NICE National Institute for Health and Care Excellence

NICE guidance

Leukomed Sorbact for preventing surgical site infection

Medical technologies guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces MIB197.

1 Recommendations

1.1 Evidence supports the case for adopting Leukomed Sorbact for closed surgical wounds after caesarean section and vascular surgery.

1.2 Leukomed Sorbact should be considered as an option for people with wounds that are expected to have low to moderate exudate after caesarean section and vascular surgery. It should be used as part of usual measures to help reduce the risk of surgical site infection. More evidence is needed on the use of Leukomed Sorbact on wounds after other types of surgery.

1.3 Cost modelling shows that the reduced rate of surgical site infection with Leukomed Sorbact compared with standard surgical dressings leads to savings of:

- £107 per person after caesarean section
- £18 per person after vascular surgery.

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. Cost savings are expected because fewer people will need to stay in hospital for treatment of surgical site infection. For more details, see the NICE resource impact report.

Why the committee made these recommendations

Leukomed Sorbact is an interactive dressing that binds to the microbes that cause surgical site infection so they are removed when the dressing is changed.

Evidence suggests that using Leukomed Sorbact instead of standard dressings after caesarean section and vascular surgery reduces the rate of surgical site infection and leads to cost savings. So Leukomed Sorbact is recommended for wounds expected to have low to moderate exudate.

2 The technology

Technology

2.1 Leukomed Sorbact (Essity), is a sterile, single-use, bacteria-binding, adhesive-bordered wound dressing. It is used to prevent surgical site infection (SSI) in closed surgical wounds that have low to moderate exudate.

2.2 The dressing comprises an absorbent non-woven wound contact pad and an outer transparent adhesive polyurethane film. The pad is made of a white viscose polypropylene and polyester mesh that is coated with the proprietary compound dialkylcarbamoyl chloride (DACC). DACC is hydrophobic, meaning that it does not mix with water and tends to bind to itself or other hydrophobic materials if water is present. In a moist wound, DACC binds to hydrophobic bacteria and fungi that cause SSI. These bound microorganisms are then removed from the wound site when the dressing is changed. Binding to DACC does not cause bacteria to be lysed (broken open), which avoids causing inflammation at the wound site. The polyurethane film is designed to maintain a moist environment and protect the wound from external contamination. The dressing is available in various sizes.

Innovative aspects

2.3 The innovative aspect is the DACC component. This binds and inactivates bacteria through hydrophobic interaction, which helps to reduce colonisation of the wound by potentially harmful microbes.

Intended use

2.4 Leukomed Sorbact is intended to be applied by a surgeon or theatre nurse in the operating theatre after surgery. It can also be used in the early postoperative period when the dressing needs to be replaced.

Costs

2.5 The cost of Leukomed Sorbact is £9.15 per dressing (excluding VAT). There are no other costs for implementing this technology and no training costs. For more details, see the website for Leukomed Sorbact.

3 Evidence

Clinical evidence

The relevant clinical evidence consists of 5 studies, including 3 randomised trials

3.1 The external assessment centre (EAC) considered 5 publications:

- 1 randomised controlled trial (RCT; Stanirowski et al. 2016a)
- 2 pilot RCTs (Totty et al. 2019; Stanirowski et al. 2016b)
- 1 non-RCT (Bua et al. 2017) and
- 1 unpublished audit (Taylor et al. 2020).

The EAC excluded 5 studies identified by the company because 4 did not include Leukomed Sorbact and there were significant uncertainties about the design of 1 study.

The evidence considered is limited to caesarean section and vascular surgery

3.2 Stanirowski et al. 2016a and 2016b were both done in Poland in women having elective or emergency caesarean section. Totty et al. 2019 and Bua et al. 2017 were UK studies in people having vascular surgery. Taylor et al. 2020 contained audit data provided by the company on women having caesarean section in 1 UK health board.

