FIU Herbert Wertheim College of Medicine
FLORIDA INTERNATIONAL UNIVERSITY

Administrative Policy
POLICY NO.: 200.03.101A

POLICY TITLE: Device Failure Causing Patient Harm

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Approved by: Quality Improvement Patient Safety Committee (QIPSC)

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SUMMARY & PURPOSE: The Office of Clinical Risk Management of Herbert Wertheim College of Medicine (HWCOM) investigates and tracks reported incidents regarding any reusable or disposable device that may have caused or contributed to a serious patient injury, permanent damage, impairment or unexpected death due to device failure or malfunction ("reportable event"). HWCOM will report any device it determines has caused a reportable event to the manufacturer. Although HWCOM is not governed by the *Safe Medical Device Act* (SMDA) of 1990, it is HWCOM's policy to identify events that may cause harm to patients and to improve patient safety. *1*

SCOPE/APPLICABILITY: This policy applies to the HWCOM Clinical Locations where faculty, students and /or staff provide care to patients and utilize any device that could co*ntribute* to a patient injury. The HWCOM Clinical Locations are: FIU Health Modesto Maidique, ("MMC"), FIU Health Broward, Green Family Foundation NeighborhoodHELP Mobile Health Centers and Household visits and the Linda Fenner 3D Mobile Mammography Center. For the faculty, students and staff that are providing patient care in the *affiliated* hospitals, outpatient and diagnostic centers the policies and procedures of those institutions will govern their reporting responsibilities.

1 HWCOM Clinical areas are not governed by SMDA. This law governs incidents for hospitals.

POLICY: The HWCOM Clinical Risk Manager will be contacted promptly regarding any device that may have failed, malfunctioned, and caused serious patient injury, permanent damage, impairment or unexpected death. An incident report will be completed, and the device will be investigated and tracked by the Clinical Risk Manager. Any device that has contributed to patient injury due to failure or malfunction will be reported to the manufacturer within 30 days of reporting. If an unexpected death occurs because of a device failure or malfunction, reporting to the manufacturer is within 5 days of notice of cause of death.

DEFINITIONS:

Safe Medical Device Act (SMDA) of 1990: The United States Congress enacted the Safe Medical Device Act (SMDA) to increase the reporting regarding serious problems with medical devices. Manufacturers must report to the Food Drug Administration (FDA) all device-related deaths, serious injuries, and malfunctions.

HWCOM Clinical Locations*:* For the purposes of this policy, HWCOM clinical locations refer to FIU Health Modesto Maidique ("MMC"), FIU Health Broward, Green Family Foundation NeighborhoodHELP Mobile Health Centers and Household visits and the Linda Fenner 3D Mobile Mammography Center.

Device: Is an instrument, apparatus, machine, implant, part or accessory. The device can be *reusable* or *disposable*. A device *is not* a drug or a pharmaceutical agent.

Device failure or Device Malfunction: The failure or malfunction of a device occurs when the device fails to meet its performance specifications or fails to perform as intended by the manufacturer instructions. The device can be either reusable or disposable.

Device injury: A device injury can be a life-threatening injury, causing damage, impairment, unexpected death or may require additional medical or surgical intervention to repair the injury.

Emergency Medical Systems :("EMS") (Ambulance or fire rescue). (911).The **Miami-Dade Fire Rescue Department** ("MDFRD") provides emergency medical services to Miami-Dade County, and **Broward Sheriff's office** ("BSO") provides emergency services to Broward County.

QIPSC- Quality Improvement Patient Safety Committee

PROCEDURE:

1. If a device failure or malfunction occurs and the patient has sustained an injury, stabilize and attend to the patient injury. Notify the patient's physician immediately. The patient may require transfer to a hospital as ordered by the physician. For FIU Health MMC hospital transfers contact 911 Emergency Medical response (EMS). For FIU Health Broward call Emergency Rapid Response Team at Broward Health Medical Center at 1-954-355-5085. The Green Family Foundation NeighborhoodHELP Mobile Health Centers and Household teams and the Linda Fenner 3D Mobile Mammography Center contact 911 EMS in a medical emergency. Please refer to policy *Response to Medical Emergencies***,** Policy No**.: 200.02.100A**
2. If an injury has occurred because of a failed or malfunctioned device, notify the Director of Operations, the Director of Quality, and the relevant departmental Medical Director for providers at the FIU Health MMC and FIU Health Broward location. For Green Family Foundation NeighborhoodHELP Mobile Health Centers and the Linda Fenner 3D Mobile Mammography Center contact the Humanities, Health, and Society Medical Director. For *all* locations, contact the Clinical Risk Manager immediately and directly by calling (305) 348-9174.
3. The failed or malfunctioned device *shall* ***not be discarded whether it is a disposable or reusable device.*** Place the device in a biohazardous bag and retain the packaging box and any accompanying literature for the Clinical Risk Manager. Label the bag with the patient's

name, date of birth, and patient ID number. *Note:* Save all packaging materials, instructional and operating manuals for the Clinical Risk Manager.

4. Do not clean the device when placed in the biohazardous bag. ***Do not release*** the device directly to the manufacturer unless instructed by the Clinical Risk Manager.
5. The Operations Manager will contact the manufacturer. The manufacturer should complete an investigation and complete a quality report. Please request that a copy of the final quality report be sent to the Operations Manager.
6. The Operations Manager will forward the manufacturer's quality report to the Clinical Risk Manager.
7. If the manufacturer requests the failed or malfunctioned device, please inform the Clinical Risk Manager and the Risk Department will follow up with the manufacturer regarding releasing the device. Please do not release the device to manufacturer without clearance from the Clinical Risk Manager.
8. The person with the most knowledge regarding the incident will complete an incident report. Please list all the witnesses that were present when the device failed or malfunctioned. Please provide complete first and last name of all witnesses. The device malfunction or failure will be reported through the HWCOM incident reporting system in accordance with Incident Reporting Administrative Policy No.: **200.03.100A**
9. The following information should be INCLUDED when completing an incident report:
    - Device name
    - Manufacturer
    - Model & Catalogue #
    - Lot & serial #
    - Device Expiration Date (if applicable)
    - Is Device reusable or Disposable?
    - Is it an implantable device?
10. All stock and supplies of the failed or malfunctioned device will be removed from all HWCOM Clinical locations until the Clinical Risk Manager clears the device for safe patient use.
11. The Clinical Risk Manager will complete an investigation of the device and based on the investigation will advise the site Operations Manager if the device is safe for patient care.

SUPPORTING/REFERENCE DOCUMENTATION:

- Safe Medical Device Act of 1990 user guide pages 1-26 last update April 1996

RELATED POLICIES, PROCEDURES, AND ASSOCIATED FORMS:

- HWCOM Administrative Policy: *Incident Reporting No.:* **200.03.100A**
  HWCOM Administrative Policy: *Responding to a Medical Emergency No.:* **200.02.100A**