Updated November 14, 2016 (added studies/edits highlighted in yellow)

<u>**CLINICAL STUDIES -**</u> QuikClot® products are cleared for external use. Some of these publications describe clinical studies performed that do not describe cleared indications.

Matsuda Y, et al. Kaolin-containing Hemostatic Gauze Reduced The Re-bleeding Rate Following Catheter Ablation for Atrial Fibrillation. Presentation at American Heart Association's 2016 Scientific Sessions and Resuscitation Science Symposium. 2016 November 12-16. New Orleans, LA.

-) QuikClot[®] InterventionalTM (KG, n=235, 13.1% antiplatelet agents usage) was compared to standard gauze (n=190) in patients who underwent catheter ablation to treat atrial fibrillation.
-) The rate of re-bleeding "was significantly lower in KG group than in normal gauze group (6.0% vs. 11.5%, P = 0.039). Notable, the efficacy of KG was more prominent in the reduction of rebleeding events after the removal of gauze compression (0.4% vs. 5.7%, P < 0.001)."

Lechner R, Helm M, Mueller M, Wille T, Friemert B.

Efficacy of Hemostatic Agents in Humans with Rotational Thromboelastometry: An in-vitro Study. *Mil Med.* 2016; 181:907-912.

-) The efficacy of QuikClot (CG), Celox (CX), QuikClot ACS+ (ACS+), and standard gauze (SG) were compared using rotational thromboelastometry (ROTEM) with blood from eight male volunteers who had no coagulation disorders.
-) Clotting time, clot formation time, alpha angle, maximum clot firmness, and lysis index were all measured to quantify hemostatic efficacy of dressings that are used in the military setting. Nonactivated, intrinsically activated, extrinsically activated, and fibrin-based ROTEM were used to elucidate different mechanisms of action (e.g. the intrinsic & extrinsic pathways).
-) With the exception of clot lysis, "CG achieved a significant improvement in all coagulation parameters in human blood...and significantly outperformed the other hemostatic agents in CT, °, and CFT".

Choron RL, Hazelton JP, Hunter K, Capano-Wehrle L, Gaughan J, Chovanes J, Seamon MJ. Intra-abdominal packing with laparotomy pads and QuikClot[™] during damage control laparotomy: A safety analysis.

Injury. 2016 Jul 21. [Epub ahead of print].

- This retrospective study included 68 patients (40 lap pad (LP) alone, 28 lap pad and QuikClot (LP+QC)) who underwent damage control laparotomy (DCL) at a Level -1 Trauma Center between 2011 and 2014.
-) Of 28 LP+QC patients, Combat Gauze was used in 19 and TraumaPads were used in 9.
-) "The surgeons at our institution now select augmented packing with QC for sicker patients, as we believe this may have additional advantage over standard LP packing."

Leonard J, Zeitlow J, Morris D, Berns K, Eyer S, Martinson K, Jenkins D, Zeitlow S. <u>A Multi-institutional Study of Hemostatic Gauze and Tourniquets in Rural Civilian Trauma.</u> *J Trauma Acute Care Surg.* 2016 May 27. [Epub ahead of print].

-) This retrospective study included patients across 10 institutions who were treated for hemorrhage in the prehospital setting using QuikClot (QC) or the Combat Application Tourniquet (CAT).
-) Forty patients were treated with QuikClot on injuries that did not achieve hemostasis with direct pressure and were not amenable to tourniquet use. "QC was effective in 89% of cases."
-) "QC and CAT are effective for hemorrhage control in the rural prehospital setting...but also medical causes of bleeding."

Koo KC, Park SU, Jang HS, Hong C-H.

Tubeless percutaneous nephrolithotomy with non-absorbable hemostatic sealant (Quikclot®) versus nephrostomy tube placement: a propensity score-matched analysis.

Urolithiasis. 2015; 43:527-533.

- This study compares "40 (35.4%) patients who received tubeless Quikclot® applied PNL and 52 (46.0%) patients who received nephrostomy placement PNL."
-) The authors note that a number of negative side effects have been seen when using absorbable hemostats in this manner but that "Quikclot in tubeless PNL led to significant reductions in pain and analgesic requirements, without increased risks of postoperative bleeding and complications."
-) "Tubeless Quikclot® PNL was safe and provided effective hemostasis of significant parenchymal bleeding."

Escott MA, Gleisberg GR, Anderson JL, Crocker KJ, Aiken MC.

