GLOBAL CHALLENGE OF ANTIMICROBIAL RESISTANCE – THE CONTRIBUTION OF LEUKOMED® SORBACT® TO COST-EFFICIENT PREVENTION OF POST-OPERATIVE WOUND INFECTIONS (SSI)

Antimicrobial resistance (AMR) is one of the greatest global public health threats. The main causes worldwide are lack of clean water and sanitation, inadequate infection prevention and control, and antibiotic misuse. AMR is expensive: prolonged hospitalization, higher medication requirements and, last but not least, death and disability are the consequences.

Bacterial **antibiotic resistance** in **therapy-associated infections** is a **cause for concern**. The WHO defines at least 9 pathogens [A]as critical and high priority for the development of new antibiotics. [1]With the **UN General Assembly in** 2016, AMR became an **urgent political concern**. A community of governments, multilateral organizations, civil society and the private sector is working globally on necessary multisectoral action; however, broad implementation of initiatives is often lacking. [2]

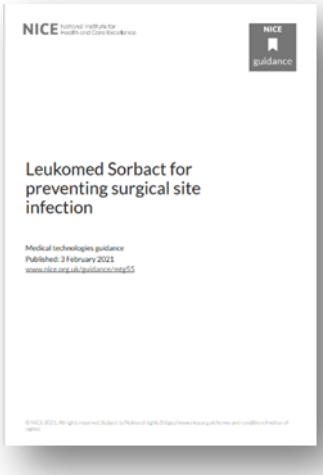
Surgical site infection (SSI) is one of the most common therapy-associated infections.

Cumulative SSI rates worldwide range from 0.9% (USA), 2.6% (Italy), 2.8% (Australia) to 6.1% in low-middle income countries and 7.8% in South East Asia. [3] SSI rates are highly variable, depending, among other things, on the type of surgery, contamination class of the surgery, patient-specific and surgery-specific risks. [4] SSI rates of 3-15% have been reported after caesarean section (CS) deliveries. [5] After vascular surgery, data from a national survey in England showed SSI rates of 2.7%. [6]

The primary goal in the context of SSI is prevention.

A large number of guidelines exist on this (KRINKO [4], ACSIS [7], CDC [8], NHMRC [9], NICE [10], and others). The **NICE guidance MTG55**, published in February 2021, also recommends **Leukomed® Sorbact®** as an **option for SSI prevention after CS and vascular surgery.** [11]

Leukomed® Sorbact® is a sterile wound dressing for single use in closed surgical wounds. The outer transparent polyurethane adhesive film creates a moist environment and protects the wound. Underneath is an absorbent pad covered with a green contact layer coated with **dialkyl carbamoyl chloride (DACC)**. The patented substance



- Leukomed Sorbact reduces SSI after caesarean section (4.1)
- Leukomed Sorbact reduces SSI after vascular surgery (4.2)
- The clinical experts were broadly optimistic that Leukomed Sorbact may be useful for other types of surgery. (4.4)
- Using Leukomed Sorbact to reduce SSI risk after caesarean section may enhance recovery (4.5)
- Leukomed Sorbact has only uncommon, minor adverse events (4.7)

https://www.nice.org.uk/guidance/mtg55/resources/leukomed-sorbact-for-preventing-surgical-site-infection-pdf-64372117923781

[A] Priority 1 (critical): *Acinetobacter baumannii*, carbapenem-resistant (CR), *P. aeruginosa*, (CR), *Enterobacteriaceae*, (CR), ESBL-forming. Priority 2 (high): *Enterococcus faecium*, Vancomycin-resistant, *S. aureus,* Methicillin-resistant, Vancomycin-intermediate and -resistant, *Helicobacter pylori,* Clarithromycin-resistant, *Campylobacter spp.,* Fluoroquinolone-resistant (FR), *Salmonellae*, (FR), *Neisseria gonorrhoeae*, Cephalosporin-resistant, (FR).

irreversibly binds hydrophobic bacteria and fungi so that microorganisms are inhibited in their growth and removed during dressing changes.

The **purely physical binding does** not produce endotoxin release or cell debris, as germs are not killed. As a result, the **development of resistance** to DACC is neither known nor expected. In vitro studies show **high binding capacities independent of antibiotic resistance** [12] as well as **strong antimicrobial activity** through growth inhibition of the **pathogens** tested here and **rated as critical** by the **WHO**: *S.aureus* (MRSA), *E.faecium (*VRE), *P.aeruginosa (*ESBL), *E.cloacae* (ESBL) and *A.baumannii*. [13]
Leukomed® Sorbact® is suitable for postoperative and traumatic wounds with up to moderate exudation, e.g. surgical incision, lacerations and skin abrasion. [14]

Leukomed® Sorbact® can reduce the rate of surgical wound infections, antibiotic use and associated hospital admissions.

