GUAM MEMORIAL HOSPITAL AUTHORITY
ADMINISTRATIVE MANUAL

APPROVED BY:	RESPONSIBILITY:	EFFECTIVE DATE:	POLICY NO.:	PAGE:
PeterJohn D. Camacho, MPH Hospital Administrator/CEO	Risk Management	May 28, 2018	A-EC800	1 of 8
POLICY TITLE: MEDICAL DEVICES TRACKING REQUIREMENT				
LAST REVIEWED/REVISED: 10/2017				
ENDORSED: EMC 12/2017				

PURPOSE:

To establish a device tracking mechanism for certain medical devices as designated by the Food and Drug Administration (FDA) under the Safe Medical Device act of 1990 Tracking Requirement. With such a mechanism of tracking, information can be readily available to the manufacturers and/or FDA in the event FDA orders a recall or patient notification due to serious adverse health consequence or unreasonable risk of substantial harm with continued or prolonged use of medical devices designated for tracking by the FDA.

Medical Devices that need to be tracked are certain permanently implantable devices and life-sustaining or life-supporting devices used outside the user facility.

This policy must be complied with in conjunction with the **SAFE MEDICAL DEVICES ACT OF 1990: REPORTING AND TRACKING REQUIREMENTS.**

DEFINITIONS:

Device Failure: failure of a device to perform or function as intended, including any deviations from the device's performance specifications or intended use.

Serious adverse health consequences: any significant adverse experience related to a device, including device-related events which are life-threatening or which involve permanent or long-term injuries or illnesses.

Permanently implantable device: a device that is intended to be placed into a surgically or naturally formed cavity of the human body to continuously assist, restore, or replace the function of an organ system or structure of the human body throughout the useful life of the device. The term does not include any device which is intended and used for temporary purposes or which is intended for explanation.

Life-supporting or life-sustaining device used outside a device user Facility (GMHA): means a device which is essential, or yields information that is essential, to the restoration or continuation of a bodily function important to the continuation of human life that is intended for use outside a hospital, nursing home, ambulatory surgical facility, or diagnostic or outpatient treatment facility. Physician's offices are not device user facilities and, therefore, devices used therein are subject if they otherwise satisfy the statutory and regulatory criteria.

Serious Injury or Illness: 1) is life threatening; 2) results in permanent impairment of a body function or permanent damage to the body structure; or 3) necessitates medical or surgical

intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

SCOPE:

This policy applies to all personnel but is not limited to physicians, nurses, technicians and other medical and support personnel who use or operate medical devices subject to tracking.

CATEGORIES OF DEVICES TO BE TRACKED:

- Life-supporting or life-sustaining device that are used outside a device user facility (GMHA), if the failure of these devices would be likely to have serious adverse health consequences;
- permanently implantable devices, if failure of these devices would be reasonably likely to have a serious adverse health consequences; and
- any other devices designated by FDA as those which must be tracked

LIST OF DEVICES SUBJECT TO TRACKING:

I. Permanently Implantable Devices

- Vascular graft prosthesis of less than 6mm in diameter
- Vascular graft prosthesis of 6 mm and greater in diameter
- Ventricular bypass (assist device)
- Implantable pacemaker pulse generator
- Cardiovascular permanent pacemaker electrode
- Annuloplasty ring
- Replacement Heart valve
- Automatic implantable cardioverter/defibrillator
- Tracheal prosthesis
- Implanted cerebellar stimulator
- Implanted diaphragmatic/phrenic nerve stimulator
- Implantable infusion pumps
- Temporomandibular joint (TMJ) implant

II. Life-sustaining or Life Supporting Devices used Outside Device User Facilities (GMHA)

- Breathing frequency monitors (apnea monitor including ventilator efforts monitor)
- Continuous ventilator
- DC defibrillator and paddles

III. FDA Designated Devices

- Silicone inflatable breast prosthesis
- Silicone gel-filled breast prosthesis
- Silicone gel-filled testicular prosthesis

- Silicone gel-filled chin prosthesis
- Silicone gel-filled Angelchik reflux valve
- Infusion pumps (electromechanical only)
- Silicone gel- filled penile prosthesis
- Inflatable penile implant

SPECIFIC RESONSIBILITIES AND TRACKING PROCEDURE:

I. Hospital Risk Management Program Officer

A. The Hospital Risk Management Program Officer shall have overall oversight responsibility for implementing and managing the hospital's medical device tracking program.

B. The Hospital Risk Management Program Officer will be responsible for reviewing and analyzing all reportable incidents, and completing and submitting reports to outside agencies.

C. The Hospital Risk Management Program Officer must make certain that all necessary information is documented.

D. The Hospital Risk Management Program Officer shall inform the Associate Administrator of Medical Services of any incidents regarding tracked medical devices so that he/she can make necessary recommendations as related to the follow-up of the patient.

E. The Hospital Risk Management Program Officer shall prepare a monthly summary report of any tracked medical device-related patient incidents and submit to the Hospital Administrator and Patient Safety Committee.

II. Materials Management Department

A. Upon purchasing or otherwise acquiring an interest in a **tracked device**, Materials Management Department **must** provide the device manufacturer with a copy of the **SMDA TRACK FORM 101 or complete provided registration tracking form.**

1. Name and address of the hospital.

2. Lot number, batch number, model number, or serial number (or other identifier used for tracking) of the device

3. Date the device was received

4. The person from whom the device was received

5. If applicable, the date the device was explanted, the date of the patient's death, or the date the device was returned to the distributor, or permanently retired from use, or otherwise permanently disposed of.

