

Hemoflex® Combat

Effective bleeding control

STERILE R



гемофлекс®
— комбат —

Средство гемостатическое стерильное

Предназначено для использования при чрезвычайных ситуациях.
Эффективно для временной остановки наружного артериального, венозного
и капиллярного кровотечений.

Быстро и эффективно останавливает кровотечение.
Обладает бактерицидным действием.
Не вызывает экзотермической реакции при контакте с тканями организма.
Легко моделируется по форме раны.



Разработано при поддержке



7,5 × 45 см

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гемофлекс®

Relevance

Bleeding and blood loss are of the main reasons of people death in man-made and natural disasters, accidents and military conflicts. Therefore, one of the most vital issues of the modern urgent medicine

is timely efficient prehospital bleeding control,

especially when large veins or arteries are injured, as well as reliable hemostasis during transportation of the casualty to a medical care unit^{1,2}.

Solution

Local hemostatic agents are used as a first urgent medical aid to control bleeding of various intensity both in Russia and abroad. The most widely used external bleeding temporary control products are those based on N-acetyl-1,4-β-D-glucosamine biopolymer, better known as chitosan^{3,4}.

The hemostatic capabilities of chitosan were first mentioned in 1983 when it was shown that contact of the biopolymer with defibrinated/heparinized blood/red blood cells leads to formation of a gel-like blood clot⁵. It encouraged use of this biopolymer for manufacturing of the medical hemostatic products.

¹Bennett B.L., Littlejohn L. Review of new topical hemostatic dressings for combat casualty care // Mil. Med. – 2014. – Vol. 179, № 5. – P. 497-514. ²Granville-Chapman J., Jacobs N., Midwinter M.J. Pre-hospital haemostatic dressings: a systematic review // Injury. – 2011. – Vol. 42, № 5. – P. 447-459.

³Mazurek P., Kuliński S., Gosk J. The possibilities of using a chitin and chitosan in wounds treatment // Polim. Med. 2013. – Vol. – 43, № 4. – P. 297-302.

⁴Kheirabadi B. Evaluation of topical hemostatic agents for combat wound treatment // US Army Med. Dep. J. – 2011. – P. 25-37.

⁵Malette W.G., Quigley H.J., Gaines R.D., Johnson N.D., Rainer W.G. Chitosan: a new hemostatic // Ann. Thorac. Surg. – 1983. – Vol. 36, № 1. – P. 55-58.

Innovations

In-house researches and developments along with the use of innovative biomedical polymer processing technologies enabled introducing a national highly competitive medical product for temporary control of external bleedings, Hemoflex® Combat Hemostatic Sterile Agent. This took place under the Federal Target Program “Development of the Pharmaceutical and Medical Industry of the Russian Federation to 2020 and Beyond”.

Hemoflex® Combat

is a new medical product to be used in the first urgent aid for temporary control of external arterial, venous or capillary bleeding. Its main active component is chitosan, a biopolymer with hemostatic properties, antibacterial action, biocompatibility, and biodegradation capability.

