

The Next Generation in Hemostatics

CHITOGAUZE® PRO Z-FOLDED HEMOSTATIC CHITOSAN DRESSING

ChitoGauze® PRO
has greater success than
Combat Gauze™
See *in vivo* study, pages 3-4

Antibacterial Properties

Proven effective against 26 microorganisms including **MRSA, VRE & A. baumannii**.

See page 5 for a complete listing

Erythrocyte & Platelet Interaction *with* Chitosan

Supports **Localized Clotting** to stop bleeding & **Reduce the Risk of Re-bleeding**. See Mechanism of Action on page 6 for references

Battlefield Design

Z-Folded for rapid application,
Highly Flexible for conforming to complex wound surfaces,
Vacuum-Sealed for small cube space. See page 6



ChitoGauze® PRO



What's Inside...

ChitoGauze[®]PRO Product Overview 1-2

IN VIVO STUDIES

Oregon Medical Laser Center, Providence
St. Vincent Medical Center, Portland, Oregon

Comparison of Hemostatic Efficacy of ChitoGauze[®]PRO and Combat Gauze[™] in a Lethal Femoral Arterial Injury in Swine Model..... 3-4

Abstract from Academic Emergency Medicine
May 2010, Vol. 17, No. 5, Supplement
Medical College of Georgia School of Medicine,
Medical College of Wisconsin Affiliated Hospitals

Comparison of ChitoGauze[®]PRO and Combat Gauze[™] for Hemorrhage Control in a Swine Model 4

ADDITIONAL DOCUMENTATION

The Antibacterial Efficacy of the ChitoGauze[®]PRO Dressing 5

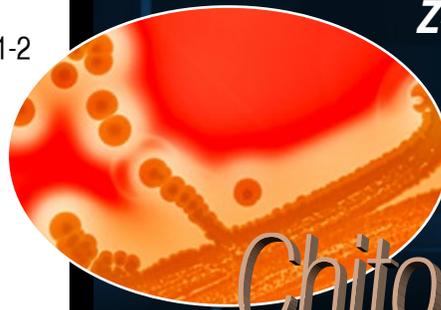
The ChitoGauze[®]PRO Mechanism of Action 6

Summary of ChitoGauze[®]PRO Features & Benefits..... 6

Instructions for Use 7

A Strategic Partnership: North American Rescue and HemCon Technologies..... 7

The next generation
Z-folded Hemostatic Chitosan Dressing
designed for the battlefield...



ChitoGauze[®]PRO

Introducing ChitoGauze[®]PRO from HemCon Medical Technologies - a revolutionary hemostatic capability designed specifically for the rapid control of severe external hemorrhage on the modern battlefield.

ChitoGauze[®]PRO is optimized to maximize hemostatic performance and reduce the risk of re-bleeding. It provides effective hemostasis outside

of the normal clotting cascade and has natural antibacterial properties against a wide range of gram positive and gram negative microorganisms, including MRSA, VRE, and A. baumannii. These antibacterial properties are beneficial in presence of debris and environment before the injured are treated with antibiotics or are transferred to a medical treatment facility.



ChitoGauze[®]PRO is a trademarks of HemCon Medical Technologies, Inc.

Combat Gauze[™] is a trademark of Z-Medica Corporation.

ChitoGauze[®]PRO BY HemCon[®]

ITEM# 30-0049
NSN# 6510-01-591-7740

DIMENSIONS: Packaged - H 6 in. x W 5 in. x D 0.65 in.
Gauze - L 4 yd x W 3 in.
WEIGHT: 0.7 oz

ChitoGauze[®]PRO vs. Combat Gauze[™]

