

PERMATAGE

SETTABLE, NONABSORBABLE HEMOSTATIC BONE PUTTY

Contains Hydroxyapatite/ β -TCP (>62% by weight) and Vitamin E Acetate (5% by weight)

An FDA-cleared, settable (hardening) nonabsorbable polymer and hydroxyapatite/beta tricalcium phosphate-based putty, for use in the control of bleeding from bone during surgical procedures.

IMPORTANT APPLICATION INFORMATION

- Before applying **PERMATAGE**, be sure to irrigate and dry to ensure a clean bone surface.
- Using sterile technique and dry gloves, vigorously knead and mix **PERMATAGE** for at least 45 seconds, until **PERMATAGE** is a single, uniform light tan color and consistency.
- Using sterile technique and dry gloves and/or instruments, apply **PERMATAGE** to the bone immediately following mixing.
- Immediately following mixing, apply enough pressure and spread **PERMATAGE** into the pores of the bone so that it can interdigitate.
- The ideal duration of application / working time (for adherence to bone and spreadability) is approximately two (2) minutes following the completion of mixing.
- Be sure to remove excess **PERMATAGE**.

PERMATAGE is packaged as two individual putties that, upon being hand-mixed for a minimum of 45 seconds, form a cohesive putty (hand moldable and shapeable) of uniform light tan color and consistency for immediate application to bleeding bone.

A fully-mixed **PERMATAGE** putty can be partitioned into pieces for use in different locations. Any subsequent recombination of the divided putty should be completed shortly after mixing, as **PERMATAGE** begins to harden in minutes following mixing.

Once applied, the cohesive **PERMATAGE** putty interdigitates, adheres, and expands into the pores of the bone to control bleeding and remain in place as it begins to set (harden), even under normal irrigation conditions.

PERMATAGE is a nonabsorbable device designed to function as a permanent implant.

Under complete submersion in phosphate buffered saline (at 37°C), **PERMATAGE** was found, in a benchtop (in-vitro) study, to have expansion of approximately 4.0%.

PERMATAGE does not exceed body temperature (37°C) during the mixing or hardening processes.

Several pre-clinical studies were completed to assess the biocompatibility, hardening, and efficacy of **PERMATAGE**. **PERMATAGE** showed no signs of toxicity or negative tissue reaction. The results of these studies are available upon request by physicians.

PERMATAGE is gamma-irradiated and is provided terminally sterilized in packaging that was specifically designed to assure shelf stability.

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KEY CHARACTERISTICS

PERMATAGE	OTHER HARDENING CALCIUM APATITE BONE TAMPONADE
COMPONENTS	
Biocompatible / non-irritating	Acidic component is neutralized following complete mixing
Contains nonabsorbable polymer, hydroxyapatite/beta-tricalcium phosphate (biphasic and monophasic particles up to 630 microns in size), and Vitamin E	Contains calcium phosphate powder and dilute sodium silicate liquid
PREPARATION AND HANDLING	
Immediately hand mixable and putty-like in consistency ("Putty-Putty") out of package	Requires spatula and bowl to mix solid and liquid out of package
Immediately cohesive, hand moldable, shapeable, and can be applied following mixing for 45+ seconds or until visually homogeneous	Not cohesive ("paste-like") in consistency and is workable for 60+ seconds after mixing
Does not exceed 37°C during mixing or hardening process; ready-to-use at room temperature	Must be cooled to at or below 21°C (70°F) prior to use
APPLICATION	
Interdigitates and expands (~4.0%) in the pores of the bone	Contracts / does not expand
Adheres to bone and resists dislodgement/ remains in place during the hardening process, even under normal irrigation	Can be removed using normal surgical tools if need be, even after hardening
Nonabsorbable, permanent implant	Resorbable implant
Unused, mixed product can be discarded without risk	Components must be mixed prior to disposal to render materials harmless to personnel and environment



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