Cutimed® Sorbact®

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Cutimed® Sorbact®

Basics about wound infections

Factors Affecting Wound Healing

- **Patient Related Risk Factors**
  - Age
  - Nutrition
  - Underlying diseases
  - Medication
  - Psycho-social factors
  - Pain

- **Wound Related Risk Factors**
- Areas to consider:
  - Wound duration
  - Size and depth
  - Anatomical location
  - Inflammation
  - Infection
  - Wound bed condition

When do Micro-organisms Cause a Problem?

- Most micro-organisms are found in / on healthy individuals
  - eg: skin flora, gut flora

- Harmless in their usual habitat, bacteria even provide protection against pathogenic species
  - Carriers are unaware of them

- Infection is caused if micro-organisms are transferred to other parts of the body
  - Unnatural habitat, e.g. in a wound

Typical Wound Pathogens

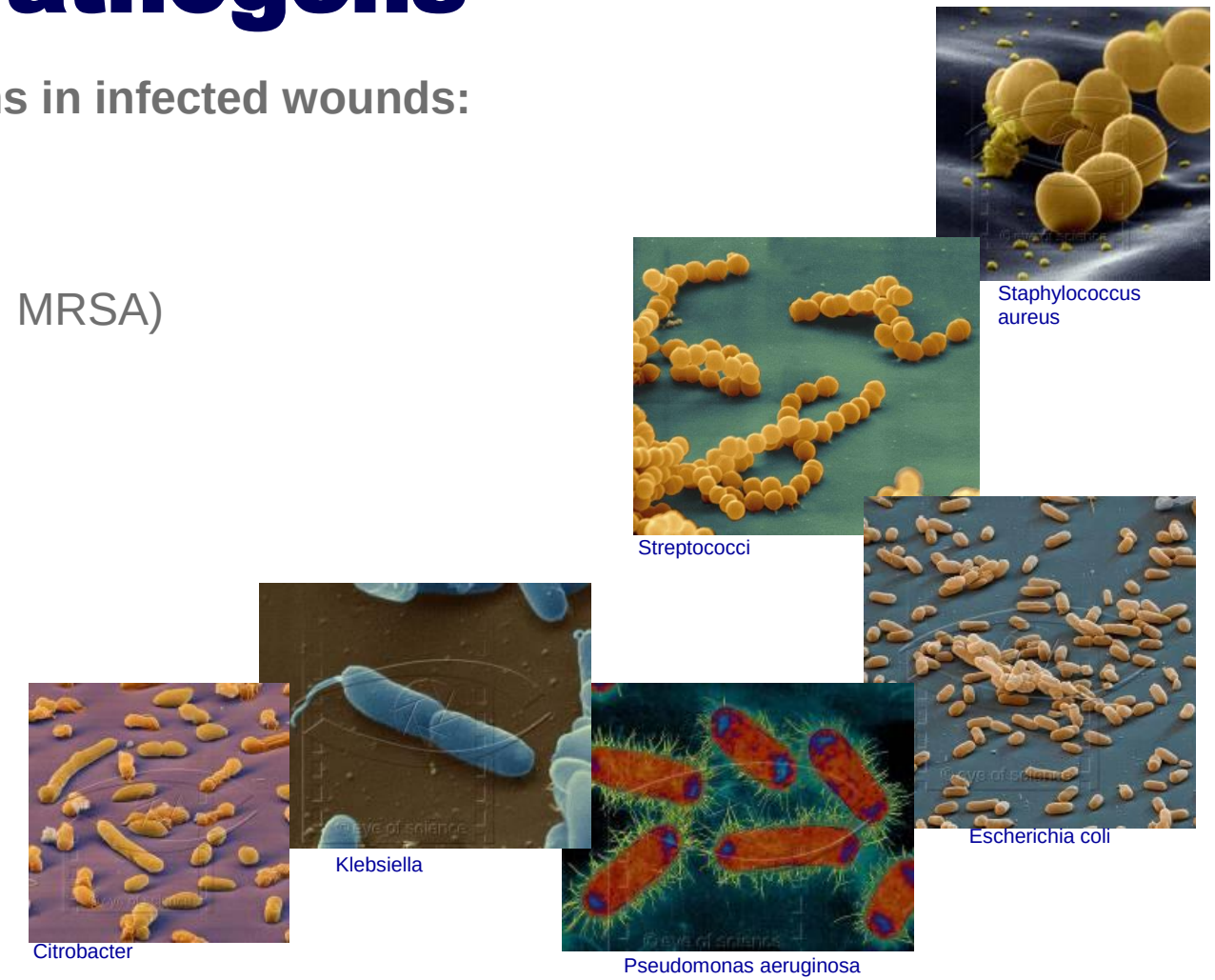
Some common microorganisms in infected wounds:

Gram-positive bacteria

- *Staphylococcus aureus* (incl. MRSA)
- Streptococci
- *Enterococcus* (incl. VRE)

Gram-negative bacteria

- *Pseudomonas aeruginosa*
- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Enterobacter* spp

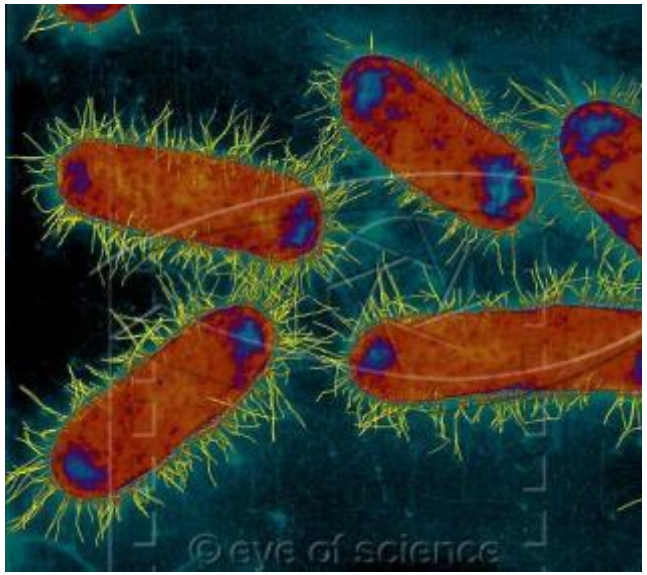


Wound Infection

What is wound infection?

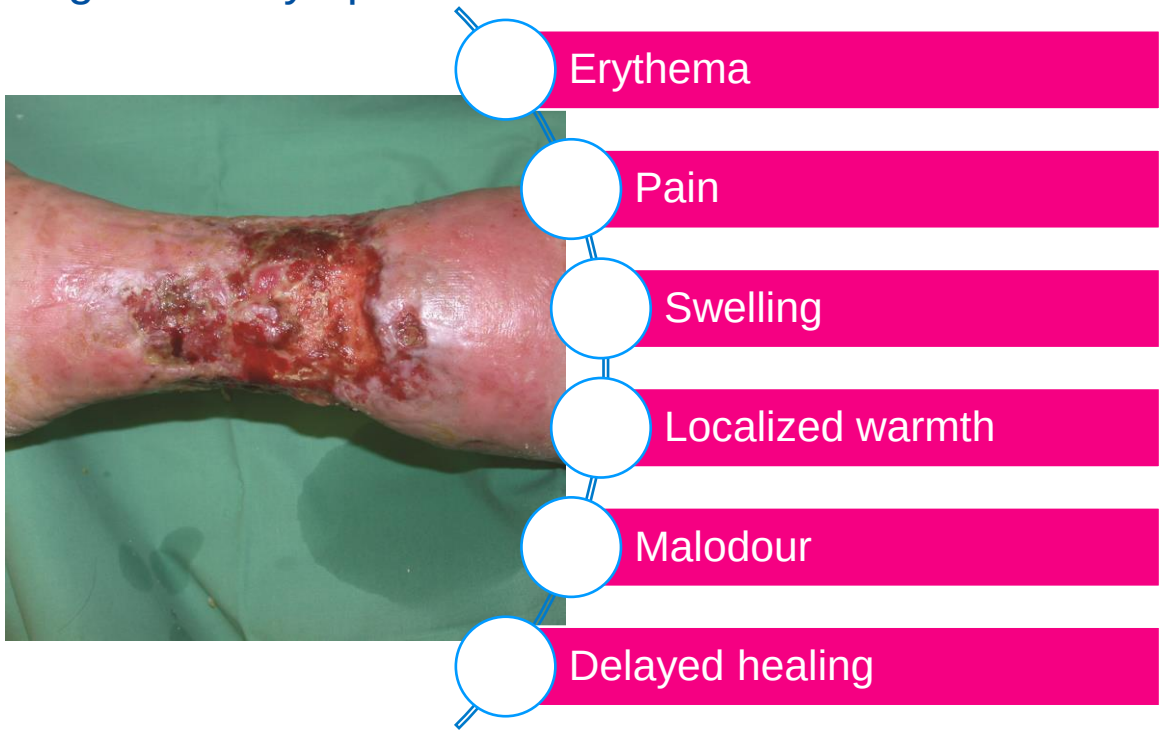
- The presence of microbes in sufficient number or virulence that causes a local and/or systemic response in the host.

- The presence of microorganisms within the wound causes local tissue damage and impedes wound healing



Wound Infection – Symptoms*)

Signs and Symptoms of Wound Infection



„Not infected“ is defined as if there are no systemic or local symptoms or signs of infection

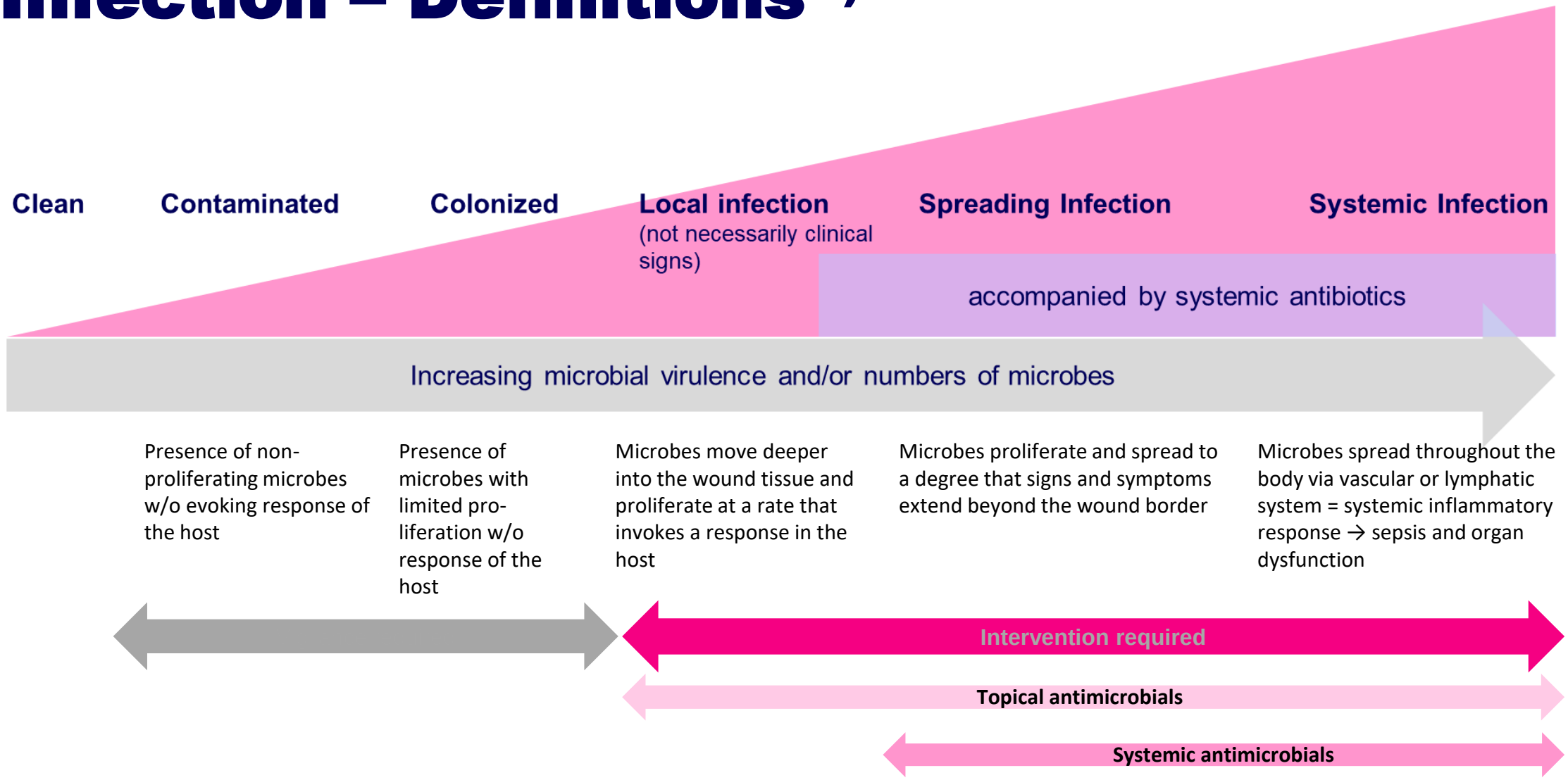
„Infected“ is defined as if there are at least two of these items are present:

