NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

Leukomed Sorbact for preventing surgical site infection

1 Technology

1.1 Description of the technology

Leukomed Sorbact (Essity), also known as Sorbact surgical dressing, 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 levels of exudate.

The dressing comprises an absorbent non-woven wound contact pad and an outer transparent adhesive polyurethane film. The pad is made of white viscose polypropylene and polyester laminated to the proprietary dialkylcarbamoyl chloride (DACC)-coated mesh. DACC's hydrophobicity (inability to mix with water and tendency to bind together in the presence of moisture) means it can physically bind to hydrophobic microorganisms responsible for SSI. Hydrophobic interaction moves these microorganisms from the wound surface and binds them to the dressing meaning they are removed at dressing change. The claimed clinical benefit of Leukomed Sorbact is a reduced risk of SSI due to bacteria binding to the dressing preventing endotoxins (toxic substances released by bacteria which cause inflammation and delayed healing) from being released into the wound bed. A secondary benefit of reducing the risk of SSIs is a claimed reduction in the prescription of SSI associated antibiotics. The company also claim that the DACC molecules are not absorbed by the body and, as a result of no chemical agent being released into the wound, antibiotic resistance is unlikely. The polyurethane film is designed to maintain a moist environment and

protect the wound from external contamination. The dressing is available in various sizes.

Leukomed Sorbact is intended to be applied after an operation in the operating room by a surgeon or theatre nurse. It can also be used in the early period after an operation if a dressing needs to be replaced.

1.2 Relevant diseases and conditions

Leukomed Sorbact is intended for use in the prevention of surgical site infection in closed surgical wounds with moderate exudate following clean or clean-contaminated (surgery where bacteria density is high) incisions. The company estimate 4.5 million clean or clean-contaminated operations are undertaken in the UK each year.

Surgical site infection is a type of healthcare-associated infection in which a wound infection occurs after an invasive (surgical) procedure. NICE's guideline on preventing and treating surgical site infection states that at least 5% of patients undergoing a surgical procedure develop a surgical site infection which are usually caused by contamination of an incision with microorganisms from the patient's own body during surgery.

A surgical site infection surveillance programme conducted by Public Health England (PHE) reported cumulative SSI incidence between April 2014 and March 2019. The risk of SSI varies between surgery types, typically contaminated or clean-contaminated surgery procedures are associated with increased risk of SSI. The PHE reported an incidence of 8.7% for large bowel surgery indicative of the high bacterial load, 2.5% for vascular surgery and <1% for knee or hip replacement surgery. A table presenting all surgery types included in the data analysis can be found in the surveillance of surgical site infections in NHS hospitals in England, April 2018 to March 2019 annual report.

1.3 Current management

The NICE guideline on preventing and treating surgical site infection recommends a range of preoperative, intraoperative and postoperative

measures to prevent SSI. It also suggests offering prophylactic antibiotics before a clean surgery involving the placement of an implant or before a clean-contaminated surgery. The guideline recommends covering surgical incisions with an appropriate interactive dressing (where the dressing components interact with the wound bed) at the end of the operation and that dressings should be changed or removed using aseptic non-touch technique. The guideline does not specify which interactive dressings to use.

NICE has recommended PICO negative pressure wound dressings for closed surgical incisions in people at a high risk of SSI.

1.4 Regulatory status

Leukomed Sorbact received a CE mark in June 2014 as a class IIb device.

1.5 Claimed benefits

The benefits to patients claimed by the company are those relating to the prevention of surgical site infections:

- Faster discharge
- Faster recovery time and return to normal function
- Reduced pain and discomfort
- Improved quality of life
- Improved post-operative mortality rate

The benefits to the healthcare system claimed by the company are:

- Reduction in SSI-attributable length of stay
- Reduction in the use of systemic antibiotics
- Reduction in outpatient attendances

2 Decision problem

Population	People that have post-operative clean or clean-contaminated wounds with moderate exudate
Intervention	Leukomed Sorbact
Comparator(s)	• Conventional post-surgical wound dressings • Negative pressure wound therapy

Outcomes	The outcome measures to consider include: • Incidence of surgical site infection • Rate of wound dehiscence • Rate of abnormal scarring • ASEPSIS (additional treatment, serous discharge, erythema, purulent exudate, separation of tissues, isolation of bacteria, stay duration as an inpatient) wound score • Length of post-operative stay in hospital relating to SSI • Readmission related to SSI • Time until full wound closure • Prescription and dose of antibiotics for SSI • Patient pain and discomfort • Condition specific and generic quality of life measures • Outpatient clinic attendances • Post-operative mortality rate • Device-related adverse events	
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared. Sensitivity analysis should be undertaken to address uncertainties in the model parameters.	
Subgroups to be considered	Where evidence allows: • Site of surgery (including but not limited to c-section, vascular) • Clean • Clean contaminated surgery	
Special considerations, including those related to equality	Older people are at an increased risk of surgical site infection. Age is a protected characteristic. Leukomed Sorbact can be used following the delivery of a baby by caesarean section. Pregnancy and maternity are protected characteristics.	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No

Any other special considerations	Leukomed Sorbact should not be used where a person has a known sensitivity to active components of the dressing.

3 Related NICE guidance

Published

- Surgical site infections: prevention and treatment (2019) NICE guideline NG125
- Prevena incision management system for closed surgical incisions (2019) NICE medtech innovation briefing 173
- PICO negative pressure wound dressings for closed surgical incisions (2019) NICE medical technologies guidance 43
- Prevention and control of healthcare-associated infections overview (2019) NICE Pathway

In development

NICE is developing the following guidance:

- The V.A.C. Veraflo Therapy system for infected wounds. NICE medical technology guidance. Publication expected October 2020.

4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- Association for Perioperative Practice
- Association of Breast Surgery
- Association of Surgeons of Great Britain and Ireland
- Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland
- British Association of Paediatric Surgeons
- British Obesity and Metabolic Surgery Society
- British Society for Gynaecological Surgery
- Royal College of Nursing
- Royal College of Surgeons

- Society of Vascular Nurses
- The Vascular Society

4.2 Patient

NICE's Public Involvement Programme contacted the following organisations for patient commentary and asked them to comment on the draft scope:

- British Obesity Surgery Patients Association (BOSPA)
- British Skin Foundation (BSF)
- Children's Burn Trust (CBT)
- Colostomy Association
- Crohn's and Colitis UK (NACC)
- Diabetes UK
- Foot in Diabetes UK
- IA (Ileostomy and Internal Pouch Support Group)
- Leg Ulcer Charity
- Leonard Cheshire disability
- LifeSIGNS
- MRSA Action UK
- Pressure Ulcers UK
- Self injury Support