

MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2026
Follow up for implants (by projects /programs department MOH)
Follow up for instruments / non-implants (by engineering department MOH)

Item	Manufacturer	link
Organ Recovery OR Packs	AVID Medical	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/organ-recovery-pack-correction-avid-medical-issues-correction-medical-convenience-and-organ-recovery?utm_medium=email&utm_source=govdelivery
- Brilliance iCT - CT 6000 - IQon Spectral CT - Spectral CT - Spectral CT 7500	Philips Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/685
Dexcom G6 Continuous Glucose Monitoring System's	Dexcom Inc.	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/continuous-glucose-monitoring-software-correction-dexcom-issues-correction-dexcom-g6-and-g6-pro?utm_medium=email&utm_source=govdelivery
IV Gravity Burette Set	ICU Medical	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/intravascular-administration-set-recall-icu-medical-removes-iv-gravity-burette-set?utm_medium=email&utm_source=govdelivery
Alcon Custom Paks	Alcon	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/custom-surgical-pack-recall-alcon-removes-custom-pak-ophthalmic-procedure-paks?utm_medium=email&utm_source=govdelivery
NOxBOXi Nitric Oxide Delivery Device	NOxBOX Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/681
Bubble Sensor	MAQUET Cardiopulmonary GmbH	https://ade.sfda.gov.sa/Fsca/PublishDetails/683

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Codman Microsensor Basic Kits and Cerelink ICP Sensor	Integra LifeSciences	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/early-alert-convenience-kit-needle-issue-integra-lifesciences?utm_medium=email&utm_source=govdelivery
IMRIS Neuro III-SV	IMPRIS Imaging Inc	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/system-correction-impris-imaging-inc-issues-correction-imris-neuro-iii-sv?utm_medium=email&utm_source=govdelivery
Zenith Alpha 2 Thoracic Endovascular Graft	Cook Medical	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/endovascular-graft-recall-cook-medical-removes-zenith-alpha-2-thoracic-endovascular-graft?utm_medium=email&utm_source=govdelivery
ErgoStar Catheter	Draeger	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/catheter-mount-recall-draeger-removes-ergostar-catheter-mounts?utm_medium=email&utm_source=govdelivery
TS-10	Sysmex Corporation	https://ade.sfda.gov.sa/Fsca/PublishDetails/660
Leksell GammaPlan	Elekta Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/662
Vanta Implantable Neurostimulator (INS)	Medtronic Inc.	https://ade.sfda.gov.sa/Fsca/PublishDetails/661
Impella RP with SmartAssist and Impella RP Flex with SmartAssist devices	Abiomed	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/early-alert-heart-pump-issue-abiomed?utm_medium=email&utm_source=govdelivery

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FreeStyle Libre 3 and FreeStyle Libre 3 Plus sensors	Abbott Diabetes Care	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/glucose-monitor-sensor-recall-abbott-diabetes-care-removes-certain-freestyle-libre-3-and-freestyle
CEREPAK Detachable Coil Systems	J&J MedTech	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/detachable-coil-system-recall-ij-medtechcerenovus-inc-remove-cerepak-detachable-coil-system?utm_medium=email&utm_source=govdelivery
HAMILTON MEDICAL AG	HAMILTON-C2 with neonatal option	https://ade.sfda.gov.sa/Fsca/PublishDetails/718
Centricity Universal Viewer Softwar	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/720
Philips Allura and Azurion systems	Philips Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/263
OLYMPUS CleverCut and FlowCut Sphincterotomes	Olympus Corporation of the Americas	https://ade.sfda.gov.sa/Fsca/PublishDetails/714
Brevera Breast Biopsy System Disposable 9 Gauge Needle	Hologic Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/711
Philips Azurion Systems	Philips Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/715
MobileDiagnost wDR.	Philips Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/717

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Prismaflex Set deaeration chambers	Vantive	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/early-alert-dialysis-tubing-set-issue-vantive?utm_medium=email&utm_source=govdelivery
Anesthesia Circuit Kits	Medline	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/anesthesia-kit-recall-medline-removes-anesthesia-circuits-and-anesthesia-circuit-kits?utm_medium=email&utm_source=govdelivery
Vapor 2000 and Vapor 3000	Draeger	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/anesthetic-vaporizer-recall-draeger-removes-vapor-2000-and-vapor-3000-vaporizers?utm_medium=email&utm_source=govdelivery
AXIOS Stent and Electrocautery Enhanced Delivery Systems	Boston Scientific	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/early-alert-stent-and-electrocautery-enhanced-delivery-system-issue-boston-scientific?utm_medium=email&utm_source=govdelivery
Medihoney® Wound and Burn Products	Derma Sciences, Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/693
Hickman/Broviac Central Venous Catheters	Becton Dickinson & Co. (BD)	https://ade.sfda.gov.sa/Fsca/PublishDetails/686
Triangle Tip Knife J – Single Use Electrosurgical Knives	Olympus Corporation of the Americas .	https://ade.sfda.gov.sa/Fsca/PublishDetails/687
Proxima Sterile Surgical Gowns, Packs, and Drapes.	Medline Industries Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/692

