

FIRST AID: If in contact with eyes, immediately flush with water for 15 minutes. Call a physician. If in contact with skin, flush with plenty of water. Wash thoroughly with soap and water. Call a physician if irritation persists. If ingested, do not induce vomiting. Call a physician or a poison control center immediately. Take product label with you when seeking medical attention.

NOTICE TO USER: Please ensure the instruments, equipment or device material to be disinfected is compatible with Resert XL HLD solution. **SEE PACKAGE INSERT FOR LIST OF COMPATIBLE MATERIALS.** If you are uncertain as to material composition of your item, confirm with the manufacturer before proceeding.

STORAGE: Resert XL HLD solution should be stored in its original sealed container at controlled room temperature 15 - 30°C (59 - 86°F).

DISPOSAL: Check state and local disposal regulations. Discard residual solution into drain. Flush drain thoroughly with water. Triple rinse the container with water and dispose in accordance with federal, state, provincial and municipal requirements. Do not re-use the empty container.

CAUTION: Corrosive to copper, brass, tungsten carbide, Monel S, silver, chromium-plated brass and nickel-plated steel. May be corrosive to aluminum under prolonged exposure.

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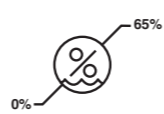
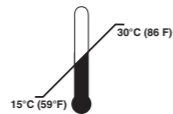
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4450-XJWRE(1010)

STERIS®

Resert™ XL HLD

High Level Disinfectant



Net Contents:

REF 4450-AWWR 4 Liters (1.06 Gal)

Active Ingredient: Hydrogen Peroxide 2.0% w/w

High Level Disinfectant for Medical Devices and Instruments

**8 minute high level disinfection at 20°C
21 Day Reuse when hydrogen peroxide level
is at least 1.5% hydrogen peroxide.**

KEEP OUT OF REACH OF CHILDREN

READ THE LABEL BEFORE USING



Irritating to Eyes and Skin. (R36/38)

Avoid contact with skin and eyes. (S24/25)

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. (S26)

After contact with skin, wash immediately with plenty of water. (S28)

Wear suitable gloves and eye/face protection. (S37/39)

US Patent No. 07354604



MICROORGANISMS

VEGETATIVE ORGANISMS:

Pseudomonas aeruginosa (ATCC 15442) Poliovirus, Chat strain type 1 (ATCC VR-1562)
Staphylococcus aureus (ATCC 6538) Herpes Simplex Type 1
Salmonella choleraesuis (ATCC 10708) Adenovirus Type 5

SPORES:

Bacillus subtilis (ATCC 19659)
Clostridium sporogenes (ATCC 7955)

VIRUS:

MYCOBACTERIA:

Mycobacterium terrae (ATCC 15755)

FUNGI:

Trichophyton mentagrophytes (ATCC 9533)

INDICATIONS FOR USE:

Resert™ XL HLD is a ready-to-use liquid chemical germicide. The product is a 2.0% nominal hydrogen peroxide solution. The minimum recommended concentration (MRC) is 1.5%. Resert XL HLD is intended to be used by health care practitioners in clinical settings as a ready-to-use liquid chemical disinfectant for the high level disinfection of semi-critical medical devices for which alternative methods of terminal reprocessing are not suitable or available.

High Level Disinfectant: Resert™ XL HLD High Level Disinfectant is a high level disinfectant when used or reused undiluted for a maximum of 21 days at a minimum temperature of 20°C for a minimum immersion time of 8 minutes. Resert XL HLD High Level Disinfectant solution is intended for processing heat sensitive medical devices, for which heat sterilization is not suitable, when used according to the Directions for Use. Resert XL HLD solution is compatible with manual (bucket and tray) systems made from polypropylene, acrylonitrile-butadienestyrene (ABS), polyethylene, polycarbonate plastics and 316 stainless steel. The use of Resert XL HLD solution in automated endoscope reprocessors (AER) must be part of a validated reprocessing procedure. Resert XL HLD solution may not be suitable for all instruments. **SEE NOTICE TO USER AND PACKAGE INSERT.**

For medical devices and instruments, determine whether the reusable device to be reprocessed is a critical or semi-critical device. Critical devices are devices that are introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body. Sterilization is required. DO NOT use Resert XL HLD solution as the final treatment prior to use. Semi-critical devices are medical devices and instruments that come in contact with intact skin or mucous membrane (which are not normally considered to be sterile) such as respiratory equipment, surgical mirrors, flexible endoscopes, etc. High Level Disinfection is required.

DIRECTIONS FOR USE:

CLEANING/DECONTAMINATION: Blood and other body fluids must be thoroughly cleaned from all surfaces of medical devices and instruments before application of the disinfectant. For complete disinfection of medical instruments and equipment, thoroughly clean, rinse and rough dry surfaces before immersion in Resert XL HLD solution. Clean and rinse the lumens of hollow instruments before filling with Resert XL HLD solution.

Refer to the reusable device or instrument manufacture's instructions for disassembly, decontamination, cleaning and leak testing of their equipment.

HIGH LEVEL DISINFECTION: Place pre-cleaned, rinsed and dried medical devices and instruments in undiluted Resert XL HLD solution. Follow the instrument manufacturer's instructions for reprocessing to ensure that all of the instrument's surfaces have been fully contacted with Resert XL HLD solution. Once the instrument has been immersed and all surfaces in contact with the disinfectant solution, soak the instrument for 8 minutes. Track the soak time using a timer. **Do not heat the solution.** Rinse the instrument with sterile water or potable tap water (see package insert for details). Resert XL HLD solution may not be suitable for all instruments. **SEE NOTICE TO USER AND PACKAGE INSERT FOR DETAILED INSTRUCTION ON USE WITH AUTOMATED ENDOSCOPE REPROCESSING.**

REUSE PERIOD FOR DISINFECTION: Resert XL HLD solution has demonstrated disinfection efficacy in the presence of organic soil contamination and microbiological burden during reuse. The Hydrogen Peroxide concentration of Resert XL HLD solution during its use-life must be verified by the Verify® Chemical Monitoring Strip for Resert Solutions prior to each use, to determine that the minimum recommended concentration (MRC) of 1.5% is present. Resert XL HLD solution may be used and re-used within the limitations indicated above for up to a maximum of 21 days. Resert XL HLD solution must be discarded after 21 days, even if the test strip indicates a concentration above the MRC. The Resert XL HLD solution in its original packaging is good until date of expiry.

PRECAUTIONARY STATEMENTS: KEEP OUT OF REACH OF CHILDREN. CAUTION: Avoid contact with eyes and skin. Wear suitable protective clothing. Avoid contamination of food in the use and storage of this product. Do not store in food processing areas. Store in dry, well ventilated area away from chemicals, direct light, heat or open flame. Do not mix with other cleaning or disinfecting products.