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CarboJet® CO_2 Bone Preparation System Setup and Usage Guide

CarboJet Complete Assembly

CAUTION: Federal law restricts this device to sale by or on the order of a physician. Prior to use of a Kinamed device, please review the instructions for a complete listing of indications, contraindications, warnings, precautions, and directions for use.

Indications and Contraindications

Indications For Use:

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. Do not attempt to resterilize and reuse the CarboJet tube set as this could damage its filtration system and pose significant risk to the patient.

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.

Excerpted from document B00040

Warnings

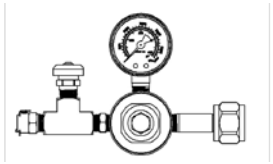
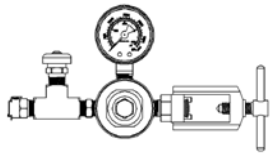
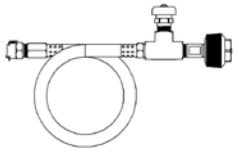
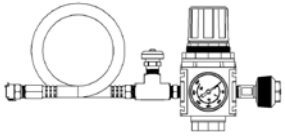
1. Only Medical Grade CO_2 gas may be used with the CarboJet device. Use of other gas may result in gas embolism, serious injury, or death.
2. Atmospheric air must be cleared from system prior to use. See Steps 3 and 9.
3. Only Kinamed CarboJet tube sets may be used to connect the CO_2 source with the CarboJet handpiece.
4. Ensure the CO_2 inlet pressure to the tube set does not exceed 50 PSI (345 kPa or 3.45 BAR).
5. The CarboJet pressure regulator contains chemicals including lead, known to the state of California to cause cancer and birth defects or other reproductive harm.
6. Avoid placing the tip of the CarboJet nozzle into or in close proximity to a venous sinus.

Step 1: Secure a CO_2 source

There are several types of outlet fittings used on CO_2 supply cylinders/systems. Check that the pressure regulator supplied with your ***CarboJet*** system is equipped with the corresponding inlet fitting. Kinamed provides pressure regulators with various types of inlet fittings. Evaluation surgeries should always be performed with a 40 liter or larger CO_2 tank (e.g. "E size" cylinder of gas) and not with boom/headwall CO_2 sources. Static pressure and flow rate using these cylinders are optimal, predictable and provide the surgeon a baseline of performance to be expected when switching to a boom/headwall CO_2 source later.

Step 1 (continued)

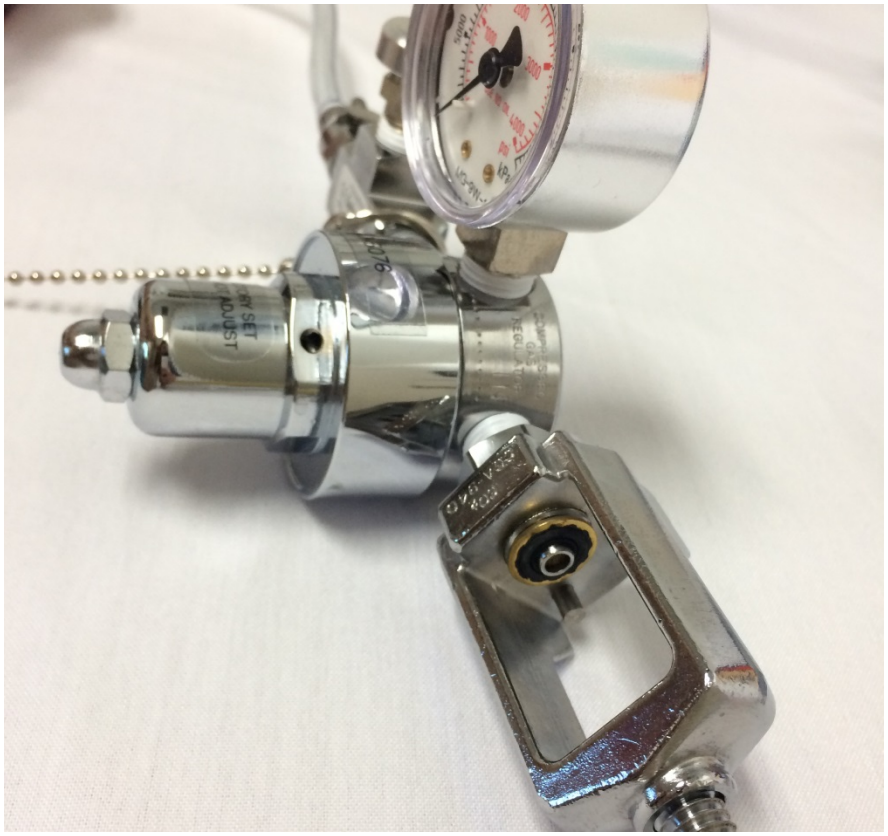
Recommended CO_2 Source: "E-Size Cylinder" (with CGA 940 pin-index yoke tank connection)
Alternatives: Boom/ Headwall Source CO_2. Kinamed provides the adaptors and regulators seen below.

