ETHICON
Johnson & Johnson SURGICAL TECHNOLOGIES

04/08/2023

URGENT: FIELD SAFETY NOTICE

PDS™ II (polydioxanone) Suture
PDS™ Plus Antibacterial (polydioxanone) Suture
(Impacted Product Codes and lots are listed in Attachment 1)
– 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 EU, EEA, EU Candidates, Switzerland, and United Kingdom.

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 MDFieldActionsUKirl@its.jnj.com within three (3) business days. **Please return the BRF even if you do not have product subject to this recall**.

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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.
5. To return product subject to this recall, please complete the Business Reply form attached to this notice with your completed address and collection details with a contact email address and our returns team will email you to arrange.
6. Keep this notice visibly posted for awareness until all product subject to this recall has been returned to us.
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 MDFieldActionsUKirl@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.

If you have additional questions regarding this voluntary product recall or require any assistance with returning product, please either contact your sales representative or MDFieldActionsUKirl@its.jnj.com

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.

ATTACHMENTS:

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

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– Voluntary Product Recall (Removal) –

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
FZ420E	QMMASH	31.10.2025	10705031118102	30705031118106
FZ420E	TAMCDQ	31.12.2027	10705031118102	30705031118106
FZ500E	RBMCLH	31.01.2026	10705031073487	30705031073481
MPZ489H	PAM210	31.12.2023	10705031149410	30705031149414
MPZ489H	PAM326	31.12.2023	10705031149410	30705031149414
MPZ493H	RJMBUK	31.07.2026	10705031149427	30705031149421
MPZ496H	QCMDCS	28.02.2025	10705031075443	30705031075447
MPZ497H	RLMCDE	30.09.2026	10705031149441	30705031149445
MPZ9626H	PHM665	30.06.2024	10705031149472	30705031149476
MPZ9626H	RGMAPK	31.05.2026	10705031149472	30705031149476
MPZ9626H	SCMBTJ	28.02.2027	10705031149472	30705031149476
PDP072H	SCMRZE	29.02.2024	10705031122574	30705031122578
PDP421H	RJMQQP	31.07.2023	10705031123540	30705031123544
PDP421H	RLMBXB	30.09.2023	10705031123540	30705031123544
PDP423H	SDMLCZ	31.03.2024	10705031123564	30705031123568
PDP442H	RKMCMP	31.08.2023	10705031123588	30705031123582
PDP442H	RLMMZU	30.09.2023	10705031123588	30705031123582
PDP443H	SMMHDP	31.10.2024	10705031123595	30705031123599
PDP489H	RKMJAS	31.08.2023	10705031123786	30705031123780
PDP497H	RLMCKT	30.09.2023	10705031123854	30705031123858
PDP497H	SKMLRP	31.08.2024	10705031123854	30705031123858
PDP498H	RKMDBD	31.08.2023	10705031123861	30705031123865
PDP684H	RJMEJC	31.07.2023	10705031124059	30705031124053
PDP684H	SDMJQQ	31.03.2024	10705031124059	30705031124053
PDP9615H	RLMHCC	30.09.2023	10705031124677	30705031124671
PDP9625H	RJMEKR	31.07.2023	10705031124691	30705031124695
PDP9626H	RKMMTB	31.08.2023	10705031124707	30705031124701
PDP9626H	SAMHHE	31.12.2023	10705031124707	30705031124701
PDP9631H	RMMBTD	31.10.2023	10705031124714	30705031124718
PDP9715H	SAMBRS	31.12.2023	10705031124752	30705031124756
PDP9715H	SMMEMZ	31.10.2024	10705031124752	30705031124756
PDP9733H	TAMDHC	31.12.2024	10705031124769	30705031124763
PDP9861H	SBMESR	31.01.2024	10705031124875	30705031124879

