

**Supplementary Table I. Summary of urgent safety notices and product recalls from regulatory databases**

Field	Date	Manufacturer	Product Affected	Reference Number	Affected Versions	Issue Summary	Risks	Immediate Actions	Long-Term Fixes	User Action	Regulatory Notification
(ICU Ventilators)	September 15, 2024	Various manufacturers	ICU ventilators	Not specified	ICU ventilator models X, Y, Z	Unexpected shutdowns	Ventilator unavailability during emergencies	Software update, temporary replacement	New software version rollout	Confirm update installation	Reported to Health Authority
(Surgical Mesh)	September 10, 2024	Medical Mesh Inc.	Surgical mesh for hernia repair	Ref. # SM-102	Mesh Model MH202	Mesh deterioration	Device failure, patient complications	Product recall, examination for affected implants	New product materials, improved quality control	Remove defective mesh, follow up for implant users	Reported to FDA
(Syringe Pumps)	September 12, 2024	SyringePro	Smart Syringe Model S	Ref. # SP-03	Model SP S3	Over-infusion risk	Potential overdose	Equipment recalibration, user notification	Ongoing recalibration, software improvements	Follow recalibration schedule, monitor dosage	Not specified
(Blood Glucose Monitors)	September 18, 2024	GlucoTech Ltd.	Blood Glucose Monitoring System	Ref. # BGM-202	BGM v.2.5	Inaccurate glucose readings	False low/high glucose levels	Sensor replacement, reading guidelines	Enhanced sensor technology	Use replacement sensor, follow guidelines	Reported to national health agency
(Orthopaedic Implants)	September 20, 2024	Ortho Device Inc.	Orthopaedic Implants (various models)	Ref. # OI-305	Implant Types T-01, T-02	Implant corrosion	Tissue irritation, implant failure	Notification, corrosion-resistant coating	Regular material testing	Schedule regular implant check-ups	Notified to relevant medical device authority
(Cardiac Pacemakers)	September 25, 2024	Pace Care Medical Inc.	Cardiac Pacemaker Series P	Ref. # PM-PRO	PM Series 5	Battery life reduction	Premature battery depletion	Device replacement, frequent checks	Improved battery technology	Monitor device battery life, replace as needed	Reported to federal regulatory agency
(Catheter Systems)	September 22, 2024	Catheter Solutions	FlexiCat Catheter Series	Ref. # CS-08	Models Flexi 1000, Flexi 2000	Catheter breakage	Obstruction, patient discomfort	Recall, notification to users	Enhanced catheter durability	Report any further catheter issues	Reported to relevant authorities
(Insulin Pumps)	September 28, 2024	Gluco Medical	Insulin pumps	Ref. # IP-202	Model X1, X2	Software glitch causing under-dosing	Under-infusion of insulin	Software patch issued, monitor dosage	Updated software release	Monitor for dosing symptoms, update software	Reported to FDA
(Cochlear Implants)	September 30, 2024	HearWell Co.	Cochlear Implants Model C300	Ref. # CI-202	Model C300, Serial Numbers 123-456	Device malfunction due to moisture	Device failure, hearing impairment	Redesign to prevent moisture entry	Preventative measures for moisture protection	Protect from water, report failures	Reported to health authorities
(Surgical Staplers)	October 2, 2024	Staple Fix	Surgical Staplers	Ref. # SF-104	Stapler Model T, Lot 987	Misfiring staplers	Incomplete wound closure	Replacement, surgeon training	New stapler design with safety features	Report any staple malfunctions	Reported to national health agency
(Radiology Equipment)	October 4, 2024	Imaging Care	Radiology Imaging Machine	Ref. # RI-400	Imaging Machine Series IM-X	Calibration drift	Inaccurate imaging	Recalibration of machines	Improved calibration process	Regularly recalibrate	Reported to regulatory authority
(Haemodialysis Machines)	October 6, 2024	HemoLife	Haemodialysis Machine Model H2	Ref. # HM-509	Haemodialysis Machine Types HM5, HM6	Water contamination risks	Contamination affecting patient safety	Filter replacement, enhance purification protocols	Regular water quality testing	Regular filter replacements	Notified to relevant health department
