HEALTHCARE PURCHASING NEWS

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LEARNING OBJECTIVES

- ***Describe device reprocessing steps and its complexity in dental settings.***
- ***Provide recommendations on how to address reprocessing challenges.***
- ***Explain performance of reprocessing equipment to get the best possible outcomes.***

SELF-STUDY SERIES

Removing the mystery from reprocessing

Concepts and first steps for reprocessing in the dental setting

by Nita Mazurat, DDS

Reprocessing is the science and practice of preparing instruments and devices for use and reuse in patient care. To many dental personnel, reprocessing of instruments when they were students was a magical, if not mysterious process, where contaminated devices were exchanged for clean and sterile ones. This mythical component remains for many clinicians since they do not (nor have time to) participate in reprocessing activities in their practices. Fortunately, oral healthcare knowledge of reprocessing, both what to do and how to do it, has advanced through awareness and adoption of established Reprocessing Standards: AAMI ST79:2017 in the United States and Canadian Standards Association (CSA) Z314-18 in Canada. Both standards were developed for use in all healthcare settings with emphasis on the hospital setting; although CSA is planning to develop a standard with a focus on non-hospital or 'community' users.

Reprocessing is a great deal more than a 'sterilizer in a room' and is comprised of many steps.

Steps for reprocessing:

- ✓Cleaning at chairside, also known as 'cleaning at point of care'
- ✓Transport to the central sterilization area
- ✓Pre-cleaning and disassembly of devices (eg mirrors, composite guns, syringes)
- ✓Cleaning, rinsing
- ✓Drying
- ✓Inspection
- ✓Testing for functionality
- ✓Packaging
- ✓Monitoring
- ✓Sterilization (loading and unloading)
- ✓Storage
- ✓Traceability
- • Aseptic presentation

Aseptic presentation is not part of reprocessing, however, because it includes removal of sterile devices from their packaging for patient care. Contamination during operatory set up can negate the careful work of the previous steps.

Manufacturers' instructions for use

During reprocessing, critical decision making is a skill that must be accompanied by strict adherence to instructions from the manufacturer for products and procedures to achieve cleanliness, functionality, and sterility. Let's examine some of these hallmark concepts surrounding manufacturers' instructions for use (IFUs). Please note that these concepts are not in any order and they are all important! All of our activities are driven by the need for patient safety.

- Only instruments and devices, from here forward simply referred to as 'devices,' manufactured with the intent of use and licensed for use in healthcare should be used in healthcare as these have had to be demonstrated to be safe for use during patient care. 'Do no harm' is the overlying umbrella for patient care.
- Devices developed for use in healthcare are 'labeled', meaning that the manufacturer has to provide instructions for their reprocessing.

1. Obtain and follow manufacturers' instructions for use, known as MIFUs in Canada and IFUs in the United States.
Assumptions about how to reprocess may result in devices that are not sterile and therefore, not safe for patient care. Only the manufacturer knows the composition of the device and how it should optimally be reprocessed to prevent premature degradation of the device while providing

instructions to achieve sterility. Manufacturers are required to provide instructions for reprocessing for all classes of instruments, which should include the necessary information required by the FDA (United States) and Health Canada (Canada)[1] from preparation at point of care to storage.

In the excitement of purchasing new devices, it is easy to forget that the first question to ask is 'how will this be reprocessed?' and it will take a team effort to remind each other to develop this change in purchasing practices. Requesting the manufacturers' IFUs prior to purchasing any devices is done to ensure that:

a) The written reprocessing instructions provided by the manufacturer adhere to ISO standards. Preferably these instructions are 'validated'. Validated instructions are instructions that have been shown either by the manufacturer labs or by an independent testing company to verify that when the reprocessing instructions provided by the manufacturer are followed, this will result in a sterile device.[2]

b) Equipment required for reprocessing is available in your office. For example, your hygienists recommend purchasing a new type of highspeed suctioning device that would be more effective during ultrasonic scaling. Upon checking the instructions for reprocessing it was found that the manufacturer had only provided the IFUs of a gravity sterilizer. Even after contacting the company, no instructions were provided for use with a dynamic-air-removal sterilizer. Since your office uses a steam flush pressure pulse (SFPP) sterilizer (a type of dynamic-air-removal sterilization), your office would not be able to sterilize the device because the device has only been tested (validated) in a gravity sterilizer.

Reprocessing is tailored and is not a 'one set of sterilization parameters fits all' process. Until the manufacturer is able to provide instructions for the type of sterilizer that you have in your office, you are not able to reprocess the device, and therefore should not buy it. Only buy what you can clean and sterilize!

One further comment: Often a manufacturer's representative will try to be helpful by providing their assurance that the device can be sterilized using 'a standard cycle.' Unless those assurances are provided by the manufacturer using written instructions, wait for the validated instructions prior to purchase.

