

## MEDICAL DEVICES

### RECALL AND SAFETY NOTICE 2026

**Follow up for implants (by projects /programs department MOH)**

**Follow up for instruments / non-implants (by enginnering department MOH)**

Item	Manufacturer	link
Organ Recovery OR Packs	AVID Medical	<a href="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&amp;utm_source=govdelivery">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&amp;utm_source=govdelivery</a>
- Brilliance iCT - CT 6000 - IQon Spectral CT - Spectral CT - Spectral CT 7500	Philips Healthcare	<a href="https://ade.sFDA.gov.sa/Fsca/PublishDetails/685">https://ade.sFDA.gov.sa/Fsca/PublishDetails/685</a>
Dexcom G6 Continuous Glucose Monitoring System's	Dexcom Inc.	<a href="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&amp;utm_source=govdelivery">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&amp;utm_source=govdelivery</a>
IV Gravity Burette Set	ICU Medical	<a href="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&amp;utm_source=govdelivery">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&amp;utm_source=govdelivery</a>
Alcon Custom Paks	Alcon	<a href="https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/custom-surgical-pack-recall-alcon-removes-custom-pak-ophthalmic-procedure-packs?utm_medium=email&amp;utm_source=govdelivery">https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/custom-surgical-pack-recall-alcon-removes-custom-pak-ophthalmic-procedure-packs?utm_medium=email&amp;utm_source=govdelivery</a>
NOxBOXi Nitric Oxide Delivery Device	NOxBOX Ltd.	<a href="https://ade.sFDA.gov.sa/Fsca/PublishDetails/681">https://ade.sFDA.gov.sa/Fsca/PublishDetails/681</a>

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Bubble Sensor	MAQUET Cardiopulmonary GmbH	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/683">https://ade.sfda.gov.sa/Fsca/PublishDetails/683</a>
Codman Microsensor Basic Kits and Cerelink ICP Sensor	Integra LifeSciences	<a href="https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/early-alert-convenience-kit-needle-issue-integra-lifesciences?utm_medium=email&amp;utm_source=govdelivery">https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/early-alert-convenience-kit-needle-issue-integra-lifesciences?utm_medium=email&amp;utm_source=govdelivery</a>
IMRIS Neuro III-SV	IMPRIS Imaging Inc	<a href="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&amp;utm_source=govdelivery">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&amp;utm_source=govdelivery</a>
Zenith Alpha 2 Thoracic Endovascular Graft	Cook Medical	<a href="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&amp;utm_source=govdelivery">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&amp;utm_source=govdelivery</a>
ErgoStar Catheter	Draeger	<a href="https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/catheter-mount-recall-draeger-removes-ergostar-catheter-mounts?utm_medium=email&amp;utm_source=govdelivery">https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/catheter-mount-recall-draeger-removes-ergostar-catheter-mounts?utm_medium=email&amp;utm_source=govdelivery</a>
TS-10	Sysmex Corporation	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/660">https://ade.sfda.gov.sa/Fsca/PublishDetails/660</a>

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<b>Item</b>	<b>Manufacturer</b>	<b>link</b>
Leksell GammaPlan	Elekta Inc	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/662">https://ade.sfda.gov.sa/Fsca/PublishDetails/662</a>
Vanta Implantable Neurostimulator (INS)	Medtronic Inc.	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/661">https://ade.sfda.gov.sa/Fsca/PublishDetails/661</a>