

Masterclass GUIDES

Topical External Haemostat:

OMNI-STAT®

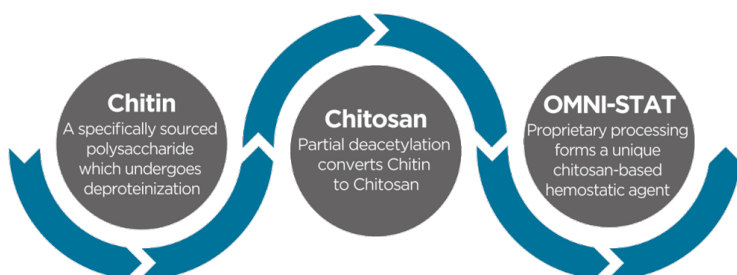
Introduction

This Masterclass Guide is a concise overview aimed at exploring the use of a temporary topical external hemostat, and how to incorporate this in to your clinical practice.

What Is OMNI-STAT®?

- Hemostasis is the first stage of wound healing process and data supports that chitosan and its derivatives have been shown to a positive effect¹
- Bleeding control is essential in any clinical setting, and safety in performing tasks such as sharp debridement in the OR and in the Wound Clinic is essential
- **Rapid bleeding control enables the clinician to quickly advance to the next stage of wound healing**
- OMNI-STAT® is **intended for minor external bleeding from wounds and procedures: for temporary topical dressing for bleeding control associated with minor wounds**
- This unique technology involve hemostatic agents that offer **fast and effective solution for minor, moderate and severe bleeding**
- OMNI-STAT® is derived from the proprietary processing to form a unique chitosan based hemostatic agent
- CELOX™ vascular is indicated for the local management and control of surface bleeding from vascular access sites to percutaneous
- Firstly, a specific source of chitin is selected, followed by its deproteinization
- Then it is converted into chitosan via partial deacetylation
- This **may improve quality of granulation tissue at the wound site.**² It is **safe and easy to use with no adverse events reported**³

Figure 2: OMNI-STAT® products are chitosan derived hemostats.



Keywords

- Wound repair
- Rapid bleeding control
- Hemostatic agents
- Temporary Topical External Hemostat
- Surgical and non surgical wounds
- Chitin
- Chitosan
- Blood clotting mechanism

Figure 1: OMNI-STAT® Gauze, left, and Granules, right



How Does OMNI-STAT® Work?

- The **granules hold very high surface area**
- When they come into contact with blood, they **absorb fluids and concentrate platelets to form a gel like clot**
- The gel like clot **plugs the bleeding source, essentially sealing up the wound**
- This newly created physical barrier, as well as the activation of platelets via platelet concentration, enable OMNI-STAT® and CELOX™ **in the stoppage of bleeding, and reduces chances of a rebleed**⁵
- **Mechanism is independent of the body's normal clotting mechanism**
- **Works in hypothermic conditions**
- **May offer benefits that aid patients with impaired coagulation**
- **Controls minor moderate severe bleeding in as quickly as a minute**⁶
- **Effective in the presence of common anticoagulants, and clotting dysfunction**⁷
- **Does not damage healthy tissue**⁸

Method and instructions for OMNI-STAT® and CELOX™

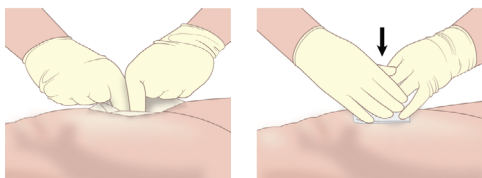
OMNI-STAT® and CELOX™ are cleared for use under the supervision of a healthcare professional.

Wound Care	Trauma and Critical Situations	Emergency Departments	Hard to Control Bleeding Areas	Operating Rooms
<p>OMNI-STAT® gauze and granules may be used for:</p> <ul style="list-style-type: none"> • Diabetic Foot Ulcers • Venous Stasis Ulcers • Pressure Ulcers • The properties of OMNI-STAT® may enable the specialist to perform more aggressive sharp debridement on high-risk anticoagulated patients, in an outpatient or inpatient setting⁴ 	<p>CELOX™ Z-Fold Gauze may be used in the setting of:</p> <ul style="list-style-type: none"> • Arterial injuries • Road traffic accidents <p>CELOX™ may be used for:</p> <ul style="list-style-type: none"> • Knife trauma • Bullet or shrapnel wounds • Venous and arterial bleeding • Complex or irregularly shaped injuries 	<p>Granules can be used for:</p> <ul style="list-style-type: none"> • Hair-bearing areas • Skin tears • Lacerations • Avulsions • Punctures 	<p>The technology can also be used for:</p> <ul style="list-style-type: none"> • Bleeding that's hard to control • Anticoagulant patients • Vascular access sites • Bleeding fistulas • Areas that could be difficult or impossible to pack with standard gauze 	<p>Any products may be used:</p> <ul style="list-style-type: none"> • To control external bleeding • Exudate from sutures • Surgical procedures such as amputations • Post sharp debridement • Split thickness donor sites • Cath lab, interventional/radiology, dialysis centres <p>CELOX™ Vascular can be used for:</p> <ul style="list-style-type: none"> • Local management and control of surface bleeding from vascular access sites • Percutaneous catheters or tubes utilizing introducer sheaths up to 16 French

OMNI-STAT® Gauze (4in x 4in)

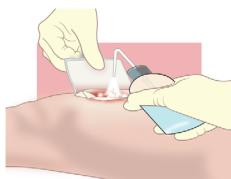
How to Use/ Recommendations for Removal

- 1 Tear open OMNI-STAT® gauze pack. Blot away any excess blood or exudate from the wound.
- 2 Apply pre-folded OMNI-STAT® onto the wound to cover the entire bleeding area. OMNI-STAT® should be applied directly to the source of bleeding.
- 3 If bleeding source is below the wound surface, then OMNI-STAT® gauze can be unfolded and tightly packed into wound.
- 4 Apply firm pressure for 1 to 3 minutes depending on the severity of the bleeding. If bleeding continues apply pressure for 3 more minutes. If OMNI-STAT® gauze becomes saturated then use an additional OMNI-STAT® gauze pack.



