I. Title

*Reporting of Devices and Supplies Involved in Patient Injury, Illness, or Death*

II. Policy

In compliance with the [Safe Medical Device Act (SMDA) of 1990](https://www.fda.gov/medical-devices/safe-medical-device-act-smda-1990) and FDA regulations, all incidents involving medical devices, related equipment hazards and explanted devices suspected of a possible failure or malfunction that has or may have caused or contributed to a patient’s death, serious illness, or serious injury will be reported to Risk Management.

III. Procedures

All employees who are involved with patient care, review patient care, repair devices or provide device preventative maintenance have a duty under the Act to report device-related incidents (e.g., device failure, device malfunction, inadequate design or labeling and user error). This duty extends to physicians, nurses, health professionals, students, volunteers and all other persons affiliated with the facility. A medical device is very broadly defined under the SMDA. When a device-related incident occurs, employees should:

- Save the device, packaging and all related parts, and note the device’s clinical engineering number or serial number.
- Place a "Defective . . . Do Not Use" tag on the device and remove it from use.
- Notify the patient’s physician or refer the visitor to the Emergency Department or refer the employee to Employee Injury Management.
- Telephone Risk Management immediately and provide the following information:
  1) brief description of the incident
  2) time and date
  3) patient's name
  4) room and bed number
  5) name of attending physician notified
  6) product name
  7) location of the product
  8) serial number of the product
  9) model number
  10) name of the manufacturer, if known.
- Complete an on-line [Patient Safety Net report](#) within twenty-four hours following the occurrence.
The Risk Management office will file the report(s) with the manufacturer of the device and/or the FDA when it is a **FDA Reportable Event**. Since these reports must be filed within **ten working days** of the date of the incident, **prompt** reporting to Risk Management is essential.

Reporters do not need to assess the likelihood that a malfunction will recur. The regulation assumes that if a malfunction has occurred once, the malfunction will recur.

Malfunctions are **not** reportable if they are not likely to result in death, serious injury or other significant adverse event experience.

A malfunction which is or can be corrected during routine service or device maintenance **must be reported** if the recurrence of the malfunction is likely to cause or contribute to a death or serious injury if it were to recur.

### IV. Relevant Federal and State Statutes
- Safe Medical Device Act (SMDA) of 1990
- FDA Reportable Events

### V. Related UTMB Policies and Procedures
- IHOP - 09.13.13 - Unusual Event Reporting
- IHOP - 09.13.16 - Sentinel Events

### VI. Dates Approved or Amended

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### VII. Contact Information
- Risk Management
- (409) 772-8509