Name of Policy: Reprocessing Single Use Medical Devices – Third Party Provider **Policy Number**: 3364-100-53-04 **Department:** Hospital Administration Medical Staff **Approving Officer**: Chief Executive Officer-UTMC **Responsible Agent**: Sr. Director, Supply Chain Management **Scope**:	THE UNIVERSITY OF TOLEDO MEDICAL CENTER **Effective date**: 4/1/2020 Initial Effective Date: 11/13/02
☐ New policy proposal ☒ Minor/technical revision of existing policy ☐ Major revision of existing policy ☐ Reaffirmation of existing policy	

(A) **Policy statement**

The utilization of reprocessed medical devices designated by the manufacturer as 'single use' is permitted at the University of Toledo Medical Center (UTMC) only when the single use devices identified for reprocessing have been approved by the Food and Drug Administration (FDA).

(B) **Purpose of policy**

To ensure appropriate guidelines are followed for the selection of qualified third party reprocessing suppliers of single use medical devices and UTMC's utilization of reprocessed devices.

(C) **Definitions**

- Original Device: A new, unused single-use device.
- Single-Use Device: A device that is intended for one use or on a single patient during a single procedure.
- Reprocessed Single-Use Device: An original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of creating an additional single use on a patient.

(D) **Procedure**

Selection and Requirements of UTMC and Third-Party Processor

(1) The supply chain department is responsible for qualifying all vendors providing reprocessing services. All items recommended for reprocessing will have documentation on file as being FDA approved.

(2) UTMC departments utilizing reprocessed medical devices are responsible for overseeing the quality of devices and services.
(3) Reprocessing vendor must ensure:
   a. Devices are not reprocessed more than the established or designated number of times
   b. Devices will be removed from service in the event of a recall
   c. Devices will not be used and will be removed from service any time the integrity of the product is compromised
(4) Any unapproved device sent to or picked up by the reprocessing company will not be reprocessed and will be discarded.

Device Selection and Approval

(1) A multi-disciplinary team of physicians, operating room clinicians, infection control, nursing, value analysis and supply chain will review and approve all single use medical devices identified as a reprocessing candidate.
(2) Evidence must be provided by the reprocessing vendor regarding the fact that the physical and performance characteristics of the device is not adversely affected by cleaning, sterilization, and subsequent use.
(3) Annual meetings will be held with reprocessing vendors to review the program and service performance.

Approved by:	Review/Revision Date: 9/10/03 5/9/07 2/3/2011 2/1/2014 4/1/2017 4/1/2020
/s/_____ _____ Monecca Smith, MSN, RN Date AVP Patient Care Services and Chief Nursing Officer /s/_____ _____ Samer Khouri, MD Date Chief of Staff *Review/Revision Completed by:* *Supply Chain Management* *Infection Control* *Medical Staff*	Next review date: 4/1/2023