CO_2 Regulator/Adaptor Options:		Excerpted from document B00176
25-200-0100	CarboJet Pressure Regulator (with CGA 320 tank connection)	
25-200-0110	CarboJet Pressure Regulator (with CGA 940 pin-index yoke tank connection)	
25-200-0150	CarboJet Boom/Headwall Source CO_2 **Adaptor**, (with DISS connection, Extension hose. Set source pressure to 50psi)	
25-200-0162	CarboJet Boom/Headwall Source CO_2 **Regulated-Adaptor**, (with DISS connection, Extension hose. Min Inlet Pressure: 72psi, Max: 300psi)	

CO_2 Tank Size

If using an alternative CO_2 tank, Kinamed recommends that you do not use the very smallest size CO_2 tanks as these quickly lose pressure and gas stream force at the nozzle as the CO_2 is depleted from the tank. Even when the gauge measures 500 psi (3447 kPa) static pressure, the flow at the nozzle will tend to fall when in use and the gas stream force will decline noticeably, diminishing cleaning performance of the system. Available cylinder sizes vary from market to market, but **we recommend that at least a 40 liter CO_2 tank be used with *CarboJet*.**

Step 2: Inspect Regulator



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 on Page 12. The regulator is used outside of the sterile field and should not be sterilized.

Step 3

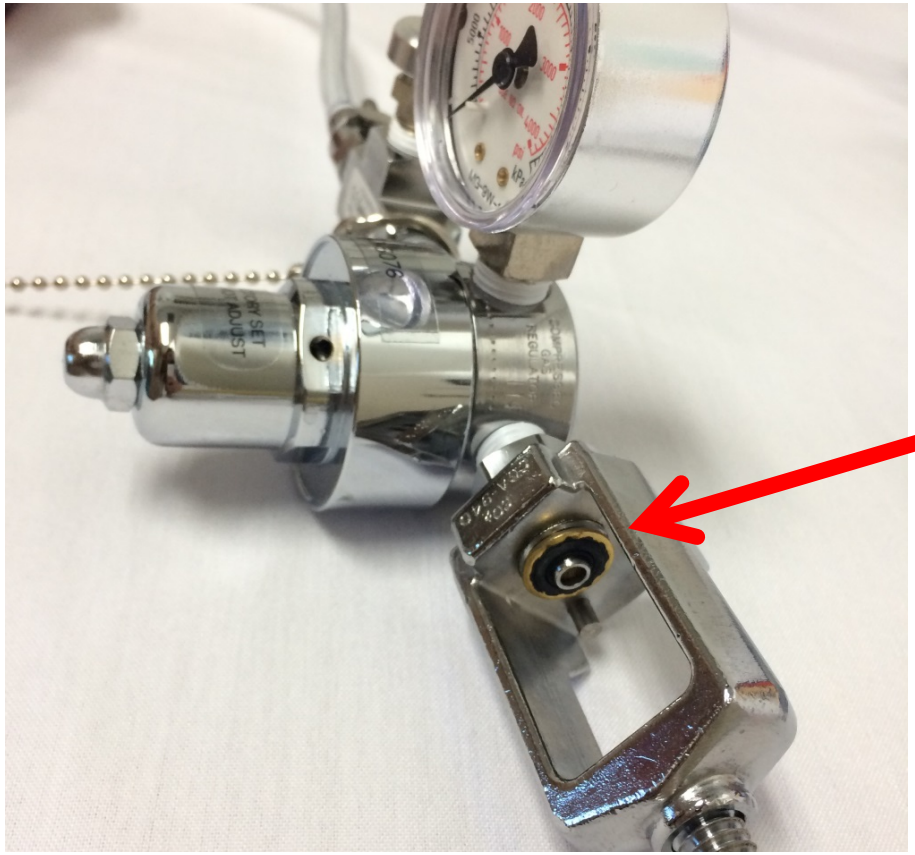
Prepare CO_2 Cylinder

Secure the CO_2 cylinder to a wall, post, or in an appropriate cart so that it cannot tip or fall.

Step 3 (continued)

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.

Step 4: Install Regulator



*Make sure the required washer is in place before connecting to the CO_2 source.

All regulators used with cylinders/tanks come fitted with an appropriate washer.

Step 4 (continued)

Install Regulator

Install the pressure regulator to the CO_2 cylinder/source making sure it is securely fitted.

Step 4 (continued)

Install Regulator

CAREFULLY open the cylinder valve and check for audible leaks. If any hissing is heard, 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. When using a CO_2 cylinder tank, check the gauge on the regulator to assess internal tank pressure. The gauge reads tank pressure only. Regulator delivery pressure to the ***CarboJet*** 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.

Kinamed offers replacement washers for its regulators.

For Regulator 25-200-0110: Order Replacement Washer Part no. 25-200-0274

For Regulator 25-200-0100: Order Replacement Washer Part no. 25-200-0272

Step 4 (continued)

Regulator FAQs

What does the regulator do?

The main purpose of the regulator is to set the correct gas pressure that is delivered to the tubeset and handpiece. There is an internal mechanism in the regulator that "regulates" this outflow pressure to 50 pounds per square inch (psi) or 345 kilopascals (kPa). Note that this internal mechanism should not be altered or tampered with.

What does the gauge indicate?

Reps or hospital staff sometimes assume that the pressure gauge is an indication of the force/pressure of gas exiting the handpiece or nozzle – this is not the case. The gauge on the regulator shows the pressure inside the tank, and has nothing to do with the 50psi (345 kPa) outflow pressure. Check the gauge regularly to ensure at least 500 psi (3447 kPa). This will ensure gas supply doesn't run out at a critical moment. Cleaning performance of the system may fall off when tank pressure goes below 500 psi.