- Local swelling or induration
- Erythema >0.5 cm around the wound
- Local tenderness or pain
- Local increased warmth
- Purulent discharge

Note: Key signs may be masked in patients with poor vascularity

*) International Wound Infection Institute Wound infection in clinical practice. Wounds International 2016

Infection – Definitions*)



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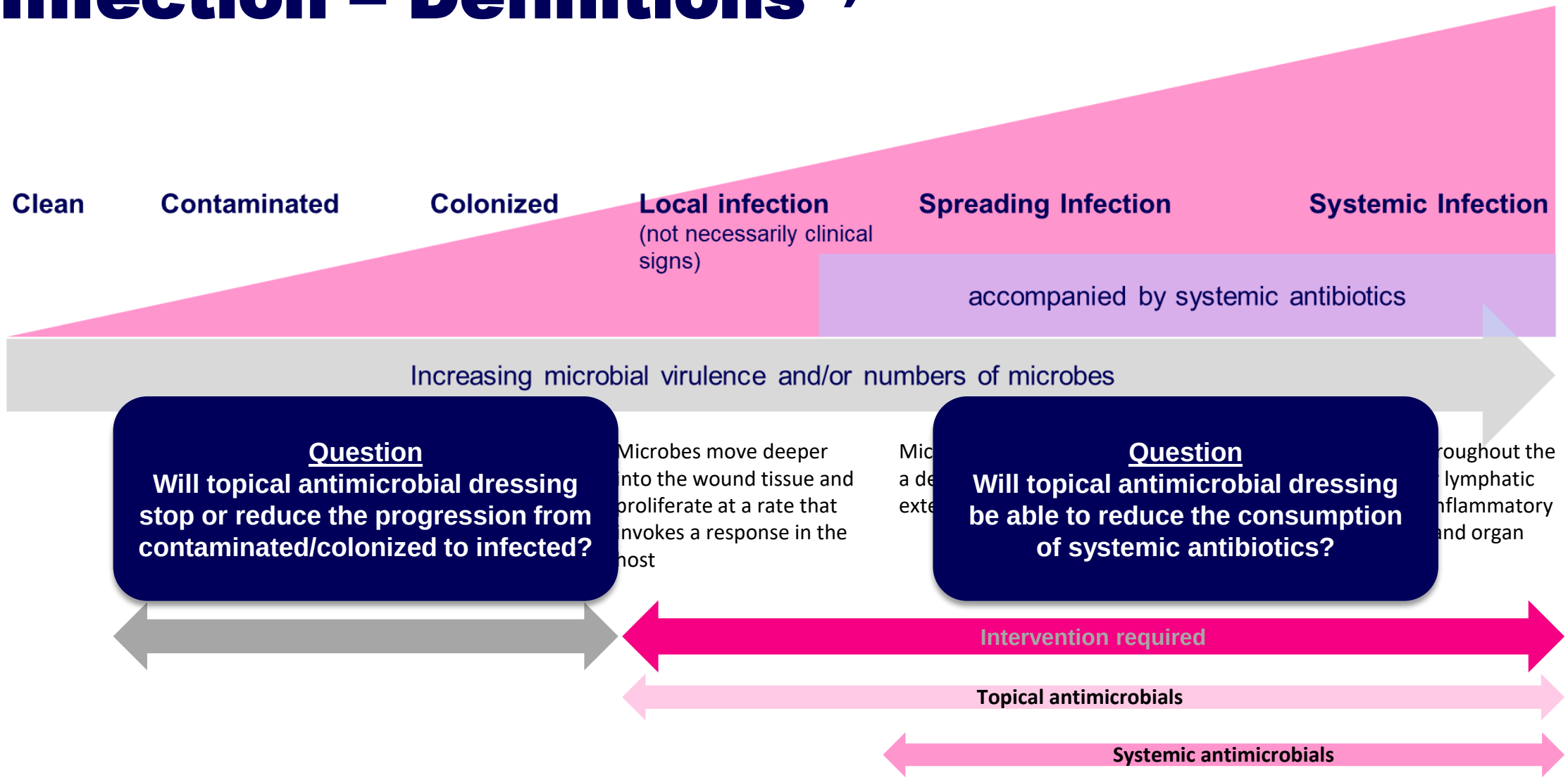
Infection – Definitions*)



*) International Wound Infection Institute Wound infection in clinical practice. Wounds International 2016

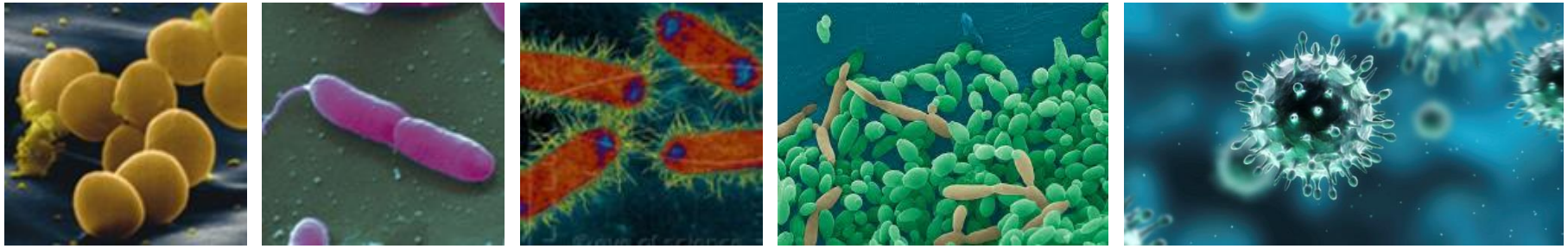
What is Antimicrobial resistance?

Definition

Antimicrobial resistance is the ability of a microorganism to resist the action of an antimicrobial agent.

- Some bacteria are naturally resistant to certain antibiotics (intrinsic or inherent resistance).

- A more worrying problem is when some bacteria, that are normally susceptible to antibiotics, become resistant as a result of genetic changes (acquired resistance).



Sources:

- **Fishman N;. Policy statement on amtimicrobial stewardship by the Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA), and the Pediatric Diseases Society (PIDS). Infect Control Hosp Epidemiol 2012; 33:322–7.**
- **European Centre for Disease Prevention and Control, ecdc.europa.eu**

Reduce the bioburden, avoid spreading and even system infections

What is under discussion?

Resistance

Everyone knows about the resistance of bacteria against antibiotics. By today the expression '**MRSA**' represents all kind of bacteria being resistant. In near future an increasing number of patients will die due to lack of effective antibiotics.

- *Are antimicrobial dressings effective against MRSA?*
- *Do antimicrobial dressings provoke additional resistant streams?*

Resistance reduces effectiveness.

Biofilm

Some bacteria protect themselves against antimicrobial agents while building a surrounding biofilm.

Most debridement techniques eliminate biofilm. However bacteria might response while creating new biofilm.

- *Overcome antimicrobial dressings biofilm?*

Biofilm limits effectiveness.

Inflammation

Inflammation delays wound healing. Endotoxins trigger inflammation. They are present at chronic wounds. Bacteria being killed by antimicrobial dressings release endotoxins.

- *Can antimicrobial dressings reduce the level of endotoxins?*

Inflammation delays healing.

Pharmacological, immunological, metabolic impact

The majority of antimicrobial dressings do not solely limit the bacterial load within the dressing. Their mode of action might have a pharma-cological, immunological or metabolic impact on the human body. Because of this the usage of certain dressings is limited in regard of time and/or patient group.

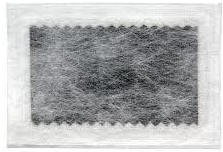
- *What is impact of antimicrobial dressings on the human body?*

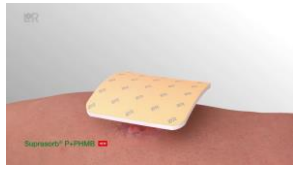
Pharmacological, immunological, metabolic impact limits the usage.

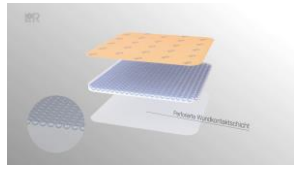
The variety of topical dressings managing wound infections

Different modes of action may have a different impact on wound healing

Silver dressings	•Aquacel Ag (Convatec) •Allevyn Ag (S+N) •Mepilex Ag (Mölnlycke) •Biatain Ag (Coloplast) •…
PHMB	•Suprasorb PHMB (Lohmann & Rauscher) •Kendall AMD Schaumverband (Cardinal Health)
Iodine	•Inadine (Systagenix) •Idosorb (S+N)
Honey	•Gentell Honey Gauze Dressing (Gentell) •Medihoney™ (DermaSciences) •Activon (Advance Medical)
DACC	•Cutimed Sorbact/ Sorbact (Essity / Abigo)







The difference of topical dressings managing wound infections

Different modes of action may have a different impact on wound healing

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DACC	•Cutimed Sorbact/ Sorbact (Essity / Abigo)

With different active agents

Antimicrobial dressings are seen as …
… dressings that contain antimicrobial substances.

… apart from these kind of definition, there are dressings which do not contain antimicrobial substances, but deliver highly effective antimicrobial properties.

without releasing any active agent into the wound

The difference of topical dressings managing wound infections

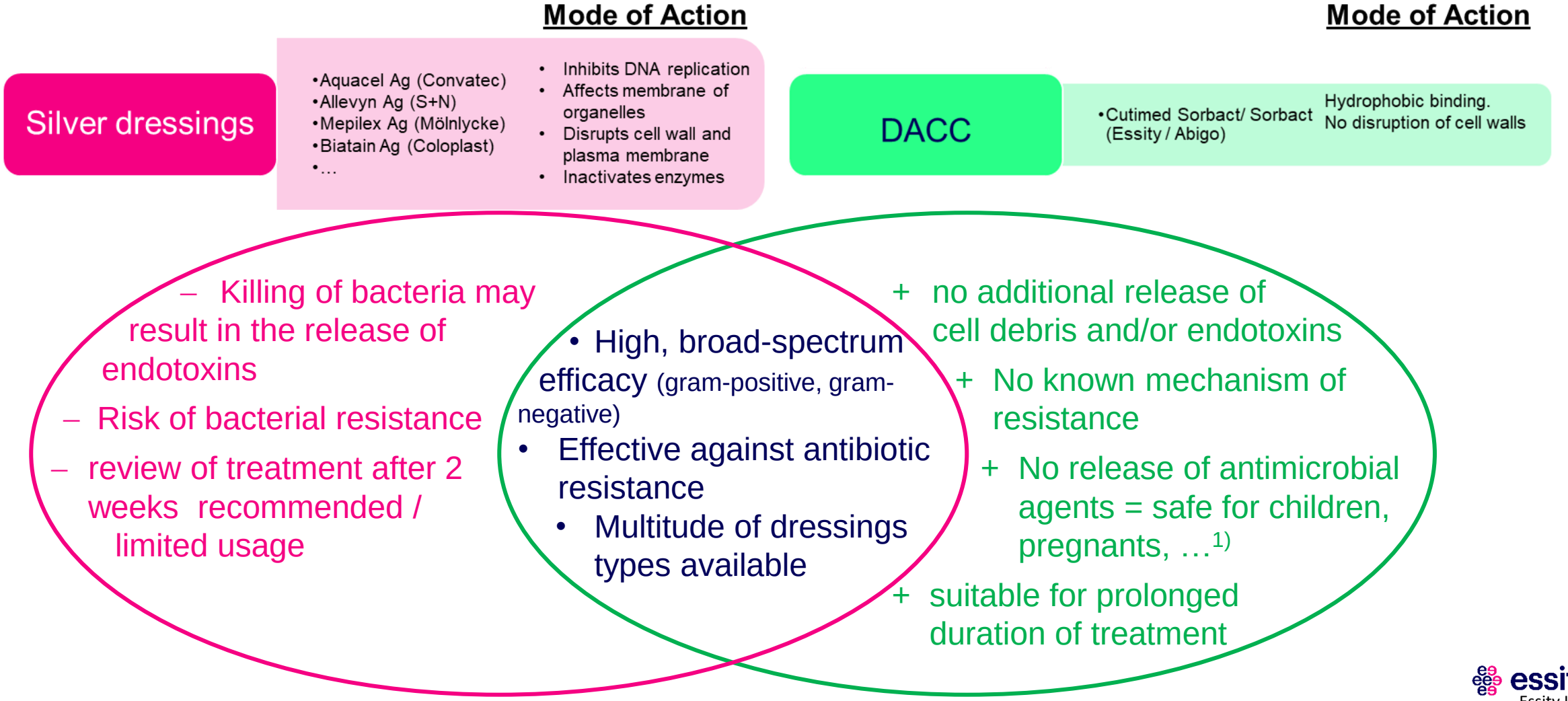
Different modes of action may have a different impact on wound healing

