

**DON'T LOSE SIGHT:
INTENTIONALLY
APPROACHING EYE
DEVICE
REPROCESSING**

DISINFECTION AND STERILIZATION





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KATHARINE HAS SPENT OVER 14 YEARS IN HEALTH CARE IN VARIOUS ROLES AND SUBSPECIALTIES TO INCLUDE MOTHER INFANT CARE, OCCUPATIONAL HEALTH, PREVENTATIVE MEDICINE, AND PEDIATRICS, PROVIDING DIRECT PATIENT CARE AS A CERTIFIED MEDICAL ASSISTANT. SHE IS BOARD CERTIFIED IN INFECTION PREVENTION AND CONTROL (CIC). FURTHER EDUCATION AND TRAINING INCLUDES A BACHELOR'S OF SCIENCE IN HEALTH ADMINISTRATION AND HEALTH MANAGEMENT, AS WELL AS A MASTER'S OF PUBLIC HEALTH FOCUSED IN EPIDEMIOLOGY. WITH OVER THREE YEARS OF EXPERIENCE IN INFECTION PREVENTION AND CONTROL, HER WORK PRIMARILY FOCUSES ON HIGH LEVEL DISINFECTION AND STERILIZATION, EDUCATION AND TRAINING, IN ADDITION TO COLLABORATION WITH OVER 45 COMMUNITY HEALTH PRIMARY AND SPECIALTY CARE CLINICS INCLUDING OPHTHALMOLOGY, OPTOMETRY, WOMEN'S HEALTH AND DENTAL.

LISA WALDOWSKI, DNP, RN, CIC EXECUTIVE DIRECTOR INFECTION PREVENTION AND CONTROL, WELLSTAR HEALTH SYSTEM



LISA IS AN EXPERT IN INFECTION PREVENTION AND CONTROL WITH OVER 30 YEARS OF EXPERIENCE IN THE HEALTHCARE INDUSTRY. AN EXPERT IN THE ACCREDITATION AND REGULATORY STANDARDS, LISA KNOWS HOW TO DEVELOP AND IMPLEMENT COMPREHENSIVE INFECTION PREVENTION AND CONTROL PROGRAMS AND EDUCATION. LISA RECENTLY JOINED WELLSTAR HEALTH SYSTEM AS THEIR EXECUTIVE DIRECTOR OF INFECTION PREVENTION AND CONTROL. PRIOR TO JOINING WELLSTAR HEALTH SYSTEM, LISA HAS WORKED FOR: KAISER PERMANENTE WASHINGTON AS REGIONAL DIRECTOR OF INFECTION CONTROL, TIER1 HEALTHCARE AS A PRINCIPAL CONSULTANT IN ACCREDITATION, NEW YORK EYE AND EAR INFIRMARY OF MT. SINAI AS DIRECTOR OF INFECTION CONTROL, AND THE JOINT COMMISSION AS THE ENTERPRISE INFECTION CONTROL SPECIALIST. LISA HOLDS A DOCTOR OF NURSING PRACTICE – SYSTEMS LEADERSHIP AND A MASTER OF SCIENCE IN NURSING. SHE IS BOARD CERTIFIED IN INFECTION PREVENTION AND CONTROL (CIC).

LEARNING OBJECTIVES

- DESCRIBE THE IMPORTANCE OF REVIEWING INVENTORY OF OPHTHALMOLOGICAL DEVICES
- EXPLAIN THE CHALLENGES RELATED TO REVIEWING MANUFACTURERS INSTRUCTIONS FOR USE (IFU)
- REVIEW EVIDENCE-BASED GUIDELINES RELATED TO EYE DEVICES
- EXPLORE INFECTION PREVENTION PRACTICES FOR OPHTHALMOLOGICAL AND OPTOMETRIC DEVICES BASED ON INTENDED USE
- DESCRIBE THE IMPORTANCE OF IMPLEMENTING AND EVALUATING CLEANING, DISINFECTION AND STERILIZATION PRACTICES.
- EXPLAIN THE ROLE OF EDUCATION, TRAINING AND COMPETENCY, AND POLICY AND PROCEDURE IN ESTABLISHING PROTOCOLS FOR THE MANAGEMENT OF OPHTHALMOLOGICAL AND OPTOMETRIC DEVICES.

