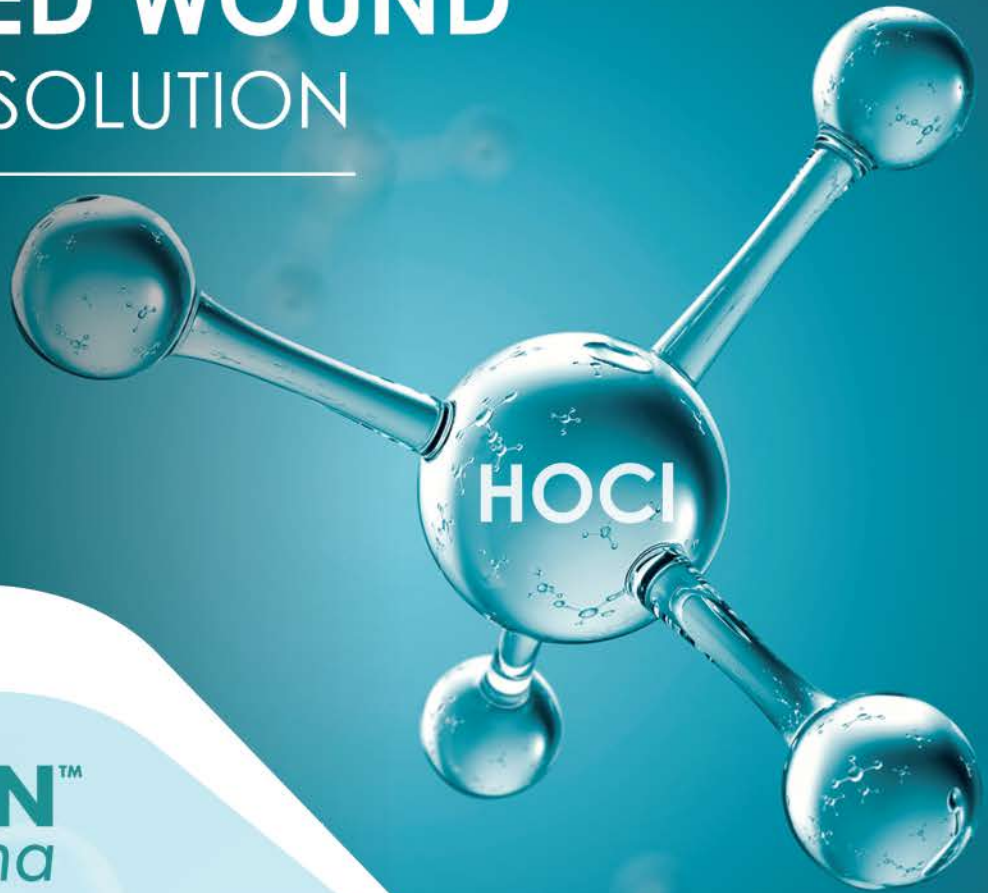


PERFORMANCE STABILIZED HOCl

ADVANCED WOUND IRRIGATION SOLUTION

For Managing Acute And Chronic Wounds



ELECTROCYN™

sōma



MANAGING WOUND BED BIOBURDEN
FOR SAFE AND NATURAL
WOUND HEALING

Cleansing
Debridement
Irrigation



V3bio

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6/962-07/2021


1. INTRODUCTION

Wound cleansing provide optimal healing environment and decreases the risk of infection on wound site. The process loosens and washes cellular debris including purulent material, exudates, pus, residual from previous dressings and reduces bioburden. In addition, routine wound cleansing provides better visibility and monitoring of wound condition.

a. Choosing the right solution

The ideal solution for wound cleansing should be :

- » Safe and non-toxic to healing tissue
- » Biocompatible (non-cytotoxic, non-irritant, non-sensitizer)
- » Able to manage wound bioburden (acts against wide range of microbes)
- » Does not create antimicrobial resistance
- » Compatible with wound dressing
- » No contraindications
- » Neutral pH (not too acidic or too alkaline)
- » Universal application – suitable for all type of wound
- » Suitable for long term use without adverse effect
- » Reduce wound odour
- » Effective against biofilm



b. Clinical findings with other chemical-based wound cleanser*

Clinical findings on various wound antiseptis solution indicates that hypochlorous based wound care solution has positive clinical outcomes as compared to other chemical based wound care solution.



