

QuikClot[®]
COMBAT
GAUZE[®]

- ❖ CoTCCC Recommendations
- ❖ Composition of Hemostatic Gauzes
- ❖ QuikClot Combat Gauze® Mechanism of Action
- ❖ QuikClot Combat Gauze® CE Mark Indications
- ❖ Independent Safety Testing
- ❖ Standardized Swine Hemorrhage Model
- ❖ Efficacy
- ❖ Celox™ Rapid Time to Hemostasis

- Tactical Combat Casualty Care Guideline Change (2014): Hemostatic Dressings – “use Combat Gauze® as the CoTCCC hemostatic dressing of choice.”¹
- Tactical Combat Casualty Care Guideline Change (2017): Hemostatic Dressings, no change to Combat Gauze® – “use Combat Gauze® as the CoTCCC hemostatic dressing of choice.”²
 - CoTCCC alternative hemostatic adjuncts:
 - Celox™ Gauze**
 - ChitoGauze™
 - XStat™ (Best for deep, narrow-tract junctional wounds)

**** Celox™ Rapid is not CoTCCC recommended**

Composition of Celox™ Gauze and ChitoGauze™

- Chitosan is a naturally occurring amino polysaccharide.
- Chitosan forms a mucoadhesive plug when in contact with blood.

Composition of XStat™

- Sponges that expand when fluid is absorbed. Available with and without chitosan.

Composition of Combat Gauze®

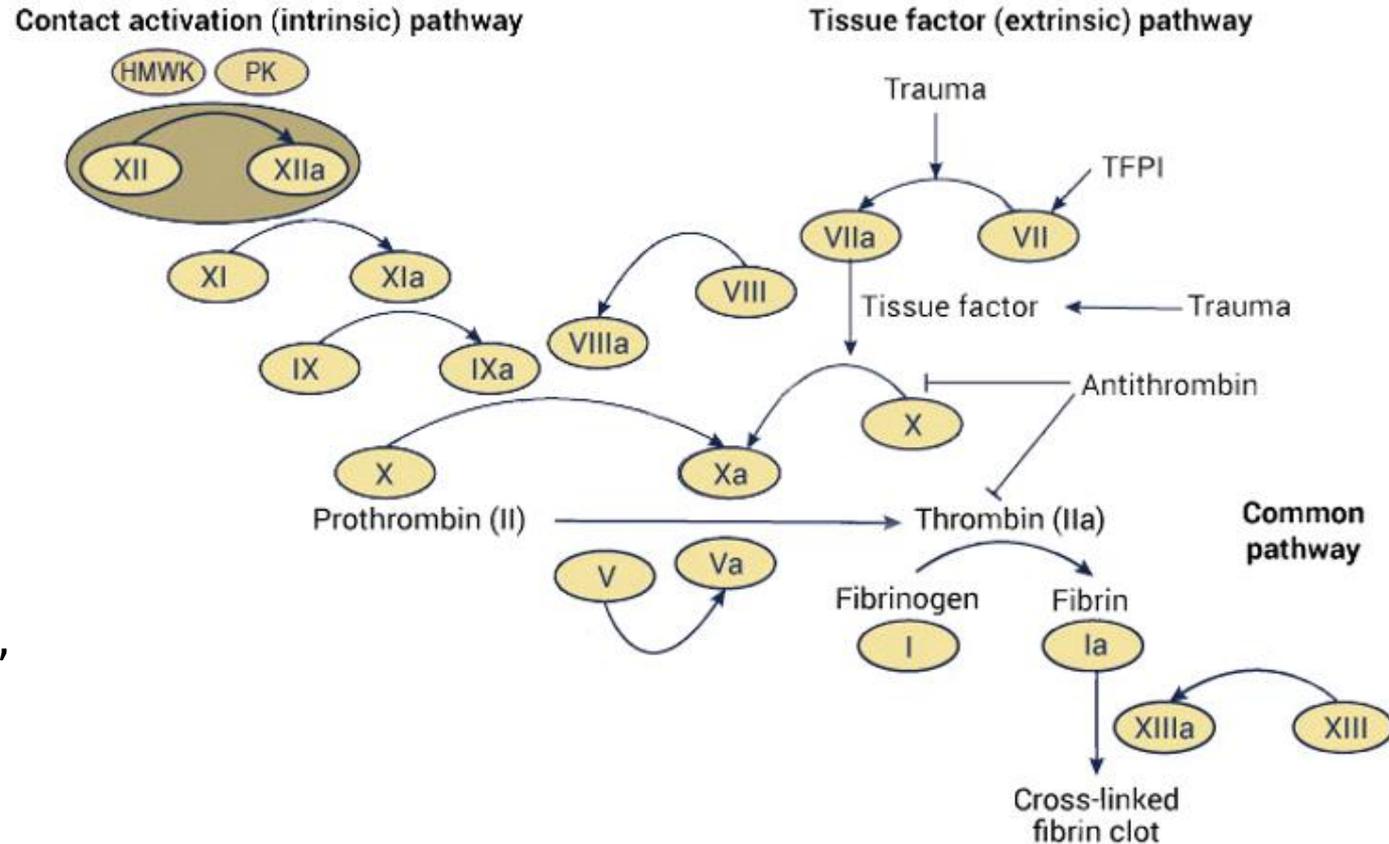
- Kaolin is a naturally occurring inorganic mineral.
- Kaolin is impregnated in a non-woven gauze.
- Kaolin accelerates the body's natural clotting process^{3,4}.
- Kaolin forms a robust clot which is maintained during movement^{5,6}.

