



# Your Sterilizer Experts

**Manufacturing – Distribution – Maintenance- Guaranteed!**

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The attached manual is for your records.

Go to the below web site to look for parts

<http://bit.ly/All-American-Sterilizer-Parts>

# ALL AMERICAN

## OPERATING INSTRUCTIONS

### Non-Electric Pressure Steam Sterilizers

Models 1915X



1915X

Gross Volume 15.5 qt.  
14.75 liter



## CAUTION! READ THESE IMPORTANT SAFEGUARDS!

FAILURE TO FOLLOW INSTRUCTIONS AND/OR IMPROPER USE MAY RESULT IN SCALDING, BODILY INJURIES OR EXPLOSION.

When using the pressure steam sterilizer, basic safety precautions should always be followed:

1. Read and understand instruction manual before operating unit.
2. Do not touch hot surfaces. Use handles and pot holders.
3. Close supervision is necessary when the sterilizer is used near children.
4. Extreme caution must be used when moving a sterilizer containing hot liquids.
5. Do not use the sterilizer for other than intended use.
6. Always check the pressure release devices for clogging before use.
7. This sterilizer operates under pressure. Improper use may result in scalding injury. Make certain unit is properly closed before operating. Read Operating Instructions.
8. Never loosen wing nuts until the steam pressure gauge registers zero and you have allowed any remaining pressure to escape by opening the control valve (lever in the vertical position).
9. Do not open the sterilizer until the unit has cooled and internal pressure has been reduced. Gauge should read zero at the time. Read Operating Instructions.
10. Never use the sterilizer for cooking or processing food.
11. Do not use this sterilizer with oil.
12. Do not subject your sterilizer to sudden extreme temperature changes, as this will cause expansion or contraction which can crack a cast aluminum utensil. Do not move a sterilizer from a cold storage area directly onto a hot flame or element. Do not add cold water to a sterilizer which has boiled dry and is still hot. Do not cool the sterilizer suddenly by pouring cold water on it or wrapping cold wet towels around it.
13. As in all clinical laboratory settings, wear safety glasses when attending to your sterilizer.

**SAVE THESE INSTRUCTIONS**

# Operating Instructions for Non-Electric Pressure Steam Sterilizers

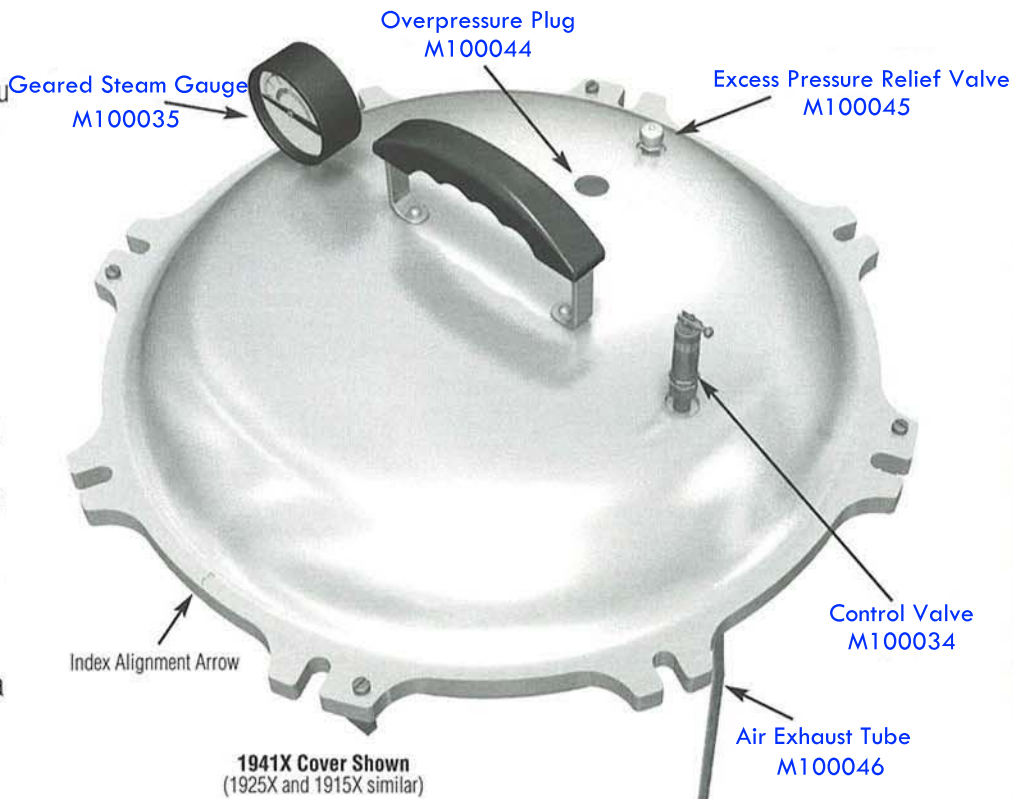
**IMPORTANT: DO NOT OPERATE THIS PRESSURE STEAM STERILIZER UNTIL YOU HAVE THOROUGHLY READ THESE OPERATING INSTRUCTIONS.**

## CLEANING

When you are done using your sterilizer, you need to empty the water from the unit, rinse thoroughly and dry completely. This procedure needs to be done daily. Do not leave water in the unit overnight. Rinse thoroughly between water changes. Store your sterilizer in a dry area. On your next use, fill the sterilizer with clean distilled water. Distilled water is the recommended water. If distilled water is not available, then you may use your local water. If your local water supply contains lime or high levels of minerals, the unit will require periodic cleaning to remove and prevent the buildup of deposits.

Units should be cleaned whenever there is a buildup of lime or mineral deposits. After many cycles, a white deposit may begin to form on the bottom of the sterilizer. We recommend cleaning with a lime remover. Manufacturers of coffee makers have cleaning solutions which may be used. There are also solutions available at your local hardware and drug stores that can be used to clean aluminum. Follow the manufacturer's instructions and make up a solution of the cleaner, filling your sterilizer above the standard operating level. Let the sterilizer stand a few minutes then rinse thoroughly. You may have to repeat this procedure a few times to fully remove the lime and mineral deposits from your sterilizer.

