



# Purchasing a Steam Sterilizer Factors to Consider

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## **Steam sterilization is the “gold standard” of sterilization methods**

It kills microorganisms rapidly without the use of toxic chemicals. Unfortunately, it can only be used for reusable devices that tolerate high temperatures.

## **Types of Table-top Steam Sterilizers**

When purchasing a sterilizer, insist on written information from vendor or manufacturer demonstrating that the sterilizer is capable of sterilizing the devices and packaging used in your office.

Steam sterilizers replace air in its chamber with steam. Air is evacuated either through gravity displacement or by dynamic air removal. Dynamic air removal (as in pre-vacuum or vacuum sterilizers) is more efficient and is required for sterilizing several types of devices. Dynamic air removal sterilizers are generally preferred unless the office is sterilizing material that can only be sterilized by gravity displacement sterilizers (such as open liquids).

## **Prior to Purchasing**

Consider whether steam sterilization is cost-effective for your office. Single-use instruments or 3<sup>rd</sup> party reprocessing may make more sense than does reprocessing reusable devices in-house. Consider capital outlay, equipment maintenance, staff training and staff time, sterilizer packaging materials and quality control supplies.

Consider also whether the space in your office can accommodate reprocessing. It must allow for the required separation of soiled and clean devices and the steps in the cleaning process.

## **What to consider when choosing a third party reprocessor**

- Transportation arrangements and turn-around time
- Number and cost of instruments that you will need while some are away being reprocessed
- Reprocessing fees
- Proof that the 3<sup>rd</sup> party reprocessor meets accepted medical device reprocessing standards

## **What to consider when choosing to reprocess reusable medical devices in your office or clinic:**

- The purchase price of the sterilizer
- Time and cost required for daily testing and maintenance
- Cost of preventive maintenance and periodic testing
- Operational costs (electricity, distilled water, detergents, cleaners, insurance, etc.)
- Cost of additional instruments to accommodate prolonged cycle times
- Cost of training staff
- Cost of packaging
- Cost of Biological Indicator monitoring and other quality controls required by the manufacturer
- Cost of personal protective equipment (PPE) required for staff that reprocess.
- Time to document each load and results of monitoring
- Availability of adequate space to locate the sterilizer within the designated “clean” area where reprocessing will take place in your office. Prior to purchase, obtain dimensions (e.g. height, width and depth) of sterilizer to ensure that it will fit.

## **Purchasing a Sterilizer**

When seeking quotes from suppliers, it is important to specify the type of load and instruments you intend to reprocess. The manufacturer should state clearly the type of load and instruments for which the sterilizer is suitable. Purchase only the type of sterilizer that is suitable for the types of loads you intend to process.

**Ensure the sterilizer has a Health Canada medical device license.**

## **Consider the following:**

- Clarity of instructions for use and for maintenance (daily, monthly, annually)
- The number of instruments that will be reprocessed per load and per day
- Whether the devices are solid (e.g. forceps, dental probes) or porous or lumened (e.g. textiles, suction tips, dental hand-pieces)?
- For lumened devices, the limitations of the sterilizer with respect to length and diameter of lumens.
- The type of wrapping required and manufacturer’s instructions for use of wrap
- The presence or absence of a printer or electronic log for documenting each sterilizer cycle. It is recommended that this capability be present on the sterilizer at the time of purchase to facilitate the requirement to log physical parameters of each cycle.

## **Ensure that you have documentation which:**

- Specifies who is responsible for installation and for performing tests to ensure the sterilizer will perform to specifications.
- Specifies the qualifications of technical service providers
- Indicates that the sterilizer can sterilize the medical devices you will be using
- Indicates how to load the sterilizer (e.g. lumened instruments, hollow instruments, textiles, power tools, dental hand pieces, wrapped sets of instruments)
- Indicates if there are any unique requirements for operating the sterilizer. This might include operational constraints specific to altitude (e.g. Calgary is at approximately 3500 feet and ft. McMurray is at approximately 1213 feet elevation) and water supply (e.g. reservoir, potable, treated water).
- Defines recommended sterility assurance monitoring:
  - Appropriate biological and chemical indicators
  - Appropriate Class II (Bowie-Dick) chemical indicator for dynamic air removal sterilizers.

## **Service and Maintenance**

### **Ask the vendor if they:**

- provide a sterilizer for a trial period prior to committing to a purchase
- provide onsite training for the use of the sterilizer
- provide a service contract
- provide periodic testing
- provide evidence that the test person is qualified
- have the necessary calibrated test equipment
- have loaner equipment in case of shutdown for repairs and guarantee a response time
- place restrictions on the provision of loaners

IF NOT, then ask whether the vendor recommends a particular servicing agent.

## **You Purchased a Sterilizer. Now What?**

A sterilizer must be tested after installation and before it is put into service. Successful testing includes no growth of organisms (“negative” tests) after the placements of appropriate biological indicators in the empty chamber for at least 3 sterilizer cycles, and then again with a full test load of devices.

Dynamic air removal sterilizers must also be tested three times with an air detection test pack (a Bowie-Dick test) in an empty chamber.

A sterilizer that fails these tests must not be put into service until the cause is found and corrected and repeat testing confirms effective operation.

The same pre-use testing requirements apply after the following circumstances:

- a) major repairs to a sterilizer
- b) relocation of the sterilizer to another office
- c) unexplained sterilization failures
- d) changes in steam supply or delivery