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Piercer Periodical

April, 2021. v1.1

Sterility: All things autoclaves

This month's deep dive:

Sterilisers. They are a lot more than a beeping pressure cooker.

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A brief history of sterilisation

Although many attribute sterilisation to surgery, it actually wasn't practiced for the first 600 years of surgery's history, and as you can imagine, without the basic principles of antiseptic technique, many deaths were attributed to the unknown - including sin or evil spirits!

Let's take a walk through history and watch the development of sterility and the modern autoclave.

3000 BC: The Egyptians used palm wine and vinegar for embalming as a method of antiseptics.[1]

1450 BC: Moses recorded the first purification system using water and also stated rules for purification of a house after somebody died inside.[2]

400 BC: Hippocrates II was a Greek physician born in 460 BC, and was the first person to disprove that disease wasn't a punishment for sin, and he separated philosophy from medicine.

150 AD: A Greek medical practitioner, called Galen (130-200 AD), would boil instruments as a form of disinfection when caring for wounds of Roman gladiators.

400 AD: In the 4th Century, Susruta wrote a book stating therein that one should burn sulphur to clean surgical rooms.

500-1500 AD: During the Middle Ages, sulphur was also recommended for disinfecting houses and items. They would also burn the clothing of a plague victim to prevent further spread of the plague.

1745: During an epidemic of cattle plague, sulphur fumigation was used for disinfection.[3]

1690: The "Digester" was invented by Denis Papin as a method of removing fats from bones inside a high-pressure steam environment, which was the first pressure cooker.[4]

1683: The microscope was invented by Antonj van Leeuwenhoek and microorganisms were first observed.[5]

1758: The first recorded surgical gloves were used during childbirth by Dr. Johann Julius Walbaum.[6]

1795: Nicolas Appert, a French chef and inventor, invented a method of preserving meats and vegetables in jars by sealing and boiling them.

[1] https://www.oie.int/doc/ged/D8963.PDF
[2] https://brnskll.com/shares/mosaic-law-related-to-purification/
[3] https://www.oie.int/doc/ged/D8963.PDF
[4] http://www.scienceandsociety.co.uk/results.asp?image=10182360&wwwflag=2&imagepos=1
[5] https://www.britannica.com/biography/Antonie-van-Leeuwenhoek
[6] https://peoplepill.com/people/johann-julius-walbaum

1847: A Hungarian Obstetrician, Ignaz Semmelweis, observed hand scrubbing preventing infection.

1862: Louis Pasteur contributed greatly to germ theory and the further study of infectious diseases. [7]

1867: Joseph Lister, a British surgeon and pioneer of antiseptic surgery, introduced the principle that bacteria shouldn't be given entry into a wound. He used a carbolic solution spray on his patients and surgical team as he operated. [8]

1879: The first Autoclave was invented by Charles Chamberland based on the "Digester". [9]

1881: Boiling as a form of sterilisation was introduced for use with surgery equipment and dressings.

1885: Steam sterilisation was first used for surgical dressings by Ernst von Bergmann. [10]

1886: The first aseptic operating theatre was made by Gustav Neuber and all surfaces and tools used were washed with Mercury chloride as a form of disinfectant. [11]

1889: William Halsted had Goodyear create gloves to protect nurses from harsh cleaning chemicals. [12]

1900: Rigid instrument containers were invented to safely transport sterile surgical equipment. [13]

1933: Getinge-Castle introduced a steriliser that had a dial top operating valve and allowed for control of temperature by a thermometer in the discharge outlet at the bottom of the chamber.

1956: The standards for processing reusable medical devices was published as Principles and Methods of Sterilization in Health Care Sciences by J.J. Perkins.

1958: Pre-vacuum autoclave cycles are developed, which air is actively removed from the chamber and allowed for sterilisation of hollow instruments and eventually sealed pouches.

1987: The modern "Steam-flush pressure-pulse" (SFPP) technology was developed.[14]

1989: The STATIM, high speed steam autoclave, was introduced by SciCan internationally.

2005: The autoclave pouch is improved upon with a self-sealing element.[15]

[7] https://www.britannica.com/biography/Louis-Pasteur
[8] https://www.britannica.com/biography/Joseph-Lister-Baron-Lister-of-Lyme-Regis
[9] https://prabook.com/web/charles.chamberland/2495424
[10] https://www.britannica.com/biography/Ernst-Gustav-Benjamin-von-Bergmann
[11] https://www.sciencemuseum.org.uk/objects-and-stories/medicine/surgeons-and-surgical-spaces
[12] https://www.pastmedicalhistory.co.uk/the-history-of-surgical-gloves/
[13]https://www.aesculapusa.com/content/dam/aesculap-us/us/website/aesculap-inc/healthcareprofessionals/or-soultions/pdfs/DOC132-Rev%20F-SterilContainer-System-Catalog.pdf
[14] https://www.steris.com/healthcare/knowledge-center/sterile-processing/everything-about-autoclaves
[15] https://patentimages.storage.googleapis.com/a4/d3/74/cf815b8d480a74/US20070023309A1.pdf

