SPOROX®II STERILIZING AND DISINFECTING SOLUTION

SPOROX® II Sterilizing & Disinfecting Solution is a ready-to-use liquid chemical germicide which, when used following the Directions for Use, is recommended for the sterilization or high-level disinfection of heat-sensitive medical equipment for which alternative methods of terminal reprocessing are not suitable or available.

GERMICIDAL LEVEL OF ACTIVITY

When used according to the Directions for Use, SPOROX II Sterilizing & Disinfecting Solution can be used as a sterilant or as a high-level disinfectant.

Sterilant: SPOROX II Sterilizing & Disinfecting Solution can be reused, when validated by the SPOROX® Test Vials, for a period not to exceed 21 days. The required contact time is 6 hours at 20°C.

High-Level Disinfectant: SPOROX II Sterilizing & Disinfecting Solution can be reused, when validated by the SPOROX Test Vials, for a period not to exceed 21 days. The required contact time is 30 minutes at 20°C.

REUSE PERIOD

SPOROX II Sterilizing & Disinfecting Solution can be reused for a period not to exceed 21 days, when used according to the Directions for Use. Always validate reuse of the solution with SPOROX Test Vials to determine adequate presence of hydrogen peroxide – refer to the SPOROX Test Vials package insert for additional details and directions for use. SPOROX II Sterilizing & Disinfecting Solution has a minimum effective concentration (MEC) of 6.0% for hydrogen peroxide. It is recommended that the solution be tested ***before and after each reprocessing cycle.***

- DO NOT RELY ON DAYS-IN-USE TO DETERMINE THE EFFICACY OF THE SOLUTION.
- ADDING FRESH PRODUCT TO USE SOLUTION DOES NOT EXTEND THE USE LIFE.

GENERAL INFORMATION ON SELECTION OF GERMICIDES FOR MEDICAL DEVICE REPROCESSING

General instructions for processing medical devices: The terminal reprocessing protocol must be selected based upon the intended use of the device and the type of expected patient contact, as per the Spaulding Classification, see definitions below. Check with the manufacturer of the medical device for any specific reprocessing instructions and compatibility information.

Critical Medical Devices *- (such as needles, catheters and surgical instruments) are introduced directly into the bloodstream or other normally sterile areas of the body. Critical medical devices require sterilization. Liquid chemical sterilization is not the preferred method of terminal reprocessing. It is used for heat sensitive critical devices for which alternative methods of reprocessing are not suitable or available.*

Semi-critical Medial Devices - (such as anesthesia equipment and GI endoscopes) come in contact with mucous membranes but do not ordinarily penetrate the bloodstream or normally sterile areas of the body. Whenever possible, semi-critical devices should be sterilized, otherwise they should be high-level disinfected.

MICROBIOLOGY DATA

The following microorganisms are inactivated by SPOROX II Sterilizing & Disinfecting Solution:

Bacteria
Mycobacterium tuberculosis
Staphylococcus aureus
Salmonella choleraesuis
Pseudomonas aeruginosa
Acinetobacter calcoaceticus
Enterobacter aerogenes
Enterococcus faecalis
Escherichia coli
Klebsiella pneumoniae
Proteus mirabilis
Proteus vulgaris
Burkholderia cepacia
Salmonella paratyphi
Serratia marcescens
Shigella dysenteriae
Streptococcus pyogenes

Fungi
Aspergillus niger
Candida albicans
Trichophyton mentagrophytes

Viruses
Hepatitis A
Herpes Simplex Type 1
Herpes Simplex Type 2
HIV-1 (AIDS Virus)
Influenza A2(Japan 305/57)
Poliovirus Type 2
Respiratory Syncytial Virus
Rhinovirus Type 39
Rotavirus

Bacterial Spores
Bacillus subtilis
Clostridium sporogenes
Clostridium tetani

DIRECTIONS FOR USE

This solution is recommended for the sterilization or high-level disinfection of heat-sensitive medical equipment for which alternative methods of terminal reprocessing are not suitable or available.

RECOMMENDED REPROCESSING PROCEDURES

Monitoring: It is recommended that a procedure be put in place to monitor the temperature of the SPOROX II Sterilizing & Disinfecting Solution along with a timing mechanism to ensure the required contact time for either high level disinfection or sterilization. The SPOROX II Sterilizing & Disinfecting Solution must be checked regularly to ensure the MEC of hydrogen peroxide using the SPOROX Test Vials - refer to the package insert for the test vials for additional information and directions for use.

