

# Prevention and Treatment of Infection in Post-surgical Wounds: A White Paper

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### Executive summary

Wound infections following surgical procedures are a significant problem and are a major cause of discomfort, poor healing, sepsis and even death with increased health care costs. Surgical site infections (SSI) may be caused by antimicrobial resistant bacteria that are also prevalent in hospitals and exacerbated by the presence of biofilm, leading to poor clinical outcomes such as delayed healing, leaking or foul-smelling wounds, excess scarring, and occasionally additional surgery.

Prevention and treatment of SSIs is an imperative and a major challenge, but in this era of antimicrobial resistant microorganisms the challenge is to use treatments that do not increase their number. This can be done by using antimicrobials that act effectively using a "physical" antimicrobial action, such as the dialkylcarbamoyl chloride (DACC)-coated wound dressing family of Sorbact. This White paper demonstrates evidence that supports the clinical effectiveness of using Sorbact as part of a clinical pathway to enable healing progression, manage wound exudate and prevent/treat infections after several different surgical procedures (vascular surgery, caesarean section, skin grafting, pilonidal sinus excisions, orthopaedic surgery, burns and in use with NPWT).

This White Paper also highlights the fact that the National Institute for Health and Care Excellence have recommended the use of specific DACC-coated dressings in the treatment of some post-surgical wounds. Additionally, the evidence presented supports the positioning of Sorbact dressings in aligning with an Antimicrobial Stewardship strategy in the prevention and treatment of infection in post-surgical wounds in that these dressings acting by a physical mode of action) do not induce resistance in microbial organisms.

#### **Key Points**

- Surgical site infections are very common and account for approximately 20% of nosocomial infections
- Surgical site infections are exacerbated by the presence of biofilm and antimicrobial-resistant organisms
- These infections lead to poor clinical outcomes such as delayed healing
- Treatment may require the use of antibiotics that can increase the risk of the development of antimicrobial resistance
- An alternative to the use of antibiotics in the treatment of surgical site infections is the use of antimicrobial agents that have a physical mechanism of action
- Dressings coated with dialkylcarbamoyl chloride (DACC) have proven effectiveness in treating a wide variety of surgical site infections

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# Glossary

Term	Definition
Antimicrobial resistance	when microorganisms change over time and no longer respond to medicines (antimicrobial agents) making infections harder to treat and increase the risk of disease spread.
Antimicrobial stewardship	a set of coordinated measures designed to improved and appropriate use of antimicrobials to improve outcomes, reduce microbial resistance, and decrease the spread of infections.
Bacterial endotoxins	a component of the outer membrane of the cell wall of gram-negative bacteria. They are released from bacteria after cell death and lysis of the cell and are implicated in the development of gram-negative shock.
Biofilm	a thin community of bacteria enclosed in a self-produced matrix that adheres to a biological or non-biological surface. The formation of a biofilm creates a barrier resistant to the effects of antibiotics.
Debridement	a medical procedure to remove dead, damaged, or infected tissue from a wound to improve the healing potential of the wound.
Dialkylcarbamoyl chloride (DACC) -coated dressings	wound dressings coated in a fatty acid derivative that irreversibly binds bacteria at the wound surface that are then removed when the dressing is changed. Wound dressing examples include Leukomed Sorbact and Cutimed Sorbact.
Granulation tissue	new connective tissue that forms on the surface of a wound during the healing process.
Implant	device(s) or tissue(s) placed inside or on the surface of the body to replace missing body parts (e.g., prosthetics) or deliver medication, monitor body functions, or provide support to organs and tissues.
Intravenous (IV)	within or administered into a vein.
NICE	the National Institute for Health and Care Excellence. An executive non- departmental public body of the Department of Health and Social Care in England that publishes a variety of guidelines (e.g., the use of new and existing medicines, treatments, and procedures).
Nosocomial	a disease acquired in a healthcare facility. Also referred to as healthcare- associated or hospital-acquired infections.
Pilonidal sinus	a small hole or tunnel in the skin of the cleft at the top of the buttocks that can form a small cyst or abscess. It may fill with fluid or pus when infected.
Prophylactic	preventing the spread or occurrence of disease or infection.
Randomised controlled trial (RCT)	a type of experiment or study on two or more groups to assess the impact of an intervention. Participants are randomly assigned to receive an intervention (experimental group(s)) or not (the control group).
Re-epithelialisation	the resurfacing of a wound with new epithelium. It is usually the final healing stage of a wound whereby the surface layer over the wound regenerates from the edges of the wound site.
Surgical site infection (SSI)	an infection that occurs at the site of a surgical operation.
World Health Organisation	the WHO. A United Nations agency to coordinate international health activities and to aid governments improve their health services.