Successful Hemostasis



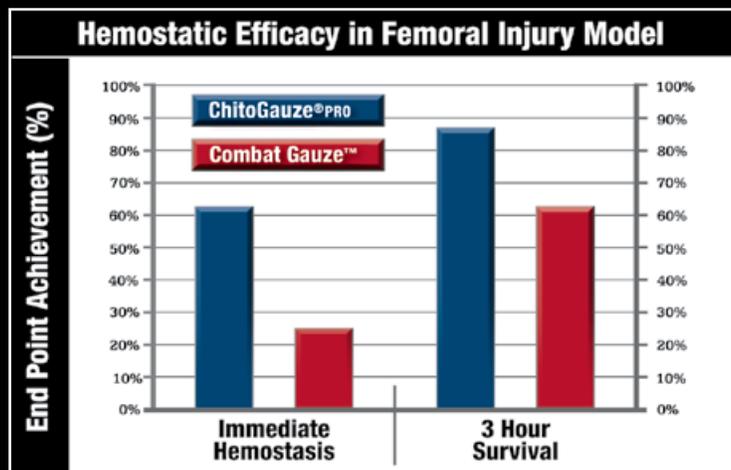
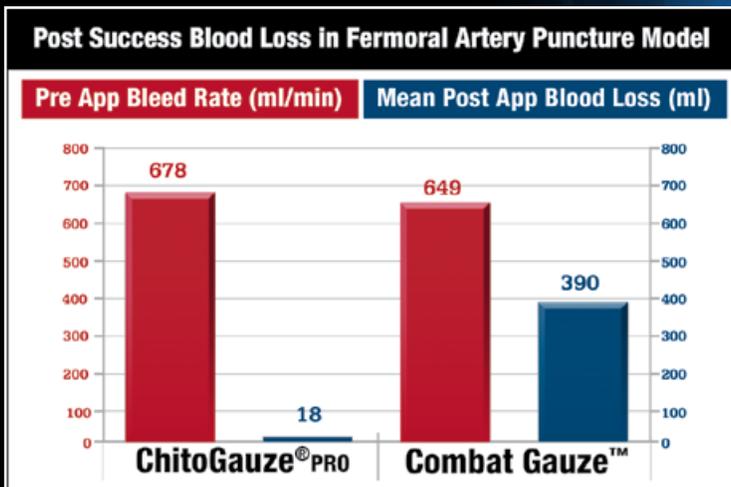
*Failure: Bleeding did not stop after the first three minutes of the bandage application and a second dressing application was required.

ChitoGauze[®]PRO had greater success in achieving immediate hemorrhage control with less blood loss than Combat Gauze[™]



- The proven hemostatic properties of chitosan enhance the ability of medical gauze to control hemorrhage
- Offers antimicrobial properties against 26 bacterial organisms
- Readily conforms into wound surfaces with complex geometries to rapidly staunch bleeding and seal the wound site
- Non-woven, polyester/rayon blend medical gauze is chitosan impregnated to maximize its performance
- Small cube maximizes storage space
- Z-folded & packaged in a custom North American Rescue vacuum-sealed pouch featuring Red-Tip Technology®

In recent *in vivo* studies on a lethal femoral arterial puncture injury at the Oregon Medical Laser Center (see pages 3-4), ChitoGauze® PRO had greater success than Combat Gauze™ in achieving sustained hemostasis and therefore controlling critical blood loss* (see figures, below).



Testing conducted at Oregon Medical Laser Center, Providence St. Vincent Medical Center, Portland, Oregon. Results on file at HemCon Medical Technologies, Inc.

HEMOSTATICS

The Global War on Terrorism (GWOT) has been the catalyst for tremendous advances in the development of advanced hemostatic agents for use in the control of life threatening hemorrhage. Uncontrolled hemorrhage continues to be the leading cause of preventable combat death on the modern battlefield and the second leading cause of death in the civilian setting. Quickly accessing and stabilizing the wound with effective hemostatic techniques is the key to saving lives on the battlefield. There exists a great need for an easy to apply hemostatic agent that is effective in achieving hemostasis in severe traumatic combat wounds.

A hemostatic agent must meet minimum requirements of efficacy in order to be considered for use in the tactical environment:

- Must be able to staunch large-vessel arterial and venous bleeding within 3 minutes of application to the wound
- Must require no special preparation
- Should capitalize on intuitive training behaviors consistent with current CoTCCC guidelines and protocols
- Must be lightweight, durable and meet the weight and cube constraints of the Individual First Aid Kit (IFAK)
- Must be stable and functional in extreme ambient temperatures for several months or longer
- Must be safe to use, posing no risk to the tissue, vasculature or the patient as a whole

ChitoGauze® PRO meets all these challenges head on...