The CarboJet regulator warranty label shows a date. Is this a service date, replacement date, or just a warranty period?

It is a replacement date. When the pressure regulator is approaching or reaches the end of its Warranty Period, we recommend that you contact Kinamed Customer Service (at 800-827-5775 or contact@kinamed.com) to discuss replacement options.

Tank Pressure should be at least 500 psi

Cylinder is running low on CO_2

Warranty Period label affixed to tank-mounted pressure regulator

Step 5: Sterilize Instruments

Steam sterilize the instrument set including the handpiece and all non-disposable nozzles in the ***CarboJet*** Sterilization Tray per recommended procedures (see product insert/IFU document B00040).

Step 6: Connect Tube Set

Open the pouch containing the sterile tube set and deliver the contents to the sterile field. Using the white quick disconnect fittings at each end of the tube set, connect the female end of the tube set to the handpiece and then pass the male end of the tube set out of the sterile field and connect it to the pressure regulator.

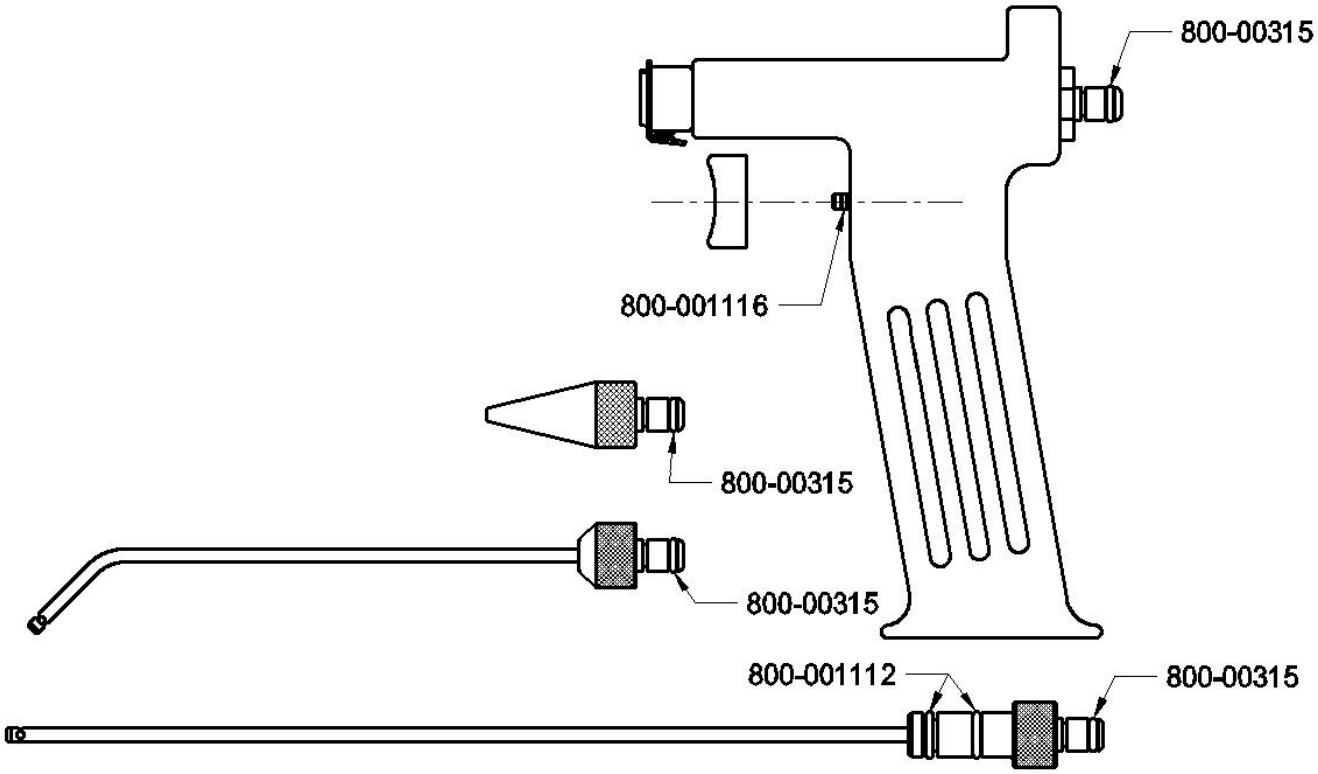
Step 6 (continued)

Both tubing end fittings are simply pushed into place until an audible click is heard. If the quick disconnect fittings do not “click” into place, reset the spring loaded actuator on the corresponding mating fittings (see arrows above).

Step 7: Select Nozzle

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.

Kinamed Supplies O-Ring Replacement kits, part no. 25-200-0270, which provide replacement O-rings for a complete instrument set.

