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	Document Type:	Policy
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	Department/Section:	Sterilization and Reprocessing Unit
	Document Title:	STERILIZATION POLICY

PURPOSE:

To ensure the proper sterilization method of all instruments, equipment and devices in the Sterilization and Processing Unit.

LEVEL:

Sterilization and Reprocessing Unit (SRU)

DEFINITION OF TERMS:

Biological Indicator- test systems containing viable bacterial spores providing a defined resistance to a sterilization process.

Bowie-Dick Test -a test used in the prevacuum sterilization cycle to check for air entrapment and is conducted daily.


Chemical Indicator- test system that reveal a change in one or more predefined variables based on a chemical or physical change resulting from exposure to the process.

Load List- the number of reusable instrument(s)/sets included in the sterilization cycle

Reprocessing- all steps that are necessary to make contaminated reusable medical device ready for its intended use. These steps may include cleaning, functional testing, packaging, labeling, disinfection and sterilization.

Sterilization- a validated process use to render an object free from viable microorganisms, including viruses and bacterial spores, but not prions.


PCD/ Process Challenge Device- is a device used to assess the effective performance of a sterilization process by providing a challenge to the process that

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is equal to or greater than the challenge posed by the most difficult-to-sterilize item routinely processed.¹

POLICY:

1. The SRU shall keep up-to-date and accessible documentation and records of its sterilization processes.
 - 1.1. There shall be a complete record of each sterilization cycle, including the load control label, recording chart or printout, process recording record, and sterility record.
 - 1.2. The record shall also include details of:
 - a) the sterilization cycle, including date and time;
 - b) exposure time;
 - c) temperature;
 - d) pressure;
 - e) sterility test results;
 - f) and the kind, quantity, and origin of the devices sterilized
2. The record shall allows team members to track individual items or devices associated with a sterilizer or sterilization cycle.
 - 2.1. The record shall also includes additional information that may be required for a recall action.
3. The SRU shall store and retain the sterilization data for a maximum of three (3) years. After the specified period, all records shall be disposed of according to hospital policies.
4. To check if the autoclave is functioning properly, the Bowie & Dick Test shall be carried out before the autoclave is used; Biological and chemical checks (sterilization indicators) are performed during the sterilization cycle to ascertain whether or not sterilization parameters are met.

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- 4.1. The Bowie & Dick test enables to ensure that air is properly removed from the sterilization chamber (see Standard Operating Procedure on Performing the Bowie and Dick Test for further details.
5. There shall be a complete daily testing of the sterilizers using a PCD equipped with biological indicators, and documents the results.
 - 5.1. Biological indicators will be used to test each type of sterilization cycle that will be used during the day.
 - 5.2. Include a PCD equipped with biological indicators for every load containing implantable devices. Implantable devices are quarantined until the results of the biological indicator test are available.
6. Sterilization procedures shall be monitored using biological, mechanical, and chemical indicators.
 - 6.1. Do not use instrument packages if mechanical or chemical indicators indicate inadequate processing.
 - 6.2. Chemical indicators should be inspected immediately when removing packages from the sterilizer; if the appropriate color change did not occur, do not use the instruments.
7. The SRU Technicians shall prepare each device or set of devices for sterilization according to manufacturers' instructions, including drying, lubrication, and disassembly.
 - 7.1. Lubricants shall be compatible with the sterilization process used.
8. The SRU staffs shall operate the sterilization equipment and conduct the sterilization safely and accurately.
 - 8.1. The team can test its most complex or challenging pack or container to verify that all devices can be sterilized.
9. The SRU staffs shall follow the standard operating procedures, the sterilizer's operating manual, and manufacturers' instructions for devices and equipment

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when loading the sterilizer to avoid wrong usage that may affect the performance of the device.


