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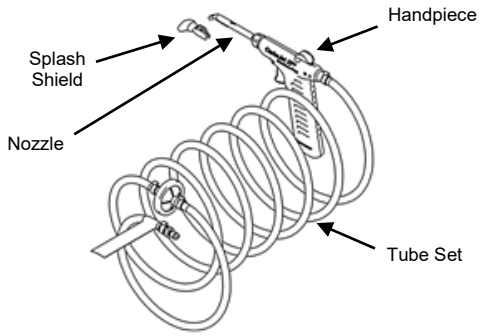
KINAMED® CarboJet XF® Bone Preparation Solution Instructions for Use

Patents: www.Kinamed.com/patents

INDICATIONS FOR USE

The CarboJet XF 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 XF system (handpiece, tube set, nozzle, and optional splash shield) is indicated for single use only. Do not attempt to resterilize and reuse CarboJet XF as this could damage its components, including its filtration system, and pose significant risk to the patient.



MR SAFETY INFORMATION

Location of Use	MR Safety Information
Within the USA	The CarboJet XF System has not been tested for safety and compatibility in the MR environment (it has not been tested for heating, migration, or image artifact in the MR environment).

PROCEDURES FOR USE:

PRIOR TO SURGERY

1. There are several types of outlet fittings used on CO_2 supply cylinders/systems. It is essential to check that the pressure regulator supplied with your CarboJet XF System is equipped with the corresponding inlet fitting. Kinamed provides the pressure regulator with various types of inlet fittings. Please contact Kinamed Customer Service or your sales representative if you need assistance matching the regulator to the CO_2 source.

2. The CarboJet pressure regulator should be inspected for damage, dirt, dust, oil, or grease. Remove dust or dirt with a clean cloth. Do not use the regulator if oil, grease, or damage is present. No other maintenance is required for the regulator, except as described in Step 4 below. The regulator is used outside of the sterile field and should not be sterilized. The warranty label that is affixed to the pressure regulator shows the recommended replacement date. Contact Kinamed Customer Service when the pressure regulator is approaching or reaches the end of its warranty period to discuss replacement options.

3. When using a CO_2 cylinder tank, secure the CO_2 cylinder to a wall, post, or in an appropriate cart so that it can not tip or fall. CAREFULLY open the cylinder valve a very small amount for only an instant. Then close the valve quickly to blow out any foreign matter in the valve port.

4. Install the pressure regulator to the CO_2 cylinder/source making sure it is securely fitted. Some regulators come fitted with the appropriate washer. Make sure any required washer is in place before connecting to the CO_2 source. When using a CO_2 cylinder tank, carefully open the cylinder valve and check for audible leaks and check the gauge on the regulator to assess tank pressure. The CarboJet regulators provide measuring functions, as summarized in the table below.

Part Number	Description	Measurement	Degree of Accuracy
25-200-0100	CO_2 Pressure Regulator with CGA 320 Tank Connector	CO_2 tank pressure in pounds per square inch (psi) or kilopascal (kPa)	±50psi or ±345 kPa
25-200-0110	CO_2 Pressure Regulator with CGA 940 Connector		
25-200-0120	CO_2 Pressure Regulator with 27mm Connector (Italy)		
25-200-0130	CO_2 Pressure Regulator with DIN 6 Connector		
25-200-0140	CO_2 Pressure Regulator with DIN477 FA9 Connector		

Regulator delivery pressure to the CarboJet XF System is factory set to 50 psi (345 kPa). The hospital's Biomedical Engineering department should routinely confirm the regulator's outlet pressure in accordance with maintenance intervals for similar types of equipment.

If using a CarboJet® Boom/Headwall Source CO_2 Adaptor, please consult the Adaptor's Instructions for Use (document B00176) for important information regarding these devices.

5. **VERY IMPORTANT:** When using a CO_2 cylinder tank, after the surgery is completed, be sure to close the cylinder valve completely prior to removal of the regulator from the cylinder.