QuikClot Combat Gauze® for Civilian Prehospital External Hemorrhage Control.

Poster Session Presented at: Texas EMS Conference. 2015 November 22-25. Dallas, TX.

-) The study evaluated the effectiveness of QuikClot Combat Gauze® in 28 patients treated by EMS services compared to standard treatment.
-) In the cases studied, 93% showed significant improvement to patient condition and bleeding compared to pre-treatment. 7% showed no significant change in these conditions. 0% showed negative responses to QuikClot use.
-) Study concluded that the "patient data indicates superior improvement utilizing QuikClot Combat Gauze® for the management of hemorrhage control in EMS" and "early application of Combat Gauze may have a significant effect on patient outcomes and negative consequences of hemorrhagic shock."

Shina A, Lipsky AM, Nadler R, Levi M, Benov A, Ran Y, Yitzhak A, Glassberg E. Prehospital use of hemostatic dressings by the Israel Defense Forces Medical Corps: A case series of 122 patients. *L*Trauma Acute Care Surg. 2015: 70(4):S204 S200

J Trauma Acute Care Surg. 2015; 79(4):S204-S209.

- This study compiled 122 prehospital cases where QuikClot Combat Gauze® (QCG) was applied 133 times between January 2009 and September 2014 by the Israeli Defense Forces.
- Injuries were penetrating (85.2%), blunt (3.3%) and combined (11.5%).
-) "Hemorrhage control with the hemostatic dressing was reported to be successful in 88.6% of junctional applications and in 91.9% of nonjunctional applications. These results suggest that the QCG is an effective tool for hemorrhage control in both junctional and nonjunctional injuries."
-) "Of note, in five patients, successful [QuikClot] dressing application was used after tourniquet failure."

Travers S, Lefort H, Ramdani E, Lemoine S, Jost D, Bignand M, Tourtier JP. Hemostatic dressings in civil prehospital practice: 30 uses of QuikClot Combat Gauze. Euro J of Emerg Med. 2015 Sep 8. [Epub ahead of print].

- This prospective study collected questionnaire data from physicians and/or nurses following 30 prehospital uses of QuikClot Combat Gauze between June 2011 and May 2014.
-) "For 26/30 uses, [QuikClot] hemostatic dressing was justified by the inefficiency of other hemostasis techniques. Those 30 applications were associated with 22 complete cessations of bleeding, six decreases of bleeding, and ineffectiveness in two cases." No side-effects were seen.
-) The low usage (30) was due to the study design "to use hemostatic dressing only in case of failure or inability to perform other hemostasis gestures. The results of our study have since led us to expand the use of these [QuikClot] devices."

Zietlow JM, Zietlow SP, Morris DS, Berns KS, Jenkins DH.

Prehospital Use of Hemostatic Bandages and Tourniquests: Translation from Military Experience to Implementation in Civilian Trauma Care.

J Spec Oper Med. 2015 Summer;15(2):48-53

-) This retrospective study highlights the use of 62 QuikClot Combat Gauze dressings in 52 patients. The injuries treated with QuikClot Combat Gauze were 50% head and neck, 35% penetrating wounds, and 15% other mechanisms of injury.
- QuikClot Combat Gauze "was highly successful at stopping bleeding, with 59 of 62 injuries (95%) achieving hemostasis."
-) The use of tourniquets and hemostatic gauze in prehospital civilian care is safe and highly effective, with success rates of 98.7% and 95%, respectively." The authors note the importance of initial training and that skills are maintained at 98% in two years "despite infrequent use of only about two times per month."

Trabattoni D, Fabbiocchi F, Olivares P, Basadonna G, Calligaris G, Bartorelli A. <u>A KAOLIN-BASED HEMOSTATIC GAUZE AS AN ADJUNCTIVE TOOL FOR BLEEDING</u> <u>CONTROL AFTER VASCULAR CLOSURE DEVICES USE IN TAVI PATIENTS.</u> *Int J Recent Sci Rsh.* 2015 March; 6(3):2919-2921.

-) The effectiveness QuikClot Interventional was investigated in controlling bleeding after vascular closure devices (VCDs) were used in patients undergoing transcatheter aortic valve implantation (TAVI). All patients were on anticoagulants ("aspirin (90%), LMWH (2.5%) or aspirin + clopidogrel (7.5%)").
-) "QuikClot[™] interventional gauze was firmly applied over the access site in all the 12 cases of minor bleeding after Proglide implantation, obtaining complete and fast bleeding control (mean compression time 2.3 ±1.8 min)."
-) "QuikClot Interventional Hemostatic Bandage tested after transfemoral aortic valve replacement demonstrated to be safe and effective in reducing compression time and preventing oozing or bleeding after large sheath removal with a suture vascular device."

