Institutional Handbook of Operating Procedures Policy 09.13.27	
Section: Clinical Policies	Responsible Vice President: EVP and CEO Health System
Subject: General Clinical Procedures and Care	Responsible Entity: Health System

I. Title

UTMB Surgical Devices and Implants Utilization

II. Policy

This policy establishes consistent requirements for the quality control of all acquired surgical implants and medical devices. All UTMB personnel that receive, dispense, utilize or remove implants or other surgical devices in patients are required to follow these procedures.

These procedures will ensure:

1. proper verification, sterility checks and acquisition processes;
2. tracking and accurate patient charging; and
3. reporting and record keeping responsibilities for reporting back to the manufacturer for tracked devices that are subject to a tracking order;

Only items that have been approved through the value analysis team may be utilized for patient care. These items will both be purchased and dispersed by UTMB (final distributor) and delivered by an approved vendor/distributor (as scheduled via the senior supply and/or surgical service coordinator).

All surgical devices or implants will be tracked according to FDA regulations and charged to the appropriate patient by UTMB surgical services. Surgical Services will maintain a record of all implants and explants according to FDA Medical Device Tracking Guidelines.

III. Procedures

If applicable, this section provides the UTMB community with a sequential, step-by-step guide of all actions required to comply with the policy. The procedures should be clear and concise.
Before dispensing any medical device or implant to the sterile field, a verification process should include a review of the product label for the name/size, package integrity, and expiration date.

1. This review process should be accomplished with the surgical nurse in conjunction with the verbal surgical order and confirmed by the doctor to verify that the correct medical device or implant is to be opened onto the surgical field.
2. A visual inspection should be made for any indication that the device or implant was compromised during the storage process. If compromised, or the item was not acquired and/or approved by UTMB purchasing/Value Analysis, the item shall not be used.
3. Documentation of all medical devices and/or implants/explants should be entered into the medical record for appropriate tracking, and for the UTMB billing department to accurately charge.

IV. Relevant Federal and State Statutes

Code of Federal Regulations Title 21—Food and Drugs, Chapter 1, Food and Drug Administration, Department of Health and Human Services, Sub Chapter H – Medical Devices

U.S. Food and Drug Administration (FDA), (2010). *Medical Device Tracking; Guidance for Industry and FDA Staff.* May 27, 2014

V. Related UTMB Policies and Procedures

IHOP - 09.13.11 - Medical Device Recall, Alert, Safety Hazard Notification and Response

VI. Dates Approved or Amended

Originated: 05/28/2014	
Reviewed with Changes	*Reviewed without Changes*
	05/11/2017

VII. Contact Information

Perioperative Nursing
(409)266-7878