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ENSEMBLE ORTHOPEDICS RECEIVES FDA CLEARANCE FOR PYROCARBON CMC INTERPOSITIONAL IMPLANT

AUSTIN, TX — December 4, 2020: Ensemble Orthopedics, Inc. today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration for its Ensemble CMC Implant. The Ensemble CMC was designed to treat patients with early-stage osteoarthritis of the carpometacarpal (CMC) joint using a minimally invasive, simple surgical procedure.

The Ensemble CMC has a proprietary saddle shape that replaces the natural bearing surfaces of the carpal and metacarpal bones with an interpositional implant that allows for normal, pain-free motion. This combines the advantages of minimal joint resection with an inherently stable design, thus making the implant suitable for higher demand patients. The Ensemble CMC device is inserted with minimal disruption to the joint capsule and preservation of critical stabilizing soft tissues offering the potential for faster rehabilitation. The Ensemble CMC is available in three sizes and utilizes a simple instrument set.

“In my experience with CMC implants, the unique design of the Ensemble CMC distributes loads across joint surfaces providing superior implant stability and resistance subluxation/dislocation throughout its range of motion,” Thomas Trumble, MD, Chief Medical Officer of Ensemble Orthopedics says. “Because the Ensemble CMC interpositional implant is stemless, it can be inserted through a smaller incision with less disruption than what is required for other implants, thereby preserving all major stabilizing soft tissue structures of the thumb.”

The Ensemble CMC is constructed using On-X® PyroCarbon (pyrocarbon), a proprietary form of pyrolytic carbon produced by On-X Life Technologies, Inc. Pyrocarbon is a high strength, low modulus material shown to offer superior wear resistance when bearing against bone than either metal or ceramic. Pyrocarbon has a proven history of durability and biocompatibility in medical devices, including heart valves and orthopedic implants.

Hand osteoarthritis is an extremely common condition that causes pain while limiting function. The lifetime risk of symptomatic hand osteoarthritis is approximately 40%. Current treatment modalities typically start with pharmacological and immobilization approaches for mild cases, progressing to surgical intervention with either joint resection or joint replacement in severe cases.

Ensemble Orthopedics, a medical device company based in Austin, TX, develops minimally invasive and minimally disruptive interpositional surgical solutions for the extremity arthroplasty market. For further information, please visit <https://www.ensembleortho.com/>.