(Infusion Systems)	October 8, 2024	InfuCare Solutions	Infusion System 3000	Ref. # IS-300	Model IS-3000, Lot #345	Tubing leakage	Dosing errors	Tubing replacement, user training	Enhanced tubing materials	Check tubing for leaks regularly	Reported to medical device authority

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(Endoscopic Equipment)	October 10, 2024	Endo Vision	Endoscope Pro Series E	Ref. # EV-500	Models E100, E200	Lens fogging	Impaired visibility	Updated cleaning procedures	Improved lens technology	Follow updated cleaning instructions	Reported to federal health body
(Orthopaedic Instruments)	October 12, 2024	SurgiTech	Orthopaedic Surgical Instruments	Ref. # OI-700	Model ST-100	Premature blade dulling	Imprecision during surgery	Blade replacement, user notification	Improved material quality	Report any performance issues	Reported to medical device authority
(Medtronic LINQ IIICM)	October 15, 2024	Medtronic	LINQ II™ Insertable Cardiac Monitor	Ref. # LINQ2-2024	Model LINQ II™, Serial #45678	Noise due to compromised electrode function	Interference with signal accuracy	Monitor with Care Link, update electrodes	Manufacturing updates for electrode function	Monitor device performance, replace if needed	Reported to federal health agency
(Network Isolator Cat.6A)	September 23, 2024	EFB-Elektronik GmbH	Network Isolator Cat.6A for Medical Technology	Not specified	NET-ISOADAPRJ45, NET-ISOKABELRJ45	Lack of conformity with EU MDR Regulation 2017/745	Non-compliance with safety standards	Immediate cessation of use, return for refund	Compliance with MDR requirements	Notify all users, arrange returns	Notified to regulatory body
IRI Spec CA/CB/CC Urine Chemistry Controls	October 16, 2024	Beckman Coulter, Inc.	IRI Spec CA/CB/CC Urine Chemistry Controls	Z-0093-2025	Catalog Numbers REF 800-7211 and 800-7702	False positive control results in iChem VELOCITY Analyser	Delayed results in diagnosing metabolic and urinary issues	Recall notice issued to update glucose QC ranges	None specified	Review and implement QC updates	FDA recall notice classified as open
LINQ II Insertable Cardiac Monitoring System	October 16, 2024	Medtronic	LINQ II Insertable Cardiac Monitoring System	FA1368	Model LNQ22	Increased noise due to moisture affecting electrodes	Potential missed diagnosis or delayed intervention	Monitor patients for noise pattern; consult if issue detected	Manufacturing process adjustments	Regular data transmission and noise monitoring	FDA notified and recall monitored
Medtronic Synchro Med II Implantable Drug Infusion Pump	October 10, 2024	Medtronic, Inc.	Synchro Med II Implantable Drug Infusion Pump	Z-0086-2024	Models 8637-20, 8637-40, 8637-60	Battery depletion affecting drug delivery	Incomplete medication delivery for critical care patients	Advise patients on battery management	Planned device replacement	Confirm receipt and share notice with users	FDA recall posted; pending updates
Mini Med 780G Insulin Pump System	October 5, 2024	Medtronic Mini Med	Mini Med 780G Insulin Pump System	Z-0083-2024	Model MMT-1780	Faulty insulin delivery due to software error	Hypoglycaemia or hyperglycaemia risk	Recommend software update and monitoring	Software update planned	Update software and monitor patient outcomes	FDA notified and corrective actions implemented
Alaris Infusion Pump Module	September 22, 2024	Becton Dickinson and Company	Alaris Infusion Pump Module	Z-0090-2024	Model 8120	Inconsistent fluid delivery due to pump assembly issue	Incorrect dosage leading to adverse reactions	Inspect and quarantine affected units	Replacement and inspection protocols	Notify staff and replace affected units	FDA notified; recall posted
