

INSTRUCTIONS FOR USE CARBONMINI™ CO₂ DIFFUSER

art# 1400

Please read all information carefully. Before using the CarbonMini™ CO₂ diffuser the surgeon must understand the user instructions.

Caution:

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

Intended use:

CarbonMini™ is to be used by cardiovascular surgeons in open heart surgery procedures with a wound opening size up to 8 cm in diameter such as during minimal invasive and neonatal procedures for insufflation of CO₂ into the thoracic cavity to reduce the risk of air embolism. These instructions are intended for general use of CarbonMini™. Variations in use may occur in specific procedures due to individual techniques and patient conditions.

Preparations:

Inspect the package before opening. If damage of the package is noticed, discard the product.

- 1) Secure a CO₂ gas source with a capacity to deliver set CO₂ flow via a flow meter during the estimated time for operation.
- 2) The flow meter shall contain or be connected to a pressure regulator. The service pressure for CO₂ gas is set between 3.5-4.5 bar (50-65 psi or 350-450 kpa).
- 3) Place the foam tip at the caudal end of the wound. Bend the thin tubing so that the foam tip is placed approximately 1-2 inches (2-4 cm) below the skin surface.
- 4) Immobilize the tubing.
- 5) Connect the open part of the wide tubing to the flow meter.

Start and regulating gas flow to CarbonMini™:

- 1) Start the recommended CO₂ gas flow at least 2 minutes before opening of the heart, the lung veins and/or the great vessels.

DIAMETER OF SURGICAL WOUND OPENING	CO ₂ FLOW RECOMMENDED
< 3 cm	3 L/Min
3-4 cm	5 L/Min
5-8 cm	8 L/Min

- 2) When a suction device is used in the wound, avoid using a suction rate that exceeds the CO₂ gas flow rate. If the CO₂ gas flow rate is exceeded by the wound suction device the cavity may be depleted of CO₂ and filled with air. With extensive suctioning increase the flow rate accordingly.
- 3) The set gas flow should continue until the closure of the heart, the lung veins, and the great vessels is completed.
- 4) Avoid submerging the foam tip in fluid. If the foam tip is completely covered in fluid CarbonMini™ is not able to deliver CO₂ gas properly. If the foam tip gets soaked with fluid its full function can quickly be restored by squeezing the tip with two fingers thus removing trapped fluid.

Precautions:

- 1) CarbonMini™ is a single use device and should not be reused. Discard and do not use any unused open CarbonMini™ CO₂ diffuser.
- 2) Avoid submerging CarbonMini™ foam tip in fluid. The ability to diffuse CO₂ inside the wound will decrease as the foam tip becomes saturated with fluid. If the foam tip gets soaked with fluid its full function can quickly be restored by squeezing the tip with two fingers thus removing trapped fluid.
- 3) To prevent the surgeon from accidentally cutting the device preferably position the CarbonMini™ in the caudal end of the open surgical wound and fixate it with a suture or adhesive sterile tape. Fold away the foam tip by using the bendable tubing.

Disposal:

- 1) CarbonMini™ is a single use device and should not be reused.
- 2) CarbonMini™ should be discarded as blood contaminated materials.
- 3) Do not reuse CarbonMini™ due to the risk of infection.

Storage:

CarbonMini™ should be stored at room temperature away from moisture, direct heat and sunlight.

CarbonMini™	SPECIFICATIONS
Tubing	PVC non DEHP
Housing material	Acrylic fiber
Filter material	Hydrophobic PTFE
Bendable tubing	PVC non DEHP and stainless steel wire
Gas diffuser material	Polyurethane
Glue	Cyclohexanone
TECHNICAL DATA	
Gas flow	Recommended 3 L/min
Storage temperature	10-30°C, 50-86°F
Sterilization method	Ethylene oxide

Warranty and limitation of liability:

- A) The manufacturer warrants that the CarbonMini™ has been manufactured in accordance with its specifications and in compliance with Good Manufacturing Practices, and other applicable industry standards and regulatory requirements.
- B) The manufacturer will replace any CarbonMini™ with manufacturing defects if marked with the lot number, provided that, the defects become apparent in a period of twenty four (24) months from the manufacturers delivery of the product.
- C) The above mentioned warranty is in lieu of, and to the exclusion of any other warranty, whether written or oral, expressed or implied, statutory or otherwise and there are no warranties or merchantability or other warranties which extend beyond those described above. The remedy set out above for manufacturing defects is the sole remedy available to any person due to defects in the CarbonMini™ and the manufacturer shall not be liable for any consequential or incidental loss, damage, injury or expense arising directly or indirectly from the use of the CarbonMini™, whether as a result of any defect therein or otherwise.
- D) The manufacturer shall not be liable for any misuse, improper handling, non-compliance with warnings, precautions, and instructions, damage arising from events after the manufacturers release of the CarbonMini™, failure or omission to inspect the CarbonMini™ before use in order to ensure that the CarbonMini™ is in proper condition, or any warranty given by independent distributors or dealers.


Manufacturer:

CARDIA INNOVATION AB. Address: Lillskogs v. 22, SE-133 34 Sältsjöbaden, Sweden.


E-mail: contact@cardiainnovation.com, website: www.cardiainnovation.com. CE 0123, 510(k)#112975

The product is protected by the following patents, held by Cardia Innovation AB Patent#US6494858B1, 6994685B2, 7549973B2, Patent#Europe 1032322, 1239915, patent#Sweden515473


Explanations of Symbols on packaging labels.




Manufacturer




Lot number




Temperature limits




Sterilisation method



Single use article



Expiration date



Read IFU

Pyrogen-free

DO NOT USE IF THE PACKAGE IS DAMAGED