

Supplementary Table II. Categorised by user action and regulatory compliance

Field	User action	Regulatory notification
ICU ventilators	Confirm update installation	Reported to Health Authority
Surgical mesh	Remove defective mesh, follow up for implant users	Reported to FDA
Syringe pumps	Follow recalibration schedule, monitor dosage	Not specified
Blood glucose monitors	Use replacement sensor, follow guidelines	Reported to national health agency
Orthopaedic implants	Schedule regular implant check-ups	Notified to relevant medical device authority
Cardiac pacemakers	Monitor device battery life, replace as needed	Reported to federal regulatory agency
Catheter systems	Report any further catheter issues	Reported to relevant authorities
Insulin pumps	Monitor for dosing symptoms, update software	Reported to FDA
Cochlear implants	Protect from water, report failures	Reported to health authorities
Surgical staplers	Report any staple malfunctions	Reported to national health agency
Radiology equipment	Regularly recalibrate	Reported to regulatory authority
Haemodialysis machines	Regular filter replacements	Notified to relevant health department
Infusion systems	Check tubing for leaks regularly	Reported to medical device authority
Endoscopic equipment	Follow updated cleaning instructions	Reported to federal health body
Orthopaedic instruments	Report any performance issues	Reported to medical device authority
Medtronic LINQ II ICM	Monitor device performance, replace if needed	Reported to federal health agency
Network isolator Cat.A	Notify all users, arrange returns	Notified to regulatory body
IRI Spec CA/CB/CC urine chemistry controls	Review and implement QC updates	FDA recall notice classified as open
LINQ II insertable cardiac monitoring system	Regular data transmission and noise monitoring	FDA notified and recall monitored
Medtronic synchroMed II implantable drug infusion pump	Confirm receipt and share notice with users	FDA recall posted; pending updates
Mini Med G insulin pump system	Update software and monitor patient outcomes	FDA notified and corrective actions implemented
Alarisin fusion pump module	Notify staff and replace affected units	FDA notified; recall posted
Pipelle endometrial sampling device	Remove and destroy all affected lots	FDA recall notification issued
Spectra optia apheresis system	Perform software update immediately	Recall classified and FDA notified
Essure permanent birth control device	Complete return form and send for replacement	Recall report filed with FDA
HeartMate left ventricular assist system	Return affected units; arrange replacement	FDA notified, recall registered
MRI conditional pacemaker	Inform MRI techs and monitor device performance	Report submitted to FDA
Evo endotracheal tube	Return affected units and monitor inventory	FDA notice issued; recall status open
CADD-legacy plus pump	Verify calibration before each use	Open FDA recall status
Amplatzer septal occluder	Return affected lots and replace with newer models	Notification to FDA and distributors
Exactech hip implant	Monitor patients and adjust post-op protocols	Open recall notice filed with FDA
Trilogy evo ventilator	Conduct pre-use checks and notify support teams	FDA aware and recall status classified
Volara oscillatory therapy device	Monitor therapy delivery and contact support for updates	Reported to FDA, corrective notice sent to users

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Field	User action	Regulatory notification
Axonics sacral neuromodulation system	Verify electrode integrity before each implantation	Recall posted to FDA
Per fix plug for hernia repair	Replace with updated models where possible	FDA recall status listed as open
Neuragen nerve guide	Dispose of affected products and record incidents	Notice filed with FDA; corrective actions underway
Heart start MRx defibrillator	Conduct pre-use checks and update battery protocol	FDA notified and status updated
Abiomed	No removal: awareness, follow instructions in IFU	Informed relevant Health Authority
GE healthcare	Complete and return acknowledgment form, ensure awareness	Notified regulatory authorities
TSC International B.V.	Return acknowledgment form and affected units to TSC Life	No mention
Siemens Healthineers	Acknowledgment form, maintain awareness until corrective actions are completed	Not specified
iSTAR Medical	Complete reply form, return acknowledgment form, adhere to clinical study procedure	Informed National Competent Authority
Getinge	Acknowledge receipt of FSN, dispose affected units	Notified appropriate Regulatory Authorities
Medtronic Wireless Recharger	Return acknowledgment form, notify all users within the facility	Informed relevant Competent Authority
Elekta Disposable Biopsy Needle	Acknowledge receipt of notice, dispose affected units	Notified Regulatory Authorities
Cepheid Xpert Xpress	Complete Customer Response Form, dispose affected cartridges	Reported to applicable regulatory agencies
Olympus PK Cutting Forceps	Return Reply Form to Olympus, notify all affected departments	Informed National Competent Authority
Agfa HealthCare XERO Viewer	Acknowledge FSN, complete Customer Reply Form	Informed regulatory authority
Integra Codman Patties & Strips	Complete and return Customer Reply Form, await Return Material Authorisation (RMA) for affected products	Reported to National Competent Authorities

ICU, intensive care unit; FDA, Food and Drug Administration; QC, quality control; LINQ II ICM, insertable cardiac monitor (specific Medtronic device); MRI, magnetic resonance imaging; IFU, instructions for use; FSN, field safety notice; RMA, return material authorisation; CADD, continuous ambulatory drug delivery (pump); PK, possibly “percutaneous knife” (instruments context); XERO, brand name; not strictly an abbreviation; TSC, company abbreviation (TSC International B.V.); iSTAR, device brand (not expanded here); GE, general electric