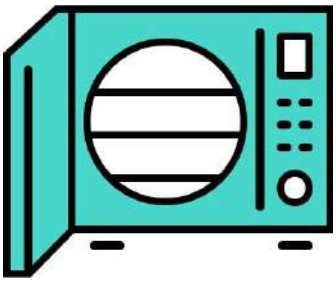
A Glossary of Terms

Antigen	A toxin or other foreign substance which induces an immune response in the body, especially the production of antibodies
Aseptic	Free from contamination caused by harmful bacteria, viruses, or other microorganisms
Bacteria	A member of a large group of unicellular microorganisms which have cell walls but lack organelles and an organised nucleus, including some that can cause disease
Biological	Relating to biology or living organisms
Degassing	The removal of air and other gases that are dissolved in a solution
Enzyme	A substance produced by a living organism which acts as a catalyst to bring about a specific biochemical reaction
Microorganism	A microscopic organism, especially a bacterium, virus, or fungus
Organism	An individual animal, plant, or single-celled life form
Pathogen	A bacterium, virus, or other microorganisms that can cause disease
Porous	(of a rock or other material) having minute spaces or holes through which liquid or air may pass
Protein	Any of a class of nitrogenous organic compounds which have large molecules composed of one or more long chains of amino acids and are an essential part of all living organisms, especially as structural components of body tissues such as muscle, hair, etc., and as enzymes and antibodies
Spore	A minute, typically one-celled, reproductive unit capable of giving rise to a new individual without sexual fusion, characteristic of lower plants, fungi, and protozoans
Sterile	Free from bacteria or other living microorganisms
Virus	An infective agent that typically consists of a nucleic acid molecule in a protein coat, is too small to be seen by light microscopy and is able to multiply only within the living cells of a host

How sterilisation works

The Oxford English Dictionary defines the word sterilise as, “Make (something) free from bacteria or other living microorganisms.”[16] It really cannot be put more simply than that.

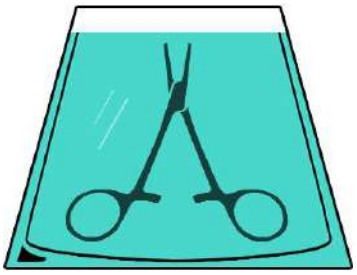
When we look at how this relates to body piercing, we first must understand why we need things to be free from living microorganisms and what those microorganisms actually are.



A microorganism is a tiny, microscopic life form, such as bacteria and viruses. Some microorganisms, known as pathogens, can cause disease.[17] In a nutshell, sterilisation is a process which removes or destroys all living organisms, including pathogens. In relation to body piercing, the purpose is to remove all organisms which can cause infections, or transmit blood borne diseases such as hepatitis or HIV.

Sterilisation can be achieved through multiple different means, such as heat, chemicals, irradiation, high pressure, and filtration. The most common method that we use in body piercing is an autoclave machine, which utilises a combination of steam and pressure for a set amount of time in order to achieve sterilisation. The AS/NZS4815 standard defines an autoclave as a “colloquial term for a steam-under-pressure sterilizer.”[18]

In an autoclave, an item (such as a piece of body jewellery, forceps, or gauze) is placed into the chamber, and is then heated by steam until it reaches its set temperature. To be effective, the autoclave chamber needs to also remove all air in and around the items so that the steam can penetrate all of its surfaces. The heat from the steam then kills the microorganisms by causing their structural enzymes and proteins to lose shape in an irreversible way.[19] The items need to be exposed to the steam for a set time period. After this time period has elapsed, the pressure in the chamber is released and the sterilisation process is complete.

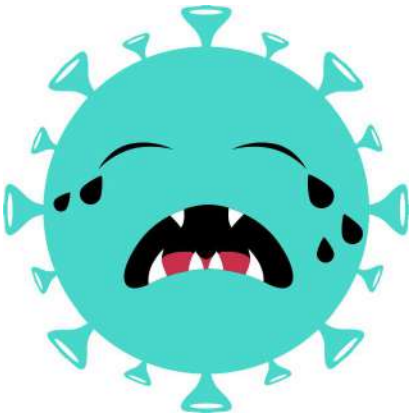


Due to the developing and expanding needs for sterilisation and storage of sterile instruments in the medical field, many advancements have been developed to increase effectiveness and useability of these sterilisers, and they have become the work horses we rely on daily in our studios.

[16] https://www.lexico.com/definition/sterilize
[17] https://www.merriam-webster.com/dictionary/pathogen
[18] https://www.standards.org.au/standards-catalogue/sa-snz/health/he-023/as-slash-nzs--4815-2006
[19] https://www.grainger.com/know-how/equipment-information/kh-how-does-autoclave-sterilization-work

Clean vs Disinfected vs Sterile

When we hear the terms **sterilise**, **disinfect,** and **clean,** we often think of the same thing. While there is some confusion around what each of these words actually mean, in a body piercing studio it is vitally important that we understand the distinct differences between them. If we take a closer look at the definitions of these words, we can see they refer to different levels of cleaning, and understanding the difference becomes a lot easier.



Clean

"Free from dirt, marks and stains." [20]
When we clean something we are removing visible debris from it. Typically with the aid of a tool such as a vacuum or some soap on a cloth.
In a piercing studio, we might vacuum our floors, dust the top of our display cases or wash our windows, making them *clean*.

Disinfect

"Cleaned (especially with a chemical) in order to destroy bacteria." [21]
Disinfection is the act of killing *most* organisms from an object. For this, we would use a chemical product such as Viraclean or Optim.
In a piercing studio, we would *disinfect* our piercing bed and trolley, as well as our countertops and door handles.

