

SPINAL APPLICATIONS

WHEN NORMAL BONE HEALING AND FUSION ARE CRITICAL

HemaQuell®

RESORBABLE BONE HEMOSTAT



Oozing bone can be problematic in the surgical field, interfering with visualization and prolonging operative time. HemaQuell Resorbable Bone Hemostat provides rapid hemostasis by filling in cut or damaged bone surfaces with a simple, ready-to-use application. And because it is completely resorbed in just 2 to 7 days, it allows bone to heal normally without interference.¹



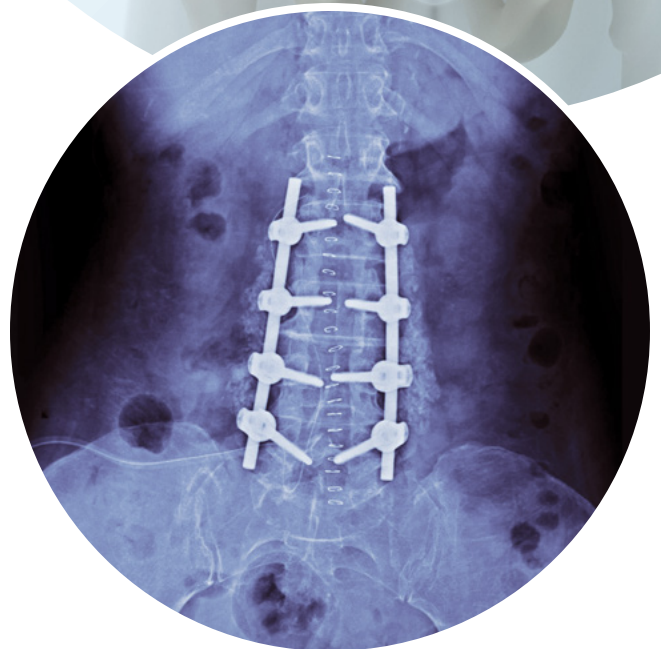
Applications

- Control bleeding from pilot/tap holes
- Control bleeding from cut bone surfaces



Primary surgical procedures

- Spinal stabilization/interbody fusion
 - Pedicle screw placement
 - Facet screw placement
- Foraminotomy (intervertebral foramen)
- Bone graft site, for example, iliac crest



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RESORBABLE BONE HEMOSTAT

- Readily adheres to bleeding bone surfaces, forming a physical barrier for rapid hemostasis
- Has the same hemostatic properties as nonresorbable bone wax
- Product is delivered in a unique extruding applicator for improved handling
- Completely resorbed in 2 to 7 days to permit normal bone healing¹
- Made from a patented blend of pharmaceutical grade, water-soluble copolymers
- Biocompatible, nontoxic and nonswelling¹

VS

Nonresorbable wax-based hemostats

- Remain permanently in place
- Physically block bone healing²
- Induce chronic, long-term inflammation^{3,4}
- Lead to the formation of bone wax granuloma^{4,5,6}
- Increase the potential for infection^{3,6,7,8}

1) Data on file, Wound Management Technologies, Inc. April 5, 2016 2) Orgill, D. et al. Polyethylene Glycol Microfibrillar collagen composite as a new resorbable bone wax. Journal of BioMedical Materials Research Vol. 39, 358-363, 1998 3) Katz, S. et al. Adverse effects of bone wax in surgery of the orbit. Ophthalmic Plastic and Reconstructive Surgery Vol. 12(2), 121-126, 1996 4) Sudmann, B. et al. Histologically verified Bone Wax (Beeswax) Granuloma after median sternotomy in 17 of 18 autopsy cases. Pathology Vol. 38(2), 138-141, 2006 5) Anfinson, O.G. et al. Complications secondary to the use of standard bone wax in seven patients. Journal of Foot and Ankle Surg. Vol. 32(5), 505-508, 1993 6) Roy, M.C. et al. Surgical Site Infections After Coronary Artery Bypass Graft Surgery, Infection Control and Hospital Epidemiology Vol. 19 (4), 1998 7) Gibbs, L.; Kakis, A.; Weinstein, P.; Conte, J.E. Jr. Bone wax as a risk factor for surgical site infection following neurospinal surgery. Infect Control Hosp Epidemiol. 25(4), 346-348, 2004 8) Jethanamest, D. et al. Delayed Wound Infection Associated with Bone Wax in Lateral Skull Base Surgery. J Neurol Surg, B, 74 - A269, 2013

Instructions for Use

1

HemaQuell Hemostat is ready for use as delivered. It will soften slightly if manipulated by hand.

2

To extrude HemaQuell Hemostat from the applicator tube, remove the protective cap, then rotate the wheel at the base of the tube clockwise to expose the desired amount of product.

3

Apply HemaQuell Hemostat directly to the bleeding bone surface using a crayonlike application. If necessary, reinforce anchorage by pressing the hemostat into the defect.

4

Alternatively, extrude HemaQuell Hemostat from the tube, mold as needed, and apply by hand or with a surgical instrument.

Caution: Since HemaQuell Hemostat is water-soluble, aggressive irrigation at the application site may lead to breakthrough bleeding and reapplication may be required.

Note: Depending on the size of the defect and the porosity of the bone, multiple tubes may be required.



Indications for Use:

HemaQuell Hemostat is indicated as an implant material for the control of bleeding from bone surfaces.

Contraindications: 1) Surgical sites that are infected 2) The use of the product to provide structural support to bone or to stop bone growth.

Warnings and Precautions: 1) HemaQuell Hemostat is provided sterile for single use only; do not resterilize. 2) Discard open, unused or damaged packages. 3) Protect the product from heat. Store at 0 to 32 degrees C (32 to 90 degrees F).

Product code: HQ6-10

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