INTRODUCTION

- EYE DEVICES:
 - SPECIALTY DEVICES ARE COMMONLY OVERLOOKED & OMITTED AS HIGH RISK
- LOCATION:
 - URGENT CARE CLINICS, EMERGENCY DEPARTMENTS, NEONATAL INTENSIVE CARE UNITS, EYE CARE CLINICS, OPERATING ROOMS, AND AMBULATORY SURGERY CENTERS
- INTENDED USE:
 - VISUAL INSPECTION, DIAGNOSTIC TOOLS, SURGICAL INTERVENTION AND TREATMENT
- UTILIZED BY:
 - OPTOMETRISTS, OPHTHALMOLOGISTS, ED/TRAUMA PHYSICIANS, OPHTHALMIC SURGEONS

EYE DEVICE OUTBREAK: NICU

- ACCORDING TO AVRIL (2018), 23 INFANTS WERE INFECTED AFTER EYE EXAMS WITH CONTAMINATED EQUIPMENT.
- DEVICE: OPHTHALMOSCOPE.
- CAUSE: LACK OF STANDARD CLEANING.

Reference: Avril, T. 23 infants infected at CHOP after eye exams with contaminated equipment .
The Philadelphia Enquirer. Aug 30, 2018.

EYE DEVICE OUTBREAK: EYE CARE CLINIC

- ACCORDING TO MONTESSORI ET.AL. (1998), 36 CASES OF EPIDEMIC KERATOCONJUNCTIVITIS (EKC) OCCURRED.
- DEVICE: DIAGNOSTIC LENS.
- CAUSE: CLEANING WAS PERFORMED WITH 70% ALCOHOL.

Reference: Montessori V, Scharf S, Holland S, Werker DH, Roberts FJ, Bryce E. 1998. Epidemic keratoconjunctivitis outbreak at a tertiary referral eye care clinic. *Am J Infect Control*. Aug;26(4):399-405. doi: 10.1016/s0196-6553(98)70035-5. PMID: 9721392. 7

EYE DEVICE OUTBREAK: POST-OPERATIVE CATARACT SURGERY

- ACCORDING TO CHERAQPOUR ET. AL. (2021), 10 PATIENTS WERE DIAGNOSED WITH ACUTE ENDOPHTHALMITIS POST CATARACT SURGERY WITH INTRAOCULAR LENS IMPLANTATION.
- DEVICE: PHACO PROBE.
- CAUSE: NO STERILIZATION BETWEEN USE.

Reference: Cheraqpour K, Ahmadraji A, Tabatabaei S A, Bohrani Sefidan B, Soleimani M, Shahriari M and Ramezani B. Oct 2021. Outbreak of postoperative endophthalmitis caused by *Pseudomonas aeruginosa*: a case report and brief literature review. *Journal of International Medical Research*. 49(11) 1–8.

Quick Safety

Issue 49 | May 2019

Disinfection of tonometers and other ophthalmology devices

Editorial Note: Please direct this Quick Safety to your organization's infection control and ophthalmology leadership.

Issue:

Health care organizations and providers that use tonometers and other devices that touch eyes need to be aware of an infection risk to patients. The American Academy of Ophthalmology has reported that transmission of adenovirus and herpes simplex virus HIV, hepatitis C virus (HCV), enterovirus 70, *Pseudomonas aeruginosa*, methicillin-resistant *Staphylococcus aureus*, *Acanthamoeba*, and prions (transmissible spongiform encephalopathies, such as Creutzfeldt-Jakob disease) could occur from failure to adequately disinfect ophthalmology devices, such as tonometers.¹

Despite this information, a review of Joint Commission survey data identified either a lack of awareness of the requirements or misinterpretation of manufacturer's instructions — combined with lack of staff training and leadership oversight — related to the disinfection of ophthalmology devices. This has resulted in multiple declarations of an immediate threat to health and safety of patients.

Lack of compliance with reprocessing has been observed with the following items:

- Tonometers
- YAG laser lens
- Eye specula

INVENTORY

DIRECT & IN-DIRECT
LENSES

SLIT LAMP

OPHTHALMOSCOPE

RETINOSCOPE

PROBES

BIOMETRY

ULTRASOUND

PACHYMETRY

TONOMETRY

HOW TO APPROACH EYE DEVICE REPROCESSING



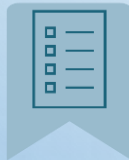
Regulation (FDA, OSHA)



CMS (Conditions of Participation)



Manufacturer Instructions for Use (IFUs)



Evidenced-based guidelines (EBGs)



Census documents or position statements



Facility-based risk assessment and policy

REGULATORY COMPLIANCE

- INFECTION CONTROL CHAPTERS & ELEMENTS OF PERFORMANCE
- NOTABLE - HIGH RISKS OF EYE DEVICE INTENDED USE, CLEANING AND DISINFECTION