Derkay CS, Baydoun HA, Stone L.

Intraoperative Use of QuikClot During Adenotonsillectomy: A Prospective Pediatric Trial. Ann Otol Rhinol Laryngol. 25 Nov 2014. pii: 0003489414560432. [Epub ahead of print].

A prospective clinical trial including 100 children ages 0-16 receiving tonsillectomy or adenoidectomy procedures

- One 4x4 QuikClot gauze was formed into tonsil sponges or tonsillar packs
- The researchers found that "intracapsular microdebrider tonsillectomy with adenoidectomy utilizing QuikClot to enhance the hemostasis results in recover times better than previously reported for this common operation in children"

Plastini MA, Choron RL, Hamilton L, Capano-Wehrle L, Chovanes JC, Hazelton JP. A Case Series Examining the Use of Combat Gauze[™] in Hemorrhage Control of Penetrating Wounds.

Poster Session Presented at: New Jersey Statewide Conference on EMS. 2014 November 13-15. Atlantic City, NJ.

- This poster is a retrospective review of 5 patients with penetrating wounds (gunshot, knife stab, or impalement wounds) that were packed with QuikClot Combat Gauze between 7/1/2010 and 9/1/2014 at Cooper University Hospital
-) "Combat Gauze controlled external hemorrhage in the acute setting for the patients identified through this study.
-) There were no documented re-bleeds, and complex care (care beyond daily dressing changes) was not required for any wound site in which Combat GauzeTM was utilized.
-) The cases reviewed for this study show that Combat GauzeTM has a role in the acute control of external hemorrhage from penetrating trauma."

Chavez-Delgado ME, Kishi-Sutto CV, Albores de la-Riva XN, Rosales-Cortes M, Gamboa-Sanchez P. <u>Topic usage of kaolin-impregnated gauze as a hemostatic in tonsillectomy.</u> *J Surg Res.* 2014 Dec; 192(2):678-85.

-) The researchers studied the use of QuikClot or standard gauze following cold dissection tonsillectomy and ligature in 230 patients 3-20 years old
-) Operative time, intraoperative blood loss, pain at 6 and 12 hours post-surgery, and use of analgesic medications were less with QuikClot than control gauze. QuikClot patients also returned to normal diet and activities faster
-) "In addition to rapid bleeding control, the dressing causes minimal inflammation and pain and allows patients to quickly return to normal activities. This novel dressing is a promising tool for ear, nose and throat surgical hemostasis"

Derkay CS, Baydoun H.

Intra-Operative Use of QuikClot During Adenotonsillectomy: Prospective Pediatric Trial Poster session presented at: ASPO. Combined Otolaryngology Spring Meetings. 2014 May 14-18. Las Vegas, Nevada.

- This is an abstract for a poster that was presented at 2014 COSM conference (Combined Otolaryngology Spring Meetings)
-) The group studied intra-capsular adenotonsillectomy performed in 100 children between the ages of 3 and 16 to see if they could reduce the use of cautery by using QuikClot. This in turn would improve outcomes (return to normal diet and activity and less use of narcotics for pain)
- They found that QuikClot "enhance[d] the hemostasis" which "result[ed] in recovery times significantly better than previously reported for this procedure"

Abbott EM, Nandyala SV, Schwend RM.

Does a kaolin-impregnated hemostatic dressing reduce intraoperative blood loss and blood <u>transfusions in pediatric spinal deformity surgery?</u> *Sping* (Phila Pa 1976), 2014 Sep 1: 39(19):E1174-80

Spine (Phila Pa 1976). 2014 Sep 1; 39(19):E1174-80.

-) 65 control patients received standard operative care with gauze, tranexamic acid (Pfizer), Gelfoam (Pfizer), thrombin packing, Surgiflo (Ethicon), or bonewax and 52 treatment patients received packing with QuikClot TraumaPads.
- The treatment group had 40% less intra-operative estimated blood loss than the control group (974 cc vs. 1620 cc, p<0.001). The treatment group also had 42% less total perioperative transfusion volume (499 cc vs. 862 cc, p<0.01)
-) "The use of a kaolin impregnated intra-operative trauma pad appears to be an effective and inexpensive method to reduce intra-operative blood loss and transfusion volume in pediatric spinal deformity surgery"

Treadwell T, Walker D.