Turn the page to learn more about this ideal solution for the control of severely bleeding wounds ▶



NORTH AMERICAN RESCUE™

HemCon
MEDICAL TECHNOLOGIES INC

Comparison of Hemostatic Efficacy of **ChitoGauze[®]PRO & Combat Gauze[™]** in a Lethal Femoral Arterial Injury in Swine Model

Hua Xie, M.D.
Lisa Lucchesi, M.S.
Jeffrey Teach, R.N.
Kenton Gregory, M.D.

Introduction

Uncontrolled hemorrhage is the leading cause of death of soldiers in wartime. **Quickly accessing and stabilizing the wound with effective hemostatic techniques is the key to saving lives on the battlefield.**

There exists a need for a hemostat that is efficacious in achieving hemostasis in severe traumatic combat wounds and easy to apply. In this study, we evaluated the hemostatic efficacy of two advanced hemostatic wound dressings: ChitoGauze[®]PRO (HemCon Medical Technologies Inc., Portland, OR) and QuikClot[®] Combat Gauze[™] (Z-Medica Co., Wallingford, CT), in a swine femoral arterial injury model.



Methods & Materials

Sixteen male Yorkshire crossbred swine with an average body weight of 40 Kg were randomly assigned into either the Combat Gauze[™] or ChitoGauze[®]PRO group. An arterial injury was created with a 6 mm arterial punch on the left femoral and free bleed of 45 seconds was required prior to application of test dressing. Each hemostatic dressing was applied through a pool of blood with the applicator blinded, followed by three minutes of manual compression. Pressure was released after three minutes and the wound was observed for bleeding. If bleeding occurred within two minutes, a second application of the test dressing was allowed. Fluid resuscitation was administered as necessary to re-establish a mean arterial pressure (MAP) at above 60 mmHg level or continuous infusion in a 3-hour observation period if MAP dropped below 60 mmHg. The primary measured outcomes were immediate hemostasis, 3-hour survival and total blood loss. Secondary endpoints were average number of applications, time to hemostasis, change of mean arterial pressure, resuscitation volume, volume of blood loss during the 45 second prebleed and femoral artery diameter.

TABLE 1. SURGICAL INFORMATION (MEAN ± SD)

	ChitoGauze [®] PRO (n=8)	Combat Gauze [™] (n=8)	P Value
Body Wt (Kg)	41 ± 2	40 ± 3	0.3
Average arterial diameter (mm)	6.1	6.2	0.9
Pre-blood loss (g)	680 ± 160	730 ± 150	0.21
Post-blood loss (g)	430 ± 1100	1180 ± 1370	0.26
Change of MAP (mmHg)	33 ± 6	36 ± 6	0.39
Immediate* hemostasis (% , n/n)	63% (5/8)	25% (2/8)	0.04**
Average time to achieve hemostasis (min)	3 ± 5	12 ± 19	0.21
3-Hour survival (% , n/n)	88% (7/8)	63% (5/8)	0.25**

*Defined as hemostasis on first application out of two possible applications; **Chi-square test; T-test unmarked

Results

Surgical information including body weight, pre-treatment blood loss, vessel size, MAP change and resuscitation volume were similar between the two treatment groups. **Average post treatment blood loss over three hours or survival was less in the ChitoGauze[®]PRO group than the Combat Gauze[™] group (430 mL vs. 1180 mL).** In the ChitoGauze[®]PRO group, seven (87.5%) animals achieved hemostasis and survived without any blood loss or oozing. Only two (25%) animals achieved immediate hemostasis and five (63%, p = 0.04) survived in the three hours observation time in the Combat

FIGURE 2. Change of Average Mean Arterial Pressure (MAP) in three-hour Observation

