

Opal®

**INSTRUMENT GRADE -
HIGH LEVEL DISINFECTANT**

OPAL® is an Instrument Grade - High Level Disinfectant solution for the reprocessing of heat sensitive semi-critical medical devices for which sterilization is not suitable. OPAL® is intended for use in manual and automated reprocessing systems.

Please read Product Insert, MSDS and Technical Bulletin prior to using OPAL® Solution for information including warnings, contraindications and precautions.

**STORAGE CONDITIONS &
EXPIRATION DATE:**

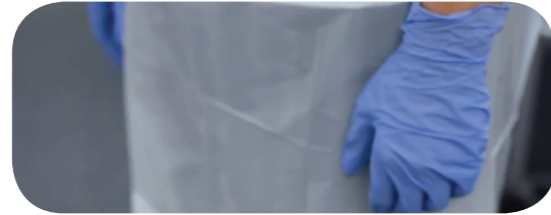
1. Store OPAL® in its original sealed container. Store below 30°C out of direct sunlight.
2. Once opened, the unused portion of the solution may be stored in its original container for up to 75 days until used.
3. The expiration date of OPAL® may be found on the container. DO NOT use product from an unopened or opened container after the labelled expiration date.
4. The reuse period of OPAL® should never exceed 28 days.

FIRST AID INFORMATION:

For advice, contact a Poisons Information Centre (Phone Australia 131 126; New Zealand 0800 764 766) or a doctor immediately.

Additional information is listed in the Material Safety Data Sheet available at www.whiteley.com.au

MANUAL CLEANING



1. Standard Precautions

- Follow the recommendations of the Australian Guidelines for Prevention and Control of Infection in Healthcare (NHMRC), Commonwealth of Australia when handling and cleaning soiled devices.
- Contact with OPAL® may stain exposed skin, clothing or environmental surfaces.
- Wear Nitrile gloves of appropriate length, eye protection, face masks and fluid resistant gowns when disinfecting devices with OPAL®.



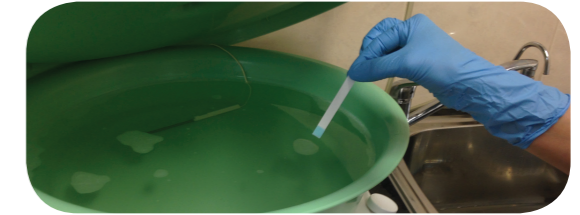
2. Cleaning/Decontamination

- Biological soils and lubricants must be thoroughly cleaned from the surfaces and lumens of semi-critical medical devices before reprocessing in the disinfectant.
- Devices to be reprocessed must first be thoroughly cleaned according to device manufacturer's recommendations for decontamination, use MATRIX™ or MEDIZYME from Whiteley Medical where approved.
- Before immersion in OPAL® solution thoroughly rinse all surfaces and lumens of cleaned devices.



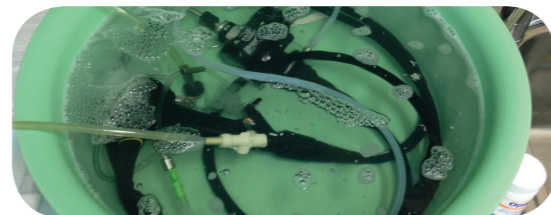
3. Preparation & Usage

- OPAL® is supplied ready-to-use and does not require activation.
- Record the date the container was opened on the container label, or in a log book. After opening, the solution remaining in the container may be stored for up to 75 days (providing the 75 days does not extend past the expiration date on the container) until used.
- Record the date the solution was poured out of the original container into a secondary container in a log book or on a label affixed to the secondary container. The solution in the secondary container can be reused for a period up to 28 days provided Test Strips show it is above the MRC.



4. Test the Solution

- OPAL® Test Strips are chemical indicators for use in determining whether the concentration of Ortho-Phthalaldehyde (OPA), the active ingredient in OPAL®, is above or below the Minimum Recommended Concentration (MRC) of 0.35%.
- Ensure the concentration of OPA is above the MRC of 0.35% by using OPAL® Test Strips prior to each reprocessing cycle.
- DO NOT rely solely on days in use. This product must be discarded after 28 days, even if the test strips indicate a concentration above the 0.35% MRC.



5. High Level Disinfection

- Place pre-cleaned medical device into compatible tray. Immerse device completely into OPAL® solution, ensuring that all lumens are also filled with the solution. Soak the device for a minimum of 6 minutes at room temperature (minimum 20°C).



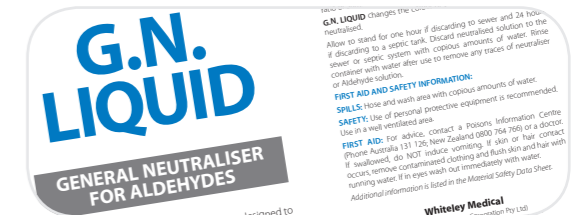
6. Rinsing Instructions & Procedure

- Thoroughly rinse device by immersing in a large volume of water (eg 8 litres or enough to fully cover the device). Manually flush all lumens with not less than 100mL of rinse water unless otherwise directed by the device manufacturer.
- Remove the device from the water and discard the rinse water.
- Always use fresh volumes of water for each rinse. Do not reuse the rinse water for any other purpose.
- Repeat the procedure for rinsing manual devices TWO additional times for a total of THREE (3) RINSES with large volumes of fresh water to remove OPAL® residues. Proper rinsing of devices is required, see warnings and precautions. Three (3) separate large volume water immersion rinses are required unless otherwise specified by device manufacturer's instructions.
- Refer to the reusable medical device manufacturer's labelling for additional rinsing instructions.



7. Drying

- A final rinse using a 70-90% ethanol solution (such as MICROL from Whiteley Medical) or a 70% isopropanol solution can be used to speed the drying process and reduce the numbers of any organism present as a result of rinsing with potable water.
- Disinfected reusable devices are either to be immediately used or stored in a manner to minimise recontamination. Refer to the reusable device/ equipment manufacturer's labelling for additional storage and/or handling instructions.



8. Disposal

- Discard any remaining solution according to State/ Territory Land Waste Management Authorities if applicable.
- G.N. Liquid or Glycine (free base) may be used as a neutraliser for OPAL® solution prior to disposal, if required. A minimum of 50mL/L of G.N. Liquid or Glycine should be used per Litre of Opal. Ensure container is rinsed well with water after product disposal.