**PURPOSE:**

To state the position of Children’s Hospital Los Angeles on the practice of reprocessing and reusing medical devices that are intended to be used only once. To ensure patient safety and to meet FDA regulations

**DEFINITION:**

1. **Single-Use Device (SUD)**: A **SUD** is a device that is intended for one use or on a single patient during a single procedure.
2. **Reprocessed Single-Use Device (SUD):** A **reprocessed SUD** is an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient.
3. **Supplemental Validation Submission (SVS): Medical Device User Free & Modernization Act (**MDUFMA) required that certain devices that had already been cleared through the 510(k) process are required to submit validation data regarding cleaning, sterilization, and functional performance in order to remain on the market. This additional data is referred to as a **supplemental validation submission (SVS).**
4. **Validation: Validation** means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.
   1. **Process Validation** means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.
   2. **Design Validation** means establishing by objective evidence that device specifications conform with user needs and intended use(s).
5. **Validation Data: Validation data** includes cleaning and sterilization data, and functional performance data demonstrating that an single-use device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification (510(k)).

**Reprocessed SUD Requirements:**

1. Disposable products or products intended for single use **shall not** be reused, re-sterilized, or reprocessed at CHLA.
2. Items which may be returned to stock are items with their original manufacturer applied wrappers intact. The wrappers must be unsoiled with secretions, food, liquids, and solutions and must not have been stored in a room with a patient on isolation precautions.
   1. Emergency set up supplies if stored at the bedside in a sealed plastic bag that is bagged in a second plastic bag may be reused as long as the outer bag is changed when the patient room is cleaned.
   2. Open unused and expired items may be donated or recycled.
3. Any item which has been wet or soiled must be discarded. These items must not be stored in the patient's bedside unit.
4. Items may be stored in a separate area or closed cart away from the patient's bedside. It is recommended that only the number of items required be taken into the patient room at the time of use and not stock piled for future use.
5. One time use, disposable medical products shall not be reprocessed at the hospital, but may be reprocessed for reuse by an FDA approved third party device reprocessing company.
6. The decision to contract with a reprocessing company will be based on a thorough review of the third party reprocessing company.
   1. This review will be done by a multidisciplinary team including representatives from Distribution Services, Peri-operative Services, and Infection Prevention.
   2. The review will include an onsite inspection of the reprocessing facility.
7. The third party reprocessor must show evidence of the following in the review:
   1. Registration and Listing with the FDA including their most recent FDA inspection report.
   2. A system or process in place for reporting adverse events
   3. A system or process in place for tracking Medical Devices
   4. A system or process in place for Medical Device Corrections and Removals
   5. Quality Systems Regulation including process validation requirements and validation data. Product labeling that includes name of manufacturer and adequate directions for use
   6. 510K clearances and Supplemental Validation Submission (SVS) if required
   7. Premarket Notification and Approval Requirements based on the FDA classification of the device.
   8. Insurance/warranty policy in good standing with coverage of no less than (insert coverage requirement)
   9. Process for handling and notification of device recall and product complaints

**PROCEDURE:**

CHLA will work with the third party reprocessor to determine which SUD’s will be reprocessed.

1. SUD’s that may be reprocessed must fit the following criteria:
   1. Third party reprocessor must have 510K clearance for the SUD
   2. SUD is on the Reprocessing Service list provided by the third party reprocessor
   3. SUD is either open and unused or used.
2. SUD’s for reprocessing will be collected in special containers or bins provided by the third party reprocessing company
   1. Standard precautions must be followed when handling all SUD’s collected for shipment to the third party reprocessor.
   2. No decontamination or cleaning is required prior to collection.
   3. Collection bins are collected and shipped by the staff of the third party device reprocessing company at CHLA.
3. The remanufacture or reprocess of the SUD done by the third party reprocessing company will incorporate all of the following elements:
   1. Decontaminate and cleaning
   2. Inspection and functional testing
   3. Repair or resharpening if needed
   4. Packaging
   5. Sterilization
4. Infection Prevention and Control and Distribution Services must be notified immediately of any product complaints or device recalls.

**REFERENCES:**

1. APIC text of Infection Control and Epidemiology, 2014. Chapter 32, Reprocessing Single-use Devices.
2. FDA: Guidance for Industry and FDA Staff Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices, 2006
3. CDC HICPAC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2017

**POLICY OWNER:**

Director, Infection Prevention and Control