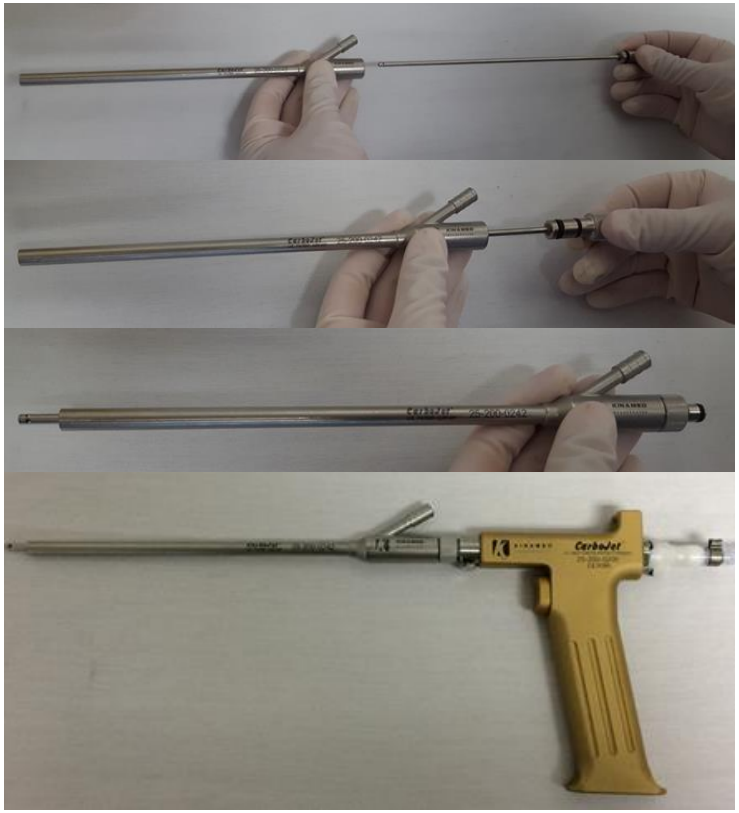


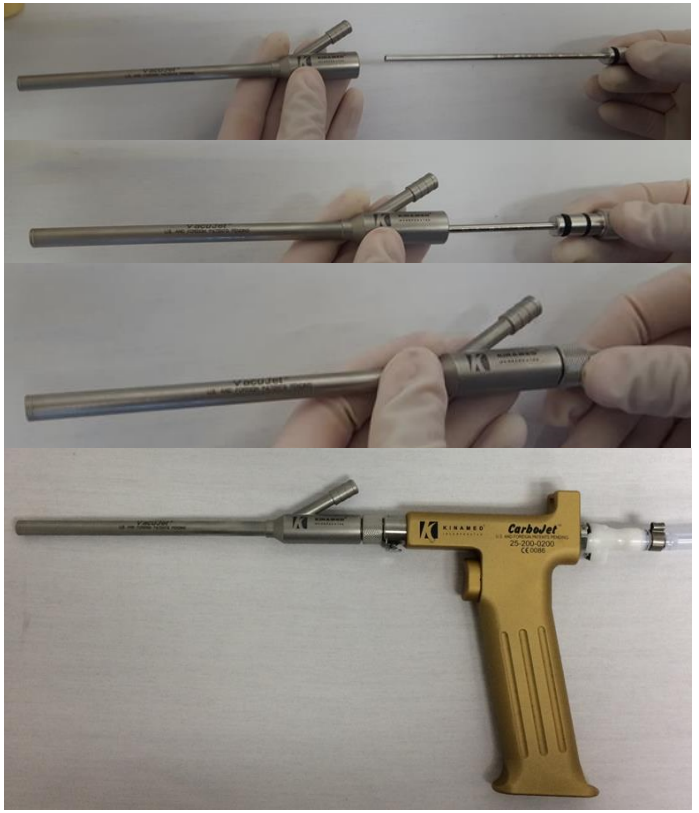
800-001112

800-00315

800-001116

Step 7 (continued)





