Institutional Handbook of Operating Procedures Policy 09.13.21	
Section: Clinical Policies	Responsible Vice President: Senior Vice President and General Counsel
Subject: General Procedures	Responsible Entity: Risk Management

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 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 the Department of 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 event report as soon as possible 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. Malfunctions are **not** reportable to the FDA if they are not likely to result in death, serious injury or other significant adverse event experience.

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

Originated: 04/01/1994	
Reviewed with Changes	*Reviewed without Changes*
01/07/2011	12/22/2016
	09/07/2018

VII. Contact Information

Risk Management
(409) 747-8728