Standard Label	Standard Text
▶ IC.01.01.01	The hospital identifies the individual(s) responsible for the infection prevention and control program.
▶ IC.01.02.01	Hospital leaders allocate needed resources for the infection prevention and control program.
▶ IC.01.03.01	The hospital identifies risks for acquiring and transmitting infections.
▶ IC.01.04.01	Based on the identified risks, the hospital sets goals to minimize the possibility of transmitting infections. Note: See NPSG.07.01.01 for hand hygiene guidelines.
▶ IC.01.05.01	The hospital has an infection prevention and control plan.
▶ IC.01.06.01	The hospital prepares to respond to an influx of potentially infectious patients.
▶ IC.02.01.01	The hospital implements its infection prevention and control plan.
▶ IC.02.02.01	The hospital reduces the risk of infections associated with medical equipment, devices, and supplies.
▶ IC.02.03.01	The hospital works to prevent the transmission of infectious disease among patients, licensed independent practitioners, and staff.
▶ IC.02.04.01	The hospital offers vaccination against influenza to licensed independent practitioners and staff. Note: This standard is applicable to staff and licensed independent practitioners only when care, treatment, or services are provided consultation, this standard is not applicable to off-site staff and licensed independent practitioners.
▶ IC.02.05.01	Implement evidence-based practices to prevent health care-associated infections due to the following: - Multidrug-resistant organism (CAUTI) - Surgical site infections (SSI)
▶ IC.03.01.01	The hospital evaluates the effectiveness of its infection prevention and control plan.

Source: The Joint Commission. Accreditation requirements: e-edition (jtrinc.com) (2022).

IFUS

- ❑ PERFORM A COMPLETE, ACCURATE HLD OR STERILIZATION PROCESS BASED ON MANUFACTURER INSTRUCTIONS FOR USE (IFUS) FOR EYE DEVICES
- ❑ STANDARDIZATION OF HLD SOLUTIONS

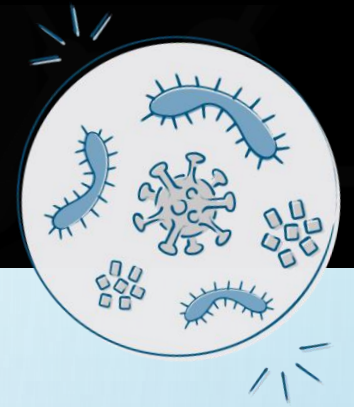





EBGS

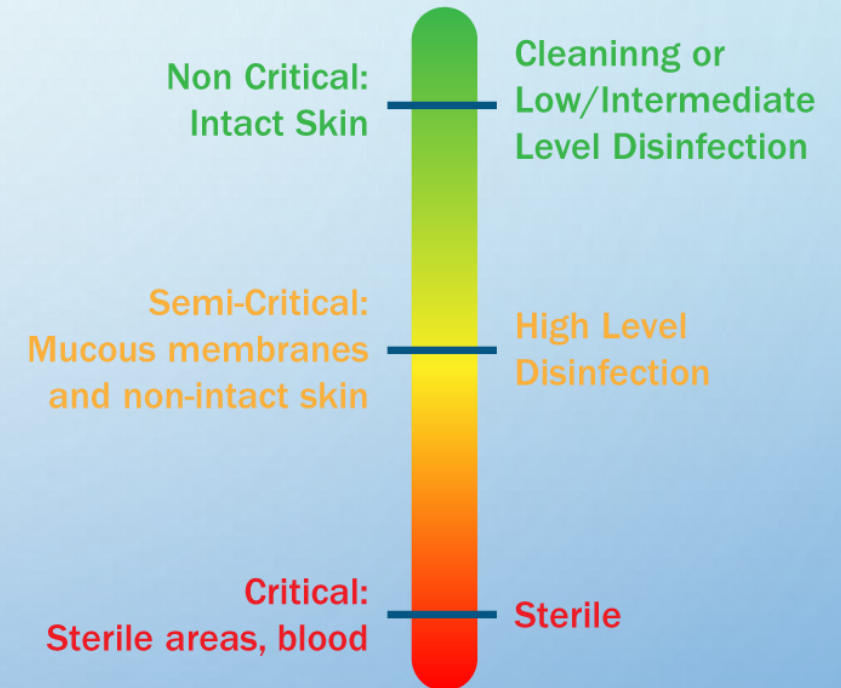
- ❑ FOLLOW THE PUBLISHED GUIDELINES:
 - ❑ AAMI ST58 (2013, R2018): CHEMICAL STERILIZATION AND HIGH-LEVEL DISINFECTION IN HEALTH CARE FACILITIES
 - ❑ AAMI ST 79 (2017): COMPREHENSIVE GUIDE TO STEAM STERILIZATION AND STERILITY ASSURANCE IN HEALTHCARE FACILITIES
 - ❑ CDC: 2008 UPDATE MAY 2019: GUIDELINE FOR DISINFECTION AND STERILIZATION IN HEALTHCARE FACILITIES



SPAULDING CLASSIFICATION SYSTEM



Patient Contact	Device Classification	Examples	Reprocessing
Intact skin	Non-critical		Low-level disinfection; Intermediate-level disinfection
Mucous membranes; Non-intact skin	Semi-critical		High-level disinfection
Sterile areas of the body; Vascular system	Critical		Sterilization



Source: Multisociety Guidelines – reprocessing flexible GI Endoscopes and accessories. November 2020.



