



BIOGENIX

## OPERATION AND MAINTAINANCE OF AUTOCLAVE

NAME		DESIGNATION	SIGNATURE	DATE
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## 2 REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				





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## 4 POLICY STATEMENT:

- 4.1 Biogenix laboratory autoclave all clinical samples received in laboratory before disposal.

## 5 PURPOSE

- 5.1 The purpose of this SOP is to provide instruction for operation and maintenance of the autoclave
- 5.2 Provide guidance related to prevention of injuries as well as effective sterilization.
- 5.3 The Zealway GI 100 series unit is intended for Biological Waste Decontamination in Biogenix Laboratory. It is vertical autoclave specially designed and easy for laboratory operation. It is devised with automatic exhaust system, special for liquid sterilization function.
- 5.4 Autoclaves in the pre-disposal treatment and sterilization of waste material operate by utilizing pressurized steam and superheated water to neutralize potentially infectious agents. Its operating temperature is programmed at 1210C, chamber pressure at 0.15 MPa and the disinfection time is fixed at 30 minutes.

## 6 SCOPE

- 6.1 The scope of this policy extends to all the staffs in the Biogenix laboratory who are authorized to use Autocalve.

## 7 DEFINITIONS

- 7.1 Sterilization refers to any process that removes, kills, or deactivates all forms of life (in particular referring to microorganisms such as fungi, bacteria, viruses, spores, unicellular eukaryotic etc.) and other biological agents like prions present in a specific surface, object or fluid, for example food or biological culture media.





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## 8 ACRONYMS

8.1 PPE – Personal Protective Equipment

## 9 RESPONSIBILITIES

9.1 Laboratory Staff

9.2 Biomedical Staff

9.3 Infection control officer

9.4 Laboratory director

## 10 PROCEDURE

10.1 Safety precautions:

10.1.1 Never autoclave the following materials:

10.1.1.1 Flammable or explosive substances.

10.1.1.2 Non-flammable liquids that have a high vapor pressure (halocarbons and the like), even in closed containers.

10.1.1.3 Gas in bottles and spray cans (even if the containers are empty).

10.1.1.4 Substances that due to decomposition caused by moist heat can generate toxic, noxious, flammable, or explosive gases or vapors or can generate flammable, noxious, toxic solids or residues.

10.1.2 The opening of the sterilization chamber door at the end of a cycle may be accompanied by the release of steam. Moreover, the internal parts of the chamber may remain at high temperature. Be particularly careful during unloading of the sterilized product and use adequate protective means.





