



axiostat[®]

stops bleeding, instantly

MIL88

**100% CHITOSAN
HAEMOSTATIC DRESSING**



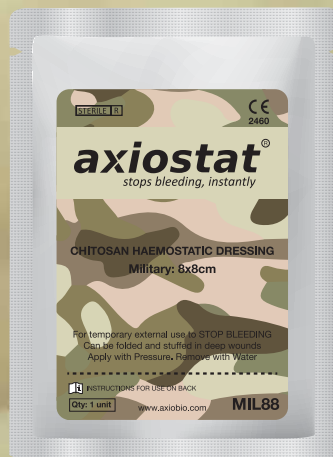
ISO
13485
CERTIFIED

CE
APPROVED

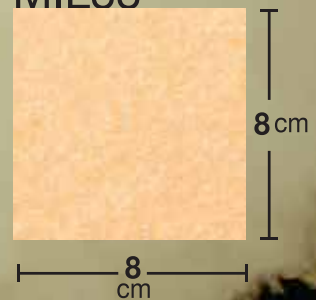
GMP
CERTIFIED

Halal
CERTIFIED

Extensively
used by
Defense Forces
Worldwide



MIL88



STOP BLEEDING, INSTANTLY.

100% CHITOSAN HAEMOSTATIC DRESSING

Sterile

Ready to Use

Can be cut, folded

& stuffed into deep wounds

Shelf Life

3 Years

Battlefield

proven technology

Painless removal

irrigate with saline

Extensively used by

Defense Forces worldwide



RECOMMENDED FOR:

- Gunshot wounds
- Puncture or Stab wounds
- Blast injuries
- Cuts, Lacerations, Abrasions
- Arterial and Venous bleeding
- Neck and Head Trauma injuries



MILITARY

Axiostat® MIL88 is designed to be used in battlefield conditions and comes in camouflaged, rugged metal pouch packing for easy carrying.

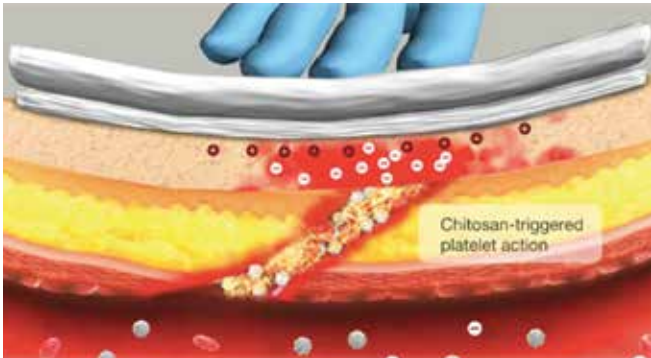
Axiostat® is currently used by Defense Forces, Paramilitary Forces & Army across India, Middle East and Europe.

MIL88 is capable of being folded and stuffed into deep wounds.

MIL88 uses a.c.t. which is battlefield proven technology to achieve hemostasis in a easier and quicker way. The product and technology assists forces to stop profuse bleeding caused due to on field calamities.



HOW AXIOSTAT WORKS

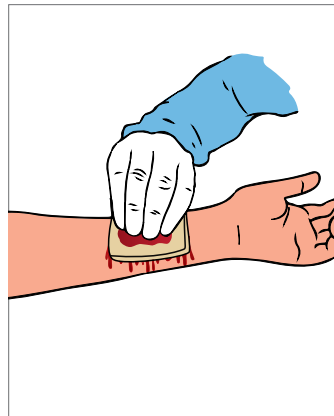


Once applied on a bleeding site, Axiostat forms a mechanical seal through its bioadhesive characteristics and prevents excessive blood loss. The carefully engineered porous structure of Axiostat then leads to quick absorption of plasma and concentration of cellular and protein components at the wound site. Finally, Axiostat immobilises the negatively charged blood cells through its cationic charge, resulting in platelet aggregation and clot formation at the wound site.

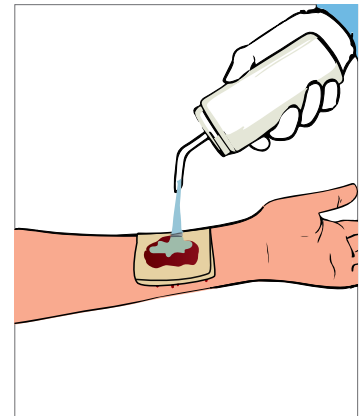
HOW TO USE AXIOSTAT

Wear Gloves and tear open the Axiostat pack. Apply Axiostat with cotton gauze on the top of the wound and apply pressure for at least 5 minutes. Apply secondary dressing to secure the area.