CLEANING, DISINFECTION, STERILIZATION



CLEAN:

REMOVAL OF MATERIAL LIKE DUST, SOIL, BLOOD, AND BODILY FLUID.



DISINFECTION:

DESTRUCTION OF ALL MICROORGANISMS EXCEPT FOR LOW-LEVEL BACTERIA SPORES.



STERILIZATION:

VALIDATED PROCESS USED TO RENDER A PRODUCT FREE FROM VIABLE MICROORGANISMS.

BE ON THE LOOK OUT FOR EYE DEVICES

LLD/INT

TONOPEN WITH
DISPOSABLE TIP



HLD

B-SCAN PROBE



STERILIZATION

OCULAR GONIOSCOPE



RISK ASSESSMENT

Program Components	Probability of Performance- Failure				Impact (Clinical/Financial/Resources)			Infection Prevention Systems				Score
	High	Med	Low	Never	High	Moderate	Minimal	Poor	Fair	Good	Excellent	≥7
Potential Risks/Problems	3	2	1	0	3	2	1	3	2	1	0	

DO YOU RECOGNIZE ME?

OCULAR GONIOSCOPE

MANUFACTURERS INSTRUCTIONS FOR USE



CLEANING & HLD

1. CLEAN WITH SOAP AND WATER
2. DRY WITH SOFT TISSUE
3. SOAK IN 2% GLUTARALDEHYDE FOR 20 MINUTES
4. RINSE THOROUGHLY
5. DRY AND STORE IN DRY CASE

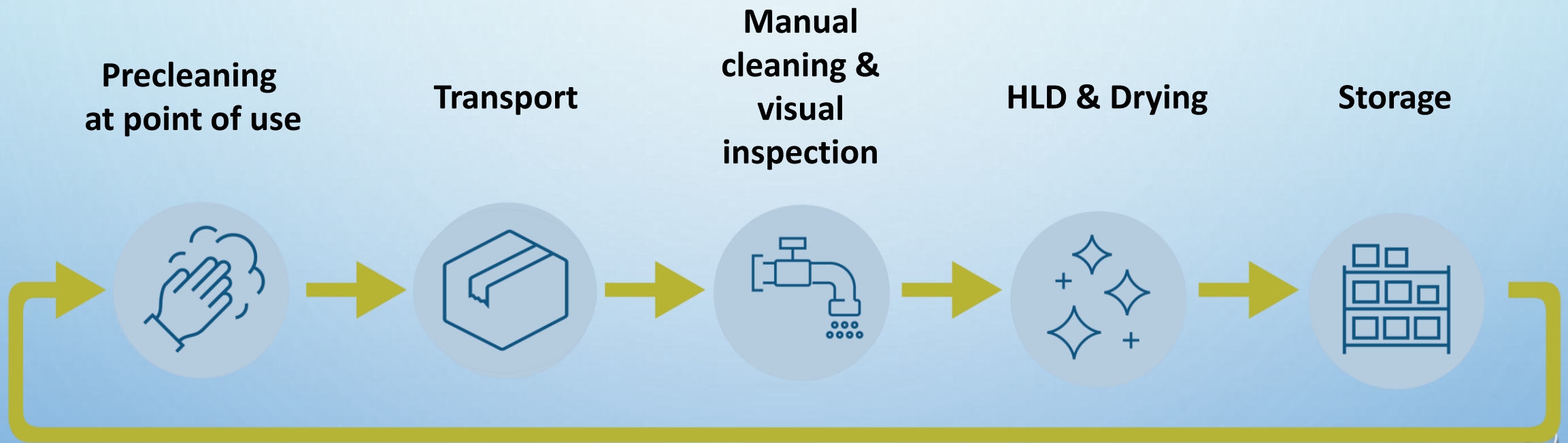
STERILIZATION

WITH ETHYLENE OXIDE GAS NOT TO EXCEED 130F

CAUTION!

