[Organization logo]

[Organization name]

Commented [AES1]: All fields in this document marked by square brackets [ ] must be filled in.

PROCEDURE FOR DRY HEAT STERILIZATION

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [AES2]: The document coding system should be in line with the organization's existing system for document coding; in case such a system is not in place, this line may be deleted.

Distribution list

Commented [AES3]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

Copy no.	Distributed to	Date	Signature	Returned	
				Date	Signature

Change history

Date	Version	Created by	Description of change
	0.1	Advisera	Basic document outline

Table of contents

1. Purpose, scope, and users

The purpose of this procedure is to define the sterilization process of medical devices in the production and service provision process.

This procedure applies to all processes with requirements for sterile medical devices.

Users of this document are all employees of [organization name] inside the scope of the QMS.

2. Reference documents

- ISO 13485:2016 standard, clauses 6.4.2, 7.5.2, 7.5.5, and 7.5.7
- ISO 14971:2019
- MDR 2017/745 Annex IX – Chapter I
- Quality Manual
- Procedure for Production and Service Provision
- Harmonized or valid ISO standards regarding dry-steam sterilization
- [other documents and regulations specifying document control]

3. Sterilization process

Although physical or chemical processes cannot ensure absolute sterilization, an object is considered to be sterile when necessary conditions have been met during a sterilization process.

Application: Oxidation of cell composition is considered to be the basis of sterilization. [illegible]

3.1. Decontamination

[Job title] must ensure the decontamination of contaminated, or presumed contaminated items (e.g., supplies, equipment, medical devices, etc.), [illegible]

The following rules apply during decontamination:

- **Transport** – [job title] collects the contaminated or presumed contaminated items and transports them to the decontamination area, avoiding contamination of facilities and employees. [illegible]

Commented [AES4]: Adapt to the organization's needs.

Commented [AES5]: Include the name of your organization.

Commented [AES6]: Delete this if your organization does not need to be compliant with MDR.

You can find the full text of the MDR on the following link: https://advisera.com/13485academy/mdr/

Commented [AES7]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "03_Quality_Manual".

Commented [AES8]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "12_Production_and_Service_Provision".

Commented [AES9]: If you are in the EU market, then use the harmonized standards https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en

If you are in the USA market, use the approved standards by the FDA https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Commented [AES10]: Adapt to the organization's practice.

Commented [AES11]: E.g., Sterilization Manager, Production Manager

Commented [AES12]: E.g., employee in Sterilization [illegible]

- **Protective equipment and clothing** – Employees who work in decontamination areas must use protective equipment and clothing. [illegible]
- **Sorting** – Employees must sort the contaminated items immediately after utilization, and avoid any further contact with contaminated items unless using appropriate protective clothing and equipment. [illegible]
- **Washing** – [job title] ensures that detergent used for washing is adequate to the materials in the item and ecofriendly. [illegible]
- **Inspection** – [job title] inspects all decontaminated items for cleanliness and sends them to packaging. [illegible]

[Job title] must ensure the following during the inspection:

- Instruments with cutting edges should be checked for sharpness. Items with dull spots, chips, or dents should be discarded.
- Pivoted instruments, for example, clamps and forceps, ought to be checked for solidness and arrangement of jaws and teeth. Tips ought to be properly adjusted, jaws should meet perfectly, and joints should move effectively.
- [illegible]
- [illegible]
- [illegible]

In case of any irregularities during the inspection and checking, [job title] must send the suspect items to be decontaminated again or repaired.

3.2. Dry heat sterilization methodology

[Job title] must ensure that a written sterilization procedure based on manufacturer's instructions is present at the place of application, and that all staff follow this written procedure. This procedure should include loading, choice of sterilization cycle, procedure after sterilization, and record keeping. [illegible]

3.2.1. Safety precautions

When operating the dry heat sterilizer, [job title] must take following precautions:

Commented [AES13]: E.g., Production Manager, Sterilization [illegible]

Commented [13A14]: The key considerations when determining sterilization operating procedures are the types of [illegible]

Commented [AES15]: E.g., Production Manager, Sterilization Manager

Commented [AES16]: E.g., Sterilization Manager

- The outer surface of the sterilizer will be comfortable to touch during the sterilization process, but sterilized instruments and inside parts of the sterilizer will be hot and dangerous to be touched by hand without proper protection. So, it is necessary to use proper tools or heat-resistant gloves, as protection, to take out sterilized hot instruments.
- The sterilizer is constructed of metal materials, plastic and silicone rubber products can be used only if their compatibility is confirmed.
- [illegible]
- [illegible]
- [illegible]

3.2.2. *To start the day*

[Job title] must inspect the heating chamber before starting the sterilization process. Once the products are loaded in the sterilizer, [job title] must check whether the doors of the sterilizer are properly closed before the sterilization process is initiated. [illegible]

Commented [AES17]: Adapt to the equipment the [illegible]

The energy consumption of the sterilizer is very small, so it can stay on for almost a whole day.