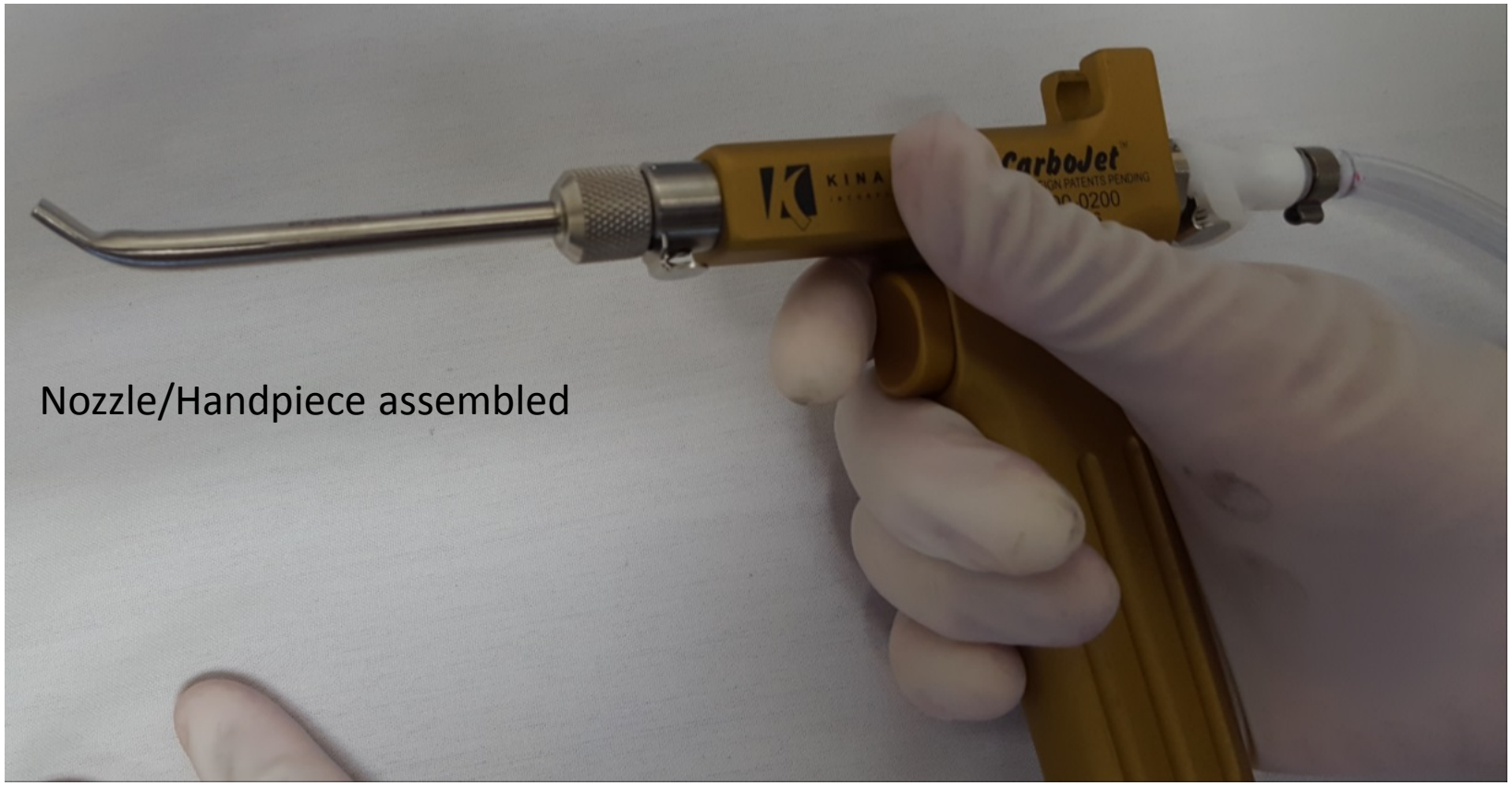
If using the intramedullary nozzle or ***VacuJet*** attachments, first ensure that the stainless steel suction tube is properly assembled on the nozzle and the “Y” end of the tube is securely supported on the O-rings at the fitting end of the nozzle. Once the nozzle assembly is complete and the nozzle is attached to the handpiece, connect a standard sterile suction tube to the “Y” port of the steel suction tube. Connect the opposite end of the suction tubing to a suction canister and pump.

Step 8: Attach Nozzle

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.

Nozzles may be changed as needed during surgery without disconnecting the CO_2 line.

Step 8 (continued)



