

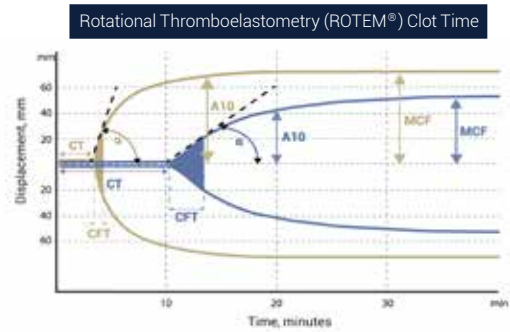
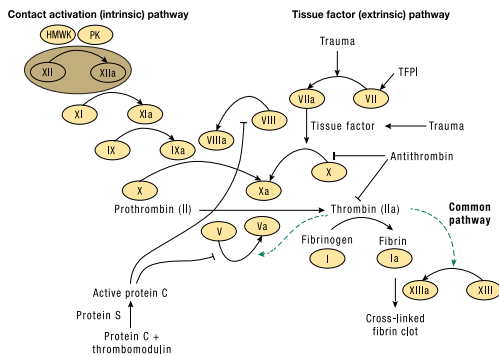


QuikClot[®]

Advanced
Bleeding
Control

Bleeding Control with QuikClot®

Uncontrolled bleeding is a major cause of preventable deaths. Approximately 40% of trauma-related deaths worldwide are due to bleeding or its consequences, establishing hemorrhage as the most common cause of preventable death in trauma.⁷ With QuikClot hemostatic devices, medical personnel can stop bleeding faster, more effectively and without excessive costs.



	CT (min)	CFT (min)	α (degrees)	A10 (mm)	MCF (mm)
QuikClot + Blood	204	4.5	81	6.7	72
Blood	605	181	56	44	54

Source: TEM Systems, Inc., 2015

The Kaolin Difference. Understanding how QuikClot works

QuikClot is non-woven gauze impregnated with kaolin, using a proprietary methodology, that accelerates the body's natural clotting cascade to achieve hemostasis. Kaolin works on contact with blood to immediately initiate the clotting process by activating factor XII.⁴ This reaction leads to the transformation of factor XII to its activated form XIIa, which instigates the rest of the coagulation cascade.⁸

QuikClot promotes clotting within minutes. Rotational Thromboelastometry (ROTEM) analysis of QuikClot treated blood shows a faster Clot Time (CT), shorter Clot Formation Time (CFT) and steeper α than blood alone which indicates that the clot is activated quickly and amplifies rapidly. The greater the amplitude of the graph, the firmer the clot (A10, MCF: maximum clot firmness). As can be seen in the graph, QuikClot treated blood forms a firmer clot faster than untreated blood.

Why use QuikClot®?

QuikClot® advantages for you and your team

Fast & Effective

- Promotes clotting within minutes of application¹⁻⁵

Efficient & Valuable

- Less expensive than protein-based products; may reduce the need for additional expensive treatments⁴
- Stops bleeding faster than standard gauze¹⁻⁵

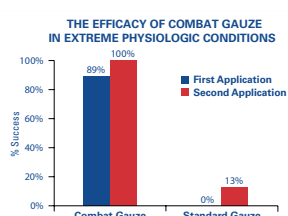
Intuitive

- Familiar and easy-to-use format
- Conforms readily to wound

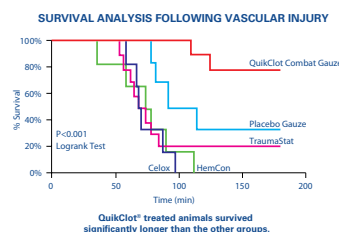
Non-allergenic

- No shellfish, human, or animal proteins
- Low-to-no risk of allergic response^{1,4}

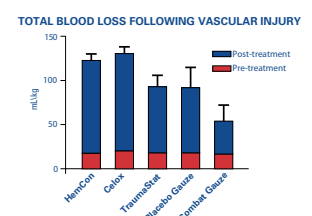
Proven Results



Source: Casper MB, Sledge DT, Miller L, Bentley A, Martin M. The efficacy of Combat Gauze in extreme physiologic conditions. *Journal of Trauma*. 2013; 117(2):30-36.