2. Devices that do not have IFUs, cannot be reprocessed and are considered single use items.

Some single use items such as burs, may come with IFUs for reprocessing prior to use only. Many disposable cotton products such as gauze, rolls, pellets, and tipped applicators, should not be reprocessed prior to use because they do not have instructions for reprocessing and sterilization only is not 'reprocessing.' This is a practice so commonly performed in healthcare, especially for providing 'sterile' cotton gauze following surgery, that it has become normalized; however, if the office is unable to purchase gauze with validated IFUs and sterile materials are required, then these disposable products need to be purchased sterile.

3. Surfaces must be clean prior to sterilization or disinfection.

Cleaning is the most important step in reprocessing because a soiled instrument cannot be effectively sterilized as the soil shields the bacteria and viruses from the sterilizing agent.

So, this begs the question: what is clean? This question can be addressed by understanding the monitoring tools and methods employed on the cleanliness assessment, which can be described in two groups: qualitative and quantitative.

Qualitative assessment methods are based on observation (which will vary based on the observer, the light conditions, magnification, etc.) or based on devices called markers (e.g. protein or blood); which will react to certain soils by way of color change and therefore providing results.

On que quantitative methods, adenosine triphosphate (ATP) is the most common technology, providing a quantitative result evidencing that organic soil has been sufficiently reduced, enabling devices for future reprocessing steps.

Another important consideration is that devices decontaminated in automatic equipment, often will be disinfected as well, thanks to the higher temperature of the cycles.

4. Cleaning should be directed by the IFUs

All cleaning requires the use of specified cleaning agents; specified water, including temperature and type, especially for the final rinse to remove residual detergent and minerals that are present in tap water; and specific equipment. Water hardness, the concentration of certain minerals, will reduce the efficiency of cleaning agents because the minerals bind with the cleaning agents such as detergents and enzymes. Knowing the water hardness in your facility and receiving guidance when purchasing cleaning agents based on this important variable can be very useful in preventing staining and premature degradation of devices.

a) Manual cleaning

Manual cleaning includes the use of appropriate brushes that are designed and purchased for this purpose. Because brushes, both toothbrushes and denture brushes, are readily available in dental offices, these are convenient and often used. However, these brushes have been carefully designed to be used for oral hygiene, not for cleaning devices. Additionally, since the oral hygiene brushes do not come with IFUs, they may not achieve optimal results for cleaning devices.

Some devices, like lumens, present their own unique challenges. There are open-ended lumens, such as hygiene handpieces that are open at both ends, that require open-ended brushes, and closed-ended lumens for areas such as the lumen in the handle, when mirrors are disassembled (check the instructions for disassembly for mirrors that are not solid state). Brushes used for cleaning lumens need to be large enough to be effective on the inner walls without being difficult to brush back and forth. Open-ended brushes need to be long enough to extrude from the distal end of the lumen. End-cleaning brushes have a 360-degree fan brush at one end for cleaning the resultant solid wall as well as the lumen. Because the cleaning of lumens is a resource-intense step, many offices have switched to disposable items when they are readily available, including air/water syringe tips and high-volume suction tips.

All cleaning and rinsing should be performed in sinks filled with water to allow full immersion of the devices so that they are cleaned and rinsed underwater (not in running water) to avoid producing spatter and aerosols.

Self-Study Test Answers: 1. B, 2. A, 3. A, 4. A, 5. A, 6. B, 7. A, 8. B, 9. A, 10. B

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b) Ultrasonic cleaning

Ultrasonic cleaning occurs when the bubbles caused by high frequency sound waves in the cleaning solution implode causing cavitation, which draws debris from the surfaces of the devices. Ultrasonic cleaners can be a single tank or multiple tank device and various sizes can be purchased.

If this is the cleaning method of choice in your office, consider the capacity that will be required for efficient cleaning, remembering that ultrasonic cleaning works because all surfaces of the devices are exposed to the solution and overcrowding will reduce the effectiveness of cleaning. Other factors that affect the efficiency of ultrasonic cleaning are:

