Annual Educational Conference & International Meeting
New Developments in Reprocessing Semicritical Items

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DISCLOSURES

- Consultation
  - Advanced Sterilization Products, Clorox
- Honoraria (speaking)
  - Advanced Sterilization Products, 3M
- Grants
  - CDC
Reprocessing Semicritical Items

New Developments in Reprocessing

- Endoscopes
- Laryngoscopes
- Infrared coagulation device
- Nasopharyngoscopes
- Endocavitary probe
- Prostate biopsy probes
- Tonometers
EH Spaulding believed that how an object will be disinfected depended on the object’s intended use:

- **CRITICAL** - objects which enter normally sterile tissue or the vascular system or through which blood flows should be sterile.

- **SEMICRITICAL** - objects that touch mucous membranes or skin that is not intact require a disinfection process (high-level disinfection [HLD]) that kills all microorganisms but high numbers of bacterial spores.

- **NONCRITICAL** - objects that touch only intact skin require low-level disinfection.
# Processing “Semicritical” Patient Care Objects

<table>
<thead>
<tr>
<th>Classification:</th>
<th>Semicritical objects come in contact with mucous membranes or skin that is not intact.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Object:</td>
<td>Free of all microorganisms except high numbers of bacterial spores.</td>
</tr>
<tr>
<td>Level germicidal action:</td>
<td>Kills all microorganisms except high numbers of bacterial spores</td>
</tr>
<tr>
<td>Examples:</td>
<td>Respiratory therapy and anesthesia equipment, GI endoscopes, endocavitary probes, etc.</td>
</tr>
<tr>
<td>Method:</td>
<td>High-level disinfection</td>
</tr>
</tbody>
</table>
# High-Level Disinfection of “Semicritical Objects”

**Exposure Time ≥ 8m-45m (US), 20°C**

<table>
<thead>
<tr>
<th>Germicide</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde</td>
<td>&gt; 2.0%</td>
</tr>
<tr>
<td>Ortho-phthalaldehyde</td>
<td>0.55%</td>
</tr>
<tr>
<td>Hydrogen peroxide*</td>
<td>7.5%</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
<td>1.0%/0.08%</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
<td>7.5%/0.23%</td>
</tr>
<tr>
<td>Hypochlorite (free chlorine)*</td>
<td>650-675 ppm</td>
</tr>
<tr>
<td>Accelerated hydrogen peroxide</td>
<td>2.0%</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>0.2%</td>
</tr>
<tr>
<td>Glut and isopropanol</td>
<td>3.4%/26%</td>
</tr>
<tr>
<td>Glut and phenol/phenate**</td>
<td>1.21%/1.93%</td>
</tr>
</tbody>
</table>

*May cause cosmetic and functional damage; **efficacy not verified
Semicritical Equipment

- Reprocessing semicritical items has been shown to have a narrow margin of safety.
- Generally, the narrow margin of safety attributed to high microbial load and complex instruments with lumens.
- Any deviation from the recommended reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection.
- Problems encountered with reprocessing semicritical equipment often related to improper cleaning.
Reprocessing Semicritical Items

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- Prostate biopsy probes
- Tonometers
Multisociety Guideline on Reprocessing Flexible GI Endoscopes: 2011

The beneficial role of GI endoscopy for the prevention, diagnosis, and treatment of many digestive diseases and cancer is well established. Like many sophisticated medical devices, the endoscope is a complex, reusable instrument that requires reprocessing before being used on subsequent patients. The most commonly used methods for reprocessing endoscopes result in high-level disinfection. To date, all published occurrences of pathogen transmission related to GI endoscopy have been associated with failure to follow established cleaning and disinfection/sterilization guidelines or use of defective equipment. Despite the strong published data regarding the safety of endoscope reprocessing, concern over the potential spread gaps in infection prevention practices. Given the ongoing occurrences of endoscopy-associated infections attributed to lapses in infection prevention, an update of the multisociety guideline is warranted.