		Mode of Action
Silver dressings	•Aquacel Ag (Convatec) •Allevyn Ag (S+N) •Mepilex Ag (Mölnlycke) •Biatain Ag (Coloplast) •…	• Inhibits DNA replication • Affects membrane of organelles • Disrupts cell wall and plasma membrane • Inactivates enzymes[1]
PHMB	•Suprasorb PHMB (Lohmann & Rauscher) •Kendall AMD Schaumverband (Cardinal Health)	Disrupts cell walls and cell membranes[2]
Iodine	•Inadine (Systagenix) •Idosorb (S+N)	Disruption of proteins and cell membranes[3]
Honey	•Gentell Honey Gauze Dressing (Gentell) •Medihoney™ (DermaSciences) •Activon (Advance Medical)	High osmolarity affects integrity of cell wall[4]
DACC	•Cutimed Sorbact/ Sorbact (Essity / Abigo)	Hydrophobic binding. No disruption of cell walls[5]

References:
1 Dakal et al. 2016, Frontiers in Microbiology
2 Kramer et al. 2019, Journal of Wound Care
3 Bigliardi et al 2017, International Journal of Surgery
4 Simões et al 2018, European Journal of Pharmaceutics and Biopharmaceutics
5 Ljung et al 2006, Journal of Woundcare / Cutting et al. 2015, Journal of Wound Care

Silver dressings vs. Sorbact

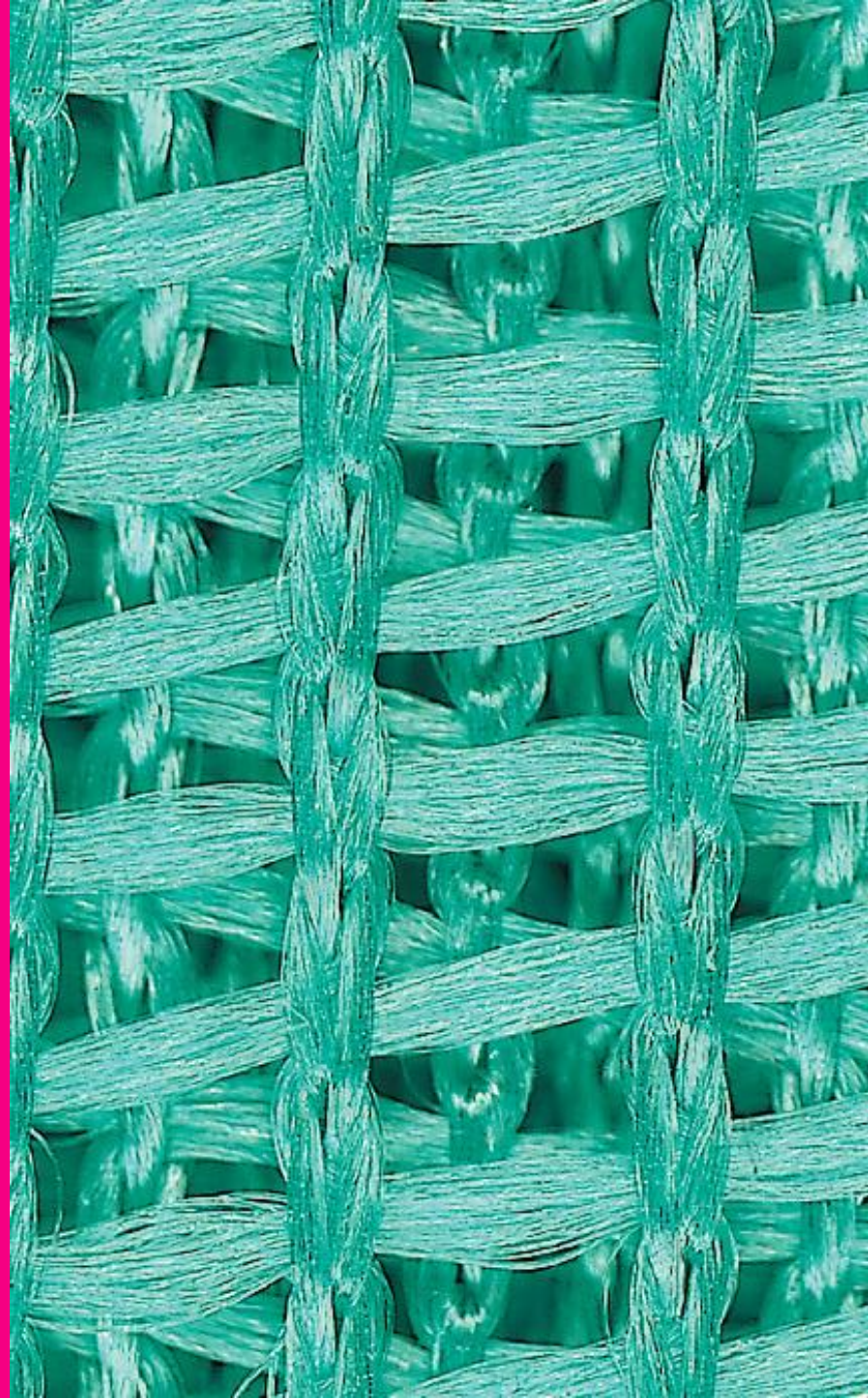
Different modes of action may have a different impact on wound healing



1)Consider IfU when using Cutimed Sorbact gel, because of limitations of the hydrogel.

Cutimed® Sorbact®

The Mode of Action



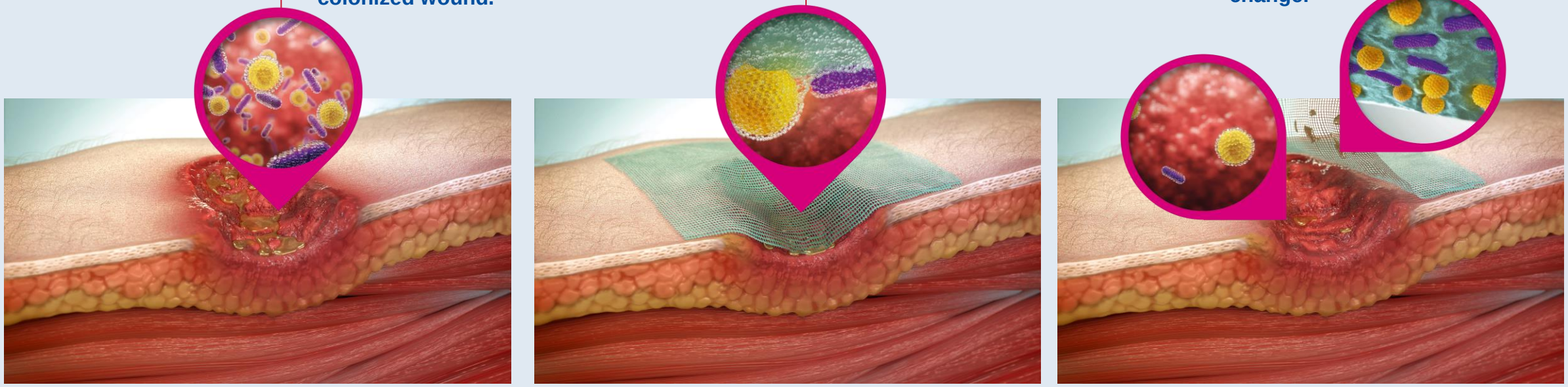
The Sorbact® Technology

Leukomed® Sorbact ® and Cutimed ® Sorbact ® utilize the safe and effective Sorbact ® Technology that binds bacteria with a purely physical mode of action.

An **infected** and **colonized wound.**

Cutimed® Sorbact® is applied directly to the wound. Bacteria and / or fungi are attracted to the **Sorbact®** mesh.

Bound pathogens are removed **with each dressing change.**



1 As shown in vitro Susilo YB, Husmark J, DACC Coated Wound Dressing and Endotoxin: Investigation on Binding Ability and Effect on Endotoxin Release from Gram-negative Bacteria. Poster presented at EWMA 2019.

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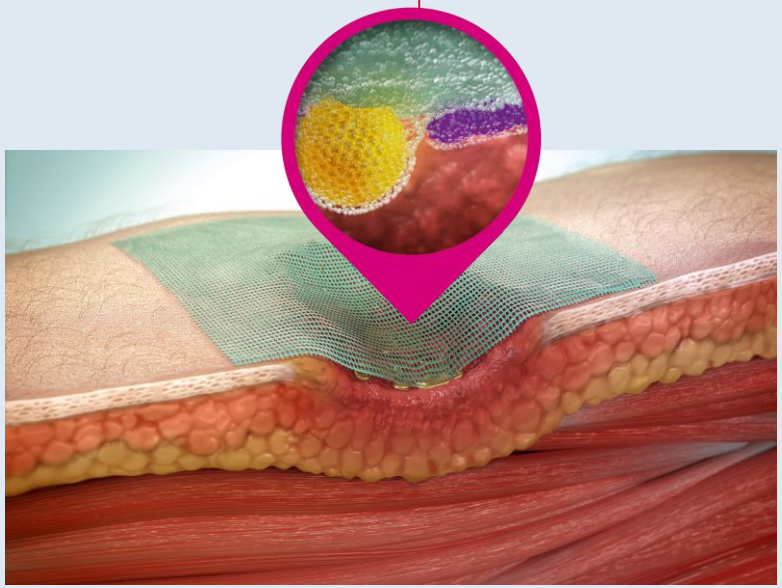


Bind

- Bacteria naturally bind and anchor to the unique Sorbact® surface
- Also binds endotoxins that may impair wound healing[1)]

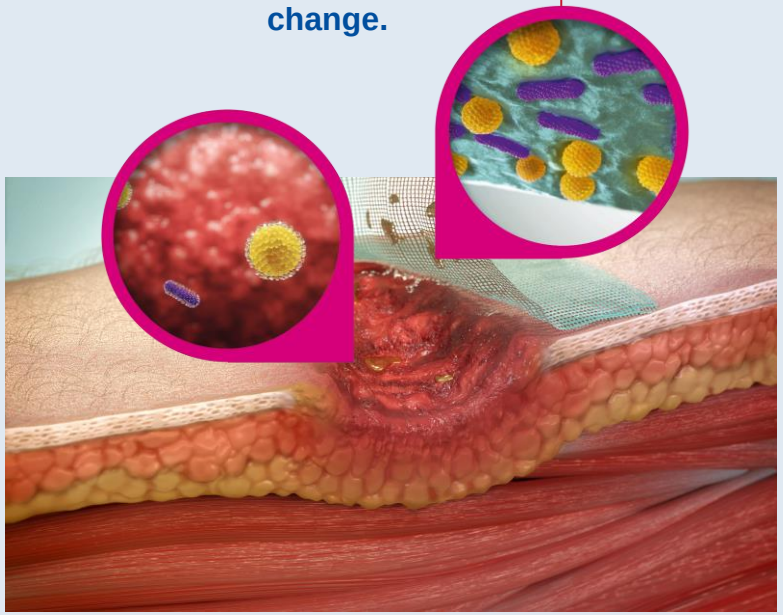
Pacify

- The bacteria are irreversibly bound, growth is
- inhibited and they are simply pacified
- Endotoxins are shown not to be released from the bacteria[1)]

Remove

- Bound bacteria, fungi and endotoxins are safely removed
- The bacterial load in the wound bed is reduced
- Reduced bioburden supports natural wound healing

