

February 2022

The self-study lesson on this central service topic was developed by 3M Health Care. The lessons are administered by Endeavor Healthcare Media.

Earn CEUs

After careful study of the lesson, complete the examination at the end of this section. Mail the completed test and scoring fee to *Healthcare Purchasing News* for grading. We will notify you if you have a passing score of 70% or higher, and you will receive a certificate of completion within 30 days. Previous lessons are available at www.hpnonline.com.

Certification

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved



this in-service for one (1) contact hour for a period of five (5) years from the date of original publication. Successful completion of the lesson and post-test must

be documented by facility management and those records maintained by the individual until recertification is required. DO NOT SEND LESSON OR TEST TO CBSPD. For additional information regarding certification, contact CBSPD - 148 Main Street, Suite C-1, Lebanon, NJ 08833 • www.cbspd.net.



HSPA (Healthcare Sterile Processing Association) has pre-approved this in-service for 1.0 Continuing Education Credits for a period of three years, until January 14, 2025. The approval number for this lesson is **3M-HPN 221401**.

For more information, direct any questions to *Healthcare Purchasing News* (941) 259-0832.

LEARNING OBJECTIVES

1. Describe recommendations for adequate water quality for cleaning medical devices
2. Identify the impact of water quality on medical device reprocessing
3. Relate water quality to adverse events described in the scientific literature

Sponsored by:



SELF-STUDY SERIES

Water for cleaning medical devices

by Jeane Aparecida Gonzalez Bronzatti and Rafael Queiroz de Souza

Cleaning is considered a fundamental step in the processing of healthcare products. It removes a variety of organic and inorganic dirt from instruments used in surgical procedures such as blood, proteins, lipids, bone, and ophthalmic viscosurgical devices, among others. In practice, medical devices are immersed, rinsed, or sprayed with water or solutions with surfactants to prevent the dirt from drying out. There are cases in which a pre-cleaning procedure in care areas needs to be carried out, for example, when there is a large amount of organic matter such as feces, blood, or other contaminants¹.

To make the removal of dirt to safe levels possible, it is necessary to use either manual or automated cleaning methods - or a combination of both. In all cases it is necessary to use water, which acts as a solvent, and is one of the essential elements of the Sinner's circle² along with four other factors: time, mechanical action, temperature, and chemical activity³.

Considering water as an essential element, its use occurs in several stages of processing: displacement of dirt through spraying in thermo-disinfecting washers and cavitation in ultrasonic washers, dilution of cleaning solutions, and in rinsing of medical devices. Thus, water quality control is essential for the cleaning process to be effective. (See Table 1.)

Additionally, there are documents that supplement the AAMI TIR34:2014 with product-specific recommendations as well as local guidelines and regulations. These additional guidelines should be consulted in the instructions for use of each product. For example, the TIR34 provides different indications for rinsing after high-level

disinfection, while the Gastroenterological Society of Australia - GESA⁵ has specific and additional recommendations for the quality of water used in the processing of endoscopes (Tables 3 and 4).

In ophthalmology, there are specific recommendations due to the occurrence of acute inflammations of the anterior chamber, or segment, of the eye following cataract surgery characterized as TASS: Toxic Anterior Segment Syndrome. That said, the guidelines of the American Society of Cataract and Refractive Surgery (ASCRS), American Academy of Ophthalmology (AAO), and Ophthalmic Outpatient Surgery Society (OOSS) recommends the use of tap water only when specified by the product's instructions for use, the latest critical water rinse⁶, as well as the Association periOperative Registered Nurses⁷.

Although there are differences in terms of recommendations, it is important to establish a control and monitoring program aimed at reducing risks for the patient and for maintaining instruments and equipment.

Water Quality Impacts on the Sterile Processing Department Detergent interactions

Chemical activity is a component of the Sinner's circle and is essential for efficient cleaning to be carried out². Detergent formulations contain surfactants, whose function is to allow water-insoluble dirt to become soluble through its molecule that contains a hydrophilic and a hydrophobic portion, acting as a bridge between water and dirt⁸.

Surfactants interact with water contaminants in the same way. During cleaning,

Table 1. Categories and recommended levels of water quality for medical device reprocessing

Specifications	Units	Utility water	Critical water
Hardness	mg/L	< 150	<1
Conductivity	µS/cm	< 500	<10
pH		6 - 9	5-7
Chlorides	mg/L	< 250	<1
Bacteria	cfu/mL	n/a (< 10)*	<10
Endotoxin	EU/mL	n/a (< 20)*	<10

*After high-level disinfection
Source: AAMI TIR34, 2014⁴.

