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INCORPORATED

820 Flynn Rd, Camarillo CA, 93012

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™ tubeset is indicated for single use only.

Procedures for use

Prior to Surgery:

1. The CarboJet™ pressure regulator is installed on a tank of carbon dioxide USP. Two types of regulator inlet fittings (CGA 320, threaded; and CGA-940, post/yoke) are available for the system allowing the regulator to be adapted to either of the two types of CO₂ tanks typically available at hospitals. The type of CO₂ tank available at the hospital must be identified prior to surgery and the proper regulator inlet fitting must be fitted to the regulator. Either the hospital bioengineering department or your Kinamed sales representative should be contacted to properly install the inlet fitting on the regulator. The regulator is then securely fitted to the CO₂ tank. The gauge on the regulator reads tank pressure only. Regulator delivery pressure to the CarboJet System is factory pre-set to 50 psi.

2. Steam sterilize the instrument set including the handpiece and nozzles in the CarboJet Sterilization Tray per recommended procedures.

During Surgery:

3. Open the pouch containing the sterile tubeset and deliver the contents to the sterile field. Connect the tubeset to the handpiece and to the pressure regulator 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 regulator. Both tubing end fittings are simply pushed into place until an audible click is heard.

4. Select a nozzle and attach it to the nose of the handpiece via its quick disconnect fitting. Push the nozzle into the fitting until it clicks in place.

5. 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 the suction tip in the sterile field, connected in turn to a suction canister and pump.

6. Open the valve on the CO₂ tank. If any hissing is heard, check to ensure that the regulator fitting is properly tightened on the CO₂ cylinder to avoid leaking.

7. 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.

8. 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.

9. 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 that will be scattered by the spray, particularly when using the wide-angle nozzle. Nozzles may be changed as needed during surgery without disconnecting the CO₂ line.

10. NOTE: For long bone use, the coaxial suction tube must be in place with 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 per 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 back and forth to ensure thorough cleaning.

11. Following CarboJet™ use, close the valve on the CO₂ tank and purge the CarboJet System by depressing the handpiece trigger. Disconnect the tubing from the regulator and handpiece. Discard the used tube set: tube sets cannot be re-sterilized and 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: All hardware components are fully immersible for cleaning. The CarboJet handpiece is made from anodized aluminum alloy: **INSURE THAT ALL CLEANING AGENTS USED ARE COMPATIBLE WITH THIS MATERIAL.** Nozzles should be removed from the handpiece for cleaning 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. Rinse thoroughly under running tap water.

The tube sets have been sterilized by gamma radiation and are sterile unless the pouches have been damaged or opened. The handpiece and nozzles are provided non-sterile and should be autoclaved per the following validated procedures:

Prevacuum: Wrapped, 4 minutes, 0 minutes dry time, 132°C min.

Gravity: Wrapped, 30 minutes, 15 psi, 121°C minimum

Unwrapped, 15 minutes, 15 psi, 121°C 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 CO₂.

WARNINGS:

❑ Only CO₂ 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 CO₂ source with the CarboJet™ handpiece.

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