- 9.1. The operating manual of the machines shall be available in the unit at all times.
 - 9.2. The load should not contact the interior surfaces of the sterilizer chamber.
 - 9.3. Technicians shall verify the configuration of the load before beginning the sterilization. Indications of acceptable loads are identified in the sterilizer's *operating manual*.
10. After the sterilization cycle and before unloading, the SRU Technician shall verify that the required parameters have been met.
 11. Inspect all packs including the results of external chemical indicators during unloading.
 12. Repeat reprocessing for any items with a damaged pack or seal, or those that are compressed, torn, wet, or have been dropped on the floor.
 13. Sterilized packages shall be clearly identifiable and distinguished from non-sterilized items to prevent the use of a nonsterilized item on clients.

DOCUMENTATION:

New Policy

DISSEMINATION:

1. Policies and Procedure Manual
2. Hospital Communicator

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REFERENCE:

¹*Process challenge devices (PCD) - Low Temperature Hydrogen Peroxide Gas Plasma | Advanced Sterilization Products.* (n.d.). ASP. Retrieved June 15, 2022, from <https://www.asp.com/en-us/education/how-to-training/process-challenge-device#:~:text=A%20PCD%20is%20a%20device,to%2Dsterilize%20item%20routinely%20processed%7E:text=A%20PCD%20is%20a%20device,to%2Dsterilize%20item%20routinely%20processed>

²*Sterilization: Packaging & Storage | FAQs | Infection Control | Division of Oral Health | CDC.* (n.d.). CDC. Retrieved May 6, 2022, from <https://www.cdc.gov/oralhealth/infectioncontrol/faqs/packaging-storing.html#:~:text=What%20types%20of%20packaging%20materials,be%20either%20woven%20or%20unwoven>


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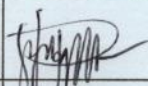

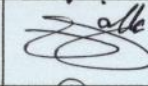
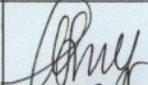
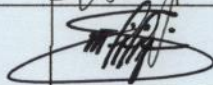
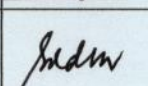


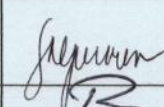

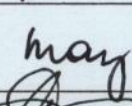
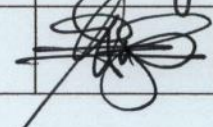
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	Document Title:	STERILIZATION POLICY

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	Document Title:	STERILIZATION POLICY

PURPOSE:

To ensure the proper sterilization method of all instruments, equipment and devices in the Sterilization and Processing Unit.

SCOPE:


Applies to all Sterilization and Reprocessing Unit staff of Dr. Pablo O. Torre Memorial Hospital

PERSON RESPONSIBLE:


Sterilization and Reprocessing Unit Technician

PROCEDURE:

1. Perform testing on the sterilization equipment to be used to ensure that it is functioning well.
2. Document the result of the testing.
3. Follow the manufacturers' instructions for devices and equipment when loading the sterilizer to avoid wrong usage that may affect the performance.
4. Verify the configuration of the load before beginning the sterilization. Indications of acceptable loads are identified in the sterilizer's operating manual.
5. The load should not contact the interior surfaces of the sterilizer chamber.
6. Operate the sterilization equipment and conduct the sterilization safely and accurately.
7. Verify that the required parameters have been met after the sterilization cycle and before unloading.
8. Inspect all packs including the results of external chemical indicators during unloading.
9. Repeat reprocessing for any items with a damaged pack or seal, or those that are compressed, torn, wet, or have been dropped on the floor.

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10. Keep up-to-date and accessible documentation and records of its sterilization processes.
11. Store and retain the sterilization data for a maximum of three (3) years. After the specified period, all records shall be disposed of according to hospital policies.