Cleaning: Cleaning medical equipment is always the most important first step in any reprocessing protocol. Check with the medical equipment manufacturer for any specific details regarding the care and cleaning of the equipment. Follow detailed instructions for disassembly of equipment to aid in the reprocessing cycle and for any recommended leak testing (when applicable). Put on protective clothing, e.g. impervious gown, protective gloves (such as chemically resistant natural rubber latex or vinyl), and face shield or goggles.

1.) Thoroughly clean medical equipment to remove blood, body fluids and other organic soil. Include all internal channels, lumens and cavities.
2.) Rinse thoroughly, especially internal channels, lumens and cavities to remove any residual cleaning agents.
3.) Damp or rough dry the equipment and air purge internal hollow lumens to prevent dilution of the germicidal solution.

High Level Disinfection and Sterilization

1.) Open a bottle of solution and empty the entire contents into the basin.
2.) Affix a secondary container label to the soaking container. Write on the label the date the solution is placed in the soaking container and the date of the final 21-day reuse period.
If the reprocessing procedure involves a reuse of SPOROX II Sterilizing & Disinfecting Solution: Test the solution for the presence of hydrogen peroxide using the SPOROX Test Vials. If the test vials indicate a "fail" result, discard the solution according to local regulations and prepare a fresh solution.
3.) DO NOT DILUTE THE SOLUTION WITH WATER. Following the device manufacturer's instructions, immerse the device in the SPOROX II Sterilizing & Disinfecting Solution. Flush the solution through all internal channels and cavities to ensure the necessary contact time with all surfaces.
For sterilization, soak the equipment for 6 hours at 20°C.
For high-level disinfection, soak the equipment for 30 minutes at 20°C.
Note: Many facilities utilize an automatic reprocessing machine to clean and disinfect endoscopes. If SPOROX II Sterilizing & Disinfecting Solution is the germicide of choice for the facility, using the solution with an automatic reprocessor must be part of a protocol that has been provided and validated by the manufacturer of the automatic reprocessor. The protocol must include solution reuse recommendations.
4.) Remove the equipment and rinse thoroughly or, for flexible endoscopes, follow rinsing instructions below. Refer to the device manufacturer for any specific instructions regarding rinsing procedures.

Rinsing Procedures for Flexible Endoscopic Devices

1.) After removing the device from disinfectant solution, place it in a sink. For video scopes, assure that a water-resistant cap is secured over the electrical connector.
2.) Connect an "All-Channel Irrigator" to the air/water and suction valves. Attach a channel cap to the channel opening. Position the weighted end of the intake tube to be elevated above the endoscope.
3.) Withdraw the plunger on the All-Channel Irrigator until its syringe fills with 30cc of air. Depress the plunger to force air through the air/water valve opening, the channel opening at the distal end of the insertion tube, and through the water and suction connectors. Repeat this process five times to expel as much solution as possible prior to rinsing.
4.) Rinse the entire endoscope under running tap water for at least two minutes.
5.) Immerse the entire endoscope, with the All-Channel Irrigator still connected, in fresh, potable tap water. The weighted end of the intake tube must also be completely immersed in the water.
6.) Withdraw the plunger on the All-Channel Irrigator until its syringe fills with 30cc of potable tap water. Depress the plunger to force water through the air/water valve opening, the channel opening at the distal end of the insertion tube, and through the water and suction connectors. Repeat this process five times until bubbling stops from all openings. Water used for rinses should be changed between rinse steps.
7.) Remove the weighted end of the intake tube from the water. Using the syringe, flush all channels and openings with air to expel as much water as possible. Repeat this process several times until bubbling can be seen from all openings.

MATERIAL COMPATIBILITY

COMPATIBLE

SPOROX II is compatible with medical equipment that is made with materials noted below. Except as noted, these materials were exposed to SPOROX II (Hydrogen peroxide activity 7.3%) for 1,000 continuous disinfection cycles (500 hours) at room temperature.

Metals
Copper
Brass
Chrome Plated Brass
Chrome Plated Steel
Stainless Steel
Titanium
Monel
Platinum
Silver
Gold Plated Steel*

Plastics
TEFLON® Non-Stick Surfaces
Polyester
Polystyrene
Polycarbonate
Polyethylene
Polypropylene
Polyvinylchloride (PVC)
Polysulfone
Acrylic
Acrylonitrile-butadiene-styrene (ABS)
Nylon

Elastomers
Neoprene
Natural Rubber
Silicone Rubber (Silastic type)
Ethylenepropylene Diene Terpolymer (EDPM)
Polyurethane

*Soaked in SPOROX II (Hydrogen peroxide activity 7.3%) for 168 continuous hours at room temperature.

