INSERT THIS END

AMDEK
CORPORATION

Steri-Dome

CARTRIDGE SD267
FOR AUTOMATIC GAS STERILIZER

DANGER

EXTREMELY FLAMMABLE,
CONTENTS UNDER PRESSURE. DO NOT USE NEAR
FIRE, HEATED SURFACES, SPARKS, OR FLAME.
DO NOT PUNCTURE OR INCINERATE CONTAINER.
EXPOSURE TO TEMPERATURES ABOVE 130°F
MAY CAUSE BURSTING.

N Y F D C of A No 4212

USE ONLY IN ACCORDANCE WITH MANUFACTURER'S INSTRUCTIONS ETHYLENE OXIDE VAPOR HARMFUL MAY CAUSE BURNS KEEP CONTAINER CLOSED AVOID BREATHING VAPOR Avoid inhalation and contact with skin or eyes In case of contact remove contaminated clothing and flush skin or eyes with plenty of water for eyes get medical attention

Do Not Re-Use Container Destroy When Empty
Store At Room Temerature Do Not Incinerate
Avoid Punturing
Active Ingredient Ethylene Oxide 100
Net wt. 67 gms. 2.37 ozs.
EPA REG. No. 19220-1

mfd. for: Amdek Corp., Sudbury, Mass. 01776
An AMDEK Product

OPERATING INSTRUCTIONS
FOR
STERI - DOME™
GAS
STERILIZER

OPERATOR MANUAL

DESCRIPTION OF STERI-DOME GAS STERILIZER

The Steri-Dome consists of a modular design with a Master Console and Modular Chamber. It utilizes a disposable g[illegible] [illegible] 100 [illegible]. The Steri-Dome [illegible] [illegible] the [illegible] Chamber. [illegible] sterilizing system. [illegible] the same time [illegible] unit, [illegible] charge of ETO. [illegible], the operator [illegible] the unit through a vent cycle [illegible], start [illegible] with a new cartridge. If the [illegible] the same time as the disconnect light, the unit did not achieve proper vacuum for the introduction of the gas. If the above happens, the operator must check the dome and gasket for proper seating and the gas transfer cable for proper connection. Since a load of liquid is in the machine, the operator must carefully unscrew the cap one revolution only to allow the unit to wind back but not to allow any gas to escape. After wind-back occurs (8 to 10 secs.), rescrew cap down to start fill cycle. The chamber operates 160 minutes at 170 F. The gas concentration while in use is approximately 1100 mg. per liter. It initially draws a 26" Hg. vacuum and operates at approximately 5" Hg. vacuum. The Modular Chamber [illegible] cannot be removed at any time during the cycle because of the vacuum. The timer on the Modular unit will shut off heat and pilot light at end of 160 minutes automatically. However, vacuum still remains until operator activates the Master Console on the vent cycle at which time the gas is removed and the vacuum released.

DESCRIPTION OF STERI-DOME GAS STERILIZER CARTRIDGE

The Steri-Dome Gas Cartridge contains 67 grams of 100 ETO. The container is aluminum with a steel cap and has a pressure of approximately 12 PSI. This pre-measured amount is sufficient to give a concentration of 1100 mg. per liter in the Steri-Dome Gas Sterilizer. These cartridges should be stored in a cool place away from sparks and flame. They are packaged in boxes of ten and cases of ten boxes (100 cartridges per case).

INSTALLATION OF STERI-DOME GAS STERILIZER

The Steri-Dome portable gas sterilizer should be located in a non-hazardous, well ventilated area. The machine should be located in an area where there is no flame or sparks and also operated by personnel who are not smoking during use of the machine. A [illegible] for venting purposes is supplied with the machine. The [illegible] should be vented [illegible] of the [illegible]. However, [illegible] should [illegible] to the [illegible] purposes. The [illegible] and thoroughly [illegible] [illegible] parts [illegible]

SPECIFICATIONS

Dimensions	Master Console	Overall 11" x 22" x 11	
	[illegible]	[illegible]	
	[illegible]	[illegible]	
Net Weight	[illegible]	[illegible]	
	[illegible]	[illegible]	
[illegible] Temperature	[illegible]		
Operating Vacuum	Maximum [illegible]	26" Hg	[illegible]
	Sterilizing	[illegible] Hg	Approximately [illegible]
Time Cycle Sterilization	1[illegible] minutes		
Time Cycle Vent or Fill	[illegible] minutes		
Sterilizing Agent	C_2H_4O	100 Ethylene Oxide	
Power	115 Volt	60 Hertz	1[illegible] Amps

OPERATION INSTRUCTIONS FOR THE STERI-DOME GAS STERILIZER

OPERATION OF THE STERI-DOME MODULAR CHAMBER

IMPORTANT! Wire basket must be used at all times to insure against heat damage from direct contact with floor of Modular Chamber.

a. The Steri-Dome Modular chamber should remain connected to a 115V, 60 Hertz outlet whether in use or not.

b. Remove the Dome and load articles and instruments to be sterilized into the wire basket adding three ml of sterile distilled water to a gauze sponge placed within the chamber for each application of the sterilizing system. If the recommended polyethylene bags are used for sterilizing articles and instruments, one drop of sterile distilled water is added to each bag, then heat sealed. The bags are placed in the Modular Chamber. Three ml of sterile distilled water are added to a gauze sponge placed within the chamber for each application of the sterilizing system.

c. Replace Dome on chamber so edges are seated properly.

d. Start timer by pushing red button on dial at which time the red indicator light will show heat is on and the timer is operating.

e. Immediately operate the Fill Cycle of the Master Console.