Criteria	HOCl	OCT	PHMB	PVP-I
Peritoneal lavage	Possible (No contraindication)	Contraindicated	Contraindicated	Contraindicated
Applicability in CNS tissue	Possible (No contraindication)	Contraindicated	Contraindicated	Toxic
Applicability on cartilage	Possible (No contraindication)	Contraindicated	Only at 0.005 %	Possible

HOCl : Hypochlorous acid

OCT : Octenidine dihydrochloride

PHMB : Polyhexamethylene biguanide

PVP-I : Povidone iodine

Source: *Consensus of Wound Antisepsis Update, Skin Pharmacol Physiol, 2018:3128-58*

Agency for Health Care Policy and Research (AHCPR) guidelines [discourages the use of antiseptics solutions such as povidone idonine, hydrogen peroxide or sodium hypochlorite](#). This is due to the fact that these conventional chemical based solution are [not effective at killing microbes at concentrations that are safe to healing tissues](#).

2. THE ADVANCED WOUND CARE SOLUTION

ELECTROCYN sōma is an electro-activated super oxidized water based solution (EASW) for cleaning, irrigation and debriding of wound. This advanced wound care solution can be applied on all types of acute and chronic wounds, making it one of the most versatile and safest solution for managing wound.

ELECTROCYN sōma is biocompatibility tested, non-irritant and ready to use without any need for dilution since it's manufactured at safe and effective concentration. The hypochlorous acid (HOCl) ensures safe preservation of the solution, preventing proliferation of microbes within the solution.

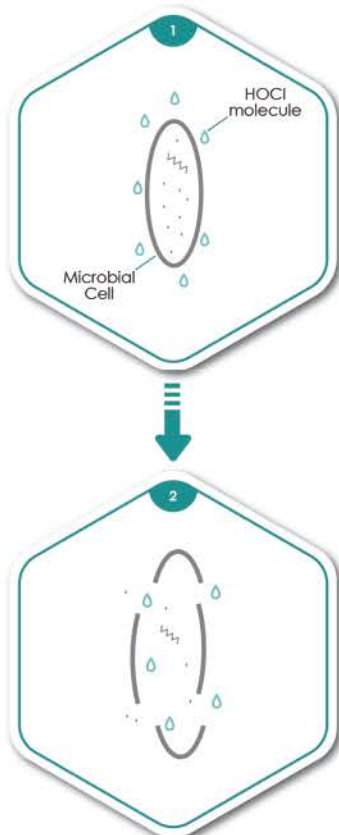


Key features

- » Antimicrobial against bacteria, virus, fungi, yeast and spore
- » Effective against biofilms
- » pH neutral and safe concentration of HOCl optimal for safe wound healing
- » Biocompatibility tested including oral and inhalation
- » Does not cause antimicrobial resistance (AMR)
- » Suitable for all types of wounds (chronic and acute) and dressing types
- » Can be used directly without requiring any dilution

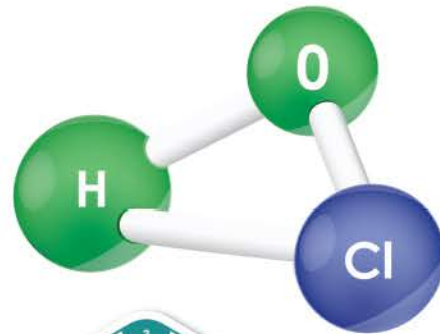
a. Mode of action

Hypochlorous acid is a weak acid that is naturally produced by white blood cells (neutrophils) and is an essential part of immune system. Upon contact with microbes, neutrophils release a burst of bactericidal substance including its most powerful oxidizing agent HOCl that disrupts cell wall of microbes. **ELECTROCYN sōma** contains safe and optimal concentration of pH stabilized hypochlorous acid that is produced using proprietary electro-activated technology



Disrupts the cell wall structures.

The neutral hypochlorous acid in **ELECTROCYN sōma** attacks the negatively charged cell wall of the microorganism and increases its permeability.



Creates osmotic gradient.

A hypotonic solution causes water to flow into the cells to equalise the osmotic gradient.

