INDICATIONS FOR USE:

STERILIZATION: This solution should be used for the sterilization of heat sensitive medical equipment for which alternative methods of sterilization are not suitable. Medical equipment which should always be sterilized is that which is classified as critical (i.e., used in procedures in which contact will be made with tissue that is normally considered sterile).

HIGH-LEVEL DISINFECTION: This solution should be used for the high-level disinfection of heat sensitive medical equipment for which sterilization is not practical. Medical equipment which should always be subjected to high-level disinfection or sterilization is that which will be used in procedures categorized as semi-critical (i.e., used in procedures in which contact will be made with mucous membranes or other body surfaces which are not normally considered to be sterile).

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

ACTIVATION: Activate the PSS SELECT GLUTARALDEHYDE PLUS solution by adding the entire contents of the activator vial which is attached to the PSS SELECT GLUTARALDEHYDE PLUS solution container. Shake well. When activated, solution changes color to bluish-green. Record the date of activation on the indicated space, in a log book or a label affixed to any secondary container used for the activated solution. See package insert for additional instructions and information regarding activated solution.

CLEANING/DECONTAMINATION: Blood and other body fluids must be thoroughly cleaned from hard, non-porous surfaces and objects before application of the disinfectant or sterilant. For complete disinfection or sterilization of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in PSS SELECT GLUTARALDEHYDE PLUS solution. Cleanse and rinse the lumens of hollow instruments before filling with PSS SELECT GLUTARALDEHYDE PLUS solution. See package insert for additional cleaning/decontamination instructions.

STERILIZATION: Immerse medical instruments/equipment completely in PSS SELECT GLUTARALDEHYDE PLUS solution for a minimum of 10 hours at 25°C. Remove equipment from the solution using aseptic technique and rinse thoroughly with sterile water. See package insert for complete instructions/information on sterilization.

HIGH-LEVEL DISINFECTION: Immerse medical instruments/equipment completely in PSS SELECT GLUTARALDEHYDE PLUS solution for a minimum of 90 minutes at 25°C. Remove from the solution and rinse thoroughly with sterile water or with potable tap water. The quality of rinse water used is dependent upon the intended use of the instrument/equipment. See package insert for complete instructions/information on high-level disinfection.

PRECAUTIONARY STATEMENTS:

Hazard to Humans and Domestic Animals

DANGER: Keep Out of Reach of Children

Direct contact is corrosive to exposed tissue, causing eye damage and skin irritation/damage. Do not get into eyes, on skin or onto clothing. Do not store in a manner which may expose children to this product (metal tub, pail, plastic bag, double-gloved hands) when handling or pouring. Avoid contamination of food. Use in well ventilated area in closed containers.

STATEMENT OF PRACTICAL TREATMENT:

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, get medical attention.

Harmful if swallowed. Drink large quantities of water and call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL:

Store at room temperature.

Solution Disposal: Discard residual solution in drain. Flush thoroughly with large quantities of water in accordance with federal, state and local regulations.

Container Disposal: Do not reuse empty container. Wrap container and put in trash.

Refer to package insert for material compatibility information and more detailed usage/product data.

CONTROL, NUMBER AND EXPIRATION DATE FOR UNACTIVATED SOLUTION ON BOTTLE

For emergency, safety, or technical information, contact Metrex at 800-841-1428.

CONTENT: 1 Gallon (3.785 liters)

REORDER NO. 344

Keep Out of Reach of Children

DANGER: see side panel for additional precautionary statements.
4) Monitoring of Germicide to Ensure Specifications are Met
During the usage of PSS Select Glutaraldehyde Plus, as a high-level disinfectant and/or sterilant, it is recommended that a thermometer and timer be utilized to ensure that the optimum usage conditions are met. In addition, it is recommended that the PSS Select Glutaraldehyde Plus be tested with a 1.8% glutaraldehyde test indicator prior to each usage. This is to ensure that the appropriate concentration of glutaraldehyde is present and to guard against a dilution which may lower the effectiveness of the solution below its MEC. The pH of the activated solution may also be periodically checked to verify that the pH of the solution is between 7.5 and 8.5.

