PRODUCT INSERT

Opal™

INSTRUMENT GRADE - HIGH LEVEL DISINFECTANT

Contains: Ortho-Phthalaldehyde 5.7g/L
Patent Pending

DIRECTIONS FOR USE

Read the OPAL™ MSDS and Product Insert prior to use. Read device manufacturers reprocessing instructions and automated endoscope reprocessing system directions before use.

CAUTION
KEEP OUT OF REACH OF CHILDREN
READ SAFETY DIRECTIONS
DO NOT SWALLOW

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STORE BELOW 30˚C **ARTG NO: 206575**

GENERAL INFORMATION

Indications For Use

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 reprocessing systems. It may also be used in automated endoscope reprocessors (AER's) that can be set to a minimum temperature of 20˚C, according to the manufacturer's instructions.

Devices to be reprocessed must first be thoroughly cleaned according to device manufacturer's recommendations for decontamination. The cleaning process should follow an established cleaning protocol consistent with professional society guidelines (i.e. "Infection Control in Endoscopy", Gastroenterological Society of Australia), and/or a standard such as AS/NZS 4187 "Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities"

Minimum Recommended Concentration

OPAL™ must be used at or above the minimum recommended concentration (MRC) of 0.35% **Ortho-Phthalaldehyde** (OPA) as determined by OPAL™ Test Strips.

Reuse Period

OPAL™ has demonstrated efficacy in the presence of organic soil contamination and simulated amount of microbiological burden during reuse.

The in-use OPAL™ solution may be reused for up to 28 days provided the MRC is above 0.35% OPA as determined by OPAL™ Test Strips. Refer to Section E. for directions for reuse.

- Never return decanted disinfectant back into its original container.

General Information Selection and use of Disinfectants for Medical Device Reprocessing

1. Choose a disinfectant with a level of antimicrobial activity that is appropriate for the reusable medical device. Follow the reusable device labelling and standard institutional practices. In the absence of complete instructions, use the following process:

(a) For patient contact devices, determine whether the reusable device to be reprocessed is a critical or a semi-critical device.

- A critical device presents a high risk of infection if not sterile. Critical devices routinely penetrate the mucous membranes during use or are otherwise used in normally sterile tissues of the body.
- A semi-critical device makes contact with mucous membranes but does not ordinarily penetrate normally sterile areas of the body.

(b) Determine if sterilization or high-level disinfection is required.

- Sterilization is required for critical devices (e.g. products that enter sterile tissue or the vascular system, such as laparoscopes, and microsurgical instruments).
- For semi-critical devices sterilization is recommended whenever feasible, otherwise high-level disinfection is the minimum acceptable process.

(c) Select a disinfectant that is labelled for the appropriate disinfection level and is compatible with the reusable device. Follow directions for that disinfectant.

2. OPAL™ should NOT be used for the high level disinfection of semi-critical devices if sterilization using other available methods that can be biologically monitored is feasible and practical.

3. OPAL™ should NOT be used to reprocess critical devices.

CONTRAINDICATIONS

1. OPAL™ should NOT be used to reprocess any urological instrumentation to be utilized for cystoscopy or other urological procedures for patients with a history of bladder cancer. In rare instances similar Ortho- Phthalaldehyde (OPA) based disinfectants have been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies.

2. OPAL™ should not be used to reprocess any instrumentation for patients with known sensitivity to similar OPA containing disinfectant solutions.

3. OPAL™ should not be used for surface disinfection.

MICROBIOCIDAL ACTIVITY:

The following table indicates the range of activity as demonstrated by testing of OPAL™ using prescribed test methods.

BACTERIA		FUNGI	VIRUSES	
Spores	**Vegetative**		**Non-enveloped**	**Enveloped**
Bacillus subtilis	Staphylococcus aureus	Trichophyton mentagrophytes	Poliovirus	Herpes Simplex Virus
Clostridium sporogenes	Salmonella enterica		Adenovirus	
	Pseudomonas aeruginosa			
	Mycobacterium terrae			
	Mycobacterium bovis			
	E. Coli			
	Proteus Vulgaris			
	Salmonella Choleraesuis			

MATERIALS COMPATIBILITY

OPAL™ has been tested and is found to be compatible with the materials shown below.