Bound pathogens are removed **with each dressing change.**



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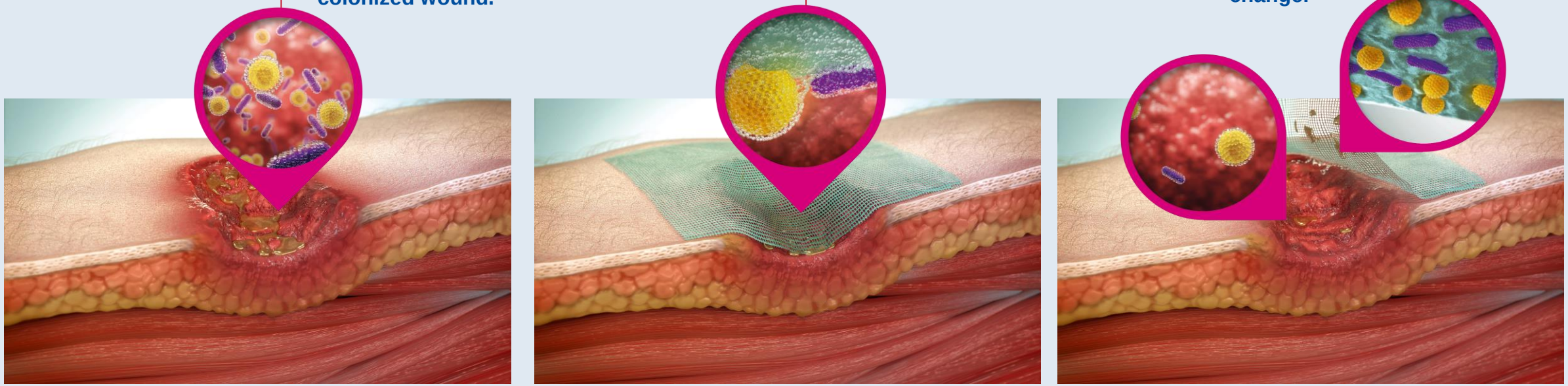
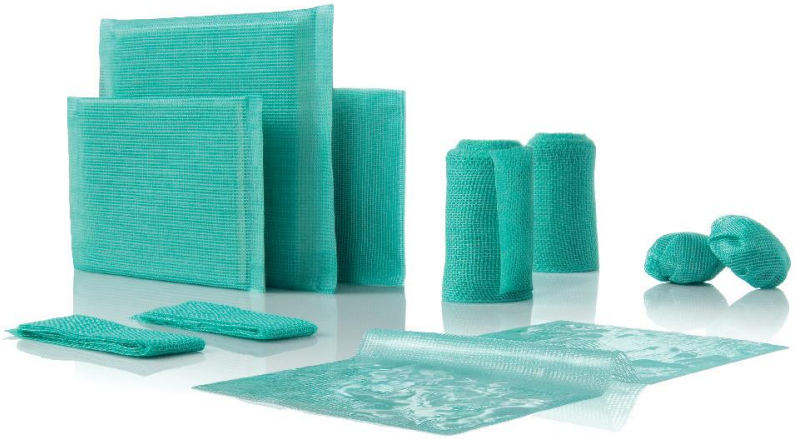


Please explore the video about Cutimed Sorbact's mode of action

Cutimed® Sorbact®

The Portfolio



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The variety of Sorbact®

The tool box for every challenge*)

Cutimed® Sorbact®

Swabs

… for shallow or deep wounds, from low to excessive exudate levels

Ribbon gauze

… for cavity wounds and fistulas. Also intended for fungal infections in skin folds.

Round swabs

… for wound cleansing or as a wound filler of minor cavity wounds

Dressing pad

… for shallow wounds with moderate to high exudate levels

Gel

… for wounds with dry to low exudate levels, supports autolytic debridement

All dressings are designed for use in the management of clean, contaminated, colonized or infected wounds.

*)You have to combine these with a secondary dressing and might need additional fixation.

Ready for use

Cutimed® Siltec® Sorbact®

… for wounds with **moderate to high** exudate levels / absorbs wound fluid and promotes a moist wound environment

Cutimed® Sorbion® Sorbact®

… for wounds with **high to excessive** exudate levels / absorbs and retains exudate, thereby enabling a moist wound environment.

Cutimed® Sorbact® Hydroactive (B)

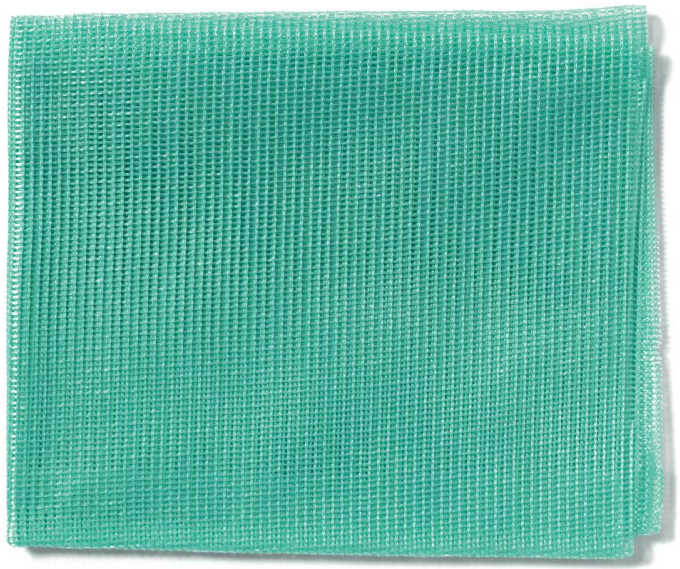
… for use in the management of **low to moderate** exuding wounds / stimulates autolytic debridement of fibrin and necrotic tissue

Cutimed® Sorbact® Swabs

… the pure and efficient tool for infection management

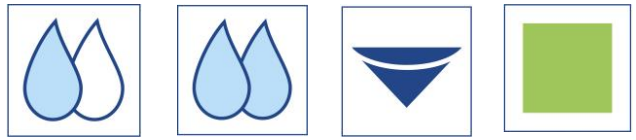
Claims

- May be left in place for up to 7 days if clinical condition allows
- Suitable for prolonged duration of treatment
- Conforms to the wound
- Allows passage of wound exudate
- …



Indications

- Cutimed® Sorbact® Swabs are intended for use in management of clean, contaminated, colonized or infected wounds …
- … such as traumatic wounds, burns, cavity wounds, fistulas, pressure ulcers, diabetic ulcers and foot and leg ulcers.



Cutimed® Sorbact® Round Swabs

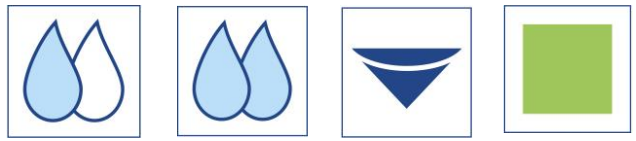
… the pure and efficient tool for cleansing or as wound filler

Claims

- May be left in place for up to 7 days if clinical condition allows
- Suitable for prolonged duration of treatment
- Allows passage of wound exudate
- …

Indications

- Cutimed® Sorbact® Round Swabs are suitable for…
- … wound cleansing or as wound filler …
- … in management of clean, contaminated, colonized or infected exuding wounds, such as minor cavity wounds.



Cutimed® Sorbact® Dressing pads

… the pure and efficient tool for infection management and light moisture management

Claims

- Absorbs and retains exudate
- Maintains a moist wound environment
- May be left in place for up to 7 days if clinical condition allows
- Suitable for prolonged duration of treatment
- …

Indications

- Cutimed® Sorbact® Dressing Pads are intended for use in management of clean, contaminated, colonized or infected wounds …
- … with moderate exudate levels, …
- … such as traumatic wounds, burns, cavity wounds, fistulas, pressure ulcers, diabetic ulcers and foot and leg ulcers.

Cutimed® Sorbact® Ribbon Gauze

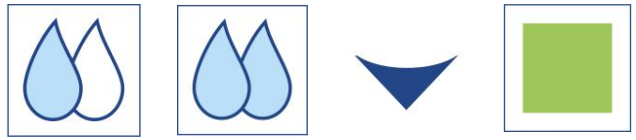
… the efficient infection management in wound caves

Claims

- Conforms to the wound
- Allows passage of wound exudate
- Does not adhere to the moist wound bed
- …

Indications

- Cutimed® Sorbact® Ribbon Gauze is intended for use in management of clean, contaminated, colonized or infected …
- … exuding wounds …
- … such as cavity wounds and fistulas.
- Cutimed® Sorbact® Ribbon Gauze is also intended for use in fungal infections in skin folds.



Cutimed® Sorbact® Gel

… donates moisture and infection management

Specific claims

- Suitable for dry to low exuding wounds
- Donates moisture and enables a moist wound environment
- Suitable for autolytic debridement

Indications

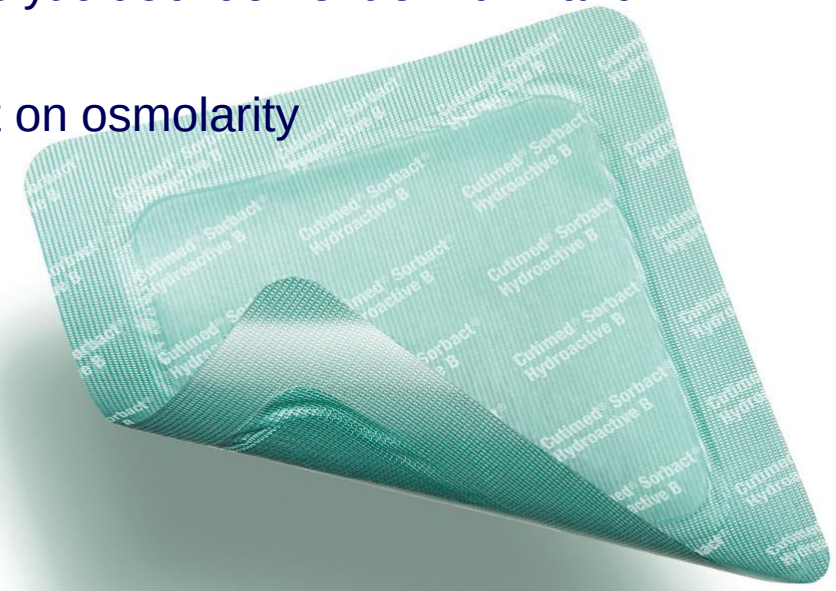
- Cutimed® Sorbact® Gel is intended for use in management of clean, contaminated, colonized or infected wounds …
- … **with dry to low exudate levels**, …
- … such as traumatic wounds, burns, cavity wounds, fistulas, pressure ulcers, diabetic ulcers and foot and leg ulcers.

Cutimed® Sorbact® Hydroactive / B

… manages infections and stimulates autolytic debridement

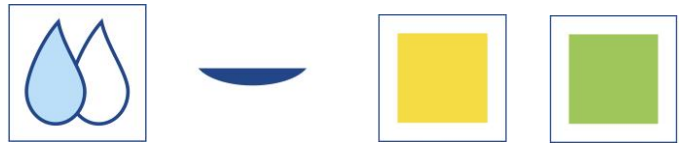
Claims

- Prevents maceration
- Atraumatic dressing change
- Highly absorbent and locks wound exudate
- Stimulates autolytic debridement of fibrin and necrotic tissue
- Dressing effect on osmolarity
- …



Indications

- Cutimed® Sorbact® Hydroactive / B is intended for use in management of clean, contaminated, colonized or infected wounds …
- … **with low to moderate exudate levels**, …
- … such as traumatic wounds, burns, cavity wounds, fistulas, pressure ulcers, diabetic ulcers and foot and leg ulcers.