Sterilise

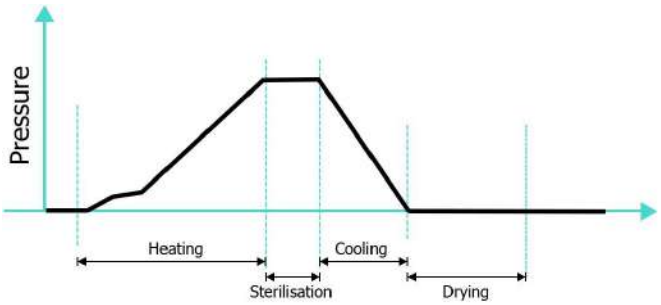
"Free from bacteria and other living microorganisms." [22]
While disinfection is powerful, it doesn't eliminate all organisms. This is where sterilisation comes in. When something is sterilised, all organisms and their spores are killed. In the piercing studio, this is done with a machine called an autoclave, where we would *sterilise* body jewellery, needles, and other tools & implements we might use for a procedure.

As you can see, there is quite a difference between cleaning, disinfecting and sterilising. Now that we understand these differences we can easily identify when and where each action is required to keep our studio safe.

[20] https://www.lexico.com/definition/clean
[21] https://www.lexico.com/definition/disinfect
[22] https://www.lexico.com/definition/sterile

Different types of Steam Sterilisers [23]

Gravity Autoclave



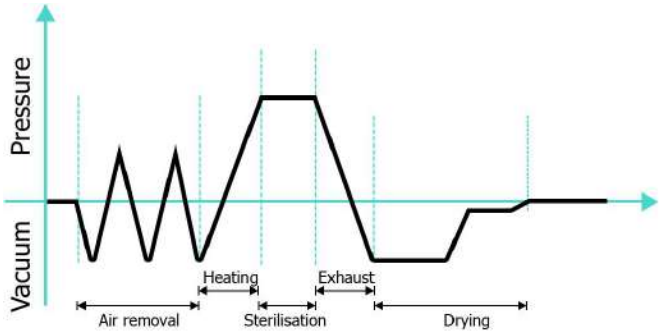
Steam displaces air inside the chamber with the aid of gravity and is the most basic type of sterilisation cycle. As air has a higher density than steam, it sinks to the bottom and is eventually displaced by the steam through the drain vent.

Typically only used for unwrapped goods and solid tools (like tapers) but not suitable for threaded/threadless jewellery or needles because it can't effectively sterilise hollow or complex items.

When a cycle is completed, the steam is released through the drain vent and the contents need to be left for quite a while to dry unless equipped with a vacuum drying feature which drastically reduces moisture in the contents.

Although suitable for some instances, a gravity autoclave is not generally suitable for a piercing studio due to its limited efficiency.

Pre-Vacuum/Post-Vacuum



Steam is able to penetrate porous and hollow areas of the load as air is mechanically removed and systematically fed through a series of vacuum and pressure pulses.

The ideal cycle for our industry as it can do wrapped and unwrapped items, solid and hollow jewellery, and even nitrile gloves.

Usually, a vacuum cycle will start with a series of pulses (alternating stem injections and vacuum draws) to remove the ambient air from the chamber and replace it with steam. This process allows steam to penetrate the contents almost instantaneously and not only gets to sterility parameters faster but is also more reliable than traditional methods.

Once sterilisation has finished, a post-cycle vacuum program can be used to drastically speed up the drying process by forcefully removing hot steam from the chamber.

[23] https://consteril.com/steam-sterilization-cycles-part-1-gravity-vs-vacuum/

Different Classes of Autoclaves [24]

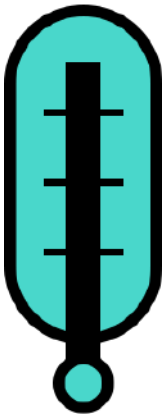
Sterilisation for body piercing services should be carried out in accordance with AS/NZS 4815:2006, which includes reprocessing of reusable medical instruments, autoclave maintenance, and the associated environment.[25]

Generally, all items, instruments, needles, and jewellery need to be either immediately used, or wrapped and packaged prior to processing to maintain sterility and allow for aseptic removal and use.

An autoclave should have a method of recording the cycle parameters (either by print-out or digital recording), or should use a Class 4/5/6 chemical indicator or process challenge device with every load.

There are a variety of different "Classes" of autoclave programs, which indicate their intended use and if it is suitable for the different types of items to be sterilised.

Class B



"Big." Small sterilisers get their name for their big performance in a small footprint. They compare to the performance of a larger hospital-sized machine and can be used for all load types.

They utilise a vacuum cycle which allows for the penetration of hollow instruments (such as threaded components), hollow instruments (such as receiving tubes), and bagged items.

Class N

"Naked." Solid products. A non-vacuum autoclave is only capable of effectively sterilising solid unwrapped items such as trays, ring openers, disassembled captive bead rings, glass plugs, etc, as they do not utilise a vacuum cycle.

Class S

"Specified." All other autoclave program types, basically a non-standardised class between type N and type B whose features are further established and tested by the manufacturer.

[24] https://www.gallay.com.au/blog/autoclaves/which-autoclave-is-best-for-dental-clinics-australia
[25] https://www.health.nsw.gov.au/environment/factsheets/Pages/tattooing.aspx

Statim 2000/5000 Cycles

Although considered the gold standard for body piercing, the Statim is designed predominantly for dental use, and therefore has a number of cycles that are not applicable for body piercing services.