Nozzle/Handpiece assembled

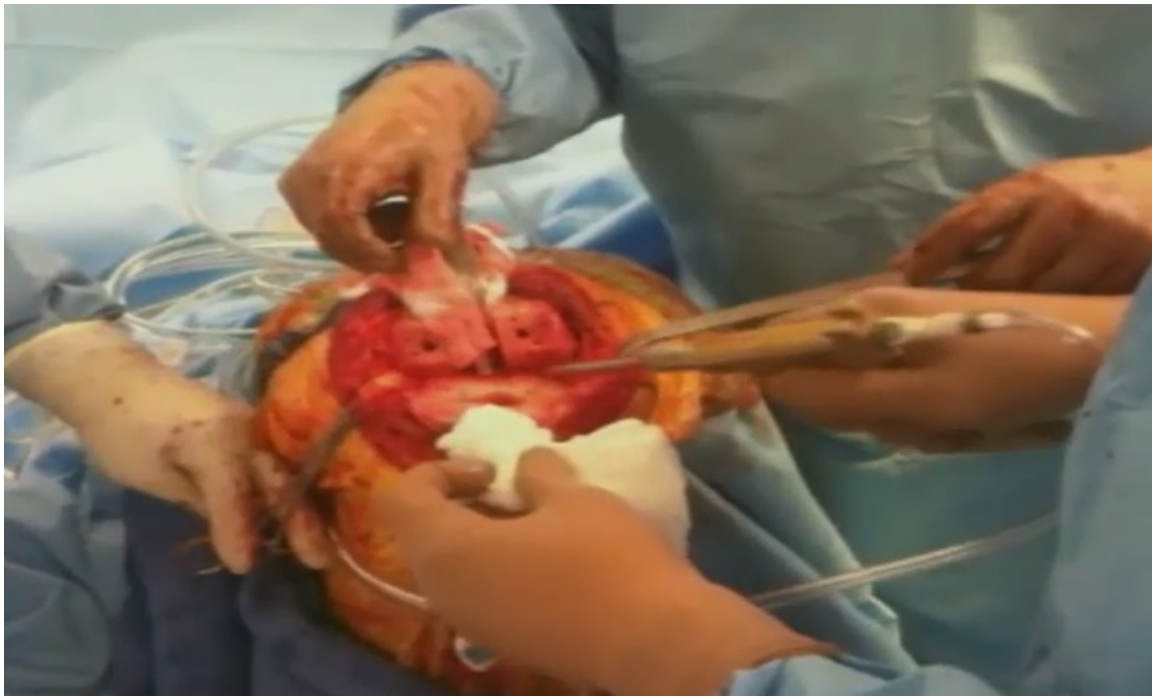
Step 9: Clear the Air

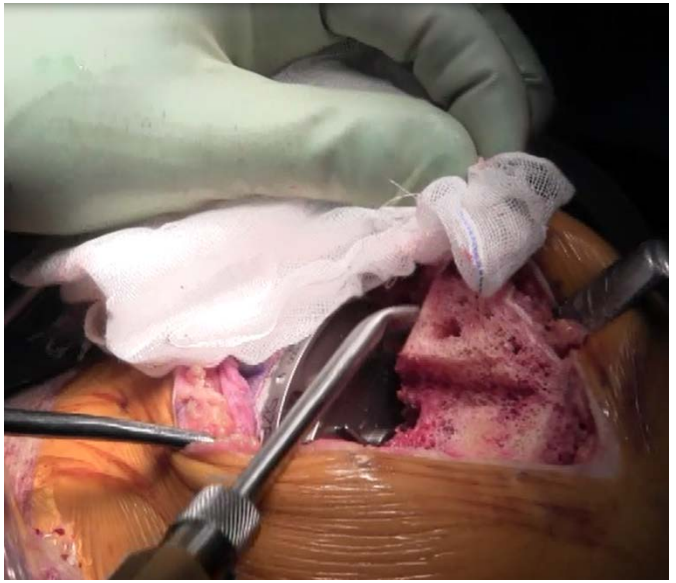
VERY IMPORTANT: With the nozzle tip pointing away from the sterile field, start the gas flow by depressing the trigger on the handpiece for a minimum of five (5) seconds. This step clears the air from the lines and provides a convenient check of all fitting connections.

Step 10: Saline Lavage & Suction

Standard orthopedic surgical procedures are followed for site preparation. Following mechanical shaping and sculpting of the bone bed, saline lavage (either pulsatile or simple bulb syringe) and suction should be used for initial clearing of debris and fluids.

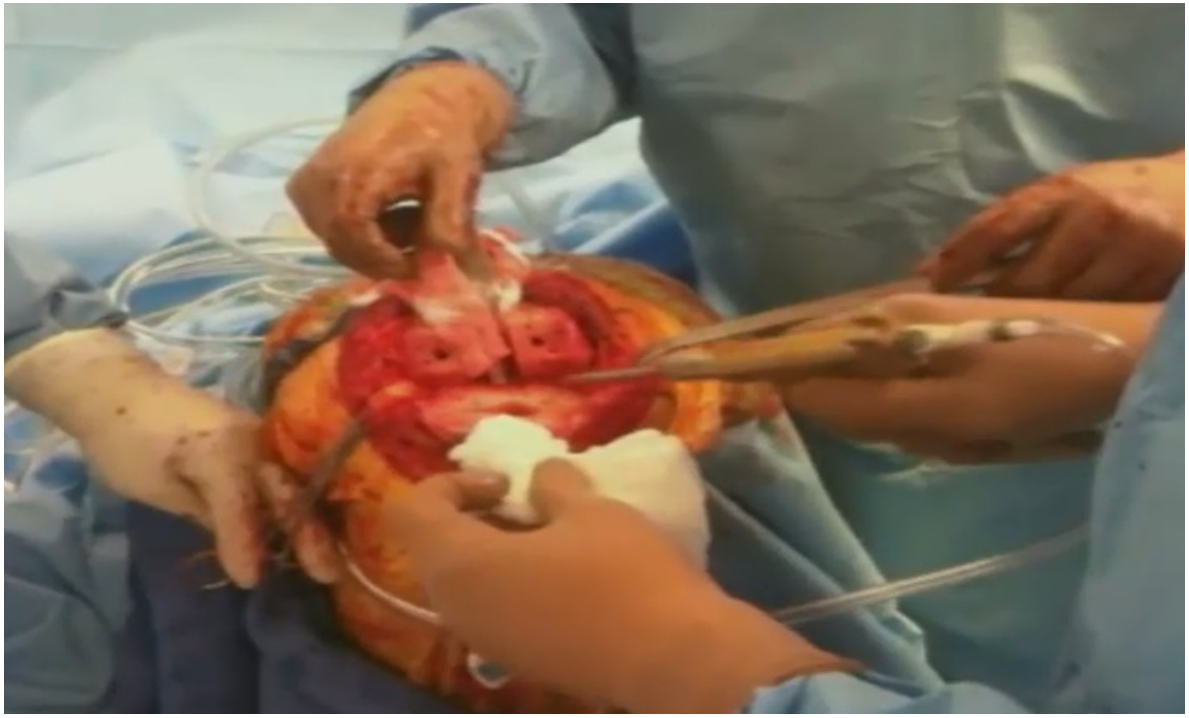
Step 11: Use ***CarboJet*** to remove lipids/ fatty marrow elements, debris and liquids