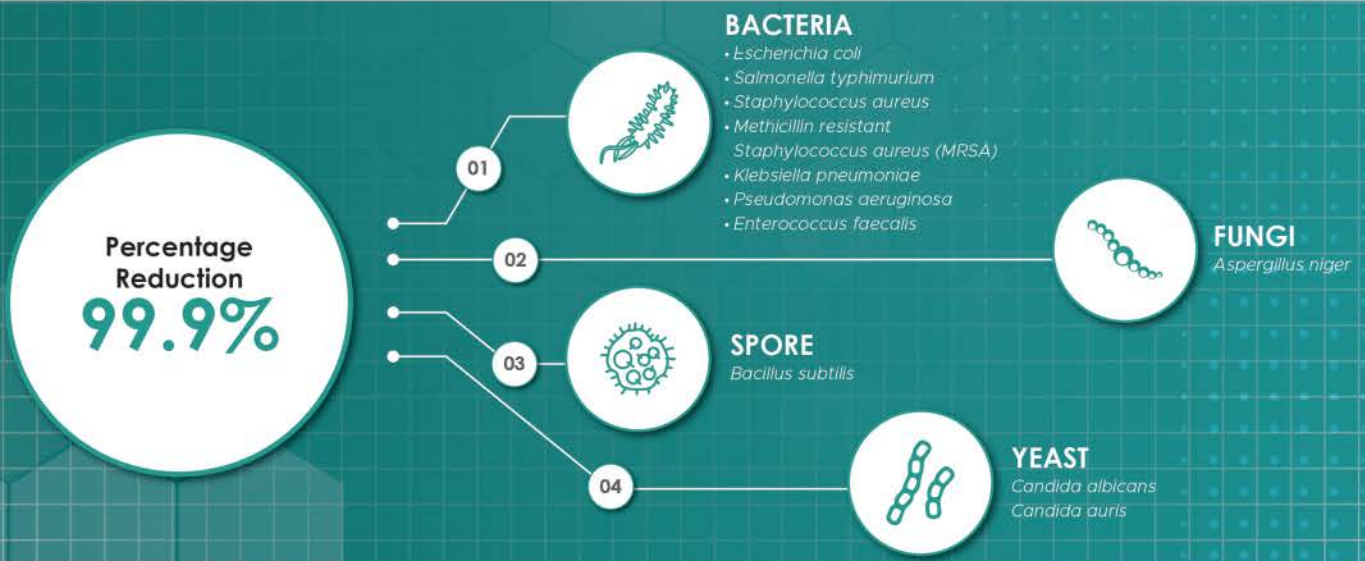
Osmolysis leads to cell rupture.

The result is osmolysis: the increasing internal pressure causes the cells to burst.

3. EFFICACY DATA

a. Antimicrobial efficacy

In-vitro test using Time-Kill Method, shows **ELECTROCYN sōma** able to reduce up to 99.99% of microbes. The test complies as per international test method ASTM E2315 (*Standard Guide for Assessment of Antimicrobial activity using Time-Kill Procedure*)



Clinical research data on various parameters including on-set time, resistance development and systemic risk has been compared among various wound irrigation solution:

HOCl has one of the lowest antimicrobial on-set time with no antimicrobial resistance, while supporting wound healing with no systemic risk of sensitization.

Criteria	HOCl	OCT	PHMB	PVP-I	Ag+	CHD
Antimicrobial on-set time	30 s - 5 min	3 hr - 10 hr	3 hr - 10 hr	30 min	> 24 hr	3 hr - 10 hr
Development of resistance	NO	NO	NO	NO	YES	YES

HOCl : Hypochlorous acid

PHMB : Polyhexamethylene biguanide

Ag+ : Silver ion based solution

OCT : Octenidine dihydrochloride

PVP-I : Povidone iodine

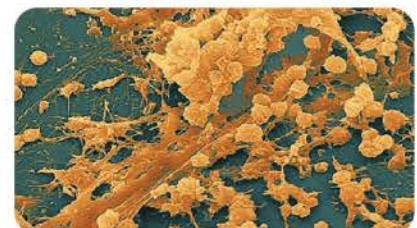
CHD : Chlorhexidine digluconate

Source: *Consensus of Wound Antisepsis Update, Skin Pharmacol Physiol, 2018:3128-58*

b. Efficacy against biofilm

Biofilms are complex colonies of microorganisms that serve as protective coatings for microbes to shield them from unfavourable environments such as heat, ultraviolet light, cold, disinfectants and antibacterial drugs used in health care. **ELECTROCYN sōma** has passed the biofilm removal efficacy test tested against *P. aeruginosa* and MRSA biofilm according to ASTM E2799 Standard. **Result shows a 99% reduction of biofilm thus reduces risk of biofilm related infections on wound.**