 **Unwrapped 134°C**	**Solid** (N) (3:30)	Can be used when running for immediate use: • Naked solid metal tools, such as forceps or clamps • Naked solid metal or glass jewellery, such as disassembled captive bead rings or plugs
	Hollow (S) (3:30)	Should be used when running for immediate use: • All metal tools (including septum clamps) • Needle blades • Receiving tubes/needle blanks • Threaded, threadless jewellery, eyelets, etc • Nitrile gloves (see AUPP Pierce Periodical on gloves) • Aseptic drapes (or other textiles)
	Hollow (S) (18:00)	N13060 regulatory programs for sterilization of eye instruments and not necessary for body piercing services
 **Wrapped 134°C**	**Hollow** (S) (3:30)	• Bagged tools (tapers, forceps, etc) • Bagged jewellery • Bagged nitrile gloves • Bagged needle blades • Bagged receiving tubes/Needle blanks
	Hollow (S) (18:00)	N13060 regulatory programs for sterilization of eye instruments and not necessary for body piercing services
 **Plastics/Rubber 121°C**	**Rubber/Plastic** (S) (15:00)	Not necessary for body piercing services. These cycles are designed for reusable rubber cleaning gloves as a method of high-level cleaning and NOT designed for procedure glove sterilization
	Rubber/Plastic (S) (30:00)	
 **Dry Cycle**	**Air Drying Only**	Only necessary if a wrapped cycle is still wet after being stopped.

Statim 2000 vs Statim 5000 [26]

The primary difference between the Statim 2000 and 5000 is simply the size of the casette and load that can be processed. The smaller 2000 unit is more commonly found for eye and dental surgery, where as the larger 5000 unit is used primarily in orthodontic and general surgery.

Despite the 5000 cassettes being 2.5 times the size, it only take an extra ~3 minutes to run a hollow unwrapped cycle which makes both units fantastic assets for use in our peircing studios. The 5000 is an excellent choice for a studio that already has a 2000, and wants to run more packages or larger items, if they do not have another larger vacuum autoclave.

Where as all newer models (G4 units) come equipped with digital recording, older 5000 units came equipetd with a physical printer as standard where the older 2000 untis had it as an optional extra.

	Statim 2000	Statim 5000
Cassette Size	28 x 18 x 4cm (1.8L volume)	38 x 18 x 8cm (5.1L volume)
Overall Size	9.5 x 41.5 x 15cm	60 x 41 x 19cm
Dry Weight	21kg	33kg
Hollow unwrapped(s) cycle	8:05 (11:45 cold)	10:50 (17:30 cold)

Differences between “Classic” and “S” models [27]

Add S: The letter ‘S’ stands for Special, from ‘Special’ or ‘Specified’ products. In these sterilizers the manufacturer of the sterilizer has to specify what can and cannot be sterilized in this type S process.

Statim 900, 2000, 5000, 7000, and the counterparts marked S made for EU/UK make are all S for "Special". Those marked S made for use outside North America have additional hardware inside for pressure measurement and different firmware for additional regional regulatory requirements.

[26] https://www.scican.com/us/products/autoclaves/statim/
[27] https://brnskll.com/shares/statim/

Maintenance of sterilisers

Not only will regular maintenance of sterilisers help to ensure the efficacy of sterilisation, but also increase the lifespan of the appliance itself, ensuring it is operating correctly.

Although some models of sterilisers may even have maintenance reminder alerts as a feature, establishing a responsible person and a maintenance schedule can help to ensure that these necessary steps will not be neglected.

Some common problems that can occur from lack of frequent maintenance are: wet packs, staining, incomplete sterilisation (biological indicator failure), cycles abort prematurely, premature component failure, and chamber corrosion.

Below are some examples of maintenance schedules for a Statim and also a steam steriliser with a chamber. It is important to note that the manufacturer's instructions and guidelines should always be followed when operating and maintaining a specific steriliser.

Only approved products and non-abrasive cleaning pads should be used when cleaning and maintaining a sterilizer. Your bench-top steriliser must be maintained in accordance with AS F2182-1998 Sterilisers.

General Steam Sterilizer Maintenance [28]

Daily Maintenance	• Clean External Surfaces • Clean Steriliser Door/Dam Gaskets with a damp cloth • Replace Distilled Water as needed • Empty Waste Water
Weekly Maintenance	• Clean Chamber/Trays (including rack and plate) • Drain Reservoir
Monthly Maintenance	• Clean Chamber and plumbing • Remove/clean door and gaskets Clean/replace the filter • Check pressure relief valve
Yearly Maintenance	• Professional service and calibration

[28] https://statim.us/info/maintenance/

Statim 2000/5000 Steriliser Maintenance [29]

Operator (yourself or your appointed staff member)

Daily	Water Reservoir	• Replace water as needed • For ophthalmic use, drain at the end of every workday, leave empty, and refill at the start of the next workday
	Waste Bottle	• Empty the waste bottle every time you refill the water reservoir • Fill the bottle with water, up to the MIN line marking. You may also add some chlorine-free disinfectant
Weekly	Cassette	• Wash the interior of the cassette with dishwashing soap or a mild detergent that does not contain chlorine • Scrub the inside with a cleaning pad designed for use with Teflon™ coated surfaces • After removing all traces of the detergent, treat interior surfaces on the cassette with the STAT-DRY™Plus drying agent to enhance the drying process.
	Biological and/or Air Filter	• Check the filter for dirt and moisture. Replace if dirty. Call for service if wet
	Water Filter	• Check the water reservoir filter every week and clean if necessary. Replace only if necessary
Every 6 months	Cassette Seal	• Replace every 500 cycles or six months (whichever is first), or whenever necessary
	Biological and/or Air Filter	• Replace every 500 cycles or six months (whichever is first)

[29] https://statim.us/info/maintenance/

Technician

Once a year	Cassette	• Check the tray, lid, and seal for damage. Replace if necessary
	Biological Filter	• Inspect the biological filter for moisture
	Solenoid Valve	• Inspect the valve and clean if dirty. Replace the plunger if defective
	Pump	• Clean the filters, replace if dirty
	Check Valve	• Remove the exhaust tube from the back of the unit during the drying phase. Check for air coming from the fitting • Remove the air compressor tube from the check valve inlet while running a cycle. Make sure no steam is leaking from the valve. Replace if there are any leaks.
	Water Reservoir	• Check the reservoir for dirt. Clean and rinse with steam process distilled water if necessary
	Calibration	• Calibrate the unit

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Autoclave Maintenance Log Book

Record keeping is a critical component of any sterilisation monitoring protocol and so is ensuring maintenance occurs at the correct intervals.