# 1. Background

#### **1.1 Surgical Site Infections**

Surgical site infections (SSI) range from minor redness and limiting discharge from a wound to wounds that reopen and cause severe life or limb threatening sepsis. SSIs are the most common type of hospital-acquired infection and account for approximately 20% of nosocomial infections and an incidence from 2.1 to 7.1 for every 1000 operations.<sup>1,2</sup> Although some surgical procedures have a particularly high incidence e.g., colorectal surgery has been reported as 23.9%<sup>3</sup> and the incidence of SSI after lower limb vascular surgery was reported to be 21%.<sup>4</sup> SSI are a major cause of morbidity, mortality, and health care costs.<sup>5</sup> Some of the most common microorganisms associated with SSIs are Staphylococcus aureus, coagulase-negative Staphylococci, Enterococcus, and Escherichia coli.<sup>6</sup> As a further challenge, the presence of biofilm is ubiguitous in SSIs and are associated with delayed healing.<sup>7,8</sup> The biofilm provides bacteria with some physical protection from environmental threats and limits their exposure to antibiotic and antimicrobial agents giving them "antibiotic tolerance", the ability to survive antibiotic exposure without developing antibiotic resistance.9

#### **1.2 Prevention of Surgical Site Infections**

Guidelines have been issued by national and international bodies suggesting evidence-based approaches to minimise risk of SSI development. Steps include, preoperative cleaning of surgical sites, use of prophylactic antibiotics when deemed appropriate, close management of patient's blood sugar's, oxygenation and temperature through the procedure, and use of a suitable covering for the wound once the surgery is complete.<sup>10</sup> Many guidelines also suggest a close surveillance programme to monitor wounds and allow early treatment.

#### **1.3 Treatment of Surgical Site Infections**

The majority of SSI will require some form of antibiotic therapy. This may be delivered as tablets in less severe infection. When SSI are more severe, they often require admission to hospital for intravenous antibiotics and management of complications at the wound site. When treating an SSI management of postoperative biofilm-associated infections involves debridement (e.g., surgical), irrigation/cleansing with antimicrobial agents and the use of specific therapeutic agents that can penetrate the mature biofilm and inhibit/kill encased bacteria.<sup>11</sup> Many patients with SSI will require prolonged stays to manage their antibiotic regimes or to allow for repeat surgical procedures related to their wound or any surgical implants present. A systematic review of dialkylcarbamoyl chloride (DACC)-coated dressings in the management and prevention of wound infection identified 17 studies with a total of 3408 patients. The results suggested that the DACC-coating reduced postoperative SSI rates and chronic wounds looked cleaner and had less bacterial load on microbiological assessment.<sup>12</sup>

#### 1.4 The Role of the Wound Dressing

Evidence has also shown that there is a role for postsurgical wound dressings as aids to prevent SSIs in that they should provide an effective physical barrier and a moist environment for optimal wound healing.<sup>13,14</sup> A review of clinical studies has shown that DACC-coated wound dressings (Sorbact) have been effective in preventing and treating a variety of SSIs.<sup>12,15</sup> These clinical studies are presented and reviewed in the next section of this White Paper.