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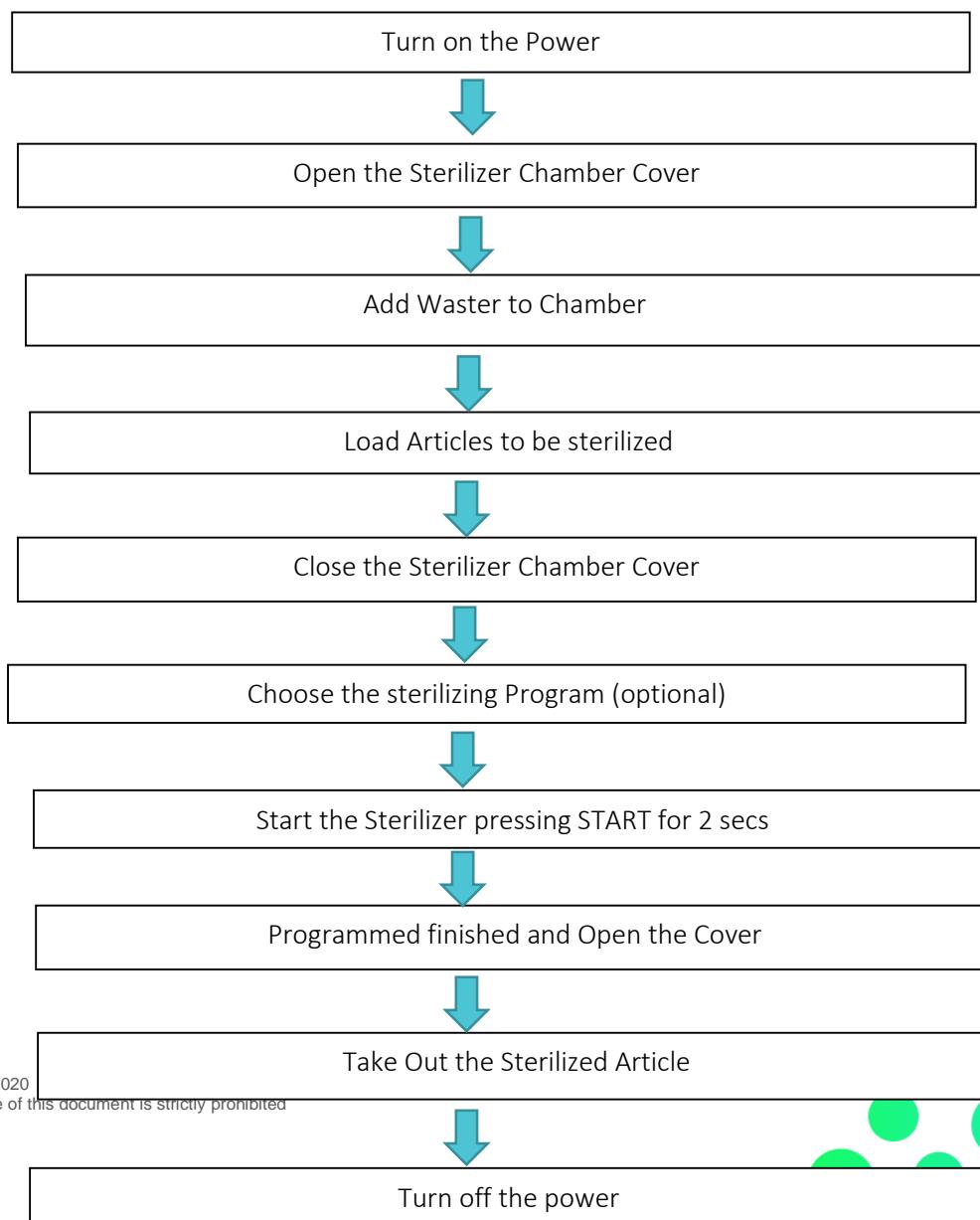
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10.1.3 Distilled Water must be used as sterilization water to avoid affecting the service life of autoclave.

10.1.4 In case of any abnormal situation (such as abnormal sound, smell, smoke), turn off the power supply immediately, pay attention to observation, and contact the biomedical department staff.

### 10.2 Operation:

#### 10.2.1 Basic Operation instructions:





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### 10.2.2 Detailed Operation instructions:

#### 10.2.2.1 Turn on the Power

10.2.2.1.1 After turn on the power, the system will do the self-checking, screen will show “Select Account”, and send out long sound. After input the password, the screen will enter into the last time login interface.

10.2.2.1.2 If the instrument is under standby condition, and no any operation within 30 minutes, the machine will enter into electricity saving mode, and screen will go dark, press any button can restore the display.

#### 10.2.2.2 Open the sterilizer chamber cover

10.2.2.2.1 Turn the handle counter-clockwise until the lid is loosened, need to turn the handle until you can not turn, so to protect the sealing ring from dropping off.

10.2.2.2.2 Push the handle rightward slightly to move the lid to one side

#### 10.2.2.3 Empty the front water tank and add water into chamber

10.2.2.3.1 Check the front water tank of the instrument(Fig1), make sure the water level is under the high water level line, empty it if too high. If you don't empty it, the water will come out from the back of the machine(Fig2)



Fig 1





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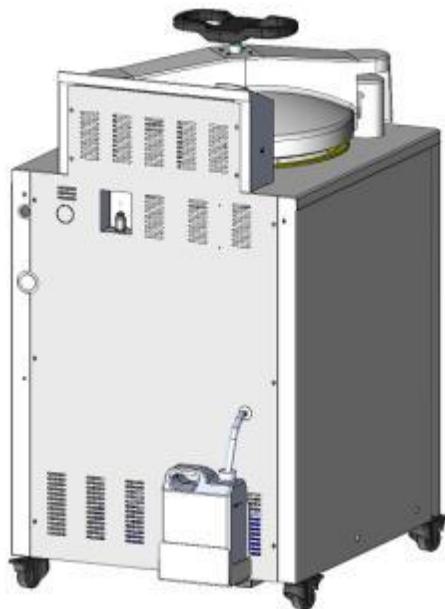


Fig 2

10.2.2.3.2 Check the water level in the chamber, if you cannot see water from the hole in the water plate, you should add water in, and the water should not be higher than the water plate.