Daily Autoclave Maintenance Log Book

Month:		**Year:**		**Autoclave:**		**Monthly Maintenance:** (date/initials)		
Daily Maintenance								**Weekly Maintenance** (date/initials)
Mon (date/initials)		**Tue** (date/initials)		**Wed** (date/initials)		**Thur** (date/initials)		**Fri** (date/initials)		**Sat** (date/initials)		**Sun** (date/initials)		

Monthly Autoclave Maintenance Log Book

Year:		Notes	Steriliser:		Date	Initials
January						
February						
March						
April						
May						
June						
July						
August						
September						
October						
November						
December						

Purified Water

There are many types of purified water such as demineralised, deionised, and distilled, which have undergone a treatment process to remove impurities and ensure the water is suited for different uses. While they are all of a high quality, the differences between the three are the processes in which they are made.

There are several ways to produce these which include reverse osmosis, distillation and carbon filtration. For the water to be legally classed as "purified", its impurities must be completely removed or decreased to extremely low levels.

Deionised Water vs Demineralised Water

Deionised water and demineralised water are almost identical, as they are generally produced using the same process of ion exchange. There are some differences in the end product which need to be taken into account depending on its desired use.

The main difference between demineralised water and distilled water is that deionisation doesn't remove uncharged molecules like bacteria or viruses and distilled water usually has less organic contaminants.

Essentially, deionised water is free of ions and demineralised water is free of minerals. Although the ion exchange process results in high quality, mineral-free water, distilled water remains to be a more pure purified water and the best choice for our industry.

Reverse Osmosis [30]

Also known as RO, reverse osmosis is a purification process that uses a partially permeable membrane to separate ions and unwanted molecules.

It is most commonly known for its use in drinking water purification from seawater, removing the salt and other effluent materials from the water molecules such as chlorine, pesticides, fluoride, and heavy metals.

Water treatment plants often use RO to remove salinity from drinking water.

[30] https://www.sciencedirect.com/science/article/abs/pii/S0048969719334655?via%3Dihub

Distilled Water

Distilled water is one of the purest and cleanest forms of water available today, and it is the oldest method to create pure water. The distillation process eradicates ALL impurities and contaminants. It is water that comes from the steam of boiled water which leaves behind any impurities in the original container, as water has a lower boiling point than most contaminants (including minerals). The steam is then condensed back to liquid form into a separate container, which is cooled for later use.

Some water is also double or triple distilled, with the condensed water being boiled and condensed a second or third time.

Distilled water has benefits over other types of water filtration and purification methods, including removal of bacteria, germs, chemicals, toxins, and chlorine. Because of its purity, it is often used by hospitals, scientific laboratories, in aquariums, for brewing beer, and as drinking water for some.

Buying vs Making Distilled Water

Although "distilled" water can be purchased in-store or online for delivery, it is often just deionised water[31] and may not meet the minimum requirements for your autoclave. Statim units should **ONLY** use steam-processed distilled water and not deionized or demineralized water.[32]

There are many options for purchasing a unit that will output distilled water for your studio from regular tap water, which not only gives you the opportunity to match your daily needs, but also can reduce purchasing costs long-term, and minimize autoclave maintenance.

There are also systems similar to hot water heaters, like the Scican VistaPure[33], that can fully automate the process and deliver high volumes of ready-to-use autoclave water on demand.

Pros of DIY Distilled Water	Cons of DIY Distilled Water
• Control over quality and quantity • Available on-demand anytime • Easily scale up production as needed • Reduced shipping/delivery costs • Takes up less space compared to bottles	• Additional time required to make • High Initial up-front cost • Additional upkeep costs • Higher electricity usage • Additional heat and humidity

[31] http://davidgray.com.au/products-main/garden-home-pest-control/distilledwater2l-detail
[32] www.scican.com/eu/media/autoclaves/en-95-112373_eu_ml_r11_statim_2000s_g4_5000s_g4_om_web.pdf
[33] https://www.scican.com/products/water-management/vistapure/

Autoclave Pouches

When sterilising tools and jewellery for non-immediate use, the most effective way to reduce recontamination is to use autoclave pouches. These are made from PET/PP translucent copolymer film front and medical kraft paper, which allows the penetration of steam, ethylene oxide, and formaldehyde during sterilisation.

Self-Sealing Pouches

With an adhesive end, these are easy-to-use pouches to maintain the sterility of tools and jewellery.

Advantages

- Easy to use and self-adhesive (no additional tools)
- Come in a variety of sizes
- Usually contains internal and external class 4 integrators
- Integrated multiple seal lines
- Usually have notches for easy opening from the non-adhesive end

Disadvantages

- More expensive than other methods
- Only available in fixed sizes, which can lead to wasted space
- Must seal perfectly along perforation line to ensure a watertight seal

Autoclave Pouch Reels

Unlike the self-sealing variety, they require specialised tools to efficiently seal the ends correctly to ensure a correct seal.