#### 1.5 Sorbact Wound Dressing Technology

When bacteria come into contact with the DACCcoated wound dressings (e.g., Sorbact® Surgical Dressing). The bacteria become irreversibly bound to the DACC-coated dressings. The bacteria thus retained within the matrix of the Sorbact dressing can then be easily removed at each dressing change. However, because this mechanism does not kill/ damage the bacteria there is no release the bacterial endotoxins (and subsequent toxic repercussions to the patient) that can be seen when "active" antimicrobial agents are used. Additionally, there is no likelihood of this dressing inducing antimicrobial resistance. There are several experimental studies that demonstrate the ability of DACC-coated wound dressings to interact (absorb, sequester and bind) with bacteria enabling the management of infection<sup>16-20</sup> and specifically against World Health Organisation (WHO) pathogens.<sup>21</sup>

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This paper concentrates on specific surgical areas of interest, identified as follows:

- 1. Caesarean section
- 2. Vascular surgery
- 3. Skin graft
- 4. Miscellaneous surgical wounds

#### **KEY POINTS - SSIs**

- Incidence of SSIs varyies from 2.1 to 7.1 for every 1000 operations
- Presence of biofilm ubiquitous in SSIs and is associated with delayed wound healing
- Antimicrobial resistance further exacerbates and delays wound healing and other clinical outcomes
- Treating SSIs utilises debridement, irrigation/cleansing with antimicrobial agents and the use of specific therapeutic agents that can penetrate mature biofilm to inhibit/kill encased bacteria
- Evidence indicates that DACC-coated wound dressings such as Sorbact are effective in preventing and treating a variety of SSIs

# 2. Surgical Procedures

#### 2.1 Caesarean Section

Caesarean section (CS) is a foetal delivery through an open abdominal incision (laparotomy) and an incision in the uterus (hysterotomy). SSI is one of the most common complications following caesarean section (see Figure 1), has an incidence of up to 15% and is associated with a maternal mortality rate of up to 3%.<sup>22</sup> SSI contribute to prolonged hospitalization time and increased treatment costs. Several clinical studies have shown the effectiveness of DACC-coated wound dressings in the prevention and treatment of SSI in CS.

Three studies provide clinical evidence for the use of DACC-coated wound dressings in caesarean surgery (Table 1). A pilot single blind randomised controlled trial (RCT) was undertaken to evaluate the prevention of SSI in women undergoing CS when treated with either a DACC-coated wound dressing or standard surgical dressing. Patients (n=142) undergoing planned or emergency CS were enrolled in the study. The rate of superficial and deep SSIs was 2.8% vs 9.8% in groups receiving DACC-coated wound dressings or standard dressings respectively (p=0.08). Additionally, patients with SSIs who received a standard surgical dressing required systemic antibiotic therapy significantly more frequently, p=0.03.<sup>23</sup>

A full scale RCT was then undertaken evaluating DACC-coated wound dressings for the prevention of SSIs in women undergoing Caesarean Section. Patients (n=543) were randomly allocated to receive either DACC-coated wound dressing or standard of care (SoC) surgical dressing following skin closure. The results showed that SSI rates in the patients treated with DACC-coated wound dressings and SSD groups were 1.8% and 5.2%, respectively, p=0.04.<sup>24</sup>



Figure 1. Patient with post-caesarean surgical site infection

A cost analysis was undertaken on data from this larger study and showed that patients treated with the DACC-coated wound dressings had six fewer outpatient visits and 33 fewer hospital bed-days. The mean length of SSI-attributable hospitalisation was 2.36 days. The overall costs of SSI prophylaxis and treatment were £48.97 and £24.69 per patient in the SoC and DACC-coated wound dressing groups respectively.

Depending on the costing model used savings suggested to be due to use of DACC-coated wound dressings were between £24.27 (a 49.6% reduction) or £119 (a 57.6% reduction) per patient compared to SoC.<sup>25</sup>

In support of the clinical data a systematic review and meta-analysis was conducted to evaluate the effectiveness of advanced dressings in SSI prevention post-caesarean section. The results showed that DACC-coated wound dressings potentially reduced SSI, but with no demonstrable benefit of silver dressings.<sup>26</sup>

