BONESEAL®
BONE HEMOSTAT
Instructions for Use

Device Description:
The BoneSeal® Bone Hemostat is a sterile, single use, biocompatible, biodegradable polymeric material intended for use in the control of bleeding from cut or damaged bone surfaces by acting as a mechanical barrier or tamponade. The barrier prevents further bleeding during the surgical procedure permitting normal healing. The BoneSeal® Bone Hemostat is composed of a dispersion of hydroxyapatite particles within a proprietary synthetic polylactic acid polymer that form a ready to use hemostatic agent. The BoneSeal® Bone Hemostat is intended for use under the direction of a licensed healthcare provider and is available in various sized ingots.

Indications for Use:
The BoneSeal® Bone Hemostat is intended for use in the control of bleeding from cut or damaged bone surfaces by acting as a mechanical barrier. The material may be used during surgical procedures or in treating traumatic injuries.
The BoneSeal® Bone Hemostat is intended for use under the direction of a licensed healthcare provider

Contraindications for Use:
- The BoneSeal® Bone Hemostat is contraindicated for use on sites with active or latent infections.
- BoneSeal® Bone Hemostat should not be used as or in conjunction with bone graft substitutes
- or bone void fillers.
- BoneSeal® Bone Hemostat should not be used to lend structural support to bone.
- BoneSeal® Bone Hemostat should not be mixed with other therapeutic materials or medicinal substances.

Instructions:
1. Peel open the BoneSeal® pouch and remove the ingot.
2. Thoroughly irrigate the tissue and remove foreign material, tissue, or bone fragments that would prevent the bone hemostat from penetrating the bone.
3. Gently dry the bone with a gauze pad or surgical sponge immediately prior to application.
4. Apply material sufficient to stop bleeding or slow oozing from the bone defect.
5. BoneSeal® can be applied with a gloved finger or a surgical instrument.
6. Remove an appropriate quantity of BoneSeal® for the area to be treated. No kneading or warming is required prior to application. Using constant pressure, apply and press the product onto the bone and spread it along the bleeding surface.
7. Excess material should be removed from the treatment site. Excess material may be removed manually or with a mechanical aid such as sterile gauze.
8. Inspect the wound carefully after a few minutes to ensure the bleeding has been controlled. If hemostasis has not been achieved, repeat steps 4-7, or use an alternate method of hemostasis treatment.
9. Discard any unused product after opening.

Warnings:
- Do not apply BoneSeal® Bone Hemostat to a contaminated or infected wound.
- BoneSeal® Bone Hemostat should not be used as a Hemostat on any tissue other than bone.
- Do not use BoneSeal® Bone Hemostat as a bone void filler or graft extender.
- Do not aspirate into extracorporeal cardiopulmonary bypass circuits or autologous blood salvage circuit.

Precautions:
- Sterility not guaranteed if package is damaged or opened. Discard damaged or open packages.
- Single Use Only.
- To prevent product contamination prior to application, always follow aseptic techniques.
- The effectiveness of BoneSeal® Bone Hemostat when utilized with other hemostats has not been evaluated.
- Product has not been evaluated for use with methyl methacrylate adhesives.
- Use of antiplatelet drug therapy and systemic heparinization may increase the risk of device failure.
- Expiration Date: This device should not be used after the end of the year, month and date shown.

Adverse Reactions:
Potential adverse reactions associated with bone hemostats include continued bleeding, pain, edema, fever, and infection.

How Supplied:
See pouch and carton labels for package quantity.
The BoneSeal® Bone Hemostat is terminally sterilized by gamma irradiation.

Storage and Handling:
The BoneSeal® Bone Hemostat should be stored at room temperature. Do not expose product to temperatures in excess of 60˚C. Once product package is opened, contents may be subject to contamination. Discard any unused product after opening.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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Made in USA.

Symbol	Description
Rx ONLY	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
#	Quantity Symbol: numeral (in place of #) indicates the quantity of units in package.
	Single sterile barrier system with protective packaging outside
STERILE R	Sterilized by irradiation
	Single Use Only. Do not reuse.
STERILIZE	Do Not Re-sterilize
	Do Not Use if Package is Damaged
	Non-Pyrogenic
MD	Medical Device
	Manufacturer
REF	Catalog Number
LOT	Lot Number
	Expiration Date (Use By): This device should not be used after the expiration date.
UDI	Unique Device Identifier
	Consult Instructions for Use
Store at room temperature	