2192-C Anchor Ct, Newbury Park, CA, 91320

CarboJet™ Bone Lavage System
Instructions for Use

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 is indicated for single use only.

Procedures for use:

1. Prior to Surgery: The CarboJet™ pressure regulator is installed on a tank of carbon dioxide USP, via the regulator's CGA 320 fitting. Line up the regulator's inlet fitting, with washer supplied, with the outlet fitting on the CO_2 tank and advance the large threaded nut onto the threads of the tank's outlet fitting. Tighten the fitting securely with a wrench. The regulator gauge reads tank pressure only: delivery pressure is factory pre-set to 50 psi.

2. Prior to Surgery: Steam sterilize the handpiece assembly and the nozzles per recommended procedures. The intramedullary nozzle should be disassembled (remove the "Y" tube) for sterilization.

3. Open the pouch containing the sterile tubing and deliver the contents to the sterile field.

4. Connect the sterile gas delivery tubing to the handpiece via the luer lock and to the pressure regulator using the white quick disconnect fitting. Hold the white plastic fitting firmly and push it straight into the regulator's outlet fitting until it clicks in place.

5. Select a nozzle and attach it to the nose of the handpiece via the quick disconnect fitting: push the nozzle straight into the fitting until it clicks in place.

6. If using the intramedullary nozzle, first ensure that the stainless steel suction tube is properly assembled on the nozzle, so that the nozzle is inside the tube 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, open the pouch containing the sterile suction tubing and delivery it into the sterile field. Connect one end of this tubing to the "Y" of the nozzle's steel suction tube. Connect the opposite end of the suction line tubing to the suction tip in the sterile field, connected in turn to a suction canister and pump.

7. Open the valve on the CO_2 tank. If any hissing is heard, check to ensure that the regulator fitting is properly tightened on the CO_2 cylinder to avoid leaking.

8. **NOTE/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.

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

10. CarboJet™ cleaning is recommended as the final step prior to introduction of the bone cement. For most sites, 20 to 30 seconds of CarboJet™ lavage should provide adequate cleaning. Direct the tip of the appropriate 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. Hold a sponge or towel just ahead of the nozzle's tip to collect debris which will be scattered by the spray, particularly when using the wide-angle nozzle. Nozzles may be changed as needed during surgery without disconnecting the CO_2 line.

11. **NOTE:** For long bone use, the coaxial suction tube must be in place and a suction pump operating at all times for effective cleaning. Long bone cleaning is most effective when working from distal to proximal, as follows: After clearing the line as in Step 8 above, 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 to ensure thorough cleaning.

12. Following CarboJet™ use, disconnect the tubing from the regulator and then from the handpiece. Discard the used tube set, and also the suction tube set. Tube sets are not re-useable.

MATERIALS: The CarboJet™ handpiece is made from aluminum alloy with stainless steel components. The tube sets are made from PVC tubing with connectors and components made from vinyl, polycarbonate, Delrin acetal, Buna-N, and stainless steel. Additional material information is available from the company upon request.

CLEANING & STERILIZATION: The tube sets have been sterilized by gamma radiation and are sterile unless damaged or opened. The handpiece and nozzles are provided non-sterile. All hardware components are fully immersible for cleaning. Nozzles should be removed from the handpiece for cleaning and sterilization, and the Y tube should be removed from its nozzle. No other disassembly is required or recommended.

Soak the components in Klenzyme™ or equivalent for two minutes, and rinse thoroughly under running tap water. Clean with Manuklenz™ or equivalent, using a soft bristle brush for the surfaces and soft narrow brush for the lumens. Rinse thoroughly under running tap water.

The following sterilization cycles have been validated:
Prevacuum: Wrapped, 4 minutes, 0 minutes dry time, 132ºC min.
Gravity: Wrapped, 30 minutes, 15 psi, 121ºC minimum
Unwrapped, 15 minutes, 15 psi, 121ºC minimum

CONTRAINDICATIONS: Total joint arthroplasty patients with significant pre-existing cardiopulmonary disorders 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:

- Only CO_2 gas may be used with the CarboJet™ device. Use of other gas may result in gas embolism, serious injury or death.

- Atmospheric air must be cleared from system prior to use. (See instruction #8, above.)

- Only Kinamed CarboJet™ tube sets may be used to connect the CO_2 source with the CarboJet™ handpiece.

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