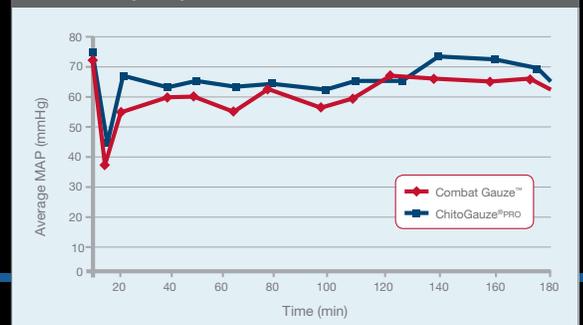
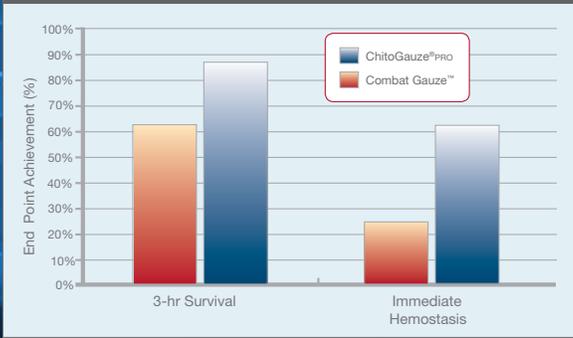


FIGURE 1. Hemostatic Efficacy in Femoral Injury Model



Gauze[™] group.

In the survived animals, five out of seven animal had complete hemostasis in first attempt using the ChitoGauze[®]PRO; two out of five animals achieved hemostasis in first attempt with the Combat Gauze[™]. Number of applications in the ChitoGauze[®]PRO group was less than that in the Combat Gauze[™] group (1.4 ± 0.5 vs. 1.8 ± 0.5). **Average time to achieve complete hemostasis in the survived animals was three minutes with the ChitoGauze[®]PRO and 12 minutes using Combat Gauze[™].**

Conclusion

Both ChitoGauze[®]PRO and Combat Gauze[™] demonstrate hemostatic effectiveness in this lethal extremity hemorrhage model. Both dressings were easy to apply into the femoral wound geometries. While both bandages performed similarly in this small sample, we did note a trend toward more blood loss among the successful Combat Gauze[™] applications as compared to ChitoGauze[®]PRO. **ChitoGauze[®]PRO had greater success in achieving immediate hemorrhage control with less blood loss than Combat Gauze[™] in this model.** ■



Figure 3 Images show a typical hemostatic effectiveness of ChitoGauze[®]PRO (top) and Combat Gauze[™] (bottom) in the femoral arterial injury model. The ChitoGauze[®]PRO has the capability to achieve immediate hemostasis. The Combat Gauze[™] usually established hemostasis following a gradual reduction of hemorrhaging.

Comparison of ChitoGauze[®]PRO & Combat Gauze[™] for Hemorrhage Control in a Swine Model

Richard B. Schwartz,
Stephen A. Shiver,
Nicholas Impel,
Eric Greenfield,
Ricaurte Soils,
E. Brooke Lerner,
Paul Vecchio,
Bradford Reynolds,
Phillip L. Coule

Medical College of Georgia
School of Medicine, Medical
College of Wisconsin
Affiliated Hospitals

Rapid hemorrhage control is crucial particularly in combat and other austere environments. ChitoGauze[®]PRO and Combat Gauze[™] are both marketed for rapid hemorrhage control.

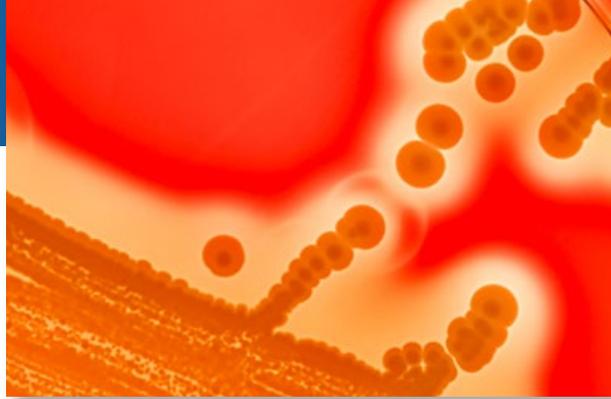
Objective: To compare the effectiveness of ChitoGauze[®]PRO to Combat Gauze[™] for controlling arterial hemorrhage.

