



October 10, 2018

The use of CarboJet® for the cleaning of bone in cemented total joint surgery and infection

To whom it may concern,

The CarboJet CO₂ Bone Preparation System has been used clinically for the cleaning and drying of cut bone surfaces in cemented joint arthroplasty since 1993. It has been manufactured and distributed by Kinamed since 1999. During this period, there have been over one hundred and fifty thousand usages of CarboJet in the United States, Europe, Canada, Australia, United Kingdom, Japan, and other countries.

There is no evidence that CarboJet use has resulted in an increase in infection rates during this long and extensive clinical history, which spans more than twenty years.

CarboJet has been cleared by many regulatory agencies around the World, including the US Food and Drug Administration and the Japanese Pharmaceuticals and Medical Devices Agency, and is CE Marked for the European Community.

Kinamed maintains a detailed complaint handling system for all our products, including CarboJet, as mandated by medical device law. No patient infections have been attributed to the use of the CarboJet system.

The medical grade CO₂ gas that is used with CarboJet, as supplied in hospitals around the World, has been in continuous use for decades as an insufflation agent in laparoscopic surgery. In addition to the use of medical grade carbon dioxide gas, the CarboJet system employs a sub-micron particle size filter in the gas delivery line that ensures sterile delivery of the gas.

A reference list of Clinicians that have longstanding experience with CarboJet is available.

Sincerely,

A handwritten signature in blue ink that reads 'Heather Neely'.

Heather Neely, RAC, CQA
Sr. Director Quality Assurance and Regulatory Compliance