Table 1. Summary of key peer-reviewed clinical evidence for use of Sorbact range in cesarean surgery						
Author	Study design	Sample size	Intervention	Outcome measures	Main findings	
Stanirowski et al, 2016 <sup>23</sup>	Single-blinded randomized, controlled pilot study	n=142	Intervention: Sorbact Surgical dressing Control: standard surgical dressing	Superficial or deep SSI within 14 days after c-section	SSI rates of 2.8% in DACC-coated dressing versus 9.8% in control (p=0.08)	
Stanirowski et al, 2016 <sup>24</sup>	Single-blinded randomized, controlled study	n=543	Intervention: Sorbact Surgical dressing Control: standard surgical dressing	Superficial or deep SSI within 14 days after c-section Cost-effectiveness of dressing to prevent SSI	SSI rates of 1.8% with DACC-coated dressing versus 5.2% in control (p=0.04) 10nly in DACC group was there no use of systemic antibiotic treatment or hospital readmission	
Stanirowski et al, 2019 <sup>25</sup>	Single-blinded randomized, controlled study	n=543	Intervention: Sorbact Surgical dressing Control: standard surgical dressing	Costings comparison	Costs were £48.97 and £24.69 per patient in the SoC and DACC-coated dressing groups respectively	

#### Key Points - Caesarean Section

- SSI is one of the most common complications following caesarean section with an incidence of up to 15%, and is associated with a maternal mortality rate of up to 3%
- Sorbact<sup>®</sup> Surgical Dressing<sup>®</sup> significantly reduced the number of patients with SSI
- Cost of SSI prophylaxis and treatment significantly less per patient in the standard of care and DACC-coated dressing groups, respectively

#### 2.2 Vascular surgery

The risk for SSIs after vascular surgery (Figure 2) is up to two in every five procedures in this high-risk surgical group and up to 5 times more common than other surgical specialties.<sup>27</sup> This is due to the nature of patients requiring vascular surgery frequently being elderly and frail, and commonly also being smokers or those suffering with diabetes.

Two studies support the use of Leukomed<sup>®</sup> Sorbact<sup>®</sup> as a wound dressing that can be used to prevent vascular post-surgical wounds (Table 2).



**Figure 2.** Infected wound on the wrist of a 67-year-old male two weeks after vein harvest for a coronary artery bypass graft

The first was a non-randomised comparative study and was undertaken to evaluate the use of DAACcoated wound dressings in the prevention of SSI after nonimplant vascular surgery. In this study, a group of consecutive patients (n=100) had their operative wounds dressed in conventional dressings and subsequent consecutive group (n=100) were treated with postoperative DACC-coated wound dressings. The results showed that the rate of SSI at 5 days was significantly lower in the DACC-coated wound dressings group compared with standard dressings (1% vs. 10%, p<0.05), but there was no difference seen at 30 days. Logistic regression suggested that the type of dressing used was the most prominent predictor variable for the presence of early SSI p=0.028, odds ratio=0.09, 95% confidence interval: 0.01-0.77.<sup>28</sup>

The second study, a two-arm, parallel-group, single blinded pilot feasibility RCT was undertaken comparing DACC-coated wound dressings versus standard care for the primary prevention of SSI in patients (n=110) undergoing clean or cleancontaminated vascular surgery. The results showed that at 30 days, there was a 36.9% relative risk reduction in the DACC-coated wound dressings arm (16.22% versus 25.71%, odds ratio 0.559, p=0.161).<sup>29</sup>

Table 2. Summary of key peer-reviewed clinical evidence for use of Sorbact range in vascular surgery					
Author	Study Design	Sample Size	Intervention	Outcome Measures	Main Findings
Bua et al, 2017 <sup>28</sup>	Prospective, non-randomised comparative study	n=200	Intervention: postoperative DACC-coated wound dressing Control: standard / conventional dressing	Primary outcome: presence of SSI Secondary outcome included evidence of healing	Rate of SSI at 5 days was significantly lower in the DACC-coated wound dressings group compared with standard dressings (1% vs. 10%, P < 0.05). There was no difference in the rates of SSI at 30 days <sup>1</sup>
Totty et al, 2019 <sup>29</sup>	Two arm pilot feasibility RCT	n=110	DACC-coated wound dressing occlusive absorbent dressing (Leukomed Sorbact, or a non-DACC-coated occlusive absorbent dressing (OPSITE Post-op))	The incidence of SSIs within 30days of surgery	At 30 days there was a 6.9% relative risk reduction in the DACC-coated wound dressings arm (16.22% versus 25.71%, odds ratio 0.559, P = 0.161)