- Using the correct cleaning agent and maintaining the required level of solution to ensure that devices being cleaned can always be submerged. Follow manufacturers' instructions for the solution specified as these remove debris in the way that the ultrasonic cleaner was designed to work. Know the target soil. Enzymatic assists in removing dried blood and in offices where the majority of procedures performed are surgical, and this would be the preferred cleaning agent. However, in an office that is mostly restorative or orthodontic, a cleaning agent that targets inorganic materials such as luting cements and restorative materials, will be more applicable. Follow the IFUs for correct dilution, correct volume of diluted agent in the ultrasonic tank, and correct water temperature. Cleaning and disinfecting the tank when changing the solution helps to reduce the microscopic bioburden.
- Removing gas bubbles caused largely by trapped air when fresh cleaning agent is placed into the tank. The bubbles need to be expelled by running or 'degassing' the ultrasonic without instruments in the tank for the time specified by the manufacturer, so these gas bubbles do not interfere with further cleaning.
- Placing the devices being cleaned in a tray or basket designed for use in the tank to allow more accessibility to cavitation and prevent the devices from touching the walls and floor of the ultrasonic tank. Stainless steel instruments should not be mixed with aluminum, brass or copper instruments in a sonic cycle as this may cause galvanic reactions that result in corrosion.
- Removing gross debris from the devices prior to ultrasonic cleaning. Clean the devices at point of care and in the reprocessing area by rinsing the devices prior to placing into the tank. When the ultrasonic cleaning solution has less debris, cleaning action is more effective. Rinsing is more effective when devices are immersed using the basket designed to be used in the ultrasonic in water and allowing this to drain prior to placement into the cleaner to remove excess water and gross debris. Lumens should be manually cleaned prior to placement into the ultrasonic washer.
- Following the ultrasonic cleaner instructions for use for loading. A single layer of instruments should only be cleaned at a time so that cavitation can reach every surface. When instruments are stacked, cavitation may be unattainable to every surface. Many dental offices use ultrasonic cleaners that are too small for the volume of instruments and devices that are used in the office, which in turn results in overfilled ultrasonic cleaners with poor cleaning results. Ensure that all items are submerged and that hinged devices are open to allow cleaning.
- Rinsing following cleaning removes residual solution and soil which need to be removed before the next steps in reprocessing. Fully immerse the instruments into the sink used for rinsing using the quality of rinse water required by the manufacturer of the devices.

Ultrasonic cleaners should be run with the lid on to prevent escape of microorganisms into the ambient office air.

Cleaning efficacy or a function test is required at least once weekly, preferably daily, either using a foil test or using a commercial ultrasonic cleaner test.

c) Automated washers

The key here is the word 'automated'. As long as MIFUs exist regarding detergents, water including type of water used and water temperature, and office personnel allow complete cycles to run, there is less human error to intervene in the cleaning process surrounding washers. Just as with ultrasonic cleaners, stainless steel instruments should not be mixed with aluminum, brass or copper instruments during cleaning in a washer or washer/disinfector. As stated earlier, the final level of clean is visual when using a washer, whereas it is microscopically clean using a washer/disinfector. The consequences of this are substantial in how devices are able to be handled in the remaining steps of reprocessing.

Key takeaways:

1. Users should request validated instructions for reprocessing before purchase of devices as well as requesting clarification for instructions for existing devices in the office inventory that are unclear, incomplete, or require parameters of sterilization that vary from the normal expected cycles.
2. Users must assemble and follow the instructions for the entire office inventory of devices.
3. Terms used in this article need to become commonplace when discussing reprocessing in oral healthcare offices. HPN

References

1. Guidance Document: Information to be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices, https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-information-manufacturers-sterilization-reusable-medical-devices.html (accessed October 2020)

2. Miller, C and Palenik, CJ Infection Control and Management of Hazardous Materials for the Dental Team: Mosby

3. https://www.iahcsmm.org/images/Lesson_Plans/CRCST/CRCST153.pdf (accessed October, 2020)

Dr. Nita Mazurat is an Educational Consultant to 3M Health Care. *Dr. Mazurat is an Associate Professor, Department of Restorative Dentistry, University of Manitoba, Winnipeg, Manitoba, Canada where she is the clinical dentist for Screening for the undergraduate programs in Dentistry and Dental Hygiene, Director of International Students, and Coordinator of Regulatory Compliance including Infection Prevention and Control. Nita has been a member of OSAP since 2005 and is a proud international editor to ICIP. She is also a member of IPAC (Infection Prevention and Control, Canada), CAMDR (Canadian Association of Medical Device Reprocessing, CSA (Canadian Standards Association) Technical Committee on Sterilization, and SCC (Standards Council of Canada, Canada's accreditation body) and is currently awaiting to hear whether or not she will be selected as an advisor to PHAC (Public Health Agency of Canada) representing oral healthcare professionals. Her passion for Infection Control is matched only by her passion for her family, her husband of 42 years and their three children, and golf.*

CONTINUING EDUCATION TEST • DECEMBER 2020

Removing the mystery from reprocessing

Concepts and first steps for reprocessing in the dental setting

Circle the one correct answer:

1. **Reprocessing of medical devices in the dental setting is done only according to internal facility policies.**
   A. True
   B. False
2. **Decontamination of medical devices is conducted with a multi-step approach, generally known as reprocessing.**
   A. True
   B. False
3. **Devices to be used in healthcare facilities should have instructions for use.**
   A. True
   B. False
4. **One key question to ask when procuring a new device is: How will this device be reprocessed?**
   A. True
   B. False
5. **Cleaning is the most important step in reprocessing.**
   A. True
   B. False
6. **Chairside cleaning includes sterilization and packaging.**
   A. True
   B. False
7. **One type of device that poses an additional reprocessing challenge is a lumened device.**
   A. True
   B. False
8. **Cavitation increase the ability of steam to penetrate the lumens.**
   A. True
   B. False
9. **Degassing (removing gas bubbles) in ultrasonic equipment must be done without instruments in the ultrasonic unit.**
   A. True
   B. False
10. **Automated washers are equipment that completely remove human errors from reprocessing.**
    A. True
    B. False

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Instrumental to Patient Care

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