

VIPER[™] II BLOWER MISTER INSTRUCTIONS FOR USE

Catalog Number	Description
BLM-700MS	Viper II Blower Mister

Explanation of Symbols on Packaging Label

STERILE EO	Sterilized using Ethylene Oxide
	Manufacturer
	Date of Manufacture
\subseteq	Use-by Date
2	Do Not Re-Use

REF	SKU / Catalog Number
LOT	Lot Number
Rx only	Prescription only / Caution: Federal (US) law restricts this device to sale by or on the order of a physician
i	Consult Electronic Instructions for Use
Ж	Non-pyrogenic

Product Description:

The VIPER II Blower Mister consists of a handpiece, a malleable shaft with a distal tip, and a tubing set $(CO_2 \text{ line tubing co-joined to fluid line tubing})$. The handpiece has a control for on/off of CO_2 / saline. A separate roller clamp provides a means to adjust fluid flow. The tubing set is approximately 10 feet (304.8 cm) in length.

Sterile, Nonpyrogenic, Disposable, Single use only.

Indications For Use:

The VIPER II Blower Mister is indicated for use during procedures when a wound or surgical site must be cleared using non-contact means for enhanced visibility.

Contraindications:

- This device is not intended for use other than as indicated above.
- This device should not be used where the effects of a CO₂ air stream or irrigation mist are contraindicated.

Warnings:

- Proper surgical procedures and techniques are the responsibility of the medical professional.
- DO NOT USE OXYGEN WITH THIS DEVICE.
- DO NOT exceed a flow rate greater than 8 liters per minute (I/min).
- Do not use air pressure greater than 50 psi.
- Use caution when moving device tip closer than 3 cm to the surgical or wound site. DO NOT ALLOW DEVICE TIP TO CONTACT TISSUE.
- Do not use this device if it shows signs of damage such as crimps, kinks or crushed areas.
- Acute bending of the stainless steel malleable shaft may cause kinking.
- Do not reuse or re-sterilize.
- Protect from extreme heat or humidity.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Precautions:

- Product is Ethylene Oxide sterilized.
- Sterile unless package is opened or damaged.
- To control the release of compressed CO₂, point tip of the device away from the wound or surgical site before turning on the device.

Adverse Effects:

None known.

Instructions For Use:

- 1. Inspect the package and product for damage and expiration date. Open the package and transfer product onto the sterile field utilizing aseptic technique.
- 2. Connect the braided tubing to a regulated source of medical CO₂ (not included). Initially adjust regulated flow control to 5 liters per min (I/min) and pressure of 30 psi. DO NOT EXCEED 8 I/min.
 - DO NOT USE AIR PRESSURE GREATER THAN 50 psi.
- 3. Close the pinch clamp on the IV tubing. Aseptically connect the IV spike to a new bag of sterile saline (not included) and place in a pressure cuff (not included). Inflate the pressure cuff to approximately 150 mmHg. Open the pinch clamp.
- 4. To control the release of compressed CO₂, point tip of the device away from the wound or surgical site before turning on the device.
- 5. Fully open the roller clamp to prime the saline line then adjust to the required flow.
- 6. To make any adjustments to the irrigation mist, adjust either the roller clamp on the fluid line or the regulated CO₂ flow control.
- 7. The handpiece has a control for on/off of CO_2 / saline.
- 8. Gently bend the malleable shaft to the desired shape to better access the wound or surgical site.
- 9. Initially hold the tip of the device 5-15 cm from the site to be visualized. Adjust distance as required for optimum clearing of the area. Use caution when moving device tip closer than 3 cm to the surgical site.
 - DO NOT ALLOW DEVICE TIP TO CONTACT TISSUE.
- 10. Dispose of device in accordance with established hospital protocol for hazardous waste.

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