Advantages

- More cost-effective per item
- Less wastage as the desired length can be cut

Disadvantages

- Requires specialised heat sealer or tape
- Potential contamination of roll during use
- Generally not as strong for heavy items (like ring-openers)
- More difficult to open while maintaining sterility

Pouch orientation in the sterilizer [34]

You should consult your autoclave manual to ensure correct orientation. Ideally, you should use a steriliser rack and load the pouches on their side, with all of the windows facing in the same direction. This ensures the drying process is efficient and stops water droplets from collecting inside the bags.

Vacuum steam sterilizers	Gravity steam sterilizers
Directs steam downwards for ventilation, so should generally be plastic (translucent) side up	Rises steam upwards and the plastic traps the steam in so should generally be plastic (translucent) side down

Autoclave pouch shelf life

Although studies have shown that a 12-month storage period will not affect sterility[35], your local health department may dictate a time period based on how you store and handle your sterilised pouches. Usually, this time period ranges from 12 months to 4 weeks[36] (for practitioners in QLD).

Event-related life: Pouch should remain sterile until something happens to it to cause otherwise.

Time-related life: The time at which the pouch is no longer considered sterile.

It's considered recommended practice to re-pouch and re-sterilise bagged items after a 9-12 month period as they generally become quite rigid and easier to compromise the longer they sit.

How to safely handle autoclave pouches

Autoclave pouches should always be handled with care to not bend, compress, puncture, or crush to avoid compromisation of sterility. Immediately transport dry bags to a clean area with clean hands.

Wearing gloves while handling sterile pouches may not be strictly required as the pores will generally only open when exposed to heat and steam, however is highly encouraged due to natural oils which may be able to penetrate the pouch.

You should handle pouches as little as possible to avoid damage, ideally only just prior to use.

[34] https://www.amerdental.com/sterilizer-q-and-a
[35] https://www.sciencedirect.com/science/article/abs/pii/003042209190004V
[36] https://www.health.qld.gov.au/__data/assets/pdf_file/0027/444753/sterilize-comply.pdf

How to safely store autoclave pouches

When pouches are exposed to steam and heat, the pores in the paper package open and allow for the transfer of the steam. If the bags are still damp out of the autoclave, they can easily be contaminated and should be left until completely dry before being handled and placed into a plastic container.

The shelf life strongly depends on the storing and handling conditions so keeping them grouped together in categorised containers which are sealed from dust and out of direct heat and light sources.

Containers should be labelled appropriately and pouches should be stored in a way that they don't sit on top of each other and are easily accessible for aseptic removal. Rubber bands, paperclips, staples and adhesives should be avoided to preserve the integrity of the pouch.

Labeling pouches

It is important to write on your autoclave pouches immediately before being sterilised to not just clearly indicate its contents but also relevant information to later prove the sterilisation history.

Although specialty printed labels are available, most piercing studios will not be high volume enough to warrant it and will generally write by hand on the packages.

Use a specialised non-toxic non-bleeding permanent marker (that conforms with the ASTM D4236 standard[37]) and write on the plastic portion or if using a self-sealing pouch you can also use a lead-free pencil on the folding tab portion. Avoid writing on the back (paper) side of the pouch as it will limit visibility of the content and potentially require additional handling to check contents.

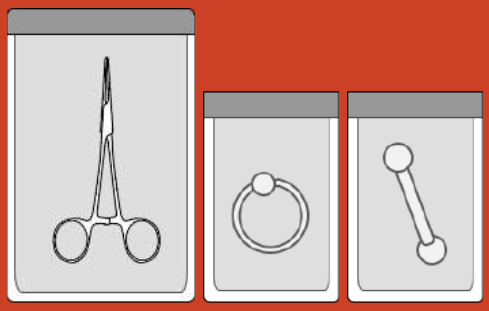
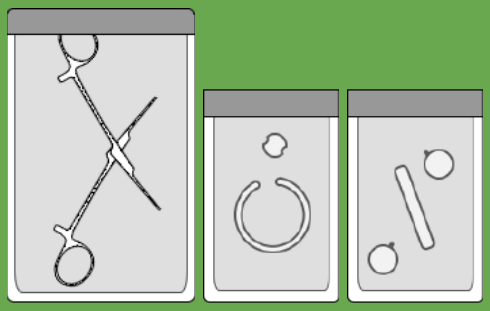
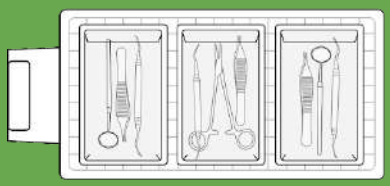
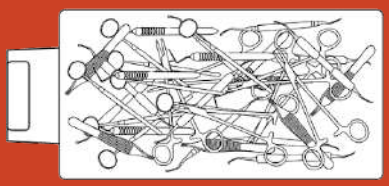
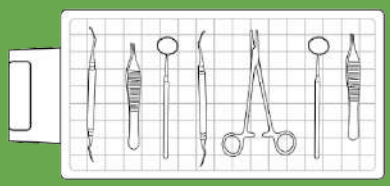
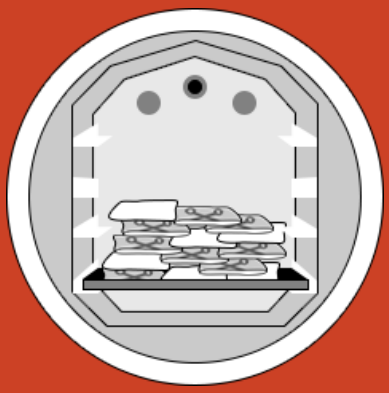
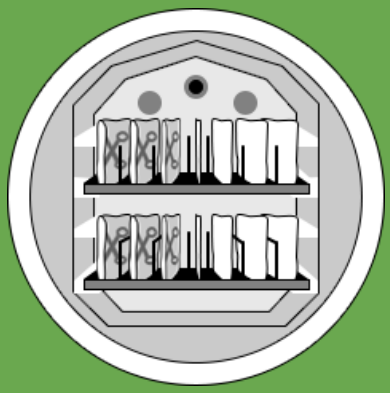
Package Identification

Steriliser	Identification (model/name) of autoclave used (if multiple are on the premises)
Date	Either expiration date OR sterilisation date (depending on policies)
Load number	A number associated with the cycle usually displayed on the steriliser
Operator	Initials or name of the person who bagged the contents
Contents	If not obvious, something to identify what's in the pouch (ie 16g 5/16")

The important key to dating sterile pouches is to make it easier to rotate older pouches first.