5) Post-Processing Handling and Storage of Reusable Devices
Sterilized or disinfected reusable devices are either to be immediately used or stored in a manner to minimize recontamination. Note that only terminal sterilization (sterilization in a suitable wrap) provides maximum assurance against recontamination. Refer to the reusable device equipment manufacturer’s labeling for additional storage and/or handling instructions.

F) STORAGE CONDITIONS AND EXPIRATION DATE
1) Prior to activation, PSS Select Glutaraldehyde Plus should be stored in its original sealed container at room temperature. Once the PSS Select Glutaraldehyde Plus has been activated, it should be stored in the original container until transferred to the containers in which the immersion for disinfection or sterilization is to take place. Containers should be stored in a well-ventilated, low-traffic area at room temperature.
2) The expiration date of the unactivated PSS Select Glutaraldehyde Plus will be found on the immediate container.
3) The use period for activated PSS Select Glutaraldehyde Plus is for no longer than 28 days following activation or as indicated by a 1.8% glutaraldehyde test indicator. Once activated, the solution requires no further dilution prior to its usage.

G) EMERGENCY AND TECHNICAL PRODUCT INFORMATION
Emergency, safety, or technical information about PSS Select Glutaraldehyde Plus solution can be obtained by contacting your PSS Select sales representative or by contacting Metrex Research Corporation Customer Service Department at 1-800-841-1428.

H) USER PROFICIENCY
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. The user should be adequately trained in the decontamination and disinfection or sterilization of medical devices and the handling of toxic substances such as liquid chemical germicides. Additional information about PSS Select Glutaraldehyde Plus can be obtained by contacting your PSS Select sales representative.

I) DISPOSAL INFORMATION
Germicide Disposal
Discard residual solution in drain. Flush thoroughly with water.

Container Disposal
- One Quart (946 mL) and One Gallon (3.8 L) Size Containers
  Do not reuse empty container. Wrap container and put in trash.
- 2-1/2 Gallon (9.5 L) and 5 Gallon (18.9 L) Size Containers
  Triple rinse empty container with water and dispose of in an incinerator or landfill.

J) HOW SUPPLIED
Reorder
343
  One Quart (946 mL) Container
  4 x Quarts (4 x 946 mL)/box; 4 boxes/case; 16 x Quarts (16 x 946 mL)/case

344
  One Gallon (3.8 L) Container
  4 x Gallons (4 x 3.8 L)/case

References supplied upon request.

Distributed By:
Select Medical Products
4345 Southpoint Blvd.
Jacksonville, FL 32216
70-0671-2

PSS SELECT GLUTARALDEHYDE PLUS
28-DAY STERILIZING & DISINFECTING SOLUTION (GLUTARALDEHYDE 3.4%)
5) Material Compatibility

PSS Select Glutaraldehyde Plus is compatible with the following reusable devices and materials: Respiratory therapy equipment, anesthesia equipment, rubber, most stainless steel instruments, plastic, most dental instruments (not including dental handpieces), many types of metals, such as stainless steel, carbon steel, and aluminum, and plated metals such as nickel plating or chrome plating.

For a listing of specific device manufacturers that have reported device compatibility with PSS Select Glutaraldehyde Plus, see Table 1 below:

<table>
<thead>
<tr>
<th>Company</th>
<th>Instrumentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acoustic Imaging</td>
<td>Transducers</td>
</tr>
<tr>
<td>Advanced Technology Lab</td>
<td>Ultrasound Scaneheads</td>
</tr>
<tr>
<td>Hewlett Packard</td>
<td>Omniprobe TEE Probe</td>
</tr>
<tr>
<td>Instrumentation Industries</td>
<td>Respiratory Therapy Equipment</td>
</tr>
</tbody>
</table>

Please refer to labeling of the reusable device for additional instructions, or call the reusable device manufacturer directly.