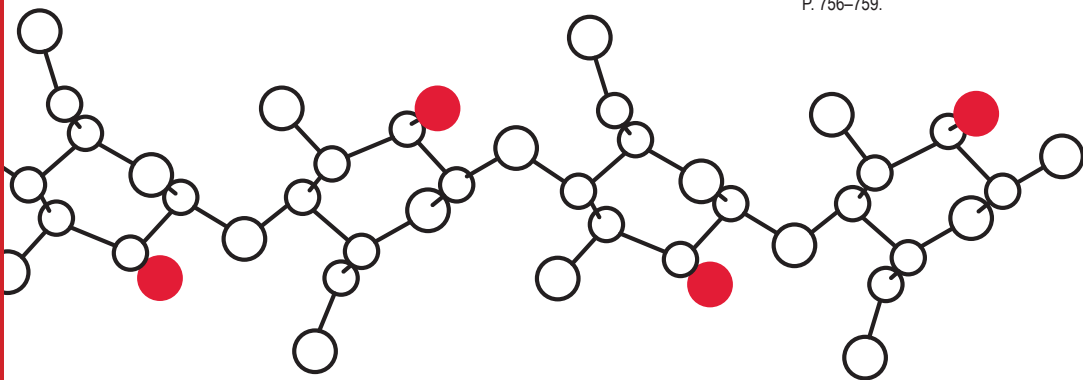
Mechanism of action

Chitosan is a high-molecular compound, where the macromolecule contains a lot of free amine groups enabling to fix hydrogen ions and receive excessive positive charge. When the biopolymer contacts with blood, the positive charge attracts the red blood cells, whose outer membrane is negatively charged, and changes their surface potential. This results to their clogging and thus formation of a gel-like clot that closes the vessel defect⁶.

So, the chitosan hemostatic action mechanism does not involve regular hemostasis system actors, i.e. clotting factors, which allows its use for patients with impaired coagulation system or in case of hypothermia⁷.

⁶Thatte H.S., Zagarins S., Khuri S.F., Fischer T.H. Mechanisms of poly-N-acetyl glucosamine polymer-mediated hemostasis: platelet interactions // J. Trauma. – 2004. – Vol. 51, № 1. – P. S13-S21.

⁷King D.R., Cohn S.M., Proctor K.G. Modified rapid deployment hemostat bandage terminates bleeding in coagulopathic patients with severe visceral injuries // J. Trauma. – 2004. – Vol. 57, № 4. – P. 756–759.



Production technology

Today the world market of the chitosan-based hemostatic products is represented by two major manufacturers: MedTrade Products Ltd (UK) and HemCon Medical Technologies Inc. (USA). They produce medical products for temporary control of external bleeding in the form of powders (Celox™ Granules) and non-woven materials (Celox™ RAPID Gauze, HemCon ChitoGauze®)^{1,4}.

Hemoflex® Combat is developed and manufactured with the use of advanced technology for processing medical polymers into non-woven nanofiber materials⁸. Unlike traditional porous, powder or fiber hemostatic materials, the non-woven materials comprising polymer nanofibers feature larger specific surface area, porosity, air permeability and higher sorption capabilities.

Both pre-clinical and clinical studies of Hemoflex® Combat have shown a high hemostatic efficiency and better hemostasis stability compared to analogs. The innovative biomedical polymer processing technology, unrivaled in Russia, allows for considerably lower final cost.

¹Bennett B.L., Littlejohn L.
Review of new topical hemostatic dressings for combat casualty care //

Mil .Med. – 2014. – Vol. 179, № 5. – P. 497-514.

⁴Kheirabadi B. Evaluation of topical hemostatic agents for combat wound treatment // US Army Med. Dep. J. – 2011. – P. 25-37.