**Never heat the sterilizer when filled with a cleaning solution.**



You may also use standard white vinegar to clean your sterilizer. Fill your sterilizer above the standard operating level with vinegar and let it stand a few minutes then rinse thoroughly. You may have to repeat this procedure a few times to fully remove the lime and mineral deposits from your sterilizer.

### Elevation above sea level.

At altitudes greater than sea level, settings need to be adequately adjusted to compensate for the effect of altitude on the boiling point of water. We suggest you increase pressure by 0.5psi for every 1000 ft. of elevation above sea level.

City Altitude	Steam Pressure Required
Sea level	15-17 psi
2000 ft	16-18 psi
4000 ft	17-19 psi
6000 ft	18-20 psi
8000 ft	19-21 psi
10,000 ft	20-22 psi



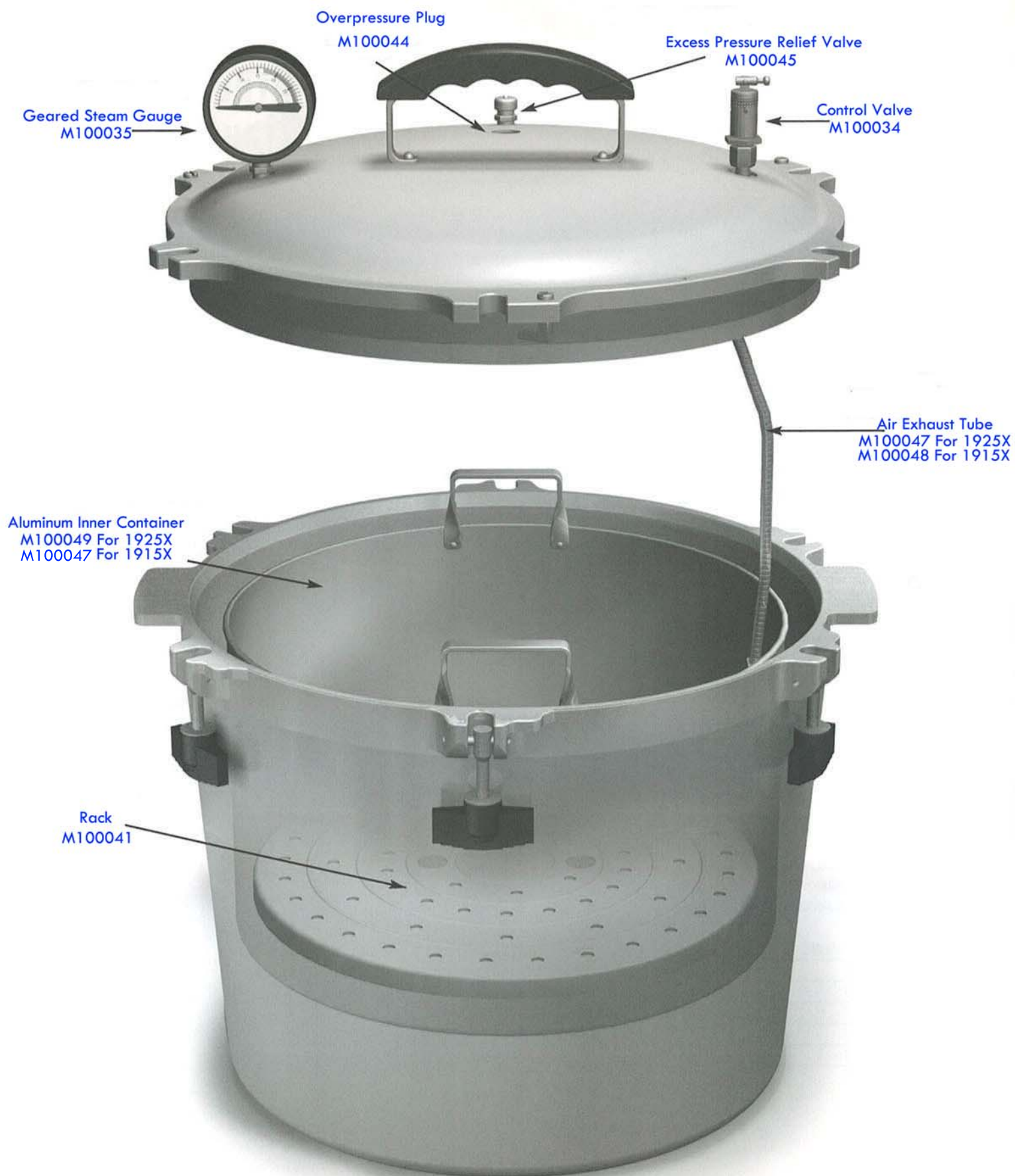


Figure B

Model 1925X shown  
(1915X similar)

## OPERATION

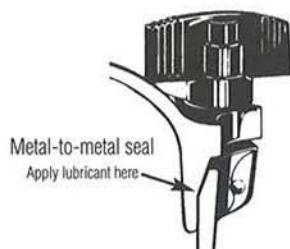


Fig. 1

### 1. LUBRICATE METAL-TO-METAL SEAL.

Apply lubrication to the point or edge where side wall and bevel meet on the inside of bottom (See Fig. 1 where arrow tip is pointing). The bevel is not the seat; only the point or edge where bevel meets the wall. We recommend using a high temperature lubricant such as a high vacuum grease. Only a thin film is required. Excess amounts may cause leakage or gumming. Most scientific supply houses have sterilizer lubricant. There are many brands available.