[illegible]

3.2.3. *Before sterilization*

[Job title] ensures that all instruments to be sterilized are dried prior to placing them in the sterilizer. If excess water is present during sterilization, this water will evaporate, but will impede the sterilization process.

[illegible]

If alcohol is used for washing instruments before sterilization, [Job title] must check whether the instruments have been properly dried before entering the sterilizer. In cases when an instrument is subjected to any other chemical solvent, [job title] must ensure that the solvent is removed before the instrument is placed into the sterilizer. [illegible]

Failure to thoroughly remove extraneous agents prior to sterilization could lead to surface staining of instruments.

[illegible]

3.2.4. *Unwrapped instruments sterilization process (Cycle I – 6 minutes)*

Commented [AES18]: Adapt to the equipment and medical [illegible]

NOTE: After sterilization, unwrapped instruments have to be covered with a sterile cover in order to prevent contamination from the immediate environment before their use. Instruments should not be stored before use.

[illegible]

Only a single layer of instruments should be placed in the tray to ensure complete sterilization. Small items should be placed in a mesh accessory basket, and then into the instrument tray, by [job title].

[illegible]

Commented [AES19]: Adapt to the equipment the [illegible]

After sterilization, the hot trays containing the instruments will be removed from the chamber with tray-removal tools and placed on a cooling rack. Instruments will not be removed from trays.

3.2.5. Unwrapped hand piece sterilization process (Cycle II – 8 minutes)

Commented [AES20]: Adapt to the equipment and medical [illegible]

[Job title] must follow the steps listed below for cleaning, rinsing, and drying air rotor hand pieces or medical drills before sterilization:

Commented [AES21]: E.g., employee in Sterilization department

- Use flash water lines/ 30 seconds/ for cleaning hand piece, use detergent and water to remove adherent material. The head of the turbine should be cleaned with cleaner or proper solvent inside the air drive to remove old lubricant and debris.
- Completely rinse hand pieces with distilled or deionized water to remove alcohols and solvents and to prevent staining or spotting, and let dry. The presence of water can slow down the process, and solvent residue present during sterilization can result in fire or explosion.
- [illegible]
- [illegible]

Commented [AES22]: E.g., Super-Lube Multi-Purpose [illegible]

To start the sterilization process, [job title] initiates Cycle II. After the end of the cycle, [job title] is required to take out the instruments and leave them to cool. [illegible]

Commented [AES23]: Adapt to the equipment the [illegible]

3.2.6. Wrapped instruments sterilization process (Cycle III – 12 minutes)

Commented [AES24]: Delete if not applicable to your organization.

[Job title] ensures that wrapped instruments are processed only in a vacuum sterilizer that is designed for wrapped instruments. [illegible]

If wrapping instruments prior to sterilization, [job title] ensures that:

- the wrapping material manufacturer's instructions are followed
- the wrapping materials are compatible with the dry heat sterilization process
- [illegible]
- [illegible]

- the correct size of pouch is used (i.e., only slightly larger than the contents)
- [illegible]

When packaging sterilized instruments, [job title] must ensure that only properly dried instruments are packed and placed in the accessory instrument rack, but no more than 7 packages.

NOTE: Packed or pouched instruments should not be put in layers in the tray if the instrument rack is not used, because pouches prevent air flow and threaten the sterilization process. [illegible]

[Job title] must use the instrument rack when packing sterilized instruments and ensure it is applied during the entire sterilization process.

[illegible]

Commented [AES25]: Adapt to the equipment the [illegible]

[Job title] attaches a pre-written or pre-printed adhesive label to each pack that includes the word "Sterile," the process date, and the sterilizer identification and cycle numbers. Do not write on the label after attaching it to the wrapping, and do not write directly onto the wrapping with a ballpoint or felt pen, as this might damage it.

[illegible]

3.2.7. Handling and storage of unwrapped instruments immediately after sterilization

[Job title] ensures that instruments that have been sterilized unwrapped are designated as "sterilized only." It is currently acceptable for instruments sterilized unwrapped to be kept for later use. However, [job title] must ensure they are:

- cooled
- protected from contamination
- [illegible]

[Job title] must have clean hands and put on clean gloves and a clean apron before handling unwrapped instruments that have been removed from the sterilizer. [Job title] must take additional precautions if the instruments are still hot.