<sup>1</sup> It is noteworthy that only a single patient in the DACC coated wound dressing group with an SSI required 7 days of I.V. antibiotic whilst in the standard dressing group all 10 patients with SSI at day 7 were treated with antibiotics and two of which required I.V. antibiotics and the other 8 patients were treated with oral antibiotics.

#### **Key Points - Vascular Surgery**

- The risk of SSIs after vascular surgery is high (up to two in every five procedures and up to five times more common than other surgical specialties)
- This high risk is because patients requiring vascular surgery are generally elderly and frail, are smokers or diabetic
- DACC-coated wound dressings have been shown to reduce the incidence of SSIs post-vascular surgery

#### 2.3 Skin Grafting

A skin graft is where healthy skin is removed from an unaffected area of the body and used to cover an area where the skin has been lost or damaged. Infection is a significant problem that can cause graft failure (see Figure 3) and infection rates can vary from 0 to 56%.<sup>30</sup> As an imperative therefore the prevention or treatment of infection is a requirement for optimizing graft take.

Three clinical studies have demonstrated the effectiveness of Sorbact dressing when used in the management of skin graft sites (Table 3) In the first study Cutimed Sorbact was used for fixation of grafts after surgery and was shown to be effective in preventing infection in 7 patients.<sup>31</sup>

In another study of a parallel three-arm prospective RCT (n=101) Sorbact was compared with two other dressings as donor site dressings in paediatric splitthickness skin grafting donor sites. The results showed that all three dressings performed equally in terms of time to re-epithelialisation and with no difference between the 3 dressings in pain scores.<sup>32</sup>

A further non-randomised retrospective clinical study was undertaken comparing two wound dressings a) DACC-coated wound dressings/ with



**Figure 3.** Site of skin graft infected with Pseudomonas aeruginosa

chlorhexidine acetate-soaked paraffin gauze versus b) a foam dressing for in patients who underwent split-thickness skin grafts. The results demonstrated that epithelialisation duration was significantly shorter in the DACC-coated wound dressing group. The control group had longer wound healing times, regardless of wound size. It was concluded that application of DACC-coated wound dressing and chlorhexidine acetate-soaked paraffin gauze to skin graft donor sites can shorten healing times and is effective in treating infected wounds.<sup>33</sup>

Table 3. Summary of key peer-reviewed clinical evidence for use of Sorbact range in skin graft/donor sites					
Author	Study Design	Sample Size	Intervention	Outcome Measures	Main Findings
Choi et al, 2015 <sup>31</sup>	Case series	n=7	Skin graft dressed with DACC-coated wound dressing	Wound infection	No wounds became infected
McBride et al, 2018 <sup>32</sup>	Prospective, randomized controlled study	n=101	Intervention: Sorbact Comparator: calcium alginate dressing or ointment- impregnated gauze	Primary outcome: days to re- epithelialisation Secondary outcome includes cost and pain management	Sorbact as effective as calcium alginate dressing regarding re- epithelialisation, pain management and cost
Lee et al, 2018 <sup>33</sup>	Retrospective evaluation	n=60	DACC-coated wound dressing with chlorhexidine acetate-soaked paraffin gauze versus a foam dressing	Epithelialisation and wound healing	Epithelialisation duration was significantly shorter in the DACC group. DACC- coated wound dressing and chlorhexidine acetate- soaked paraffin gauze to SGDS enabled healing treatment of infected wounds

#### **Key Points - Skin Graft Surgery**

- Risk of SSI after skin graft surgery ranges from 0% to 56%
- Prevention or treatment of infection in skin graft surgery is a requirement for optimising skin graft take
- DACC-coated wound dressings effective in preventing infection and for enabling healing progression in patients undergoing graft surgery

# 2.4 Miscellaneous Surgical Wounds

Table 4 summarises the clinical evidence for the use of DACC-coated wound dressings for the treatment of a variety of surgical wounds.

