



Zeolite Hemostatic Gauze

Presented by One Minute Medic, LLC

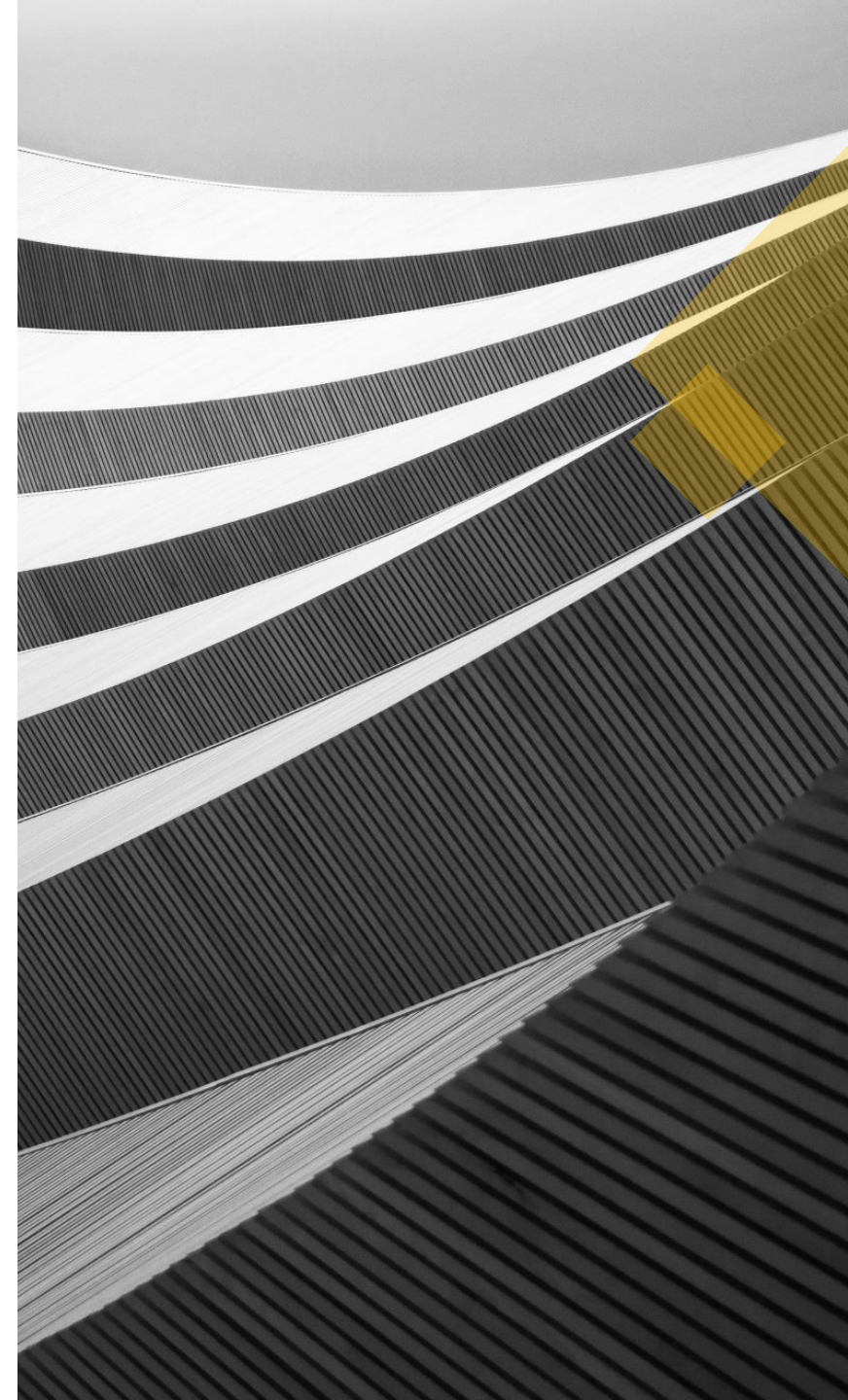


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ONE MINUTE MEDIC, LLC
BLEEDING CONTROL TECHNOLOGY



- One Minute Medic, LLC is an international company focusing on new innovation technology in medical sciences. Our partner Com-Med International Inc. has over 25 years in development, manufacturing and distribution of OEMs in a vast array of high-quality, low-cost disposable medical products to medical supply distributors. We manage as the liaison between Asian and US based companies. We have strong sourcing and manufacturing abilities to help our customers stay ahead of the game while maintaining our commitment to quality. With expert OEM capabilities, our partners can control the manufacturing outcome without the necessity of owning the manufacturing process. We understand the customer's needs in today's healthcare environment and strive to be a leading, global medical device manufacturing/sourcing organization that helps both manufacturers and clients succeed. Our team is international, professional and highly experienced. We look forward to being part of your business and success!

