Hemostatic Gauze for General Dental, Oral Surgery, Endodontal and Periodontal Procedures

Safe and Effective Gauze for All Occasions

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Abstract

Hemostatic Gauze is a collagen-like natural substance created from chemically treated cellulose. It is an effective, patented, hemostatic agent registered with the FDA to help control bleeding from open wounds and in body cavities (mouth, ears, nose, throat, vagina, anus). The material contains no chemical additives, thrombin or collagen and is hypoallergenic. When it comes in contact with blood, it expands to 3-4 times its original size and converts to a gel that dissolves over a 1-2 week period into glucose and saline. Because of its purity and the fact it simply degrades to these end products, it does not cause significant delayed healing as do other hemostatic materials that may have a similar appearance.

The work of this product takes place in each of its three stages: absorbing, swelling, and dissolving. It starts as a solid, relatively rough surface to slow down bleeding which allows certain clotting factors more time to spread through the wound. As it swells, it unites with platelets and the blood clot to more rapidly create a “plug” to reduce or stop bleeding. Finally, it reaches its soluble state where it continues to contribute to hemostasis and wound healing. These mechanisms are detailed in the paragraphs below. Part of this product’s success is in the unique timing with which it passes through the three stages.

Hemostatic Gauze is especially powerful in that, unlike some other materials, it has a three-fold usefulness: 1) chemical, 2) biochemical, and 3) physical. As it contributes to hemostasis, if one of these three effects loses its capability, one or both of the others can continue working, most notably in the swelling and liquid-phase activation processes. This soluble material is much more potent than other insoluble substances on the market – even without the addition of chemical or bovine byproducts.

Another special characteristic of this material is its bacteriostatic properties. This is especially important in contaminated wounds or in body cavities in which it is difficult or impossible to maintain a sterile field.

The Hemostatic Process

When a blood vessel is injured, blood escapes for as long as the vessel remains open and pressure within the vessel is greater than pressure outside. The normal hemostatic response to damaged vascular endothelium can be divided into three stages: 1) initial vasoconstriction, 2) platelet aggregation on and around the lesion and the formation of a platelet plug, and 3) activation of the reactions of blood coagulation.

Platelet plugs can stop bleeding from the smallest vessels. When bleeding is from larger vessels, blood clot formation is required. Hemostatic Gauze is an essential ingredient in expediting hemostasis.
Enhancing Platelet Function with Hemostatic Gauze

After an injury to the body, platelets become activated – changing from a discoid to spherical shape and extending pseudopodia. They release enzymes that stimulate other platelets to activate and chemicals that promote adhesion to blood vessel linings, to collagen, glass, metal, and to fabric, and to each other. Platelet aggregation is the property of platelets to clump with each other to form a platelet plug.

1. Hemostatic Gauze, which is in a fabric-like state, increases platelet adhesion, thereby helping to promote clotting. This is similar to adherence of platelets to damaged collagen (the fibrous protein found in connective tissue that underlies the endothelial cells).

Enhancing Blood Clotting with Hemostatic Gauze

Blood coagulation is the replacement of a relatively unstable platelet plug with a stronger, more resilient blood clot through a series of interdependent, enzyme-mediated reactions that bring about the generation of thrombin and the formation of fibrin from fibrinogen. This is accomplished through intrinsic and extrinsic pathways.

a. Intrinsic Pathway - All components necessary for the clotting process to proceed are located in blood. As such, proteins required for such clotting to take place are part of the intrinsic pathway of blood coagulation. The effectiveness of the intrinsic pathway is assessed with the activated partial thromboplastin time test (PTT).

b. Extrinsic Pathway - The pathway of blood coagulation activated by tissue factor, a protein extrinsic to blood, is known as the extrinsic pathway. Tissue factor serves as a cofactor with factor VII to allow the activation of factor X. With the exception of factor VII, all components of the extrinsic pathway are also components of the intrinsic pathway. Activity of the extrinsic pathway may be assessed in the lab using the prothrombin time test (PT).

Research has demonstrated that PPT and PT are both decreased (clotting time accelerated) with the presence of Hemostatic Gauze in the wound. It is useful in both pathways.

1. The intrinsic pathway is initiated by the activation of factor XII by certain negatively charged surfaces, such as glass, kaolin, some synthetic plastics, and fabrics. They activate factor XII to its enzyme form, factor XIIa. As Hemostatic Gauze dissolves and comes in contact with iron in red blood cells, it forms negatively charged colloidal particles that promote the activation of blood coagulation factor XII.

2. Hemostatic Gauze works faster than many other hemostatic agents. Injury to the blood vessel lining and contact of blood with tissues outside the vessel stimulates thrombin production by the activation of the clotting system. Thrombin causes platelet aggregation. Platelets exposed to thrombin secrete their granules and release their contents into surrounding plasma. Thrombin also initiates a reaction leading to a fibrin clot. In research studies, the texture and initial solid state of Hemostatic Gauze slowed the blood flow and reduced the time in which thrombin was released into
the wound. This increased platelet and whole blood adhesion rates, thereby improving hemostasis speed and function.

