How to Manage Medical Device Incidents

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Medical Device Incident

A patient care provider has a clinical objective that requires a medical device but is unable to achieve the objective and harm occurs.
1. Take care of the patient
CE FUSES AS MARKED
2. Report internally
Report an event  Click on the icon that describes the event. Don’t see what you need? Click on “Other”.

- Fall
- Medication
- Adverse Drug Reactions
- Medical Device
- Unsafe Behaviour
- Laboratory
- Blood
- Wound / Skin Injury
- Medical Imaging
- Perinatal
- Surgical Count
- Narcotic Count
- Safety Hazard
- Action ADE
- Visitor Safety
- Security / Property
- Reportable Death
- Other
3. Sequester the device

- Out of service and locked up
- Preserve disposables and packaging
- Preserve the settings
- Plug in the device
4. Preserve patient data

- Paper records: hand-written notes, printouts, etc.
- Electronic Medical Record (EMR) systems
- Medical device event and alarm logs
5. Investigate the incident
6. **Report externally**

U.S. Food and Drug Administration (FDA)
- Safe Medical Devices Act (SMDA)
- Medical Device Reporting (MDR) System
MAUDE - Manufacturer and User Facility Device Experience

The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters ¹ (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

Learn More

Search Database

Product Problem
Product Class
Event Type
Manufacturer
Model Number
Report Number
Brand Name
Product Code
Date Report Received by FDA (mm/dd/yyyy) 02/01/2019 to 02/28/2019

Go to Simple Search 10 Records per Report Page Clear Form Search
7. Avoid recurrences
Exemplar Tubing: wall thickness is uniform (Good)

Incident Tubing: wall thickness is non-uniform (Bad)
1. Take care of the patient
2. Report internally
3. Sequester the device
4. Preserve patient data
5. Investigate the incident
6. Report externally
7. Avoid recurrences
Thank you!