Please NOTE: PSS Select Glutaraldehyde Plus is incompatible with the following specific reusable devices: Acuson V510B transesophageal transducers, high-frequency cables, coagulating forceps, resectoscope instruments, and devices that have the potential for electrosurgical malfunctioning.

6) Precleaning Agent Compatibility

PSS Select Glutaraldehyde Plus is compatible with enzymatic detergents which are mild in pH, low foaming, and easily rinsed from equipment. Detergents that are either highly acidic or alkaline are contraindicated as precleaning agents since improper rinsing could affect the efficacy of the PSS Select Glutaraldehyde Plus by altering its pH.

B) CONTRAINDICATIONS

1) Sterile Usage
Routine biological monitoring is not feasible with PSS Select Glutaraldehyde Plus, and therefore, PSS Select Glutaraldehyde Plus should NOT be used to sterilize reusable medical devices that are compatible with other available methods of sterilization that can be biologically monitored, e.g., heat, ethylene oxide, or peroxide gas plasma.

2) High-Level Disinfectant Usage
PSS Select Glutaraldehyde Plus should NOT be used for sterilization of critical devices intended for single use (e.g., catheters).

3) Endoscope Usage
PSS Select Glutaraldehyde Plus Long-Life Activated Dialdehyde Solution is not the method of choice for sterilization of rigid endoscopes which the device manufacturer indicates are compatible with steam sterilization. In general, glutaraldehyde solutions that do not contain surfactants (e.g., PSS Select Glutaraldehyde NS solution) are more appropriate for flexible endoscopes, because glutaraldehyde solutions containing surfactants (e.g., PSS Select Glutaraldehyde or PSS Select Glutaraldehyde Plus Solution) are more difficult to rinse from the devices. However, these surfactant-containing disinfectants may be used for reprocessing of flexible endoscopes if a validated protocol for rinsing and leak testing is employed.

C) WARNINGS

PSS SELECT GLUTARALDEHYDE PLUS LONG-LIFE ACTIVATED DIALDEHYDE SOLUTION IS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Keep Out of Reach of Children Contains Glutaraldehyde

1) Direct contact is corrosive to exposed tissue, causing eye damage and skin irritation/damage. Do not get into eyes, on skin, or on clothing.

2) Avoid contamination of food.

3) Use in well-ventilated area in closed containers.

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, get medical attention.

If swallowed. Drink large quantities of water and call a physician immediately.

Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.

Emergency, safety, or technical information about PSS Select Glutaraldehyde Plus solution can be obtained by contacting your PSS Select sales representative or by contacting Metrex Research Corporation Customer Service Department at 1-800-841-1428.

D) PRECAUTIONS

1) Protective gloves (butyl rubber, nitrile rubber, polyethylene or double-gloved latex), eye protection, face masks, and liquid-proof gowns should be worn when cleaning and sterilizing/disinfecting soiled devices and equipment.

2) Contaminated, reusable devices MUST BE THOROUGHLY CLEANED prior to disinfection or sterilization, because residual contamination will decrease effectiveness of the germicide.

3) The user MUST adhere to the Directions for Use, because any modification will affect the safety and effectiveness of the germicide.

4) The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using PSS Select Glutaraldehyde Plus.

5) The use of PSS Select Glutaraldehyde Plus in automated endoscope washers must be part of a validated reprocessing procedure provided by the washer manufacturer. Contact the manufacturer of the endoscope washer for instructions on the maximum number of reprocessing cycles which may be used before rinsing with fresh PSS Select Glutaraldehyde Plus.

Use a 1.8% glutaraldehyde test indicator to monitor glutaraldehyde concentration before each cycle to detect unexpected dilution.