Table 3. Water quality for pre-cleaning, cleaning and rinsing (before disinfection)*

Substance or parameter	Before disinfection
Water hardness	< 150 mg/L
Chloride	< 120 mg/L

*Source: Gastroenterological Society of Australia, 2021⁵.

the use of hard water with a high concentration of calcium and magnesium ions reduces the surfactant available for cleaning medical devices because of the formation of insoluble and chemically inactive salts, compromising the cleaning efficiency^{8,9}.

Another important variable that can interfere with enzymatic activity is pH, especially in the cleaning steps when detergent is used, thus, the instructions for use of each solution must be considered so that the enzymatic activity is not compromised⁴.

Instrument conservation

Surgical instruments are made of stainless steel; however, they are not indestructible. Stainless steel is composed of iron, carbon, chromium, nickel, manganese, silica, and other metals. Surgical instruments made of stainless steel undergo a process called passivation, which makes them less "reactive" and therefore less susceptible to corrosion^{10,11}.

The process of forming the passive layer can be carried out by treating the instrument's surfaces

Table 4. Water quality for automated flexible endoscope reprocessors final rinse water*

Substance or parameter	Before disinfection
Chemical purity	As per manufacturer's instructions
Total viable count	≤ 10 cfu/100 mL
Pseudomonas aeruginosa and atypical Mycobacterium species	Nil detected/100 mL
Endotoxin	≤30 EU/mL

*Source: Gastroenterological Society of Australia, 2021⁵.

with substances that remove iron from the surface, but maintain the chromium, which is the metal responsible for the "passive" characteristic of the instrument. When broken, the passive layer can "regenerate" when exposed to air, however in the presence of dirt there will be no exposure to air and regeneration will not occur¹¹.

Certain chemicals and contaminants in the water used in reprocessing can also damage the passive layer, in addition to various stains on instruments and equipment. Table 5 summarizes the most common problems related to poor water quality and their potential causes.

In general, the investigation to determine the causes of stains involves the following activities (Table 6).

In the case of new surgical instruments, they must be removed from the

plastic packaging as this material allows condensation which can cause rust. Additionally, they must undergo reprocessing to remove oils and other residues derived from the manufacturing process¹⁰.

Adverse events

Adverse events resulting from contamination of the water used in the reprocessing of medical devices can be TASS, aseptic loss of implants, and pyrogenic reactions. Cases listed below will be described to illustrate the importance of using critical water for the last rinse, and also in the generation of steam as preventive measures.

Ophthalmology: The reported cases of TASS are associated with contamination of the instruments due to water. There are cases involving endotoxins¹² and inorganic contaminants¹³. One study evaluated the cytotoxicity of cannulas for hydrodissec-

Table 5. Examples of observed problems during device reprocessing that can be caused by poor water quality:

Problems	Potential causes
Residual dirt	Inefficient cleaning.
Instrument surface damage: Corrosion Pitting Rusting Stress fracture	- Drying of dirt on the surface - Exposure to some chemicals (e.g. saline solutions, chlorine, and low acidic or high alkaline chemistries) - Chlorinated water (especially when heated) or high/low pH water
Loss of color	- Exposure to some chemicals (e.g. chlorine solutions, and low acidic or high alkaline chemistries) - Chlorinated water (especially when heated) or high/low pH water
Discoloration	Excessive heating to stainless steel surfaces, combined with various water deposits
Gold-brown	
Orange-brown	Phosphate layer developing on surface (from poor water quality and even some phosphate-containing cleaning chemistries that are not rinsed correctly); often seen as orange-brown discoloration
"Rainbow"	Chromium oxide development observed as a "rainbow" stain that develops over time (and can include various blue-brown colors from the presence of copper and iron)
Black or purple staining (commonly observed after steam sterilization)	- High or low pH residuals remaining on the device following cleaning - Can be from water quality or insufficient rinsing (or neutralization) with low acidic or highly alkaline cleaning chemistries
White staining or deposits (observed following drying or steam sterilization)	- Water hardness - Combination with Other chemical contaminants (such as copper and iron) to give different colors - Other chemical residuals (e.g., residuals from inadequate rinsing of cleaning chemistries, other water contaminants such as silicon oxide)
White, chalky buildup in the water lines, lumens, and valves of an automated processor	High volume of water with high mineral content, resulting in mineral buildup
Biofilm (Slime development over time, often appearing as different colors)	- Ineffective maintenance of devices/equipment - Inadequate contact (during cleaning/ disinfection) and poor water draining (e.g., pooling)

Source: Adapted from AAMI, 2014⁴.