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Product Code	Batch/Lot	Expire date	GTIN - Each	GTIN - Sales Box
PDP9865H	RJMBCX	31.07.2023	10705031124899	30705031124893
W9615T	QMMCAJ	31.10.2025	10705031086906	30705031086900
W9624T	SDMPKU	31.03.2027	10705031130296	30705031130290
W9625T	REMAZK	30.04.2026	10705031130302	30705031130306
W9625T	RGMKUB	31.05.2026	10705031130302	30705031130306
W9625T	RHMCDZ	30.06.2026	10705031130302	30705031130306
W9625T	RJMJCQ	31.07.2026	10705031130302	30705031130306
W9625T	RPMAKJ	30.11.2026	10705031130302	30705031130306
W9625T	SCMLQK	28.02.2027	10705031130302	30705031130306
W9625T	SJMHCM	31.07.2027	10705031130302	30705031130306
W9626T	RCMKMU	28.02.2026	10705031082960	30705031082964
W9626T	RGMEDH	31.05.2026	10705031082960	30705031082964
W9626T	RGMEKR	31.05.2026	10705031082960	30705031082964
W9626T	RGMEUA	31.05.2026	10705031082960	30705031082964
W9626T	SDMAZQ	31.03.2027	10705031082960	30705031082964
W9626T	SEMDET	30.04.2027	10705031082960	30705031082964
W9631T	RLMAZJ	30.09.2026	10705031151819	30705031151813
W9631T	SCMHJL	28.02.2027	10705031151819	30705031151813
W9714T	SDMPZC	31.03.2027	10705031130333	30705031130337
W9716T	MM5113	31.10.2023	10705031130357	30705031130351
W9716T	QCMMCE	28.02.2025	10705031130357	30705031130351
W9716T	QJMHJD	31.07.2025	10705031130357	30705031130351
W9716T	RKMKTR	31.08.2026	10705031130357	30705031130351
W9733T	PM6878	31.10.2024	10705031130418	30705031130412
W9733T	QEMCUE	30.04.2025	10705031130418	30705031130412
W9733T	QEMEUB	30.04.2025	10705031130418	30705031130412
W9733T	QGMHMB	31.05.2025	10705031130418	30705031130412
W9733T	QGMHST	31.05.2025	10705031130418	30705031130412
W9733T	QGMJQB	31.05.2025	10705031130418	30705031130412
W9733T	QHMLLR	30.06.2025	10705031130418	30705031130412
W9733T	QKMJDB	31.08.2025	10705031130418	30705031130412
W9733T	QKMJDQ	31.08.2025	10705031130418	30705031130412
W9733T	QKMMLZ	31.08.2025	10705031130418	30705031130412
W9733T	QLMCLJ	30.09.2025	10705031130418	30705031130412
W9733T	RAMBLL	31.12.2025	10705031130418	30705031130412
W9733T	RAMBRT	31.12.2025	10705031130418	30705031130412
W9733T	RAMBZX	31.12.2025	10705031130418	30705031130412

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Product Code	Batch/Lot	Expire date	GTIN - Each	GTIN - Sales Box
W9733T	RCMAJX	28.02.2026	10705031130418	30705031130412
W9733T	RCMBPQ	28.02.2026	10705031130418	30705031130412
W9733T	RCMBUB	28.02.2026	10705031130418	30705031130412
W9733T	RCMCBT	28.02.2026	10705031130418	30705031130412
W9733T	RDMKQD	31.03.2026	10705031130418	30705031130412
W9733T	RHMKQD	30.06.2026	10705031130418	30705031130412
W9733T	RHMKUA	30.06.2026	10705031130418	30705031130412
W9733T	RJMAJQ	31.07.2026	10705031130418	30705031130412
W9733T	RJMASJ	31.07.2026	10705031130418	30705031130412
W9733T	SHMMEX	30.06.2027	10705031130418	30705031130412
W9733T	SHMMHT	30.06.2027	10705031130418	30705031130412
W9733T	SMMBPC	31.10.2027	10705031130418	30705031130412
W9733T	SMMCRC	31.10.2027	10705031130418	30705031130412
W9734T	QDMBUS	31.03.2025	10705031083028	30705031083022
W9734T	QDMCKS	31.03.2025	10705031083028	30705031083022
W9734T	RAMMXL	31.12.2025	10705031083028	30705031083022
W9734T	REMMRE	30.04.2026	10705031083028	30705031083022
W9734T	REMMXZ	30.04.2026	10705031083028	30705031083022
W9734T	RGMEUD	31.05.2026	10705031083028	30705031083022
W9734T	SLMAQH	30.09.2027	10705031083028	30705031083022
W9740T	RDMHBX	31.03.2026	10705031130425	30705031130429
W9804T	SCMEKR	28.02.2027	10705031130562	30705031130566
W9861T	ML5102	30.09.2023	10705031151895	30705031151899
W9861T	ML5528	30.09.2023	10705031151895	30705031151899
W9861T	MM5074	31.10.2023	10705031151895	30705031151899
W9861T	MM5084	31.10.2023	10705031151895	30705031151899
W9861T	MPM325	30.11.2023	10705031151895	30705031151899
W9861T	MPM504	30.11.2023	10705031151895	30705031151899
W9861T	QAMHCT	31.12.2024	10705031151895	30705031151899
W9861T	QBMAHP	31.01.2025	10705031151895	30705031151899
W9861T	RAMEPD	31.12.2025	10705031151895	30705031151899
W9861T	RHMLJM	30.06.2026	10705031151895	30705031151899
W9861T	RHMLZH	30.06.2026	10705031151895	30705031151899
W9861T	RJMCSE	31.07.2026	10705031151895	30705031151899
W9861T	RJMDHP	31.07.2026	10705031151895	30705031151899
W9861T	RJMKHU	31.07.2026	10705031151895	30705031151899
W9861T	RJMMAL	31.07.2026	10705031151895	30705031151899