DURING SURGERY:

6. Open the pouch containing a sterile CarboJet XF single assembly and deliver the contents to the sterile field. Pass the white quick connect male fitting out of the sterile field and connect it to the CO_2 source pressure regulator or adaptor. The tubing end fitting is simply pushed into place until an audible click is heard. If the quick disconnect fitting does not "click" into place, reset the spring-loaded actuator on the corresponding mating fitting.

7. If using the sterile CarboJet XF splash shield, open the sterile pouch containing the splash shield or remove it from the pouch containing the XF system assembly, and deliver the contents to the sterile field. Attach the splash shield to the tip of the nozzle.

8. When using a CO_2 cylinder tank, open the valve on the CO_2 tank. If any hissing is heard, turn the valve back to the off position and check to ensure that the washer between the regulator and cylinder is present and that the regulator fitting is properly tightened on the CO_2 cylinder to avoid leaking.

9. **VERY IMPORTANT:** With the nozzle tip pointing away from the sterile field, start the gas flow by depressing the trigger on the CarboJet XF handpiece for a minimum of five (5) seconds. This step clears the air from the line and provides a convenient check of all fitting connections.

10. Standard orthopedic surgical procedures are followed for site preparation. Following mechanical shaping and sculpting of the bone bed, saline lavage and suction should be used for initial clearing of debris and fluids.

11. CarboJet XF cleaning is recommended as the final step prior to introduction of the bone cement. For most sites, 20 to 30 seconds of CarboJet XF use should provide adequate cleaning. Direct the tip of the nozzle at the prepared bone surface and depress the trigger. Move the nozzle tip as needed to clean the bone of fat, debris, and liquids. If the CarboJet XF splash shield is not used, hold a sterile sponge or towel just ahead of and above the nozzle's tip to collect debris that will be scattered by the gas jet.

12. Following CarboJet XF use, stop the flow of CO_2 gas from the source and purge the CarboJet XF System by depressing the handpiece trigger. Disconnect the tubing from the reusable CarboJet regulator or adaptor and discard the used CarboJet XF assembly and splash shield (if used). CarboJet XF components cannot be re-sterilized and are not re-useable.

MATERIALS:

The CarboJet XF handpiece is made from thermoplastic with silicone and stainless steel components. The splash shield is made from a thermoplastic elastomer. The tube sets are made from PVC tubing with connectors and components made from vinyl, polycarbonate, Delrin acetal, Buna-N, and stainless steel. The pressure regulator is made from stainless steel and chrome plated brass components. Additional material information is available from the company upon request.

STERILITY AND HANDLING:

The CarboJet XF System has been sterilized by gamma radiation and is sterile unless the pouch has been damaged or opened. If the pouch is damaged or has already been opened, do not use it or its contents.

MAINTENANCE:

Maintenance and mechanical inspection must be performed by trained hospital personnel.

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_2 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. See instruction #9, above.
3. Only the Kinamed CarboJet XF assembly (including the tube set) may be connected to the CO_2 source.
4. Ensure the CO_2 inlet pressure to the tube set does not exceed 50 PSI (345 kPa or 3.45 BAR).
5. Avoid placing the tip of the CarboJet XF nozzle into or in close proximity to a venous sinus.

⚠ **WARNING:** The CarboJet pressure regulator can expose you to chemicals including lead, which is known to the state of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

EXPLANATION OF SYMBOLS	
MD	**Medical device**
Rx Only	**Federal Law restricts this device to sale by or on the order of a licensed physician.**
STERILE R	**Sterilized using irradiation.**
	Do not resterilize
	Do not use if package is damaged and consult instructions for use.
	Devices labeled for single use are intended to be used once only, for a single patient, because they may not perform as intended if they are reused. Reuse may lead to failure of the device to perform as intended.
PHT DEHP	**The presence of this symbol on the product label indicates that the material used for the manufacture of this specific medical device contains Di (2-ethylhexyl) phthalate DEHP.**
REF	**Catalog number**
LOT	**Lot number**
	Caution
	Date of Manufacture
	Use-by date
UDI	**Unique Device Identifier**
BIO	**Splash shield contains biological material of animal origin.**