Table 6. Investigation of stains on surgical instruments: activities and verification items.

Activity	Items to be verified:
Audit the instrument processing steps	Point-of-use cleaning procedures, disassembly of surgical instruments for cleaning, bristles of cleaning brushes, dilution of chemical solutions, manual and automated cleaning procedures, drying, inspection, packing, instructions for use compliance.
Review cleaning and sterilization equipment maintenance	Maintenance and qualification of cleaning and sterilization equipment, steam generator, steam supply network and pipes, water treatment systems, instructions for use compliance.
Inspect and remove instruments with rust	Visible rust, corrosion, and pitting (rust may transfer and "seed" onto quality instruments. *)
Review storage conditions (*instruments stored wet are subject to rust)	Instrument and packaging humidity, ambient humidity within acceptable limits, furniture and surfaces clean and dry.
Test water quality used in the various stages of processing	Control and monitoring of water according to each stage of reprocessing and the conditions required by the TIR34 and other applicable documents.

*Seavey, 2015¹⁰.

tion subjected to challenge contamination, including cleaning based on a validated standard operating procedure (SOP) and final rinsing in different water qualities, demonstrating the absence of cytotoxicity, regardless of the quality of water used in the last rinse. However, the authors highlighted that the data were obtained from new instruments, that is, in a good state of conservation¹⁴. Considering the importance of water for the conservation of instruments, the authors did not recommend the use of tap water, therefore, the TIR34 recommendations must be followed. Another relevant aspect observed by the authors is the importance of adherence to cleaning SOPs, due to the high level of cytotoxicity of dirty instruments, since the last rinse will not compensate for poor cleaning.

Orthopedics: Instruments for orthopedic surgeries present a high level of complexity, favoring the retention of dirt¹⁵⁻¹⁸ and endotoxins after cleaning and rinsing with drinking water, especially intramedullary cutters and femur scrapes¹⁹. In the case of flexible cutters, the retention of dirt can be cumulative between the steel blades that make up the flexible body and the toxicity of the accumulated residual is unacceptable for use²⁰. It's likely this problem can be accentuated with endotoxins coming from rinse water when not properly treated. Endotoxins may also be related to the aseptic loss of implants, with adherence to cleaning and final rinsing SOPs with critical water being essential^{21,22}.

Cardiac catheterization: The main adverse event reported is the pyrogenic reaction caused by endotoxins after cardiac catheterization, in which patients developed fever and chills, with or without hypotension^{23, 24}. A literature review on cardiac catheter reprocessing identified three articles reporting cases of pyrogenic reactions with a potential common cause: inappropriate water quality²⁵. In one of the studies, an increase in the amount of endotoxins and microorganisms was observed in distilled water stored by the hospital and used in the processing of

catheters²³. The results demonstrated that water storage can be one of the critical factors in controlling water quality. In the studies found in the review, interventions to contain the cases were limited to the use of endotoxin-free water, sanitization of water distribution systems, and sterilization of catheters on the same day of reprocessing (possibly, the catheters would be less exposed to residual moisture and consequent contamination). These results reinforce the need to use critical water to prevent pyrogenic reactions.

Conclusion

The quality of cleaning water must be controlled for the following reasons:

- Ensure the effectiveness of dirt removal, avoiding the reduction of detergent activity.
- Avoid recontamination of instruments with rinse water residues, including microorganisms and endotoxins.
- Preserve surgical instruments, preventing pitting, corrosion, and various stains.
- Maintain equipment efficiency, avoiding encrustations in pipes, chambers, and resistances.
- Ensure that medical devices are free from toxic waste capable of causing adverse events. **HPN**

Jeanne Aparecida Gonzalez Bronzatti: Registered Nurse, Master and Doctor in Science. Management specialist in healthcare units. Healthcare consultant in Medical Device preparation and usage. National and International Speaker.