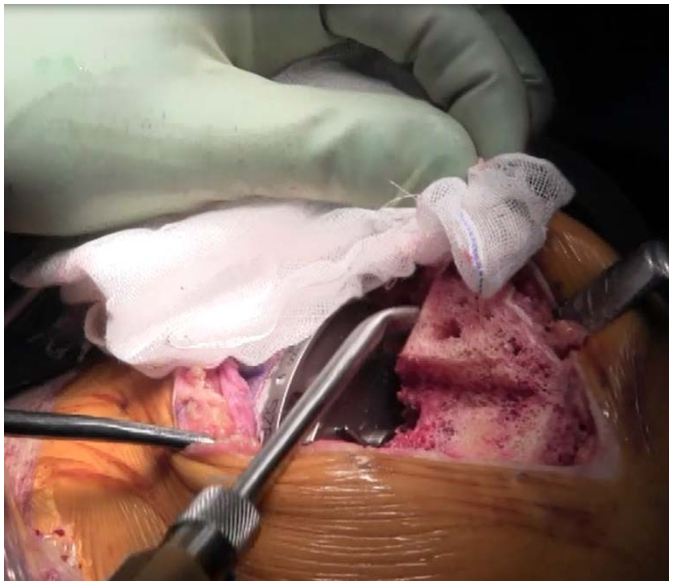




CarboJet cleaning is recommended as the final step prior to introduction of the bone cement. Before beginning to clean with ***CarboJet*** ensure that as much fluid (blood and saline) as possible is removed by suctioning. For most sites, 20 to 30 seconds of ***CarboJet*** use should provide adequate cleaning. Direct the tip of the appropriate nozzle at the prepared bone surface and depress the trigger. Avoid placing the tip of the ***CarboJet*** nozzle into or in close proximity to a venous sinus. Move the nozzle tip as needed to clean the bone of lipids/fatty marrow elements, debris and liquids.

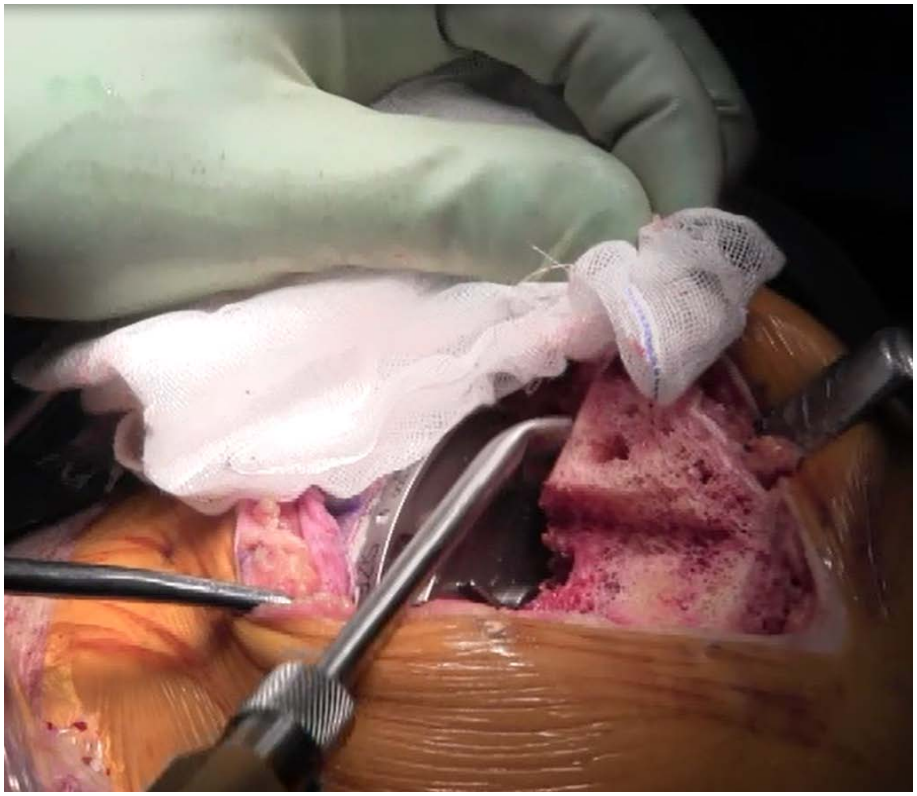
Step 11 (continued)