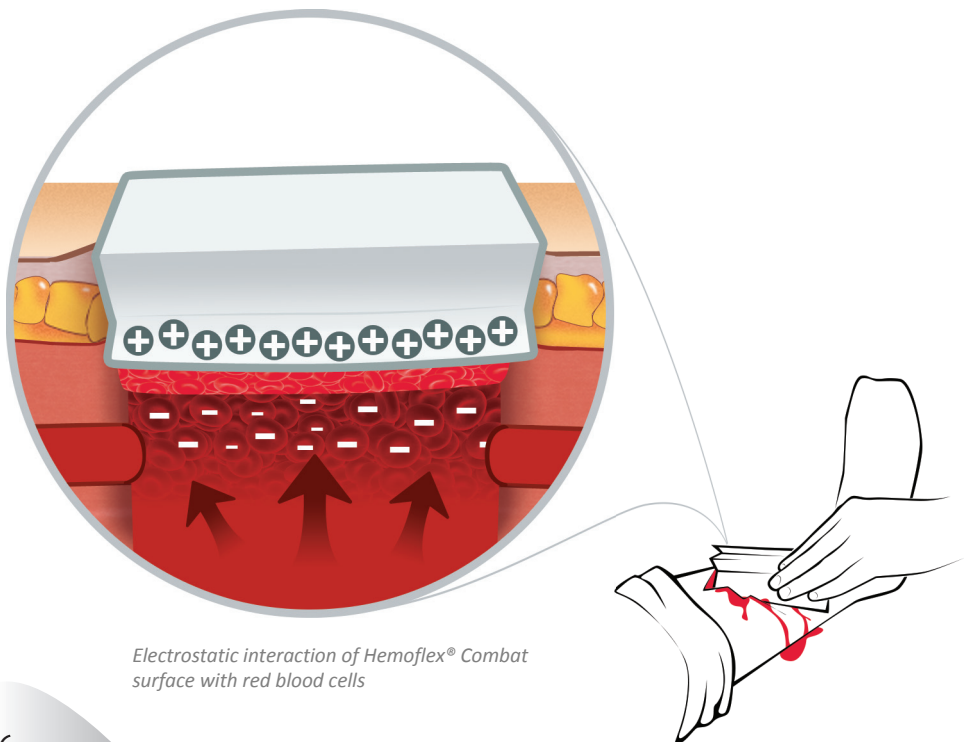
⁸Russian Federation Invention Patent for No. 2487701 dated 26.07.2011.

How Hemoflex[®] Combat works

Contact of Hemoflex[®] Combat with blood causes adhesion and clogging of negatively charged blood cells (first of all, red blood cells) on the positively charged Hemoflex[®] Combat surface. As a result, a gel-like clot forms and closes the vessel injury thus stopping the bleed.

The use of the chitosan nanofibers as part of the Hemoflex[®] Combat's patented multilayer structure⁹ improves hemostatic effect, decreases the risk of rebleeding, and causes no inflammatory response.

⁹Russian Federation Utility
Patent No. 135921 dated
29.04.2013.



Electrostatic interaction of Hemoflex[®] Combat surface with red blood cells

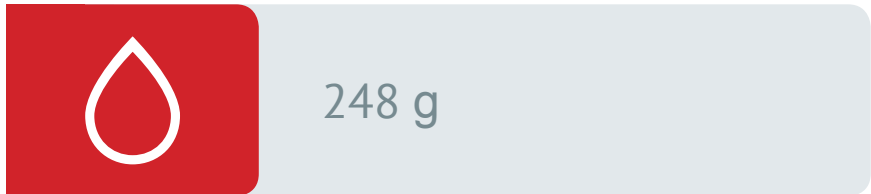
Proven efficiency of Hemoflex® Combat

Pre-clinical studies ¹⁰

The use of Hemoflex® Combat on an external arterial and venous bleeding model representing a standard injury of the upper third of thigh with complete transection of the pig's femoral artery and vein considerably decreased the bleeding time and blood loss mass compared to the control group: this proves a clear hemostatic effect.

¹⁰Research Report. Pre-clinical study of Hemoflex® Combat hemostatic agent specific activity on a swine external artery and vein bleeding model. Saint-Petersburg State Veterinary Academy, 2013.

Hemoflex® Combat



Control



Intraoperative blood loss mass

Microbiological studies¹¹

Hemoflex® Combat features a clear antimicrobial/ bactericidal effect to testing cultures *S. Aureus* ATCC 29213, *E. Coli* ATCC 25922, *S. Pyogenes* (clinical isolate), *Myc. Smegmatis* ATCC 437RW, and *C. Albicans* ATCC 90028.

¹¹The testing protocol. The Clinical Microbiology Center of the Pavlov's First St. Petersburg State Medical University, 2013.