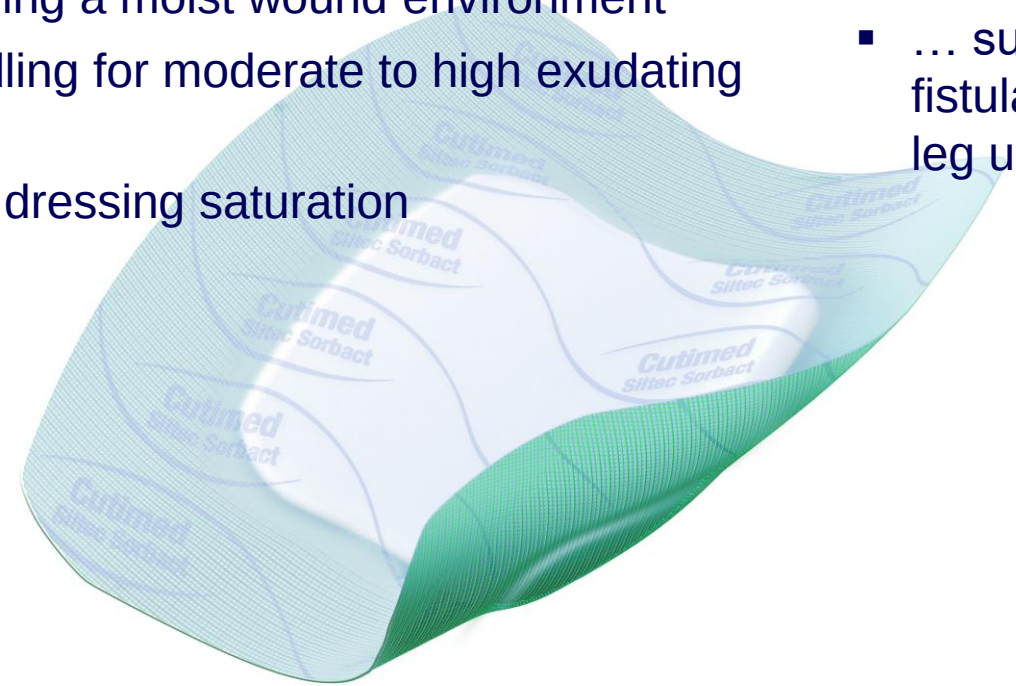


Cutimed® Siltec® Sorbact®

… combines the benefits of infection and exudate management

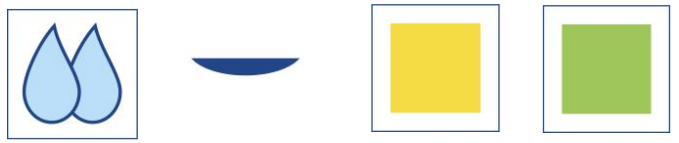
Claims

- Good flexibility and conformability
- Atraumatic removal from surrounding skin
- Fixation border keeps dressing in place
- Helps maintaining a moist wound environment
- Safe fluid handling for moderate to high exudating wounds
- Visible level of dressing saturation
- …



Indications

- Cutimed® Siltec® Sorbact® is intended for use in management of clean, contaminated, colonized or infected wounds …
- … **with moderate to high exudate levels**, …
- … such as traumatic wounds, burns, cavity wounds, fistulas, pressure ulcers, diabetic ulcers and foot and leg ulcers.



Cutimed® Sorbion® Sorbact®

… enables safe infection management and handles large amounts of exudate

Claims

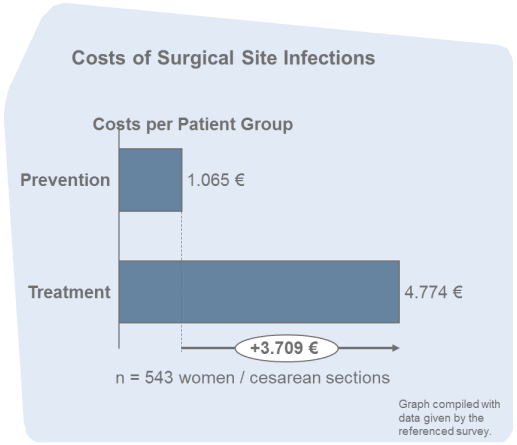
- Absorbs and retains exudate
- Maintains a moist wound environment
- Superior absorption compared to other absorbent dressings, e.g. foam
- Time savings due to less frequent dressing changes compared to foam dressings due to superior absorption
- …

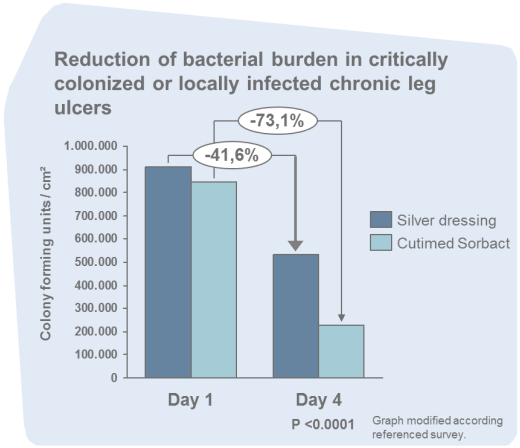
Indications

- Cutimed® Sorbiont® Sorbact® is intended for use in management of clean, contaminated, colonized or infected wounds with …
- … **high to excessive exudate levels**, …
- such as surgical wounds, traumatic wounds, pressure ulcers, diabetic ulcers and foot and leg ulcers.

Cutimed® Sorbact®

Clinical Data & Claims



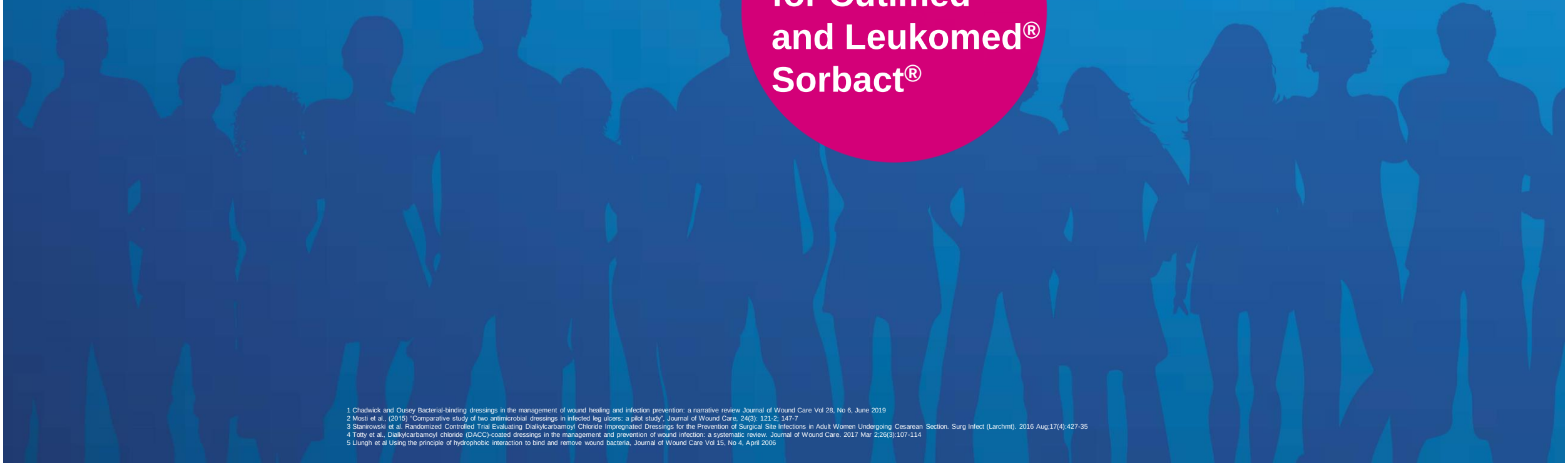


essity

New narrative review shows 4,044 patients were successfully treated in clinical studies with Sorbact® Technology[1]

- Wound infection prevention and management[2,3,4]
- Purely physical mode of action
- Binds bacteria and fungi[5]

Evidence keeps growing for Cutimed® and Leukomed® Sorbact®



1 Chadwick and Ousey Bacterial-binding dressings in the management of wound healing and infection prevention: a narrative review Journal of Wound Care Vol 28, No 6, June 2019
2 Mosti et al., (2015) "Comparative study of two antimicrobial dressings in infected leg ulcers: a pilot study", Journal of Wound Care, 24(3): 121-2; 147-7
3 Stanirowski et al. Randomized Controlled Trial Evaluating Dialkylcarbamoyl Chloride Impregnated Dressings for the Prevention of Surgical Site Infections in Adult Women Undergoing Cesarean Section. Surg Infect (Larchmt). 2016 Aug;17(4):427-35
4 Totty et al., Dialkylcarbamoyl chloride (DACC)-coated dressings in the management and prevention of wound infection: a systematic review. Journal of Wound Care. 2017 Mar 2;26(3):107-114
5 Llungh et al Using the principle of hydrophobic interaction to bind and remove wound bacteria, Journal of Wound Care Vol 15, No 4, April 2006

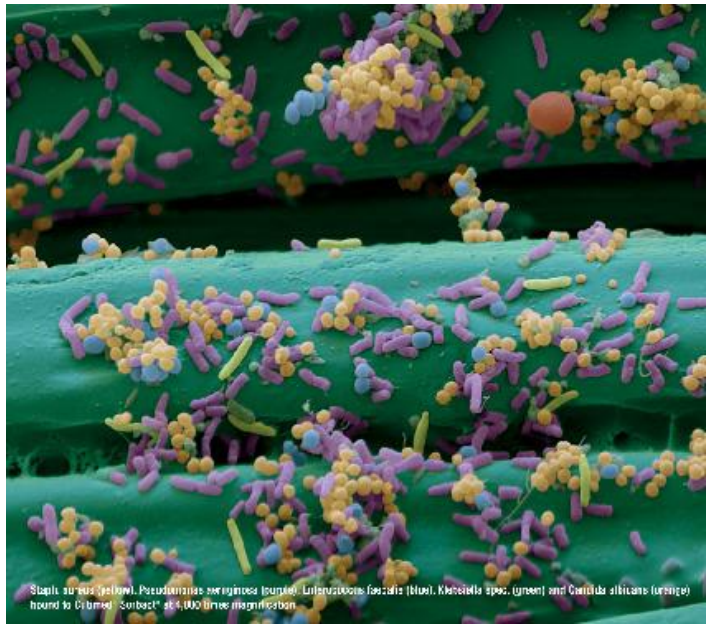
Cutimed® Sorbact® - applicable for all

Claims

- Immediate and irreversible binding of microorganisms
- Binds microorganisms, such as Staphylococcus aureus (including MRSA), … …. and Candida albicans. These microorganisms are removed from the wound each time the dressing is changed.
- No antimicrobial agents released to the wound
- Reduces bioburden in wounds
- Can be used in compression therapy
- Can be used for local wound management in conjunction with systemic antibiotic therapy

Indications

- Cutimed® Sorbact® … is intended for use in management of clean, contaminated, colonized or infected wounds …
- … such as traumatic wounds, burns, cavity wounds, fistulas, pressure ulcers, diabetic ulcers and foot and leg ulcers.



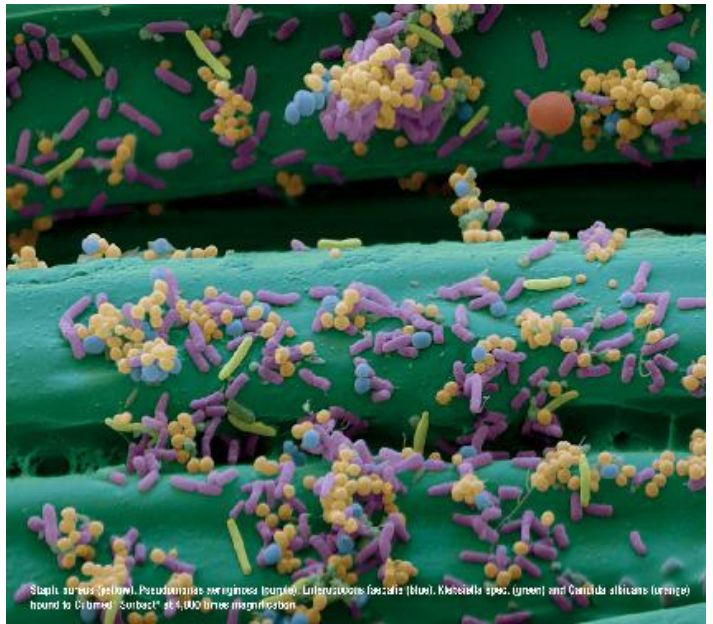
Cutimed® Sorbact® - applicable for all

Claims

- No contraindications and low risk of allergies[1)]
- Reduces the bioburden in wounds
- Immediate onset of action
- Development of bacterial or fungal resistance is not expected
- No release of active agents into the wound
- Suitable for prolonged treatment[2)]
- Does not promote the bacterial release of endotoxins
- Can be used in compression therapy
- Can be used for local wound management in conjunction with systemic antibiotic therapy

Indications

- Cutimed® Sorbact® … is intended for use in management of clean, contaminated, colonized or infected wounds …
- … such as traumatic wounds, burns, cavity wounds, fistulas, pressure ulcers, diabetic ulcers and foot and leg ulcers.



[1)] In regard of Cutimed® Sorbact® gel please follow the corresponding IfU.
[2)] However, dressing changes should consider clinical conditions and occur latest at day 7.

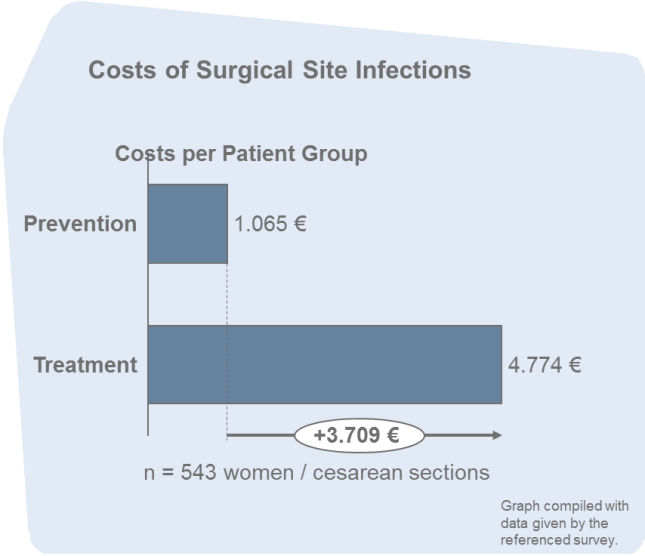
Management of clean, contaminated, colonized or infected wounds – preventive action.