Methods: Seven swine were instrumented with external jugular and carotid lines. A mean arterial pressure (MAP) of >70 was required at the start of the experiment and up to 500cc of Hextend may have been given to raise MAP. The femoral artery was surgically exposed and mobilized. The artery was bathed in 2% lidocaine until it expanded to >6mm. A wound was created in the femoral artery utilizing a 6 mm vascular punch. The would was allowed to

bleed freely for 45 seconds and then packed with either ChitoGauze[®]PRO or Combat Gauze[™], and a 4 inch roll of standard gauze was placed over the wound. Seventy-five pounds of direct pressure was applied to the wound for 2 minutes using a weighted plate and 500cc of Hextend was administered. The swine was then monitored for 3 hours. If MAP dropped below 60 during that time up to 12 liters of normal saline was administered to maintain a MAP >65. The volume of blood loss was measured and compared using a t-test.

Results: A total of 7 swine were studied: 3 received Combat Gauze[™] and 4 received ChitoGauze[®]PRO. The mean blood loss after the 45 second free bleeding period was 31.8 cc +/- 17 ChitoGauze[®]PRO and 671.3 cc +/- 586 for Combat Gauze[™] (mean difference 639.6 cc; p=0.037). Time to bleeding control was immediate for all ChitoGauze[®]PRO cases and for one Combat Gauze[™] case (remaining cases average of 54 minutes). Anecdotally, after removal of the gauze it was found that none of the ChitoGauze[®]PRO cases had formed an intra-arterial clot while all of the Combat Gauze[™] cases had formed an intra-arterial clot.

Conclusion: ChitoGauze[®]PRO controls bleeding more rapidly than Combat Gauze[™] and results in a reduction of blood loss. Future research should examine the effect of gauze type on clot formation. ■



The Antibacterial Efficacy of the ChitoGauze[®]PRO Dressing

Introduction

The broad antibacterial properties of the chitosan based HemCon Bandage, including both gram positive and gram negative bacteria, have been previously demonstrated. Testing was performed to determine if the HemCon ChitoGauze[®]PRO dressing exhibited similar performance.

Methods

Two tests were performed to determine the antibacterial performance of the ChitoGauze[®]PRO dressing.

The first was a quantitative procedure to evaluate of the degree of antibacterial activity⁴ In this test, swatches of ChitoGauze[®]PRO were inoculated with a > 6-log population a test organism. This procedure was repeated using 26 selected microorganisms⁵. After incubation, the microorganisms were eluted from the swatches by shaking in neutralizing solution. The number of microorganisms present in this liquid was determined, and the percentage reduction in the population of each was calculated.

The second was an Antibacterial Barrier/Strikethrough Test, which is a qualitative procedure to evaluate if live microorganisms could pass through a swatch of the ChitoGauze[®]PRO dressing. In this test, 2"x 2" pieces of ChitoGauze[®]PRO dressing were placed on top of a sterile piece of filter paper. The swatch of dressing and filter paper were then placed on top of Tryptic Soy Agar and inoculated with 1.0 mL of a test organism. Again, this was repeated using 26 selected microorganisms. For each organism, a positive control was tested using filter paper without the ChitoGauze[®]PRO dressing as the barrier. The media, filter paper, and dressing were incubated for 48 hours. The filter paper and dressing swatch were removed and the media was incubated for another 48 hours. Following incubation the media was observed for growth. ■

The clinical utility of these findings is unknown.

4. AATCC Test Method 100-2004 Assessment of Antibacterial Finishes on Textile Materials
5. Microorganisms tested include common nosocomial, battlefield, and hospital acquired pathogens
6. Growth was observed on all positive controls.