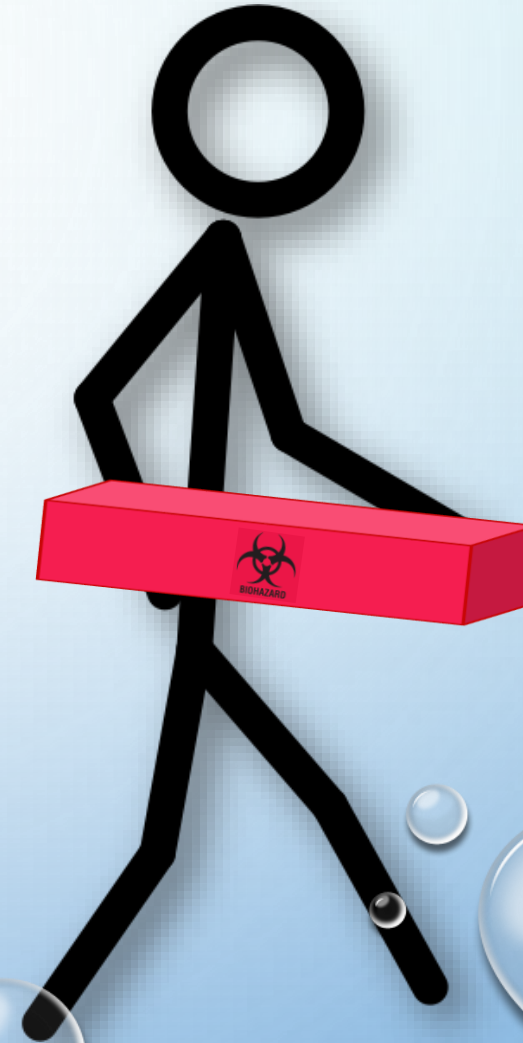
DO NOT BOIL, AUTOCLAVE OR USE ALCOHOL, ACETONE OR PEROXIDE

THE HLD PROCESS FOR EYE DEVICES



IMPLEMENTATION OF
EYE DEVICE
REPROCESSING

*WALK ME THROUGH
THE PROCESS...*



PRECLEANING

- ❑ COMPATIBLE WIPE OR PRODUCT
PER IFUS
- ❑ REDUCE THE RISK OF TOXIC
ANTERIOR SEGMENT SYNDROME
(TASS)
- ❑ REMOVE GROSS SOIL OR MOISTEN
SOIL
- ❑ IMPROVE EFFICIENCY &
EFFECTIVENESS FOR
SUBSEQUENT STEPS



TRANSPORT

- ❑ USE PUNCTURE-RESISTANT, LEAK-PROOF, BIOHAZARD LABELED CONTAINERS BASED ON THE CONTENTS BEING TRANSPORTED
- ❑ IMMEDIATELY WITHOUT DELAY
- ❑ TRANSPORT MOIST
- ❑ FOLLOW MANUFACTURER'S INSTRUCTIONS FOR USE



MANUAL CLEANING

FOLLOW MANUFACTURER'S IFUS:

- CLEANING INSTRUCTIONS

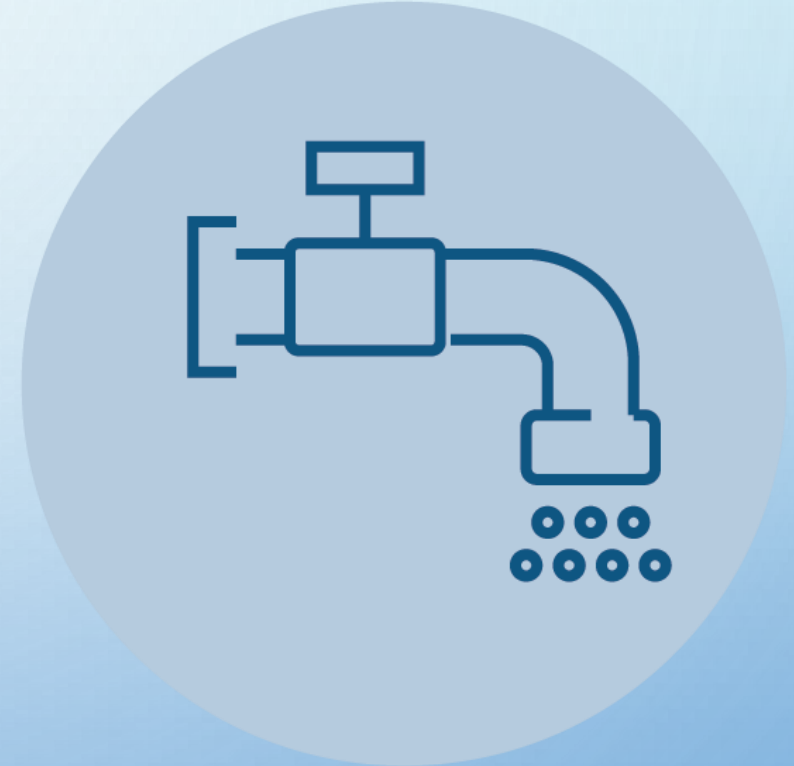
- PRODUCT SELECTION AND USE

PROVIDE:

