copy for your records.
2. Communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed. If any product subject to this recall has been forwarded to another facility, contact that facility to arrange return. Please consider including a copy of this recall letter when communicating.
3. Complete the Business Reply Form (BRF) (Attachment 3) confirming receipt of this notice and email to jnjmedical-ch@its.jnj.com (Johnson & Johnson AG) within three (3) business days. **Please return the BRF even if you do not have product subject to this recall**.
4. Customers are required to return unused PDS™ Sutures subject to this recall that are in inventory immediately. To receive credit reimbursement, customers must return product subject to this recall no

later than 30. September 2023 to Johnson & Johnson AG. Any non-affected product and any product returned after the date specified will not receive credit reimbursement.

5. To return product subject to this recall, photocopy the completed BRF, place it in the box with the product, and affix the pre-paid authorized shipping label included with the recall notification letter. Ethicon will pay for the shipping charges only if the authorized label is used. Extra shipping labels may be obtained by calling the Johnson & Johnson AG Customer Services at 0800 830 085. Your account number and mailing address have been pre-populated on the BRF. Please return products to the following address:

Johnson & Johnson AG
c/o Postlogistik
Keyword: PDS Suture Recall
Allmendstrasse 8
5612 Villmergen

6. Keep this notice visibly posted for awareness until all product subject to this recall has been returned to Johnson & Johnson AG.
7. If product subject to this recall is contained in a custom kit, please contact your custom kit assembler for return instructions.

If you require any assistance with returning product, please contact Johnson & Johnson AG Customer Services at: Tel. 0800 830 085 or E-Mail customer-ch@its.jnj.com.

Other Information

At Ethicon, 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.

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to your Sales Representative, directly to Ethicon, or your National Health Authority.

If you have any further questions related to this notice or if you need any additional communications, please contact your local Sales Representative or Johnson & Johnson AG Customer Services at: Tel. 0800 830 085 or E-Mail customer-ch@its.jnj.com.

ATTACHMENTS:

Attachment 1: Impacted Product Information
Attachment 2: Product Identification Tool
Attachment 3: Business Reply Form (BRF)

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Attachment 1: Impacted Product Information

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT LOTS. REFER TO ACTION REQUIRED FOR FURTHER INSTRUCTIONS.

Product Code	Batch / Lot	Expire Date	GTIN - Each	GTIN - Sales Box
MPZ489H	PAM326	2023-12-31	10705031149410	30705031149414
MPZ489H	PAM210	2023-12-31	10705031149410	30705031149414
MPZ493H	RJMBUK	2026-07-31	10705031149427	30705031149421
MPZ496H	QCMDCS	2025-02-28	10705031075443	30705031075447
MPZ497H	RLMCDE	2026-09-30	10705031149441	30705031149445
W9716T	MM5113	2023-10-31	10705031130357	30705031130351
W9716T	QCMMCE	2023-10-31	10705031130357	30705031130351
Z292ZE	RKMPHE	2025-07-31	10705031113602	30705031113606
Z292ZE	QJMBRC	2025-07-31	10705031113602	30705031113606
Z293E	REMMCD	2026-04-30	10705031113619	30705031113613
Z422ZE	RGMHQL	2023-11-30	10705031114074	30705031114078
Z422ZE	MPM087	2023-11-30	10705031114074	30705031114078
Z423E	QGMEZX	2025-05-31	10705031114081	30705031114085
Z441E	SEMESK	2027-04-30	10705031114111	30705031114115
Z490E	QMMBTJ	2025-10-31	10705031114265	30705031114269
Z490E	RBMKJQ	2025-10-31	10705031114265	30705031114269
Z497H	RPMBSQ	2026-11-30	10705031467217	30705031467211
Z683G	SBMPKQ	2027-12-31	10705031061538	30705031061532
PDP423H	SDMLCZ	2024-03-31	10705031123564	30705031123568
PDP442H	RKMCMP	2023-10-31	10705031048300	30705031048304
PDP442H	RLMMZU	2023-10-31	10705031048300	30705031048304
PDP443H	SMMHDP	2024-10-31	10705031123595	30705031123599
PDP489H	RKMJAS	2023-08-31	10705031123786	30705031123780

Please utilize **Attachment 2** for assistance in identifying subject products.