To remove, irrigate with saline/water and gently peel it off.

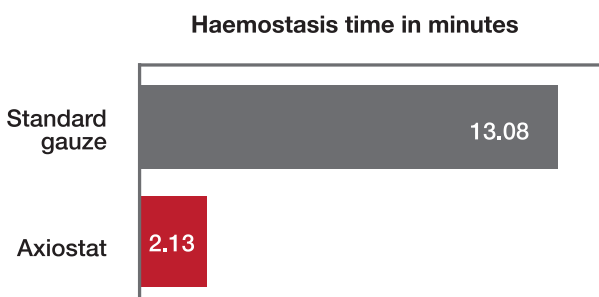


Apply Axiostat®
with Cotton Gauze on top

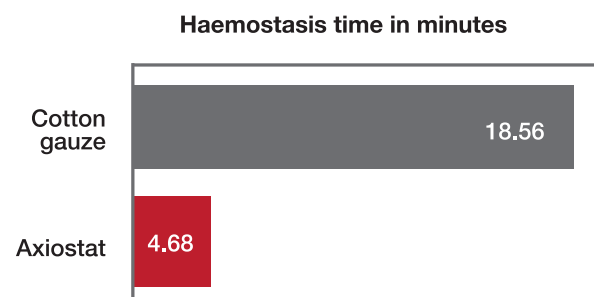


To Remove Axiostat®
Irrigate with saline
and gently peel it off.

CLINICAL DATA



Clinical Study on Trauma Patients
Published in Indian Journal of
Emergency Medicine
IJEM VOL.2 No.2 JULY-DEC 2016



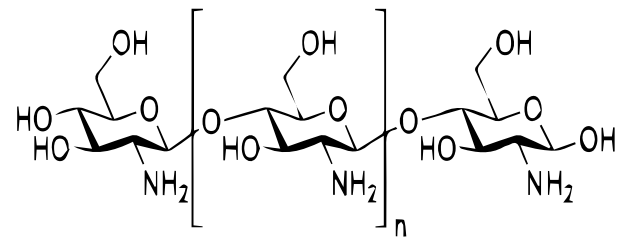
Clinical Study on Trauma Patients
Malabar Institute of Medical Science,
Calicut, Kerala, India

CHITOSAN - PHYSICAL & CHEMICAL PROPERTIES

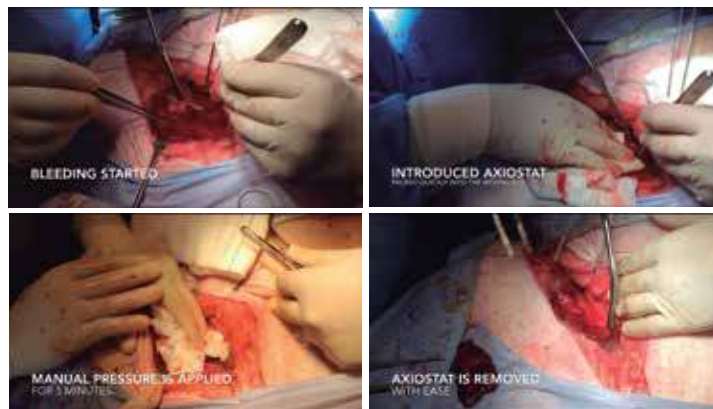
Chitosan is linear polysaccharide consisting of glucosamine and N-acetyl glucosamine chains and is derived mainly from shellfish. It has been used in many technical applications such as medical products, water purification, in cosmetics and as a fat-binding weight control product. Cationic nature of chitosan gives this polymer a mucoadhesive property which can be further activated for wound care applications. Chitosan salts are used as a matrix or scaffold material as well as in non-parenteral delivery systems for challenging drugs.

Characteristics of Chitosan:

- Biocompatible
- Bioadhesive
- 100% natural
- 0% protein
- No exothermic reaction
- Easily broken down to glucosamine



CONTROL OF ARTERIAL BLEEDING USING AXIOSTAT DRESSING ON SWINE MODEL



Adult white swines were selected to study the efficacy of Axiostat haemostatic dressing in controlling arterial bleeding compared to cotton gauze. The study was based on US Army protocol for worst case scenario bleeding.