- THERMOMETER

- TIMER

- LOW-LINTING CLOTHS



MANUAL HLD

- ❑ FOLLOW HLD PRODUCT & HLD TEST STRIP IFUS
 - ❑ DATE HLD PRODUCT AND TEST STRIPS (OPEN/EXPIRED)
 - ❑ QUALITY CONTROL HLD TEST STRIPS
- ❑ LABEL SECONDARY CONTAINER BIOHAZARDOUS, HLD PRODUCT NAME, DATE POURED, DATE EXPIRED



Manual HLD - B probe

MANUAL HLD

- RINSE WITH WATER TYPE STATED IN IFUS
- DRY PER IFUS
- DISCARD HLD PROPERLY
- ENSURE ACCESS TO SPILL KIT AND EYEWASH STATION WHEN INDICATED

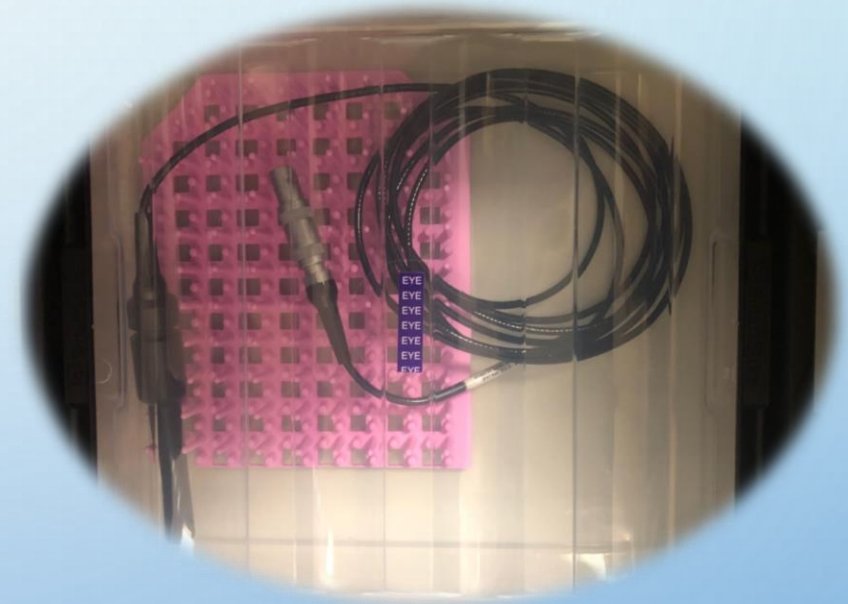
HIGH-LEVEL DISINFECTION DOCUMENTATION

- SOAKING CONTAINER
- SPECIFIC CONTENTS OF THE LOAD, IDENTIFIER OF DEVICE
- PATIENT'S NAME AND MRN, IF AVAILABLE
- EXPOSURE TIME AND TEMPERATURE
- SHELF-LIFE DATE, DATE OPENED, DATE POURED INTO SECONDARY CONTAINER, EXPIRATION DATE
- OPERATOR INITIALS
- MINIMAL EFFECTIVE CONCENTRATION (MEC) RESULTS
- ANY FAILURES TO INCLUDE CORRECTIVE ACTION



STORAGE

- ❑ STORE IN A MANNER THAT MINIMIZES CONTAMINATION
- ❑ STORAGE REQUIREMENTS:
 - ❑ FOLLOW MANUFACTURER'S STORAGE INSTRUCTIONS
 - ❑ OR DEFER TO SELECTED EVIDENCE-BASED GUIDELINES



WHY AUDIT TRACEABILITY DOCUMENTATION



Patient Safety



Risk Management



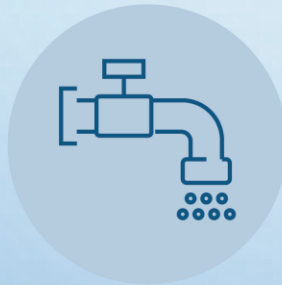
Accreditation/Survey
Readiness

THE STERILIZATION PROCESS FOR EYE DEVICES

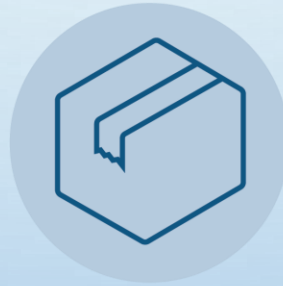
**Precleaning at point
of use/ Transport**