Metals	Plastics	Elastomers	Adhesives
Stainless Steels (17-7,302, 303, 304, 316, 430) Galvanized Steel Mild Steel Inconel Hastelloy C Nickel Plated Brass Naval Brass 464 Copper Bare Aluminium (2024, 6061) Anodized Aluminium (2024, 6061, 1100)	Polyethylene HDPE Polypropylene PVC CPVC Polysulfone Polycarbonate Acrylic ABS Delrin (Acetal) Polystyrene Nylon Teflon (PTFE) PCTG PVDF	Buna-N EPDM Viton (type HK) Silicone rubber Neoprene (Polychloroprene) Nitrile Rubber Santoprene	Epoxy Ceramics/Adhesive Ceramic Devcon Adhesive

OPAL™ is also compatible with the materials commonly used in the construction of medical endoscopes.

If questions arise regarding the compatibility of a device with OPAL™ solution, contact the device manufacturer.

CLEANING AGENT SUITABILITY

OPAL™ is suitable for use following precleaning with detergents that are mild in pH, low foaming, and easily rinsed from equipment, suitable products include MATRIX™ or MEDIZYME from Whiteley Medical.

Detergents that are either highly acidic or alkaline are not recommended as cleaning agents. Under no circumstances is OPAL™ to be mixed with detergents or other chemicals.

WARNINGS:

Caution: Keep out of reach of children.

1. OPAL™ must be used in a well-ventilated area and in closed containers with tight-fitting lids. If adequate ventilation is not provided by the existing air handling system, use in local exhaust hoods, or in ductless fume hoods/portable ventilation devices which contain filter media which absorb Ortho-Phthalaldehyde (OPA) from the air.

2. May elicit an allergic reaction. Possible allergic reactions have been reported in rare instances with similar OPA containing disinfectant products. Ensure that all users wear appropriate personal protective equipment (See Precautions) and that OPAL™ is used in a well-ventilated area.

3. Avoid contact with eyes, skin, or clothing. (See PRECAUTIONS for important information on how to protect eyes, skin and clothing). Direct contact with eyes may cause irritation. Direct contact with skin may cause temporary staining. Repeated contact with skin may cause skin sensitization. In case of eye contact, immediately flush eyes with large quantities of water for at least 15 minutes. Seek medical attention. In case of skin contact, immediately wash with water. Refer to the MSDS for additional information. Do not form sprays, mists or aerosols of this product.

4. Avoid ingestion or contamination of food. Ingestion may cause irritation or chemical burns of the mouth, throat, oesophagus and stomach. If swallowed, DO NOT INDUCE VOMITING. Drink large quantities of water and contact the Poison Information Hotline (Phone Australia 131 126; New Zealand 0800 764 766). Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.

5. Avoid exposure to vapours as they may be irritating to the respiratory tract and eyes. May cause stinging sensation in the nose and throat, discharge, coughing, chest discomfort and tightness, difficulty with breathing, wheezing, tightening of throat, urticaria (hives), rash, loss of smell, tingling of mouth or lips, dry mouth or headache. May aggravate a preexisting asthma or bronchitis condition. In case of adverse reactions from inhalation of vapour, move to fresh air. If breathing is difficult, oxygen may be given by qualified personnel. If symptoms persist, seek medical attention.

DIRECTIONS FOR USE

A. Cleaning/Decontamination:

Follow the recommendations of the Australian Guidelines for the Prevention and Control of Infection in Healthcare (NHMRC), Commonwealth of Australia or relevant national infection control guidelines when handling and cleaning soiled devices.

Blood, other body fluids and lubricants must be thoroughly cleaned from the surfaces and lumens of semi-critical medical devices before reprocessing in the disinfectant. Blood and other body fluids should be disposed of according to all applicable regulations for infectious waste disposal. Refer to the reusable device manufacturer's labelling for instructions on disassembly, decontamination, cleaning and leak testing of their equipment.

Devices to be reprocessed must first be thoroughly cleaned according to device manufacturer's recommendations for decontamination, including using a suitable product such as MATRIX™ or MEDIZYME from Whiteley Medical. The cleaning process should follow an established cleaning protocol consistent with professional society guidelines and/or national standards.

