Cleaning, Disinfection and Sterilisation Key Points

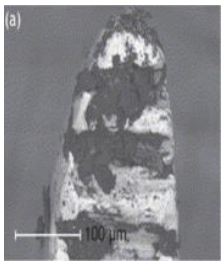
Cleaning

The single most important part of the process.

Disinfection and sterilisation are both compromised if instruments are not thoroughly cleaned first.

Disinfectant cannot penetrate organic material very well, and so cannot be as effective at killing microbes if surfaces are not scrupulously clean, nor can steam penetrate organic material so sterilisation is compromised. Routine steam sterilisation is not very effective against prions –'mad cow disease' – another reason to remove (almost) all organic material prior to processing.

Removing most of the organic material removes most of the microbes.



Dismantle instruments, follow manufacturer's instructions to the letter, observe carefully post cleaning and drying – recommend using an illuminated **magnifying glass** to examine e.g. serrated forcep hollows for thoroughness of cleaning process before proceeding further with disinfection or sterilisation.

Ideally a different person from the cleaning person inspects, then date/initials a document process.

Disinfection

Know and document what your **named** disinfectant is **stated by the manufacturer to cover**

e.g. most bacteria, viruses, fungi, TB (mycobacteria), spores

Plus document:

- **what concentration** is it used at? – state dilutions required
- **how often does it need to be made up?**
- what **contact time** must it have with items to be effective?

Disinfectant or steam cannot penetrate any organic material, especially dried organic material

Autoclaving

Validation establishes the efficacy of the sterilisation process. This is then monitored by measuring and documenting critical variables and parameters **for every cycle** for added assurance of sterilisation. It can be a complex area to follow every last detail. **Revalidation and calibration is required at least annually** and if any significant changes are made. In practice most surgeries have their autoclave installed and commissioned by an external body (e.g. accredited installers) who also do Performance Qualification (PQ) testing at that time – e.g. **you specify/list what type of items you will be autoclaving** (e.g. disassembled instruments, are there hollow lumens to be sterilised, what is their bore diameter compared to length, etc) and **how they will be packaged** (if wrapped) and specify **how loaded** (space around all to allow the steam contact with all surfaces (dishes on side or upside down). The testers then make sure that the cycle you are using is still working in those places that the steam has most trouble penetrating e.g. one part of a fully loaded autoclave, with wrapped items including a long hollow bore needle/lumen will be coolest and take longest to sterilise. Thus many autoclaves would not be able to sterilise these items, and it should not be attempted if yours has not been specifically validated for this.

You should have and keep a written copy of what the autoclave was validated to sterilise and on what (temperature/time) cycle at the time of validating and the serial number of the autoclave. The rationale being when it was set up (say 10 years ago) only scissors and forceps may have been sterilised, now **packaged** items or long **hollow needles/lumens/cannula/tubing, porous items, liquids** are required – **these require different sterilisation parameters** because steam cannot penetrate wrapped instruments or hollow lumens as easily, so the original validation would not cover these more recently added items. Update your instrument list for validators to see.

After the initial set up, commissioning, calibration and validation, **there should be an annual external service, validation and calibration check (includes biological controls) and then ongoing monitoring of every load by preferably electronic chart recorder** and/or class 4, 5 or 6 indicator strips (measure **two** parameters e.g. time and temp). The Standard does not require routine biological spore testing any more (except in large institutions/hospitals), primarily because the results are not ready for a few days and the more important thing to be assured about is '**when the autoclave door is opened at the end of the cycle is there reasonable assurance that the items in this load have been sterilised?'** Each package, basket and load should also have at least a class 1 indicator strip (e.g. temperature detection) to give clear evidence whether it has in fact been through the steriliser, or rather is to be autoclaved, when seen on the bench.

And when a **failed process occurs,** what is the **written process** to follow e.g. 'issue no instruments from this load', sign and date notation, check any visible parameters e.g. water for steam, try re sterilise cycle again, if still fails, call in external accredited service team, **document all this**.

It is not the failure that is so important, but knowing that it has failed and what is done and documented about the failure to stop potential harm.