99% Reduction In Biofilm



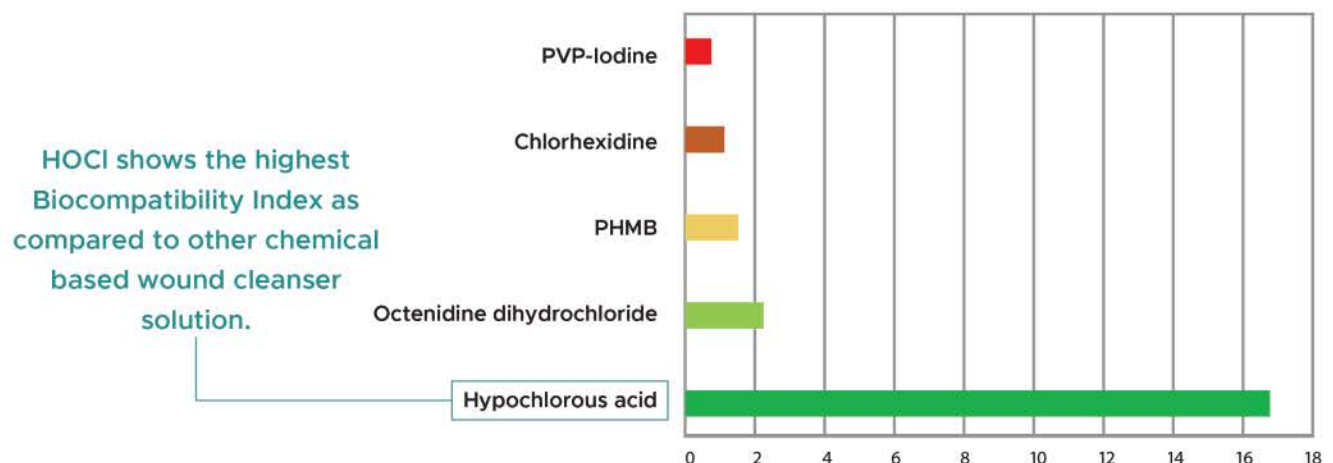
4. BIOCOMPATIBILITY STUDY

ELECTROCYN sōma, has undergone full spectrum biocompatibility study for medical devices as per ISO 10993. The results shows that **ELECTROCYN sōma** does not elicits skin irritation/sensitization and found to be non-toxic even if inhaled or ingested.



Study	Results	Conclusion
Skin Sensitization	No gross pathological changes observed	ELECTROCYN sōma is non-sensitizer to skin
Skin Irritation	No evidence of irritation when applied topically	ELECTROCYN sōma is non-irritant to skin
Acute Dermal Toxicity	No clinical signs of dermal toxicity	ELECTROCYN sōma does not causes dermal toxicity
Intracutaneous reactivity	No skin reactions observed	ELECTROCYN sōma is non-irritant
Genotoxicity	Non-clastogenic and non-auneugenic in cultured human lymphocytes in short and long term treatments	ELECTROCYN sōma has no risk of genotoxicity
Cytotoxicity	No reactivity observed on fibroblast cells	ELECTROCYN sōma is non-cytotoxic
Oral toxicity	No clinical signs of toxicity or pathological changes were observed	ELECTROCYN sōma is non-toxic to oral mucosa
Ocular Irritation	No gross pathological changes observed	ELECTROCYN sōma is non-irritant to eyes
Inhalation Toxicity	No related clinical signs of toxicity or mortality observed	ELECTROCYN sōma is non-toxic
Vaginal Irritation	Irritation index found to be zero	ELECTROCYN sōma is non-irritant

Biocompatibility index (BI) refers to the ratio of mean inhibitory concentration on L929 cells and of the concentration causing log reduction of microbial CFU. Study reveals that a **BI of > 1 indicates a solution with positive benefit over risk ratio**. An index of < 1 would mean a high risk outweighing any benefits.