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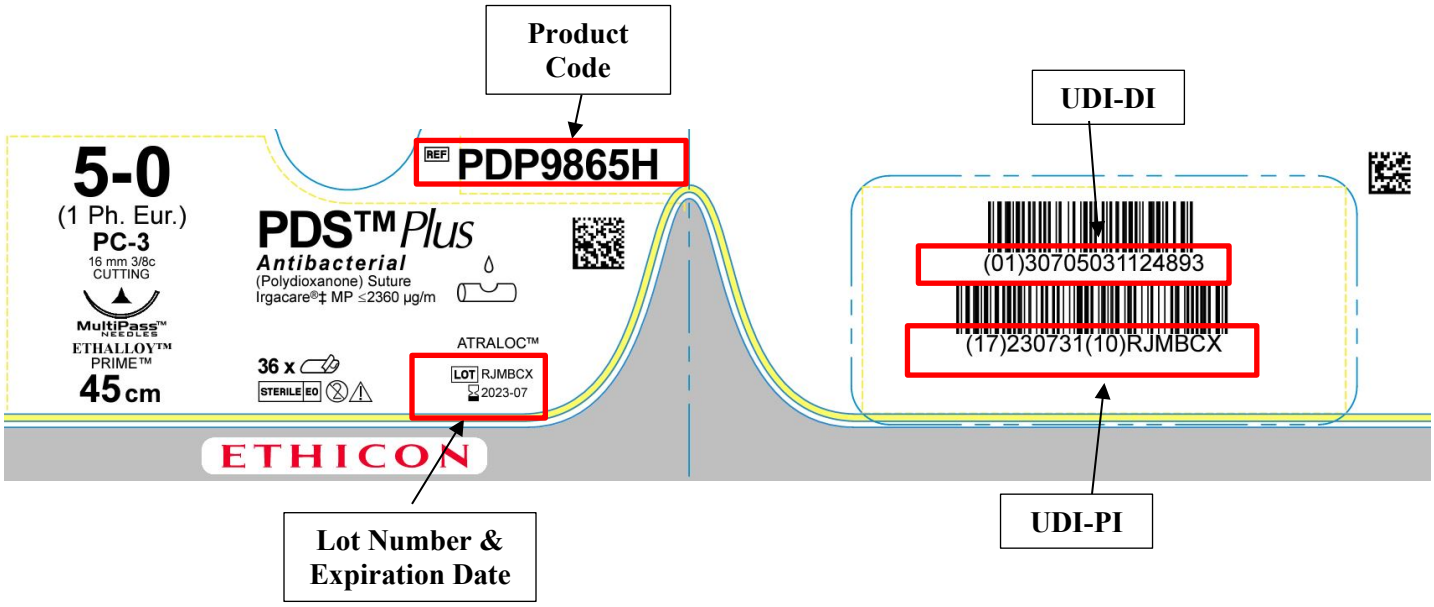
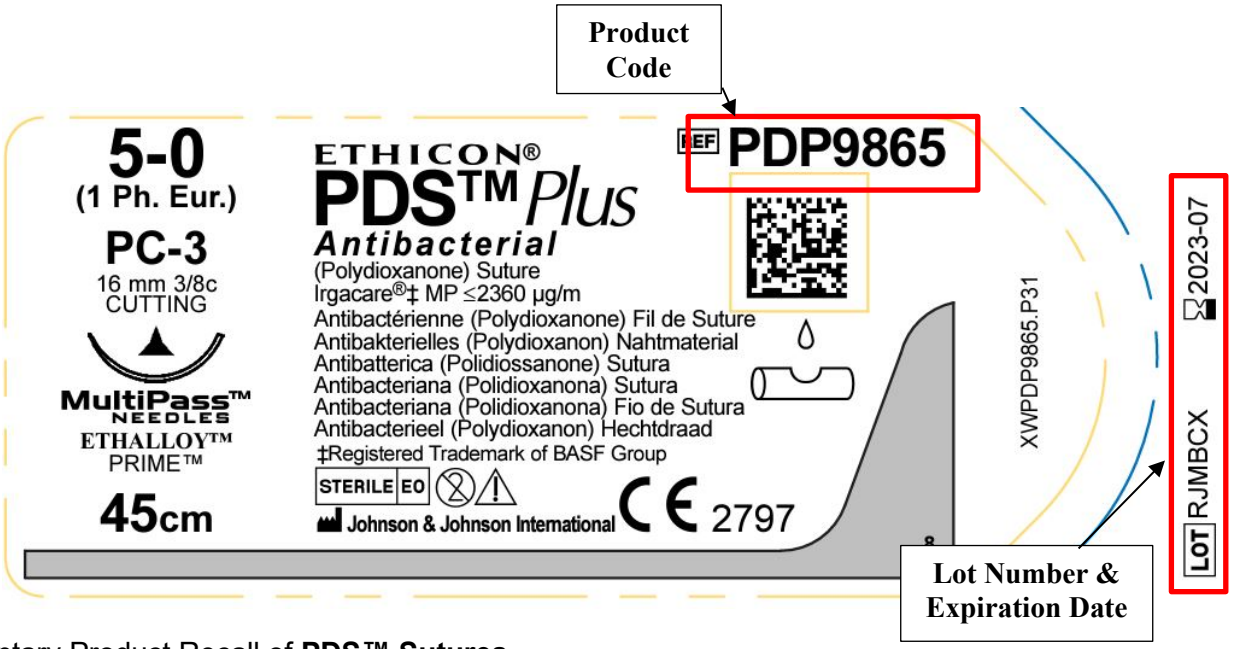
Attachment 2: Product Identification Tool

