Ostene
Bone Hemostasis Material

Immediate Impact

OSTENE—The biodissolvable bone hemostat

Baxter

Next Generation

The next generation in bone hemostasis

OSTENE is a synthetic, biodissolvable implant material[1] that:

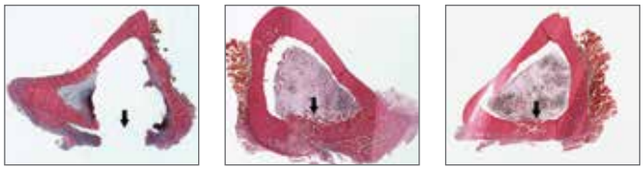
- Provides immediate bone hemostasis[1]
- Can be used on all bleeding bone surfaces[1]
- Is biocompatible[2,3]
- Has a favorable safety profile[4]
- Does not require removal—water-soluble polymer dissolves within 48 hours[5,6]
- Is a mechanical barrier that does not act biochemically[1,3]

Do not use OSTENE in sites with active or latent infections

Easy application at your fingertips

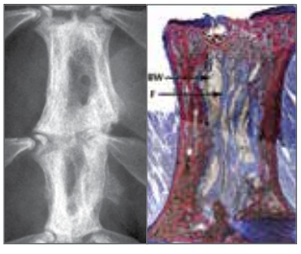
The ready-to-use sticks are soft and easy to apply. Using dry, gloved fingers, OSTENE is easily molded to the desired shape and consistency that provides immediate hemostasis when pressed into bleeding bone.

Immediate Impact

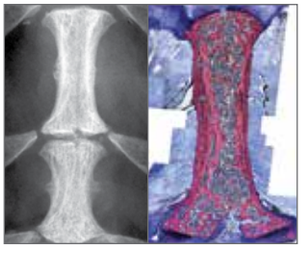


BONE WAX[5] CONTROL[5] OSTENE[5]

The rabbit tibia model was inoculated with Staphylococcus aureus introduced into the intramedullary canal through a defect created at the anteromedial facet of the proximal tibia.[5]



BONE WAX TREATED STERNUM[7]



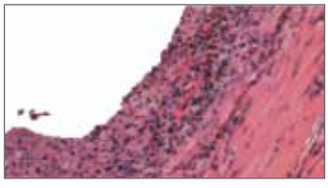
OSTENE TREATED STERNUM[7]

OSTENE is associated with reduced risk of infection*

After 4 weeks, the cross section of a rabbit tibia model subsequently inoculated with Staphylococcus aureus shows normal bone development in the cortical window of the OSTENE and control samples. The bone wax cross section shows signs of osteomyelitis with no sign of bone healing.[5]

Does NOT interfere with bone healing*

Studies on sternal, cranial, and tibial animal bone healing show OSTENE facilitates normal osteogenesis while negligible healing is shown with bone wax.[2,3,5,7,8]



CHRONIC INFLAMMATORY REACTION TO BONE WAX IN A RABBIT MODEL[2]

Does NOT cause chronic inflammation*

In an animal study, OSTENE was shown to be noninflammatory, with no evidence of an adverse inflammatory response in the cortical defect site, medullary cavity, or the surrounding tissue at 4 and 8 weeks.[2]

*As shown in animal studies, actual clinical effects of these results remain unknown.

Please see Indication and Detailed Important Risk Information for OSTENE on the back cover.

PRODUCT	ORDER CODE	QUANTITY
OSTENE Bone Hemostasis Material 1g	1503833	12 sticks per case
OSTENE Bone Hemostasis Material 2.5g	1503832	12 sticks per case
OSTENE Bone Hemostasis Material 3.5g	1503831	10 sticks per case

www.baxterbiosurgery.com

For more information, please contact your local sales representative or call 1-888-229-0001, option #4 for BioSurgery.

OSTENE [Bone Hemostasis Material] Indication

Indicated for use as a water-soluble implant material and for use in the control of bleeding from bone surfaces. OSTENE should be warmed to desired consistency using aseptic techniques.

Detailed Important Risk Information for OSTENE

Do not use OSTENE in sites with active or latent infections.

OSTENE is not intended for use in lending structural support to bone.

OSTENE is provided sterile for single use only. DO NOT RESTERILIZE. Discard any open, unused, or damaged packages.

DO NOT USE if there is a loss of sterility of the device.

OSTENE should not be subjected to excess heat. Store at room temperature away from direct heat, including sunlight.

Rx only: For safe and proper use of this device, please refer to OSTENE [Bone Hemostasis Material] Instructions for Use.

References

1. Ostene Bone Hemostasis Material [instructions for use]. Los Angeles, Calif: Ceremed Inc.PN-26 CF607 Rev. H 2011.

2. Wellisz T, Armstrong JK, Cambridge J, Fisher TC. Ostene, a new water-soluble bone hemostasis agent. *J Craniofac Surg*. 2006;17:420-5.

3. Armstrong JK, Han B, Kuwahara K, et al. The effect of three hemostatic agents on early bone healing in an animal model. *BMC Surg*. 2010;10:37.

4. Data on file. Baxter Healthcare Corporation.

5. Wellisz T, An YH, Wen X, et al. Infection rates and healing using bone wax and a soluble polymer material. *Clin Orthop Relat Res*. 2008;466:481-6.

6. Singh-Joy SD, McLain VC. Cosmetic Ingredient Review, Washington, DC 20036, USA. Safety assessment of poloxamers 101, 105, 108, 122, 123, 124, 181, 182, 183, 184, 185, 188, 212, 215, 217, 231, 234, 235, 237, 238, 282, 284, 288, 331, 333, 334, 335, 338, 401, 402, 403, and 407, poloxamer 105 benzoate, and poloxamer 182 dibenzoate as used in cosmetics. *Int J Toxicol*. 2008;27 Suppl 2:93-128.

7. Wellisz T, Armstrong JK, Cambridge J, et al. The effects of a soluble polymer and bone wax on sternal healing in an animal model. *Ann Thorac Surg*. 2008;85:1776-80.

8. Magyar CE, Aghaloo TL, Atti E, Tetradis S. Ostene, a new alkylene oxide copolymer bone hemostatic material, does not inhibit bone healing. *Neurosurgery*. 2008;63:373-8; discussion 378.

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