Fatal Trauma Bleeding

More than **1.9 million** people worldwide die from massive bleeding each year



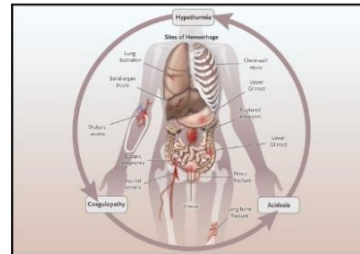
Battlefield



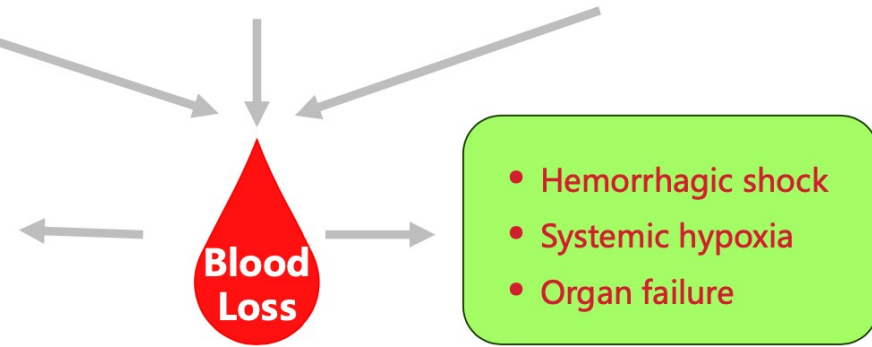
Natural Disaster



Traffic Accident



N Engl J Med 2018; 378: 370–379.



- Hemorrhagic shock
- Systemic hypoxia
- Organ failure

Technical Introduction

Zeolite Hemostatic Agent is Lifesaving measure for external hemorrhage in battlefield and Pre-hospital Trauma emergency in US



The war against wounds

no side effects. Finally, if the bleeding still does not stop then HemCon should be removed and QuikClot applied with manual compression for 5 minutes as a lifesaving measure. The recommendations of this committee will also be included in the next edition of the Prehospital Trauma Life Support manual that is produced by the National Association of Emergency Medical Technicians in cooperation with the Committee on Trauma of the American College of Surgeons.

Nature 2007, 446, 369
Military Medicine 2005, 170, 63

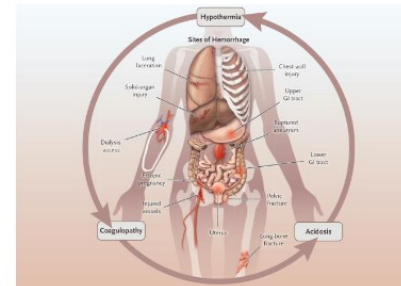
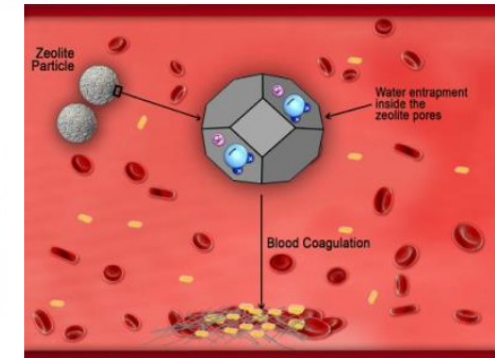


Fig. 3. Contents of the U.S. Marine Corps individual first aid kit.



