

# INSTRUCTIONS FOR USE

**SterilMed, Inc.**  
**Reprocessed Masks**  
**Manufactured by SterilMed, Inc.**  
**11400 73<sup>rd</sup> Avenue North**  
**Maple Grove, MN 55369**  
**Toll Free 1-888-541-0078/Fax 763-488-3350**  
**www.SterilMed.com**

**Caution: Federal Law restricts this device to sale by or on the order of a physician.**

## INDICATIONS FOR USE

These devices are reprocessed masks from various original equipment manufacturers (OEM). Masks are designed for use during routine and emergency anesthetic procedures on patients. Masks may also be used in airway situations and procedures.

The OEM packaged an Instructions for Use (IFU) document with the original device. The health institution that wishes the device to be reprocessed should retain this original document.

## DEVICE DESCRIPTION

Devices are reprocessed under contract with the health institution that previously used the device; the devices are used by the health institution, sent to SterilMed for reprocessing, and returned for reuse.

Reprocessed masks have been cleaned, evaluated for continued integrity, and resterilized prior to use. These devices were shipped from an owner, reprocessed, and returned for a single, subsequent use. Devices are tracked throughout the reprocessing steps to monitor and ensure the number of times reprocessed.

**This device has been reprocessed for a single use. If the device is to be used again, it must undergo reprocessing prior to use.**

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## **CONTRAINDICATIONS**

1. Patients who have not fasted
2. Patients who are more than 14 weeks pregnant or obese
3. Abdomen or thorax injury

## **WARNINGS AND PRECAUTIONS**

1. The user of the device should have adequate training and a thorough understanding of the use and applications of masks.
2. Inspect the packaging and device prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
3. Do not force the device during insertion.
4. Do not over inflate the device.

## **POTENTIAL ADVERSE EVENTS**

1. Sore throat
2. Aspiration

## **GENERAL INSTRUCTIONS AND INFORMATION**

Verify product receipt and ensure that owner's name is appropriate on the label. Inspect package and product for signs of damage or sterility compromise.

Remove the device from the sterile packaging using proper sterile technique.

Use of this reprocessed device should be limited to those physicians trained in use of this device and associated equipment. For specific information on clinical studies, individualization of treatment, patient counseling, and procedural use of this reprocessed device, refer to the medical literature and rely on training or medical experience.

If additional reprocessing of the product is desired, wipe the device with a moist sponge to remove any visible blood or tissue, package product, label as "biohazard", and ship product back to SterilMed.

## **METHODS TO TEST REPROCESSED DEVICES**

Devices have been tested to demonstrate biocompatibility following reprocessing as well as achievement of sterility. Validated methods are used for cleaning, packaging, and routine sterilization. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to release of product for reuse.

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*\* Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:*

*\* Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm*

*Instructions for Use can be found at [www.SterilMed.com](http://www.SterilMed.com). Further questions or concerns by the health practitioner can be addressed directly by contacting your SterilMed Customer Service Associate and/or the SterilMed Quality Department at 1-888-541-0078.*

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