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2040
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To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 177 dated 24/8/23 Regarding NCMDR recall of PDS TM II (polydioxanone) Suture, PDS TM Plus Antibacterial (polydioxanone) Suture from (mfr:Ethicon, Inc.).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: 100 - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

dgpa_dc Email: dg-padc@moh.gov.om




Circular No. 177/2023

08 -02-1445 H
24 -08-2023

Recall of PDS TM II (polydioxanone) Suture, PDS TM Plus Antibacterial (polydioxanone) Suture from Ethicon, Inc.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=6&rid=19664
Product	PDS TM II (polydioxanone) Suture, PDS TM Plus Antibacterial (polydioxanone) Suture.
Description	Dressings / Pads - surgical sutures, vascular loops.
Manufacturer	Ethicon, Inc.
Local Agent	Muscat Pharmacy & Stores LLC.
The affected products	Impacted Product Codes and lots are listed in the attachment.
Reason	Some listed sutures in the attachment did not meet tensile strength requirement.
Action	1. Please return unused impacted Sutures that are in your inventory immediately to Ethicon representative. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om


Dr. Mohammed Hamdan Al Rubaie
Director General



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) –

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	SAMBR5	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

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) –

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	RAMBL	31.12.2025	10705031130418	30705031130412
W9733T	RAMBRT	31.12.2025	10705031130418	30705031130412
W9733T	RAMBZX	31.12.2025	10705031130418	30705031130412

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) –

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

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) –

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	RBMCAAX	31.01.2026	10705031114142	30705031114146
Z458E	SJMSTDT	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

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) –

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.