[37] https://www.astm.org/Standards/D4236.htm

How to load a steriliser correctly

METHOD	DON'T	DO
Autoclave Pouches		
Statim 2000 Wrapped Cycle		
Statim 5000 Wrapped Cycle		
Statim 2000/5000 Unwrapped Cycle		
Chamber Autoclave Wrapped Cycle		

Autoclave Testing

Autoclaves are a crucial tool in every piercing studio, but how do we know they're doing everything properly? Autoclaves need to be constantly tested to assure that they are functioning adequately for the safety of our clients.

Autoclave sterilisation monitoring is broken down into three categories (Mechanical, Chemical, and Biological) and for effective sterilisation monitoring, methods from all three should be used to make sure sterilisation happens in every single cycle.

Mechanical Indicators

Many autoclaves have a printer or internet logging for monitoring. People often see this as a sufficient indicator that sterilisation has been achieved - however, this only shows that the mechanical indicators in the autoclave have met the correct parameters, and is not a foolproof test that sterilisation has occurred.

Mechanical Indicators include pressure sensors, thermometers, and timers built into the unit that show the autoclave unit is correctly running the cycle as it is programmed to do. While still a very important part of sterilisation monitoring, the role of the mechanical indicator should be seen as one for the first alert of a failed cycle as well as a clear and easy way to collect data for record-keeping.

Chemical Indicators

Chemical monitoring uses chemicals that are sensitive to certain perimeters of the sterilisation cycle and change colours when they are exposed to them. Like Mechanical Indicators, Chemical indicators do not prove sterilisation has occurred. However, they do provide evidence that the package was exposed to the testing conditions for the specific chemical indicator

Classifications

The International Standards Organisation, in their most current standard, ISO 11140-1:2014, has divided chemical indicators into six different types to show the intended use and performance of a specific indicator. (Note: previous standard ISO 11140-1:2005 divided indicators into classes rather than types. The words “class” and “type” are often used interchangeably when referring to indicators.)

Class 1 Indicators (Process Indicators)

Process Indicators are the most basic form which simply provides proof of exposure to a cycle.

When to use them? Often found on autoclave tape used to seal pouches/wraps for procedures. These are effective for a visual identifier an item was exposed to a sterilisation cycle or processed but do not prove the item is sterile only as a fast, visual confirmation that an item was processed.

Class 2 Indicators (Specific-Use Indicators)

Specific-use indicators are tests that are made to test a criteria set out by a relevant standard, most notably Bowie & Dick tests which are used to see if the air is properly removed from the autoclave chamber. This is to ensure porous materials such as gauze or surgical wraps may be adequately penetrated with steam however actually provides no assurance or sterility.

When to use them? Bowie & Dick tests are used in facilities that sterilize porous items daily in the first cycle of the day. While a great test, this is not commonly used in the piercing industry and often the helix process challenge device that we touch on in class 6 indicators is favored due to hollow items being more commonly sterilised than porous items.

Class 3 Indicators (Single-Variable Indicators)

Single-variable indicators are used for testing only one parameter of sterility, such as temperature. These tend only to be used in dry heat sterilisers

When to use them? Since dry heat sterilisers are not used in body piercing, these indicators have no common use in body piercing.

Class 4 Indicators (Multi-Variable indicators)

Multi-variable indicators are “two-parameter”indicators, as these test for both time and temperature. These have a colour changing indicator when appropriate parameters are met (such as changing from blue to black).

Their accuracy is +/-2°C and +/- 25% on time.

When to use them? These are often found as the built-in indicators on self-sealing pouches. Many piercing studios will have a protocol of running one multi-variable indicator inside every pouch in the load to show that steam has penetrated into the package.

Class 5 Indicators (Integrating Indicators)

Integrating Indicators give us a much better idea about the entire process due to three-parameter verification. The parameters are time, temperature, and pressure. These often come with a colour-changing indicator like a class 4, or in some cases, a line that will finish in either “Pass” or “Fail,” giving more insight into how close the item was from success or failure.

Their accuracy is +/-1°C and +/- 15% on time.

When to use them? Since these indicators test all 3 critical parameters, many studios will have a protocol to have one Class 5 integrating indicator, or Class 6 emulating indicator (which we will touch on next) in each cycle to show evidence that the cycle was successful.

Class 6 Indicators (Emulating Indicators)

Emulating indicators are also known as “Cycle Verification Indicators”. These work very similar to Class 5, but are often for a specific process. Class 5 tests for all 3 critical variables in a sterilisation process while Class 6 tests for all 3 critical variables for specified sterilisation cycles such as “134 degrees for 3.5minutes” or “121 degrees for 15 minutes” etc.

Their accuracy is +/-1°C and +/- 5% on time.

When to use them? As well as being able to be used in place of a Class 5 indicator to verify each cycle is meeting the 3 critical parameters, Class 6 emulators are used in a newer form of testing called Helix testing which is becoming more and more commonplace in the body piercing industry.

