



Ostene®

BONE HEMOSTASIS MATERIAL WATER - SOLUBLE CONTAINS NO BEESWAX

DESCRIPTION

OSTENE® is a water-soluble surgical implant material, and it can be used for the control of bleeding from bone surfaces by acting as a mechanical barrier. OSTENE® is a sterile mixture of water-soluble alkylene oxide copolymers.

INDICATIONS

OSTENE® is 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.

ACTIONS

OSTENE® achieves local hemostasis of bone by acting as a mechanical barrier. It does not act biochemically.

CONTRAINDICATIONS

1. Sites with active or latent infections.
2. The use of the product to lend structural support to bone.

WARNINGS AND PRECAUTIONS

1. 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.
2. OSTENE® should not be subjected to excess heat. Store at room temperature away from direct heat, including sunlight.

INSTRUCTIONS FOR USE

OSTENE® works best at body temperature and should be warmed to desired consistency using aseptic technique and then manipulated and softened with dry gloved fingers. The unopened foil packet may be immersed into a warm sterile solution at temperatures at or below 43°C (110°F). OSTENE® handles more like a gum or putty than a wax. OSTENE® may be pressed into bleeding bone and may be worked across the bleeding surface as indicated by the surgical circumstances and the preference of the surgeon.

STERILITY

OSTENE® is sterilized using electron beam irradiation. Removal from the sterile package using aseptic techniques should only take place immediately before use. OSTENE® MUST NOT BE RESTERILIZED BY ANY METHOD.

WARRANTY

All products are warranted to be free from defects in material and workmanship. No warranty is made for any purpose other than in the product specifications and labeling.