3. The enzyme form of clotting factor XII (factor XIIa) catalyzes the conversion of factor XI to its enzyme form (factor Xla). Factor Xla catalyzes the conversion of factor IX to the activated form factor IXa in a reaction that requires calcium ions. Factor IXa assembles on the surface of membranes in complex with factor VIII. The factor IXa / factor VIII complex requires calcium to stabilize certain structures on these proteins associated with their membrane-binding properties. Factor Xa forms a complex with factor V on membrane surfaces in a reaction that also requires calcium ions. In research studies, Hemostatic Gauze not only adhered to calcium ions, but also because its surface area initially increases as it dissolves, it expanded contact surfaces with blood coagulation factors needing calcium, thus increasing effectiveness.

4. Hemostatic Gauze helps stabilize new clots by accelerating the formation of fibrin cross-linkages.

5. Hemostatic Gauze increases whole blood viscosity significantly in a wound, thus promoting the aggregation of red blood cells. At the same time, it helps restrict the loss of red blood cells and platelets, accelerating hemostasis. Unlike most other materials used for hemostasis, Hemostatic Gauze increases blood viscosity even in patients with coagulation defects.

6. Hemostatic Gauze helps prevent dry sockets. The gauze converts to a gel, incorporates blood into the gel material blood into the gel material and increases whole blood viscosity. This promotes the aggregation of red blood cells and serves to retain and stabilize the clot. As the gauze comes in contact with the blood, the gauze expands and adheres to the platelets and the clot. The gauze also adheres to calcium ions. As it expands, it provides more contact surfaces with blood coagulation factors needing calcium (Ixa, Xa, and Xia), thereby enhancing hemostasis and clot development. In addition, as the gauze dissolves, it comes in contact with iron in red blood cells forming negatively charged colloidal particles that promote activation of blood coagulation factor XII. A stronger-than-normal clot formed this way is less susceptible to lysis that occurs with dry socket.

Indications for the Use of Hemostatic Gauze.

1. Trauma and/or surgery in healthy, non-medicated with profuse bleeding.

2. Trauma and/or surgery for patients on certain medications:
   - Aspirin: inhibit platelet aggregation by inhibiting the pathway of cyclooxygenase enzyme
   - Anti-inflammatories similar mechanism as aspirin but effect more limited
   - Anticoagulants inhibits synthesis of vitamin K-dependent coagulation factors
   - Antibiotics
altered intestinal flora which can decrease production of Vitamin K
- **Anticancer drugs**
  patient may be on drugs that reduce the number of circulating platelets

3. **Trauma and/or surgery for patients with:**
   - liver damage from alcoholism (may have decreased production of liver-dependent coagulation factors)
   - non-alcoholic liver disease
   - primary hepatitis
   - hypertension (elevated systolic blood pressure, 180-200 systolic, may cause prolonged bleeding)

4. **Trauma and/or surgery for patients with**:
   (May be in addition to drugs or infusions that stimulate or replace deficient clotting factors.)
   - Hemophilia A (factor VIII deficiency)
   - Hemophilia B or Christmas disease (factor IX deficiency)
   - Hemophilia C (factor XI deficiency)
   - Von Willebrand’s disease (absent or reduced levels of factor VIII)
   - Thrombocytopenia (defective or decreased production of platelets)
     - Acquired, Congenital
   - Disseminated intravascular coagulation or DIC (lack of clotting factors and platelets at the site where required)
   - Hypoprothrombinemia (deficiency in prothrombin or factor II)
     - Acquired, Congenital

**Conclusion:**

Bleeding in the mouth is a common problem for dentists for several reasons. The main ones are:
1. Highly vascular area
2. Many procedures create open wounds
3. Difficult to apply direct pressure in the mouth
4. Tongue and eating irritate wounds
5. Salivary enzymes can lyse clots before they have a chance to organize

Because of these factors, the dentist often needs something that can be applied locally to wounds that will aid hemostasis. The current substances are not ideal due to the high cost (too much waste), difficulty of use and they can delay healing. Hemostatic Gauze is a new product that meets the surgical needs in dental practices whether a general or specialist (oral and maxillofacial surgeon, periodontist or endodontist). The gauze applies to extractions, periodontal surgery, apicoectomy and retrofill, preprosthetic surgery, Orthognathic surgery, tumor excision, dry socket prevention and other selected procedures.

**Contraindications:**

The presence of infection.

Dr. Karl Koerner is a leading clinician and lecturer in the United States. His dental practice is in Utah but he has presented many didactic and “hands-on” presentations in oral surgery to dentists in the U.S. and abroad for the past 20 years. He works part-time at Clinical Research Associates (CRA) in Provo, Utah and helps present CRA’s research findings on dental products to dentists throughout the world. He has written two oral surgery texts and many articles on surgery in the dental literature. Dr. Koerner is a past president of the Utah Dental Association, and member of the International College of Dentistry and
Federation of Dentistry Internationale. He has earned his Fellowship in the Academy of General Dentistry.
Dr. Koerner also serves as the Director of Medical Affairs for MedSpring Group, Incorporated. In his clinical practice, he incorporates hemostatic gauze into dental surgery procedures to control bleeding and prevent dry sockets.

ActSys Medical, Inc. is the exclusive distributor of hemostatic gauze under the brand name ActCel™. For additional product information please call (800) 808-9094.

1 Zhang Qin-shang, Xu Qing-zhong. Beijing Xuan Wu Hospital. Beijing, China
2 Nelson Laboratories, Inc. Salt Lake City, UT. Report available upon request.