Sharp Debridement in the Wound Center: Why Not?

Poster session presented at: SAWC Spring. 2014 April 23-27. Kissimmee, FL.

) "The new Kaolinite based dressings have been found to be most effective in controlling moderate to severe bleeding in the wound center, hospital, and field. We have had excellent results using these products to control moderate bleeding in our wound center"

Zietlow JM, Zietlow SP, Morris DM, Berns KB, Jenkins DH.

<u>Prehospital Use of Hemostatic Bandages and Tourniquets: Translation from Military Experience to</u> <u>Implementation in Civilian Trauma Care.</u>

Abstract of presentation from: Minnesota Surgical Society Spring Meeting. 2014 April 14. Minneapolis, MN.

- Retrospective study reviewing prehospital use of tourniquets and hemostatic bandages in 125 patients (11/4/11-1/1/14)
-) "Hemostatic bandage application was to the head and neck (50%), extremities (36%) and torso (14%) with a 95% success rate"
-) "Application of tourniquets and hemostatic bandages in prehospital civilian care are highly effective with proficiency of skills maintained despite infrequent use"

Treadwell T, Walker D.

Sharp Debridement in the Wound Center: Control of Bleeding

Poster session presented at: SAWC Fall. 2014 October 16-18. Las Vegas, NV.

- Investigator used QC in patients following sharp wound debridement (n=100 for QC, n=100 for standard gauze)
-) "The use of the Kaolinite dressings, QuikClot®, has been very useful in treating excess bleeding resulting from sharp debridement in the wound center setting"
-) See data in poster. Overall, mean time to hemostasis and ambulation is reduced in QC patients vs. standard dressing (100% bleeding stopped within 8 minutes in QC group, only 38% stopped at

8 minutes in SG group)

Brindle CT.

Safe and Effective use of Kaolin Based Hemostatic Agent in Wound and Ostomy Care.

Poster session presented at: SAWC Fall. 2014 October 16-18. Las Vegas, NV.

-) Todd reviews use of QuikClot in debridement, negative pressure wound therapy, ostomy care, and palliative care
-) "Kaolin impregnated gauze is more cost effective, does not obscure the wound bed via the result of residual product adherence and stops bleeding without the need of chemical cautery which can damage healthy tissue. The ease of use and low side effect profile of these products allow for safe delivery of wound care, effective debridement with subsequent control of bleeding, and immediate response of clinicians and care givers to unexpected bleeding events."

Glassberg E.

Pre-hospital Use of Hemostatic Bandages by the Israeli Defense Force Medical Corps. A Report of 31 Cases.

Presentation at: MHSRS. 2014 August 18-21. Fort Lauderdale, FL.

- J Summary per notes provided by Anne McKeague.
- Dr. Glassberg outlined recent experiences that the Israeli Defense Forces (IDF) had with Combat Gauze (CG). Uses were noted as to the level of the provider, either Advanced Life Support (ALS) or Basic Life Support (BLS). This was in operational scenarios and a retrospective analysis of hemostatic dressings applied under operational conditions. 93% were ALS trained, and 6% were BLS trained. Any failures were due to technique of application.
-) 92% success rate in extremity hemorrhage. Two successful applications following tourniquet failure. This was based on an N=55.
- Separate set of data reported in the last 4 weeks (that was just prior to Dr. Glassberg coming to MHSRS) in which 67 CG were applied due to the increased activity in that area. They recorded a 91% success rate.
-) They noted they are satisfied with CG with no plans to change, but they would look at new evidence for a better hemostatic if there was one, but currently that doesn't exist so there are no plans for IDF to change from CG.

Gebauer S, Hoopes D, Finlay E.

From the battlefield to the palliative care arsenal: application of QuickClot Combat Gauze for aggressive palliation of hemorrhagic shock in the setting of end-stage liver disease-associated compartment syndrome.

J Pain Symptom Manage. 2013 Oct; 46(4): e6-e8.

- A 36-year-old man with end stage liver disease (causing coagulopathy) received a fasciotomy of his right thigh due to compartment syndrome. Uncontrolled bleeding followed.
-) QuikClot was used to stabilize the patient. The wound was packed with 3 packages of Combat Gauze. The patient later died due to liver disease.
-) "From a systems perspective, the cost of QCG is far less (approximately \$50.00 per roll12) than that of repeated transfusions of blood and blood products."
-) "QCG is a unique treatment option to consider when providing palliative care to patients with

coagulopathies."

