The safety and effectiveness of the combined use of VITAGEL with antibiotic solutions or powders have not been established.

The safety and effectiveness of VITAGEL for use in urological procedures have not been established.

In clinical procedures, VITAGEL should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.

Precaution C: Anesthetized animals have not been exposed to VITAGEL. THROMBIN-JMI™ should be given to pregnant women only if clearly indicated.

ADVERSE EVENTS

In a randomized, prospective, concurrently controlled clinical trial, 318 patients were treated with VITAGEL™ Surgical Hemostat. Of these, 167 patients were treated with VITAGEL and 151 patients were treated with the control. This study was used to assess the safety and effectiveness of VITAGEL™ Surgical Hemostat in patients undergoing general, hepatic, and iliac crest groups. The study population was comprised of 167 patients who were treated with VITAGEL™ Surgical Hemostat and 151 patients who were not (Control group). The median time for complete hemostasis was compared using the Student’s t-test, with p<0.01 as a clinically significant difference.

Additional data were collected on the incidence of adverse events in the study group. A total of 278 patients were treated in at least one study site (anastomotic, sternal edge, or capillary bleed). Of these, 167 patients were treated with VITAGEL™ Surgical Hemostat and 111 patients were treated with the control.

ADVERSE REACTIONS TO THROMBIN

Thrombin (factor IIa), a serine protease, is a large, gel-forming complex of thrombin and fibrinogen. The thrombin/fibrinogen gel matrix is stabilized by the addition of calcium ions, which cross-link the fibrin monomers to form a network.

Do not inject VITAGEL™ Surgical Hemostat into any blood vessels.
VITAGEL™ SURGICAL HEMOSTAT

DIRECTIONS FOR USE

HOW TO ASSEMBLE VITAGEL™ SURGICAL HEMOSTAT

1. Remove CellPaker from the centrifuge and hold in a vertical position with the Luer tip up. Remove cap from Luer tip.

2. Connect CellPaker to Transfer Syringe

   - Remove and discard transfer syringe Luer cap. Transfer syringe tip is sterile. Attach transfer syringe to CellPaker.

3. Transfer Plasma from CellPaker to Transfer Syringe

   - Turn red outer sleeve of CellPaker to transfer plasma to syringe. The volume of plasma transferred should be equal to the volume of the VITAGEL syringe being used.

4. Place Plasma Containing Transfer Syringe into Sterile Field

   - Place the Sterile VITAGEL Syringe into Sterile Field

   - The VITAGEL suspension syringe is sterile. Circulating nurse peels open the VITAGEL syringe pouch. Scrub nurse unscrews and removes the VITAGEL syringe.

5. Expel Air from VITAGEL and Plasma Syringes

6. Assemble Syringes with Delivery System

   - It is important to attach the cannula or sprayhead last.
   - a) Attach Luer ends of VITAGEL and plasma syringes to joiner.
   - b) Align ends of plunger rods until even. Expel syringe contents, if necessary.
   - c) Slide syringe clip over the ends of plunger rods.
   - d) Slide support over assembled device until firmly seated.

7. Attach Spray Head or Cannula, According to the Surgeon’s Preference

HOW TO APPLY VITAGEL TO THE BLEEDING SITE

1. Discontinue all blood recovery and cell-saving devices, as appropriate. Blot surface dry.

2. Apply product as a thin, uniform coating and overlap the edges to ensure complete coverage. Avoid disrupting the gel.

3. If discrete bleeding is observed, additional VITAGEL may be applied by underlying the formed gel with the tip of the cannula and delivering the material directly to the site.

4. If bleeding continues, remove the first application as completely as possible, blot, and reapply VITAGEL.

Manufactured by:
Angiotech BioMaterials
Palo Alto, CA  94303 U.S.A.
for
ORTHOVITA
45 Great Valley Parkway
Malvern, Pennsylvania 19355 U.S.A.
Tel 610 640 1775
Fax 610 640 174
www.orthovita.com

U.S. Patent Nos. 5,290,552; 6,096,309 and 5,997,811

10/2004 209A