



# MRSAid™

PHOTODISINFECTION SYSTEM

## ***INSTRUCTIONS FOR USE***

### **For MRSAid™ Nasal Treatment Kit**

**NOTE: The general user manual for the Ondine MW1000 MRSAid™ Photodisinfection laser system should be reviewed by all users prior to use.**

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## **1 Indications for use**

The MRSAid™ Photodisinfection System is a laser-based antimicrobial system intended for the decolonization of potentially-pathogenic bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA), from the anterior nasal passages.

These instructions are for the MRSAid™ Nasal Treatment Kit and should be read along with the general User Manual for the MRSAid™ Photodisinfection Laser.

## **2 Contraindications**

### **2.1 Contraindications**

The MRSAid™ nasal treatment kit components should not be used if the patient has allergies or hypersensitivity to:

- methylene blue
- chlorhexidine digluconate

### **2.2 Relative contraindications**

The MRSAid™ nasal treatment kit components should be used with care if the patient has any of the following pre-existing conditions:

- Severe G6PD (glucose-6-phosphate dehydrogenase) deficiency
- Undiagnosed nasal bleeding
- Nasal anatomical defect/abnormality sufficient to inhibit formulation application or illumination

## **3 Warnings**

Federal and Provincial law restricts this device to sale by or on the order of a physician with appropriate training.

Use of the MRSAid™ Laser System is restricted to healthcare providers who have received the training requirements listed below. These requirements include, but are not limited to:

- A thorough understanding of the MRSAid™ Laser User Manual, including sections pertaining to laser safety

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- A review of laser operation followed by a demonstration of the MRSAid™ Laser System
- Hands on training with the MRSAid™ Laser System

## **4 Precautions**

### **4.1 Laser Safety**

Read the User's Manual (#MW2000) thoroughly before operating the MRSAid™ Photodisinfection Laser System. Pay particular attention to the "Warnings" section of the manual which explains the cautions to be used in order to ensure safe operation.

### **4.2 Re-Use**

The single use MRSAid™ Nasal Treatment Kit components must not be sterilized and/or reused.

### **4.3 Storage**

Store laser system and treatment kit components in a cool, dry place. Protect all components of the system from prolonged exposure to direct sunlight. The laser system should be stored in temperature conditions between 5 °C to 45 °C. Do not operate the laser system in ambient temperatures below 12 °C or above 35 °C. The treatment kit components should be stored in temperature conditions between 10 °C to 35 °C. Do not use the treatment kit components in ambient temperatures below 15 °C or above 30 °C.

### **4.4 Packaging Integrity**

The disposable products are guaranteed only if the package is unopened and undamaged. Prior to use, visually inspect the packaging to ensure that it has not been visibly damaged. Do not use if the integrity of the package has been compromised. Do not use product if the "Use Before Date" found on the package labeling has been passed.

Before use, carefully examine all of the equipment to be used in the procedure for defects. Do not use any equipment if damaged.

### **4.5 Disposal**

After use, dispose of all equipment in accordance with applicable specific requirements relating to hospital waste, and potentially biohazardous materials.



## **5 Potential Adverse Events**

### **5.1 Potential short-term adverse events**

Potential short term adverse events associated with use of the MRSAid™ Nasal Treatment Kit are:

- Temporary staining of tissue around the nares
- Sense of warmth during the illumination step of the treatment
- Permanent staining of clothing

### **5.2 Potential long-term adverse events**

No long term adverse effects from use of the MRSAid™ Nasal Treatment Kit are known at this time.

## **6 Individualization of Treatment**

The risks and benefits described above should be considered for each patient before use of the MRSAid™ Nasal Treatment Kit.

Patient selection for treatment using the MRSAid™ Nasal Treatment Kit should be according to hospital and/or physician discretion.

## **7 How Supplied**

### **7.1 For single-use only**

The MRSAid™ nasal light diffuser tip assembly and formulation applicator are provided separately in a clean, non-sterile format. Do not attempt to sterilize and/or reuse these components.

### **7.2 Inspection prior to use**

Before use, visually inspect the packaging of disposable components to ensure they are not damaged. All equipment to be used for the procedure should be examined carefully for defects. Examine the light diffuser and associated optical cable for bends, kinks, or other damage. Do not use if any component is damaged.



## 7.3 Procedure set-up

Some or all of the following additional materials, which are not included in the MRSAid™ Photodisinfection Laser System or Nasal Treatment Kit packaging, may be required for the procedure:

- Protective clothing/bib
- Facial tissue and/or gauze to inhibit dripping of solution from nares and for patient to evacuate nasal cavities before treatment
- Antibacterial wipes
- Operator gloves
- Biohazard disposal container
- Light to visually inspect nares
- Nasal culture supplies

## 7.4 Compatibility

The MRSAid™ Nasal Treatment Kit components are designed to be used exclusively with the MRSAid™ Photodisinfection Laser System. Do not use in combination with any other laser system.

## 8 Directions for Use

The following are guidelines provided for use of the MRSAid™ Nasal Treatment Kit system:

1. Using clean technique, remove the light diffuser tip assembly from its package. Connect the connector plug of the light diffuser assembly to the MRSAid™ Photodisinfection Laser System cable port. Take care to not allow the diffuser tips themselves to contact surfaces that may be dirty or harbor pathogenic organisms.
2. Instruct the patient to blow their nose thoroughly and don a protective bib.
3. Open the formulation applicator package. Using the applicator swab, apply a generous quantity of the solution to the patient's nares using a different applicator for each side. Ensure uniform and full coverage of all surfaces below the turbinates.
4. If the patient desires, provide them with the supplied eyewear to diminish the perceived brightness during the illumination step. **Note:** the light itself does not pose a danger to the eye, however some patients may still be bothered by bright lights.



5. Gently insert the light diffuser tips fully into both nares and instruct the patient to hold them in position. Do not initiate illumination until the tips are in place.
6. The MRSAid™ Photodisinfection Laser can then be adjusted to the appropriate settings (i.e. 1500 mW for 180 sec treatment, repeat treatment x 2). To begin illumination, depress the footswitch or use the front panel switch, activating the laser and initiating the self-timing mechanism.
7. If the optional patient switch is provided, the patient can hold it and push the button to discontinue the treatment for any reason.
8. When the self-timer is completed the laser will shut off automatically. Repeat the above steps according to the desired treatment protocol.
9. Following the procedure, dispose of all single use items. Power down the laser using the key provided. Wipe down the laser enclosure and connections using an antibacterial wipe or solution.
10. Immediately after treatment, it is recommended that the patient avoid excessive wiping or blowing of the nose for a period of at least 30 minutes. This is to ensure that the disinfectant remains in place for sufficient time to effect maximum antibacterial activity.