2. Remove the cover from sterilizer by loosening the bakelite wing nuts in a counter-clockwise motion. Always undo two opposite wing nuts at a time. Next, remove inner container from the sterilizer. (see Figure A, page 2) Pour clean water (distilled is preferred) in sterilizer to a depth of not less than  $\frac{3}{4}$  of an inch nor more than 1 inch. Place inner container rack (see Figure A, page 2) into the bottom of the container (see Figure A, page 2) with the lip or edge side downward. The purpose of the inner container rack is to provide an air space in the bottom of the container so that air may circulate freely. Place articles to be sterilized inside the container. (Be sure to arrange items so that the free circulation of steam can occur during sterilization.) You may wish to place a towel or cloth on top of the items in the container to absorb any moisture which may drip down from the cover. Then place packed container

into the sterilizer. Make certain that the air exhaust tube channel (located on the inside of the container) is in position on the right side of the container when it is placed in the unit. This is necessary so that when the cover is placed on the unit you can guide the air exhaust tube (Part M100046) (see Figure A, page 2) into the channel.

### 3. Place sterilizer cover on unit, making sure that the index alignment arrow on the cover aligns with index line/arrow on side of bottom.

*Make certain when placing the cover on the unit that the flexible tube is inserted into the guide channel on the inside wall of the aluminum container.* It is helpful to place the container in the unit with the guide channel on the right hand side as you face the unit. Tighten the wing nuts on the cover evenly, always tightening down two opposite wing nuts at one time. This will draw the cover down evenly and assure a proper seal. NEVER USE A WRENCH OR ANY MECHANICAL DEVICE TO TIGHTEN WING NUTS. NEVER HAMMER OR STRIKE THE WING NUTS OR COVER WHILE OPENING OR CLOSING.

4. Place unit on heat source. If the water you have placed in the unit is cold, it will require approximately 35 minutes before steam begins escaping from the control valve. Since it requires more time to bring cold water up to operating temperature than it takes warm or hot water, you can reduce this time factor by:

- A. Pouring in hot water in place of cold, or
- B. Pouring in cold water and then turning on the heat source so that the water is getting warmed prior to your beginning the sterilization procedure

In both cases, observe the proper water level.

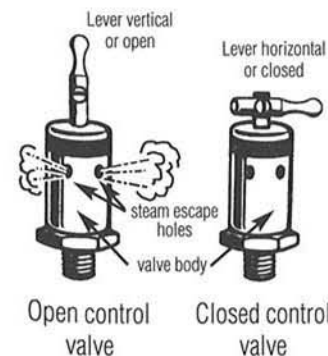


Fig. 2

Fig. 3

5. Open CONTROL VALVE (See Fig. 2) by placing valve lever in an upright position. The steam generated at the bottom of the sterilizer will travel around the outside of the container and then down through the material in the container to the bottom and force the air from the bottom of container up through the flexible air exhaust tube and out of the control valve. **It is important that the steam be permitted to escape vigorously from the unit for at least seven minutes, or until you see a continuous flow of steam, and then you may close the control valve.** This process of permitting the steam to escape is called EXHAUSTING and is necessary to remove the air trapped in the unit. **The greatest cause of sterilization failure is the trapping of air in the material being sterilized. Trapped air cannot escape. It is imperative that all trapped air be exhausted.** With the control valve in the closed position (See Fig. 3), pressure will rise inside the sterilizer and will be indicated on the pressure gauge. When pressure gauge reaches 17-19 pounds, reduce heat as necessary to maintain constant pressure of 17-19 pounds within the unit.
6. **STERILIZATION PERIOD.** The sterilization period begins when the pressure steam gauge needle registers in the green sterilization band shown on the face of the gauge. The sterilization pressure range is 17-21 PSI. **AT THIS TIME YOU BEGIN THE TIMING OF THE STERILIZATION CYCLE AND CONTINUE TIMING FOR NOT LESS THAN 35 MINUTES.**



7. At the end of the sterilization period, turn off the heat source and move the lever on the control valve to an upright (vertical) position so that the steam is permitted to escape. When the lever is in an upright position, the steam will escape at maximum. To avoid touching the hot lever, you may use any object such as a pencil or hot pad, etc., to move the lever from the closed to open (vertical) position. When the pressure gauge indicates zero, loosen the wing nuts evenly by turning two opposite wing nuts counter-clockwise at one time. The wing nuts, side handles and top handle will be hot. Always use hot pads when handling. Having removed all wing nuts from the slots in the cover, you may lift the cover slightly and turn the cover counter-clockwise for easy removal. **When removing the cover, always tilt and angle the cover away from yourself or any other people in the area to prevent injury from the hot steam.**

In the event your cover sticks, use a large standard screwdriver to pry the top loose. Place the end of the screwdriver at an angle between the cover and bottom near a wing nut assembly. Do not go straight in with the screwdriver or you will damage the metal-to-metal seal. Gently pry upward using the screwdriver as a lever. Continue to pry upward at each wing nut assembly area uniformly so that the cover is raised evenly. In most cases, the cover should come off rather quickly. If you need further assistance, please read metal-to-metal seal maintenance instructions on this page.

The inner container may then be removed from sterilizer for unloading. Use hot pads when removing.

To start another sterilization cycle, repeat procedure as outlined.

If the sterilizer is not going to be used again, before putting the unit away, all water should be emptied from the unit and the unit be thoroughly dried inside. It is recommended that the water be poured out of the unit while the bottom is still warm. The heat will help dry the unit if you leave the cover off for 15 minutes before placing the cover on the unit for storage. For storage purposes, it is only necessary to slightly tighten the wing nuts enough to hold the cover on the bottom. When storing, it is recommended that the control valve be left in a vertical position to permit air to circulate into the bottom.