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PDS™ Plus Antibacterial (polydioxanone) Suture

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– Voluntary Product Recall (Removal) –

Product Code	Batch/Lot	Expire date	GTIN - Each	GTIN - Sales Box
W9861T	RMMJDB	31.10.2026	10705031151895	30705031151899
W9861T	RMMQTB	31.10.2026	10705031151895	30705031151899
W9861T	SCMBAL	28.02.2027	10705031151895	30705031151899
W9863T	QEMCZJ	30.04.2025	10705031151901	30705031151905
W9863T	QLMLBS	30.09.2025	10705031151901	30705031151905
W9863T	QMMARX	31.10.2025	10705031151901	30705031151905
W9863T	RAMPQC	31.12.2025	10705031151901	30705031151905
W9863T	SLMCXZ	30.09.2027	10705031151901	30705031151905
W9867T	QDMBUQ	31.03.2025	10705031151918	30705031151912
W9869T	RCMKSU	28.02.2026	10705031130708	30705031130702
W9872T	RAMMXU	31.12.2025	10705031130722	30705031130726
W9957T	PGZ717	31.05.2024	10705031131057	30705031131051
W9957T	RCMKML	28.02.2026	10705031131057	30705031131051
W9957T	RDMDHK	31.03.2026	10705031131057	30705031131051
W9957T	RKMCKK	31.08.2026	10705031131057	30705031131051
W9957T	SCMCRD	28.02.2027	10705031131057	30705031131051
Z292ZE	QJMBRC	31.07.2025	10705031113602	30705031113606
Z292ZE	RKMPHE	31.08.2026	10705031113602	30705031113606
Z293E	REMMCD	30.04.2026	10705031113619	30705031113613
Z421E	SMMKKU	31.10.2027	10705031114050	30705031114054
Z422E	MMK542	31.10.2023	10705031114067	30705031114061
Z422E	MMK877	31.10.2023	10705031114067	30705031114061
Z422E	PGM513	31.05.2024	10705031114067	30705031114061
Z422E	RDMLXJ	31.03.2026	10705031114067	30705031114061
Z422ZE	MPM087	30.11.2023	10705031114074	30705031114078
Z422ZE	RGMHQL	31.05.2026	10705031114074	30705031114078
Z423E	QGMEZX	31.05.2025	10705031114081	30705031114085
Z441E	SEMESK	30.04.2027	10705031114111	30705031114115
Z443E	PHM746	30.06.2024	10705031114135	30705031114139
Z458E	QPMDHB	30.11.2025	10705031114142	30705031114146
Z458E	RBMCAX	31.01.2026	10705031114142	30705031114146
Z458E	SJMSDT	31.07.2027	10705031114142	30705031114146
Z489E	MPZ045	30.11.2023	10705031114258	30705031114252
Z490E	QMMBTJ	31.10.2025	10705031114265	30705031114269
Z490E	RBMKJQ	31.01.2026	10705031114265	30705031114269
Z492E	RBMECK	31.01.2026	10705031114272	30705031114276
Z494E	RDMAEC	31.03.2026	10705031114296	30705031114290