Arterial puncture was made on the femoral artery of swines and was allowed to bleed

for 45 seconds. Axiostat was applied with pressure through a pool of blood. Haemostasis was observed after 5 minutes of using Axiostat. However, cotton gauze couldn't control bleeding even after 15 minutes.

After achieving haemostasis, Axiostat was easily extracted through saline irrigation.

ABOUT AXIO

Axio was founded in 2008 by Leo Mavelly, a bioengineer who developed novel biopolymer platform based products for wound care. Axio has the distinction to be the first company from India to design, develop and commercialize an Emergency Haemostat for Trauma care. Vision of Axio is to develop affordable, high impact medical products that can solve unmet healthcare needs of emerging markets.


Controlling life-threatening bleeding continues to be the major cause of death from traumatic injuries. Axiostat® is its flagship product developed to reduce the mortality due to traumatic bleeding. Axio is a ISO 13485 certified company with an experienced team focused on bringing high-impact medical products to market. Marquee investors such as ACCEL PARTNERS, IDG VENTURES have invested in Axio.

PATENT CERTIFICATE



CERTIFICATIONS

CE CERTIFIED



EC Certificate
Full Quality Assurance System

Certificate No.: 216694-2017-CE-IND-NA-PS Rev.2 Initial certification date: 21 June 2013 Valid: 21 June 2018

This is to certify that the quality system of:

Axio Biosolutions Pvt. Ltd.
Plot 18, Gujarat Pharma Techno Park,
Sari Matoda, Sanand Taluka,
Ahmedabad-382220, Gujarat, India

For design, production and final product inspection/testing of:
Chitosan Haemostatic Dressing

Has been assessed with respect to:
The conformity assessment procedure described in Article 11.1.a and Annex II (Module H1) of Council Directive 93/42/EEC on Medical Devices, as amended and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.


Place and date:
Hevik, 8 May 2017

For:
DNV GL NEMKO PRESAFE AS

Tone Kolpus
The Certificate has been digitally signed.
See www.dnvgl.com/verify for more info

MSDC-0243, Version 4.0 DNV GL NEMKO PRESAFE AS - Vertisveien 3, N-1363 Høvik, Norway - Registered Enterprise No. NO 997 067 401 MVA Page 1 of 2

ISO 13485 CERTIFIED



Management System Certificate

Certificate No.: 216691-2017-AO-IND-NA-PS Project No.: PRUC-554291-2016-49SL-ND Initial certification date: 23 January 2017 Valid until: 28 February 2019

This is to certify that the management system of:

Axio Biosolutions Pvt. Ltd.
Plot 18, Gujarat Pharma Techno Park,
Sari Matoda, Sanand Taluka,
Ahmedabad-382220, Gujarat, India

With sites as listed overleaf.

Complies with the requirements of:
ISO 13485:2003/NS-EN ISO 13485:2012

The Certificate is valid for the following scope:
Design, manufacturing and sales of chitosan haemostatic dressing


Place and date:
Hevik, 22 May 2017

For:
DNV GL NEMKO PRESAFE AS

Tone Kolpus
The Certificate has been digitally signed.
See www.dnvgl.com/verify for more info

MSDC-0243, Version 4.0 DNV GL NEMKO PRESAFE AS - Vertisveien 3, N-1363 Høvik, Norway - Registered Enterprise No. NO 997 067 401 MVA Page 1 of 2

HALAL CERTIFIED



HALAL INDIA CERTIFICATE

Product Name:
HIP25780817

Date of Expiry:
31 August 2018

This is to certify that the product(s) listed below have been certified Halal in accordance with Shari'ah (Islamic) Law and Guidelines.

Manufacturer/Company:
AXIO-BIO-SOLUTIONS PVT. LTD.

Product Name:
Chitosan Haemostatic Dressing

Ingredients:
Adherent, Hemostatic, Sanitizer, Instillate

Place of Origin:
Plot 18, Gujarat Pharma Techno Park,
Sari Matoda, Sanand Taluka,
Ahmedabad, Gujarat,
India.

The product(s) contains permitted ingredients, therefore is lawful for Muslim consumption.

The Certification validity is for one year from the date of issue. Kindly refer to the annexure of this certificate for the list of Halal certified products.

