Section: UTMB On-line Documentation 01.07 - Policy Subject: Infection Control & Healthcare Epidemiology Policies and Procedures 08.29.18 - Revised Topic: 01.07 - Disposable Patient Care Items 1981 - Author

01.07 - Disposable Patient Care Items

Purpose To prevent exposure of patients and staff to unsafe patient care items

and to comply with applicable regulations.

Audience All employees of UTMB hospitals, clinics, outpatient surgical center,

contract workers, volunteers, and students.

Policy All medical devices labeled "single-use" or "disposable" that have

exceeded their expiration date, been opened but not used, or have been used or contaminated must be discarded unless reprocessed by an insured, FDA-registered third party reprocessor approved by the

Infection Control and Healthcare Epidemiology Department.

Standards for Third Party Reprocessors UTMB shall conduct an extensive on site evaluation of reprocessing procedures by third party reprocessors.

- Single use or disposable medical devices may be reprocessed only by manufactures that are under contract with UTMB to provide reprocessing services. The legal department must review all contracts between UTMB and device reprocessors.
- The Director must evaluate prospective reprocessing companies to determine whether procedures used for reprocessing are scientifically valid and will provide products that are safe for reuse.

Monitoring

 Any infections, or adverse events possibly related to the use of a reprocessed device will be documented and reported to the Department of Infection Control and Healthcare Epidemiology.

References:

CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.

Guidance for industry and for the FDA staff: Enforcement priorities for single-use devices reprocessed by third parties and hospitals, Aug 14, 2000, US Food and Drug Administration, http://www.fda.gov/cdrh/reuse/1168.html