Source: Rheinboldt BL, Scherer MR, Seng D, Durbak WA, Holcomb JB. Determination of efficacy of new hemostatic dressings in a model of extremity arterial hemorrhage in swine. *J Trauma*. 2005; 57(4):824-832.



Source: Rheinboldt BL, Cohen DR, Seng D, Durbak WA, Holcomb JB. Determination of efficacy of new hemostatic dressings in a model of extremity arterial hemorrhage in swine. *J Trauma*. 2005; 57(4):824-832.

It's QuikClot Combat Gauze Technology Packaged for Hospital Applications: The US Military Committee on Tactical Combat Casualty Care (CoTCCC) recommends QuikClot Combat Gauze® as the hemostatic agent of choice for compressible hemorrhage not amenable to tourniquet use⁶



QuikClot hemostatic devices are clinically proven to stop bleeding significantly faster and more effectively than standard gauze, helping you and your team save more lives.¹⁻⁵

- FDA/CE cleared for local management of bleeding wounds such as cuts, lacerations and abrasions, temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.

QuikClot devices come in various sizes, with or without X-ray detectable strips, and can be utilized in multiple units of the hospital such as:

• Emergency Room

Procedures such as nosebleeds, lacerations, bleeding AV fistula, avulsions, amputations, road rash, traumatic wounds, etc.

• Intensive Care Unit

Procedures such as oozing lines, tubes and drains, fresh tracheostomy, skin tears, etc.

• Operating Room

Surgical wounds such as debridement, amputation, plastic surgery, pockets, ports, reconstructive, maxillofacial, skin incisional bleeding, traumatic wounds, etc.

• Wound Care

Procedures such as bleeding wounds, amputations, etc.



QuikClot® TraumaPad

QuikClot TraumaPad is a 3-ply, 12-inch x 12-inch pad with an x-ray detectable strip, packaged in a foil peel pouch for aseptic removal.



QuikClot® Roll Hemostatic Dressing

QuikClot Roll Hemostatic Dressing is a 3-inch x 4-yard, rolled gauze with an x-ray detectable strip, packaged in a foil peel pouch for aseptic removal.



QuikClot® Z-Fold Hemostatic Dressing

QuikClot Z-Fold Hemostatic Dressing is a 3-inch x 4-yard, z-folded gauze with an x-ray detectable strip, packaged in a foil peel pouch for aseptic removal.



QuikClot® 2x2

QuikClot 2x2 is a 2-inch by 2-inch square with an x-ray detectable strip, packaged in a foil peel pouch for aseptic removal.



QuikClot® 4x4

QuikClot 4x4 is a 4-inch by 4-inch square with an x-ray detectable strip, packaged in a foil peel pouch for aseptic removal.