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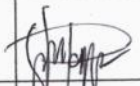









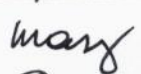
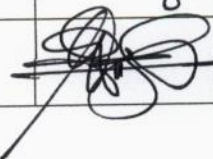
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KEY TASKS	PERSON RESPONSIBLE
1. Performs testing on the sterilization equipment to be used to ensure that it is functioning well	SRU Technician
2. Documents the result of the testing	
3. Follows the manufacturers' instructions for devices and equipment when loading the sterilizer to avoid wrong usage that may affect the performance	
4. Verifies the configuration of the load before beginning the sterilization. Indications of acceptable loads are identified in the sterilizer's operating manual	
5. Ensures that the load does not come in contact with the interior surfaces of the sterilizer chamber	
6. Operates the sterilization equipment and conduct the sterilization safely and accurately	
7. Verifie that the required parameters have been met after the sterilization cycle and before unloading	
8. Inspects all packs including the results of external chemical indicators during unloading.	
9. Repeats reprocessing for any items with a damaged pack or seal, or those that are compressed, torn, wet, or have been dropped on the floor	
10. Keeps up-to-date and accessible documentation and records of its sterilization processes	
11. Stores and retains the sterilization data for a maximum of three (3) years	

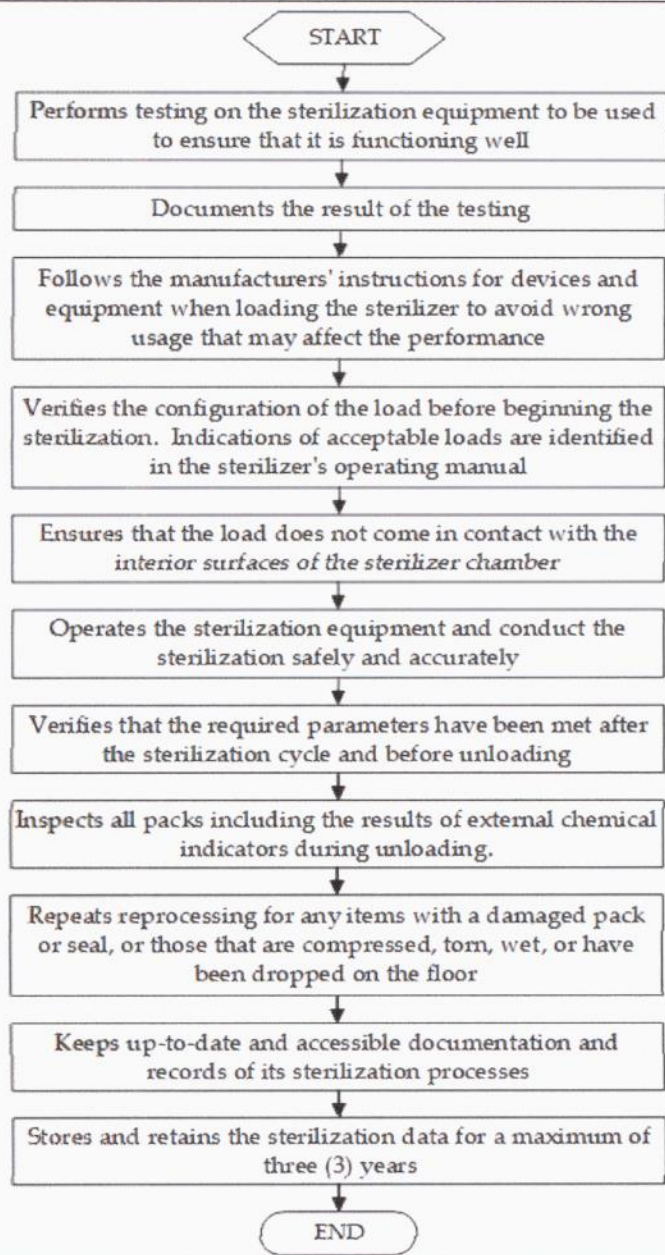
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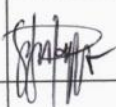
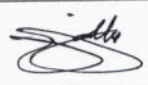
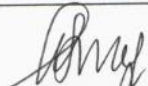
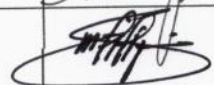


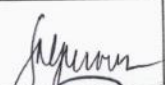


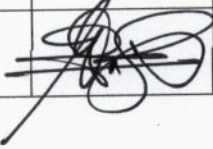
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FLOWCHART



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