Stanirowski et al: RCT evaluating DACC impregnated dressings for the prevention of surgical site infections in adult women undergoing cesarean section; Surgical Infections; 2016

Scientific Abstract / Key messages

- The aim of the study was to evaluate the **efficacy and cost-effectiveness** of DACC impregnated dressings to prevent **surgical site infections (SSI)** in women undergoing cesarean sections (CS) .
- A **randomized, controlled t**rial was conducted with **543 women** undergoing CS. Patients were randomly allocated to receive either Sorbact surgical dressing* (Sorbact) or standard surgical dressing (SSD) following skin closure.
- **The SSI rates** in the Sorbact group were **significantly lower (1.8%)** than in the SSD group (5.2%) (p = 0.04). **The total costs** of SSI prophylaxis and treatment were greater in the SSD group compared to the Sorbact group (5775 EUR vs. 1065 EUR, respectively). Only in the Sorbact group, none of the patients required systemic antibiotic treatment or hospital readmission.
- The study confirmed the efficacy and cost-effectiveness of Sorbact dressings in SSI prevention among women undergoing CS. **Using Sorbact significantly decreases the risk of SSI after CS and reduces the total costs** (prophylaxis and treatment) for SSI management. That means utilizing Sorbact is a cost-effective way to prevent SSI.

*In the study, Sorbact Surgical Dressing from ABIGO was used which equals BSN's Leukomed Sorbact dressing.



Impact on sales & benefit for our customers

considerably enlarges the sales potential for the Sorbact technology:
for treatment and prevention
for chronic and for post-op wounds

When to use this?

to convince new customers of the unique Sorbact technology for existing customer: to demonstrate that prevention is another key benefit of Cutimed Sorbact important: silver dressings are not recommended for prevention.

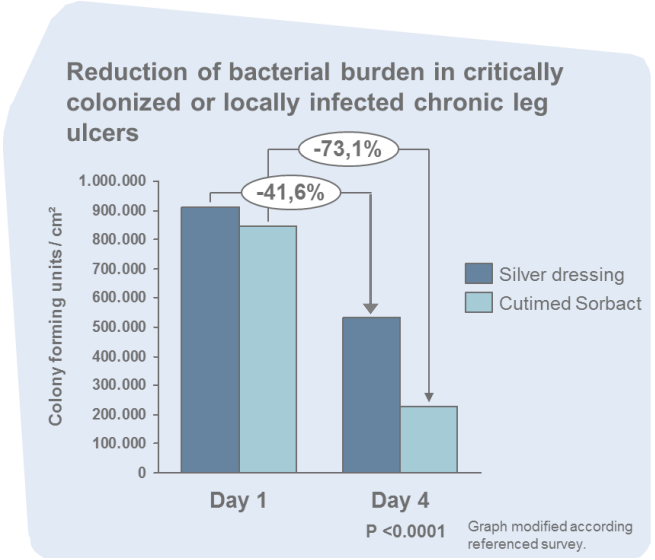
Evidence level: I

Management of clean, contaminated, colonized or infected wounds – infection management.

Mosti et al: Comparative study of two antimicrobial dressings in infected leg ulcers: a pilot study; Journal of Wound Care; 2015

Scientific Abstract / Key messages

- To **compare the efficacy** of a microorganism-binding (Cutimed Sorbact) dressing **with a silver-containing** hydrofiber (Aquacel Ag) **dressing** in controlling the bacterial load of heavily colonized or locally infected **chronic venous leg ulcers (VLUs)**, before surgical management with homologous skin grafts.
- A **randomized comparative single center study** recruited patients presenting with hard-to-heal critically colonized or locally infected leg ulcers. Patients were randomly assigned to treatment with Aquacel Ag or Cutimed Sorbact. Dressings were changed daily over a four-day observation period, after which they were taken for a skin grafting procedure. Swab samples from ulcer beds were taken in order to quantify the bacterial load at inclusion (D0) and at the **end of day 4** (D4).
- Both groups (n=20 Aquacel Ag, n=20 Cutimed Sorbact) had **15 patients with VLUs and 5 with arterial leg ulcers.** Analyzing bacterial load variation showed a significant reduction of bacterial burden at D4 in both groups. In the Aquacel Ag group, an average bacterial load reduction of 41.6% was found, with an average reduction of 73.1% in the Cutimed Sorbact group (p< 0.00001).
- Sorbact and Aquacel Ag dressings are effective in reducing the bacterial burden in chronic leg ulcers, but Sorbact dressings are significantly more effective.



Cutimed® Sorbact® is more efficient than silver!

Impact on sales & benefit for our customers

- fundamental information on the potential of the Sorbact technology
- suitable to explain the effectiveness
- suitable to explain the safety (no side-effects)

When to use this?

- to convince new customers of the unique Sorbact technology
- to explain how effectively Cutimed Sorbact reduces the bacterial load
- to show that Cutimed Sorbact delivered a better reduction of bacterial load than Aquacel Ag

Evidence level: III

Binds common wound microorganisms.

Ronner et al: Adhesion of methicillin-resistant Staphylococcus aureus to DACC coated dressings; Journal of Wound Care; 2014

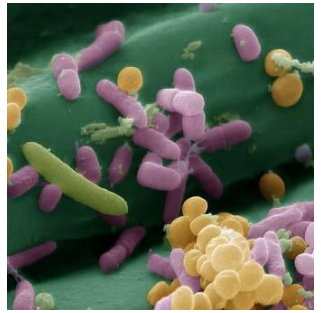
Scientific Abstract / Key messages

- The aim of this in vitro study was to **demonstrate the binding capacity** of **multiple methicillin-resistant Staphylococcus** aureus (MRSA) strains and compare the binding capacity to **methicillin-sensitive** Staphylococcus aureus (S. aureus).
- The binding of S. aureus to a surface was assessed by bioluminescent monitoring of the bacterial ATP levels. This assay can be used as an in **vitro diagnostic model for bacterial binding in a wound**.
- Eleven strains of S. aureus were examined including MRSA, all of which efficiently and equally adhered to the DACC coated dressing (Sorbact). The binding capacity was all in the same range 0.7–2.9x106 CFU/cm2, regardless of the antibiotic resistance properties of the specific strain.
- The decrease of wound bioburden of S. aureus including MRSA is the result of the high binding capacity shown in this study and by earlier data. The findings in this study strengthen the held view that development of antibiotic resistance has minimal impact on the surface structures of the microorganisms in wounds.

Evidence level: IV

Magnification x 2,000

Cutimed Sorbact overcomes antibiotic resistance!



Impact on sales & benefit for our customers

- explains the mode of action of Cutimed Sorbact: binding!
- describes the variety of bacteria which are bound effectively

When to use this?

- whenever the mode of action needs to be explained
- to convince customers that even the challenging (=resistant) bacteria are bound, eg. MRSA

Reduces bioburden in wounds.

Mosti et al: Comparative study of two antimicrobial dressings in infected leg ulcers: a pilot study; Journal of Wound Care; 2015

Scientific Abstract / Key messages

- To **compare the efficacy** of a microorganism-binding (Cutimed Sorbact) dressing **with a silver-containing** hydrofiber (Aquacel Ag) **dressing** in controlling the bacterial load of heavily colonized or locally infected **chronic venous leg ulcers (VLUs)**, before surgical management with homologous skin grafts.
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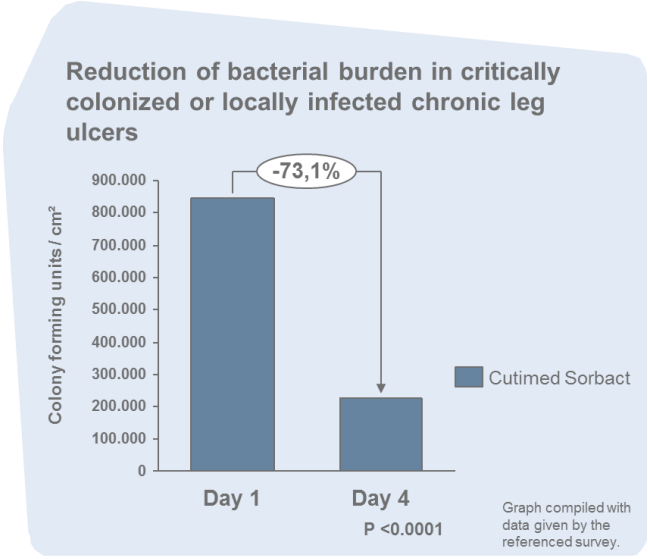

Cutimed Sorbact is effective in reduction of bacterial load!

Impact on sales & benefit for our customers

- underlines the effectiveness of Cutimed Sorbact
- superiority vs. an established benchmark product

When to use this?

- to overcome the perception that “binding” is weaker than “killing”
- important is that the bacterial load is considerably decreased

Microorganisms are removed from the wound each time the dressing is changed.

Mosti et al: Comparative study of two antimicrobial dressings in infected leg ulcers: a pilot study; Journal of Wound Care; 2015

Scientific Abstract / Key messages

- To **compare the efficacy** of a microorganism-binding (Cutimed Sorbact) dressing **with a silver-containing** hydrofiber (Aquacel Ag) **dressing** in controlling the bacterial load of heavily colonized or locally infected **chronic venous leg ulcers (VLUs)**, before surgical management with homologous skin grafts.
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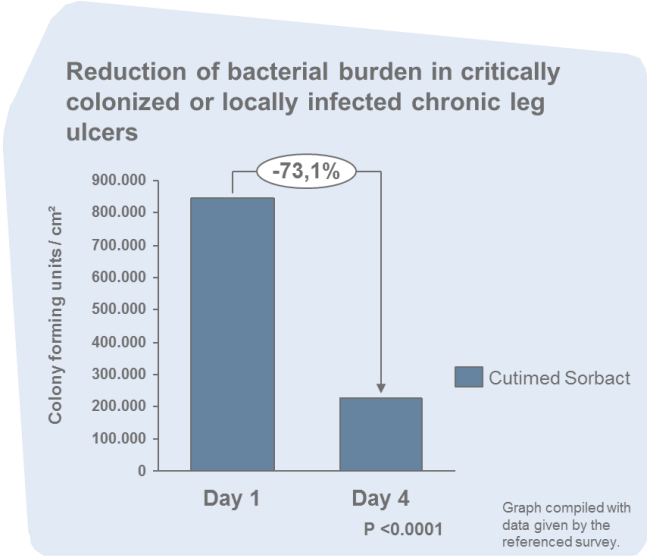

Impact on sales & benefit for our customers

- underlines the physical principle of Cutimed Sorbact
- underlines the safety aspect (physical ≠chemical)

When to use this?

- whenever customers have concerns re. chemical agents
- whenever customers are concerned about bacterial resistance

Can be combined with compression therapy.

Brambilla et al: VERUM – A European Approach for Successful Venous Leg Ulcer Healing: Implementation of a Comprehensive Therapy Concept in Daily Practice; EWMA Journal; 2014

Scientific Abstract / Key messages

- The aim of this study was to **determine whether a clear treatment s**trategy is helpful for the implementation of a holistic therapy concept. In order to generate additional information about the practicality and implementation of holistic **therapy concepts necessary for successful healing of VLUs**, a therapy concept consisting of **compression therapy and moist wound care** was implemented in daily medical practice.
- **63 patients** from Germany, Italy, and Austria were treated for **12 weeks** with an appropriate moist wound dressing, and short-stretch compression bandages in the initial oedema phase, followed by compression treatment using a compression stocking system.*
- **~ 85% of wounds were significantly reduced** in size, and **53% of wounds healed completely** within 12 weeks. The patients' well-being was substantially improved, leading to high compliance. As the majority of patients had not experienced any progress in healing for extended periods of time due to their complicated health situation or ineffective treatment, these results were rated very positively by patients and physicians. In addition, the bacteria-binding wound dressing allowed infected wounds to be treated without antibiotics.
- Holistic therapy concepts can be successfully implemented in daily practice independent of national or local wound care traditions.

Figure 2: A 3-month-old Ulcus cruris venosum of a 59-year-old patient who was diagnosed with disturbed perfusion. The ulcer showed signs of infection and red wound edges. Treatment was initiated on 19th April 2011 (a). Wound closure was achieved on 31st May 2011 (b).