10.2.2.3.3 The water level inside the chamber may decrease after each cycle, please add new water on time. Lack of water for a long time may cause damage to the heater.

10.2.2.4 Load articles to be sterilized

10.2.2.4.1 Take the baskets out, and put the articles to be sterilized into the baskets

10.2.2.4.2 Put the water plate first, then put the baskets on the water plate, do not put the basket directly on the heater.

10.2.2.5 Close the sterilizer chamber cover





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10.2.2.5.1 Push the handle left word slightly until the arm leans against the arm stopper

10.2.2.5.2 Turn the handle until it is secured and at the same time the door lock icon is white and not blinking. The handle must end in a position either horizontally or vertically, you can even loosen it a little bit to make it positioned horizontally or vertically.

Note :

Before closing the cover, check if there are objects in or on the sealing ring, clean it to avoid damaging the sealing ring that may cause the steam leakage.

Only when the lid close icon on the screen changes to white and not blinking, the machine will start to work.

10.2.2.6 Select or set the program;

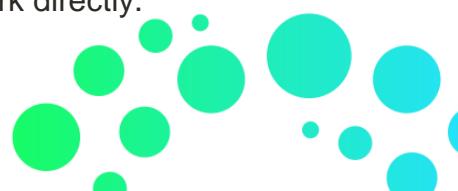
10.2.2.6.1 Default Program is set is SOLID (121° C for 30 mins)



10.2.2.7 Start to sterilize

10.2.2.7.1 After power turned on, screen displays the latest saved program. If you continue to use the program, long press " to start the work directly.

10.2.2.7.2 Choose the saved program, use UP or DOWN to choose the program you want, long press START to start work directly.





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10.2.2.8 Program finished & Open the cover;

10.2.2.8.1 When reach the set sterilizing time, melting time or lid open temperature (only self-defined mode), the system will send out an alarm.

10.2.2.8.2 When the program is finished and the temperature is below 3 below the boiling point in solid mode or 20 below boiling point in liquid mode, the "complete" on the screen flashes, and the system will send out 5 long sound, indicating the end of sterilization. At this time, if you open the cover, you should pay attention not to get burnt.

10.2.2.8.3 when the temperature is lower than 40 the system returns to the standby state and the cover can be opened safely.

Note :

If the handle is turned by mistake during sterilization, the handle cannot be continue turned due to locked, but there might be a little steam release. In this case, press STOP button to stop the instrument immediately. When open the lid, turn the handle slightly toward the opposite direction that it is wrongly operated, and then turn the handle in counter clockwise until the cover is released.\

Never press STOP button casually to stop the running program during sterilizing of liquids to avoid the liquid overflowing into the sterilizer chamber and even blocking the valve and pipelines.

Be careful not get burnt by the hot steam while open the lid.

10.2.2.9 Take out the sterilized articles:

10.2.2.9.1 Always wear the heat insulation gloves when taking articles out after sterilization, and wait until the steam disappears before reaching into the sterilizer sterilization, and wait until the steam disappears before reaching into the sterilizer chamber.





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10.2.2.9.2 When sterilize the liquids, make sure taking articles out with enough low hen sterilize the liquids, make sure taking articles out with enough low temperature, due to temperature, due to slow cooling speed of liquid. Slow cooling speed of liquid.

10.2.2.10 Turn off the power

10.2.2.10.1 The power switch should be turned off at the end of the day's sterilization work or when it is not in use for a long time.

10.2.2.10.2 At the end of the day's work, it is recommended to drain out all water in the sterilization chamber.

10.2.3 Cleaning & Maintenance of Autoclave:

10.2.3.1 Cleaning:

10.2.3.1.1 Water change and chamber cleaning:

10.2.3.1.1.1 Water change:

10.2.3.1.1.1.1 If the water in the chamber is not changed for a long time, the dirt inside will cause damage to solenoid valve.