Rafael Queiroz Souza: Registered Nurse, Master, Doctor and Post-Doctor in Sciences from the University of São Paulo; Specialist in teaching and production of knowledge related to safety in the reprocessing of medical devices



References

1. Rutala WA, Weber DJ. Healthcare Infection Control Practices Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities [internet]. Atlanta: Center for Diseases Control and Prevention. HICPAC; 2008. Available from: http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008. Accessed January 11, 2022.
2. Sinner H. Über das Waschen mit Haushaltswaschmaschinen: In welchem Umfange erleichtern Haushaltswaschmaschinen und geräte das wäschehaben im Haushalt? Hamburg: Haus+Haim Verlag; 1959.
3. World Health Organization. Decontamination and reprocessing of medical devices for health-care facilities. World Health Organization. 2016. Available from: <https://apps.who.int/iris/handle/10665/250232>. Accessed January 11, 2022.
4. Association for the Advancement of Medical Instrumentation (AAMI). Water for the reprocessing of medical devices. Arlington: AAMI; 2014. (AAMI Technical information report 34. TIR34:2014).
5. Devereaux BM, Jones D, Wardle E, on behalf of the Infection Control in Endoscopy Committee. Infection Prevention and Control in Endoscopy 2021. Melbourne: Gastroenterological Society of Australia, 2021.
6. American Society of Cataract and Refractive Surgery, Ophthalmic Outpatient Surgery Society, American Academy of Ophthalmology. Guidelines for the Cleaning and Sterilization of Intraocular Surgical Instruments. 2018. Available from: <https://www.aao.org/clinical-statement/guidelines-cleaning-sterilization-intraocular#Approvals>. Accessed January 11, 2022.
7. Association of Perioperative Registered Nurses. Guideline Quick View: Instrument Cleaning. *AORN Journal* November 2020; 112 (5) 585-592. doi: <http://doi.org/10.1002/aorn.13254>.
8. Lyon S. Water quality and its impact on the decontamination process. *Managing Infection Control*. 2008; 82-97. Available from: <http://www.surgerytheater.com/document/1325112596.pdf>. Accessed January 11, 2022.
9. Panta G, Richardson AK, Shaw IC. Quality of water for reprocessing of medical devices in healthcare facilities in Nepal. *J Water Health* 1 August 2021; 19(4) 682-686. doi: <https://doi.org/10.2166/wh.2021.071>.
10. Seavey R. Nursing Lesson Plan: troubleshooting instrument stains. International association of Healthcare Central Service Materiel Management. 2015.
11. Kaiser HJ, Schwab P, Tiley JF. Spotting, Staining, and Corrosion of Surgical Instruments. *Infection control today*. 2000. Available from: <https://www.infectioncontrolday.com/view/spotting-staining-and-corrosion-surgical-instruments>. Accessed January 11, 2022.
12. Holland SP, Mathias RG, Morck DW, Chiu J, Slade SG. Diffuse lamellar keratitis related to endotoxins released from sterilizer reservoir biofilms. *Ophthalmology*. 2000 Jul;107(7):1.227-33.
13. Hellinger WC, Hasan SA, Bacalis LP, Thornblom DM, Beckmann SC, Blackmore C, Forster TS, Tiley JF, Ross MJ, Nilson CD, Mamalis N, Crook JE, Bendel RE, Shetty R, Stewart MW, Bolling JP, Edelhauser HF. Outbreak of toxic anterior segment syndrome following cataract surgery associated with impurities in autoclave steam moisture. *Infect Control Hosp Epidemiol*. 2006 Mar;27(3):294-8.
14. Souza RQ, Gonçalves CR, Ikeda TI, Cruz AS, Graziano KU. The impact of the final rinse on the cytotoxicity of critical products submitted for processing. *Rev Esc Enferm USP*. 2015; 49(Esp):86-91. doi: [10.1590/S0080-623420150000700013](https://doi.org/10.1590/S0080-623420150000700013).
15. Blevins FT, Salgado J, Wascher DC, Koster F. Septic arthritis following arthroscopic meniscus repair: a cluster of three cases. *Arthroscopy*. 1999; 15(1):35-40. doi: [10.1053/ar.1999.v15.015003](https://doi.org/10.1053/ar.1999.v15.015003).