Caterson EJ, Carty MJ, Weaver MJ, Holt EF.

Boston bombings: a surgical view of lessons learned from combat casualty care and the applicability to Boston's terrorist attack.

J Craniofac Surg. 2013 Jul; 24(4):1061-7.

-) "Application of this kaolin-impregnated gauze helps to activate the clotting cascade and has been shown to be effective to staunch bleeding on the battlefield."
- "Tourniquets and combat gauze work quite effectively for extremity trauma"

Fedor PJ.

Novel Use of a Hemostatic Dressing in the Management of a Bleeding Leech Bite: A Case Report and Review of the Literature.

Wilderness & Environmental Medicine. 2012; 23:44-48.

-) QuikClot was used on a man's leech bite that had previously been treated with "standard wound care" but continued to ooze. QuikClot "allowed for rapid hemostasis without rebleeding."
-) "Leech bites are notorious for unstoppable bleeding." This is due to the anticoagulant and antiplatelet factors contained in leech saliva.
-) "QuikClot is the most common and inexpensive" over-the-counter hemostatic dressing available to civilians.

Lamb KM, Pitcher HT, Cavarocchi NC, Hirose H.

Vascular site hemostasis in percutaneous extracorporeal membrane oxygenation therapy. The Open Cardiovascular and Thoracic Surgery Journal. 2012; 5:8-10.

-) The efficacy of QuikClot Combat Gauze® (QCG) was assessed when applied to bleeding from the femoral artery or vein, internal jugular vein, tracheostomy and gastrostomy in patients receiving percutaneous extracorporeal membrane oxygenation support
-) QCG controlled bleeding at these sites within 24 hours, resulting in "a significant reduction in both localized bleeding complications and the need for blood transfusion"
-) QCG "is the most cost-effective product compared to…other hemostatic products such as Surgicel®, Gelfrom®, and Fibrillar®"

Patel SA, Martin M, Chamales I.

Vaginal Hemorrhage From Transobturator Sling Controlled with QuikClot Combat Gauze. *Military Medicine*. 2012; 177.8: 997-998.

-) Combat Gauze was used in a single patient bleeding from the right dissection site during a transobturator sling procedure.
-) When standard gauze was ineffective, "Combat Gauze was placed into the extravaginal/extraperitoneal and vaginal spaces and successfully controlled hemorrhage after 10 minutes of direct pressure."
-) "Advanced hemostatic dressings such as Combat Gauze offer an additional option for the surgeon to utilize and may provide temporary or even definitive hemorrhage control with major vascular

injuries."

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.

-) QuikClot® InterventionalTM (QCI) was evaluated for safety and efficacy in femoral artery closure following diagnostic or interventional procedures
- Patients treated with QCI achieved hemostasis in a mean time of 4.9 minutes allowing for early ambulation at 4 hours without any incidence of re-bleeding or hematoma
-) QCI "allows for a shorter and painless hemostasis procedure"

Hama Yi.

The Usefulness of QuikClot® to Treat Femoral Puncture Sites Following Atrial Fibrillation Ablation.

Leading Innovation from Nihon Kohden. 2012 Feb. 13.

-) This specialized study sought to determine the effectiveness of QuikClot® when applied to femoral puncture sites following atrial fibrillation ablation for 61 patients on anticoagulants (warfarin and heparin).
-) Successful hemostasis without rebleeding was achieved in all but one of the cases (98.4%), with the subsequent case achieving hemostasis after a second application.
-) The study concluded that even in patients on blood thinners, "QuikClot is a superior device that can ensure trouble-free hemostasis simply by applying pressure."

Trabattoni D, Montorsi P, Fabbiocchi 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; 21.8: 1687-1691.

-) 200 patients treated with aspirin, clopidogrel, LMW Heparin or warfarin received randomized treatment with QuikClot® or standard manual compression following cardiac catheterization via the femoral artery
-) QuikClot® significantly reduced the mean time to hemostasis to 5.4 minutes from 25 minutes in the manual compression group

Politi L, Aprile A, Paganelli C, Amato A, Zoccai GB, Sgura F, Monopoli D, Rossi R, Modena MG Sangiorgi GM.