Please refer to the pictures below to identify the location of the subject product code, lot, and UDI for impacted PDS™ Sutures by using the packaging labels. Please note that the pictures below are representative examples only. Refer to Attachment 1 for a list of affected product codes and lots.

PDS™ Plus Sales Unit Box



PDS™ Plus Individual Unit



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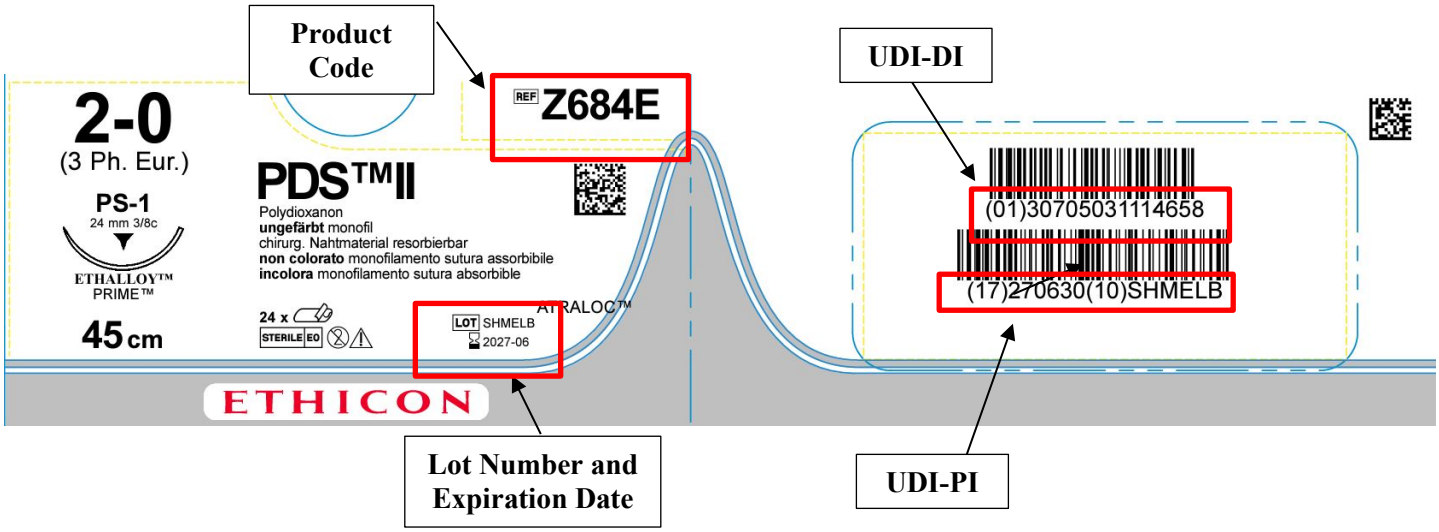
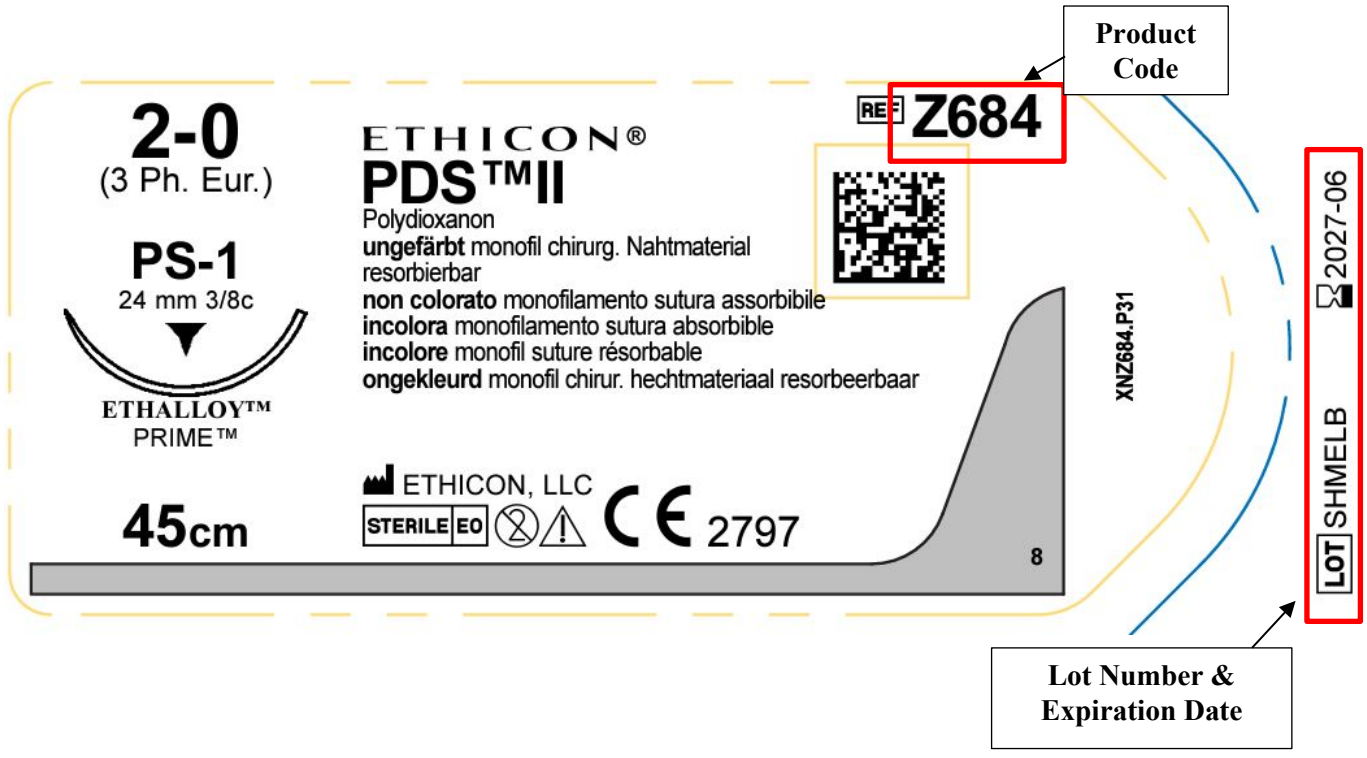
PDS™ II Sales Unit Box



PDS™ II Individual Unit



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Attachment 3: Business Reply Form

Business Reply Form (BRF)

Your timely response to this recall notification is requested. Please complete this form and email it to jnjmedical-ch@its.jnj.com (Johnson & Johnson AG) **within 3 business days, even if you do not have product subject to this recall to return.**

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

Your Name/Title:	Date:
Email Address:	Telephone Number:
J&J Account Number:	
Reference PO for Credit, if needed:	
Signature*: **Your signature provides confirmation that you have received and understood this notification.*	
Your comments are welcome.	

Product Inventory – *please check one*

☐ We have NO inventory of product subject to this recall (removal).
☐ We have product subject to this recall (removal) and are returning the following products (see next page):

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PRODUCT CODE	PRODUCT LOT	EXP DATE	QUANTITY RETURNING (EACHES)