REPROCESSING OF REUSABLE MEDICAL EQUIPMENTS POLICY

INTRODUCTION

Reusable medical devices are devices that health care providers can reuse to diagnose and treat multiple patients. Examples of reusable medical devices include surgical forceps, tweezers and stethoscopes.

When used on patients, reusable devices become soiled and contaminated with microorganisms. To avoid any risk of infection by a contaminated device, reusable devices undergo "reprocessing," a detailed, multistep process to clean and then disinfect or sterilize them. When the labelling instructions for reprocessing are completely and correctly followed after each use of the device, reprocessing results in a medical device that can be safely used more than once in the same patient, or in more than one patient. Adequate reprocessing of reusable medical devices is vital to protecting patient safety.

GUIDELINES FOR MEDICAL DEVICE REPROCESSING

Guidelines around medical device reprocessing come from industry governing bodies as well as the device manufacturers' Instructions for Use and the healthcare facility's policies and procedures. The Spaulding classification is a representative system used for sorting medical devices into a reprocessing criticality category based on use risk. It can be used to help determine the level of processing necessary for an instrument.

Device Type	Description
Non-Critical Devices	Devices that contact intact skin but not mucous membranes
Semi-Critical Devices	Devices that encounter mucous membranes or non-intact skin
Critical Devices	Devices that enter sterile tissue or the vascular system

Non-Critical Medical Device Reprocessing

Non-critical devices include those that contact intact skin but not mucous membranes. Examples of non-critical medical devices include

- Stethoscopes
- blood pressure cuffs
- stretchers
- tweezers

Devices in this category must be cleaned, and if shared between patients, low- or intermediate-level disinfected.

Semi-Critical Medical Device Reprocessing (Not used in school setting)

Semi-critical devices may encounter mucous membranes or non-intact skin during a procedure. Examples of semi-critical medical devices include

- cystoscopes
- anesthesia equipment
- laryngoscopes
- endoscopes. Semi-critical devices should be free from microorganisms, but small numbers of bacterial spores may remain.3 Semi-critical devices must be cleaned, and sterilization is recommended. High-level disinfection is acceptable for devices unable to be sterilized.

Critical Medical Device Reprocessing (Not used in school setting)

Critical devices enter sterile areas of the body, including contact with the vascular system. Examples of critical medical devices include

- surgical forceps
- scalpels, implants
- biopsy instruments
- urinary catheters

Critical devices require cleaning followed by sterilization. Common methods of sterilization include steam sterilization, vaporized hydrogen peroxide sterilization, and liquid chemical sterilization.

HOW ARE CRITICAL MEDICAL DEVICES REPROCESSED?

At the point of use, reusable, single-use disposable, and waste items should be separated:

1. Separation of sharps placed in a puncture-resistant container.
2. Soils should be prevented from drying on instruments before transport is completed.
3. Instrument transport spray gel or foam may keep instruments moist for up to 72 hours without causing damage to instruments.

Cleaning

Cleaning is the next step in surgical instrument reprocessing. Cleaning is the removal of visible and non-visible soil and other foreign materials from medical devices being reprocessed. Disinfection and sterilization cannot be achieved until the instrument is thoroughly cleaned.

Inspection

After an instrument is cleaned and prior to packaging, it generally goes through an inspection process, both to verify cleanliness and to detect any defects or necessary repairs or replacements. surgical instrument tray.

Packaging

Once an instrument has been cleaned, it is prepared and packaged for sterilization. Instrument wraps, trays and pouches may be used for packaging.

Sterilization

Instruments can be sterilized once they are clean. The most commonly used methods of sterilization include steam sterilization and low temperature sterilization such as vaporized hydrogen peroxide sterilization & biological indicators autoclave

Sterility Assurance Monitoring – Sterility assurance monitoring provides assurance that an instrument was subjected to a cycle that met the cycle parameters validated for the sterility assurance product. Sterility assurance monitoring verifies that the sterilization cycle performed met the intended sterilization parameters. Some sterility assurance products include biological indicators, chemical indicators, Bowie-Dick tests and reusable test packs.

BENEFITS OF REPROCESSING MEDICAL EQUIPMENT

To ensure patient and staff safety as well as stay compliant, reprocessing medical devices is a necessary practice when the device or instrument is reusable. Reprocessing a device offer economic benefits for the healthcare facility, as the alternative is purchasing disposable instruments or devices for use during only a single patient procedure. While other costs are associated with medical device reprocessing (device repair and replacement, cleaning chemistries, capital purchases like sinks, washer/disinfectors, sterilizers, etc.), reprocessing through a third party or within the hospital has economic benefits for the facility.

CHALLENGES OF REPROCESSING MEDICAL EQUIPMENT

Challenges may arise when enforcing a reprocessing procedure within a healthcare facility. Ensuring the facility is following regulations and guidelines from DHA is vital to promoting patient and staff safety and remaining complaint. More importantly, each step of the reprocessing cycle must be done carefully and thoroughly to reduce the risk of patient infection (Healthcare-Associated Infection) or injury. Following hospital procedures, industry standards and best practices, and the original equipment manufacturers' (OEM) Instructions for Use (IFU) all play an important role in a healthcare facility's reprocessing program.

HOW TO REPROCESSED REUSABLE MEDICAL DEVICES

This system is widely known as the Spaulding Classification, from the name of the person that popularized it in the 1950-1960s. A summary of the classification is below.

Patient Contact Device	**Classification**	**Minimum Inactivation Level**
Intact skin	**Non-Critical**	Physical Removal (e.g., by cleaning) Low Level Disinfection (effective against certain bacteria, viruses and fungi) Intermediate Level Disinfection (effective against bacteria, mycobacteria, most viruses and fungi, but not spores)
Mucous membranes or non-intact skin	**Semi-Critical**	High Level Disinfection (effective against all microbial pathogens, with the exception of large numbers of bacterial spores)
Sterile areas of the body, including blood contact	**Critical**	Sterilization (free from all viable microorganisms)

Critical devices with the highest risk, including many types of surgical devices, contact sterile areas of the body. Such devices should be sterile (free from microbial contamination).

Semi-critical devices often are considered a lower risk as they contact mucous membranes or nonintact skin (e.g., certain types of gastrointestinal endoscopes and other diagnostic devices). It is preferred that these devices also should be rendered sterile before use, but they often are subjected to a high-level disinfection process, which should, in theory, inactivate or remove most, but not all, disease-causing microorganisms.

The remaining devices are considered noncritical and low risk because they only contact intact skin, which has natural barrier properties. Such devices routinely are subjected to gross cleaning (to remove visible soil) and/or some disinfection (generally using products with inactivation claims against some notable bacteria and viruses, but overall less effective than high level disinfection). Despite that, the overall risk will depend on many factors such as patient risk factors, staff contact (as the device can be a source of contaminating microorganisms to hands and gloves that can be transferred from person to person), where the device is used (e.g., in a general ward or an intensive care unit), and infection prevention best practices.

The most widely used method for device disinfection/sterilization in healthcare facilities is moist heat, ranging from approximately 70 to 138 (steam under pressure) degrees Celsius.

Disinfection and sterilization processes usually are developed, tested and commercialized in accordance with international and/or national regulatory requirements. These processes can vary

significantly, as do the practices in various countries regarding their use. An understanding of these processes will influence the design, risk analysis and development of the instructions for use to ensure the safe and effective use of the device worldwide.

Implementation Date: September 2020

Review Date: September 2021

Reviewed by: _____
May Ann Angeles, DHA-RN
Lead School Nurse

Approved By: _____
Zara Harrington
Principal