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 Interv Cardiol.* 2011; 24.1: 65-72.

-) Following a percutaneous procedure for radial artery access, 120 patients were randomized into 3 groups: QuikClot® InterventionalTM compressed for 15 minutes and standard gauze compressed for 15 minutes and 2 hours.
-) The study found that after 15 minutes the QuikClot® group achieved hemostasis 80% of the time

while the standard gauze group was successful only 10% of the time. No patients in the QuikClot® group formed radial artery occlusions (RAO) while the standard gauze groups had 5% and 10% RAO respectively.

) QuikClot® "does not require a learning curve for the operator or cath lab personnel or a patient monitoring after removing at the end of 15 minutes [of] compression" which could reduce costs.

Pahari M, Moliver R, Lo D, Pinkerton D, Basadonna G.

<u>QuikClot[®] Interventional[™] Hemostatic Bandage (QCI): a novel hemostatic agent for vascular</u> <u>access.</u>

Cath Lab Digest. 2010; 18.1: 28-30.

-) Collected data on 243 clinical procedures at 15 centers that used QuikClot® InterventionalTM (QCI) as an adjunct to manual compression.
-) QCI successfully controlled bleeding in 97.12% of procedures done including those on anticoagulated patients.
-) Physicians said "they were highly satisfied and would use product again."

Ran Y, Hadad E, Daher S, Ganor O, Kohn J, Yegorov Y, Bartal C, Ash N, Hirschhorn G. QuikClot Combat Gauze use for hemorrhage control in military trauma: January 2009 Israel Defense Force experience in the Gaza Strip--a preliminary report of 14 cases. Prehosp Disaster Med. 2010 Nov-Dec; 25(6):584-8.

QuikClot Combat Gauze "dressings were applied to injuries to the head, neck, axilla, buttocks, abdomen, back, and pelvis in 10 cases, and to extremities in four cases. In 13 cases (93%), injuries were caused by blast or gunshot mechanisms. The success rate was reported as 79% (11/14). Failure to control hemorrhage was reported in three cases in three different locations: neck, buttock, and thigh. All failures were attributed to severe soft tissue and vascular injuries. No complications or adverse events were reported."

) "This report on the clinical field use of the QCG dressing by ALS providers suggests that it is an effective and safe product, and applicable for prehospital treatment of combat casualties. This report further suggests that QCG should be issued to medics as well as ALS providers. Larger clinical investigations are needed to confirm these findings."

Rhee P, Brown C, Martin M, Salim A, Plurad D, Green D, Chambers L, Demetriades D, Velmahos G, Alam H.

QuikClot Use in Trauma for Hemorrhage Control: Case Series of 103 Documented Uses. *J Trauma*. 2008; 64:1093-1099.

-) This study focuses on 103 cases where the zeolite version of QuikClot was used in military and civilian traumas.
-) "QuikClot has been effectively used by a wide range of providers in the field and hospital to control hemorrhage."

<u>**Preclinical Studies**</u> – QuikClot® products are cleared for external use. Some of these publications describe preclinical studies performed in an animal model and do not describe cleared indications.

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 Spring; 15(1):57-60.

-) QuikClot Combat Gauze® (QCG) was compared to standard gauze in a porcine model of femoral artery and vein transection. Following the removal of 30% of the animals blood volume, induction of hypothermia, vessel transection and one minute of free bleeding, the wounds were packed with either QCG or standard gauze followed by petroleum gauze and standard packing materials.
-) After the application of pressure and observation, the extremity was moved until rebleeding occurred. QCG "was able to tolerate movements more than the control group (p<0/0001)."
-) "QCG produces a robust clot that can withstand significant movement."

Johnson D, Westbrook DM, Phelps D, Blanco J, Bentlye M, Burgert J, Gegel B. <u>The effects of QuikClot Combat Gauze on hemorrhage control when used in a porcine model of</u> <u>lethal femoral injury.</u>

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."

Gould J, Dubey D.

Effectiveness of a Kaolin-Based Hemostatic Dressing in an Anticoagulated Porcine Model. Poster session presented at: SAWC Fall. 2014 October 16-18. Las Vegas, NV.