MSDC-0243, Ver 3.0 August 2017

GMP CERTIFIED



Food & Drugs Control Administration
BLOCK NO. 4, 1ST FLOOR, DR. JYRAJ MEHTA BHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA PIN: 382010

Certificate No.: **S-GMP/1709349**

G.M.P. CERTIFICATE

This is to certify that M/s. AXIO BIOSOLUTIONS PVT. LTD., PLOT NO. 18, GUJARAT PHARMA TECHNO PARK, SARI MATODA, TAL. SANAND, DIST. AHMEDABAD is holding valid drug manufacturing licenses in Form No. 25 bearing No. G/29/2176 issued by this administration under the provisions of Drugs & Cosmetics Act 1940 & Rules there under. Under the said license the firm is permitted to manufacture & sell drugs covered under the following categories:

Drug Form (s)	Category (ies)
Non absorbable chitosan dressing	Surgical Dressing

The firm has employed competent technical staff to undertake manufacturing & testing of the permitted drugs. They are following GOOD MANUFACTURING PRACTICES in manufacturing and testing as laid down under the REVISED SCHEDULE M - III of Drugs & Cosmetics Act 1940 & Rules There under. The manufacturing plant is subjected to inspection at suitable intervals by competent authority.

This certificate is valid from Dt: 15/09/2017 to 14/09/2019.

Dr. M. G. KOSHIAU
Commissioner
Food & Drugs Control Administration,
Gandhinagar, Gujarat State

Email: comfaca@gujarat.gov.in
Phone: 91-79-22553417, Fax: 91-79-225-23400

MANUFACTURED IN ISO 13485, GMP CERTIFIED FACILITIES

Axio products are manufactured in ISO 13845 certified facility owned and operated by Axio.

- State of the art manufacturing facility is located in Pharma tech park at City of Ahmedabad, Gujarat, India.
- Custom built imported machinery with 75-80% automated processing.
- Minimal human intervention reducing handling errors.
- 5000sq.ft cleanroom area built according to cGMP, FDA guidelines under Class 10000 manufacturing area.
- Gamma sterilization done terminally. Full traceability from finished product to raw material source.
- **ISO 13485, GMP Certified**
- All 3rd party vendors audited and qualified by EU notifying body.

We at Axio benchmark ourselves to global standards and follow appropriate regulatory guidelines in respective countries of operation. We follow a process that is based on a strong foundation of manufacturing quality standards, mutually beneficial relations with our customers, dealers and all professionals associated with us.



RESEARCH & DEVELOPMENT

Axio envisages a future where contemporary knowledge of biomaterials, medicine and engineering will be integrated in designing novel solutions to address the huge unmet need in management of trauma and chronic-infectious wounds.

We are a deep science medtech company with extensive R&D expertise in biomaterials. Our platform-based approach enables us to develop medical products that are engineered to enhance its efficacy even at higher scale. With such a vision, we introduced our first line of hemostatic products that are probably one of the best available trauma hemostats in the market today.

Axio's research philosophy is to translate the biomaterials research into real-world products and bring them to patients' bedside at an affordable cost. Here innovation is a daily practice as we explore uncharted territories in novel materials and technologies. The research & development team at Axio is developing novel solutions that are smarter, friendlier and quicker than the conventional products.



PUBLISHED CLINICAL PAPERS ON AXIOSTAT

Axiostat - A new generation Haemostatic Dressing for controlling acute Haemorrhage in accident victims: A Clinical Evaluation

AXIOSTAT® A NEW GENERATION HEMOSTATIC DRESSING FOR CONTROLLING ACUTE HAEMORRHAGE IN ACCIDENT VICTIMS: A CLINICAL EVALUATION

Mohamed Kabeer K.K., Venugopalan R.P., Subhash V.C., and Sajan K.S.
 Department of Emergency Medicine, Mubbar Institute of Medical Science Hospital, Calicut, India.
 Axiostat Biosolutions Pvt. Ltd., Bangalore, India. Email: info@axiostat.com

SUMMARY: Accidents and trauma are one of the leading causes of death and disability throughout the world. In developing countries like India, where emergency trauma care is still in its infancy, it accounts for almost 10% deaths every year. Lack of adequate pre-hospital care and uncontrolled bleeding from wound site are stated to be the prominent reasons for such deaths. In this study, we investigated the efficacy of a novel chitosan-based hemostatic dressing (Axiostat®, Axiostat Biosolutions, India), as a hemorrhage control device in pre-hospital scenario.