## MAINTENANCE:

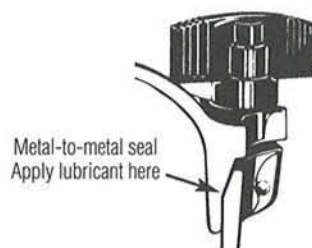


Fig. 1

1. **METAL-TO-METAL SEAL.** (See Fig. 1) Periodically check your seal. The metal-to-metal seal must be lubricated periodically (as stated in the instructions) to prevent the cover from sticking to the bottom because of dryness or lack of lubrication. If the sterilizer is operated without any lubricant, this could result in severe damage to the metal-to-metal seal and make it very difficult to remove the cover in some cases, and also become very difficult to maintain a steam-tight seal. It is recommended that a small amount of high temperature lubricant, such as high vacuum grease, be applied every third or fourth use. The metal-to-metal seal must not be permitted to become dry. It is also important to wipe off the metal-to-metal seal by using a clean towel to remove any build-up of

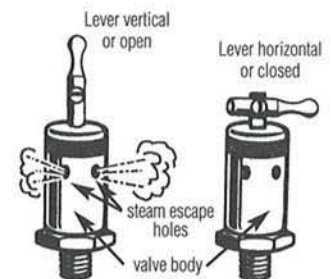
foreign material or particles trapped in the lubricant. To remove any build-up of hardened lubricant on the seal, use 0000 grade steel wool in a circular motion around the metal-to-metal seal.

2. **Pressure Gauge**  
Part NO. M100035 (See Fig. 4) Do not immerse the pressure gauge in water when cleaning the unit. The



Fig. 4  
Pressure Gauge

pressure gauge normally does not require any maintenance except to make certain the opening into the gauge on the underside of the cover is open and free of any foreign matter. If the gauge is ever dropped, the unit should not be used until the gauge has been checked to make sure that it is functioning properly. If your gauge needs to be checked, take it to a local scientific supply house.



Open control valve

Fig. 2

Closed control valve

Fig. 3

3. **Control Valve, Part No. M100034** (See Fig. 2 & 3) To ensure long life and proper operation of the control valve, periodic cleaning is recommended. To clean, unscrew the "knurled top" portion and clean thoroughly in hot soapy water. If any foreign material has built up inside the unit, clean the ball and seat using a



solvent such as acetone or a similar product. Be sure to clean the control valve in hot soapy water once again after using any solvent.

In the event that you are unable to properly clean any buildup of foreign material in your control valve, then it is recommended that the control valve be discarded and replaced with a new control valve.

4. **Air Exhaust Tube, Part No. M100046**



Fig. 5

(See Fig. 5) It is essential that the air exhaust tube be frequently checked to make sure that air passes freely through it. We recommend that you blow air through the air exhaust tube at least once a month to make certain it is not blocked or plugged with any foreign material. The air exhaust tube is not part of the control valve and can be removed separately from the cover in the event that it is blocked. Clean out the air exhaust tube by using a small diameter wire, running it through the entire length of the tube several times. If you notice a buildup of any foreign material on the inside of the air passage or a buildup of any corrosion on the inside of the air passage, then it is recommended that you discard this tube and replace it with a new air exhaust tube.

5. **Excess Pressure Relief Valve Part No. M100045** (See Fig. 6) This sterilizer is equipped with a new type of excess pressure relief valve. It is designed for longer, maintenance-free service; however, we do recommend that the valve be replaced every three years in normal service. The valve is designed to

release pressure at 26 PSI (plus/minus 1 PSI). Each valve is equipped with a deflector cap which will direct any steam released in a downward direction. Also it is possible to manually

release steam and pressure in this unit by simply grasping the deflector cap and pulling upwards slightly. The deflector cap will be hot. Always use hot pads when handling. This will instantly release pressure inside the unit until you release the cap and the valve, at which time the valve instantly reseals, thereby stopping any further pressure from escaping.

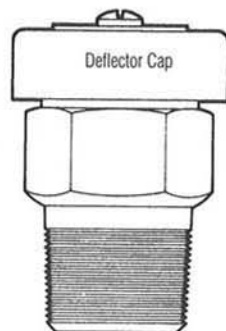


Fig. 6 Part No. M100045 Excess Pressure Relief Valve

6. **Overpressure Plug, Part No. M100044**

This ALL-AMERICAN Sterilizer is equipped with an additional safety device which is the Overpressure Plug, Part No. M100044. The purpose of the overpressure plug is to offer an extra margin of safety whenever the sterilizer is used. The overpressure plug is designed to release pressure in the range of 30 to 50 PSI.

The overpressure plug is made from silicone and is red in color and is found on the top surface of the sterilizer cover, located directly to the rear of the top handle, in front of Part No. M100045 Excess Pressure Relief Valve. See Figure A (page 2) and Figure 7.

For the most efficient results and best possible performance, it is recommended that you replace the overpressure plug every 6 months. It should always be replaced whenever it becomes hard or deformed.

At least every month during period of

use, the opening in the cover where the overpressure plug fits should be checked to determine that no foreign material, residue, or buildup of grease is present, and the opening be cleaned with hot soapy water (a toothbrush is helpful) to maintain a clean opening. This cleaning/inspection is in addition, of course, to normal daily cleaning performed after using the unit.

The overpressure plug can be removed for cleaning using fingers to pull it out of its opening from the underside of the cover. Before you re-install the overpressure plug, check the opening in the cover to be sure that it is absolutely free of any foreign material or grease/residue buildup. After cleaning, reinsert the overpressure plug by pushing the round top side into the opening from the underside of the cover. When the overpressure plug is correctly in position, the indented portion will be visible from the underside of the cover. Be certain to check after inserting plug that the round top of plug and top lip are fully thru the opening and that the top lip is not folded under. See Figure 7.

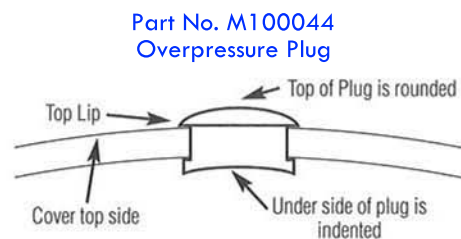
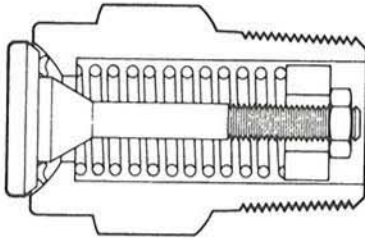


Fig. 7

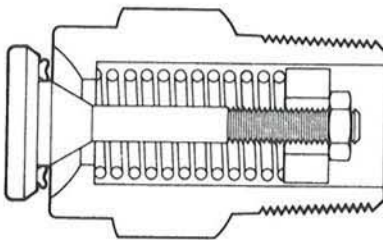
## How Part No. M100045 Works

### Closed



Resilient seal design prevents leakage. Sealing efficiency increases with increased pressure up to cracking pressure. Metal-to-metal seat on low pressure side supports spring load, prevents sticking.