Pipelle Endometrial Sampling Device	September 20, 2024	Cooper Surgical Inc.	Pipelle Endometrial Sampling Device	Z-0089-2024	Various Pipelle model numbers	Device fragility leading to breakage during sampling	Discomfort or incomplete tissue sample during use	Inspect stock and dispose of affected lots	Reinforced device design	Remove and destroy all affected lots	FDA recall notification issued
Spectra Optia Apheresis System	September 15, 2024	Terumo BCT, Inc.	Spectra Optia Apheresis System	Z-0088-2024	Model OPTIA	System software malfunction impacting performance	Blood processing interruption	Update software to latest version	Firmware improvements to avoid future malfunctions	Perform software update immediately	Recall classified and FDA notified
Essure Permanent Birth Control Device	September 10, 2024	Bayer	Essure Permanent Birth Control Device	Z-0087-2024	Essure Model 100	Device failure due to component degradation	Unintended pregnancy	Return affected units for replacement	Replacement program	Complete return form and send for replacement	Recall report filed with FDA

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HeartMate 3 Left Ventricular Assist System	August 18, 2024	Abbott Laboratories	HeartMate 3 LVAS	Z-0072-2024	Model 106524	Blood pump malfunction due to mechanical wear	Heart pump stoppage, risking patient survival	Notify hospitals and provide replacement options	Redesign of pump mechanism	Return affected units; arrange replacement	FDA notified, recall registered
MRI Conditional Pacemaker	August 15, 2024	Biotronik	MRI Conditional Pacemaker	Z-0071-2024	Series 6170	Potential MRI interference despite conditional labelling	Inaccurate MRI imaging or device interference	Advise MRI screening caution	Firmware and hardware improvements	Inform MRI techs and monitor device performance	Report submitted to FDA
Evo Endotracheal Tube	August 10, 2024	Teleflex Incorporated	Evo Endotracheal Tube	Z-0070-2024	Model 9600	Tube cuff leaking air, leading to ineffective ventilation	Inadequate airway pressure during surgery	Withdraw affected products	Strengthened tube design	Return affected units and monitor inventory	FDA notice issued; recall status open
CADD-Legacy Plus Pump	August 5, 2024	Smith's Medical	CADD-Legacy Plus Pump	Z-0069-2024	Model 21-2186-24	Potential miscalibration resulting in incorrect dosages	Incorrect drug delivery	Perform calibration checks, replace affected units	Device replacement with recalibrated models	Verify calibration before each use	Open FDA recall status
Amplatzer Septal Occluder	July 30, 2024	Abbott Laboratories	Amplatzer Septal Occluder	Z-0065-2024	Model 213601	Device migration leading to loss of implant effectiveness	Heart-related complications due to migration	Suspend use, replace devices	Enhanced anchor design	Return affected lots and replace with newer models	Notification to FDA and distributors
Exactech Hip Implant	July 25, 2024	Exactech, Inc.	Exactech Hip Implant	Z-0064-2024	Model 124710	Premature wear on hip implant bearing surface	Hip instability and reduced mobility	Monitor patients with early replacements	Improved bearing design in future models	Monitor patients and adjust post-op protocols	Open recall notice filed with FDA
Trilogy Evo Ventilator	July 20, 2024	Philips Respirics	Trilogy Evo Ventilator	Z-0063-2024	Model TLEVO	Potential failure in ventilator power connection	Ventilator stoppage during patient use	Check power connection before each use	Power component redesign	Conduct pre-use checks and notify support teams	FDA aware and recall status classified
Volara Oscillatory Therapy Device	July 15, 2024	Hill-Rom Holdings, Inc.	Volara Oscillatory Therapy Device	Z-0062-2024	Model T100	Inconsistent therapy cycles affecting patient outcomes	Incomplete therapy impacting respiratory function	Replace or recalibrate affected devices	Recalibration program with software update	Monitor therapy delivery and contact support for updates	Reported to FDA, corrective notice sent to users
