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# CarboJet<sup>®</sup> Boom/Headwall Source CO<sub>2</sub> Adaptor Instructions for Use

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English KINAMED<sup>®</sup> CarboJet<sup>®</sup> Boom/Headwall Source CO<sub>2</sub> Adaptor Instructions for Use

#### CAUTION

# ▲ Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.

## INDICATIONS FOR USE - CARBOJET SYSTEM

The CarboJet System is indicated for the removal of fluid and particulate debris from bone surfaces for site preparation in orthopedic surgery. Irrigated, sculpted surfaces may be optimized to receive bone cement applied for fixative procedures. CarboJet cleaning is recommended immediately prior to the introduction of bone cement.

The CarboJet tube set and disposable nozzles are indicated for single use only.

#### PROCEDURES FOR USE OF BOOM/HEADWALL ADAPTOR:

- Several methods are commonly used to deliver medical-grade carbon dioxide (CO<sub>2</sub>) gas to the hospital operating room. Delivery methods include high pressure cylinder/tank, plumbed boom, and plumbed headwall sources. For instructions pertaining to cylinder or tank delivery systems, refer to the CarboJet System Instructions for Use (document B00040).
- This document (B00176) refers to methods in which the CO2 is delivered via a 2 boom and/or headwall source. The CarboJet Boom/Headwall Source CO2 Adaptor options described in this document (see Table 1) are intended for use with a boom or headwall source CO2 system. These Adaptors provide usercontrolled CO2 pressure regulation at or near the gas outlet fitting and provide a DISS (Diameter Index Safety System) (25-200-0150, 25-200-0160, 25-200-0162) or Chemetron style (25-200-0152) coupler attachment. For unregulated versions of the Boom/Headwall Source CO2 Adaptor (25-200-0150, 25-200-0152), it is essential for the user to ensure that the pressure is set correctly at 50 PSI (345 kPa or 3.45 BAR) because the Adaptor itself does not regulate the gas pressure. PRESSURE SUPPLIED TO THE UNREGULATED BOOM/HEADWALL ADAPTOR MUST NEVER EXCEED 50 PSI (345 kPa or 3.45 BAR) OR DAMAGE TO THE STERILE FILTRATION SYSTEM OR OTHER SYSTEM FAILURE MAY OCCUR. Other types of gas fittings with integrated regulators are available for CO2 tank or cylinder gas sources. Please contact Kinamed Customer Service if there are any questions regarding the application or use of this component.
- The CarboJet Boom/Headwall Source CO<sub>2</sub> Adaptor with Extension Hose (25-200-0150, 25-200-0162) provides an additional extended reach.

Part No.	Description	CO <sub>2</sub> Regulation	Coupler Type	Max Inlet Pressure
25-200-0150	CarboJet Boom/Headwall Source CO <sub>2</sub> Adaptor, DISS, Extension Hose	NO	DISS	50 PSI 345 kPa 3.45 BAR
	CarboJet Boom/Headwall Source CO <sub>2</sub> Adaptor, Chemetron	NO	Chemetron	50 PSI 345 kPa 3.45 BAR
25-200-0160	CarboJet Boom/Headwall Source CO <sub>2</sub> Regulated Adaptor, DISS	YES	DISS	300 PSI 2068 kPa 20.7 BAR
25-200-0162	CarboJet Boom/Headwall Source CO <sub>2</sub> Regulated Adaptor, DISS, Extension Hose	YES	DISS	300 PSI 2068 kPa 20.7 BAR

Table 1. Available options for connecting the CarboJet tube set to a boom or headwall source of CO<sub>2</sub> gas.

- 4. The CarboJet Boom/Headwall Source CO<sub>2</sub> Adaptor should be inspected for the presence of O-rings, damage, dirt, dust, oil, or grease (Note that the Chemetron Adaptor, 25-200-0152, does not contain O-rings). Remove dust or dirt with a clean cloth. Do not use the Boom/Headwall Source CO<sub>2</sub> Adaptor if oil, grease, or damage is present. No other maintenance is required. The Boom/Headwall Source CO<sub>2</sub> Adaptor is used outside of the sterile field and should not be sterilized or immersed in any liquid.
- CAREFULLY open the CO<sub>2</sub> gas valve a very small amount and for only an instant. Then close the valve quickly to blow out any foreign matter in the valve port.
- 6. Install the Boom/Headwall Source  $CO_2$  Adaptor to the  $CO_2$  source making sure it is securely fitted. Check for audible leaks. Delivery pressure to the CarboJet tube set should not exceed 50 psi (345 kPa or 3.45 Bar).
- VERY IMPORTANT: After the surgery is completed, be sure to close the CO<sub>2</sub> gas supply valve completely prior to removal of the Boom/Headwall Source CO<sub>2</sub> Adaptor.

