



ORTHOCON® Receives 510(k) Clearance to Market HEMASORB Apply®

HEMASORB® Absorbable Bone Hemostat Matrix is Now Available in an Applicator

Irvington, NY (June 1, 2011) – ORTHOCON®, Inc., a privately-held therapeutic device company, today announced that the Food and Drug Administration cleared HEMASORB Apply™ for clinical use and sale in the United States.

HEMASORB Apply is a proprietary, custom-designed applicator preloaded with HEMASORB® Absorbable Bone Hemostat Matrix. The product is provided ready-to-use and enables precise application of HEMASORB to stop bone bleeding during surgical procedures and in treating traumatic injuries. Currently marketed bone hemostat products require surgeons to use their fingers or surgical instruments for application. Unlike bone waxes, HEMASORB is putty-like in consistency, does not require preparation, and is now provided in a syringe-like applicator. Furthermore, HEMASORB is absorbable, biocompatible, and water resistant.

Commenting on the significance of the HEMASORB Apply clearance, John J. Pacifico, ORTHOCON's President and Chief Executive Officer, said the following: "This regulatory clearance is an important achievement for ORTHOCON. There has been very little innovation in the bone hemostat field since bone wax was first introduced in the late 1800s. We believe that the widespread adoption of flowable surgical hemostats has created new opportunities for advanced surgical products that more efficiently and effectively control bone bleeding, and we are confident that HEMASORB Apply will help secure ORTHOCON's leadership position in this therapeutic category. Both HEMASORB and HEMASORB Apply are clearly differentiated from wax-like hemostats, and they are changing the way surgeons think about surgical hemostasis."

Since its initial market introduction in 2010, HEMASORB has been approved for sale at leading hospitals throughout the United States and has been used successfully by hundreds of surgeons. ORTHOCON is confident HEMASORB Apply will provide surgeons with an innovative and cost effective tool to assist in their management of intra-operative bone bleeding, and the company fully expects HEMASORB to become the standard of care for bone hemostasis.

Control of bleeding from cut bone is a problem in many operative procedures including spine, orthopedic, craniomaxillofacial, and cardiac surgeries. Excessive bleeding during surgery may impair the surgeon's view of the operative field, may result in the need for blood transfusions, and may be associated with postoperative complications. ORTHOCON estimates that over 3.5 million patients undergoing surgeries in the United States, Europe, and Canada each year could benefit from the intra-operative use of HEMASORB.



About ORTHOCON

Founded in 2005, ORTHOCON develops, manufactures, markets, and sells implantable products to stop bone bleeding.

ORTHOCON is funded by leading international venture capital investment firms. The company occupies 8,000 square feet at its state-of-the-art facility in Irvington, New York. For more information, please visit www.orthocon.com.

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