CarboJet® Clinical Summary

The **CarboJet CO2 Bone Preparation** system offers important benefits that are not available through the use of any other product. These benefits include:

- 1. The improved ability to perform total knee arthroplasty (TKA) without the use of a tourniquet (<u>see study by Jones</u>). The tourniquetless TKA technique is associated with a <u>reduction in post-op pain and opioid consumption</u> (see <u>published study</u> and <u>AAOS abstract by Meneghini</u>), as well as other clinical benefits. There is widespread availability of scientific literature describing the adverse effects of tourniquet use in TKA, including the following linked studies:
 - Faster recovery without the use of a tourniquet in total knee arthroplasty
 - <u>Does Tourniquet Use in TKA Affect Recovery of Lower Extremity Strength and Function?</u>
 - Effects of tourniquet use on quadriceps function and pain in total knee arthroplasty

A major challenge with Tourniquetless TKA is achieving an optimal "cement technique" because of the additional fluid debris present in the bone and at the implant interfaces. *CarboJet* addresses this challenge and enables surgeons to perform TKA without a tourniquet without compromising their cement technique. In fact, by adopting *CarboJet* and eliminating the tourniquet, cement penetration can actually be improved, as described in a recent *Journal of Arthroplasty* study which compared a group with no tourniquet and with *CarboJet* versus a group with tourniquet and without *CarboJet* (see 2019 study by Meneghini et al).

- 2. A demonstrated increase in cement penetration into the cancellous bone matrix in TKA as compared to pulsatile saline lavage (see studies by <u>Meneghini et al</u> and <u>Goldstein et al</u>) as a result of effective removal of lipids/ fatty marrow, blood, and saline from the bone bed. Aseptic loosening was shown in a recent study to be the <u>number one</u> cause of knee arthroplasty failure (<u>see study by Schroer et al</u>). Also see the White Paper on Aseptic Loosening (<u>linked here</u>), which discusses some of the numerous studies showing similar results over the last decade. Below are links to some of these studies:
 - Why are total knee arthroplasties being revised?
 - Why are total knee replacements revised?: analysis of early revision in a community knee implant registry.
 - Revision total knee arthroplasty in the young patient: is there trouble on the horizon?
- 3. A demonstrated <u>increase in the bone-cement interface strength</u> (<u>see study by Stanley et al</u>). In this study, bone-cement interface strength was shown to be 58% higher with *CarboJet* cleaning versus saline.
- 4. The <u>ability to gain access in the posterior regions of the knee</u> to <u>achieve bone bed cleaning and drying</u> in both TKA and UKA (unicompartmental knee arthroplasty) (<u>see technique vignette by Dr. Dennis McGee</u>). It is extremely difficult to gain access to the posterior femoral bone cuts in TKA, and particularly UKA with its small incision, for adequate cleaning and drying of the bone bed using saline methods.

- 5. A demonstrated <u>decrease in large intraoperative cardiac emboli</u> as evidenced by reduced cardiac echogenic load (<u>see study by Lassiter et al</u>). The embolization of fat and marrow contents into the vascular tree is a very serious issue that demands our best efforts to mitigate.
- 6. A demonstrated improvement in the removal of immunogenic elements from Osteochondral Allografts (OCA) (see study by Cole et al). Given that postoperative antibody development may impact graft integrity and longevity in OCA surgery, there is tremendous interest in decreasing the amount of antigenic cellular material present in osteochondral allografts.
- 7. Improved 10-year survivorship rates for hip resurfacing arthroplasty <u>(see study by Amstutz & Le Duff)</u>. This long-term, large-cohort study showed that the addition of CarboJet to the author's hip resurfacing technique improved 10 year survivorship rates.

In summary, by addressing these important issues, *CarboJet* contributes to our shared mission to provide the highest standard of patient care.