AXIOSTAT®: How does it work?

TREATMENT PROTOCOL

- The wound was carefully inspected prior to application for inclusion in the study.
- A randomly selected dressing, either Axiostat® or cotton gauze was placed on the bleeding wound.
- Moderate pressure was applied with fingers for about 2 minutes.
- When bleeding was persistent, second application of Axiostat® or Cotton gauze was used above the previous one.
- The Axiostat® dressing was kept for 30 minutes after complete hemostasis was achieved.
- It was then removed easily by applying saline or water on to it and gently lifting it off.
- Once hemostasis was achieved and dressing removed, patients were treated as per institutional standard of care.

STUDY DESIGN

A total of 104 patients with scalp injuries were enrolled for the study. The selected patients were randomly assigned into the test and control groups. The test group received Axiostat® (47 subjects) and the control group received the conventional cotton-gauze dressing (47 subjects). The dressing was applied as detailed in the treatment protocol. The time at which the blood oozing through or from periphery of the dressing stopped, was considered as the efficacy endpoint. Finally, the total blood loss from the wound was determined by measuring weight of the dressing after first application. The wound characteristics in selected patients are presented in adjacent charts.

RESULTS

The Axiostat® showed greater efficacy in controlling bleeding in comparison to the cotton gauze. The average time for hemostasis with cotton gauze was about 18.56 ± 5.04 minutes, while the Axiostat® achieved hemostasis in under 5 minutes (4.98 ± 1.04 min). Additionally, total blood loss from the wound site decreased by over 50% in Axiostat® treated patients compared to the control group. Additionally, no adverse reactions were reported with the use of Axiostat®. Cases of uncontrolled bleeding was observed in 01 subjects treated with cotton gauze and only 9 in Axiostat® treated group.

CONCLUSION

These results show that Axiostat® enables rapid hemostasis and can prevent significant blood loss during emergency trauma and accidents. Additionally, it also allows easier removal from the wound site without leaving any residue, which helps in rendering wound clean. In conclusion, the study successfully demonstrated the potential of Axiostat® as a first-line intervention in controlling acute hemorrhage in emergency care.

ACKNOWLEDGEMENTS

We thank the Emergency Medicine Department, Mubbar Institute of Medical Science Hospital (MIMS), Calicut, Kerala, for hosting this study.

Assessing the efficacy of Haemostatic Dressing Axiostat in Trauma Care at a Tertiary Care Hospital in India: A comparison with Conventional Cotton Gauze

Original Research Article
 Received on 10.11.2016, Accepted on 26.11.2016
 Indian Journal of Emergency Medicine
 Volume 2 Number 2, July - December 2016
 DOI: http://dx.doi.org/10.21889/ijem.2395.1111.2216.1

Assessing the Efficacy of Haemostatic Dressing Axiostat® In Trauma Care at a Tertiary Care Hospital in India: A Comparison with Conventional Cotton Gauze

Patel Kotan*, Patel Anjali**, Patel Rignesh**, Patel Bhavika**, Parmar Priyank***, Patel Dev****

Abstract

First aid is most urgent need to stabilize patient condition before any kind of intervention is sought. Scientists estimate the volume of blood in a human body to be approximately 7 percent of body weight. An observational study of 61 patients with bleeding wounds chosen by random assortment was carried out. All patients were divided in two groups: Group -I, Axiostat® (Chitosan Haemostatic Dressing) and Group -II, Conventional Cotton dressing. The patients were divided in both groups by 1:1 randomization. A total of thirty patients in group -I and thirty one patients in group -II were subjected to the study. A standard pattern was followed for application of dressing to bleeding wound in both groups and different parameters were recorded. Results showed that hemostatic time in group-I (Axiostat®) was 2.12981.35 minutes where in group-II (cotton gauze) it was 13.0866.40 minutes. Only 61% of patients who were applied with cotton gauze showed no rebleeding after removal whereas 83% patients showed no rebleeding after removal of Axiostat® in 30 minutes. Axiostat® could be easily applied and removal was also effective by application of saline where about 63% of patients showed an excellent ease of removal when only 10% of patients applied with cotton gauze showed excellent removal. The aim of this study was to evaluate the efficacy and safety of use of external hemostatic Axiostat® to control the flow of blood and attain haemostasis in comparison with conventional cotton gauze dressing.