This document provides an update of the previous guideline, with additional discussion of new or evolving reprocessing issues and updated literature citations, where appropriate. Specific additions or changes include review of expanded details related to critical reprocessing steps (including cleaning and drying), reprocessing issues for various endoscope attachments such as flushing catheters, discussion of risks related to selected periprocedural practices including...
GI ENDOSCOPIES AND BRONCHOSCOPIES

- Widely used diagnostic and therapeutic procedure
- Endoscope contamination during use (GI $10^9$ in/$10^5$ out)
- Semicritical items require high-level disinfection minimally
- Inappropriate cleaning and disinfection has lead to cross-transmission
- In the inanimate environment, although the incidence remains very low, endoscopes represent a risk of disease transmission
TRANSMISSION OF INFECTION

- Gastrointestinal endoscopy
  - >300 infections transmitted
  - 70% agents Salmonella sp. and P. aeruginosa
  - Clinical spectrum ranged from colonization to death (~4%)

- Bronchoscopy
  - 90 infections transmitted
  - *M. tuberculosis*, atypical *Mycobacteria*, *P. aeruginosa*

Since 2003, changes in
- High-level disinfectants
- Automated endoscope reprocessors
- Endoscopes
- Endoscopic accessories

However, efficacy of decontamination and high-level disinfection is unchanged and the principles guiding both remain valid.

Additional outbreaks of infection related to suboptimal infection prevention practices during endoscopy or lapses in endoscope reprocessing (unfamiliarity with endoscope channels, accessories, attachments; gaps in infection prevention at ASC)
Transmission categorized as:

- Non-endoscopic and related to care of intravenous lines and administration of anesthesia or other medications
  - Multidose vials
  - Reuse of needles and syringes
  - Intravenous sedation tubing

- Endoscopic and related to endoscope and accessories
  - Failure to sterilize biopsy forceps between patients
  - Lapses in reprocessing tubing used in channel irrigation
Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Unresolved Issues

- Interval of storage after which endoscopes should be reprocessed before use
  - Data suggest that contamination during storage for intervals of 7-14 days is negligible, unassociated with duration, occurs on exterior of instruments and involves only common skin organisms
  - Data are insufficient to proffer a maximal outer duration for use of appropriately cleaned, reprocessed, dried and stored endoscopes
  - Without full data reprocessing within this interval may be advisable for certain situations (endoscope entry to otherwise sterile regions such as biliary tree, pancreas)
Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Unresolved Issues
  - Optimal frequencies for replacement of: clean water bottles and tubing for insufflation of air and lens wash water, and waste vacuum canisters and suction tubing
    - Concern related to potential for backflow from a soiled endoscope against the direction of forced fluid and air passage into clean air/water source or from tubing/canister against a vacuum into clean instruments
  - Microbiologic surveillance testing after reprocessing
    - Detection of non-environmental pathogens indicator of faulty reprocessing equipment, inadequate solution, or failed human process
Endoscope Reprocessing, Worldwide

- Worldwide, endoscopy reprocessing varies greatly
  - India, of 133 endoscopy centers, only 1/3 performed even a minimum disinfection (1% glut for 2 min)
  - Brazil, “a high standard ... occur only exceptionally”
  - Western Europe, >30% did not adequately disinfect
  - Japan, found “exceedingly poor” disinfection protocols
  - US, 25% of endoscopes revealed >100,000 bacteria

Schembre DB. Gastroint Endoscopy 2000;10:215
ENDOSCOPE DISINFECTION

- CLEAN-mechanically cleaned with water and enzymatic cleaner
- HLD/STERILIZE-immerse scope and perfuse HLD/sterilant through all channels for at least 12 min
- RINSE-scope and channels rinsed with sterile water, filtered water, or tap water followed by alcohol
- DRY-use forced air to dry insertion tube and channels
- STORE-prevent recontamination
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Reprocessing of Rigid Laryngoscopes

- Limited guidelines for reprocessing laryngoscope’s blades and handles
- Many hospitals consider blade as semicritical (HLD) and handle as noncritical (LLD)
- Blades linked to HAIs; handles not directly linked to HAIs but contamination with blood/OPIM suggest its potential and blade and handle function together
- Ideally, clean then HLD/sterilize blades and handles (UNCHC-blades wrapped in a tray-Sterrad; handle wrapped in tray [without batteries]-steam); the blades and handles placed together in a Ziploc bag. Blades and handles checked for function prior to packaging.
Contamination of Laryngoscope Handles

J Hosp Infect 2010;74:123

- 55/64 (86%) of the handles deemed “ready for patient use” positive for S. aureus, enterococci, Klebsiella, Acinetobacter

Anesth Analg 2009;109:479

- 30/40 (75%) samples from handles positive (CONS, Bacillus, Streptococcus, S. aureus, Enterococcus) after cleaning

AANA J 1997;65:241

- 26/65 (40%) of the handles and 13/65 (20%) of the blades were positive for occult blood. These blades and handles were identified as ready for patient use.
ADULT LARYNGOSCOPE SET
DO NOT DISCARD REUSABLE
PLACE ALL CONTENTS OF BAG IN GREEN TUBS IN DIRTY UTILITY ROOM
How should we process and store laryngoscope blades?