E) DIRECTIONS FOR USE

1) Activation

Activate the PSS Select Glutaraldehyde Plus by adding the entire contents of the Activator Plus vial which is attached to the PSS Select Glutaraldehyde Plus container. Shake well. Activated solution immediately changes color to blush-green, thereby indicating solution is ready to use.

2) Preparatory Cleaning

PSS Select Glutaraldehyde Plus is intended for use in manual (bucket and tray) systems made from polypropylene, ABS, polyethylene, glass-filled polypropylene or specially molded polycarbonate plastics. Record the date of activation (mixing date) and expiration date on the PSS Select Glutaraldehyde Plus container label in the space provided, in a log book, or on a label affixed to any secondary container used for the activated solution.

3) Usage

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

a) Sterilization (Bucket/Tray Manual System)

Immerse medical equipment/device completely in PSS Select Glutaraldehyde Plus for a minimum of 10 hours at 25°C to eliminate all microorganisms including Clostridium sporogenes and Bacillus subtilis spores. Remove equipment from the solution using sterile technique and rinse thoroughly with sterile water following the rinsing instructions below.

b) High-Level Disinfection (Bucket/Tray Manual System)

Immerse medical equipment/device completely in PSS Select Glutaraldehyde Plus for a minimum of 90 minutes at 25°C to destroy all pathogenic microorganisms, except for large numbers of bacterial endospores, but including Mycobacterium tuberculosis (Quantitative TB Method). Remove devices and equipment from the solution and rinse thoroughly following the rinsing instructions below.

c) Rinsing Instructions

Following immersion in PSS Select Glutaraldehyde Plus, thoroughly rinse the equipment or medical device by immersing it completely in three separate copious volumes of water. Each rinse should be a minimum of one minute in duration unless otherwise noted by the device or equipment manufacturer. Use fresh portions of water for each rinse. Discard the water following each rinse. Do not reuse the water for rinsing or any other purpose, as it will be contaminated with glutaraldehyde.

Refer to the reusable device/equipment manufacturer’s labeling for additional rinsing instructions.

STERILE WATER RINSE

The following devices should be rinsed with sterile water, using sterile technique when rinsing and handling:

1. Devices intended for use in normally sterile areas of the body;
2. Devices intended for use in known immunocompromised patients, or potentially immunocompromised patients based on institutional procedures (e.g., high risk population served); and
3. When practicable, bronchoscopes, due to a risk of atypical Mycobacteria contamination from potable water supply.

POTABLE WATER RINSE

For all other devices, a sterile water rinse is recommended when practicable, otherwise a high-quality potable tap water rinse is acceptable. A high-quality potable water is one that meets Federal Clean Water Standards at the point of use.

When using potable water for rinsing, the user should be aware of the increased risk of recontaminating the device or medical equipment with Pseudomonas and atypical (fast growing) Mycobacteria often present in potable water supplies. A device (e.g., colonoscope) that is not completely dried provides an ideal situation for rapid colonization of bacteria. Additionally, Mycobacteria are highly resistant to drying; therefore, rapid drying will avoid possible colonization but may not result in a device free from atypical Mycobacteria. Although these bacteria are not normally pathogenic in patients with healthy immune systems, AIDS patients or other immunocompromised individuals may be placed at high risk of infection by these opportunistic microorganisms. A final rinse using a 70% isopropyl alcohol solution is useful to speed the drying process and reduce the numbers of any organism present at the time of rinsing with potable water.

d) Reuse

PSS Select Glutaraldehyde Plus solution has also demonstrated efficacy in the presence of 2% organic soil contamination and a simulated amount of microbiological burden during reuse. This solution may be used and reused within the limitations indicated above for up to 28 days after activation. Do not use activated solution beyond 28 days. Efficacy of this product during its use-life must be verified by a 1.8% glutaraldehyde test indicator to determine that the minimum effective concentration (MEC) of 1.8% is present.