B. Upon receipt of the tracked device, Materials Management Department shall tag and label the device with **SMDA-Tracked Requirement.**

C. Upon receipt of **SMDA TRACK Form 102 or Manufacturer Registration Form,** from the end-user (Operating Room Nursing Personnel or Respiratory Care Department Personnel), this information will be provided to the manufacturer of the tracked device by the Materials Management Department.

A. In the event of Product Recall or Alert of tracked device, Materials Management Department shall communicate with the appropriate end-user or department and inform of such notification. **Policy No. A-EC1000, Product Recalls and Alerts, of the Administrative Manual** shall be followed**.**

D. The Materials Management Department shall maintain written records of each time a tracked device is used by a patient **(SMDA TRACK Forms 101 and 102)** and other information as may be required by FDA. Patient information will be provided by Operating Room Nursing Personnel.

III. Nursing Services and Operating Room

B. When a tracked device is used in or by a patient in Operating Room, Nursing Personnel must provide the Materials Management Department with the following information **(SMDA TRACK FORM 102)**.

1. Name and address of the hospital

2. Lot number, batch number, model number, or serial number (or other identifier used for tracking) of the device

3. Date the device was provided to the patient

4. Name, address, telephone and social security number (if available) of the patient receiving the device

5. Name, mailing address and telephone number of the prescribing physician

6. Name, mailing address and telephone number of the physician regularly following the patient, if different than the prescribing physician.

C. In the event of Product Recall and Alert notification, Nursing Services shall follow **Policy No. A-EC1000, Product Recalls and Alerts, of the Administrative Manual**.

D. In the event of medical device incident resulting in death, serious injury or serious illness, reporting shall be in accordance with **Policy No. A-EC700, Reporting Adverse Medical Device Incident, of the Administrative Manual**.

IV. Respiratory Care Department

A. When a tracked device (life-sustaining or life-supporting device) is used in or by a patient outside the hospital, Respiratory Care Department shall provide information contained in **SMDA TRACK FORM 102** to Material Department who in turn will provide the device manufacturer with needed information.

B. In the event of Product Recall and Alert notification, Respiratory Care Department shall follow **Policy No. A-EC1000, Product Recalls and Alerts, of the Administrative Manual**.

C. In the event of medical device incident resulting in death, serious injury or serious illness, reporting shall be in accordance with **Policy No. A-EC700, Reporting Adverse Medical Device Incident, of the Administrative Manual**.

V. Bio-medical Shop

A. The supervisor of the Bio-Medical Shop shall play a key role in maintaining the medical device tracking program, investigating incidents, and evaluating the safety tracked devices.

B. The Bio-Medical Shop shall obtain relevant information regarding previous hazards, product recall and alerts related to tracked devices through contact with the FDA and/or manufacturers. All such information shall be shared with the Hospital Risk Management Program Officer.

C. The Bio-Medical Shop shall assist the Hospital Risk Management Program Officer in collecting the tracked medical device operating information, service and maintenance history information as needed.

D. The Bio-Medical Shop shall assist in conducting an investigating of the tracked device-related incident, evaluate the safety of the device, and will determine whether the tracked device along with relevant supplies, accessories, and packaging should be impounded, repaired, returned to service or taken out of service.

REFERENCES:

- ECRI Advisory
- Federal Register
- Hospital Risk Management Vol. 15/Number 6

RELATED POLICIES:

- A-EC700, Reporting Adverse Medical Device Incident, of the Administrative Manual.
- A-EC1000, Product Recalls and Alerts, of the Administrative Manual.

RESCISSION:

6180-1A, Medical Devices Tracking Requirements, of the Administrative Manual made effective June 3, 1992.

ATTACHMENTS:

I. SMDA Track Form 101
II. SMDA Track Form 102

ATTACHMENT I

SAFE MEDICAL DEVICE ACT OF 1990
TRACKING REQUIREMENT
SMDA TRACK FORM 101

Instructions: To be completed by Materials Management upon purchasing or otherwise acquiring a tracked device (including receipt from Operating Room or Respiratory Care after explanted/removed from patient).
Send to appropriate department with device.
Send copy to manufacturer and a copy to Risk Management indicating date sent to manufacturer.

Manufacturer:_____

Lot Number_____

Batch Number_____

Model Number_____

Serial Number_____

Size_____

Other identifier used for tracking the device_____

Date the device was received____/____/____

If applicable:

Date the device was explanted____/____/____
Date of the patient's death____/____/____
Date the device was returned to the distributor____/____/____
Date permanently retired from use____/____/____
Date permanently disposed of____/____/____

Completed by:

Print
Name:_____Signature:_____Date:_____

GUAM MEMORIAL HOSPITAL AUTHORITY
850 Governor Carlos Camacho Road
Tamuning, Guam 96913

ATTACHMENT II

SAFE MEDICAL DEVICE ACT OF 1990
TRACKING REQUIREMENT
SMDA TRACK FORM 102

Instructions: To be completed by Operating Room or Respiratory Care reporting person upon receipt of a tracked device for use in or by a patient.
Forward to Materials Management Department
Materials Management: Send copy to manufacturer and a copy to Risk Management indicating date sent to manufacturer.

Manufacturer & Device Name: _____

Lot Number_____

Batch Number_____

Serial Number_____

Size_____

Warranty Expiration Date_____/_____/_____

Other identifier used for tracking the device_____

Date the device was provided to the patient_____/____/____

If pacemaker, was/were implant/lead left in patient? Yes____ No____

If pacemaker, was a disposable lead introducer set used? Yes____ No____ Size____

Name of prescribing Physician_____

Name of Surgeon_____

Submitted by:

Print Name_____ Signature_____Date_____

Cc: Risk Management PATIENT ADDRESSOGRAPH

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