-) This study was performed by Z-Medica. Pigs treated with Coumadin (Warfarin) or Plavix (Clopidogrel) were studied. Injuries were made to the liver, spleen, and mesentery. Either QC or standard gauze was applied with pressure for 5 minutes. If bleeding ceased, a "pass" was recorded.
-) In Coumadin treated animals, 95.83% of QC tests passed while only 23.68% of SG passed (p=0.000). In Plavix treated animals, 92.45% of QC tests passed while only 29.72% of SG passed (p=0.000).
-) "In this study, the kaolin-based hemostatic dressing controlled bleeding in liver, mesentery, and spleen injuries more effectively in Plavix (clopidogrel) and Coumadin (warfarin) treated animals

than SG."

Johnson D, Bates S, Nukalo S, Staub A, Hines A, Leishman T, Michael J, Sikes D, Gegel B, Burgert J. <u>The effects of QuikClot Combat Gauze® on hemorrhage control in the presence of hemodilution</u> <u>and hypothermia.</u>

Ann Med Surg. 2014 June; 3(2):21-25.

-) This porcine study compared the effectiveness of QuikClot Combat Gauze® (QCG) to control gauze on hemorrhage in a hemodiluted and hypothermic model.
-) QCG was "more effective at hemorrhage control allowing more intravenous volume resuscitation to be administered before rebleeding compared to a standard pressure dressing."
-) QCG reduced the overall hemorrhage volume compared to control gauze by an average of 92.5%, achieved successful hemostasis in 84.6% of trials vs. 30.8% for control gauze, and retained on average more than 4 times as much IV volume resuscitation as control gauze. The author establishes ideal qualities of hemostatic agents and states that "QCG meets each one of these criteria", and notes that the packaging makes the product quick and easy to use.

Sena MJ, Douglas G, Gerlach T, Grayson JK, Pichakron KO, Zierold D. <u>A pilot study of the use of kaolin-impregnated gauze (Combat Gauze) for packing high-grade</u> <u>hepatic injuries in a hypothermic coagulopathic swine model.</u> *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."

Inaba K, Branco BC, Rhee P, Putty B, Okoye O, Barmparas G, Talving P, Demetriades D. Long-term preclinical evaluation of the intracorporeal use of advanced local hemostatics in a damage-control swine model of grade IV liver injury. *LTrauma* 2013; 74.2: 528-545

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.

Satterly S, Nelson D, Zwintscher N, Oguntoye M, Causey W, Theis B, Huang R, Haque M, Martin M, Bickett G, Rush RM Jr.

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

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."

Gegel B, Burgert J, Gasko J, Campbell C, Martens M, Keck J, Reynolds H, Loughren M, Johnson D. <u>The effects of QuikClot Combat Gauze and movement on hemorrhage control in porcine model.</u> *Mil Med.* 2012; 177.12: 1543-1547.

-) QuikClot Combat Gauze® (QC CG) and standard packing (control) were assessed in a static and moving hemorrhage model to simulate military and civilian trauma.
-) QC CG 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."
-) QC CG "is an effective hemostatic agent for use in civilian and military trauma management."

Johnson D, Agee S, Reed A, Gegel B, Burgert J, Gasko J, Loughren M.

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

Causey MW, McVay DP, Miller S, Beekley A, Martin M.

The efficacy of Combat Gauze in extreme physiologic conditions. *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.

Kheirabadi BS, Mace JE, Terrazas IB, Fedyk CG, Estep JS, Dubick MA, Blackbourne LH. Safety evaluation of new hemostatic agents, smectite granules, and kaolin-coated gauze in a vascular injury wound model in swine.

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

Kheirabadi BS, Scherer MR, Estep JS, Dubick MA, Holcomb JB. Determination of efficacy of new hemostatic dressings in a model of extremity arterial hemorrhage in swine.

J Trauma. 2009; 67.3: 450-460.

- J 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

Arnaud F, Parreno-Sadalan D, Tomori T, Delima MG, Teranishi K, Carr W, McNamee G, McKeague A, Govindaraj K, Beadling C, Lutz C, Sharp T, Mog S, Burris D, McCarron R. <u>Comparison of 10 Hemostatic Dressings in a Groin Transection Model in Swine.</u> *J Trauma*. 2009; 67(4): 848-855.

- A porcine femoral transection model was used to compare ACS+, Celox, Instaclot, WoundStat, Alpha bandage, BloodStop, X-sponge (CG), Chitoflex, HemCon, and Polymem FP-21.
-) "It was found that three new types of hemostatic dressings, namely Celox, WoundStat, and X-Sponge, and a currently deployed product, ACS+, performed better than standard gauze in controlling bleeding and improving survival in pigs during a 3-hour observation period."