### Open



When system pressure overcomes spring force, poppet opens, momentarily exposing variable orifice between poppet and body to pass increasing flow with minimum pressure rise without blowdown.

### Resealing

Resilient seal automatically establishes line of contact with spherical seat. Seal provides dead tight reseal very close to cracking pressure.

**Operating characteristics** of the No. M100045 excess pressure relief valve are:

- A. Zero leakage to 95-98% of cracking pressure.
- B. Increased sealing efficiency as pressure increases. Resilient "Q" ring seal is forced against metal seat as pressure increases up to set cracking pressure.
- C. Cracking pressure accuracy. Valves are preset to required cracking pressure of 26 PSI.

## IMPORTANT STERILIZATION FACTS

Steam is an ideal sterilizing agent since it kills microbes quickly, and steam has the additional important property of self-caused forced penetration. A large volume of steam condenses to a very small volume of water and more steam is drawn in to replace it. This causes excellent penetration of fabrics and some papers and plastic films. *Hot air or sterilizing gases do not approach steam in their ability to penetrate.*

The greatest cause of sterilization failure is the trapping of air in the material being sterilized so that it cannot escape. When this happens, the air forms a cool air pocket which has a lower temperature than the surrounding steam. It can also form an air-steam mixture which has a lower temperature than the pure steam. The most frequent causes for this failure are dressing packs wrapped too tightly, made too large, failure to turn basins and other metal or glass containers onto their sides, and failure to properly follow the directions as to current sterilizer operation and maintenance. (Refer to Item 5, page 4, regarding "exhausting" to remove trapped air.)

It is essential that all sterilizers be regularly checked for proper steam penetration to the center of the load. Since the first sign of sterilization failure is a drop in the temperature at the *center* of the dressing pack or sterilizer load, it is recommended that a temperature measuring device be used at the center of each pack or load of instruments. Indicating tape or strips are no substitute for the self-contained types as... "melt indicator inside a small glass vial," as temperature accuracy is essential. The pressure gauge on the sterilizer indicates the approximate temperature at the *exhaust line*, not at the center of the packs. The gauge cannot indicate the presence of trapped air, therefore, center-of-pack controls or vials are recommended. Different types and brands of sterilization indicators are available from your hospital supply or scientific supply dealer.

### PRESSURE GAUGE

**ACCURACY:** The gauges are rated as having an accuracy of 3%-2%-3%. This designates plus or minus 3% of the full span for the first and last quarter of the dial, and 2% for the middle 50% of the dial.

More specifically, this gauge rating comes from the pressure gauge standard ANSI B40-1-1980. This standard is entitled "Gauges-Pressure, Indicating Dial Type-Elastic Element," and covers every aspect of pressure gauge manufacture and use. The gauge is considered "Accuracy Grade B" in accordance with this specification.



## RETURN/SERVICE

Should the pressure sterilizer ever be dropped, the unit must be examined to determine if any damage has occurred. We recommend the unit be returned to our factory to be thoroughly checked inside and out for any damage. Prior to return to the factory, all sterilizers **must** be cleaned to remove any biological material or contaminants. We will examine the entire unit, including the control valve and gauge, and determine if the unit has sustained damage, and notify you of our findings.

A Return Authorization (RA) Number is required by our company to return any product manufactured by Wisconsin Aluminum Foundry. Merchandise returned without an RA Number will be refused. To obtain an RA Number contact our company by either writing, faxing or calling our Customer Service Department at 800-801-9934. All defective merchandise must be returned to our factory before credit or a replacement will be issued; do not destroy the defective merchandise. Any products returned must include paperwork stating the reason for the return, when and where the item(s) were purchased, model numbers, quantities, etc., and who to contact with any questions.

Should you have any questions at all about the operation of your ALL-AMERICAN Pressure Sterilizer, please write the Consumer Products Division, and we will promptly answer your questions.

To order any replacement parts, please refer to the parts price list. If you do not have a copy of our current parts price list, you may write the company and one will be forwarded to you by return mail.

## ALL-AMERICAN PRESSURE STEAM STERILIZER LIMITED WARRANTY

This quality sterilizer is designed and manufactured to provide many years of satisfactory performance under normal use. Wisconsin Aluminum Foundry pledges to the original owner that should there be any defects in material or workmanship during the first year after purchase, we will repair or replace it at our option. This pledge does not apply to damage caused by shipping. To obtain service under the warranty:

1. A Return Authorization (RA) Number is required by our company to return any product manufactured by Wisconsin Aluminum Foundry. Merchandise returned without an RA Number will be refused. To obtain an RA Number contact our company by either writing, faxing or calling our Customer Service Department at 800-801-9934. All defective merchandise must be returned to our factory before credit or a replacement will be issued; do not destroy the defective merchandise. Any products returned must include paperwork stating the reason for the return, when and where the item(s) were purchased, model numbers, quantities, etc., and who to contact with any questions. Prior to return to the factory, all sterilizers **must** be cleaned to remove any biological material or contaminants.

## IMPORTANT — PLEASE READ

Any alterations, modifications or changes of any type made to the sterilizer or to any component thereof will void this warranty!

We want you to obtain maximum performance from using this quality sterilizer and we ask that you take the time to read and follow the operating instructions. Failure to follow instructions, damage caused by improper replacement parts, abuse, or misuse will void this pledge. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state. This is Wisconsin Aluminum Foundry's personal pledge to you and is being made in place of all other express warranties.