Impact on sales & benefit for our customers

- Multinational trial to confirm that our products work effectively in combination (wound care under compression)

When to use this?

- whenever we are promoting our ITS approach "Chronic Venous Disease"

*Products used in this study: Cutimed Sorbact, Cutimed Protect, Cutimed Siltec, Comprilan, Tensoplast, JOBST UlcerCARE

Cutimed Sorbact as NPWT wound filler and wound contact layer

Evidence level: IV

May be left in place for 7 days, if clinical conditions allow.

Bateman: Evidence is building to support using a DACC-coated antimicrobial wound contact layer with NPWT; Wounds UK; 2015

Scientific Abstract / Key messages

- **A case series** was performed to determine clinical benefits of using Sorbact as **a liner for NPWT**.
- **10 patients** with heavily exuding and infected wounds of various etiology which were being treated with NPWT but still not healing were enrolled. NPWT was used with gauze as the filler, which was changed twice a week, and **Sorbact as the liner,** which remained in situ and was only **replaced every 7 days**. Mean treatment duration with the Sorbact dressing and NPWT was 27 days.
- **After 2 weeks**: exudate and **bioburden re**duction in all patients. After **3 weeks**: Mean **wound size reduction of 40%** in all patients. Total number of days in hospital: reduction from 476 to 266 days (44%) for patients with these wounds.
- Use of Cutimed Sorbact as a NPWT liner was associated with good clinical outcomes resulting in reduced treatment times and, therefore, cost savings.

Evidence level: IV

Impact on sales & benefit for our customers

- underlines how cost-effectively (time-saving) Cutimed Sorbact is (insight: nursing time is a bottleneck in most settings)

When to use this?

- this study was performed to show the combined use of Cutimed Sorbact with NPWT – important to know that the NPWT dressing (foam or gauze) should be changed according to manufacturers' recommendation

Suitable for prolonged duration of treatment.

Bateman: Evidence is building to support using a DACC-coated antimicrobial wound contact layer with NPWT; Wounds UK; 2015

Scientific Abstract / Key messages

- **A case series** was performed to determine clinical benefits of using Sorbact as **a liner for NPWT**.
- **10 patients** with heavily exuding and infected wounds of various etiology which were being treated with NPWT but still not healing were enrolled. NPWT was used with gauze as the filler, which was changed twice a week, and **Sorbact as the liner,** which remained in situ and was only **replaced every 7 days**. **Mean treatment duration with the Sorbact dressing and NPWT was 27 days.**
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- Use of Cutimed Sorbact as a NPWT liner was associated with good clinical outcomes resulting in reduced treatment times and, therefore, cost savings.

Evidence level: IV

Primarily the prove for this claim comes from the nature of the mode of action. However this case series supports this.

Impact on sales & benefit for our customers

- while the use of silver dressing is limited to 10 days, Cutimed Sorbact can be used for longer, if needed.
- Cutimed Sorbact can be used for the treatment, but also for the prevention of (re-) occurrence of infection.
- the prevention aspect can be very important in case of high risk surgery (orthopedic surgery, including hip and knee implants).

When to use this?

- safety aspects, eg in the homecare setting (no daily wound inspections possible)
- infection prevention in high risk surgery (post-operatively).

No contraindications known.

Denyer: Management of the infant with epidermolysis bullosa; Infant; 2009

Scientific Abstract / Key messages

- This expert opinion describes the management and subsequent care of infants with epidermolysis bullosa.
- Epidermolysis bullosa (EB) is an umbrella term for a group of inherited skin disorders in which the common factor is marked fragility of the skin and mucous membranes. There are many different types of EB and the effects vary from blistering of the feet and hands to death in early infancy in the most severe form.
- The article points out that regarding blister and wound management in EB infants, Cutimed Sorbact dressings are a useful inclusion in the EB formulary.
- The recommendation of Cutimed Sorbact dressings for EB infants in this article is an example that Sorbact is suitable for even extremely sensitive and fragile patient groups.

Evidence level: V

Impact on sales & benefit for our customers

- this is important for every patient – Cutimed Sorbact can be used on every patient with a contaminated/colonized/infected wound
- our target group of patients is not restricted

When to use this?

- this is important for every patient – Cutimed Sorbact can be used on every patient with a contaminated/colonized/infected wound.

Patients epidermolysis bullosa are well known for being highly sensitive.

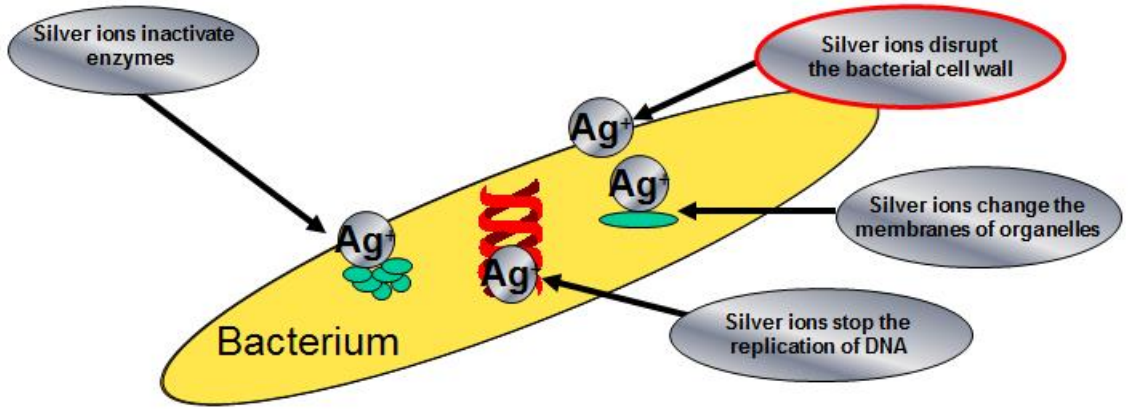
Primarily the prove for this claim comes from the nature of the mode of action and our post market surveillance.

Does not kill bacteria, and thus does not trigger endotoxin release.

Cutting and McGuire: Safe bioburden management. A clinical review of DACC technology; Journal of Wound Care; 2015

Scientific Abstract / Key messages

- This **review** contains **an educational part** about the Sorbact technology and an evidence part which summarizes and gives an overview on the evidence base of Cutimed Sorbact.
- Unlike common antimicrobial dressings, the **Cutimed Sorbact range does not kill pathogens**, but instead binds them to its surface, so they can be **safely removed at dressing c**hange. As a result, it can **be used long term** with minimal risk of side effects.
- With Cutimed Sorbact it is possible to **reduce inflammation** by **eliminating the endotoxin release** triggered by the cell-wall disruption of bacteria killed by the use of antiseptics and antibiotics. Common antiseptics and antibiotics work in several ways to kill bacteria. After the bacterial cell wall is ruptured, intracellular antigenic material and cell wall endotoxins are released into the wound fluid. Following the deaths of millions of bacteria, the wound fluid becomes decidedly inflammatory.
- Trapping bacteria onto a hydrophobic material without killing them therefore becomes an attractive way of managing wound bioburden and improving healing.



Impact on sales & benefit for our customers

- unlike silver dressing (silver disrupts bacterial cell walls with release of bacterial endotoxins) Cutimed Sorbact binds and removes bacteria
- this leads to a proven reduction of bacterial load

When to use this?

- whenever the reduction of bacterial load is needed, it is important to point out that this does not require to kill bacteria
- killed bacteria and their released endotoxins can still lead to complications.

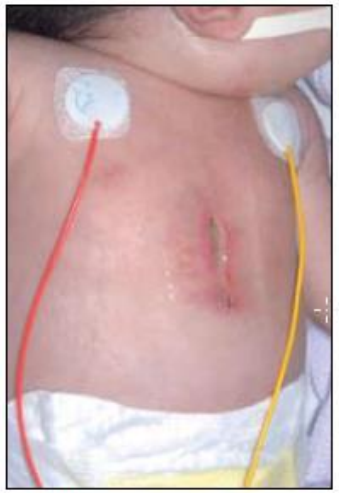
Suitable for children, pregnant and breastfeeding women.

Weerasena and McGinnis: The use of a novel dressing Cutimed Sorbact in managing an infected wound in a neonate; Wounds UK Poster; 2010

Scientific Abstract / Key messages

- Neonates are at particularly high risk of sepsis which can originate from bacterial colonization and proliferation in a wound. Development of a wound infection after implantation of a epicardial pacemaker is quite a serious complication.
- A premature neonate (38 weeks gestation) who was born with congenital complete heart block underwent an implantation of a pacemaker at 3 days of age. 3 days post surgery the neonate was diagnosed with sepsis or necrotising enterocolitis.The neonate was also tested positive for MRSA and had a critically colonized wound
- Cutimed Sorbact was applied to the wound and changed twice a week. The neonate was discharged from the hospital 25 days later.
- The antimicrobial treatment with Sorbact was successful and considered as suitable for this premature neonate.

Evidence level: IV



Initial photograph showing extent of wound

Photograph following completion of treatment

Impact on sales & benefit for our customers

- first choice dressing in pediatric hospitals or wards due to its safety and effectiveness, even in most sensitive patients

When to use this?

- it provides a clear differentiation vs. silver dressings
- treatment of children, treatment during pregnancy
- patients with sensitive or compromised skin .

No known mechanisms for development of bacterial or fungal resistance to hydrophobic interaction.

Cutting and McGuire: Safe bioburden management. A clinical review of DACC technology; Journal of Wound Care; 2015

Scientific Abstract / Key messages

- This **review** contains **an educational part** about the Sorbact technology and an evidence part which summarizes and gives an overview on the evidence base of Cutimed Sorbact.
- Unlike common antimicrobial dressings, the **Cutimed Sorbact range does not kill pathogens**, but instead binds them to its surface, so they can be **safely removed at dressing c**hange. As a result, it can **be used long term** with minimal risk of side effects.
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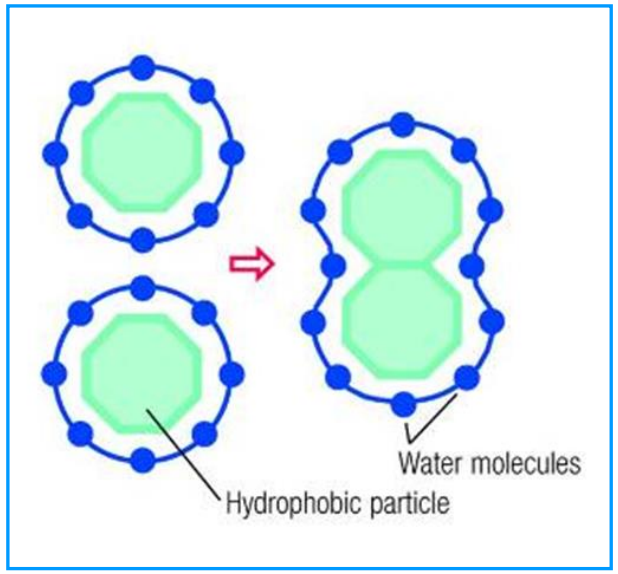

Impact on sales & benefit for our customers

- bacteria will not develop resistance against a principle which helps them survive: they need hydrophobic cell surfaces to bind to host tissues and to nutrients
- Cutimed Sorbact will remain an effective weapon against bacteria also in the future

When to use this?

- there is a growing awareness of antimicrobial resistance
- increasing understanding of the value of Cutimed Sorbact's physical principle

N=859 isolates. USA. Tertiary care facility

Staphylococcus (n=148)
Escherichia (n=256)
Pseudomonas (n=54)
Klebsiella (n=69)
Enterococcus (n=64)
Enterobacter (n=44)
Candida (n=52)

66 (7.7%) were able to grow on LB agar +Ag^+
Most strains multiple-antibiotic drug resistance
32/66 *sil* + by PCR

Finley PJ et al. Antimicrobial Agents and Chemotherapy 2015

Protocol for a longitudinal cohort study: Identification and Characterization of Silver Tolerant Bacteria in Venous Leg Ulcers

Hadar Lev-Tov, M.D.; Cheyanne R. Head, B.S.; Irena Pastar, Ph.D.
Dr Phillip Frost Department of Dermatology and Cutaneous Surgery, University of Miami Miller School of Medicine, Miami, FL

Introduction

Venous leg ulcers (VLU) are a major health problem which significantly impact quality of life, but also impose a large financial burden on the healthcare system.[1] Silver-based dressings have been frequently used in wound management due to the antimicrobial and antifungal properties of silver; however, recently studies have raised concerns regarding the prevalence of silver-resistance[2] and its implications on wound management.[3] Silver resistance, which may be acquired in as little as three weeks, is carried through plasmids that are often accompanied by other drug-resistant genes, suggesting that the presence of silver in dressings may encourage multi-drug resistance.[5]

Objective

To investigate the effectiveness of Dialkylcarbomoyl chloride (DACC)- based dressings in modifying bacterial load in venous leg ulcers (VLU). Herein we present preliminary results that are *blinded* to the intervention.