- Processed via sterilization or HLD
- Packaged in some way
- Stored in a way that prevents recontamination. Examples of compliant storage include, but are not limited to, a peel pack post steam sterilization (long-term) or wrapping in a sterile towel (short term)
- Should not place unwrapped blades in an anesthesia drawer
Reprocessing Semicritical Items

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Infrared Coagulation (IRC)

- IRC is a widely used method for treating hemorrhoids. The procedure involves applying infrared light to compress and seal hemorrhoid veins.
- The manufacture sells a sterile disposable sheath and states removing and soaking lightguides between procedures is no longer required.
- The manufacturer also states that the lightguide is damaged by immersion in a disinfectant (as the lightguide is not sealed at the end and disinfectant gets between the quartz glass and the covering).
Infrared Coagulation (IRC)

- CDC guideline recommends immersion for reprocessing endocavitary probes with covers because integrity of the cover is compromised.

- Since the lightguide cannot be immersed we investigated an alternative procedure:
  - Wipe the probe for 2 minutes with 1:10 bleach (5000 ppm).
  - Wipe probe with sterile water for 1 minute and let air dry.
This method, which removed or inactivated $>6\log_{10}$ of mycobacteria, should eliminate all contaminating pathogens.
Wiping the non-immersible IRC probe for 2 min with 5000 ppm chlorine was effective in removing/inactivating microorganisms from the instruments.
Reprocessing Semicritical Items

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Sterile Endoscopic Sheaths to Replace High-Level Disinfection

Fig 1. Commercial sterile, disposable, polyurethane endoscopic sheath (Slide-on EndoSheath System, Medtronic ENT, Jacksonville, FL) studied in 100 nasopharyngoscopic procedures.
Sterile Endoscopic Sheaths to Replace High-Level Disinfection
Use of a high-quality sheath, combined with detergent cleaning and disinfection with 70% alcohol can provide decontaminated instrument

Table 1. Results of bacterial cultures of 100 nasopharyngoscopes used in a clinical examination at 3 sampling times: baseline, preprocedure, with a cleaned and high-level disinfected scope ready to use; immediately postprocedure, after removing the sheath but before reprocessing; and after cleaning, disinfection with 70% ethanol and drying

<table>
<thead>
<tr>
<th></th>
<th>Baseline, preprocedure (range cfu)</th>
<th>Immediately postprocedure, after sheath removal, before reprocessing (range cfu)</th>
<th>After cleaning, 70% ethanol disinfection and drying (range cfu)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. nasopharyngoscopes studied</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>No. positive cultures of head (cfu)</td>
<td>16 (2-100)</td>
<td>13 (2-32)</td>
<td>0 (...)</td>
</tr>
<tr>
<td>Coagulase-negative</td>
<td>6 (2-100)</td>
<td>8 (4-32)</td>
<td>0 (...)</td>
</tr>
<tr>
<td>Staphylococcus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>1 (12)</td>
<td>0 (...)</td>
<td>0 (...)</td>
</tr>
<tr>
<td>Corynebacterium spp</td>
<td>2 (2-10)</td>
<td>0 (...)</td>
<td>0 (...)</td>
</tr>
<tr>
<td>Bacillus spp</td>
<td>10 (2-92)</td>
<td>5 (2-10)</td>
<td>0 (...)</td>
</tr>
<tr>
<td>No. positive cultures of shaft (cfu)</td>
<td>8 (1-10)</td>
<td>1 (10)</td>
<td>0 (...)</td>
</tr>
<tr>
<td>Coagulase-negative</td>
<td>3 (2-10)</td>
<td>1 (10)</td>
<td>0 (...)</td>
</tr>
<tr>
<td>Staphylococcus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>0 (...)</td>
<td>0 (...)</td>
<td>0 (...)</td>
</tr>
<tr>
<td>Corynebacterium spp</td>
<td>1 (6)</td>
<td>0 (...)</td>
<td>0 (...)</td>
</tr>
<tr>
<td>Bacillus spp</td>
<td>6 (1-8)</td>
<td>0 (...)</td>
<td>0 (...)</td>
</tr>
</tbody>
</table>

cfu, Colony-forming units.
Sterile Endoscopic Sheaths to Replace High-Level Disinfection

Elackattu et al. Laryngoscope. 2010;

Microbial counts on insertion shafts for sheath and HLD group were similar, with 1/50 and 0/50.