Keywords: Axiostat®, Bleeding, Chitosan, Cotton, Dressing, Trauma.

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Evaluating the effectiveness of Axiostat hemostatic dressing material in patients on Oral platelet drugs

Chitosan based Axiostat dental dressing following extraction in Cardiac patients under Antiplatelet Therapy

10.5005/ijp-journals-10024-2130

ORIGINAL RESEARCH

the Journal
 OF CONTEMPORARY DENTAL PRACTICE

Evaluating Effectiveness of Axiostat Hemostatic Material in achieving Hemostasis and Healing of Extraction Wounds in Patients on Oral Antiplatelet Drugs

Saurabh Sharma, Tejraj P Kale, Lingaraj J Balhimath, Ashishak Motimath

Sinha A et al.: Chitosan based Axiostat Dental Dressing following Extraction in Cardiac Patients

CASE REPORT

Chitosan based Axiostat Dental Dressing following Extraction in Cardiac Patients under Antiplatelet Therapy

Nishant Sinha¹, Abok Muzumdar¹, Jaydip Mitra¹, Gunita Sinha¹, Shalabh Baurthiyal¹, Sharda Baurthiyal¹

1-C.M.P. Dental, K.G. Hospital (C.A.W.), 2-C.M.O. K.G. Hospital (C.A.W.), 3-B.D.M.O. K.G. Hospital (C.A.W.) A.S.B., Private Dental Surgery, Dr. Nishant Sinha, C.M.P. Dental, K.G. Hospital (C.A.W.), Contact: Dr. www.ijpdr.com

ABSTRACT

Aim: The aim of this study was to evaluate the efficacy of Axiostat Hemostatic Dental dressing in achieving hemostasis post-extraction and determining its effect on pain and healing of the extraction wound, compared with control, i.e., conventional method of extraction in patients on oral antiplatelet therapy.

Materials and methods: Totally, 40 patients on oral antiplatelet drugs were included in the study and over 80 extractions were done applying split mouth study design, without altering patients drug regime. Extraction sites were divided into two groups: Group I received Axiostat Hemostatic Dental Dressing (study site), and group II received conventional method; pre-

maxillofacial treatment, earlier concept of stopping these medications is associated with increased risk of thromboembolic event. The present study highlights an alternative approach using ADD which aids in quick hemostasis, accelerates healing, and reduce postoperative pain.

Keywords: Antiplatelet, Axiostat, Chitosan, Extraction, Hemorrhage, Wound healing

How to cite this article: Sharma S, Kale TP, Balhimath LJ, Motimath A. Evaluating Effectiveness of Axiostat Hemostatic Material in achieving Hemostasis and Healing of Extraction Wounds in Patients on Oral Antiplatelet Drugs. J Contemp Dent Pract 2017;18(9):802-805.

ABSTRACT

Hemostasis in cardiac patients following dental extraction under antiplatelet therapy is often challenging due to the risk of post extraction bleeding if it is not stopped or altered before extraction or risk of thromboembolism if they are stopped or altered before extraction. The various hemostatic measures that are traditionally being used in patients following dental extractions, Chitosan based dental dressing (AXIOSTAT) is a milestone, which is being increasingly used by many dental surgeons. 50 cardiac patients undergoing single tooth extraction in dental clinic of the railway hospital without stopping or altering the antiplatelet therapy and AXIOSTAT dental dressing was placed in the extracted socket for Hemostasis. Patients were checked for the effectiveness of AXIOSTAT as a hemostatic measure in the study. All patients who underwent extraction under the protocol that we followed showed the average hemostatic time in all the patients was 1.5 minutes. None of the patients showed thrombotic bleeding in this study. The Chitosan based AXIOSTAT dental dressing is a wonderful hemostatic agent that is routinely being used in many fields but due to lack of awareness among dental surgeons it is less used in dentistry. This study will certainly be one small step in this matter, but a thorough study is needed to check for the effectiveness of Chitosan based AXIOSTAT dental dressing in other surgical extraction and different oral surgery procedures.