Before immersion in OPAL™ solution thoroughly rinse and dry all surfaces and lumens of cleaned devices.

B. Preparation and 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. Refer to Section E. for directions for reuse.

C. High Level Disinfection Procedure:

1. Manual Reprocessing: Ensure the concentration of OPA is above the MRC by using OPAL™ Test Strips prior to each reprocessing cycle. 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). Remove the device from the solution and rinse thoroughly according to device manufacturer's rinsing instructions. In the absence of manufacturer's rinsing instructions, follow the rinsing instructions and procedure in Section D.1.

2. Automated Reprocessing: Place device into an Automatic endoscope reprocessor that can be set to a minimum temperature of 20°C. Load the reprocessor with OPAL™ solution and select a high level disinfection cycle that provides for a minimum disinfectant immersion or contact time of 6 minutes. Select an automated rinsing cycle that provides thorough rinsing equivalent to the device manufacturer's rinsing instructions and consistent with the automated processing rinsing instructions provided below.

D. Rinsing Instructions and Procedure:

1. Manual Reprocessing:

- Following removal from OPAL™, thoroughly rinse the semi-critical device by fully immersing it in a large volume of water. Use rinse water that is consistent with the directions provided below (see Section D.3. Rinse Water).
- Keep the device entirely submersed for a minimum of 1 minute in duration, unless a longer time is specified by the reusable device manufacturer.
- Manually flush all lumens with large volumes (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.

2. Automated Endoscopic Reprocessing (AER):

- Select a rinse cycle on an automatic reprocessor that has been validated for use with OPA-based disinfectants. Perform automated rinsing in accordance with the reprocessor manufacturer's instructions.
- Ensure that the automated rinse cycle selected will thoroughly rinse the medical device including all channels with large volumes of rinse water equivalent to the device manufacturer's recommendations.
- Each rinse should be a minimum of 1 minute in duration, unless otherwise specified by device manufacturer's instructions. Ensure that a fresh volume of rinse water that is consistent with the directions provided in Section D.3. Rinse Water is used for each rinse. Do not reuse the rinse water for any other purpose.
- Refer to the reusable medical device manufacturer's labelling for additional rinsing instructions.

3. Rinse Water:

Sterile Water Rinse: When practical and feasible, the following devices should be rinsed with sterile water, using sterile technique when rinsing and handling:

- Devices intended for use in known immunocompromised patients, or potentially immunocompromised patients based on institutional procedures (e.g. high risk population served).
- Where practical, bronchoscopes, due to a risk of contamination from potable water supply. Although microorganisms in this type of water system 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 opportunistic microorganisms present in potable water.

When using potable water for rinsing, the user should be aware of the increased risk of recontamination of the device or medical equipment with microorganisms which may be present in potable water supplies.

The use of a bacterial retentive (0.2 micron) filter system may eliminate or greatly reduce the amount of these waterborne bacteria from the potable water source. Contact the manufacturer of the filter for instructions on preventative maintenance and periodic replacement of the filter to avoid colonization or formation of biofilms in the filter.

Water treatment systems, such as softeners or deionizers, may add microorganisms to the treated water to the extent that microbial content of the water at the point of use could exceed that of the pre-treated drinking water. To ensure proper water quality, adherence to maintenance of the water treatment system(s) is strongly recommended.

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.

E. Reusage for Disinfection:

Prior to each use the concentration of OPA in the OPAL™ solution must be verified using OPAL™ Test Strips to be above the MRC of 0.35%. 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. DO NOT use beyond the 28 day reuse period or the labelled expiration date even if the concentration is above the MRC. Maintain the solution at room temperature between 20-30°C during the 28-day reuse period.

Never return decanted disinfectant back into its original container. Discard the solution immediately if any of the following are noted - the solution changes colour or becomes cloudy, the solution is subject to copious dilution or if the solution is compromised in any way.

F. Monitoring of Germicide:

Users are directed to test the solution with OPAL™ Test strips prior to each use throughout the entire reuse period. This is to ensure that the concentration of OPA in the solution remains above 0.35% throughout the reuse period.

During manual disinfection with OPAL™ it is recommended that a timer and thermometer be utilized to ensure that the contact time of 6 minutes at a minimum of 20°C is achieved. For automated reprocessing ensure that the automated reprocessor is capable of monitoring the cycle to ensure specified use conditions are met.