Removal Instructions:

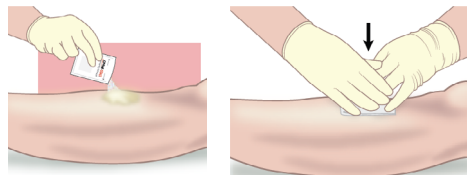
At first dressing change after use, OMNI-STAT® should be cleansed and removed from the wound using standard wound cleansing protocols. If required OMNI-STAT® should be soaked with saline prior to removal (physically) and then any residual irritated away with water or saline.



OMNI-STAT® Granules (3g)

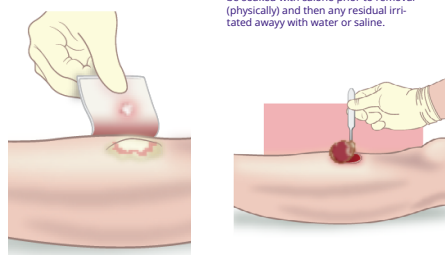
How to Use/ Recommendations for Removal

- 1 Peel open OMNI-STAT® outer pouch and remove inner pouch.
- 2 Tear open OMNI-STAT® inner pouch. Blot away any excess blood or exudate from the wound.
- 3 Pour enough OMNI-STAT® onto the wound to cover the entire bleeding area. OMNI-STAT® should be applied directly to the source of bleeding.
- 4 Quickly cover with gauze and apply firm pressure for 1 to 3 minutes depending on the severity of the bleeding. If bleeding continues apply pressure for 3 more minutes. If further OMNI-STAT® is required use an additional pouch.



Removal Instructions:

At first dressing change after use, OMNI-STAT® should be cleansed and removed from the wound using standard wound cleansing protocols. If required OMNI-STAT® should be soaked with saline prior to removal (physically) and then any residual irritated away with water or saline.



What Is the Evidence?

Various studies and trials to portray the efficacy and reliability of the OMNI-STAT® and CELOX™ products. **OMNI-STAT® and CELOX™ are brand names of equivalent proprietary chitosan technology.**

Hemorrhage Control

- In an animal study conducted by Kozen et al., a standard industry model of a complex groin injury with transection of the femoral vessels and 3 minutes of uncontrolled bleeding was created in 48 swine.
- Results show that OMNI-STAT® significantly improved hemorrhage control and survival⁹**
- Rall et al. report that in independent in-vivo test conducted, subjects treated with CELOX™ (OMNI-STAT®)* Gauze demonstrated the **highest rate of observed survival with 90% when compared to the current standard of care**, Combat Gauze demonstrated a 60% survival rate. CELOX™ (OMNI-STAT®) also has a substantial history of use on the battlefield (with conventional and special forces) and has repeatedly proven itself in austere settings¹⁰
- A study by Millner et al. supports the evidence that OMNI-STAT® **acts independently of classical clotting pathways and should be effective in patients with clotting dysfunction, who suffer major hemorrhage¹¹**

Vascular Access

- Eason et al. found that CELOX™ Vascular **resulted in 100% hemostasis following 5 minutes compression**. It performed considerably better than both the standard gauze negative control (57% n=7) and the D-Stat Dry positive control (67% n=9).
- Johnson et al. assessed CELOX™ in two in vivo wound models, a lethal wound model of arterial bleeding in 6 subjects and a vascular closure site. Results showed **100% survivability and 0 occurrence of re-bleed**. CELOX™ was effective in both stopping the major arterial bleeding and in sealing the simulated vascular closure site¹²

Wound Care

- Snyder et al. report that OMNI-STAT® statistically **significantly reduced time to hemostasis vs standard gauze**. Mean time to hemostasis for OMNI-STAT® was 1 min 19sec. The quality of the **granulation tissue of the wound after 1 week was significantly improved (90%)** and pain scores evaluated showed **virtually no pain upon application or removal¹³**

Figure 3: OMNI-STAT®: Time to Hemostasis.

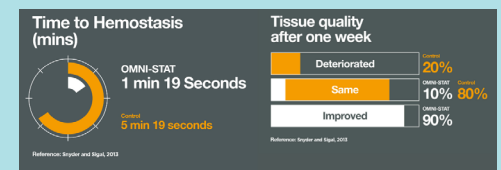


Figure 4: OMNI-STAT®: Case images.



Key Points^{11,12,13}

- Fast, safe, easy to use and effective
- Proven to control bleeding on a broad variety of wounds
- Controls bleeding even in the presence of common anticoagulants
- Shows many of the characteristics of an ideal hemostat
- Cost-effective

*"...the clots are stronger compared to clots formed in the control group and may provide an extra margin of safety in the presence of elevated blood pressures."*¹²

*"Use of a chitosan-based hemostatic agent was able to achieve hemostasis in patients on anticoagulant therapy who required aggressive surgical debridement, including debridement of bone, and in two patients who had an elevated or near critical INR level."*¹⁶

References

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Useful Links

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Visit the OMNI-STAT® website

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Masterclass Guides: Wound Masterclass. Chitosan Based Haemostat: OMNI-STAT®. Volume 1. No 3. December 2022