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

II. Policy

A. Policies from FDA
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.

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 Hospitals

Departments and practitioners within UNC Hospitals 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 can be consulted for advice when a third party reprocessor is considered and implemented.

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

**D. Definition of Terms**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Single-Use Device (SUD)</td>
<td>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 the device as single use or disposable and does not include instructions for reprocessing.</td>
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<tr>
<td>Opened-but-Unused</td>
<td>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.</td>
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<tr>
<td>Reuse</td>
<td>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.</td>
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<tr>
<td>Reprocessing</td>
<td>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.</td>
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<tr>
<td>Re-sterilization</td>
<td>Re-sterilization 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.</td>
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<tr>
<td>&quot;Single Use Only&quot; Symbol</td>
<td>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 - ②.</td>
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**Approval Signatures**

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<tr>
<th>Step Description</th>
<th>Approver</th>
<th>Date</th>
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<tbody>
<tr>
<td></td>
<td>Thomas Ivester: CMO/VP Medical Affairs</td>
<td>11/2023</td>
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Applicability

UNC Medical Center