Name of Policy:	**Sterility Assurance of Patient Care Items**
Policy Number:	3364-109-EQP-301
Department:	Infection Control Hospital Administration Medical Staff
Approving Officer:	Chair, Infection Control Committee Chief Medical Officer Chief of Staff
Responsible Agent:	Infection Preventionist
Scope:	The University of Toledo Medical Center and its Medical Staff

THE UNIVERSITY OF TOLEDO MEDICAL CENTER

Effective Date: 12/01/2021

Initial Effective Date: 8/28/2001

_____ New policy proposal
_____ Major revision of existing policy
__X__ Minor/technical revision of existing policy
_____ Reaffirmation of existing policy

(A) Policy Statement

All hospital processed sterile items will be considered sterile by event related package integrity. This means that these items may be used as long as the integrity of the package has not been compromised by becoming torn, wet, damaged, or otherwise suspected of being contaminated (e.g., humidity, microbial contamination of the environment).

(B) Purpose of Policy

The purpose of the policy is to outline the procedure required to maintain the integrity of stored sterile packaging and to maintain a supply of necessary patient care items or instruments that are ready and safe for use.

(C) Procedure

(1) Items that are designated as reusable and require sterilization will be properly wrapped and processed according to Association for the Advancement of Medical Instrumentation (AAMI) ST-79 standards to ensure an effective barrier to microorganisms is provided.

(2) Sterilized packaging used will be compatible with the sterilization device that ensures the contents and package integrity is maintained as sterile until opened.

(3) A sterilization load sticker or lot control number and a control date for stock rotation will be placed on each packaged item for load identification and recall purposes.

(4) Sterilized items will be stored in a manner that reduces the potential for contamination in a cabinet or shelf in a clean storage area. Handle sterilized item as little as possible. Sterilized items must be rotated on their respective shelving to ensure previously processed items are used before potential expiration.

(5) Sterilized items that remain on storage shelves for extended lengths of time will be stored in a closed or covered cabinet. Open shelving may be used but must be in an area where traffic and ventilation is controlled. When a protective dust cover is present on an item, the cover should be wiped off or carefully removed before the item is used.

(6) Sterilized items designated for the outlying areas will be transported in such a way that the item sterility or cleanliness will not be compromised.

(7) Each unit is responsible for the inspection of sterilized items maintained in that area. Package integrity should be checked while auditing supply outdates for stored sterilized items.

(8) The user must inspect all packages before the package is opened. Sterilized items whose package integrity has been compromised must be returned to Sterile Processing. Inspect packaging for:

(a) Torn, wet, broken seal or otherwise damaged package.

(b) Must verify that the external chemical indicator has been exposed to sterilization.

NOTE: The loss of sterility is event related, not time related. Therefore, it is important to ensure proper storage of items in a manner that does not compromise the packaging of the product.

References:

Association for the Advancement of Medical Instrumentation. (2017). ANSI/AMMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

Sterile Processing In: Association for Professionals in Infection Control and Epidemiology. *APIC Text of Infection Control and Epidemiology.* 4th Ed. (pp. 105.1-105.7).

Sterilization and Disinfection. In: Association of periOperative Registered Nurses*, Guidelines for Perioperative Practice*. 2021 Ed. (pp. 815-889).

Approved by:		**Review/Revision Date:**
/s/ Michael Ellis, MD Chair, Infection Control Committee	Date	05/16/2005 07/28/2008 04/25/2011 07/01/2014 06/30/2017 11/15/2018 11/16/2021
/s/ Andrew Casabianca, MD Chief of Staff	Date	
/s/ Michael Ellis, MD Chief Medical Officer	Date	
Review/Revision Completed By: *Infection Control Committee*		**Next Review Date**: 11/2024
Policies Superseded by This Policy: 31:EQP-301		