Do not use an automated reprocessor if it cannot monitor time and temperature parameters appropriately. Refer to the reprocessor manufacturer's labelling for germicide monitoring instructions.

G. Special Instructions for Transesophageal Echocardiography (TEE) Probe Reprocessing:

As with all devices, carefully follow all probe manufacturer recommendations such as use of a sterile protective sheath when performing TEE. Soaking for a minimum of 6 minutes in OPAL™ solution at a minimum of 20°C is required for high level disinfection.

Excessive soaking (for example, longer than 1 hour) of the probes during high level disinfection and/or not rinsing three times with a fresh quantity of water each time as described in the rinsing instructions may result in residual solution remaining on the device, the use of which may cause staining, irritation or chemical burns of the mouth, throat, oesophagus and stomach.

H. Post-Processing Handling and Storage of Reusable Devices:

Disinfected reusable devices are either to be immediately used or stored in a manner to minimize recontamination. Refer to the reusable device/ equipment manufacturer's labelling for additional storage and/or handling instructions.

PRECAUTIONS

Follow the recommendations of the Australian Guidelines for the 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.

1. Contaminated reusable devices MUST BE THOROUGHLY CLEANED prior to disinfection, since residual contamination will decrease effectiveness of the germicide.

2. The user MUST adhere to the Directions For Use since any modification will affect the safety and effectiveness of the germicide.

3. Wear nitrile gloves of appropriate length, eye protection, face masks, and fluid resistant gowns when disinfecting devices with OPAL™.

4. Minimize exposure to vapours by using OPAL™ in well-ventilated areas or by using in automated reprocessors with an effective vapour containment system. Use the product in closed containers with tight-fitting lids. If adequate ventilation is not provided by the existing air handling system, use in local exhaust hoods, or in ductless fume hoods/portable ventilation devices which contain filter media which absorb Ortho-Phthalaldehyde (OPA) from the air.

5. The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using an OPA product such as OPAL™.

6. The use of OPAL™ Instrument Grade - High Level Disinfectant in automated reprocessors must be part of a validated reprocessing procedure supplied by the automated reprocessor manufacturer to ensure a minimum contact or immersion time of 6 minutes at a minimum of 20°C.

7. Use OPAL™ Test Strips as a chemical indicator to ensure the concentration of OPA in the solution is at or above 0.35% prior to each reprocessing cycle in order to detect unexpected dilution. Follow the directions for use provided with the OPAL™ Test Strips.

STORAGE CONDITIONS AND 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.

EMERGENCY AND TECHNICAL PRODUCT INFORMATION

For further hazard information please refer to the Material Safety Data Sheet (MSDS). For advice, contact a Poisons Information Centre (Phone: Australia 131126, New Zealand 0800 764 766) or a doctor .

Emergency, safety, or technical information about OPAL™ can be obtained from Whiteley Medical's web site **www.whiteley.com.au** or phone **+61 2 4961 9333** or contacting your local Whiteley Medical sales consultant.

USER TRAINING AND PROFICIENCY

The user should be adequately trained in the decontamination and disinfection of medical devices, as well as in the safe handling of cleaning chemicals and disinfectants.

Additional information about OPAL™ Instrument Grade - High Level Disinfectant can be obtained from Whiteley Medical.

DISPOSAL INFORMATION

Discard any remaining solution according to State/Territory Land Waste Management Authorities if applicable. Glycine (free base) may be used as a neutralizer for OPAL™ solution prior to disposal, if required. A minimum of 5 grams of glycine (free base) should be used to neutralize one litre of solution.

The minimum recommended neutralization time is one hour. Neutralised OPAL™ solutions will develop a dark brown colour. Discard residual solution into drain. Flush drain thoroughly with water. Once neutralised, the disinfectant will be safe for disposal via a septic system.

Do not reuse empty containers. Containers should be triple rinsed with water and disposed of as per local regulations. For emergencies and additional information please refer to the MSDS.

SUPPLY INFORMATION

OPAL™ Instrument Grade -High Level Disinfectant
2x5 litre containers per carton
Product Code: 150103

OPAL™ High Level Disinfectant Test Strips
50 strips/container - 2 containers
Product Code: 303019