## ALL-AMERICAN PRESSURE STEAM STERILIZERS PARTS LIST

Part No.	Description
M100031	Clamp bolt
M100032	Pin for clamp bolt
M100033	Bakelite wing nut
M100034	Control valve
M100035	Geared steam gauge
M100036	Lens for steam gauge (replacement)
M100037	Bakelite top handle
M100038	Bakelite top handle screw
M100039	Retaining bayonet clamp
M100040	Retaining bayonet clamp screw
M100041	Rack for <b>inside</b> aluminum container, fits 1915X, 1925X
M100044	Overpressure plug for sterilizer, red color
M100045	Excess pressure relief valve
M100046	Air exhaust tube for 1915X
M100047	Aluminum container for 1915X
M100048	Thermometer, stainless steel, dual scale, C scale 10-150°; F scale 50-300°

\*There is a factory installation fee for the thermometer. We recommend that the thermometer be installed at the factory.

**NO GUARANTEE OR RESPONSIBILITY FOR THE PROPER FUNCTIONING OF THIS PART CAN BE ASSUMED BY THE COMPANY IF IT IS NOT INSTALLED AT THE FACTORY.**



## SPECIFICATIONS



### Model 1915X (15 qt/14 liter)

Gross Capacity	15 qt/14 liter
Overall Height	12 1/4" / 31.2cm
Bottom Height	7 3/4" / 19.7cm
Inside Diameter	12 5/8" / 32.1cm
Unit Weight	15 lbs. / 6.8 kg.
<b>Inner Container No. 2163</b>	
Inside Depth	5 3/4" / 14.6cm
Inside Diameter	11 1/8" / 28.3cm
Circumference	35 3/4" / 91.1cm
Capacity	9.5 qt/9 liter
Volume	550in <sup>3</sup> /9029cm <sup>3</sup>
Carton Dimensions	15 1/2" x 14 1/2" x 13 1/2"
	39.4cm x 36.8cm x 34.3cm
Shipping Weight	20 lb. / 9.1kg.
Unit Pack: 1	Cube: 1.76



### Model 1925X (25 qt/24 liter)

Gross Capacity	25 qt/24 liter
Overall Height	16 3/4" / 42.5cm
Bottom Height	12 1/4" / 31.2cm
Inside Diameter	12 5/8" / 32.1cm
Unit Weight	18 1/4 lbs. / 8.3kg
<b>Inner Container No. 2162</b>	
Inside Depth	10 1/4" / 26cm
Inside Diameter	11 1/8" / 28.3cm
Circumference	35 3/4" / 91.1cm
Capacity	17.6 qt/16.6 liter
Volume	1016in <sup>3</sup> /16,655cm <sup>3</sup>
Carton Dimensions	15 1/2" x 14 1/2" x 18 1/2"
	39.4cm x 36.8cm x 47cm
Shipping Weight	24 lb. / 10.9kg.
Unit Pack: 1	Cube: 2.41



### Model 1941X (41 qt/39 liter)

Gross Capacity	41 qt/39 liter
Overall Height	19" / 48.3cm
Bottom Height	14 1/4" / 36.2cm
Inside Diameter	15 1/4" / 38.7cm
Unit Weight	33 lbs. / 15kg.
<b>Inner Container No. 2164</b>	
Inside Depth	10 1/2" / 26.7cm
Inside Diameter	14" / 35.6cm
Circumference	44 1/2" / 113cm
Capacity	27.9 qt/26.4 liter
Volume	1613in <sup>3</sup> /26,451cm <sup>3</sup>
Carton Dimensions	19" x 19" x 20 1/2"
	48.3cm x 48.3cm x 52.1cm
Shipping Weight	41 lb. / 18.6kg.
Unit Pack: 1	Cube: 4.28

## ELECTRIC MODELS ARE ALSO AVAILABLE



### Model 25X (25 qt/24 liter)

<b>Model 25X-120:</b> 120 Volt, 50/60 Hz 1050 watts/8.75 amps	
<b>Model 25X-240:</b> 240 Volt, 50/60 Hz 1050 watts/4.38 amps	
Gross Capacity	25 qt / 24 liter
Overall Height	16 3/4" / 42.5cm
Bottom Height	12 1/4" / 31.2cm
Inside Diameter	12 5/8" / 32.1cm
Unit Weight	26 lbs. / 11.8kg.
<b>Inner Container No. 2156</b>	
Height	8 1/2" / 21.6cm
Diameter	11 1/8" / 28.3cm
Circumference	35 3/4" / 91.1cm
Capacity	14.5 qt / 13.7 liter
Volume	835in <sup>3</sup> / 13,688cm <sup>3</sup>
Carton Dimensions	19 1/2" x 17 1/2" x 19"
	56.5cm x 44.5cm x 48.3cm
Shipping Weight	30 lb. / 13.6kg.
Unit Pack: 1	Cube: 3.75
<b>Optional No. 2180 Support Base</b> 2" / 5cm high	
Outside Diameter	12 3/4" / 32.4cm
Inside Diameter	12 3/8" / 31.4cm
Elevates Sterilizer Above Surface	1 3/8" / 3.5cm



### Model 50X (25 qt/24 liter)

<b>Model 50X-120:</b> 120 Volt, 50/60 Hz 1650 watts/13.75 amps	
<b>Model 50X-240:</b> 240 Volt, 50/60 Hz 1650 watts/6.88 amps	
Gross Capacity	25 qt / 24 liter
Overall Height	16 3/4" / 42.5cm
Bottom Height	12 1/4" / 31.2cm
Inside Diameter	12 5/8" / 32.1cm
Unit Weight	29 lbs. / 13.2kg.
<b>Inner Container No. 2156</b>	
Height	8 1/2" / 21.6cm
Diameter	11 1/8" / 28.3cm
Circumference	35 3/4" / 91.1cm
Capacity	14.5 qt / 13.7 liter
Volume	835in <sup>3</sup> / 13,688cm <sup>3</sup>
Carton Dimensions	22 1/4" x 17 1/2" x 19"
	56.5cm x 44.5cm x 48.3cm
Shipping Weight	34 lb./15.4kg.
Unit Pack: 1	Cube: 4.28
<b>Optional No. 2180 Support Base</b> 2" / 5cm high	
Outside Diameter	12 3/4" / 32.4cm
Inside Diameter	12 3/8" / 31.4cm
Elevates Sterilizer Above Surface	1 3/8" / 3.5cm