QUIKCLOT COMBAT GAUZE® MECHANISM OF ACTION



Kaolin works on contact with blood to immediately initiate the clotting process by activating factor XII⁴.

This reaction leads to the transformation of factor XII to its activated form XIIa, which instigates the rest of the coagulation cascade⁷.



Military/Emergency Medical Responder/Law Enforcement products:

- Indicated for temporary external use to control traumatic bleeding.

Hospital products:

- Indicated as a topical dressing for the local management of bleeding wounds such as cuts, lacerations, and abrasions. It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.

Cath Lab products:

- Indicated as an adjunct to manual compression and for local management and control of surface bleeding from vascular access sites, percutaneous catheter or tubes utilizing introduction sheaths up to 12 Fr. or 7 Fr. in patients on drug-induced anticoagulant treatment.

- QuikClot Combat Gauze[®] has been independently evaluated by DoD in a swine model of vascular injury (arterial & venous).
- The injured vessel(s) was repaired after treatment with QuikClot Combat Gauze[®] and circulatory blood was restored.
- The treated vessels were examined, and end organs distal to the treated vessels were also examined for emboli.
- There was essentially no difference in vascular function when comparing QuikClot Combat Gauze[®] to standard gauze (Kerlix[™]).
- QuikClot Combat Gauze[®] – no resultant emboli.
- Independent safety data for thrombi and emboli is not available for: Celox[™] Gauze, Celox[™] Rapid, Chitogauze[™], ChitoSam[™], Hemo-Bandage[™], NuStat[™], and WoundClot[™].

- A rigorous hemorrhage model was developed in 2011 to evaluate new hemostatic agents and compare them to the current standard of care, QuikClot Combat Gauze[®] .
- Model utilizes a 6mm femoral artery punch to induce hemorrhage, followed by 45 seconds of free bleeding.
- Model includes flex and stretch of legs to simulate walking.
- Goal of the model – to be utilized to test if an agent is significantly more effective at controlling hemorrhage compared to the standard of care (QuikClot Combat Gauze[®]).

- Independent testing (2012) using the DoD Standardized Swine Hemorrhage Model has been performed on QuikClot Combat Gauze[®] (Standard of Care), QuikClot Combat Gauze[®] XL, Celox[™] Gauze, and ChitoGauze[™].
- Independent testing using the DoD Standardized Swine Hemorrhage Model compared to QuikClot Combat Gauze[®] (standard of care) has NOT been performed on Celox[™] Rapid, ChitoSam[™], WoundClot[™], NuStat[™] and HEMO Bandage.
- Results of this study showed the other hemostatics tested, compared to QuikClot Combat Gauze[®], did NOT have a statistically significant reduction in post-treatment blood loss or survival.
- Re-bleeding was also measured in this study. QuikClot Combat Gauze[®] had zero rebleeding recorded.

Clot stability– independent studies have determined QuikClot Combat Gauze[®] to have a stable clot despite severe patient movements, fluid resuscitation, and varying extreme physiological conditions.

