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## 3.6 Reprocessing

### Background

'Reprocessing' is a general term used to describe the steps taken to prepare medical instruments/devices for use. It can include cleaning, disinfection, and or sterilization. Reprocessing often occurs throughout the hospital setting, in dedicated areas such as Central Services Departments and endoscope reprocessing areas, as well as areas that are not centered on reprocessing, like ambulatory care clinics and patient units.



Although not as easily identifiable, reprocessing occurs in the long-term care setting as well. Instruments such as foot care equipment, wound care items, and ear syringes, are all examples of equipment commonly found in long-term care that requires reprocessing. It is important for an ICP in the long-term care setting to understand the complexity of the reprocessing process, in order for he/she to objectively evaluate the reprocessing practices happening in his/her setting.

### The ICP Role



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Reprocessing is a complex process often involving multiple steps. Too often individuals underestimate the time, dedication, and complexity of reprocessing. The ICP must be an advocate for appropriate reprocessing of instruments. He/she must be on the alert for areas that are reprocessing instruments incorrectly, and must have the authority to take action when an area of concern is identified.

The ICP must have a sound understanding of the various types of reprocessing and must understand the methods by which each type of instrument must be reprocessed. At times, the ICP may wish to conduct reprocessing audits to verify what is being reprocessed where, and the methods by which items are being reprocessed.

The ICP has an integral role in educating others about the principles of reprocessing. Teaching others that reprocessing is a process and not a single action, is vital to ensuring that reprocessing efforts in healthcare settings receive the time and attention it requires.

### Key Concepts

**Definitions** (taken from PIDAC's Best Practice document<sup>1</sup>)

**Biological Monitor** Spore-laden strips or vials that are used to monitor the effectiveness of the sterilization process

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<b>Cleaning</b>	The physical removal of foreign material (e.g. dust, soil, organic material such as blood, secretions, excretions, and microorganisms). Cleaning physically removes rather than kills microorganisms. It is accomplished with water, detergents, and mechanical action. Thorough and meticulous cleaning is required before any equipment/device may be decontaminated, disinfected and/or sterilized
<b>Decontamination</b>	The process of cleaning, followed by the inactivation of microorganisms, in order to render an object safe for handling
<b>Disinfection</b>	The inactivation of disease-producing microorganisms. Disinfection does not destroy bacterial spores. Medical equipment/devices must be cleaned thoroughly before effective disinfection can take place
<b>High Level Disinfection</b>	The level of disinfection required when processing semicritical medical equipment/devices. High level disinfection processes destroy vegetative bacteria, mycobacteria, fungi and enveloped (lipid) and non-enveloped (non-lipid) viruses, but not necessarily bacterial spores. Medical equipment/devices must be thoroughly cleaned prior to high level disinfection
<b>Indicator</b>	Indicators reveal a change in one or more of the sterilization process parameters. They do not verify sterility, but they do allow the detection of potential sterilization failures due to factors such as incorrect packaging, incorrect loading of the sterilizer, or equipment malfunction
<b>Low Level Disinfection</b>	Level of disinfection required when processing noncritical medical equipment/devices or some environmental surfaces. Low level disinfectants kill most vegetative bacteria and some fungi as well as enveloped (lipid) viruses. Low level disinfectants do not kill mycobacteria or bacterial spores. Medical equipment/devices must be thoroughly cleaned prior to low level disinfection
<b>Reprocessing</b>	The steps performed to prepare used medical equipment/devices for use (e.g. cleaning, disinfection, sterilization)
<b>Sterilization</b>	The level of reprocessing required when processing critical medical equipment/devices. Sterilization results in the destruction of all forms of microbial life including bacteria, viruses, spores, and fungi. Equipment/devices must be cleaned thoroughly before effective sterilization can take place

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## Classification of Instruments

Instruments and devices can all be classified according to Spaulding's Classification. This method of classification was developed in 1968 by Earle Spaulding to assist clinicians in determining how items needed to be reprocessed based on the level of risk associated with their use.