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THUNDERBEAT™ Hand Instrument	Olympus Corporation of the Americas .	https://ade.sfda.gov.sa/Fsca/PublishDetails/688
MediHoney Wound and Burn products	Integra LifeSciences	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/early-alert-wound-and-burn-dressing-issue-integra-lifesciences?utm_medium=email&utm_source=govdelivery
Insufflation Unit models UHI, UHI-2, and UHI-3	Olympus	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/early-alert-insufflation-unit-issue-olympus?utm_medium=email&utm_source=govdelivery
ShockPulse-SE Lithotripsy System	Olympus Corporation of the Americas .	https://ade.sfda.gov.sa/Fsca/PublishDetails/704
Olympus resection/inner sheaths of resectoscopes.	Olympus Corporation of the Americas .	https://ade.sfda.gov.sa/Fsca/PublishDetails/702
Grip Cable Failures on da Vinci S and Si Reusable Instruments with Jaws	Intuitive Surgical Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/697
da Vinci S and Si Tenaculum Forceps and Permanent Cautery Hook	Olympus Corporation of the Americas	https://ade.sfda.gov.sa/Fsca/PublishDetails/706
Automated Compounding Device Inlet	Baxter Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/709
Generation 1 Purge Cassettes	Abiomed, Inc	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/early-alert-heart-pump-purge-cassette-issue-abiomed?utm_medium=email&utm_source=govdelivery

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Electrophysiology and Ultrasound Catheters	Medline	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/catheter-recall-expansion-medline-industries-removes-reprocessed-electrophysiology-and-ultrasound?utm_medium=email&utm_source=govdelivery
Ivenix Large Volume Pump	Fresenius Kabi	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/infusion-pump-software-correction-fresenius-kabi-issues-correction-ivenix-large-volume-pump-software?utm_medium=email&utm_source=govdelivery
MAJ-210 Single use Biopsy Valves	Olympus Corporation of the America	https://ade.sfda.gov.sa/Fsca/PublishDetails/736
Hugo™ RAS System	Medtronic SA	https://ade.sfda.gov.sa/Fsca/PublishDetails/733
BD Alaris neXus and Alaris Plus syringe pumps	Becton Dickinson & Co. (BD)	https://ade.sfda.gov.sa/Fsca/PublishDetails/727
Trilogy Evo, Trilogy Evo O2, Trilogy EV300	Respironics Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/734
EVO+ Visian Toric Implantable Collamer® Lens (TICL)	STAAR Surgical AG	https://ade.sfda.gov.sa/Fsca/PublishDetails/730
Philips Interventional Hemodynamic System	Philips Medical Systems Nederland B.V.	https://ade.sfda.gov.sa/Fsca/PublishDetails/731
CLARITY II ICD system	Lutronic Corporation	https://ade.sfda.gov.sa/Fsca/PublishDetails/749

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MINOP® Trocar – Outer Diameter 6 mm, 4 channels	Aesculap	https://ade.sfda.gov.sa/Fsca/PublishDetails/746
Various BVM Resuscitators	Intersurgical Limited	https://ade.sfda.gov.sa/Fsca/PublishDetails/747
Cryoprobes	Erbe USA	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/early-alert-flexible-cryoprobe-issue-erbe-usa?utm_medium=email&utm_source=govdelivery
Omnipod 5 Pods	Insulet	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/early-alert-insulin-pump-issue-insulet?utm_medium=email&utm_source=govdelivery
curved-tip staplers	Intuitive Surgical	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/early-alert-surgical-stapler-issue-intuitive-surgical?utm_medium=email&utm_source=govdelivery
heating pads	Navajo	https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/heating-pad-recall-navajo-manufacturing-company-removes-handy-solutions-neck-shoulders-heating-pad
Streamline Airless System	B. Braun	https://www.fda.gov/medical-devices/early-alert-bloodline-set-hemodialysis-systems-issue-b-braun-medical-inc?utm_medium=email&utm_source=govdelivery
1.0MM and 1.5MM Fine Round Diamond Bur	Stryker Instruments	https://ade.sfda.gov.sa/Fsca/PublishDetails/759
EDAN Patient Monitoring and Fetal Monitoring Devices	Edan Instruments Inc...	https://ade.sfda.gov.sa/Fsca/PublishDetails/758
SOLTIVE Superpulsed Laser System	Gyrus ACMI, Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/755

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HF (high-frequency) bipolar cable	Olympus Corporation of the Americas .	https://ade.sfda.gov.sa/Fsca/PublishDetails/754
PALAMIX® uno and PALAMIX® duo	Heraeus Medical GmbH	https://ade.sfda.gov.sa/Fsca/PublishDetails/756
Leksell® Vantage Arc System	Elekta Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/753
IVascular navitian	Life Vascular Devices Biotech S.L	https://ade.sfda.gov.sa/Fsca/PublishDetails/752
Vanta Implantable Neurostimulator (INS)	Medtronic Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/661
Instinct Plus Endoscopic Clipping Device	Wilson-Cook Medical Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/750
BiPAP A40 Pro Ventilator, BiPAP A40 EFL Ventilator, and BiPAP A30 EFL Ventilato	Respironics Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/138