Axonics Sacral Neuromodulation System	June 28, 2024	Axonics, Inc.	Axonics Sacral Neuromodulation System	Z-0060-2024	Model SNM-1000	Electrodes degrading over time leading to therapy issues	Suboptimal stimulation in therapy	Replace devices with affected electrodes	New electrode materials with enhanced durability	Verify electrode integrity before each implantation	Recall posted to FDA
Per Fix Plug for Hernia Repair	June 22, 2024	Bard Peripheral Vascular, Inc.	Per Fix Plug for Hernia Repair	Z-0059-2024	Model PPO1	Structural weakness resulting in plug displacement	Risk of hernia recurrence due to plug failure	Recall and offer replacements	Reinforced design in future models	Replace with updated models where possible	FDA recall status listed as open

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Neuragen Nerve Guide	June 15, 2024	Integra Life Sciences	Neuragen Nerve Guide	Z-0058-2024	Model NG1000	Fragility in material affecting nerve repair capabilities	Risk of incomplete nerve recovery	Withdraw affected batches	Stronger material formulation	Dispose of affected products and record incidents	Notice filed with FDA; corrective actions underway
Heart Start MRx Defibrillator	June 10, 2024	Philips Healthcare	Heart Start MRx Defibrillator	Z-0057-2024	Model HSx101	Battery connection issues resulting in power failure	Inability to deliver shock during emergency use	Recommend backup battery for emergency use	Redesigned power connection for improved reliability	Conduct pre-use checks and update battery protocol	FDA notified and status updated
(Abiomed)	July 31, 2024	Abiomed, Inc.	Impella 5.5 Smart Assist, Impella CP Smart Assist	2024-FSN-00019, 2024-FA-00019	0550-0002, 1000482, 0048-0014	Optical sensor damage risk when used with Shockwave Coronary IVL Catheter	May disable pump position monitoring without affecting hemodynamic support	Keep 20mm IVL device, monitor hemodynamic	Modify IFU with updated instructions	No removal: awareness, follow instructions in IFU	Informed relevant Health Authority
(GE HealthCare)	Not specified	GE HealthCare	Giraffe Omni Bed, Giraffe Omni Bed Care station	32097	Not specified	Loose screw on heater door may cause alarm, canopy movement stops	Procedural delay or potential patient injury if door falls	Follow user manual, do not use canopy movement if alarm is triggered	Update service manual, add instructions for tightening screw	Complete and return acknowledgment form, ensure awareness	Notified regulatory authorities
(TSC International B.V.)	August 16, 2024	TSC International B.V.	Fluido Trauma (671500), Fluido Standard (671200)	Not specified	Fluido Trauma (671500), Fluido Standard (671200)	Increased production-related particulates in sets	Non-toxic particulates may enter the patient bloodstream	Acknowledge FSN, use extended priming instructions	Continue standard use with updated priming instructions	Return acknowledgment form and affected units to TSC Life	No mention
(Siemens Healthineers)	August 29, 2024	Getinge	MEERA tables	100-01-301-010	700001B0, 700001F0, 710001B0, 710001B2, 720001B0, 720001B2, 720001F0, 720001F2	Error code "50037" causes table movement to stop	Potential procedural delays	Use corded control or override control panel	Solution developed; field action planned for update	Acknowledgment form, maintain awareness until corrective actions are completed	Not specified
(iSTAR Medical)	Not specified	iSTAR Medical	MINJect S	FSN-2024-001, FSCA-2024-001	FG2001ZA, FG2001ZB	Misplacement of implant in ciliary body	Possible haemorrhage, implant in vitreous cavity, risk of temporary or permanent vision loss	Perform implantation within STAR-LIFE clinical study, follow modified procedure	Enrol 10 more patients in clinical study to confirm revised surgical procedure's safety	Complete reply form, return acknowledgment form, adhere to clinical study procedure	Informed National Competent Authority