#### 2.4.1 Orthopaedic Wounds

Orthopaedic injuries can include any injury to the musculoskeletal system. Often, these injuries relating to the bones and joints are a result of an accident or trauma to the body or the result of a surgical intervention.<sup>34</sup> Wound healing in orthopaedic care is affected by the causes of the wound, as well as concomitant therapies used to repair musculoskeletal structures.<sup>35</sup> Orthopaedic wounds can present many different challenges e.g., blistering, pain, need for implants and external fixation/pin sites. In addition, excess exudate can lead to wound breakdown, increased bacterial burden and delaying healing (Figure 4), causing an increased risk of superficial SSI, and ultimately increasing the risk of severe deep SSI (Catastrophic in the presence of metallic implants). As such a wide variety of wound dressings are used each with a different attribute(s) to overcome a specific challenge.



Figure 4. Infected knee replacement surgery wound

A recent study<sup>36</sup> evaluated seven different postoperative dressings (n=307 patients) as part of a quality improvement program and to identify the most appropriate dressing for the management of postoperative wounds in orthopaedic patients. The results showed that most healthcare professionals were satisfied, very satisfied, or extremely satisfied with the ease of application of all dressings.

#### 2.4.2 Pilonidal Sinus Excision Wounds

A pilonidal sinus is a small hole or tunnel in the skin is a common condition that affects mainly young adults. It occurs in the cleft at the top of the buttocks. Pilonidal sinus is caused by the forceful insertion of hairs into the skin of the natal cleft in the sacrococcygeal area. This promotes a chronic inflammatory reaction, causing an epithelialised sinus. It may become infected and fill with fluid or pus, causing the formation of a cyst or abscess (Figure 5). Pilonidal disease presents a significant disease burden worldwide affecting the working age population.<sup>37</sup> Management of this disease consist mainly of excision of the sinus tracts, frequently leaving the resulting wound open to heal by secondary intention and importantly, given the location of the wound, leaving it open to infection which will delay healing.<sup>38</sup> Thus, the dressing used to treat the pilonidal sinus wound is important in terms of enabling wound healing progression and preventing/treating further infection.



**Figure 5.** Non-healing pilonidal sinus wound with suspected infection

A recent study compared wound healing progression for pilonidal sinus wounds using two different types of dressing (e.g., a DACC-coated dressings versus alginate dressings).<sup>39</sup> The results showed that there were significantly more patients with completely healed wounds after 75 days in the DACC-coated wound dressing group than in the alginate group: 78 of 103 (75.7%) versus 58 of 97 (60%) respectively (odds ratio 2.55, 95% confidence interval 1.12 to 5.92; p=0.023). During follow-up, wounds with alginate dressings had more fibrin than those with DACC-coated wound dressings, but this difference was not significant (p=0.079).

#### 2.4.3 Complex Post-operative Surgical Wounds

Negative pressure wound therapy (NPWT) consists of a closed, sealed system that applies negative pressure (suction) to the wound surface.<sup>40</sup> Indications for the use of NPWT are broad and compared with standard wound care, NPWT may reduce the risk of SSIs.<sup>41</sup> In order that the negative pressure is applied across the entire wound surface wound fillers (foam and gauze are used), but foam is more absorbent, while gauze is more malleable and conformable. The wound filler (primarily foam) may in some circumstances grow into the newly forming wound tissue causing pain and damage to granulation tissue upon removal, in these circumstances a liner is used to prevent this.

Cutimed Sorbact has been shown to be an effective liner when used in NPWT in both animal<sup>42,43</sup> and clinical studies.<sup>44,45</sup> Figure 6 shows an complex infected surgical wound.