The evidence suggests Leukomed Sorbact reduces SSI in caesarean section and vascular surgery

3.3 Up to 30 days after surgery, surgical site infection (SSI) rates were lower for people having Leukomed Sorbact compared with those having

standard dressings. The difference in infection rates was not always statistically significant depending on the trial size. The largest RCT was considered to have the least risk of bias (Stanirowski et al. 2016a). In this study, the SSI rate was 1.8% for Leukomed Sorbact compared with 5.2% for standard dressings at 14 days after caesarean section (statistically significant, p=0.04). In Stanirowski et al. 2016b, the SSI rate was 2.8% for Leukomed Sorbact compared with 9.8% for standard dressings at 14 days after caesarean section (not statistically significant; p=0.08). In Bua et al. 2017, the SSI rate was 1% for Leukomed Sorbact and 10% for standard dressings at 5 to 7 days after vascular surgery (statistically significant, p<0.05). In Totty et al. 2019 and Bua et al. 2017, SSI rates were 16% and 9% at 30 days respectively for Leukomed Sorbact after vascular surgery, compared with 26% and 10% for standard dressings. The differences were not statistically significant (p=0.161 and p=0.83, respectively).

The evidence suggests that Leukomed Sorbact may reduce antibiotic use

3.4 In 3 studies there was less need for antibiotic treatment with Leukomed Sorbact compared with standard dressings (Bua et al. 2017, Stanirowski et al. 2016a and 2016b). In all studies the number of people reported as having antibiotics was low in both arms, and the reported differences were not statistically significant in Stanirowski et al. 2016a (0 in Leukomed Sorbact group, 4 in control group, p=0.13).

The evidence suggests that Leukomed Sorbact may reduce readmissions from wound complications

3.5 In Stanirowski et al. 2016a, women with SSI in the standard dressings group each had 2.9 outpatient hospital visits. Women with SSI in the Leukomed Sorbact group had 4.6 visits, a difference that was statistically significant, p=0.02. However, this was a secondary analysis in a small subgroup of women. The same study found that women with SSI who had Leukomed Sorbact had fewer additional days in hospital (0 days compared with 8.2 days for standard dressings, p=0.22).

Cost evidence

The published economic evidence suggests Leukomed Sorbact is cost saving

3.6 The economic analysis in the Stanirowski et al. 2016a and Stanirowski et al. 2019 studies showed that Leukomed Sorbact is cost saving when compared with standard surgical dressings. In Stanirowski et al. 2016a, total costs for preventing and treating SSI were 5,775 euros in the standard dressings group compared with 1,065 euros in the Leukomed Sorbact group. In Stanirowski et al. 2019, the same data were used and a decision-analytic model was applied from a UK NHS perspective. This showed a cost saving of £119.07 per person in favour of Leukomed Sorbact.

The company's cost modelling finds Leukomed Sorbact to be cost saving for caesarean section, vascular surgery and all surgery

3.7 The company submitted a simple decision tree model with 2 interventions, Leukomed Sorbact or standard surgical dressings. There were 2 outcomes, SSI or no SSI. The time horizon was 30 days. The company reported base-case cost savings per person with Leukomed Sorbact of £107.43 for caesarean section, £23.55 for vascular surgery, and £20.56 for all surgery. The company's sensitivity analyses found these results to be robust to parameter changes.

The EAC agrees with the company's cost model but disagrees about including all surgery because of lack of evidence

3.8 The EAC agreed with the company's model and its assumptions and made 1 change, to the cost of an SSI episode for vascular surgery. Leukomed Sorbact remained cost saving but the cost savings were lower than those estimated in the company's model for vascular surgery, at £17.82 per patient. The cost savings remained robust to parameter changes. The EAC chose not to model the use of Leukomed Sorbact for all types of surgery because it considered that there was insufficient clinical evidence to do so.

4 Committee discussion

Clinical-effectiveness overview

Leukomed Sorbact reduces SSI after caesarean section

4.1 The committee noted that Stanirowski et al. 2016a was a well-performed randomised controlled trial (RCT) with a limited risk of bias. The results showed a statistically significant reduction in surgical site infection (SSI) 14 days after caesarean section with Leukomed Sorbact compared with standard dressings. The committee and clinical experts discussed the relatively low rate of systemic antibiotic use in women who had SSI in this study. The committee considered that this was likely to be explained by the infections being relatively mild. The clinical experts stated that intravenous antibiotics were only needed for treating the most severe SSIs. The committee concluded that using Leukomed Sorbact reduced the rate of SSI after caesarean section compared with standard dressings.