### Model 75X (41 qt/39 liter)

<b>Model 75X-120:</b> 120 Volt, 50/60 Hz 1650 watts/13.75 amps	
<b>Model 75X-240:</b> 240 Volt, 50/60 Hz 1650 watts/6.88 amps	
Gross Capacity	41 qt / 39 liter
Overall Height	19" / 48.3cm
Bottom Height	14 1/4" / 36.2cm
Inside Diameter	15 1/4" / 38.7cm
Unit Weight	45 lbs. / 20.4kg.
<b>Inner Container No. 4156</b>	
Height	10 1/4" / 26cm
Diameter	14" / 35.6cm
Circumference	44 1/2" / 113cm
Capacity	27.3 qt / 25.8 liter
Volume	1578in <sup>3</sup> / 25,856cm <sup>3</sup>
Carton Dimensions	24" x 24" x 21"
	61cm x 61cm x 53.3cm
Shipping Weight	51 lb. / 23.1kg.
Unit Pack: 1	Cube: 7
<b>Optional No. 4180 Support Base</b> 3" / 7.6cm high	
Outside Diameter	16 1/4" / 41.3cm
Inside Diameter	15" / 38.1cm
Elevates Sterilizer Above Surface	2 1/4" / 5.7cm



# Your Sterilizer Experts

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516-997-7434 (Fax)

Web site [www.sterilizers.com](http://www.sterilizers.com)

Email [info@sterilizers.com](mailto:info@sterilizers.com)

To whom it may concern:

Subject: FDA 510K approval for sterilizers manufactured prior to May 28<sup>th</sup>, 1976

1. There is no need for 510K FDA approvals for "Wisconsin Aluminum Foundry Inc" (which is also called "The All American Sterilizer". This is because according to the FDA rulings, these sterilizers were manufactured and commercially distributed before May 28, 1976 and didn't require Pre Market Approvals.
2. The FDA clause regarding this can be found in **Subpart E- Premarket Notification Procedures Section 807.85 Exemption from pre market notification in Section 1**
3. One of the ways to prove that the sterilizer was manufactured and distributed before May 28<sup>th</sup>, 1976, is to show catalog pages, promotional material with dates prior to May 28<sup>th</sup>, 1976
4. Attached you will find two documents:
  - a. The FDA documentation explaining that point 2.
  - b. Catalog of this sterilizer with dates prior to May 28<sup>th</sup>, 1976

Please call if you have a need for further help,

Alfa Medical  
Customer Service.



act, or because the Commissioner has found, under section 510(g)(4) of the act, that such registration is not necessary for the protection of the public health:

(a) A manufacturer of raw materials or components to be used in the manufacture or assembly of a device who would otherwise not be required to register under the provisions of this part.

(b) A manufacturer of devices to be used solely for veterinary purposes.

(c) A manufacturer of general purpose articles such as chemical reagents or laboratory equipment whose uses are generally known by persons trained in their use and which are not labeled or promoted for medical uses.

(d) Licensed practitioners, including physicians, dentists, and optometrists, who manufacture or otherwise alter devices solely for use in their practice.

(e) Pharmacies, surgical supply outlets, or other similar retail establishments making final delivery or sale to the ultimate user. This exemption also applies to a pharmacy or other similar retail establishment that purchases a device for subsequent distribution under its own name, e.g., a properly labeled health aid such as an elastic bandage or crutch, indicating "distributed by" or "manufactured for" followed by the name of the pharmacy.

(f) Persons who manufacture, prepare, propagate, compound, or process devices solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution.

(g) [Reserved]

(h) Carriers by reason of their receipt, carriage, holding or delivery of devices in the usual course of business as carriers.

(i) Persons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer (i.e., patient, physician, layman, etc.) with a device or the benefits to be derived from the use of a device; for example, a hearing aid dispenser, optician, clinical laboratory, assembler of diagnostic x-ray systems, and personnel from a hospital, clinic, dental laboratory, orthotic or prosthetic retail facility, whose primary responsibility to the ultimate consumer is to dispense or pro-

vide a service through the use of a previously manufactured device.

[42 FR 42526, Aug. 23, 1977, as amended at 58 FR 46523, Sept. 1, 1993]

### Subpart E—Premarket Notification Procedures

#### § 807.81 When a premarket notification submission is required.

(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:

(1) The device is being introduced into commercial distribution for the first time; that is, the device is not of the same type as, or is not substantially equivalent to, (i) a device in commercial distribution before May 28, 1976, or (ii) a device introduced for commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II.

(2) The device is being introduced into commercial distribution for the first time by a person required to register, whether or not the device meets the criteria in paragraph (a)(1) of this section.

(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

(ii) A major change or modification in the intended use of the device.

(b) A premarket notification under this subpart is not required for a device

for which a premarket approval application under section 515 of the act, or for which a petition to reclassify under section 513(f)(2) of the act, is pending before the Food and Drug Administration.

(c) In addition to complying with the requirements of this part, owners or operators of device establishments that manufacture radiation-emitting electronic products, as defined in § 1000.3 of this chapter, shall comply with the reporting requirements of Part 1002 of this chapter.

#### § 807.85 Exemption from premarket notification.

(a) A device is exempt from the premarket notification requirements of this subpart if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and the device meets one of the following conditions:

(1) It is intended for use by a patient named in the order of the physician or dentist (or other specially qualified person); or

(2) It is intended solely for use by a physician or dentist (or other specially qualified person) and is not generally available to, or generally used by, other physicians or dentists (or other specially qualified persons).

(b) A distributor who places a device into commercial distribution for the first time under his own name and a repackager who places his own name on a device and does not change any other labeling or otherwise affect the device shall be exempted from the premarket notification requirements of this subpart if:

(1) The device was in commercial distribution before May 28, 1976; or

(2) A premarket notification submission was filed by another person.