Cleaning



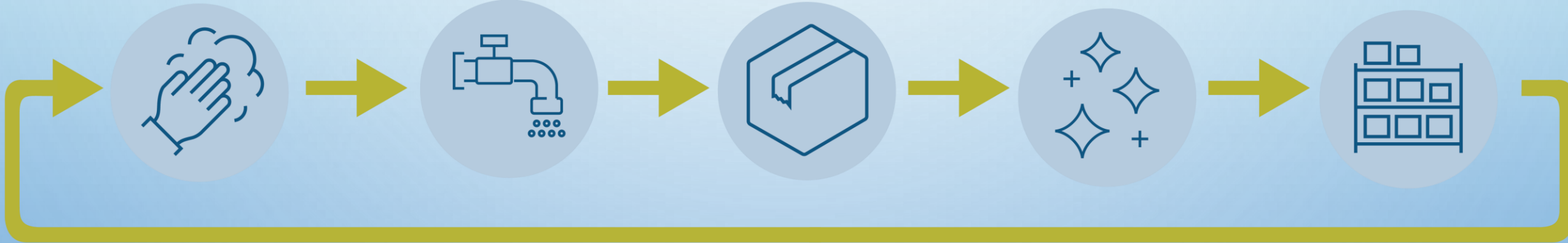
**Inspection, Prep
& Packaging**



Sterilization

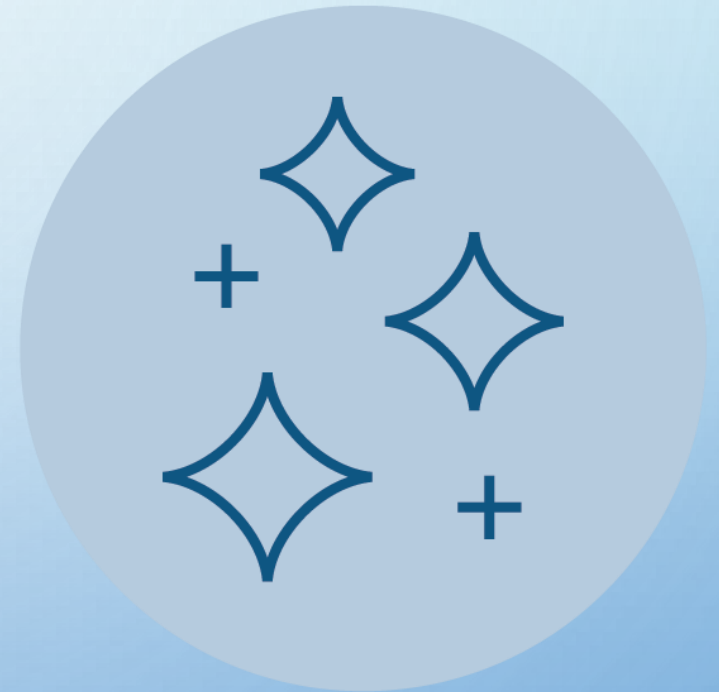


Storage



STERILIZATION

- FOLLOW INSTRUCTIONS FOR USE (IFUS)
- FOLLOW STERILIZERS (IFUS)
- DRY PER IFUS



TRAINING & COMPETENCY



TRAINING AND COMPETENCY IS NON-NEGOTIABLE.

PROVIDE:

EDUCATION

HANDS-ON TRAINING

UNIQUE TRAINING FOR
SPECIFIC DEVICES THAT
HAVE THEIR OWN
INSTRUCTIONS FOR USE

OFFER TRAINING:

TO NEW HIRES

ON AN ONGOING BASIS

ENSURE STAFF ARE
COMPETENT

DOCUMENT TRAINING AND
COMPETENCY

TRAINING MUST INCLUDE

DEVICE MANUFACTURER
IFU



EVIDENCE-BASED
GUIDELINES



ORGANIZATION'S POLICY
AND PROCEDURE



USE YOUR RESOURCES

MANUFACTURER
MATERIALS



PROFESSIONAL
RESOURCES



VENDOR
PARTNERS



SUPER
USERS



PROCESS IMPROVEMENT

DEFINE

- Eye device goals and deliverables

MEASURE

- Current eye device reprocessing performance

ANALYZE

- Root cause of defects

IMPROVE

- Eliminate defects

CONTROL

- Prevent process degradation

KEY PERFORMANCE INDICATORS

Outcome Measures

Achievement of infection prevention goals identified from IC Risk Assessment

Number of adverse events related to Eye Devices

100% compliance with HLD and Sterile Processing quality control systems

100% compliance with required training

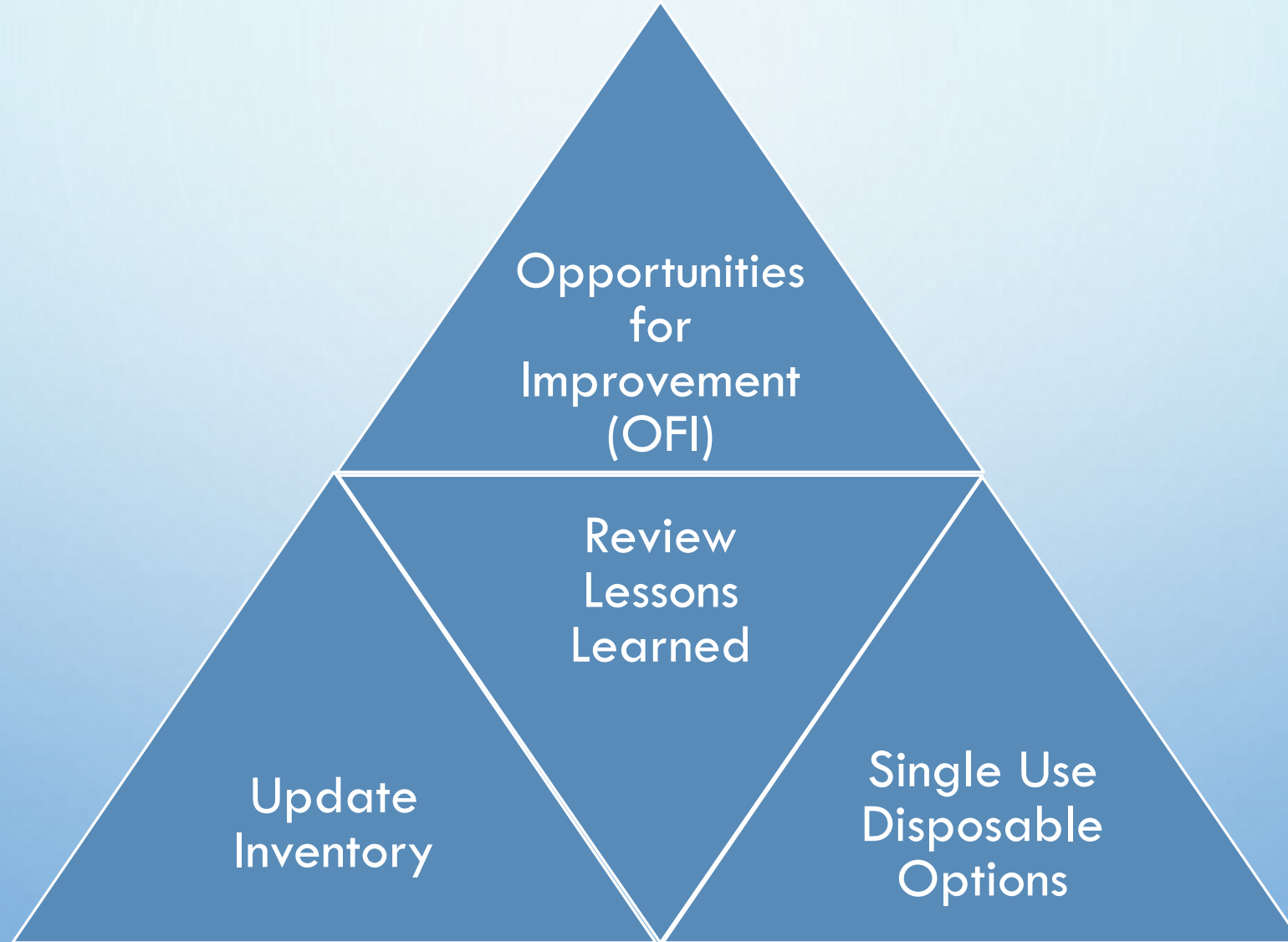
Process Measures

100% compliance to adherence to:

HLD and sterilization IFUs for eye devices

Pre-cleaning, transport and storage for eye devices

EVALUATION



RECOMMENDATIONS FOR A STANDARDIZED EYE DEVICE PROCESS



- ✓ Inclusion and prioritization of IC Risk Assessment, IC Plan
- ✓ Monitor inventory
- ✓ Follow manufacturer's IFUs
- ✓ Standardize products, supplies, and processes (to include documentation)
- ✓ Provide knowledgeable oversight, audits, and validation
- ✓ Initial and ongoing education, training, and competency
- ✓ Engage leadership
- ✓ Standardize selected evidence-based guidelines and P&Ps

CONCLUSION

INFECTION PREVENTIONIST'S PLAY A SIGNIFICANT ROLE IN:

- ✓ ENSURING HIGHLY RELIABLE CLEANING, DISINFECTION AND STERILIZATION PROCESSES
- ✓ PROVISION OF HIGH QUALITY, SAFE PATIENT CARE

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