OPERATION OF THE STERI-DOME MASTER CONSOLE

The Steri-Dome Master Console [illegible] be.

FOR FILL

a. [illegible]

b. When disconnect light comes on, cycle is completed. If desired at this time, the unit can be disconnected from the Modular Chamber.

c. After Master Console completes any cycle, prior to starting on a new cycle, cartridge cap must be unscrewed so that unit can wind back to a starting position.

FOR VENT

a. If Master Console has been used for other chambers, be sure to connect gas transfer cable and electrical cord to chamber to be vented.

b. Make sure the vent line (nylon tubing) is connected directly to outside or into wet sponge supplied with unit.

c. Switch to Vent position with or without using an empty cartridge and screw cap down until machine starts. Unit has been vented when disconnect light comes on.

OPERATOR WARNING

This equipment must not be used in a hazardous area or near spark or flame and should not be used by or near anyone who is smoking.

PRE-CONDITIONING OF ARTICLES TO BE STERILIZED

Instruments or articles to be sterilized must be pre-cleaned with water, soap or detergents to remove adhering tissues and blood, serous exudates and other debris. All instruments or articles must be pre-soaked in water for a minimum of one hour and drained immediately prior to exposure with ethylene oxide. Articles that cannot be immersed in water must be sterilized in an ethylene oxide autoclave with a built-in automatic moisture-vapor-pre-treatment re-hydrative system. For sterility assurance of items with tightly mated surfaces, i. e., surgical instruments, hypodermic needles and syringes, it is recommended practice to dissemble the items as far as practical. Hollow bore needles and plastics or rubber tubings must be open and free from plugs. Use only single polyethylene bags for instruments or articles for each application. Do not use tightly polyethylene wrappings or sealed containers '.

PACKAGING FOR USE IN THE STERI-DOME GAS STERILIZER

The ideal packaging material to be used for gas sterilization is polyethylene with a thickness of 4 mils or less. Although cloth and paper are acceptable, they do not offer the maximum protection for maintaining sterility against bacteria and moisture penetration. Both paper and cloth offer ideal penetration of ethylene oxide; however, they must be guarded on the shelf against moisture contact. It also should be noted that large amounts of extremely dry cloth lower the relative humidity within the sterilizing chamber and do waste chamber space. Nylon should not be used as packaging in the Steri-Dome gas sterilizer because it does not allow good penetration of ethylene oxide gas and therefore with the relatively short sterilizing cycle, it is not suitable as a packaging material in the Steri-Dome Gas Sterilizer.

AERATION OF ARTICLES THAT HAVE BEEN GAS STERILIZED

Aeration is the time necessary for the residual ethylene oxide gas to dissipate from absorbent materials. Therefore, all rubber and plastic items must be considered absorbent and therefore require aeration time. The present recommended aeration times at room temperature for plastic and rubber articles are 7 days. Metal and glass and other non-absorbent materials require no aeration time and therefore can be used immediately. This 7-day time requirement can be replaced by the use of an aeration unit. The present Steri-Dome Aeration Unit is of 8 cubic feet capacity and has a time cycle of 12 hours. Therefore, with use of such a unit, the 7-day time can be reduced to 12 hours. It is important that either an aeration unit or the 7 days be adhered to by the user. Aeration does take place even though materials are packaged.

MONITORING THE STERI-DOME ETHYLENE OXIDE GAS STERILIZER

There are two ways of checking the efficiency of a gas sterilizer:

(1) Chemical indicators are very economical and easily placed on each bundle or package to be gas sterilized. They are used not only to chemically check the unit each cycle but are used to aid in identifying shelf packages which already have been sterilized. These are available in tape form and cardboard inserts, both of which visually change color on exposure to ETO.

(2) Biological - there are at the present time several commercially available spore strips and other devices which allow the operator to check a unit with a known population of resistant spores. This form of checking the performance of a sterilizer is recommended at least on a weekly basis as opposed to the chemical indicators which are used on each bundle. Once again, these biological tests will not give proper results if pre-conditioning and moisture standards are not adhered to.

AMDEK BOEKEL

STERI-DOME

FOR CUSTOMER SERVICE OR INFORMATION
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