Leukomed Sorbact reduces SSI after vascular surgery

4.2 In the prospective non-randomised Bua et al. 2017 study there were fewer SSIs with Leukomed Sorbact compared with standard dressings at 5 to 7 days and at 30 days. Although the number of people included in the Totty et al. 2019 pilot RCT was relatively small, there were fewer SSIs in those who had Leukomed Sorbact. The committee recognised the limitations of the evidence. But it concluded that the study results and the plausibility of the clinical benefit for this group was sufficient to support the use of Leukomed Sorbact after vascular surgery. It welcomed further research in this area.

The evidence does not support a broader recommendation to use Leukomed Sorbact in all types of surgery

4.3 No evidence was presented to support the use of Leukomed Sorbact in

surgery other than caesarean section and vascular surgery. It was noted that Leukomed Sorbact could potentially be particularly useful in plastic surgery and breast surgery, which involve subcutaneous dissection. One clinical expert stated that Leukomed Sorbact is being used after gynaecological surgery at their hospital, but no data are currently available on this use. The committee concluded that the current evidence could not be extrapolated to support the use of Leukomed Sorbact after all types of surgery. It also concluded that it would welcome further research on the use of Leukomed Sorbact in other types of surgery.

Feedback from clinical experts was positive

4.4 Comments from clinical experts about the clinical benefits of Leukomed Sorbact were positive, noting that it seemed to reduce SSI and was easy to use. The clinical experts were broadly optimistic that Leukomed Sorbact may be useful for other types of surgery.

Other patient benefits or issues

Using Leukomed Sorbact to reduce SSI risk after caesarean section may enhance recovery

4.5 In Stanirowski et al. 2016a, developing SSI led to an increase in mean hospital stay of 8.2 days in the control group. Women with SSI in the Leukomed Sorbact group had more outpatient visits than women with SSI in the control group (4.6 per person compared with 2.9 per person, respectively). This was a secondary analysis in a small subgroup of women. The clinical experts explained that reducing SSI may have additional benefits, such as new mothers being able to care for their babies and a positive effect on postnatal mental health. The committee concluded that reducing the incidence of SSI after caesarean section was likely to reduce the need for prolonged hospital stays and enhance recovery.

Compared with PICO negative pressure wound therapy,

Leukomed Sorbact is comfortable and discreet

4.6 The clinical experts reported that people using Leukomed Sorbact had found it to be comfortable and had positive feedback. Unlike the battery-powered PICO, it can be worn while showering and does not make any noise.

Side effects and adverse events

Leukomed Sorbact has only uncommon, minor adverse events

4.7 The clinical experts noted only 1 report of contact dermatitis after the use of Leukomed Sorbact. The external assessment centre (EAC) identified 1 adverse event registered with the US Food and Drug Administration, in which a person who had a total knee replacement developed a chemical burn after using Leukomed Sorbact. About 1 month after surgery, the person attended the emergency department because of a chemical burn with eschar over the surgical site. The eschar was surgically removed, and the person was discharged after 2 days. This was described in the report as a 'device malfunction' but no other details were reported. The company's submission included an observational study in a poster presentation (Coldwell et al. 2014). In this study there were 2 hypersensitivity reactions to the adhesive in 55 people who had Leukomed Sorbact in an Australian primary care setting.

Relevance to the NHS

The studies using Leukomed Sorbact are relevant to the NHS

4.8 The Stanirowski et al. 2016a and 2016b studies, which investigated the use of Leukomed Sorbact after caesarean section, were both done in Poland. The clinical experts advised, however, that the care pathway and outcome measures reported in these studies were relevant to an NHS setting. The 2 studies investigating the use of Leukomed Sorbact for vascular surgery (Totty et al. 2019 and Bua et al. 2017) were done in the UK. The committee concluded that the evidence was relevant to the

NHS.

NHS considerations overview

Most wounds from vascular surgery and caesarean section are expected to have low to moderate exudate

4.9 Leukomed Sorbact is indicated when a wound is expected to have low to moderate exudate. The clinical experts advised that this would be most caesarean section or vascular surgery wounds. They also explained that people with wounds at risk of high exudate could usually be identified at the time of surgery and would not have Leukomed Sorbact dressings.

Cost modelling overview

The company's cost model is appropriate for caesarean section and vascular surgery but not for other types of surgery

4.10 The committee agreed with the EAC that the company's cost model was appropriate for analysing the costs of using Leukomed Sorbact after caesarean section and vascular surgery. It noted that only small adjustments were needed. The committee also agreed with the EAC that cost modelling was inappropriate for an all surgery group because there was no evidence to support the benefits of Leukomed Sorbact for all types of surgery.