Microorganism	Gram Stain	Log Reduction
Staphylococcus aureus (MRSA) ATCC 33591	+	>4.1
Staphylococcus aureus (MRSA) ATCC BAA-1556	+	>4.2
Staphylococcus epidermidis ATCC 12228	+	>4.2
Pseudomonas aeruginosa ATCC 9027	-	>4.1
Enterococcus faecalis (VRE) ATCC 51299	+	>4.0
Acinetobacter baumannii ATCC 15308	-	>4.4
Citrobacter freundii ATCC 8090	-	>4.3
Enterobacter cloacae ATCC 13047	-	>4.1
Streptococcus mutans ATCC 25175	+	>4.0
Streptococcus pneumoniae ATCC 10015	+	>5.1
Escherichia coli ATCC 8739	-	>4.1
Klebsiella pneumoniae ATCC 4352	-	>4.0
Streptococcus pyogenes ATCC 19615	+	>4.2
Salmonella choleraesuis ATCC 10708	-	>4.1
Stenotrophomonas maltophilia ATCC 12714	-	>4.0
Citrobacter koseri ATCC 25408	-	>4.1
Proteus mirabilis ATCC 4630	-	>4.2
Proteus vulgaris ATCC 12454	-	>4.3
Moraxella catarrhalis ATCC 8193	-	>4.1
Clostridium difficile ATCC 9689	+	>4.0
Shigella species ATCC 11126	-	>4.0
Micrococcus luteus ATCC 49732	+	>4.0
Vibrio cholerae ATCC 11558	-	>4.1
Enterobacter aerogenes ATCC 13048	-	4.8
Enterococcus faecalis (VRE) ATCC 700802	+	2.6
Serratia marcescens ATCC 13880	-	5.0

The ChitoGauze[®]PRO Mechanism of Action

ChitoGauze[®]PRO stops hemorrhagic bleeding by controlling the rate of blood flow through the dressing and allowing for significant erythrocyte and platelet interaction with the uniformly chitosan coated surface.

ChitoGauze[®]PRO is optimized to maximize hemostatic performance. The robust uniformly applied chitosan coating on the gauze, allows for significant chitosan blood interaction in conjunction with optimized fluid handling performance. The chitosan coated surface of ChitoGauze[®]PRO helps to retard blood flow through the dressing thereby diminishing rapid bleeding. The chitosan coating on the gauze further reduces blood loss by helping to adhere the dressing to the wound site providing a physical barrier to prevent bleeding. **Significant aggregation of erythrocytes¹ and activation of platelets^{2,3} supports localized clotting within and on the gauze to stop bleeding and reduce risk of rebleeding.**

ChitoGauze[®]PRO provides effective hemostasis outside of the body's normal clotting cascade and has natural antibacterial properties. The material composition of the dressing has been uniquely formulated to allow for the maximum benefit of the chitosan coating. The structure of ChitoGauze[®]PRO allows high surface area blood interaction throughout the dressing. The dressing is highly flexible and suitable for easy application to superficial as well as deep and narrow wounds. It readily conforms to wound surfaces with complex geometries to allow efficient staunching of all bleeding. The ChitoGauze[®]PRO dressing is also designed to aid with rapid deployment to the wound by a z-folded configuration that speeds application time when hemostasis is critical. ■

1. Olsen, R.; Schwartzmiller, D.; Weppner, W. Winandy R.; In *Chitin and Chitosan: Sources, Chemistry, Biochemistry, Physical Properties and Applications*; Skjak-Braek G.; Anthonen, T.; Sandford, P. *Biomedical Applications of Chitin and Its Derivatives*; 813-828; Elsevier Applied Science, London, New York 1989
2. Chou TC, Fu E, Wu CJ, Yeh JH, *Biochem. Biophys. Res. Comm.* 302, 480-483, 2003
3. *Studies conducted by Prof. John Whitelock, University of New South Wales, in conjunction with an Australian ARC Linkage Grant.*

Summary of ChitoGauze[®]PRO Features & Benefits

Introduction

With a proven military track record and a full understanding of battlefield needs, HemCon designed ChitoGauze[®]PRO as an efficacious and easy-to-apply dressing that maximizes the limited time before massive blood loss turns deadly. On the battlefield, every second counts when it comes controlling traumatic extremity bleeding, the #1 cause of preventable death in combat.

Indications for Use (Rx)

ChitoGauze[®]PRO is a hemostatic dressing for the external, temporary control of severely bleeding wounds.