<table>
<thead>
<tr>
<th>TABLE I. Microbial Results.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td>-----------------------------</td>
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<tr>
<td>Baseline FNPL handles</td>
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<tr>
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<tr>
<td>Baseline FNPL shafts</td>
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<tr>
<td>Post-use FNPL handles</td>
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<tr>
<td>Post-use FNPL shafts</td>
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<tr>
<td></td>
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<tr>
<td>Results after disinfection for both study arms (Klenzyme + ETOH for the IPDSS group vs. Klenzyme + Cidex OPA + ETOH for the traditional group)</td>
</tr>
<tr>
<td>FNPL handles postdisinfection</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>FNPL shaft postdisinfection</td>
</tr>
</tbody>
</table>

IPDSS = individually packaged disposable sterile sheath; CI = confidence interval; FNPL = Flexible nasopharyngolaryngoscopes; N/A = not applicable; ETOH = ethyl alcohol; OPA = ortho-phthalaldehyde.
Sheath on Nasopharyngoscope

- Two peer-reviewed studies have shown that a sterile, disposable sheath on a nasopharyngoscope during a clinical examination, combined with enzymatic detergent cleaning and disinfection with 70% ethanol can provide a reliably decontaminated, patient ready instrument that eliminates the need for HLD of nasopharyngoscopes (with this specific sheath and this device).

- Thus, this practice (this sheath plus cleaning plus alcohol) may be an option to high-level disinfection.
Reprocessing Semicritical Items

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- Endoscopes
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Endocavitary Probes

- Probes - Transesophageal echocardiography probes, vaginal/rectal probes used in sonographic scanning
- Probes with contact with mucous membranes are semicritical
- Guideline recommends that a new condom/probe cover should be used to cover the probe for each patient and since covers may fail (1-80%), HLD (semicritical probes) should be performed
Endocavitary Probe Covers

- Sterile transvaginal probe covers had a very high rate of perforations before use (0%, 25%, 65% perforations from three suppliers)

- A very high rate of perforations in used endovaginal probe covers was found after oocyte retrieval use (75% and 81% from two suppliers) but other investigators found a lower rate of perforations after use of condoms (0.9-2.0%)

- Condoms superior to probe covers for ultrasound probe (1.7% condom, 8.3% leakage for probe covers)
Trophon EPR
(uses VHP to achieve HLD in 7m-no independent efficacy data)
Reprocessing Semicritical Items

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Prostate Biopsy Probe

- Evaluated effectiveness of HLD when assembled (needle biopsy holder in probe) and unassembled.

- Inoculated (10^6-10^7 *P. aeruginosa*): internal lumen/outside surface of needle biopsy holder; internal lumen of probe with and without needle biopsy holder in place

- Conclusion: HLD achieved when unassembled but not when assembled
Disinfection of Prostate Probe


Needle guide must be removed from the probe for disinfection

**Table 1. Effectiveness of Glutaraldehyde Disinfection of Various Components of a Probe Used in Ultrasound-Guided Prostate Biopsy**

<table>
<thead>
<tr>
<th>Inoculation site and status</th>
<th>Experiment set</th>
<th>Size of <em>P. aeruginosa</em> inoculum, cfu</th>
<th>No. of positive results/no. of experiments</th>
<th><em>P. aeruginosa</em> yield on culture, mean cfu</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal lumen of needle guide in probe</td>
<td>A</td>
<td>$1.56 \times 10^7$</td>
<td>0/5</td>
<td>No growth</td>
</tr>
<tr>
<td>Outside surface of needle guide in probe</td>
<td>B</td>
<td>$1.21 \times 10^7$</td>
<td>6/6</td>
<td>$1.2 \times 10^6$</td>
</tr>
<tr>
<td>Internal lumen of probe</td>
<td>C</td>
<td>$1.69 \times 10^7$</td>
<td>6/6</td>
<td>$2.82 \times 10^6$</td>
</tr>
<tr>
<td>Needle guide not removed from probe</td>
<td>D</td>
<td>$1.81 \times 10^7$</td>
<td>0/5</td>
<td>No growth</td>
</tr>
<tr>
<td>Needle guide removed from probe</td>
<td>E</td>
<td>$1.81 \times 10^7$</td>
<td>0/5</td>
<td>No growth</td>
</tr>
</tbody>
</table>