Culture	Contact time (h)					Control
	3	6	8	14	24	
<i>S. Aureus</i> ATCC 29213	--	--	--	--	--	480 colonies
<i>E. Coli</i> ATCC 25922	10 colonies	--	--	--	--	95 colonies
<i>S. Pyogenes</i> (clinical isolate)	20 colonies	17 colonies	4 colonies	--	--	27 colonies
<i>C. Albicans</i> ATCC 90028	--	--	--	--	--	6 colonies
<i>Myc. Smegmatis</i> ATCC 437RW	±±	±±	±	--	--	±±

- Negative culture

± Positive culture intensity

Clinical testing¹²

The use of Hemoflex® Combat for control of external arterial, venous and capillary bleeding in groin surgery produced a hemostatic effect in all the cases. No rebleeding was observed after removal of the product out of the wound, and no undesirable side effects including allergies were recorded.

¹²Hemoflex Pro and Hemoflex Combat Sterile Hemostatic Agent Clinical Testing Protocol. Clinical Microbiology Center of the Pavlov's First St. Petersburg State Medical University, 2014.

How to use Hemoflex® Combat

Hemoflex® Combat has a clear application instruction and is Z-folded in the individual package for quick and efficient use in emergencies. Hemoflex® Combat is to be used in four stages:



- 1 Open the package and take Hemoflex® Combat (hereinafter the Product).

The sealed package keeps Hemoflex® Combat sterile until use. Never use Hemoflex® Combat if its package is damaged



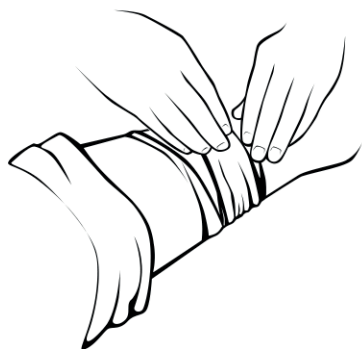
- 2 Unfold the Product and place it directly on the source of bleeding. Make sure that the Product covers the wound completely. Apply another Product additionally, if required.

The Z-folding allows to unfold Hemoflex® Combat gradually and to cover the whole wound surface evenly. Provide maximum contact of Hemoflex® Combat with the source of bleeding. Packing Hemoflex® Combat into the wound would decrease blood loss and the risk of infection.



- 3** Compress manually for 2 to 3 minutes. Make sure that the bleeding has stopped. In case of rebleeding, remove the used Product and use a new one.

After Hemoflex® Combat is packed into the wound, apply manual pressure on the injured area for a short time for better contact of Hemoflex® Combat with the source of bleeding. Manual compression for 2 to 3 minutes would considerably accelerate bleeding control process. Evaluate bleeding control visually. Bleeding may not stop if large vessels are badly damaged. This way remove Hemoflex® Combat from the wound as quick as possible and use a new one. If repeated use of Hemoflex® Combat appears ineffective, use a tourniquet.



- 4** After the bleeding is stopped, leave the Product in the wound and apply a pressure dressing. Seek medical advice.

Evaluate bleeding control visually; no blood should drip out of the wound. Hemoflex® Combat packed into the wound during transportation of the casualty reduces the risk of rebleeding and infectious contamination of the wound.

Removal of Hemoflex® Combat after use

Unlike powder and porous hemostatic products, the soft and flexible Hemoflex® Combat material can be easily, quickly and completely removed from the wound with blood clot remaining intact during initial surgical debridement.

Advantages of Hemoflex® Combat

Safe and fast bleeding control

- Lower blood loss
- Lower risk of rebleeding
- Lower death probability
- Shorter first aid time

Safe application

- Bactericidal action
- No animal proteins or clotting factors
- No tissue inflammatory response
- No heat burn
- No risk of embolism
- Sterile

Usability

- Elastic
- Easily takes the shape of the wound
- Individual package
- No specific preparation before use
- Simple and quick use in emergencies

Easily removable

- Atraumatic removal
- No damage to blood clot
- Lower risk of rebleeding



Original photo: PAP / EPA / MAXIM SHIPENKO

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www.hemoflex.ru