INCOMPATIBLE MATERIALS

SPOROX II may not be compatible with certain materials as listed below. These materials were soaked in SPOROX II (Hydrogen peroxide activity 7.3%) for 1,000 continuous disinfection cycles (500 hours) at room temperature. Check with the instrument manufacturer for additional compatibility information on specific materials, such as adhesives. Do not soak instruments in SPOROX II for periods longer than required for high-level disinfection or sterilization.

- Aluminum
- Carbon Steel
- Nickel-Plated Steel
- Metallic Carbide
- Solder70/30
- Nickel-Silver Alloy

- SPOROX II may remove the coating from anodized aluminum. The surface of some aluminum alloys can be pitted or corroded.
- SPOROX II may remove the nickel plating from nickel-plated steel.
- Contact with nickel/silver alloys and solder 70/30 may cause the concentration of hydrogen peroxide to decrease rapidly.

CONTRAINDICATIONS

1. **Sterilant Usage**

Routine biological monitoring is not feasible with SPOROX II Sterilizing & Disinfecting Solution, and therefore, SPOROX II Solution should NOT be used to sterilize 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. SPOROX II Solution should not be used for sterilization of critical devices intended for single use (e.g. catheters).

2. **High-Level Disinfectant Usage**

SPOROX II Solution should NOT be used to high level disinfect a semi-critical device when sterilization is practical.

3. **Rigid Endoscope Usage**

SPOROX II Solution is not the method of choice for sterilization of rigid endoscopes which the device manufacturer indicates are compatible with steam sterilization.

STORAGE AND EXPIRATION

Store SPOROX II Sterilizing & Disinfecting Solution in an upright position, in a cool, dry place in areas inaccessible to small children.

The expiration date of SPOROX II Sterilizing & Disinfecting Solution may be found on the bottom of each bottle. Upon opening a bottle, use the entire contents. An unopened bottle of SPOROX II Sterilizing & Disinfecting Solution has a shelf life of 2 years from its time of manufacture.

8.) Remove endoscope from sink and wipe dry. If reprocessing a video scope, remove the water-resistant cap from the electrical connector.

9.) Discard the water following each rinsing procedure. The water should not be reused for rinsing or any other purpose as it will be contaminated.

10.) Follow rinsing with 70% isopropyl alcohol rinse. Thoroughly air dry. Hang the endoscope to dry.

A sterile water rinse should be used with critical medical devices, devices intended for use with known or potentially immunocompromised patients and bronchoscopes. For semi-critical medical devices, a potable water rinse is acceptable if a sterile water rinse is not practical. The potable water rinse should meet Federal Clean Water Standards.

Handling and Storage: Reprocessed medical devices should be handled using aseptic procedures and stored in a manner to minimize the possibility of contamination before its next use. Refer to the device manufacturer for any specific instructions regarding the storage of the device.

WARNINGS AND PRECAUTIONS

KEEP OUT OF REACH OF CHILDREN

DANGER: Corrosive to eyes. Due to corrosive nature, may be harmful or fatal if swallowed. Do not get in eyes, on skin or clothing. Wear face shield or goggles. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

IF IN EYES: Immediately rinse eyes with water, remove any contact lenses and continue rinsing eyes for at least 15 minutes. Call a physician immediately.

IF SWALLOWED: DO NOT INDUCE VOMITING. Promptly give a glass of water to drink and call a physician or poison center immediately.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

Note to physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Active oxygen in the product may temporarily whiten the skin on contact. Wear protective gloves such as chemically resistant natural rubber, latex or vinyl. In case of contact with skin, rinse immediately with water. Should whitening occur, the skin will return to normal within several minutes. For additional information regarding the safety and effectiveness of this product, call 1-800-677-9218, Monday through Friday, 8:45 a.m. to 4:30 p.m. (Eastern time).

PACKAGING DESCRIPTION

Order No.	Item Description	Case Contents
75156	SPOROX II Sterilizing & Disinfecting Solution	1 gallon plastic bottles, 4 per case
75196	SPOROX Test Vials Intro Kit	30 Test Vials, 1 Bottle Indicator Solution, 30 Pippettes, 1 Pippettor , 4 Kits per case

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