sure is ineffective or impractical. For large bleeding wounds in junctional locations where a tourniquet cannot be applied (e.g., axilla or groin [Fig. 2]), a number of new hemostatic dressings have shown some benefit.³⁴

The New England Journal of Medicine 2018, 378, 370-379

Zeo-Innov Technology

NEW HEMOSTATIC MECHANISM

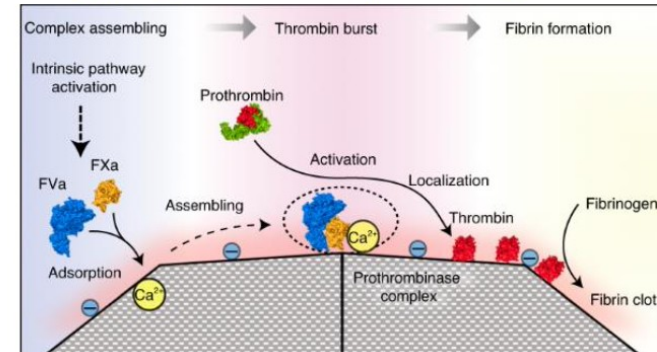
The concept of inorganic platelet was proposed for the first time:

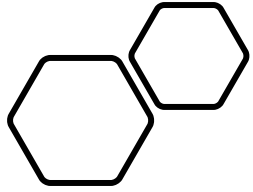
Zeolite provides a platform for the assembly and activation of coagulation factors, which is highly similar to the role of platelets in physiological processes

Jie Fan, etc., Nature Catalysis, 2021,4,607-614



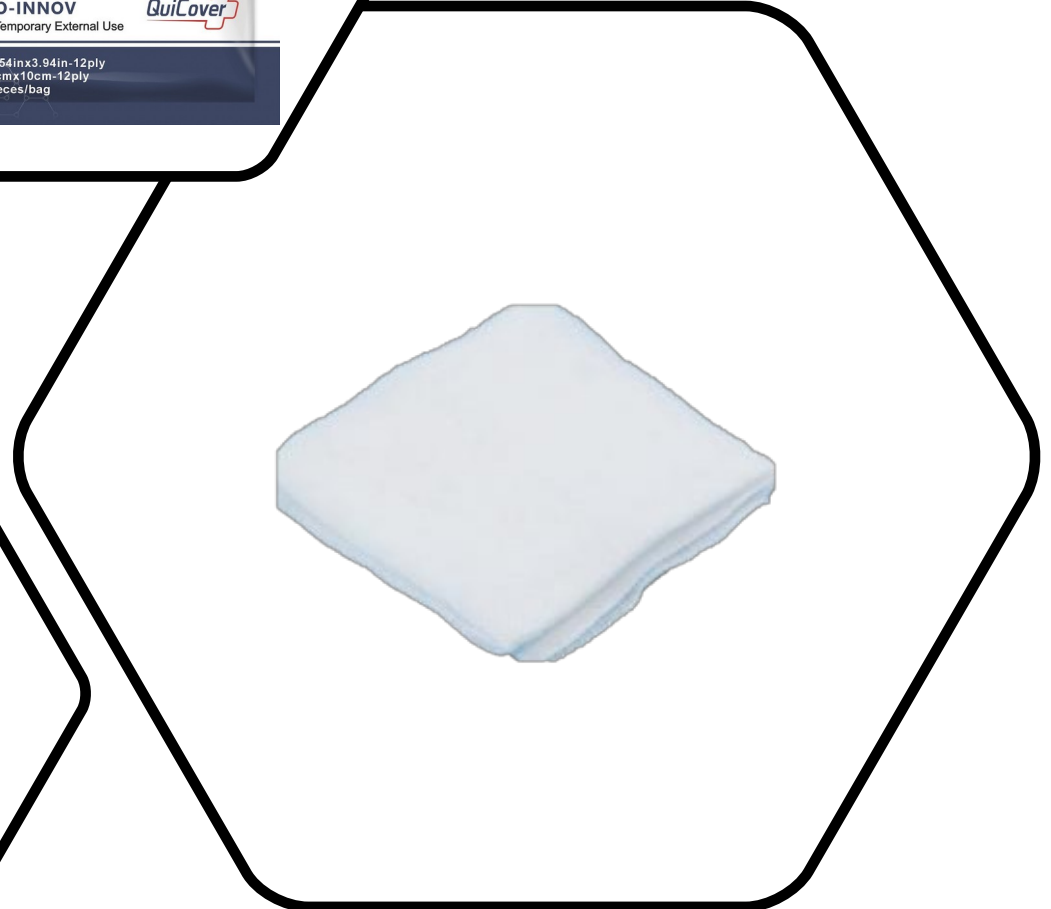
As the zeolite gauze covers the wound, the zeolite particles on the surface of the gauze can **rapidly enrich endogenous coagulation factors** to form a protein corona, which in-turn activates the intrinsic coagulation pathway. **In-situ generated thrombin** with high activity on the zeolite surface can **accelerate the clotting progress and stop bleeding faster**.