Description of the Device

Composed of a polyester/rayon blend non-woven medical gauze that is coated with chitosan, the ChitoGauze[®]PRO dressing is z-folded and packaged in a rugged, vacuum-sealed, foil pouch with red tear notches. The pouched dressing is terminally sterilized with gamma irradiation to a sterility assurance level (SAL) of 10⁻⁶. The hemostatic properties of chitosan enhance the ability of the medical gauze to control bleeding (see *Mechanism of Action*, left). ChitoGauze[®]PRO offers antibacterial properties against a wide range of gram positive and gram negative organisms, including methicillin resistant *Staphylococcus aureus* ATCC33591 (MRSA), *Enterococcus faecalis* ATCC51299 (VRE) and *Acinetobacter baumannii* ATCC1530 (see page 5).

Biocompatibility

Biocompatibility has been demonstrated per ISO10993.

In Vivo Efficacy

In vivo testing evaluated the efficacy of ChitoGauze[®]PRO versus lap sponges, uncoated gauze and coated gauze (competitive) in an extreme trauma model. ChitoGauze[®]PRO exhibited equivalent or superior efficacy (see pages 3-4).

Antibacterial Properties

Method and results described on page 5.

Sterility

A sterility validation for ChitoGauze[®]PRO was completed following ISO 11137:2006 requirements to demonstrate a 10⁻⁶ SAL using the VDmax25 method. ■



NORTH AMERICAN RESCUE®
www.NARescue.com • 888.689.6277



HemCon ChitoGauze®PRO Instructions for Use

The highly flexible, hemostatic **ChitoGauze®PRO** is easily applied with minimum training required. These simple steps need to be followed.

Identify the source of bleeding and apply **ChitoGauze®PRO** onto and in direct contact with the source of bleeding. Continue packing the dressing completely into wound track.

Use enough **ChitoGauze®PRO** to fill the wound and come in contact with ALL bleeding surfaces.

- If all of the dressing does not fit into wound cavity, use excess dressing to back the wound site.
- For larger wounds, more than one dressing may be required.

Apply pressure until bleeding is controlled.

Wrap and secure dressing on wound to maintain pressure.

ChitoGauze®PRO is easily removed and does not cause tissue damage



Combining advanced research & product design to increase survivability on the modern battlefield

PORTLAND, OR – GREER, SC August 16, 2010 — HemCon Medical Technologies, Inc. (“HemCon”), an innovative developer of advanced medical products, and North American Rescue, LLC (“NAR”), a leading supplier of Tactical Combat Casualty Care (TCCC) solutions to the Department of Defense are pleased to announce a Strategic Alliance for the development of advanced tactical medical solutions. As part of this new partnership HemCon will serve to broaden the Medical Device Development capabilities of NAR by opening up new opportunities and resources in the TCCC arena and NAR brings its extensive product development, marketing and distribution knowledge of the tactical health care market. As part of this alliance HemCon has granted NAR the exclusive distribution rights of HemCon’s revolutionary ChitoGauze®PRO hemostatic dressings.

“HemCon is excited to form this partnership with NAR to expand the reach of our life-saving technology in the Department of Defense (DOD) and Foreign Military markets,” said John W. Morgan, CEO of HemCon Medical Technologies, Inc. “NAR’s strong military expertise

and relationships made it the ideal partner to continue bringing HemCon’s innovative technologies to the soldiers in need.”

“NAR believes that the ultimate goal is to continuously provide innovative solutions that will have a direct correlation to decreasing preventable death in Tactical Medicine and Rescue situations,” said Samuel D. Wyman III, President of North American Rescue, LLC. “In HemCon, we see the ideal partner that brings us advanced technology such as ChitoGauze®PRO that allows us to achieve our long term goals of providing the very best in life saving innovations on the modern battlefield.”

HemCon’s hemostatic dressings have been widely used by the DoD since 2003, and have demonstrated a high rate of effectiveness in controlling bleeding on the battlefield. The uniquely formulated gauze dressing impregnated with chitosan, ChitoGauze®PRO, offers the latest in battlefield care requirements through its convenient z-fold gauze design, strong hemostatic properties and unique antibacterial benefits.

NAR will use HemCon’s ChitoGauze®PRO platform and other technologies as the basis for the development of additional products and solutions intended to improve the standard of care for warfighters everywhere. ■