Methods

We designed an exploratory, single center, observer masked, active control, randomized trial to investigate the effectiveness of Dialkylcarbomoyl chloride dressing (Cutimed® Sorbact®) in modifying bacterial load in VLU. Nine subjects with VLU were randomized to receive Dialkylcarbomoyl chloride or silver (Acticoat®) dressings in addition to standard care consisting of sharp debridement and 4-layer compression system. All patients received silver-based therapy in the weeks leading up to randomization. Wound tissue was collected at baseline, 2 and 3 weeks into treatment. Quantification of bacterial load was performed using Real-Time PCR amplification of 16S rRNA gene. After initial growth on nutrient rich media, all isolates were tested for growth on Luria Broth agar supplemented with 250 µM Ag+ using patch method. Bacterial colonies able to grow on silver agar were identified based on 16S rDNA gene sequence.

Results

- All wounds demonstrated high levels of silver tolerant bacteria, both aerobic and anaerobic, gram positive and negative species.
- At baseline, 9 of the 9 subjects demonstrated aerobic and 8 out of 9 subjects demonstrated ≥70% anaerobic silver tolerant colonies.

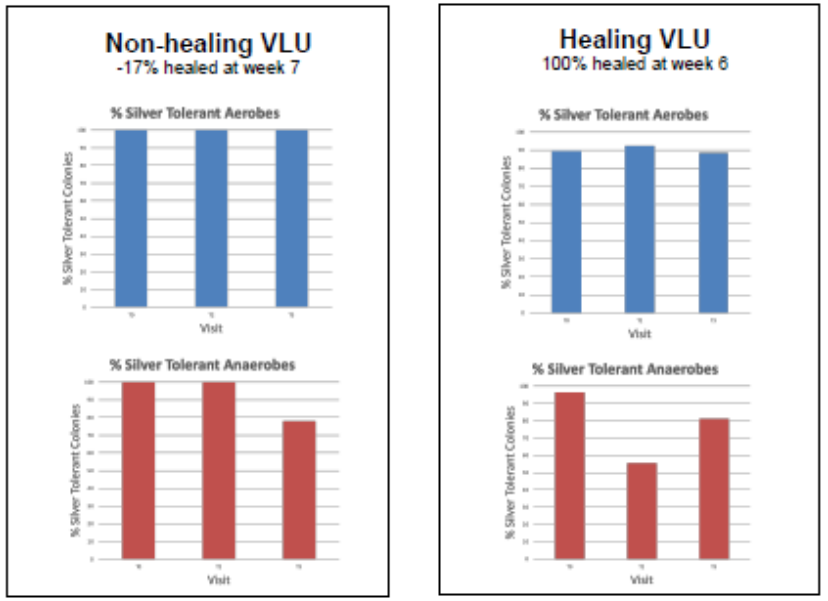

Figure 1. Percentages of aerobic and anaerobic silver tolerant bacteria for a representative healing and non-healing VLU.

Subject 002	T0	*Escherichia coli & Staphylococcus aureus*
	T2	*Shigella sp., Klebsiella pneumoniae & Enterobacter*
	T3	*Escherichia coli & Staphylococcus aureus*
Subject 015	T0	*Morganella morganii & Staphylococcus aureus*
	T2	*Morganella morganii & Staphylococcus aureus*
	T3	*Morganella morganii & Staphylococcus aureus*
Subject 020	T0	*Escherichia coli, Staphylococcus aureus, Staphylococcus epidermidis*
	T2	*Enterobacter cloacae/hormaechei, Staphylococcus aureus, Streptococcus agalactiae*
	T3	*Enterobacter cloacae/hormaechei, Staphylococcus aureus, Streptococcus agalactiae*

Table 1. Representative silver tolerant species found at each timepoint identified by colony 16s rDNA PCR and sequencing.

- The most common silver tolerant species identified were *Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, Corynebacterium sp.* and *Morganella sp.*

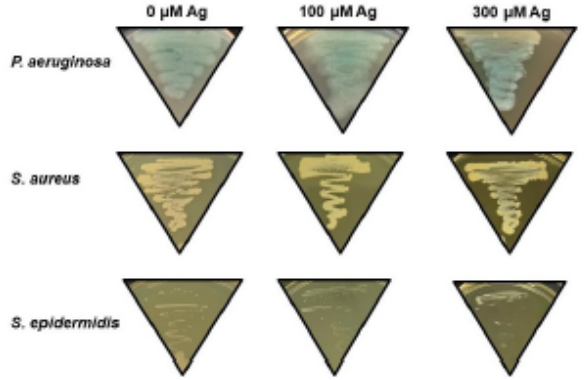

Figure 2. Growth of bacterial isolates from patient VLUs on Luria Broth agar supplemented with 0, 100 and 300 µM Ag+.

Summary

- Silver tolerance in bacterial isolates from VLU may be more widespread than previously thought.
- ≥70% of aerobic bacteria demonstrated silver tolerance at baseline in 9 out of 9 subjects.
- Identification of silver resistance genes, minimum inhibitory concentration evaluations and influence of silver resistance on healing outcome are ongoing.

References

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SIGNIFICANT AND RAPID REDUCTION OF FREE ENDOTOXIN CONCENTRATION BY DIALKYLCARBAMOYL CHLORIDE (DACC)-COATED WOUND DRESSING

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Introduction

Endotoxin or Lipopolysaccharide (LPS) is a component of the outer cell membrane of the gram-negative bacteria, and is mainly released when the bacteria grow, die or damaged. The lipid A domain of endotoxin is responsible for its toxicity.

Endotoxin is a known potent trigger for inflammation. Several *in vitro* studies suggest that endotoxin also contributes to a delay in wound healing [1-4]. Therefore, reduction of endotoxin in the wound may lead to less inflammation and better wound healing process.

Dialkylcarbamoyl chloride (DACC)-coated wound dressing reduces bio-burden in the wound by hydrophobic binding of microorganisms. It is hypothesized that the hydrophobic interaction also occur between the DACC-coated wound dressing and the hydrophobic Lipid-A part of endotoxin.

Aims

1) To explore the ability of DACC-coated wound dressing to bind endotoxin from *Pseudomonas aeruginosa in vitro*.

2) To investigate its effect on the level of endotoxin released from gram-negative bacteria.

Materials & Methods

For endotoxin binding experiment, two punched circular (14 mm Ø) DACC-coated wound dressing (Sorbact ® Compress) were incubated with of 50 µl of purified *P. aeruginosa* endotoxin solution at different concentrations for various durations up to 48 h at 37°C, followed by vigorous vortexing for 1 minute. After removal of he wound dressing pieces, the samples were analysed for endotoxin.

To investigate the effect of DACC-coated wound dressings on the level of endotoxin released from gram-negative bacteria, another two punched circular pieces (14mm Ø) of DACC-coated dressing (Sorbact ® Compress) were incubated with 50 µl of 10^8 CFU/ml *P. aeruginosa* for 1 hour at 37°C. After incubation, intact bacteria were separated by centrifugation and filtration. The supernatants were analyzed for endotoxin.

Endotoxin analyses were performed using Limulus assay.

Results & Discussions

In this *in vitro* study, DACC-coated dressing was able to consistently reduce endotoxin concentration by 93-99% ($P \leq 0.0001$) after 24 h. Even at a very high endotoxin concentration of 11000 EU/ml, 99% reduction can be seen after 24 h incubation (Fig. 1). A significant endotoxin reduction of 39% ($P \leq 0.001$) was observed already at 5 minutes, and continued over time to 48 h (Fig. 2). Moreover, endotoxin that bound to the dressing adhered strongly, given that it was not released by the extensive vortexing for 1 minute.

After a one-hour incubation of clinically relevant *P. aeruginosa* strain with DACC-coated dressings, no increase of free endotoxin concentration was observed. Instead, free-endotoxin concentration was reduced to below detection limit (from 420 EU/ml to <0.2 EU/ml, >99.95% reduction).

Conclusion

This is the first study to show that DACC-coated wound dressing is able to significantly and rapidly bind purified and shed endotoxin from *P. aeruginosa*. This ability to remove both endotoxin and bacterial cells may lead to less inflammation in the wound and better wound healing process.

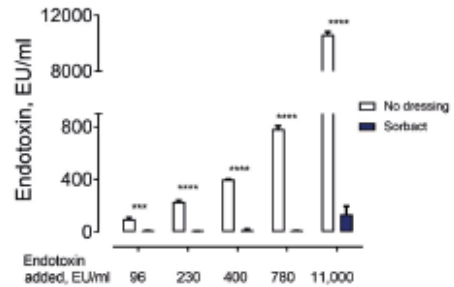

Figure 1: Binding of purified *P. aeruginosa* endotoxin by DACC-coated dressing. Endotoxin remaining in the medium after overnight incubation with the DACC dressing discs was analyzed by a quantitative Limulus assay. Significant differences are indicated by asterisks, ***P ≤ 0.001, ****P ≤ 0.0001.

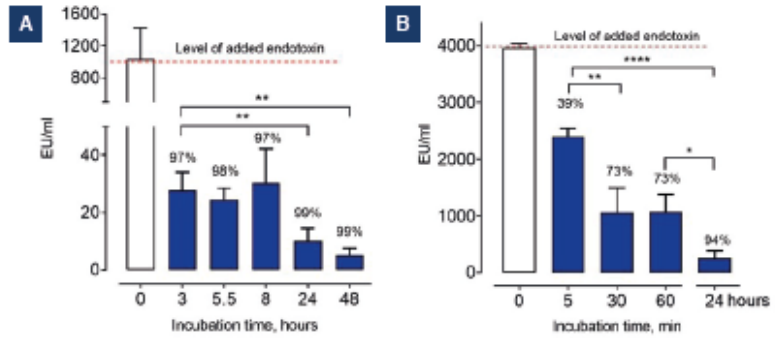

Figure 2: Kinetics of binding of purified *P. aeruginosa* endotoxin to DACC-coated dressing. Endotoxin remaining in the medium was analyzed at various time points during incubation with the dressing discs and performed at 1000 (A) and 4000 (B) EU/ml of endotoxin. The unfilled bars in A and B represented the initial concentration at the start of incubation. Significant differences are indicated by asterisks, *P ≤ 0.05, **P ≤ 0.01, ****P ≤ 0.0001.

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Back to the Questions

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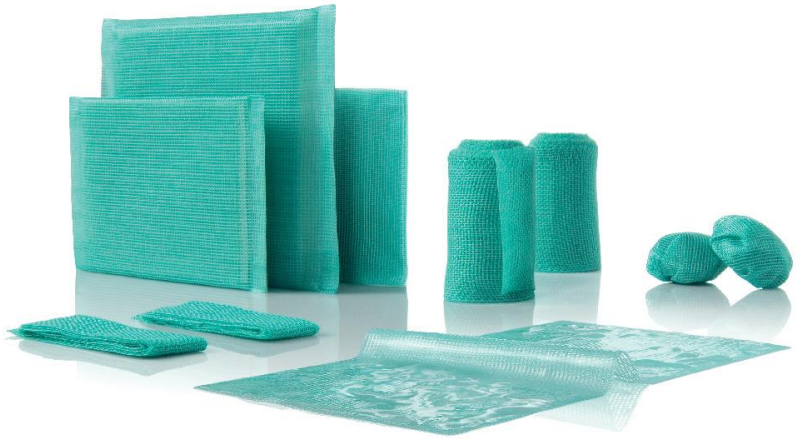
Back to the Questions

Question
Will topical antimicrobial dressing stop or reduce the progression from contaminated/colonized to infected?

In regard of Chronic Wounds
Cutimed® Sorbact® is indicated for clean, contaminated, colonized and infected wounds. However, this is part of research.

In regard of Acute Wounds
Leukomed® Sorbact® provided sound evidence for Cesarian sections.[1)] Cost effectiveness has been also proven. [2)]



Question
Will topical antimicrobial dressing be able to reduce the consumption of systemic antibiotics?

It will be hard to provide robust scientific evidence, however it is common understanding that early and professional management of wounds might reduce the need for systemic antibiotics.

1) Stanirowski et al: RCT evaluating DACC impregnated dressings for the prevention of surgical site infections in adult women undergoing cesarean section; Surgical Infections; 2016
2) Cost effectiveness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