10.2.3.1.1.1.2 Connect the drainage to the chamber drain port, then open it counter clock wisely.

10.2.3.1.1.2 Chamber cleaning

10.2.3.1.1.2.1 Clean the chamber once a week

Note:

Make sure the water inside is not hot before draining out

Drain the water completely when the machine is not used for a long time.





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### 10.2.3.1.1.3 Heater cleaning;

10.2.3.1.1.3.1 Take out the water plate and check whether the surface of heater is clean or not. Otherwise, wash with soft brush, and then empty the dirty water

10.2.3.1.1.3.2 Do not move or damage the temperature control switch on the heater

10.2.3.1.1.3.3 Suggest to clean once a month.



10.2.3.1.1.3.4 Clean the instrument surface

10.2.3.1.1.3.5 The surface of instrument may be cleaned slightly by using the soft cloth with little neutral detergent solution, and then dried with cloth





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10.2.3.1.1.3.6 Do not use phenol or oil thinner to clean the surface of the instrument to avoid damaging the surface of the instrument or causing the paint to fall off.

10.2.3.1.2 Maintenance:

10.2.3.1.2.1 Check of Leakage Circuit Breaker

10.2.3.1.2.1.1 Press the T button at the back of leakage circuit breaker, if it dumps off, means normal, if no, please turn off and contact the dealer.

10.2.3.1.2.1.2 Press the power switch, pull up the leakage circuit breaker, can connect the power again

10.2.3.1.2.1.3 Check once half year

10.2.3.1.2.2 Safety valve test

10.2.3.1.2.2.1 Enter into the administer menu (Refer to Setting of Administrator Menu), then press DOWN to choose the safety valve test, choose ENABLE, press SET/ENT to save and exit.

10.2.3.1.2.2.2 The instrument will start to do safety valve test; you can press STOP to stop it.

10.2.3.1.2.2.3 If the temperature goes over the max temperature and safety valve is not releasing, means there is problem with the safety valve, please stop the test and contact distributor.

10.2.3.1.2.2.4 Press STOP can put an end to the testing, screen will show E03, this is normal, you can

10.2.3.1.2.2.5 press STOP button after the temperature goes down to 105 to return to standby condition.

10.2.3.1.2.3 Cleaning & Replacement of Sealing ring:





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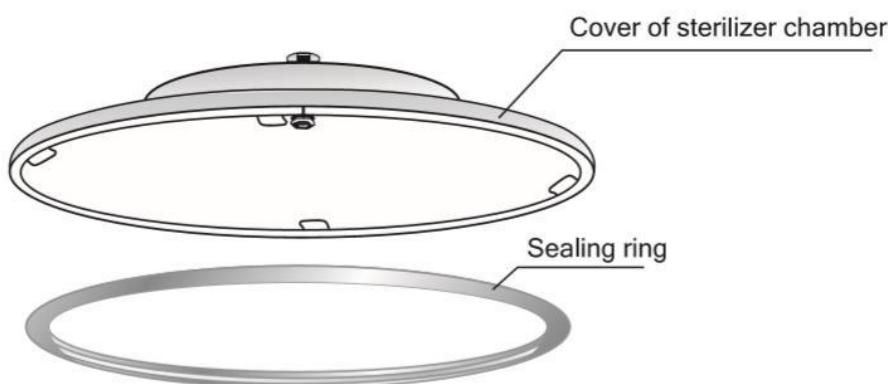
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10.2.3.1.2.3.1 Wipe the surface of the sealing ring and its contact parts with soft and clean cloth at least once a week to avoid steam leakage resulted from damage by dirt.

10.2.3.1.2.3.2 If the edge of the sealing ring of cover becomes white or hardened, it may lead to steam leakage and must be changed.

10.2.3.1.2.3.3 Sealing ring change way Pull one corner of the sealing ring to take off, when installing, press the sealing ring in part by part.



### 10.2.4 Quality Control:

10.2.4.1.1 Chemical Indicator tape is coming along with Autoclave Bag.

10.2.4.1.2 Post completion check for the change in color of chemical indicator from colorless to black.

## 11 CROSS REFERENCE:

11.1 User manual Zealway GI 100 Autoclave

## 12 RELEVANT DOCUMENTS & RECORDS:

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### 12.1 BG-REC-GEN-037 Autoclave Maintenance Checklist