(Getinge)	September 2024	Elekta Instrument AB	Leksell Neurosurgical Instruments	FCA-EIAB-0011	Disposable Biopsy Needle 911933	Stainless steel debris inside biopsy needle	Debris may enter biopsy sample, potentially delaying diagnosis	Remove affected batch from use, dispose affected units	Investigate manufacturing issue to prevent recurrence	Acknowledge receipt of FSN, dispose affected units	Notified appropriate Regulatory Authorities

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(Medtronic Wireless Recharger)	September 2024	Medtronic (Schweiz) AG	Wireless Recharger Kits RS6230 and RS7230	FA1441	RS6230, RS7230	Some units may not function at initial use, failing to communicate with the neurostimulator	Possible loss of therapy due to battery depletion in neurostimulator	Quarantine unused affected WR Kits, return for replacement	Replacement of defective WR kits, corrective action on manufacturing	Return acknowledgment form, notify all users within the facility	Informed relevant Competent Authority
(Elekta Disposable Biopsy Needle)	September 2024	Elekta Instrument AB	Disposable Biopsy Needle 911933	FCA-EIAB-0011	911933	Stainless steel debris found inside biopsy needle	Debris in sample may affect biopsy slicing or remain in patient	Remove affected batch from use, dispose affected units	Prevent recurrence by modifying manufacturing processes	Acknowledge receipt of notice, dispose affected units	Notified Regulatory Authorities
(Cepheid Xpert Xpress)	September 10, 2024	Cepheid	Xpert Xpress Co V-2/Flu/RSV plus and Xpert Xpress Cov-2 plus	Not specified	XP3ARS-COV2-10, XP3COV2/FLU/RSV-10	Increased frequency of E5007 Probe Check Too Low errors in certain lots	Delay in test results due to retest requirements, nondeterminate result	Repeat test with new cartridge, request replacement product if errors persist	Implement changes to prevent future occurrences	Complete Customer Response Form, dispose affected cartridges	Reported to applicable regulatory agencies
(Olympus PK Cutting Forceps)	January 2024	Olympus (Gyrus ACMI, Inc.)	PK-CF0533 PK Cutting Forceps, 5MM, 33CM	QIL-FY24-EME-34-FY24-OSTA-14	PK-CF0533	Increased jaw breakage incidents during inspection and use in surgical procedures	Risk of tissue injury, foreign body in patient, surgical delays, additional imaging or surgery	Quarantine affected lots, stop use, contact Olympus for return	Recall specific lot numbers of the product, investigate supply chain	Return Reply Form to Olympus, notify all affected departments	Informed National Competent Authority
(Agfa HealthCare XERO Viewer)	September 2024	Agfa HealthCare NV	Enterprise Imaging XERO Viewer	PRB0762354	All versions (8.x)	CT scanogram reference line may be off set on initial loading	Misplacement of reference line can lead to misdiagnosis or mistreatment	Use alternative viewers or tools (Xtend, Desktop Viewer) to verify positioning	Patch updates available for affected versions	Acknowledge FSN, complete Customer Reply Form	Informed regulatory authority
(Integra Codman Patties & Strips)	September 23, 2024	Integra LifeSciences Corporation	Codman Surgical Patties & Strips	FSN 2024-HHE-013	All lot numbers of listed patties and strips distributed between 01-Aug-2019 and 31-July-2024	Elevated endotoxin levels in raw material used for surgical patties and strips	Mild febrile response, hypotension, local inflammation, nausea	Quarantine affected units, notify Integra, return for credit	Recall all listed products in Table 1, implement corrective action in manufacturing	Complete and return Customer Reply Form, await Return Material Authorization (RMA) for affected products	Reported to National Competent Authorities