Clinical trials ([15], [16], [17], 18]) provide the basis for the recommendations of NICE guidance MTG55 [11] that Leukomed® Sorbact® **reduces SSI rates compared with** standard dressings in **CS** and **vascular surgery**. In addition, the NICE guidance summarises from the clinical evidence that Leukomed® Sorbact® can both **reduce antibiotic use** and **reduce** the rate of **readmissions for wound complications**. Leukomed® Sorbact® is generally well tolerated, suitable for everyday use (showering is possible) and discreet, which is especially true when compared to PICO negative pressure therapy. [11]

Evidence				
Reference	**Stanirowski et al 2016a**	**Stanirowski et al 2016b**	**Bua et al 2017**	**Totty et al 2019**
Trial Design	RCT	Pilot RCT	Controlled Trial	Pilot RCT
Participants	543 women – c-section	142 women – c-section	200 patients – non-implant vascular	144 patients – non-implant/implant vascular
Interventions	DACC vs. standard	DACC vs. standard	DACC vs. standard	DACC vs. standard
Outcome	SSI – 14 days	SSI -14 days	SSI - 5-7 & 30 days	SSI – 30 days
Results	65% RRR in SSI	71% RRR in SSI	47% RRR in SSI	37% RRR in SSI

Leukomed® Sorbact® is cost-efficient.

The cost analysis of [16] showed total costs for SSI prevention and treatment of €1,065 compared to €5,775 in the standard dressing group, of which €2,543 additional costs were due to additional hospitalization alone. A decision analytic model from an NHS perspective using clinical data from [16] showed a cost saving of £119 per patient in favour of Leukomed® Sorbact®.[19] NICE guidance MTG55 [11] concludes that **reducing SSI rates** with Leukomed® Sorbact® compared with standard dressings results in **cost savings of £107 per patient after CS** and **£18 per patient after vascular surgery,** which extrapolates to an annual NHS saving of £5.3m for CS and £1.2m for vascular surgery.
During the NICE process, the clinical experts were positive about the clinical benefits of Leukomed® Sorbact® , noting that the product appears to reduce wound infections and is easy to use. The clinical experts were broadly optimistic that Leukomed® Sorbact® could also be useful for other types of surgery.

When used appropriately, Leukomed® Sorbact® can play an effective and cost-reducing role in SSI prevention, making a valuable contribution to the management of antimicrobial resistance.

[1] WHO. 27.02.2017. Online. https://www.who.int/news/item/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed
[2] Wellcome. 16.11.2020. Online. https://wellcome.org/reports/global-response-amr-momentum-success-and-critical-gaps
[3] Ling ML et al. APSIC guidelines for the prevention of surgical site infections. Antimicrob Resist Infect Control. 2019;8:174.
[4] Prävention postoperativer Wundinfektionen. Bundesgesundheitsbl 61, 448–473 (2018). https://doi.org/10.1007/s00103-018-2706-2
[5] Saeed KB et al. Incidence of surgical site infection following caesarean section. BMJ Open. 2017;7(1):e013037.
[6] Troughton R et al. Mapping national surveillance of surgical site infections in England: needs and priorities. J Hosp Infect. 2018;100(4):378-385. 6
[7] Ban KA et al. American College of Surgeons and Surgical Infection Society: SSI Guidelines, 2016 Update. J Am Coll Surg. 2017;224(1):59-74.
[8] Berríos-Torres SI et al. Centers for Disease Control and Prevention Guideline for the Prevention of SSI, 2017 JAMA Surg. 2017;152(8):784-791.
[9] NHMRC. 2019. Online. https://www.nhmrc.gov.au/about-us/publications/australian-guidelines-prevention-and-control-infection-healthcare-2019
[10] NICE guideline [NG125]. Last updated: 19.08.2020. Online. https://www.nice.org.uk/guidance/ng125
[11] NICE. Leukomed Sorbact for preventing surgical site infection. [MTG55]. 03.02.2021. Online. https://www.nice.org.uk/guidance/MTG55
[12] Ronner AC et al. Adhesion of meticillin-resistant Staphylococcus aureus to DACC-coated dressings. J Wound Care. 2014;23(10):484-488.
[13] Husmark J et al. Antimicrobial effect of a DACC-coated bacteria-binding wound dressing against WHO pathogens. EP006 presented at EWMA, Nov. 2020
[14] BSN medical GmbH, Hamburg. IFU. Leukomed Sorbact. Status April 2014
[15] Stanirowski PJ et al. DACC-impregnated dressing for the prevention of SSI in women undergoing CS: a pilot study. Arch Med Sci. 2016;12(5):1036-1042. doi:10.5114/aoms.2015.47654
[16] Stanirowski PJ, et al. Randomized Controlled Trial Evaluating DACC Impregnated Dressings for Prevention of SSI in Women Undergoing CS. Surg Infect (Larchmt). 2016;17(4):427-435.
[17] Totty JP et al. A pilot feasibility randomised clinical trial comparing DACC-coated dressings versus standard care for the primary prevention of SSI. Int Wound J. 2019;16(4):883-890.
[18] Bua N et al. DACC Dressings in the Prevention of SSI after Nonimplant Vascular Surgery. *Ann Vasc Surg*. 2017;44:387-392.
[19] Stanirowski PJ et al. Cost-effectiveness of a bacterial-binding dressing to prevent surgical site infection following CS. J Wound Care. 2019;28(4):222-228.