In a case series of seven patients with a variety of different wound types, Cutimed Sorbact was found to be easy to apply following NPWT. It could be fashioned into the shape required and its ability to conform to irregular wound margins was as good as that experienced with gauze. In some cases when Cutimed Sorbact was used as wound filler and contact layer, the granulation tissue did not infiltrate the material and dressing removal was atraumatic and overall eliminating the liner helped save time and money. Additionally, wound response and healing outcomes of Cutimed Sorbact-based NPWT were reported to be as good as those seen with conventional wound filler materials.<sup>45</sup>



Figure 6. Infected surgical wound

#### Key Points - Miscellaneous Wounds

- Various miscellaneous surgical wounds have been successfully treated with DACC-coated wound dressings
  - Orthopaedic wounds
  - Pilonidal sinus excision wounds
  - Surgical wounds treated with negative pressure wound therapy (e.g., pilonidal sinus, burns, haematoma, surgical debridement wounds)
- DACC-coated wound dressings effective at exudate management and wound progression

Table 4. Summary of key peer-reviewed clinical evidence for use of Sorbact range in miscellaneous wounds					
Author	Study Design	Sample Size	Intervention	Outcome Measures	Main Findings
Pickles et al, 2022 <sup>36</sup>	Observational study	n=307	Mepore <sup>®</sup> , Opsite <sup>®</sup> Post-Op Visible, Leukomed <sup>®</sup> Control, Sorbact <sup>®</sup> surgical dressing, Mepilex <sup>®</sup> Border Post-Op, Tegaderm <sup>®</sup> and Aquacel <sup>®</sup> Ag Surgical	Clinician satisfaction with wound dressings	Equivalent satisfaction
Romain et al, 2020 <sup>39</sup>	Randomised controlled trial	n=246	DACC-coated wound dressing or alginate dressings	Proportion of wounds healed after 75 days	Wounds healed at 75 days was significantly higher for DACC-coated compared with alginate dressings
Jeffery et al, 2014 <sup>45</sup>	Case series	n=7	DACC-coated wound dressing	Wound progression	DACC-coated wound dressing promoted wound progression

#### 2.4.4 Umbilical Cord Care

In the first few days following birth, the umbilical stump can become infected (omphalitis). Rates of omphalitis can vary from 0.2% to 0.7% with sepsis as the most common complication, that can progress to septic shock and death (estimated mortality rate between 7% and 15%).

Importantly the use of Sorbact has been shown to be effective in preventing omphalitis in new-borns. A prospective randomized study was undertaken to evaluate 2 different regimens for umbilical disinfection in new-born infants: (i) patients were treated with either a DACC-coated wound dressing (n=1213) or had daily cleansing with 0.5% chlorhexidine in 70% ethanol (n=1228). The results demonstrated that overall, 377 (15.4%) cases of infection were reported, but there was no significant difference in infection rates between the DACC coated wound dressing group and the 0.5% chlorhexidine in 70% ethanol solution group 16.3% and 14.6% respectively, p>0.05 (Table 5).<sup>46</sup> However, the massive use of chlorhexadine glutamate has led to the development of a reduced susceptibility to it among bacteria in general and in Staphylococcus aureus specifically.<sup>47</sup> As result of this, the potential to develop resistance to chlorhexidine is increased and this has widespread implications for a wide range of applications, including treatment of wounds.<sup>48</sup>

Table 5. Summary of key peer-reviewed clinical evidence for use of Sorbact range in umbilical cord care					
Author	Study Design	Sample Size	Intervention	Outcome Measures	Main Findings
Meberg & Schøyen, 1990⁴⁵	Prospective randomized controlled study	n=2441	Intervention: Cutimed Sorbact Control: daily cleansing with 0.5% chlorhexidine in 70% ethanol	Wound infection	No significant difference in either overall rate of infection

#### **Key Points - Umbilical Cord Care**

- Risk for an infected umbilical cord ranges from 0.2% to 0.7%
- Infected umbilical cords may progress to septic shock and death with an estimated mortality rate between 7% and 15%)
- DACC-coated wound dressings are as effective in managing umbilical cord infection as standard of care (0.5% chlorhexidine in 70% ethanol)