References: **1.** Trabattoni D, Montorsi P, Fabbiochi F, Lualdi A, Gatto P, Bartorelli A. A new kaolin-based haemostatic bandage compared with manual compression for bleeding control after percutaneous coronary procedures. *Eur Radiol.* 2011;21:1687-1691. **2.** Politi L, Aprile A, Paganelli C, et al. Randomized clinical trial on short-time compression with kaolin-filled pad: a new strategy to avoid early bleeding and subacute radial artery occlusion after percutaneous coronary intervention. *J Interven Cardiol.* 2011;24:65-72. **3.** Trabattoni D, Gatto P, Bartorelli A. A new kaolin-based hemostatic bandage use after coronary diagnostic and interventional procedures. *Int J Cardiol.* 2012;156(1):53-54. **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.** Pahari M, Moliver R, Lo D, Pinkerton D, Basadonna G. QuikClot® Interventional™ Hemostatic Bandage (QCI): a novel hemostatic agent for vascular access. *Cath Lab Digest.* 2010;18(1):28-30. <http://www.cathlabdigest.com/articles/QuikClot-Interventional-Hemostatic-Bandage-QCI-A-Novel-Hemostatic-Agent-Vascular-Access>. Accessed on August 10, 2014. **6.** Tactical Combat Casualty Care Guidelines 2 June 2014. http://www.usaisr.amedd.army.mil/pdfs/TCCC_Guidelines_140602.pdf. Accessed March 25, 2015. **7.** Curry N, Hopewell S, Dorée C, Hyde C, Brohi K, Stanworth S. The acute management of trauma hemorrhage: a systematic review of randomized controlled trials. *Crit Care.* 2011;15(2):R92. **8.** Dee KC, Puleo DA, Bizios R. *Tissue-Biomaterial Interactions.* Hoboken: Wiley & Sons, 2002.



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QUIKCLOT® FOR ADVANCED BLEEDING CONTROL

QuikClot® products are cleared for external use/surgical wounds. Some of the pre-clinical publications are outside the cleared indications and are included for educational purposes only.

The effects of QuikClot Combat Gauze on hemorrhage control when used in a porcine model of lethal femoral injury.

Johnson D, Westbrook DM, Phelps D, Blanco J, Bentlye M, Burgert J, Gegel B.
Am J Disaster Med. 2014 Fall; 9(4):309-315.

- A lethal femoral artery and vein transection model was used to compare QuikClot Combat Gauze (QCG) to standard pressure dressing (control).
- QCG was found to be much more effective than the control:
 - Initial success of hemorrhage control was higher for QCG
 - Prevention of rebleeding following both induced hypertension and large volume fluid resuscitation was higher for QCG
 - Absence of rebleeding following active range of motion testing ($p = 0.0001$) was higher for QCG
 - None of the swine in the QCG group rebled. Only one animal in the control group did not rebleed."
- "QCG is an effective hemostatic agent for use in trauma management. QCG is superior in controlling hemorrhage compared to standard pressure dressings."

A pilot study of the use of kaolin-impregnated gauze (Combat Gauze) for packing high-grade hepatic injuries in a hypothermic coagulopathic swine model.

Sena MJ, Douglas G, Gerlach T, Grayson JK, Pichakron KO, Zierold D.
J Surg Res. 2013 Aug;183(2):704-9.

- Coagulopathic animals (60% exchange transfusion with Hextend) were injured with a grade V liver injury in the left middle hepatic lobe. After 30 seconds of bleeding, Combat Gauze or control gauze was applied.
- The abdomen was closed and animals were observed for 2 hours.
- Survival in the Combat Gauze group was higher than in the plain gauze group.
- "Animals treated with Combat Gauze maintained a higher MAP following injury...Most notably, animals in the CG group lost considerably less blood than those in the [plain gauze] group."

Long-term preclinical evaluation of the intracorporeal use of advanced local hemostatics in a damage-control swine model of grade IV liver injury.

Inaba K, Branco BC, Rhee P, Putty B, Okoye O, Barmparas G, Talving P, Demetriades D.
J Trauma. 2013; 74.2: 538-545.

- Evaluated the long-term safety and efficacy of QuikClot Combat Gauze®, Celox®, and Celox Gauze® versus standard gauze in a high-grade liver injury.
- Celox Gauze® had higher mortality at all time points, higher need for repacking at 48 hours due to rebleeding, more deaths by bleeding, and a higher incidence of deaths by small bowel obstruction than QuikClot Combat Gauze. All animals treated with Celox® products had adhesions.
- Combat Gauze® was found to be effective and created a durable hemostasis.

QUIKLOT® FOR ADVANCED BLEEDING CONTROL

QuikClot® products are cleared for external use/surgical wounds. Some of the pre-clinical publications are outside the cleared indications and are included for educational purposes only.