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Product Code	Batch/Lot	Expire date	GTIN - Each	GTIN - Sales Box
Z496E	QHMLML	30.06.2025	10705031114319	30705031114313
Z496E	RKMPRL	31.08.2026	10705031114319	30705031114313
Z497E	PGZ730	31.05.2024	10705031114333	30705031114337
Z497E	QLMLEZ	30.09.2025	10705031114333	30705031114337
Z497E	RKMQQD	31.08.2026	10705031114333	30705031114337
Z497H	RPMBSQ	30.11.2026	10705031467217	30705031467211
Z498E	SCMDEB	28.02.2027	10705031114340	30705031114344
Z683G	SBMPKQ	31.01.2027	10705031461536	30705031461530
Z684E	MJK736	31.07.2023	10705031114654	30705031114658
Z684E	PAZ713	31.12.2023	10705031114654	30705031114658
Z684E	PCK645	29.02.2024	10705031114654	30705031114658
Z684E	PCK823	29.02.2024	10705031114654	30705031114658
Z684E	QBMHXB	31.01.2025	10705031114654	30705031114658
Z684E	QGMCMZ	31.05.2025	10705031114654	30705031114658
Z684E	RDMKJS	31.03.2026	10705031114654	30705031114658
Z684E	SHMELB	30.06.2027	10705031114654	30705031114658
Z9625H	SMMBDA	31.10.2027	10705031467354	30705031467358

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

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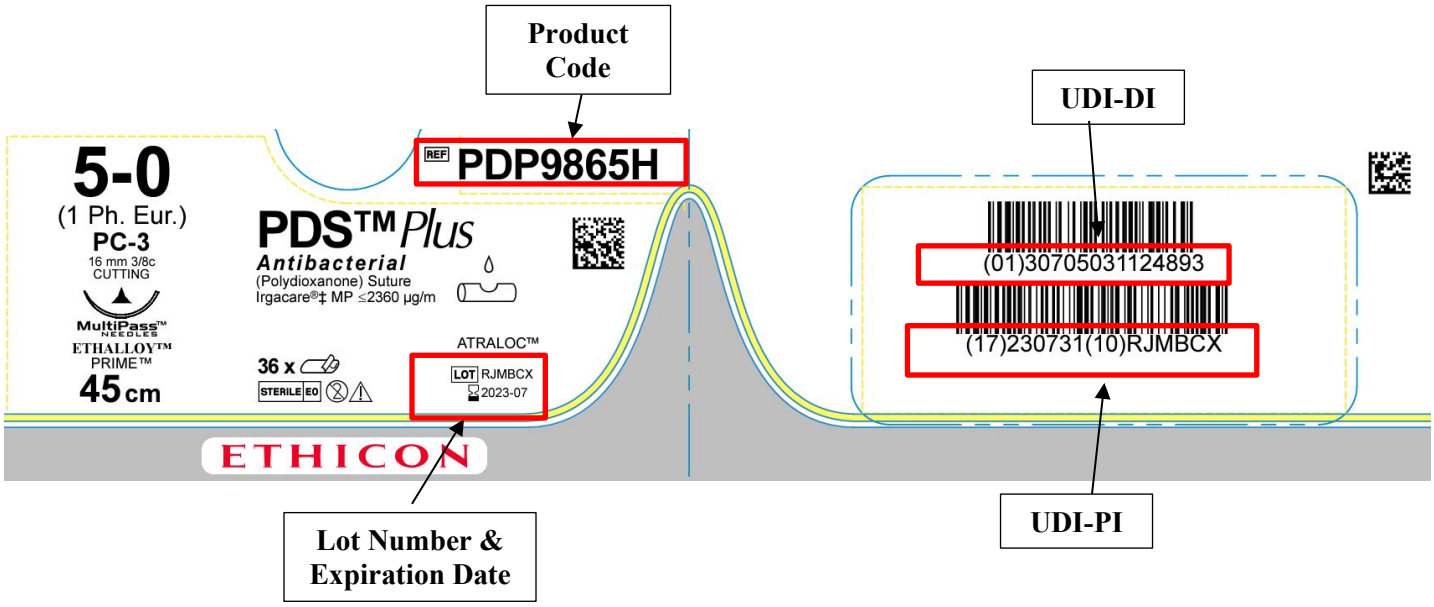
Attachment 2: Product Identification Tool

