

## INFORMATION PAPER

MCMR-MMO-AC

18 September 2008

SUBJECT: Description of Combat Gauze<sup>R</sup> and WoundStat<sup>R</sup> Hemostatic Agents.

1. Background. On 23 June 2008, the Surgeon General approved a course of action to replace the entire theater inventory of HemCon<sup>R</sup> dressings with two new hemostatic agents, Combat Gauze<sup>R</sup> and WoundStat<sup>R</sup>. Under this directive, Combat Gauze<sup>R</sup> will be used as the first line hemostatic agent and WoundStat<sup>R</sup> will be used as a rescue dressing in the event that Combat Gauze<sup>R</sup> is ineffective or unavailable.

2. Purpose. To provide comparative descriptions of Combat Gauze<sup>R</sup> and WoundStat<sup>R</sup>.

3. Combat Gauze<sup>R</sup>.

a. Manufacturer. Z-Medica, Inc., Wallingford, CT.

b. U.S. Food and Drug Administration Clearance. Combat Gauze<sup>R</sup> received 510(k) clearance for marketing on 16 October 2007.

c. Description. Combat Gauze<sup>R</sup> is composed of a three inch by four yard strip of sterile gauze coated with kaolin, which is the active ingredient. Kaolin is a particular type of inorganic clay mineral. Shelf life is three years

d. Mechanism of Action. Combat Gauze<sup>R</sup> stops bleeding through activation of the natural blood clotting cascade. Kaolin is a potent procoagulant.

e. Adverse Effects. None reported. Combat Gauze<sup>R</sup> is easily removed from the wound using sterile saline.

4. WoundStat<sup>R</sup>.

a. Manufacturer. Traumacure, Inc., Bethesda, MD.

b. U.S. Food and Drug Administration Clearance. WoundStat<sup>R</sup> received 510(k) clearance for marketing on 23 August 2007.

c. Description. WoundStat<sup>R</sup> is a granular hemostatic agent. Each WoundStat<sup>R</sup> package contains 5.5 ounces of smectite. Smectite is a particular type of inorganic clay mineral. Shelf life is three years.

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d Mechanism of Action. WoundStat<sup>R</sup> stops bleeding through activation of the natural blood clotting cascade. Smectite is a potent procoagulant. The granules also become highly plastic and strongly adhere to and seal the wound when exposed to blood or fluids.

e. Adverse Effects. The USAISR study found that WoundStat<sup>R</sup>'s granules, which are very small, can easily enter the lumen of an injured artery or vein. Because of the potent procoagulant activity of smectite, there is concern that this product potentially could pose a risk of thrombosis should granules remain within the vessel after completion of surgical repair and restoration of blood flow. Extensive and meticulous debridement is required to ensure complete removal of WoundStat<sup>R</sup> granules from the wound.