[illegible]

[illegible]

When labeling wrapped instruments, [job title] writes on the labels before attaching them to the wrapping. Do not write on the wrapping directly with a ballpoint or felt pen, as this might damage it.

[Job title] ensures that the instruments are stored in clean and enclosed cupboards, drawers, or boxes in an orderly manner that prevents damage to the wrapping.

3.2.8. Handling and storage of wrapped instruments immediately after sterilization

[Job title] ensures careful handling and storage of sterilized packs to make sure that the contents remain sterile until the pack is opened.

If a wrapped item or pack is wet, is dropped on the floor, is torn, or has broken seals, it is no longer sterile. In this case, [job title] unwraps the instrument and return it to the start of the decontamination process.

[Job title] ensures that wrapped instruments are stored in clean, enclosed cupboards, drawers, or boxes in an orderly manner that prevents damage to the wrapping (i.e., dry, with little variation in temperature and minimal handling).

3.3. Validation of the sterilization process

There is no practical way of determining that items processed in a dry heat sterilizer have been sterilized. Instead, tests need to be carried out regularly to confirm that during each sterilization cycle, the sterilizer reproduces the operating conditions that were previously established as effective for sterilization. Essentially, testing is necessary to confirm that the machine consistently does what it was designed and set up to do.

Commented [AES26]: Delete if not applicable to your organization.

Commented [AES27]: E.g., employee in Sterilization

Following installation of a new sterilizer. These checks and tests are performed by [job title] and recorded in the [Record for Sterilization].

Commented [AES28]: Adapt according to applicable legal and

The validation report must be prepared in accordance with applicable standards and regulations stated in Section 2 of this procedure.

3.3.1. Preparing test loads

The effectiveness of the sterilizer must be evaluated by [job title] through test loads, and results should be consistent. The tests should be carried out with the number of instruments recommended for the particular sterilizer, and which can be identified as a full load of [single metal instruments normally sterilized during the day, particularly those with hinges or marked surfaces, as well as lumens].

Commented [AES29]: Examples are cutters, pliers, mirrors,

NOTE: "Full load" means that the tray is filled with one layer of non-overlapping instruments.

3.3.2. Biological test protocol

Commented [AES30]: Adapt to the equipment the

[Job title] prepares a challenge load of instruments and performs the following steps:

Commented [AES31]: E.g., Sterilization Manager, QA Manager,

1. First, verify functionality by preparing, starting, and running the selected cycle.
2. For Cycle I and Cycle II, [job title] needs to place test utensils on the tray in one layer. For Cycle III, put test utensils in self-sealing nylon bags or other recommended bags.
3. In Cycle III, put chemical indicators in all bags, and for Cycles I and II, put indicator strips below instruments to be sure that they remain in place.
4. For Cycle III, put a spore test strip in a bag and seal the bag. Be very careful to avoid destroying the strip during insertion into the bag or placing the test utensils in the bag. Examine the envelope of the biological indicator before and after sealing a process to ensure its reliability. A damaged envelope can indicate possible contamination from the environment, which could result in the growth of pathogens.
5. The test strip should be located in the center of a tray that is filled in one layer, or in the center of a rack that is fully loaded.
6. When the sterilizer achieves a working temperature of 270 °F (132°C), put the tray in the sterilizer.
7. The process of sterilization begins at this time.
8. At the end of the sterilization process, remove the strip very carefully, and check the strip for any irregularities (punctures, tears, damage to the seal). Record integrity in the Biological Test Data Manual. If there any signs of damage to the envelope or seal, it is necessary to repeat the test from step 1 through step 9. If you are sending the test to an external test center, follow the instructions provided in the test kit. If you are implementing an in-house test, maintain sterile conditions for removing the strip from the envelope and transferring it to a tube for incubation. Follow the instructions for temperature and incubation time. Note any actions that could result in cross contamination.
9. Check if the chemical indicator has changed in color.
10. Review all documentation to make sure that the sterilizer works properly during this process.

Commented [AES32]: Adapt to the equipment the

11. If, during the testing, there are conditions that may cause failure of the test, such conditions should be indicated by [job title].

4. Managing records kept on the basis of this document

Record name	Code	Storage			
		[illegible]	[illegible]	[illegible]	[illegible]
Record for Sterilization	PR14.6	[illegible]	[illegible]	[illegible]	[illegible]

Commented [AES34]: Adapt the information in this column to [illegible]

Commented [AES33]: Adapt the information in this column to [illegible]

Commented [AES35]: If the record is in electronic form, write [illegible]

5. Appendices

- Appendix 1 – Record for Sterilization

[job title]
[name]

_____

[signature]

Commented [AES36]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.