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



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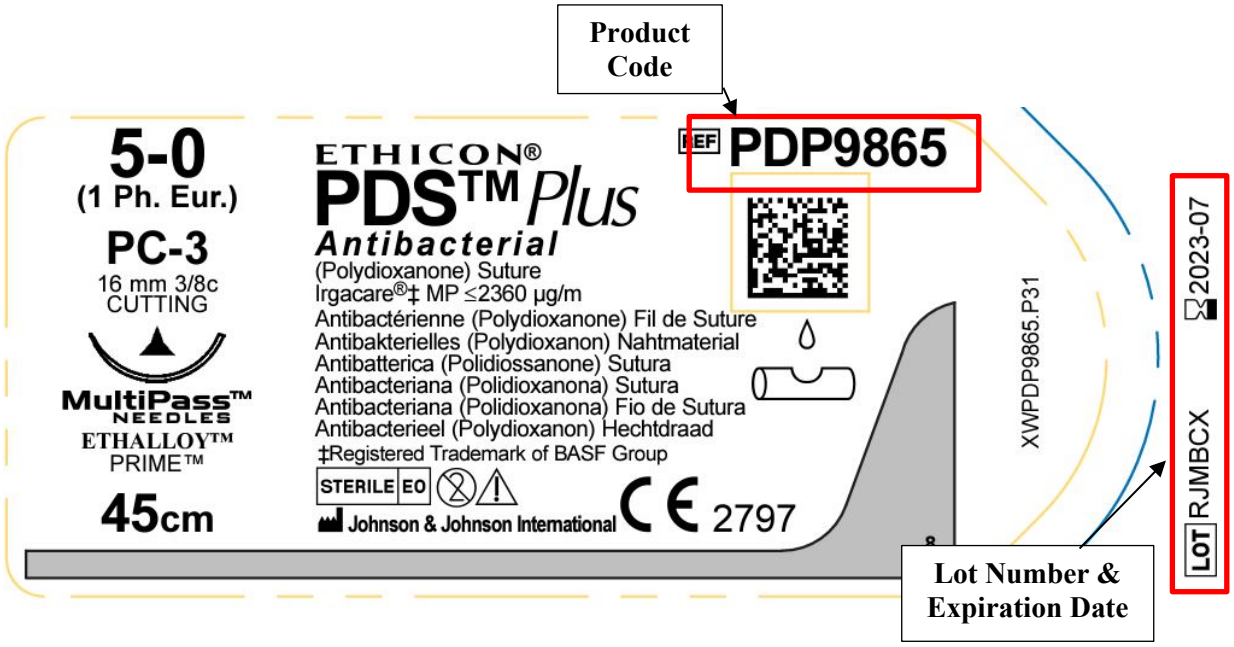
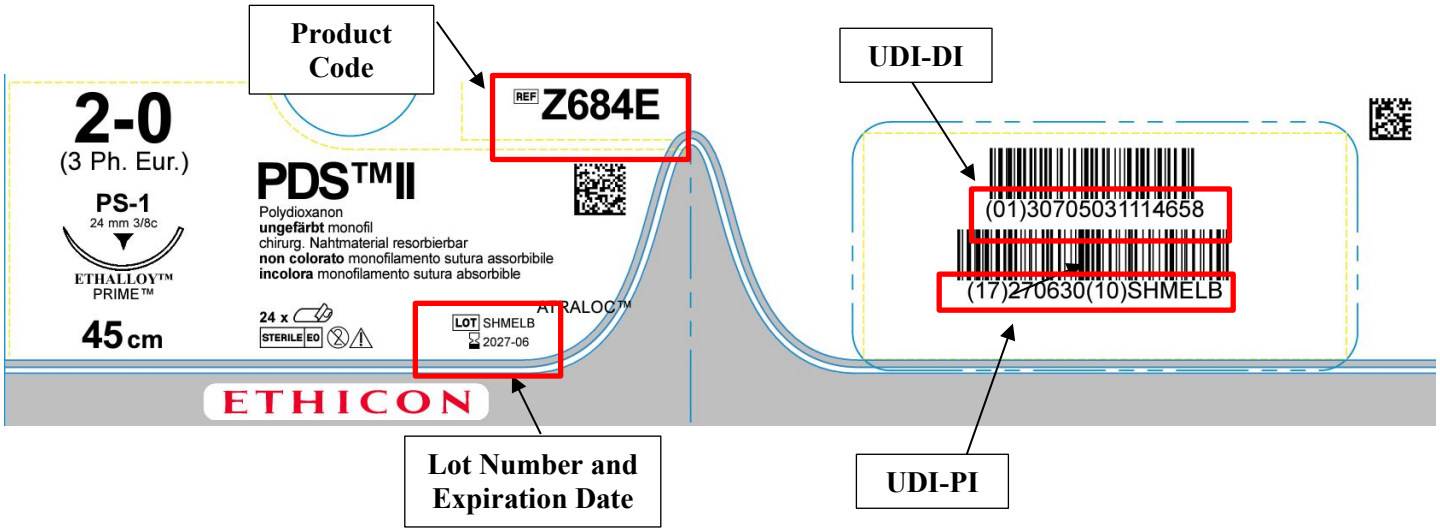
PDS™ Plus Individual Unit