Below is a chart outlining the three categories of Spaulding's Classification. This chart includes examples of types of equipment in each classification. A more thorough list, based on Spaulding's Classification, can be found in PIDAC's *Best Practices for Cleaning, Disinfection, and Sterilization In All Health Care Settings* document.<sup>1</sup>

Spaulding's Equipment/Device Classification	Definition	Minimum Reprocessing Requirement	Equipment Examples
<b>Critical</b>	Enters sterile tissue/sterile body site, including the vascular system	<b>Sterilization</b>	Surgical instruments, foot care equipment, endoscopes that enter sterile cavities, dentistry equipment
<b>Semi-Critical</b>	Comes into contact with non-intact skin or mucous membranes but does not penetrate them	<b>High Level Disinfection</b>	Endoscopes that do not enter sterile tissue, respiratory equipment, breast pump accessories, speculums
<b>Non-Critical</b>	Touches only intact skin and not mucous membranes, or does not directly touch the patient at all	<b>Low Level Disinfection</b> (in some cases cleaning alone will suffice)	Environmental surfaces, bedpans, stethoscopes, blood pressure cuffs, baby scales

## Decontamination

Any instrument to be reprocessed must be decontaminated first. Decontamination is a process that renders a piece of equipment safe for handling without personal protective equipment.<sup>1</sup> It is the 'cleaning' phase of reprocessing. An item that has not been decontaminated cannot be effectively reprocessed. It has been said that decontamination is the most important step to reprocessing equipment and devices.


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In a Central Processing Department, decontamination occurs in a separated, designated area. Staff members working in decontamination are required to wear appropriate PPE and cannot leave the area before removing their PPE and performing hand hygiene. The area has specific requirements for air flow, temperature, and humidity, as well as the choice of materials and equipment found in the area.



In areas other than Central Processing Departments, such as long-term care homes or clinic settings, it is imperative that individuals conducting reprocessing understand the importance of the decontamination phase of reprocessing. You cannot sterilize or disinfect soiled instruments, so proper decontamination is essential no matter what setting you are from.

### **Single Use Devices**

Some medical equipment has been deemed single-use by the manufacturer. Devices that are deemed single-use are indicated using a . Any semi-critical or critical item labeled as single use must not be reprocessed and reused, unless it is done so by a licensed reprocessor. At the time of the development of this resource, no licensed reprocessor is available in Canada.

In the past, some designated single-use devices were reprocessed in healthcare facilities to save money. The ICP should be on the look out for devices that are designated as single-use and should ensure that they are being disposed of appropriately.

### **Reprocessing Areas**

Best Practices suggest that reprocessing should occur in a centralized area. For most healthcare equipment, including surgical instruments, this centralized area is often known as the Central/Sterile Processing Department (CPD or SPD). Facilities should make every effort possible to ensure that as much of the instrument reprocessing as possible is conducted in this designated area. The more areas conducting reprocessing, the more difficult it is to control and monitor practices. In addition, strict environmental factors must be maintained, such as temperature, humidity, water quality, and air flow.



Identifying a designated area for reprocessing can be somewhat of a challenge in the non-acute care setting, including family practice offices and long-term care, for example. If reprocessing must occur in these types of settings, it is essential that a designated space is made available for reprocessing. The space must be adequate, providing enough room to separate the 'dirty', 'clean', and 'sterile' aspects of reprocessing.

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## **Monitoring**

There are a number of methods by which disinfection and sterilization processes can be monitored and verified.

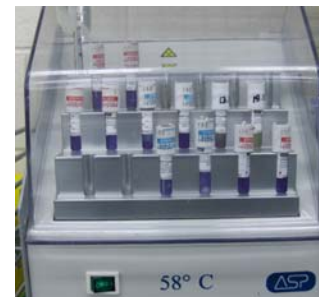
To begin, mechanical indicators are used to monitor sterilizer machinery. These indicators report on the parameters met during the various sterilization cycles. These time, temperature, and pressure indicators are often available by print-out from these machines and should be checked following each cycle.



Chemical indicators are used for instruments undergoing sterilization. Chemical monitors are often those that experience a colour change once a sterilant has contacted the indicator. Both external and internal chemical indicators are used. Tape on the outside of a wrapped package that changes colour during sterilization is an example of an external chemical indicator. Best Practice recommendations suggest that external chemical indicators should be used for each pack.

Internal chemical indicators are also available. Internal indicators are used to detect penetration into the pack. The indicator strips shown in the picture are examples of internal indicators and are used inside of sterile packs. All chemical indicators should be checked by staff members prior to utilizing the reprocessing equipment for care.