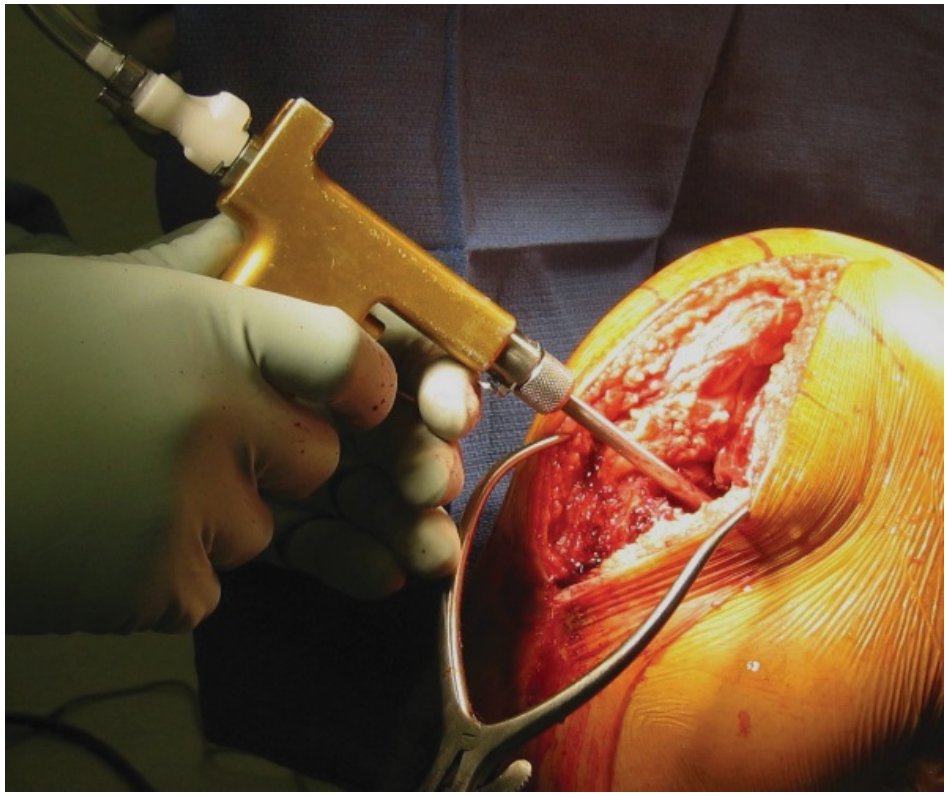




VERY IMPORTANT: Hold a sponge or towel just ahead of and above the nozzle's tip to collect debris that will be scattered by the gas jet.

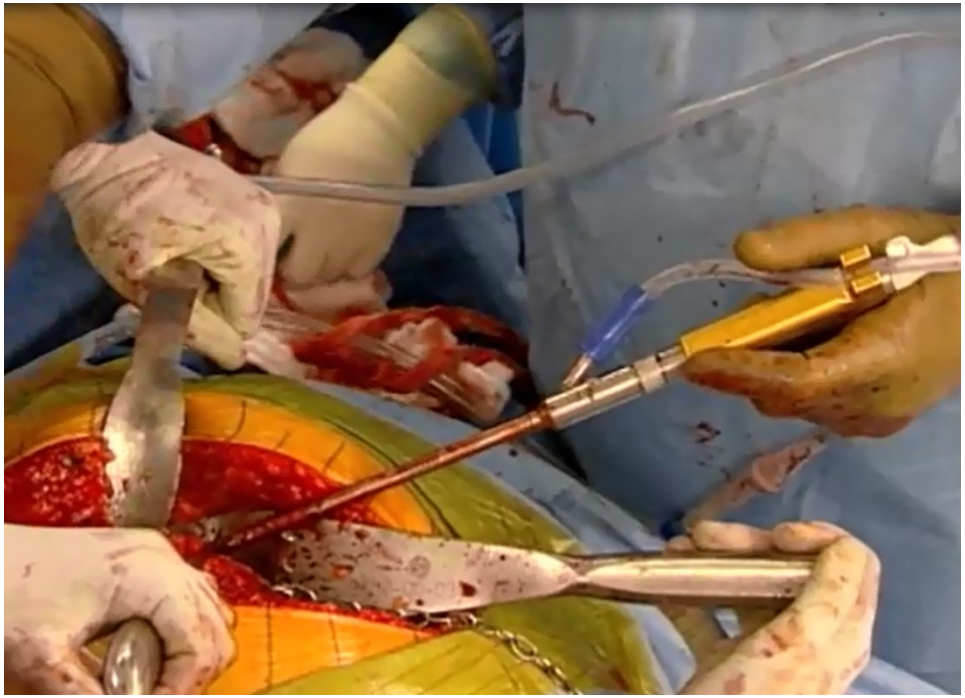
Step 11 (continued)





NOTE: The 40 degree nozzle (25-200-0246) can be rotated in the handpiece to direct the gas flow for optimal cleaning of various bone surfaces, and is especially useful accessing the posterior condyle in TKA/UKA.

Step 12: Long Bone Use



NOTE: For long bone use, the coaxial suction tube must be in place over the long CO_2 nozzle with a suction pump operating at all times for safe and effective cleaning. Long bone cleaning is most effective when working from distal to proximal, as follows: insert the long bone nozzle into the prepared femur, with the suction pump running, and then depress the ***CarboJet*** trigger. With the trigger depressed, slowly draw the nozzle proximally to clean the prepared canal. The nozzle may be rotated back and forth to ensure thorough cleaning. Since continued bleeding typically re-wets the bone bed after initial cleaning, it is important to remember that the primary function of CarboJet is to remove lipids/fatty marrow elements from the bone bed. Re-bleeding can be addressed by making a couple of final passes with the ***CarboJet*** nozzle immediately before introduction of the cement.

Step 13: Close CO_2 Valve

Following ***CarboJet*** use, close the valve on the CO_2 tank and purge the ***CarboJet*** System by depressing the handpiece trigger.

Step 14: Disconnect Tubing

Disconnect the tubing from the regulator and handpiece. Discard the used tube set and any disposable nozzles. Tube sets and disposable nozzles cannot be re-sterilized and are not reusable.

Step 15: Complete!

VERY IMPORTANT: After the surgery is completed, double check that the cylinder valve is completely closed prior to the removal of the regulator from the cylinder. The regulator may be left in place on the CO_2 tank so that it is ready and available for use on the next case.

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For more information:

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