Source : Consensus of wound antisepsis Update 2018, Skin Pharmacol Physiol 2018;31:28-58

5. CLINICAL EVIDENCE ON SAFETY AND EFFICACY

Various studies reveal that in comparison to chemical based wound irrigation such PVP-I and Ag, hypochlorous acid (HOCl) wound irrigation is found to be more effective in :

- » Faster wound healing and improved granulation
- » Fewer persistent infections
- » Reduced pain and wound malodor
- » Reduced use of antibiotics
- » Reduced treatment time and hospitalization



Comparison	Type of Wound	Findings
HOCl vs NaCl ¹	Laparotomy/ Peritonitis	HOCl: significant prevention of surgical site infection (SSI)
HOCl vs NaCl ⁶	Diabetic wound	HOCl : significant reduction in wound size and hospitalization, improvement in wound score
HOCl vs PVP-I ^{4,8}	Diabetic foot ulcer	HOCl: significantly better wound healing and control of infection, reduced treatment time
HOCl vs PVP-I ⁷	Diabetic foot ulcer	HOCl : significant reduction in malodor, reduction in infection, improved granulation and lower occurrence of erythema
HOCl vs PVP-I ^{3,5,10}	Chronic wound, SSI	HOCl: significant wound size reduction, fewer persistent infections from <i>P.aeruginosa</i> , <i>S.aureus</i> and <i>Klebsiella spp</i> , reduced pain score and hospitalization
HOCl vs PVP-I ²	Diabetic foot ulcer, VLU, burns	HOCl: faster granulation , reduction in wound size and surrounding edema, better cosmetic results in burn wounds
HOCl vs Ag+ ⁹	Burns	HOCl: 11% reduction in use of antibiotics, 50% reduction in hospitalization

Reference / Source

- 1) Evaluation of intraoperative peritoneal lavage with super-oxidized solution and normal saline in acute peritonitis. *Arch Int Surg*
- 2) Evaluation of effect and comparison of superoxidised solution (Oxum) v/s povidone iodine (Betadine). *Indian J Surg* 2011
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- 8) Use of a new antiseptic agent for the local treatment of diabetic foot ulcers. *J Wound Heal* 2005
- 9) Treatment of 2nd and 3rd degree burns in 64 pediatric patients without routine antibiotics using new "super-oxidized solution technology." *Texas Surgical Society Congress, San Antonio, April 1-3, 2005*
- 10) Treatment of surgical site infection with aqua oxidation water: comparison with povidone iodine. *Acta Medica Nnagasakiensia* 2001

6. INDICATIONS

- » For cleaning and irrigation of **chronic wound** such as diabetic foot ulcer, pressure ulcer, bed sore, venous leg ulcer (stage I-IV)
- » For cleaning and irrigation of **acute wound** such as lacerations, cuts, burns (1st and 2nd degree) and surgical wounds.



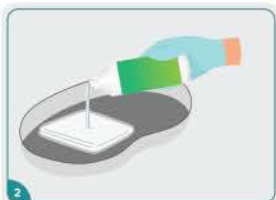
7. DIRECTIONS FOR USE

ELECTROCYN sōma is suitable for regular wound cleaning due to its non-toxicity, non-irritant and supports safe wound healing the solution reduces microbial load on wound and enhances granulation tissue.



Apply ELECTROCYN sōma directly to the wound

Spray or pour directly into the wound until point of saturation. This action helps to moisten the wound and assist removal of debris and other visible contaminants. **ELECTROCYN sōma** should be used directly without any dilution.



Irrigate while cleaning and debriding

Soak a gauze or cleaning pad with **ELECTROCYN sōma** in a kidney dish. Manually clean the wound with light abrasion. Continue to irrigate to remove wound debris until it's cleared sufficiently, and wound bed is ready for dressing.



Wound bed cleaning

In wounds that require more critical management, apply **ELECTROCYN sōma**-soaked gauze into the freshly cleaned wound and leave for 10-15 minutes. This action increases the contact time to have sufficient antimicrobial effect on the wound. If wound packing is required, **ELECTROCYN sōma** is suitable for soaking the packing medium before placement and it's compatible with all types of wound dressing.

ELECTROCYN™ sōma

Advanced wound management solution

PRODUCT RANGE



1,000 ml

Type:
CAP CLOSURE

Ref: ES7100W



500 ml

Type:
CAP CLOSURE

Ref: ES5100W



250 ml

Type:
CAP CLOSURE

Ref: ES4100W



250 ml

Type:
TRIGGER SPRAY

Ref: ES4400W



100 ml

Type:
MIST SPRAY

Ref: ES3300W



30 ml

Type:
MIST SPRAY

Ref: ES1300W

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