Hemostasis in a noncompressible hemorrhage model: an end-user evaluation of hemostatic agents in a proximal arterial injury.

Satterly S, Nelson D, Zwintscher N, Oguntoye M, Causey W, Theis B, Huang R, Haque M, Martin M, Bickett G, Rush RM Jr.
J Surg Educ. 2013; 70.2: 206-211.

- Celox®, ChitoGauze®, Combat Gauze®, and HemCon® bandages were applied to arterial injuries by participants including military personnel and physicians due for deployment.
- No significant difference in hemostasis was seen between the products used.
- Combat Gauze® was reported as being "the most effective at controlling hemorrhage" and was "rated as the easiest dressing to use by the soldiers."

The effects of QuikClot Combat Gauze and movement on hemorrhage control in porcine model.

Gegel B, Burgert J, Gasko J, Campbell C, Martens M, Keck J, Reynolds H, Loughren M, Johnson D.
Mil Med. 2012; 177.12: 1543-1547.

- QuikClot Combat Gauze® (QCG) and standard packing (control) were assessed in a static and moving hemorrhage model to simulate military and civilian trauma.
- QCG was found to be "statistically and clinically superior at controlling hemorrhage" over control standard packing and QuikClot Combat Gauze® "produces a more robust clot that can withstand significant movement."
- QCG "is an effective hemostatic agent for use in civilian and military trauma management."

The effects of QuikClot Combat Gauze on hemorrhage control in the presence of hemodilution.

Johnson D, Agee S, Reed A, Gegel B, Burgert J, Gasko J, Loughren M.
US Army Med Dep J. 2012; 25.6: 36-39.

- QuikClot Combat Gauze® was assessed for hemorrhage control in the presence of hemodilution in a lethal femoral injury (30% of blood volume was removed and replaced with fluids).
- Results indicate that there was significantly less bleeding in the QuikClot Combat Gauze® group compared to the control group in this hemodilution study.
- "The QuikClot Combat Gauze® was easy to open, simple to use to pack the wound, and did not require premixing."

The efficacy of Combat Gauze in extreme physiologic conditions.

Causey MW, McVay DP, Miller S, Beekley A, Martin M.
J Surg Res. 2012; 177.2: 301-305.

- The efficacy of QuikClot Combat Gauze® was assessed in a model of severe acidosis and coagulopathy to mimic a post-traumatic environment.
- Combat Gauze® had a higher success rate in achieving hemostasis at 89% for the first and 100% for the second application than standard gauze (0% for the first and 13% for the second application).
- Results indicate that Combat Gauze® significantly outperforms standard gauze dressings in this extreme physiologic model of a vascular injury.

QUIKCLOT[®] FOR ADVANCED BLEEDING CONTROL

QuikClot[®] products are cleared for external use/surgical wounds. Some of the pre-clinical publications are outside the cleared indications and are included for educational purposes only.

Safety evaluation of new hemostatic agents, smectite granules, and kaolin-coated gauze in a vascular injury wound model in swine.

Kheirabadi BS, Mace JE, Terrazas IB, Fedyk CG, Estep JS, Dubick MA, Blackburne LH.

J Trauma. 2010; 68.2: 269-278.

- Kheirabadi, et al studied the safety of QuikClot Combat Gauze[®], WoundStat[®], and standard gauze in controlling bleeding.
- WoundStat[®] severely injured vessels and could cause lung thrombosis.
- Results indicate that Combat Gauze[®] is as safe as standard gauze.

Determination of efficacy of new hemostatic dressings in a model of extremity arterial hemorrhage in swine.

Kheirabadi BS, Scherer MR, Estep JS, Dubick MA, Holcomb JB.

J Trauma. 2009; 67.3: 450-460.