Lastly, biological indicators are indicators that actually test the success of the sterilization process. They consist of a bacterial spore being run through the sterilization cycle that is then incubated to test for kill. These indicators come in either strip form or vial form. Biological indicators (BI) should be used at the beginning of each day that a sterilizer is used as well as when any implantable devices are reprocessed. Many Central Processing Departments have mini-incubators in their setting in order to conduct the BI testing on-site. The picture to the right shows an example of such an incubator.



The test is read by observing for a colour change in the vials once the required time has elapsed.

## **Bowie Dick Test**



The Bowie-Dick test is a test that detects air leaks in systems that rely on air removal to achieve sterilization. Standard steam sterilizers are an example of this type of sterilizer. The test is composed of a visual indicator page sandwiched between a stack of papers. The Bowie-Dick test is then placed inside the sterilizer and run through a load. The visual indicator page is then examined for uniformity of colour change. If the colour change is not uniform, it indicates a problem with the air removal in the chamber. The Bowie-Dick test should be performed each day that the applicable sterilizer is used.

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While the indicators described above are primarily used when sterilizing, it is important to recognize the role indicators play when performing disinfection as well. For example, if a facility is using a liquid disinfectant for reprocessing of semi-critical devices, many such products require that test strips be used to ensure the product concentration is still appropriate for disinfection.

Be sure to investigate the need for test strips and other monitoring processes whenever your facility begins a new reprocessing practice.

### **Flash Sterilization**

Flash sterilization, also known as emergency sterilization, is a special steam sterilization cycle used for unplanned sterilization of instruments.<sup>2</sup> It is often done without wrapping the item (i.e. 'open pan sterilizing'). In the past, flash sterilization was a common practice in many operating rooms and was often used as a convenient method of compensating for an inadequate supply of instruments.

Often times when flash sterilization is conducted the instrument reprocessing process does not involve the same amount of time and care. Decontamination is minimal or non-existent, the cycle is shortened and does not involve a drying cycle, and the instrument is not wrapped so is left open to the air.

Because flash sterilization does not ensure the same level of reprocessing as the standard reprocessing methods, flash sterilization is now recommended for **emergency situations only**. Instrument shortages do not constitute an emergency.

Flash sterilization should **never** be used for implantable equipment/devices. An example of an emergency would be when an item has been dropped during an operative procedure and no appropriate alternative is available. Lack of instrument inventory and short operation turn-around times are not considered emergencies.

When flash sterilization is used, appropriate documentation must occur on both a flash sterilization log as well as the client's chart. See the Ontario Hospital Association/PIDAC fact sheet following this topic overview for further information.

### **Endoscope Reprocessing**

Most hospitals in Ontario perform procedures that require the use of endoscopes. Improperly disinfected endoscopes have been linked to the transmission of organisms. Hospitals must ensure that thorough processes are established and followed for the reprocessing of



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endoscopes. Endoscopes that do not enter sterile tissue, as is the case with standard endoscope procedures, require the use of a high level disinfectant. If any additional equipment is used that enters sterile tissue, such as a biopsy probe, then that item must undergo sterilization (or be disposed of if it is a single use device).

Comprehensive reprocessing standards for endoscopes have been published by the Society of Gastroenterology Nurses and Associates, Inc., most recently updated in 2008. They are available following this topic overview.

## **PIDAC**

PIDAC has a Best Practice document regarding instrument reprocessing entitled *Best Practices for Cleaning, Disinfection, and Sterilization in All Health Care Settings*. Covering a variety of topics including single use devices, occupational health and safety, environmental issues, decontamination, scope reprocessing, and much more, it can be found at [www.pidac.ca](http://www.pidac.ca).

## **References & Resources**

1. Provincial Infectious Diseases Advisory Committee. (2006). *Best practices for cleaning, disinfection, and sterilization In all health care settings*, [http://www.health.gov.on.ca/english/providers/program/infectious/diseases/best\\_prac/bp\\_cds\\_2.pdf](http://www.health.gov.on.ca/english/providers/program/infectious/diseases/best_prac/bp_cds_2.pdf)
2. Canadian Standards Association. (2002). *Recommended standard practices for emergency (flash) sterilization*. Toronto, ON: CSA