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Origination	04/2004	Owner	Sherie Goldbach
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Reuse of Single Use Devices (SUDs)

I. Description

Describes the infection prevention policy for re-use of single-use medical devices (SUD)

II. Rationale

Reprocessing of single-use medical devices is regulated by the FDA to ensure that the product poses no infection risk and that it meets all other safety and performance standards as required of the original manufacturer.

III. Policy

A. Policies from FDA

Increasing public concern regarding the risk of infection and injury caused by reuse of devices labeled for single use prompted the FDA to issue enforcement guidelines for SUDs in August 2000. This document provides guidance to third party and hospital reprocessors about their responsibility as manufacturers engaged in reprocessing devices labeled for single use. Hospitals and third party reprocessors are subject to all the regulatory requirements currently applicable to the original equipment manufacturers, including premarket submission requirements.

B. Scope of Enforcement by FDA

All devices marketed by the manufacturer as single-use disposable devices are covered by this regulation. The only exclusions to this regulation are permanently implantable pacemakers, "opened but unused" SUDs, and hemodialyzers.

C. Policy within UNC Medical Center

Departments and practitioners within UNC Medical Center (UNCMC) will not reuse single-use items. The only exception to this policy is the following: a third party reprocessor may be considered and will be used in cases where the device can be reprocessed safely. Infection Prevention must be notified when a third party reprocessor is considered and implemented.

Opened-but-unused items may be resterilized if the manufacturer provides a written statement on how to resterilize the item in a manner that will not alter the physical characteristics or quality of the device.

D. Definition of Terms

Term	Definition
Single-Use Device (SUD)	A single-use device, also referred to as a disposable device, is intended to be used on one patient during a single procedure. It is not intended to be reprocessed (cleaned, disinfected, sterilized) and used on another patient. The labeling may or may not identify th device as single use or disposable and does not include instructions for reprocessing.
Opened-but-Unused	Opened-but-unused devices are single-use, disposable devices whose sterility has been breached or compromised, or whose sterile package was opened but not used on a patient, that is, they have not been in contact with blood body fluids, or contaminated.
Reuse	The repeated use or multiple use of any medical device including devices intended for reuse or single use, with reprocessing (cleaning, disinfection, sterilization) between uses.
Reprocessing	Reprocessing includes all the steps performed to make a contaminated reusable or single-use device patient ready. The steps may include cleaning, functional testing, repackaging, relabeling, disinfection, or sterilization.
Resterilization	Resterilization is the application of a terminal process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to an acceptable sterility assurance level, to a device that has previously undergone a sterilization process.
"Single Use Only" Symbol	There are multiple symbols, icons, and pictures used by industry to indicate an item is single use only. A frequently used symbol shows a circle with the numeral 2 inside covered by a diagonal line - ⊘.

Approval Signatures

Step Description	Approver	Date

Policy Stat Administrator	Kimberly Novak-Jones: Nurse Educator	12/2020
	Thomas Ivester: CMO/VP Medical Affairs	12/2020
	Emily Vavalle: Dir Epidemiology	12/2020
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