**Note.** CFU, colony forming units; *P. aeruginosa*, *Pseudomonas aeruginosa.*
**Disinfection of Prostate Probe**


---

<table>
<thead>
<tr>
<th>Cleaning</th>
<th>High-level disinfection or sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean immediately after use</td>
<td>Steam sterilize all heat stable reusable components</td>
</tr>
<tr>
<td>Disassemble the transducer (ie, remove needle guide from the probe)</td>
<td>Alternatively, perform high-level disinfection of the probe and the needle guide separately following disassembly</td>
</tr>
<tr>
<td>Brush clean (if possible) or flush each lumen and thoroughly clean all surfaces of reusable components with enzymatic or nonenzymatic detergent</td>
<td>Perform high-level disinfection for all heat-sensitive components to ensure that the disinfectant reaches all areas inside the lumens and that the minimum effective concentration of the high-level disinfectant is used</td>
</tr>
<tr>
<td>Rinse with tap water</td>
<td>Rinse with sterile water, filtered water, or tap water (the US Food and Drug Administration specifies use of sterile water for rinsing)</td>
</tr>
<tr>
<td>Dry with disposable cloth and/or towel or air dry</td>
<td>If filtered water or tap water is used, follow with an alcohol rinse (not immersion of the probe in alcohol) to enhance drying and ensure that no residual water is left for microbial growth</td>
</tr>
<tr>
<td>Perform visual inspection to ensure the device is clean</td>
<td>Dry</td>
</tr>
<tr>
<td></td>
<td>Store appropriately to ensure the device is not recontaminated</td>
</tr>
</tbody>
</table>

**NOTE.** Users should be familiar with the manufacturer’s recommendations for use and disinfection of the specific device used by the facility.
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Adenovirus 8
A Common Cause of Epidemic Keratoconjunctivitis
Adenovirus 8

- Adenovirus is extremely hardy when deposited on environmental surfaces and may be recovered from plastic and metal surfaces for more than 30 days.
- Elimination of adenovirus from inanimate surfaces and ophthalmic instruments is essential in preventing outbreaks of epidemic keratoconjunctivitis.
- Unfortunately, no reports that validate CDC recommendations for disinfecting tonometer tips.

CDC. MMWR 1985; 34:533.
Applanation tonometers-Soap and water cleaning and then disinfected by soaking them for 5 to 10 minutes in a solution containing either:

- 5,000 chlorine (~1:10 household bleach)
- 3% hydrogen peroxide
- 70% ethyl alcohol
- 70% isopropyl alcohol
Disinfectants and Antiseptics
Adeno 8 at 1 and 5 min, Rutala et al. AAC, April 2006

- Ineffective <2 log$_{10}$ reduction
  - Bactoshield (4% CHG)
  - Vesphene (phenolic)
  - 70% isopropyl alcohol
  - 3% hydrogen peroxide
  - TBQ (0.06% QUAT)
  - Novaplus (10% povidone iodine)
  - Soft ‘N Sure (0.5% triclosan)
  - Acute-Kare (1% chloroxylenol)
  - Sterilox (218 and 695 ppm chlorine)
  - Dettol (4.8% chloroxylenol)
  - Accel TB (0.5% accelerated hydrogen peroxide)
  - Microcyn (~80 ppm chlorine)
Disinfectants and Antiseptics
Adeno 8 at 1 and 5 min, Rutala et al. AAC, April 2006

- $\sim 4 \log_{10}$ reduction
  - Clorox, 1:10, $\sim 6,000$ ppm chlorine (but not 1:50)
  - Clorox Clean-up, $\sim 1,910$ ppm chlorine
  - Clorox disinfecting spray (65% ethanol, 0.6% Quat)
  - Steris 20 sterilant, 0.35% peracetic acid
  - Ethanol, 70%
  - Lysol disinfecting spray (79.6% ethanol, 0.1% Quat)
  - Cidex, 2.4% glutaraldehyde
  - Cidex-OPA, 0.55% OPA
  - Wavicide, 2.65% glutaraldehyde
CDC Guidelines

- **CDC, 1985.** Applanation tonometers-soap and water cleaning and then disinfected by soaking them for 5 to 10 minutes in a solution containing either:
  - 5,000 chlorine
  - 3% hydrogen peroxide
  - 70% ethyl alcohol
  - 70% isopropyl alcohol

- **CDC, 2008.** Wipe clean tonometer tips and then disinfect them by immersing for 5-10 minutes in either 5000 ppm chlorine or 70% ethyl alcohol. Category II.

- These results emphasize the proper selection of disinfectants for use in disinfecting semicritical items (e.g., applanation tonometers)
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D/S guidelines must be followed to prevent exposure to pathogens that may lead to infection
THANK YOU!