A **Helix Test** is a process challenge device that aims to check the adequate removal of air and penetration of steam into thin hollow objects. The reusable device features a metal or plastic capsule connected 1.5m long tube. A Class 6 chemical indicator is inserted into the capsule, and the device is put into a cool autoclave chamber for the first cycle of the day.

For the test to pass, the autoclave must first remove all air from the tube and then steam must be able to go through the entire tube and maintain the capsule contents at sterilisation conditions (134 degrees for 3.5 minutes).

Biological indicators

Biological indicators, or spore tests, are testing systems containing living microorganisms.

These are placed in a sterilisation cycle then incubated with a control (that does not get sterilised) to test that the micro-organisms were killed and prove sterilisation was achieved.

In most spore test kits, you will find “Geobacillus stearothermophilus” spores as these are known for their particularly high resistance towards high heat and steam, making them some of the most difficult spores to kill in an autoclave. With the added benefit of presenting no real danger to humans, this makes them a great choice for testing sterilisation.

Mail-in vs in-office

There are 2 types of spore testing systems, with the main difference being where the spore tests are incubated. Spores can either be incubated and tested using a mail-in service, where the test and the control are sent to a lab and incubated, then results are sent via email the studio; or using in-office incubation devices that use vials with a colour-changing fluid to show growth or lack of growth in the spore test and control vials.

While neither method of incubation is necessarily better, Australia and New Zealand (as well as many other parts of the world), lack options for mail-in spore testing. While the added time of postage won’t affect the incubation of the test, many piercing studios need to post their spore tests overseas, and it can severely delay results, especially with the risk of lost postage. In-office incubation has the advantage of generally having results within 24 hours - however, these studios lack the benefit of 3rd party verification.

Due to the challenges faced by many studios to get adequate 3rd party verified spore testing, the Association of Professional Piercers (APP) has allowed international members to substitute third party testing with daily helix testing and/or weekly in-studio spore testing to meet membership requirements. In correlation, the AUPP will accept daily helix testing or weekly in-house spore testing to meet spore test requirements.

Record keeping

AS/NZS 4815:2006 - section 8 (Quality Management) requires that records must be kept and maintained for a period of seven (7) years.[38]

With the need for good sterilisation monitoring comes the need for good record-keeping. We would all hope to never have a reason for our sterilisation practices to be called into question - however, the task of proving your studio's sterilisation abilities are up to scratch would be a lot less daunting if you are keeping good records. An ideal record keeping set-up would allow a studio to show when and how items were sterilised for each procedure and link them back to the correct indicators.

This sort of tracing can easily be done by simply using an autoclave logbook and your studio waiver forms using lot or cycle numbers. Before starting an autoclave cycle, a lot/cycle number should be generated, then this number should be written on each package being sterilised in that load as well as a class 5 or 6 indicator which will also run in the cycle. The autoclave operator will note in a logbook the cycle/lot number, date, times, temperature, pressure, and operator name. When the cycle is completed, they will also attach the numbered class 5 or 6 indicator, as well as any autoclave printouts to the logbook.

Once the sterilised items are used in a procedure, the lot/cycle number on the package should then be noted on the clients release form, then each item used on the client can be linked back to a sterilisation cycle, which can be verified by a passed class 5 or 6 indicator, and furthermore linked back to a passed spore test. Some studios also like to simplify this process and add an extra level of evidence by writing the lot/cycle number on a class 4 indicator strip placed in every package and attaching the passed and numbered indicator strip to the client's release form.

For those who bulk sterilise unwrapped tools, either for further inspection or storage for sterilization later, the suggested practice is to run a Class 5 or 6 indicator to be kept with the mechanical indicator print-out as proof that sterilisation occurred prior to storage.

If your studio uses unwrapped Statim cycles, the same information should be noted in the autoclave logbook and the cycle should be run with a Class 5 or 6 indicator numbered with the Statim cycle number. The cycle number is then noted on the clients release form and indicator added to the logbook.

[38] https://www.saiglobal.com/pdftemp/previews/osh/as/as4000/4800/4815-2006.pdf

Autoclave Cycle Log Book

Date (YY-MM-DD)	Cycle #	Cycle Time			Temp °C	Pressure	Operator	Contents/Procedure	Indicator/Integrator
		Start	End	Cycle					

AUPP Member Corner

We want your feedback

After the overwhelmingly positive response from our previous publication, we would love to know what other topics you would like us to cover or further expand upon in the future.

Send your suggestions to **contact@safepiercing.org.au**

Meeting Membership Requirements

Ensuring that you meet or exceed the minimum AUPP member requirements is an important part of the advancement and growth of our association and industry.

2020 Requirements

- Submits yearly autoclave spore tests
- Dedicated biohazard tool container (if reprocessing tools)

2022 Requirements (previously 2021)

- Sterilised piercing implements kept in enclosed non-porous containers
- Environmental requirements
    - Sterilised piercing implements kept in enclosed non-porous containers
    - Biohazardous waste containers must have a hands-free lid and marked “Biohazard”
- Sterility requirements
    1. Submits monthly autoclave spore or helix tests
    2. Uses single-use aseptic drape and/or a visual identifying prep (such as iodine) for skin penetration procedures
    3. Uses and records a class 5 integrator or class 6 emulator for every autoclave cycle
    4. Uses an autoclave with Class B or Class S programs for hollow and porous loads

2023 Requirements (previously 2022)

- Practices a minimum of one of the following tests for all actively used sterilisers
    - Daily helix tests
    - Weekly in-house spore testing
    - Monthly third party spore testing

Supporter Highlight