KEYWORDS: Axiostat Dental Dressing, Antiplatelet Therapy, Extraction, Hemostasis

GLOBAL HAEMOSTATS COMPARISON

Brand Name	Axiostat	Quik Clot	Celox	Surgicel	Spongostan
Form Factor	100% chitosan sponge	Granules, Coated Gauze	Granules, Coated Gauze	Gauze	Sponge
Active Ingredient	Chitosan	Kaolin, Zeolite	Chitosan	OR Cellulose	Gelatin
Stop Bleeding capability	Moderate to severe bleeding	Moderate to severe bleeding	Moderate to severe bleeding	Mild bleeding	Mild bleeding
Mechanism of action	100% active ingredient, Stuffable, No risk of emboli. Suitable for deep wounds	Irritation and Heat generation. Risk of emboli formation due to dispersion into blood.	Risk of emboli formation due to dispersion into blood.	Only suitable for surgical bleeding	Only suitable for surgical bleeding
Ease of removal	Easily removed using water/saline	Very difficult	Very difficult	Absorbed in the body	Absorbed in the body
Type of bleeding	External	External	External	Internal	Internal

TESTIMONIALS

**Dr. Narendra Kohli, Chief Medical Office,
Border Security Force, Chattisgarh, India**

“Myself used Axiostat blood clotting patches in operational area in Baster Dist. of Chattisgarh. I used these pads on several personnel who were injured in IED Blast and witnessed a good result of these pads”

**Dr. K.S Kumar, Commandant Medical,
Border Security Force, Jammu & Kashmir, India**

“Axiostat is a wonderful product which we used during Gunshot wounds and helped to stop bleeding. This product has great scope in battlefields to help in controlling bleeding instantly and save lives”

**Commandant Medical, Head Quarters,
Assam Rifles, India**

“It is to inform you that Axostat, which was sent to us was experimented by our doctor and found that bleeding stopped within 3 minutes. It is also found that there is not any toxic effect observed while conducting the test and no post applying infection found”.

**Colonel,
112Bn BSF, Rajasthan, India**

“This is to inform you that we had procured Axiostat and was sent for election duty. It was used in one of the accidental cases and it worked very well compared to Quikclot. There was no smell and easy to use”

A Special Report on the Chitosan-based Hemostatic Dressing: Experience in Current Combat Operations

The Journal of Trauma, 2006, 60, 655-658

Ian Wedmore, MD, John G. McManus, MD, MCR,
Anthony E. Pusateri, PhD, and John B. Holcomb, MD

Background: Hemorrhage remains a leading cause of death in both civilian and military trauma patients. The HemCon chitosan-based hemostatic dressing is approved by the US Food and Drug Administration (FDA) for haemorrhage control. Animal data have shown the HemCon dressing to reduce haemorrhage and improve survival. The purpose of this article is to report preliminary results of the hemostatic efficacy of the HemCon dressing used in the prehospital setting on combat casualties.

Methods: A request for case information on use of HemCon dressings in Operation Iraqi Freedom and Operation Enduring Freedom was sent to deployed Special Forces combat medics, physicians, and physician assistants.

Results: Sixty-eight uses of the HemCon dressing were reported and reviewed by two US Army physicians. Four of the 68 cases were determined duplicative resulting in a total of 64 combat uses. Dressings were utilized externally on the chest, groin, buttock, and abdomen in 25 cases; on extremities in 35 cases; and on neck or facial wounds in 4 cases. In 66% of cases, dressings were utilized following gauze failure and were 100% successful. In 62 (97%) of the cases, the use of the HemCon dressing resulted in cessation of bleeding or improvement in hemostasis. There were two reported dressing failures that occurred with blind application of bandages up into large cavitation injuries. Dressings were reported to be most useful on areas where tourniquets could not be applied to control bleeding. The dressings were reported to be most difficult to use in extremity injuries where they could not be placed easily onto or into the wounds. No complications or adverse events were reported.

Conclusion: This report on the field use of the HemCon dressing by medics suggests that it is a useful hemostatic dressing for prehospital combat casualties and supports further study to confirm efficacy.

A photograph of a forest scene. In the foreground, a soldier in a green uniform and helmet is kneeling on the ground, attending to a person lying face down. Another soldier stands nearby, holding a rifle. The background is filled with tall trees and a thick mist or smoke, creating a somber and urgent atmosphere. The text 'Stop Bleeding, Save Lives.' is overlaid on the top left of the image.

Stop **Bleeding,**
Save **Lives.**

axiostat[®]
stops bleeding, instantly




AXIO

INSPIRED MED - TECH


Axio Biosolutions Private Limited

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 / axiobio

www.axiobio.com

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