16. Parada SA, Grassbaugh JA, Devine JG, Arrington ED. Instrumentation-specific infection after anterior cruciate ligament reconstruction. *Sports Health*. 2009; 1(6):481-5. doi: 10.1177/1941738109347975.
17. Tosh PK, Disbot M, Duffy JM, Boom ML, Heseltine G, Srinivasan A, Gould CV, Berrios-Torres SI. Outbreak of *Pseudomonas aeruginosa* surgical site infections after arthroscopic procedures: Texas, 2009. *Infect Control Hosp Epidemiol*. 2011; 32(12):1179-86. doi: 10.1086/662712.
18. Lucas AD, Nagaraja S, Gordon EA, Hitchins VM. Evaluating Device Design and Cleanability of Orthopedic Device Models Contaminated with a Clinically Relevant Bone Test Soil. *Biomed Instrum Technol*. 2015 Sep-Oct;49(5):354-62. doi: 10.2345/0899-8205-49.5.354.
19. Goveia VR, Mendoza IYQ, Guimarães GL, Ercole FF, Couto BRGM, Leite EMM, et al. Endotoxins in surgical instruments of hip arthroplasty. *Rev Esc Enferm USP*. 2016;50(3):405-410. DOI: http://dx.doi.org/10.1590/S0080-623420160000400005.
20. Souza R, Bronzatti J, Laranjeira P, Mimica L, Silva C, Cruz A, Graziano K. Safety assessment of reprocessing of flexible intramedullary bone reamers for orthopedic surgery. *Revista SOBECC*. 2017; 22(1):17-22. doi: 10.5327/Z1414-4425201700010004.
21. Greenfield EM, Bi Y, Ragab AA, Goldberg VM, Nalepka JL, Seabold JM. Does endotoxin contribute to aseptic loosening of orthopedic implants? *J Biomed Mater Res B Appl Biomater*. 2005 Jan 15;72(1):179-85. doi: 10.1002/jbm.b.30150.
22. Wang G, Zhang P, Zhao J. Endotoxin Contributes to Artificial Loosening of Prostheses Induced by Titanium Particles. *Med Sci Monit*. 2018 Oct 2;24:7001-7006. doi: 10.12659/MSM.910039.
23. Reyes MP, Ganguly S, Fowler M, Brown WJ, Gatmaitan BG, Friedman C, Lerner AM. Pyrogenic reactions after inadvertent infusion of endotoxin during cardiac catheterizations. *Ann Intern Med*. 1980 Jul;93(1):32-5. doi: 10.7326/0003-4819-93-1-32. PMID: 7396310.
24. Kundsins RB, Walter CW. Detection of endotoxin on sterile catheters used for cardiac catheterization. *J Clin Microbiol*. 1980 Mar;11(3):209-12. doi: 10.1128/jcm.11.3.209-212.1980. PMID: 7380997; PMCID: PMC273364.
25. Ribeiro, SMCP et al. Reuse of cardiac catheters: a review. *Brazilian Journal of Cardiovascular Surgery*. 2006; 21(3):334-342. Available from: <https://doi.org/10.1590/S0102-76382006000300014>.

CONTINUING EDUCATION TEST • FEBRUARY 2022**Water for cleaning medical devices**

Circle the one correct answer:

- Cleaning is a procedure used to remove organic and inorganic matter, except hemoglobin.
A. True B. False
- The Sinner cycle requires time, mechanical action, temperature, and chemical activity.
A. True B. False
- Utility water is mainly used for flushing, washing, rinsing, and steam generation.
A. True B. False
- Medical devices such as endoscopes and ophthalmic instruments may require additional guidance on pre-cleaning and water quality. That said, additional manufacturer guidelines must be followed.
A. True B. False
- Cleaning can be compromised by both the pH of the water and the hardness of the water.
A. True B. False
- The passive layer of surgical instruments is formed by the enrichment of surface iron, which takes place through the removal of chromium, providing corrosion resistance.
A. True B. False
- Excessive chlorine in the water is responsible for the formation of deposits on the instrument surface and the clogging of water pipes.
A. True B. False
- Pooling in automated cleaning equipment, generally due to drainage failure, can induce the formation of biofilm on the equipment.
A. True B. False
- Adverse events resulting from contamination of the water used in the reprocessing of medical devices can be TASS, aseptic loss of implants, and pyrogenic reactions.
A. True B. False
- Instrument rinsing water can become contaminated during storage; therefore, this is one of the critical points in water quality control.
A. True B. False

CONTINUING EDUCATION TEST SCORING

HSPA | **HEALTHCARE STERILE PROCESSING ASSOCIATION**
The approval number for this lesson is
3M-HPN 221401.



HPN is thrilled to now offer all CEU quizzes online by scanning the QR code on the right or visiting: <https://educationhub.hpnonline.com>.
The cost to take the quiz online remains at \$10.

Due to rising costs if you would like to mail in your completed quiz using the method below the price is now \$50 for each test taken.

Request for Scoring

☐ I have enclosed the scoring fee of **\$50 for EACH test taken** — payable to **Endeavor Business Media**. We regret that no refunds can be given. (It is not necessary to submit multiple tests separately.)

Detach exam and return to:

Continuing Education Division
Healthcare Purchasing News
2477 Stickney Point Road, Suite 221B
Sarasota, FL 34231