PDS™ II Sales Unit Box



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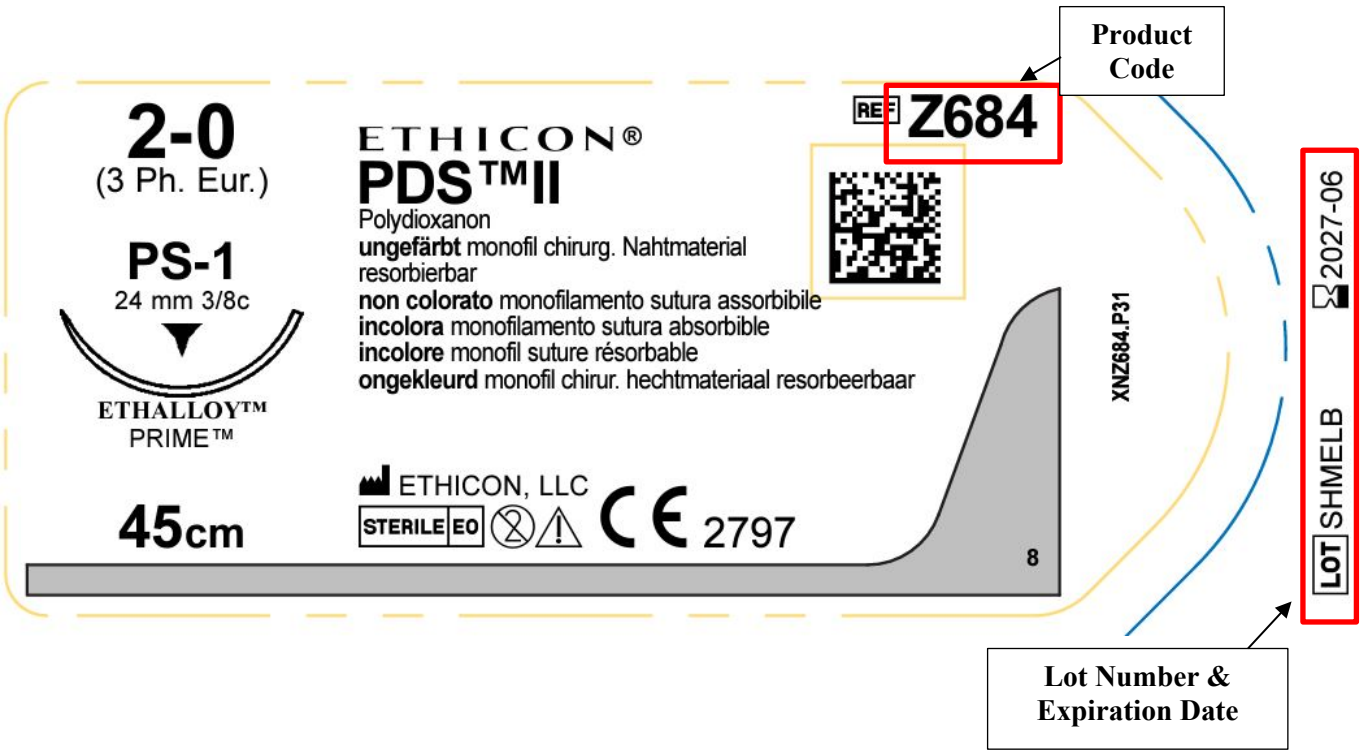
PDS™ II Individual Unit



Attachment 3: Business Reply Form

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

Business Reply Form (BRF)

Your timely response to this recall notification is requested. Please complete this form and email it to MDFieldActionsUKirl@its.jnj.com **within 3 business days, even if you do not have product subject to this recall to return.** Please complete the below in BLOCK CAPITALS and ensure the writing is legible please.

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:
Hospital name and address:	
Collection Department:	
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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PDS™ II (polydioxanone) Suture
PDS™ Plus Antibacterial (polydioxanone) Suture
(Impacted Product Codes and lots are listed in Attachment 1)
– Voluntary Product Recall (Removal) –

PRODUCT CODE	PRODUCT LOT	EXP DATE	QUANTITY RETURNING (EACHES)