- This study evaluated the efficacy of QuikClot Combat Gauze[®], TraumaStat[™], Celox-D[™], HemCon[®], and standard gauze for traumatic injuries.
- "Combat Gauze[®] was the most effective dressing tested" and resulted in the highest survival rate."
- Kheirabadi, et al found "based on these results and similar findings by our colleagues at Naval Medical Research Center, the committee has recommended replacing HC bandage with the new dressing. The new Tactical Combat Casualty Care Committee guideline recommends using CG as the first line of treatment for life-threatening hemorrhage on external wounds that is not amendable to tourniquet placement."



QuikClot[®]

Advanced
Bleeding
Control

QuikClot hemostatic dressings are made of soft, white, nonwoven, hydrophilic gauze impregnated with kaolin, an inorganic mineral that is both safe and effective in accelerating the body's natural clotting cascade¹ without any exothermic reactions or use of animal or human proteins.

QuikClot hemostatic dressings can be utilized in multiple units of the hospital such as:

◆ Emergency Room

Procedures such as nosebleeds, lacerations, bleeding AV fistula, avulsions, amputations, road rash, traumatic wounds, etc.

◆ Intensive Care Unit

Procedures such as oozing lines, tubes and drains, fresh tracheostomy, skin tears, etc.

◆ Operating Room

Surgical wounds such as debridement, amputation, plastic surgery, pockets, ports, reconstructive, maxillofacial, skin incisional bleeding, traumatic wounds, etc.

◆ Wound Care

Procedures such as bleeding wounds, amputations, etc.



QuikClot[®] TraumaPad

QuikClot TraumaPad is a 3-ply, 12-inch x 12-inch (30 cm x 30 cm) pad with an x-ray detectable strip, packaged in a foil peel pouch for aseptic removal.



QuikClot[®] 4x4

QuikClot 4x4 is a 4-inch x 4-inch (10 cm x 10 cm) square with an x-ray detectable strip, packaged in a foil peel pouch for aseptic removal.



QuikClot[®] Roll Hemostatic Dressing

QuikClot Roll Hemostatic Dressing is a 3-inch x 4-yard (7.5 cm x 3.7 m), rolled gauze with an x-ray detectable strip, packaged in a foil peel pouch for aseptic removal.



QuikClot[®] 2x2

QuikClot 2x2 is a 2-inch x 2-inch (5 cm x 5 cm) square with an x-ray detectable strip, packaged in a foil peel pouch for aseptic removal.



QuikClot[®] Z-Fold Hemostatic Dressing

QuikClot Z-Fold Hemostatic Dressing is a 3-inch x 4-yard (7.5 cm x 3.7 m), z-folded gauze with an x-ray detectable strip, packaged in a foil peel pouch for aseptic removal.

Indications

FDA/CE cleared for local management of bleeding wounds such as cuts, lacerations and abrasions, temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.

Warnings

- For prescription use only
- For external use only
- Sterility not guaranteed if package is damaged or opened
- Avoid contact with eyes
- Use aseptic techniques
- Single use only
- Do not re-sterilize
- Store in cool, dry place
- Longer compression time may be required for patients who are hypertensive or obese

Instructions For Use



- (1) Verify the expiration date on the package labels prior to using the product. Remove hemostatic dressing from packaging.
-



- (2) Apply dressing directly to the source of the bleeding and use it to apply manual compression directly over the bleeding source. The dressing can be packed in the wound tract of penetrating injuries. (More than one dressing may be required.)
-



- (3) Continue to apply manual pressure for 5 minutes, or until bleeding is controlled.
-



- (4) The hemostatic dressing may be left in place for up to 24 hours. To remove, gently remove dressing and thoroughly irrigate the wound. If the dressing is difficult to remove, irrigate with sterile saline. At the end of the procedure thoroughly irrigate the wound to remove kaolin that may be released from the dressing.

Note: Show product removal directions to medical personnel if patient is transported and the dressing remains in place.

Note: This is a general representation meant to demonstrate the Instructions For Use (IFU), please see individual package for the actual product IFU.

Reference: 1. 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.



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