- **Patient Movement** - Significant differences were measured in the amount of fluid resuscitation and movements tolerated in QuikClot Combat Gauze[®] compared to standard gauze.
- **Fluid Resuscitation** - Independent studies comparing the effects of QuikClot Combat Gauze[®] to standard gauze on hemorrhage control. QuikClot Combat Gauze[®] has been determined to have a stable clot despite severe patient movements and fluid resuscitation.
- **Hemodilution and Hypothermia** - Significantly less bleeding and stable clot utilizing QuikClot Combat Gauze[®] in the presence of hemodilution and hypothermia.

- Celox™ Rapid Claims to achieve hemostasis in 1 minute.
- The Celox™ Rapid instructions for use clearly say “**apply pressure for 1 minute or until bleeding stops**”.
- Scientific data supporting this claim comes from a 2011 Poster at the ATACCC conference. This poster declares the study was funded by Medtrade Products.

1. Tactical Combat Casualty Care Guidelines 2 June 2014. http://www.usaisr.amedd.army.mil/pdfs/TCCC_Guidelines_140602.pdf. Accessed June 12, 2018.
2. The Committee on Tactical Combat Casualty Care. Tactical Combat Casualty Care Guidelines. <http://cotccc.com/wp-content/uploads/TCCC-Guidelines-for-Medical-Personnel-170131.pdf>. Published January 31, 2017. Accessed April 13, 2017.
3. Trabattoni D, Montorsi P, Fabbicocchi F, Lualdi A, Gatto P, Bartorelli AL. A new kaolin-based haemostatic bandage compared with manual compression for bleeding control after percutaneous coronary procedures. *Eur Radiol*. 2011;21:1687-1691.
4. Lamb KM, Pitcher HT, Cavarocchi NC, Hirose H. Vascular site hemostasis in percutaneous extracorporeal membrane oxygenation therapy. *Open Cardiovasc Thorac Surg J*. 2012;5:8-10.
5. Gegel B, Burgert J, Gasko J, et al. The effects of QuikClot Combat Gauze and movement on hemorrhage control in a porcine model. *Mil Med*. 2012;177(12):1543-1547.

6. Garcia-Blanco J, Gegel B, Burgert J, Johnson S, Johnson D. The effects of movement on hemorrhage when QuikClot® Combat Gauze™ is used in a hypothermic hemodiluted porcine model. *J Spec Oper Med*. 2015;15(1):57-60.
7. Dee KC, Puleo DA, Bizios R. *An Introduction to Tissue-Biomaterial Interactions*. Hoboken, NJ: Wiley & Sons; 2002.
8. Kheirabadi B, Mace J, Terrazas I, et al. Safety evaluation of new hemostatic agents, smectite granules, and kaolin-coated gauze in a vascular injury wound model in swine. *J Trauma*. 2010;68(5):1263.
9. Kheirabadi BS. Evaluation of topical hemostatic agents for combat wound treatment. *US Army Med Dep J*. 2011;April-June:25-37.
10. Rall JM, Cox JM, Songer A, et al. *Comparison of Novel Hemostatic Gauzes to QuikClot Combat Gauze in a Standardized Swine Model of Uncontrolled Hemorrhage*. Technical Report No. TR-2012-22. Fort Sam Houston, TX. Naval Medical Research Unit San Antonio; 2012.

11. Johnson D, Gegel B, Burgert J, et al. The Effects of QuikClot Combat Gauze, Fluid Resuscitation, and Movement on Hemorrhage Control in a Porcine Model. *International Scholarly Research Network Emergency Medicine*. 2012:1-6.
12. Gegel B, Burgert J, Gasko, J, et al. The Effects of QuikClot Combat Gauze , Fluid Resuscitation, and Movement on Hemorrhage Control in a Porcine Model of Hypothermia. *British Journal of Medicine & Medical Research*. 2014;4(7):1483-1493.
13. Johnson D, Agee S, Reed A, Gegel B, Burgert J, Gasko J, et al. The Effects of QuikClot Combat Gauze on Hemorrhage Control in the Presence of Hemodilution. *US Army Med Dep J*. 2012;36-39.
14. Causey MW, McVay DP, Miller S, Beekley A, Martin M. The efficacy of QuikClot Combat Gauze in extreme physiologic conditions. *J Surg Res*. 2012;177(2):301-305.
15. Medtrade Products. <http://www.celoxmedical.com/wp-content/uploads/Rapid-Ribbon-how-to-use.pdf>. Accessed June 12, 2018.
16. Medtrade Products. <http://www.celoxmedical.com/wp-content/uploads/Celox-Rapid-reduced-compression-time-poster.pdf>. Accessed June 12, 2018.