

The pathological term “bone wax granuloma” describes the persistent residence of the non-resorbable beeswax based, bone wax hemostat within a bone defect, is known to delay bone healing and increase the potential for infection¹.

Beeswax bone wax is not resorbable. A citizen’s petition² has been filed with the FDA to prohibit the use of non-resorbable beeswax bone wax in serious indications.

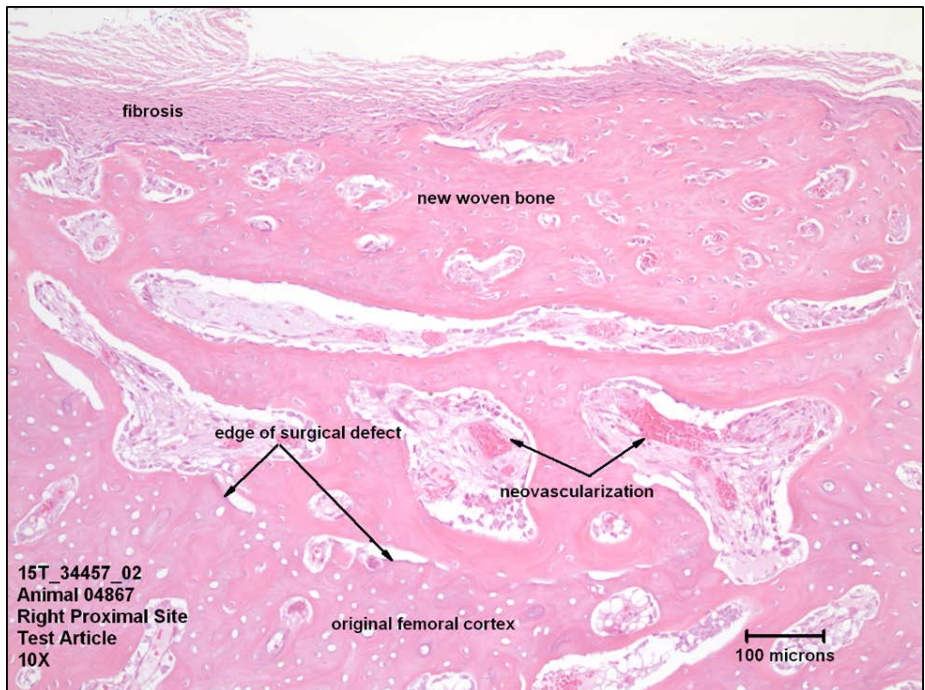
The non-resorbable beeswax bone wax product has consistently declined in sales year over year due to the building public awareness of “bone wax granuloma”. Further, the literature reports multiple case reports³ of findings of beeswax bone wax granuloma⁴ and the associated inhibition of bone healing⁵.

In a rabbit bone healing study, HemaQuell™ controlled bleeding, was resorbed within 2-7 days and did not inhibit bone healing.

The HemaQuell™ resorbable orthopedic hemostatic material is water soluble, is resorbed and does not generate “bone wax granuloma”.

Additionally, in April of 2004 the FDA issued a Public Health Notification⁶ stating the Agency’s concern over the use of absorbable hemostatic agents (collagen) as “an absorbable hemostatic agent that was used on or near a bony or neural space and left inside the patient. When wetted, the material swelled and exerted pressure on the spinal cord or other neural structures, resulting in pain, numbness or paralysis. In some cases, blood pooled behind the implanted absorbable hemostatic agents, forming a hematoma that exerted pressure on neural tissues and caused a range of neural deficits.”

HemaQuell™ dissolves in an aqueous (tissue fluid) environment and does not swell.



As the photomicrograph above shows, four (4) weeks after application of HemaQuell™, normal bone regeneration proceeds without the inhibitory influence of granuloma.

¹ Katz S. et. al. Adverse effects of bone wax in surgery of the orbit. Ophthal Plastic and Reconstructive Surgery Vol. 12(2), p. 121-126 dated June 1996

² Citizens Petition dated February 18, 2005 Re: World Wide Medical Technologies

³ Katz S. et. al. Adverse effects of bone wax in surgery of the orbit. Ophthal Plastic and Reconstructive Surgery Vol. 12(2), p. 121-126 dated June 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), p. 138-141 dated April 2006.

⁵ Anfinson OG. Complications secondary to the use of standard bone wax in seven patients. Journal of Foot and Ankle Surg. Vol. 32(5), p. 505-508 dated Sep-Oct 1993.

⁶ http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062146.htm?utm_campaign=Google2&utm_source=fd aSearch&utm_medium=website&utm_term=FDA Public Health Notification: Paralysis from Absorbable Hemostatic Agent&utm_content=1