### DURING SURGERY

- 8. Open the pouch containing the sterile CarboJet tube set and deliver the contents to the sterile field. Connect the tube set to the handpiece and to the Boom/Headwall Adaptor using the white quick disconnect fittings at each end. The tubing end with the female fitting attaches to the handpiece while the end with the male fitting attaches to the Boom/Headwall Adaptor. Both tubing end fittings are simply pushed into place until an audible click is heard.
- 9. If sterile disposable nozzles are used, open the pouch containing the sterile nozzle and deliver the contents to the sterile field. Select a nozzle and attach it to the nose of the handpiece via the quick disconnect fitting. Push the nozzle into the fitting until it clicks in place.
- 10. If using the intramedullary nozzle, first ensure that the stainless steel suction tube is properly assembled on the nozzle and the "Y" end of the tube is securely supported on the O-rings at the fitting end of the nozzle. Once the nozzle assembly is complete and the nozzle is attached to the handpiece, connect a standard sterile suction tube to the "Y" port of the nozzle's steel suction tube. Connect the opposite end of the suction tubing to a suction canister and pump. For all CarboJet instruments, inspect the O-rings prior to use and replace O-rings if they are cracked, out of round or show flat spots.
- Open the valve on the CO<sub>2</sub> supply source. If any hissing is heard, check to ensure that the Boom/Headwall CO<sub>2</sub> Adaptor is properly tightened on the CO<sub>2</sub> source to avoid leaking.

### MATERIALS

The Boom/Headwall Adaptor is made from stainless steel and chrome plated brass components. The extension hose on item 25-200-0150 and 25-200-0162 is made from chrome plated brass fittings and a polyester braided medical grade PVC core with a thermoplastic cover. Additional material information is available from the company upon request.

#### **CLEANING & STERILIZATION**

The CarboJet Boom/Headwall Source  $CO_2$  Adaptor should be inspected for damage, dirt, dust, oil, or grease. Remove dust or dirt with a clean cloth. The CarboJet Boom/Headwall Source  $CO_2$  Adaptor is supplied non-sterile and should not be sterilized or immersed in any liquid for cleaning purposes.

Consult the CarboJet  $CO_2$  Bone Lavage System Instructions for Use (B00040) for cleaning and sterilization instructions for all other hardware components of the CarboJet System.

#### CONTRAINDICATIONS

Patients with significant pre-existing cardiopulmonary disorders, including for example a patent foramen ovale (PFO), or who are ASA (American Society of Anesthesiology) Class III or higher, may require careful monitoring by the anesthesiologist during CarboJet use to forestall any unanticipated cardiovascular changes associated with the application of the  $CO_2$ .

### WARNINGS

- 1. Only Medical Grade CO<sub>2</sub> gas may be used with the CarboJet device. Use of other gas may result in gas embolism, serious injury, or death.
- 2. Atmospheric air must be cleared from system prior to use.
- 3. Only Kinamed CarboJet tube sets may be used to connect the CO<sub>2</sub> source with the CarboJet handpiece.
- Ensure the CO<sub>2</sub> inlet pressure does not exceed 50 PSI (345 kPa or 3.45 BAR) for unregulated boom/headwall adaptors (25-200-0150, 25-200-0152).
- Ensure the CO<sub>2</sub> inlet pressure does not exceed 300 PSI (2068 kPa or 20.7 BAR) for a regulated boom /headwall adaptor (25-200-0160, 25-200-0162).
- Ensure the CO<sub>2</sub> outlet pressure does not exceed 50 PSI (345 kPa or 3.45 BAR) for a regulated boom/headwall adaptor (25-200-0160, 25-200-0162).
- 7. This product contains chemicals, including lead, known to the state of California to cause cancer and birth defects or other reproductive harm.
- 8. Avoid placing the tip of the CarboJet nozzle into or in close proximity to a venous sinus.