# 3. National Institute for Health and Care Excellence Recommendations

In 2021 the National Institute for Health and Care Excellence (NICE) provided evidence-based recommendations on Leukomed Sorbact for preventing SSI after caesarean section or vascular surgery.<sup>49</sup> The committee noted that the evidence suggested that Leukomed Sorbact reduced SSI in caesarean section<sup>23,24</sup> and vascular surgery.<sup>28,29</sup> In three studies reviewed there was less need for antibiotic treatment with Leukomed Sorbact,<sup>23,24,28</sup> and using the dressing may reduce readmissions from wound complications when compared with patients treated with standard dressings.<sup>23</sup> in an economic analysis, studies showed that Leukomed Sorbact is cost saving when compared with standard surgical dressings.<sup>23,25</sup> By adopting this technology,

the NHS may save up to £5.3 million per year for caesarean section and up to £1.2 million per year for vascular surgery. These cost savings are expected because fewer people will need to stay in or be readmitted to hospital for treatment of SSI. Although the current evidence supported evidence for the benefits of the DACC-coated wound dressing in SSIs is in caesarean surgery and vascular surgery, the expert committee were "optimistic" that Leukomed Sorbact may be useful for other types of surgery.<sup>49</sup>

# 4. Antimicrobial Resistance in Post-surgical Wounds

It is important to note that when the causative pathogens of SSI are multidrug-resistant they are considerably more difficult to treat and are associated with substantially longer hospital stay, higher treatment cost, morbidity, and mortality.<sup>50</sup> For example, methicillin-resistant Staphylococcus aureus (MRSA) represents 50% of hospital-acquired infections in the United States and Europe, and these infections very difficult to treat due to their resistance to multiple antibiotics.<sup>51</sup> Multi drug resistant infections are particularly common in hospitals. Nearly 8% of hospitalized patients develop hospital-acquired infection, 20% of which could be caused by such pathogens.<sup>52</sup> Antimicrobial resistance is a growing threat to global public health. It increases morbidity and mortality and has substantial economic implications.<sup>53</sup> As a consequence, and to overcome the further development of more resistant organisms, the WHO have a list of 29 recommendations on 23 topics for the prevention of SSI in the pre-, intra and postoperative period.<sup>10</sup> Additionally, there has been the development of an antimicrobial stewardship strategy that aligns with the prevention/treatment of infection in post-surgical wounds.

#### 4.1. Antimicrobial Stewardship in Post-Surgical Wounds

The basis of AMS is enabling infection prevention and treatment programs that provide standard, evidence-based approaches to either avoid or encourage judicious use of antimicrobial agents.<sup>54</sup> However, controversy remains regarding optimal antibiotic/antimicrobial choice, dosage, and length of surgical prophylaxis.<sup>55</sup>

It has been demonstrated that there is a role for the use of wound dressings in preventing and treating SSIs<sup>56</sup> and importantly in supporting an antimicrobial stewardship programme and even more importantly this can involve the use of DACC-coated dressings.<sup>21,57</sup> Whereby these dressings work by utilising a naturally occurring property of the bacterial to promote the binding and physical uptake, sequestration, and removal of intact microorganisms from the wound bed by the dressing. As such the evidence presented in this White Paper supports the use of these dressing to manage infection in post-surgical wounds and aligns with AMS strategies.

#### **Concluding Remarks**

- Antimicrobial resistance is becoming one of the most significant healthcare challenges of the 21st Century, with an estimated 10 million deaths by 2050
- Antimicrobial stewardship has been developed as a strategy to combat the rise in AMR
- New antimicrobials (e.g., antibiotics) are required to be developed to treat the high-risk resistant pathogens as described by the World Health Organization
- DACC-coated wound dressings can be used to prevent or treat wound infection. There is a considerable amount of experimental and clinical evidence that supports the use of these wound dressings
- DACC-coated wound dressings are effective against the top five antibiotic-resistant microbes such as MRSA and is not linked to any risk of development of resistant strains of microorganisms from use
- Not inducing resistance in any microorganisms, DACC-coated wound dressings can be used as part of an AMS aligned wound infection prevention/treatment regimen

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