The EAC's base-case analysis shows Leukomed Sorbact is cost saving

4.11 The EAC's base-case analysis showed that, compared with standard dressings, using Leukomed Sorbact is cost saving by:

- £107.43 per person after caesarean section
- £17.82 per person after vascular surgery.

The standard surgical dressing used as the comparator in the cost modelling was the Opsite Post-OP dressing, the best-selling vapour-permeable adhesive film and absorbent sterile pad dressing. The clinical experts confirmed that this standard dressing was widely used in NHS practice.

The sources for the baseline risk of SSI and the costs of treating SSI after caesarean section and vascular surgery are appropriate

4.12 In the company's model, baseline SSI risks for different surgical indications were taken from NHS England or NHS Wales data. The Leukomed Sorbact SSI risk was taken from the pooled results of the clinical studies (Stanirowski et al. 2016a and 2016b for caesarean section; Bua et al. 2017 and Totty et al. 2019 for vascular surgery). The EAC considered the data sources for these inputs appropriate. The cost of SSI in caesarean section was taken from Jenks et al. 2014. The cost of SSI in vascular surgery was taken from an unpublished study (York Health Economics Consortium 2020) but the EAC considered that costs from Jenks et al. 2014 were more appropriate. The committee accepted that these sources were appropriate.

Main cost drivers

The company's sensitivity analyses show that the cost saving with Leukomed Sorbact is robust

4.13 The company's sensitivity analyses varied the rate of SSI and the costs of Leukomed Sorbact and the comparator. Leukomed Sorbact remained cost saving in all these analyses. The company did 1-way sensitivity analysis on the cost per SSI episode, varying the cost estimates within their 95% confidence intervals:

- For caesarean section, the base-case SSI episode cost was £4,048 and the breakeven point was £350.
- For vascular surgery, the base-case SSI episode cost was £3,427 and the breakeven point was £2,000.

A second sensitivity analysis investigated the effect of reducing the standard dressing cost by 50% and increasing the cost of Leukomed Sorbact by 100%, or both. For both caesarean section and vascular surgery Leukomed Sorbact remained cost saving.

The company's scenario analysis reports the breakeven points for reducing SSI risk

4.14 The company did a scenario analysis, varying the relative risk reduction by plus or minus 25%:

- For caesarean section, the base-case SSI risk was 4.35%, with a relative risk reduction of 67% and an incremental cost per person of -£107.43. The breakeven point for relative risk reduction was 6%.
- For vascular surgery, the base-case SSI risk was 2.5%, with a 42% relative risk reduction and an incremental cost per person of -£23.54. The breakeven point for relative risk reduction was 13%.

The EAC's threshold analyses estimate the breakeven points in the cost model

4.15 The EAC did threshold analyses for cost savings from using Leukomed Sorbact after caesarean section and vascular surgery. The breakeven points were estimated for key values in the cost model. For caesarean section:

- baseline SSI risk: base case 4.35%, breakeven point 0.39%
- relative risk reduction in SSI: base case 67%, breakeven point 6%
- SSI episode cost: base case £4,048, breakeven point £362.

For vascular surgery:

- baseline SSI risk: base case 2.5%, breakeven point 0.93%
- relative risk reduction in SSI: base case 42%, breakeven point 16%
- SSI episode cost: base case £2,072, breakeven point £1,004.

Leukomed Sorbact is cost saving across a wide range of SSI costs, device costs, comparator costs and relative risk reduction

4.16 There were wide margins for cost neutrality and cost savings. This satisfied the committee that even with some uncertainty around the strength of the clinical evidence, Leukomed Sorbact was highly likely to be cost saving in caesarean section and vascular surgery.

Further research

Further research on Leukomed Sorbact would be welcome

4.17 The committee noted that a multicentre RCT on the use of Leukomed Sorbact in vascular surgery is being proposed. It welcomed this, as well as the collection of real-world evidence. Also, the committee encouraged further research on using Leukomed Sorbact for a wider range of surgical indications, as well as investigating the effect of Leukomed Sorbact on people with different baseline SSI risks.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more technical analysts (who act as technical leads for the topic), a technical adviser and a project manager.

Rebecca Owens, Neil Hewitt and Harriet Unsworth
Health technology assessment analysts

Lizzy Latimer
Technical adviser

Victoria Fitton
Project manager

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