Validation of total process – structured as:

- **Installation Qualification (IQ)** (i.e. the steriliser and the area it is installed in comply with manufacturer recommendations)
- **Operational or commissioning Qualification (OQ)** (i.e. steriliser operates within stated limits when used in accordance with operational procedures)

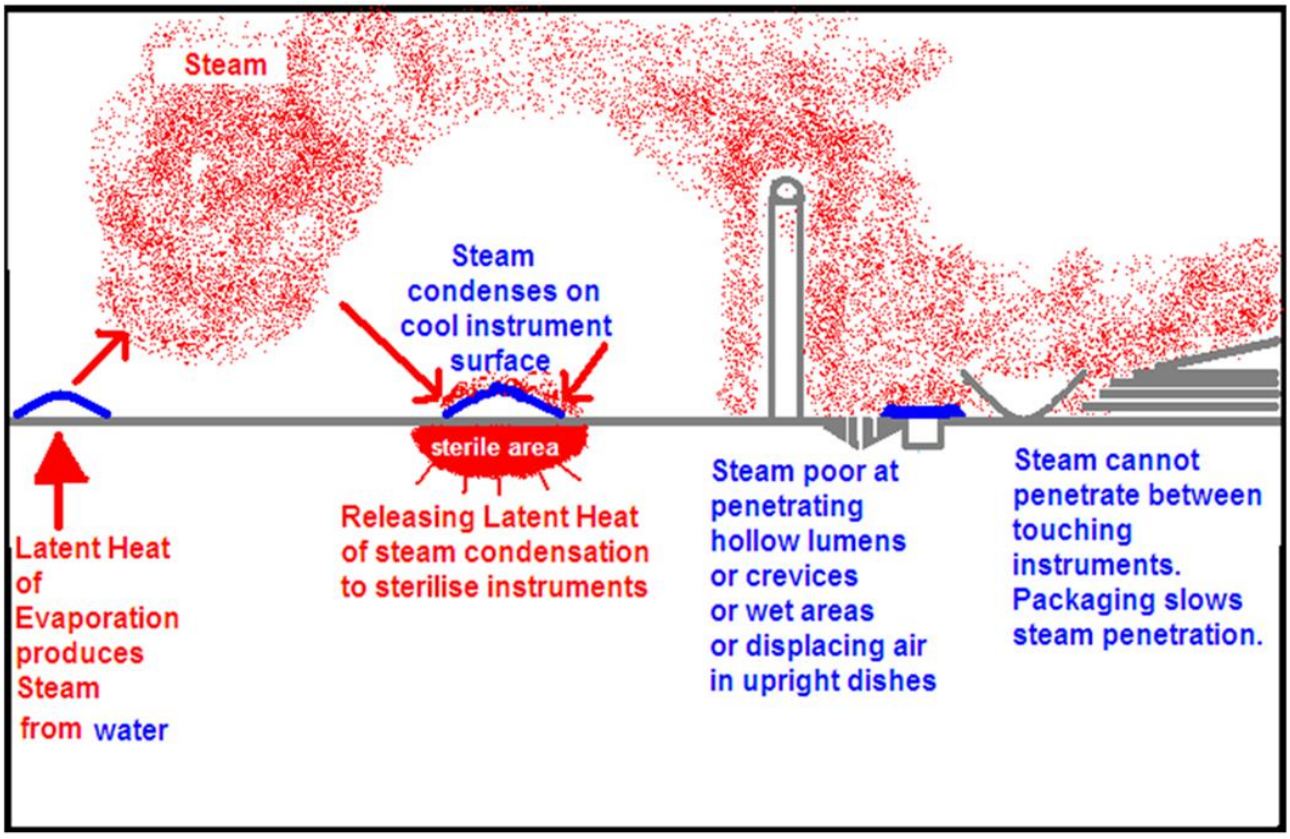
Then Performance Qualification (PQ) (i.e. both initial description of loads to be tested, how loaded, packaged, which cycle, etc, compliance then and ongoing, all documented and records kept)

- Physical qualification
- Microbiological qualification

Effective sterilisation and process validation includes many aspects including education, training, documentation and encompasses

- Cleaning
- Inspection
- Assembly of items/instruments
- Packaging (when used)
- Loading
- Sterilisation cycle
- Unloading
- Storage
- Distribution
- Performance testing, routine monitoring and recording
- Calibration and maintenance
- Validation of the whole process (includes IQ, OQ, PQ), annual

In summary, validation is largely encompassed by knowing (documentation) that staff have been trained in cleaning, loading, etc and understand the whole process including what items are able and are not able (validated) to be processed. The electronic monitoring and/or indicator strips will be part of this process. Annual (generally external) validation of the autoclave is also required. Updated training is formally required at least every 3 years.



How Autoclave Failures Can Occur