#### § 807.87 Information required in a premarket notification submission.

Each premarket notification submission shall contain the following information:

(a) The device name, including both the trade or proprietary name and the

common or usual name or classification name of the device.

(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.

(d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.

(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

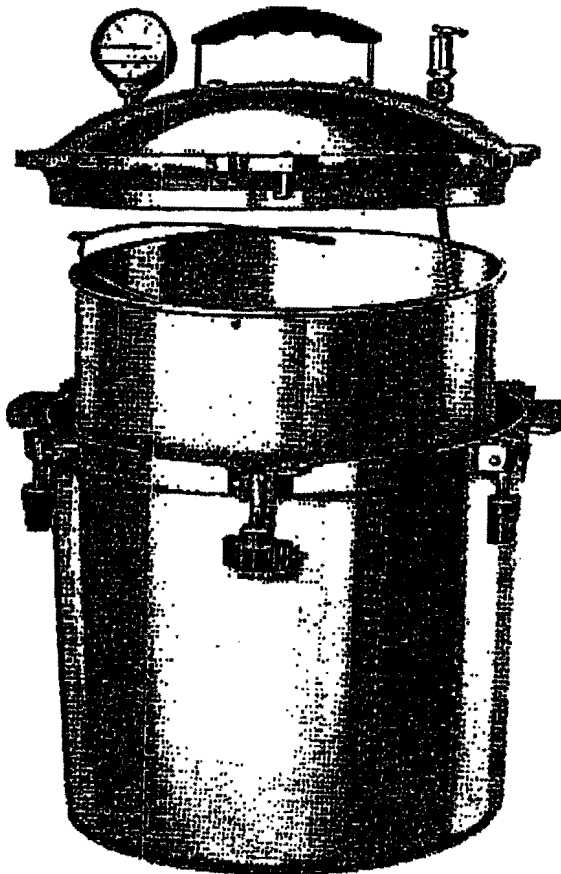
(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.

(h) A 510(k) summary as described in § 807.92 or a 510(k) statement as described in § 807.93.

(i) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

# ALL - AMERICAN

## Portable STEAM PRESSURE Sterilizer



CAST ALUMINUM  
CONSTRUCTION

STAMPED ALUMINUM  
SEAMLESS INSET CONTAINER,  
EASY TO CLEAN

CAST ALUMINUM  
CRATE RACK

FLEXIBLE METAL EXHAUST  
TUBE

DIAL GAUGE AND  
VALVE CONTROL

METAL TO METAL SEAL  
(No Rubber Gaskets)

LARGE  
STERILIZING CAPACITY

COMPLETE AND EFFECTIVE  
STERILIZATION AT THE  
LOWEST POSSIBLE COST



For complete safety and utility -- listed by Recognition Service of Underwriters' Laboratories, Inc.

### THREE POPULAR SIZES:

No. 1915½-X (15½ qt. liquid cap.), Ship. Wt. 20 lbs.

No. 1925-X (25 qt. liquid cap.), Ship. Wt. 25 lbs.

No. 1941½-X (41½ qt. liquid cap.), Ship. Wt. 39 lbs.

Each sterilizer packed in  
individual corrugated cartons.

ALL-AMERICAN Sterilizers make it possible for all doctors, dentists, first aid stations, hospitals, and laboratories to have fool-proof sterilization facilities at an extremely low cost. Used over any effective heat source, it is only a matter of minutes to secure dry sterile dressings and instruments, with all bacteria and micro-organisms destroyed. Only a small amount of water is needed, and the dry steam at 20 lbs. pressure penetrates all hinges and crevasses in any instrument and makes them sterile in 15 to 20 minutes. No wiping is necessary to remove chemical residue or moisture, and cutting edges are not dulled. Dressings are made sterile in about 30 minutes, and ready for immediate use.

The ALL-AMERICAN Sterilizers are made of high quality cast aluminum alloy, with all the special features of the famous ALL-AMERICAN Pressure Cookers. The metal-to-metal seal eliminates all rubber gaskets, and the clamping locks prevent removal of the cover while there is pressure present, as a safety feature. An accurate pressure gauge, tilted for easy reading, pressure control valve and over-pressure safety plug, metal air release tubing for quick exhaustion of all air within the Sterilizer, and cool bakelite handle and wing nuts are all thoroughly tested features that assure safe, fool-proof operation, with a minimum amount of attention.



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**ALL-AMERICAN STERILIZERS**

**JOBBER'S PRICE LIST - EFFECTIVE APRIL 15, 1976**

STOCK NO.	ITEM DESCRIPTION	UNIT PRICE	RECOMMENDED RETAIL PRICE	UNIT PACK	SHIPPING WEIGHT
1915½X	CAST STERILIZER 15½ qt. liquid cap.	\$ 36.25	\$ 65.90	1	20 lbs.
1925X	CAST STERILIZER 25 qt. liquid cap.	42.85	77.90	1	25 lbs.
1941½X	CAST STERILIZER 41½ qt. liquid cap.	79.15	143.90	1	42 lbs.
25X-110V	ELECTRIC STEROCLAVE 110 VOLTS 831 Cubic Inches Cap.	103.95	189.00	1	30 lbs.
25X-220V	ELECTRIC STEROCLAVE 220 VOLTS 831 Cubic Inches Cap.	107.25	195.00	1	30 lbs.
6054	THERMOMETER Stainless Steel 500 - 3000	10.95	19.90	1	12 oz.
INSTALLATION OF 6054	THERMOMETER INSTALLED AT FACTORY	8.80	16.00	1	
2157	GROUNDING 3 WIRE ELECTRIC CORD AND PLUG	4.35	7.90	1	14 oz.

FREIGHT TERMS: F.O.B. FACTORY IN ANY QUANTITY.

PRICES SUBJECT TO CHANGE WITHOUT NOTICE.



Please note that above prices are from 1976 and are only for demonstration purposes. Please email or call for any additional information you may need: [info@sterilizers.com](mailto:info@sterilizers.com) 1-(800)762-1586