Zeolite Hemostatic Gauze

- **Comp.:** Flexible mesoporous Zeolite-Gauze
- **Usage:** Applied with manual pressure, promotes clotting within minutes of application
- **Spec.:** 3.54in x 3.94in-12ply, 2 pieces/bag
- **Patent:** PCT/CN2019/082931, PCT/CN2019/082930



FDA 510K K211570



February 10, 2022

Hangzhou Zeo-Innov Life Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
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Shanghai, 200120
China

Re: K211570
Trade/Device Name: Zeolite Hemostatic Gauze
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 10, 2022
Received: January 11, 2022

Dear Diana Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

Compared with Combat Gauze



Effectiveness and safety evaluation of fatal swine femoral artery penetrated wound (301PLAGH)



In the fatal swine femoral artery penetrated bleeding mode, QuiCover Gauze successfully stop bleeding in 5 minutes.

Animal Experiment: Fatal Blood Loss in Rabbit Artery Injury Model			
Sample	Blank	QuiCover (Zeo-Innov)	Combat Gauze (Z-Medica)
Blood loss(g)	29.8 ± 2.9	6.1 ± 1.4 **	10.3 ± 3.7
Clotting time(s)	-	159 ± 12 **	392 ± 56
Temp. rise (°C)	± 2	± 2	± 2
Survival rate%	0	100%	87.5%

Improved hemostatic efficiency and retention rate of active component

Product Features

Jie Fan, etc., Nature Commun. 2019,(10),1932



FAST CLOTTING

REDUCTION IN CLOTTING TIME



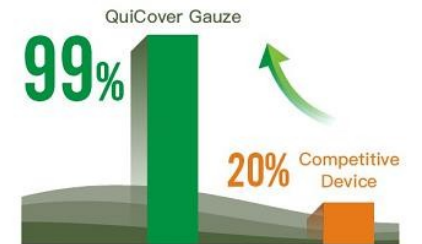
LESS BLOOD LOSS

REDUCTION IN BLOOD LOSS



HIGH STABILITY

RETENTION RATE OF ACTIVE COMPONENT



Clinical Trial

- **Objective:** Observation of the efficacy and safety of Zeolite Hemostatic Gauze in the treatment of open wound bleeding
- **Study methods:** Parallel control of non blind, random and positive instruments
- **Sample size:** 100 patients, randomly assigned to the test group or the control
- **Subjects:** open trauma massive bleeding (deep myometrium), 18-70 years old
- **Conclusions:** **The Zeolite Hemostatic Gauze is effective and safe.**
 - **Effectiveness:** the total effective rate of hemostasis in 5 minutes was 99%
 - **Safety:** No adverse event related to the study of the instruments.

- Founded in **2009**
- **Technologies & Products:** Zeolite-based hemostatic dressings for traumatic bleeding control and Protective products
- **Innovation:**
 - Certified as National high-tech enterprises
 - **Intellectual property protection: 12 patents**, including 9 invention patents and 2 PCTs
 - Strong R&D capabilities with a collaborative team of scientists in the fields of Chemistry, Material, and Medical.
 - Zeolite gauze is the **ORIGINAL** manufacturing technology with independent intellectual property rights in the world
 - 2 products obtained CFDA Innovative Medical Device registration certificate



Patents





The Exclusive Worldwide Distributor

Thank you!