



EquiAlveoPlug

INSTRUCTION MANUAL

HDE North America

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HDE EquiAlveoPlug is a gelatin collagen sponge of hemostatic action to which 5 % colloidal silver is added. It facilitates optimum wound treatment when applied to a surgical cavity and can be cut to the required size to fit smaller wound cavities. The evenly porous foam structure absorbs its own weight in blood several times over, promotes thrombocyte aggregation due to the large surface and fills the wound cavity. The plug thus formed has a constant volume, fits snugly and stabilises blood coagulum. This prevents the formation of fissures and secondary cavities which, without HDE EquiAlveoPlug, could form by contraction of the blood coagulum and trigger infection due to the invasion of contaminated saliva. Does not block the callus formation.

HDE EquiAlveoPlug remains in the wound and completely absorbed within 3-4 weeks.

The addition of colloidal silver has an antimicrobial effect and does not develop any body resistance. Unlike other potential antimicrobial additives, colloidal silver cannot be washed away from the sponge so that its insolubility produces a long-lasting depot effect. Gamma-ray sterilisation process finalizes the manufacturing cycle of the product.

In accordance with the Dangerous Substances Act of 1 November 1993 (91/155/EEC), EU Safety Data Sheets are required for dangerous substances and preparations.

The product mentioned herein is classified as a non-dangerous substance. Therefore, the provision of this data sheet is not mandated by Directive 91/155/EEC.

Composition

One HDE EquiAlveoPlug - Small (10 × 10 × 10 mm) contains:

- Hardened gelatine Ph. Eur. 13.85 mg.
- Colloid silver Ph. Eur. 0.73 mg.

One HDE EquiAlveoPlug - Large (20 × 20 × 20 mm) contains:

- Hardened gelatine Ph. Eur. 110.8 mg.
- Colloid silver Ph. Eur. 5.8 mg.

Indications

- Socket extraction as part of one or two-stage implant placement.
- The general treatment of alveoli and wound cavities, e.g. after cystostomies, apical amputations, maxillary sinus perforations, following surgical removal of tumours or retained teeth.
- Prevention of secondary cavity formation.
- Prophylaxis of wound infections.
- Secondary haemorrhage prophylaxis.

Instructions for use

After opening the blister or removing the foil from the jar, HDE EquiAlveoPlug is ready for immediate use. The size of the small sponge can be adjusted to fit the wound cavity if need be, without squeezing. Two HDE EquiAlveoPlug plugs will fit the larger wounds. The sponge is immediately placed dry and unsqueezed in the fresh, blood-filled wound cavity and should be allowed to absorb as much blood as possible (visual inspection). The sponge must not protrude over the inner gingival margin so as not to adversely affect the desired epithelisation. It constitutes definitive treatment of the alveolus, and there is no need for subsequent rinsing.

Sterility

HDE EquiAlveoPlug is supplied gamma-sterilized. The sterility of undamaged, unopened packs is guaranteed. Damaged packages should be discarded before use. Given the antimicrobial effect of this product, a safe application is guaranteed until the product used or up to the expiry date in aseptic conditions.

Contra-indications

Infected, secretory and purulent wounds; hypersensitivity to silver or gelatine.

Side effects

Recovery may be delayed if used incorrectly, especially in the case of contaminated alveolar spaces.

Interactions with other drugs

Concomitant application of alveolar pastes, wound plugs or other inserts apart from thrombin preparations as dry powder, and moistening with liquid substances or medication such as anion-active surfactants, antiseptics containing phenol, ethacridine lactate, dilute mineral acids and concentrated saline solutions can hinder wound recovery and should, therefore, be avoided.

Please avoid contact with hydrogen peroxide as this will bleach the sponge.

Storage instructions

HDE EquiAlveoPlug possesses moisture-absorbing properties. The package must be stored tightly closed, immediately after use and stored dry, protected from light. Keep all medicines out of the reach of children. HDE EquiAlveoPlug has a shelf-life of 3 years. It can be used unopened and after opening up to the expiry date. The product should no longer be used once the date on the packaging and label has elapsed. Unused sponges can easily be disposed of with laboratory waste whereas, the plastic container, lids and aluminium foil, etc. can be recycled.



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