NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

PICO single-use negative pressure wound therapy system for closed surgical incisions

1 Technology

1.1 Description of the technology

PICO (Smith & Nephew) is a canister-free, single-use negative pressure wound therapy (NPWT) system consisting of a single-use sterile pump and 1 or 2 multi-layered adhesive dressings. The proprietary dressing layer is designed to consistently deliver negative pressure across the incision and zone of injury while protecting the wound, with the aim of promoting healing by increasing blood supply. This evaluation focuses on the use of PICO for closed surgical incision wounds with low to moderate levels of exudate.

The pump included in PICO is battery powered and delivers a continuous negative pressure of 80 mmHg to a sealed wound. The pump is activated using a push button and the battery drives the pump for up to 7 days. If necessary the pump can be activated intermittently. Light-emitting diodes (LEDs) on the pump provide alerts for low-battery status and pressure leaks.

Each dressing in the PICO system is made up of 4 layers; a top film layer which acts as a physical barrier and allows evaporation of moisture; an absorbent layer to remove exudate and prevent bacteria from entering the wound; a proprietary airlock layer for even distribution of pressure and to prevent leak back of exudate to the incision site; a silicone adhesive layer closest to the skin, designed to minimise pain and damage during peel back and to contribute to the aesthetics of scar formation. The layers are designed to reduce lateral tension. The dressings are rectangular or square in shape

and come in 10 sizes (up to 25 cm × 25 cm). This includes a multisite dressing of up to 20 cm × 25 cm, which is used for awkward anatomical areas. A pair of larger dressings can absorb up to 300 ml of exudate over a 7 day period. Each dressing holds an average of 150ml of exudate. PICO is available for both inpatients and outpatients.

Training on the use of PICO is provided by the manufacturer at no additional cost.

1.2 Regulatory status

The PICO negative pressure wound therapy received a CE mark in July 2011 as a class IIb medical device.

1.3 Claimed benefits

The benefits to patients in acute care settings from the addition of the PICO negative pressure wound therapy to standard care claimed by the company are:

- Reduced incidence of surgical site complications
- Ease of use

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

- Reduced healthcare utilisation
- Lower rates of readmission and reoperation
- Reduced length of hospital stay
- Less resource use
- Reduced overall treatment cost

1.4 Relevant diseases and conditions

The PICO single-use negative pressure wound therapy system is intended to prevent and treat surgical site complications (SSC) such as surgical site infections (SSI) and dehiscence which can occur in closed surgical incisions

wounds. These complications can delay healing and result in considerable mortality and morbidity.

All patients undergoing surgery are at a theoretical risk of developing a surgical incision complication. The World Union of Wound Healing Societies (WUWHS) Closed Surgical Incision Management Consensus Document cites that patient and surgery related factors may put a patient at a high risk of developing surgical site complications. Intrinsic patient factors include uncontrolled insulin-dependent diabetes, renal dialysis, increased age, poor physical status (based on the American Society of Anaesthesiologists [ASA] physical status classification) and a high BMI. Emergency procedures including caesarean section or certain elective procedures such as cardiac or colorectal surgery and extended surgical procedures may increase the risk of SSC. In addition, hypothermia during surgery may put a patient at increased risk of SSC.

According to NICE guideline on preventing and treating surgical site infections (currently being updated), 20% of all health-care associated infections are surgical site infections and 5% of patients undergoing a surgical procedure develop a surgical site infection.

1.5 Current management

The NICE guideline on preventing and treating surgical site infections notes that patients should have post-surgical wound care which involves:

- using aseptic non-touch techniques for removing and changing surgical wound dressings
- wound cleaning with sterile saline for up to 48 hours and cleaning with tap water afterwards
- antibiotics treatment, if a surgical site infection is suspected. If dead or infected tissues seem to be slowing down the healing process, debridement (which may involve surgery) can be undertaken to remove the dead tissue.

Although closed incisions are intended to heal by primary intention, the WUWHS Closed Surgical Incision Management Consensus Document notes that NPWT shows promise for use on closed surgical incisions to aid healing in patients who are at increased risk of surgical site complications such as SSI, seroma, haematoma and dehiscence. When dehiscence occurs and if a deep infection is ruled out, a NPWT may sometimes be helpful to promote healing by secondary intention.

2 Statement of the decision problem

	Scope issued by NICE
Population	Patients having closed surgical incisions with low to moderate levels of exudate who are considered to be at high risk of developing a surgical site complication particularly SSI and dehiscence
Intervention	PICO single-use negative pressure wound therapy system
Comparator(s)	Conventional post-surgical wound dressings
Outcomes	The outcome measures to consider include: • rate of post-surgical wound complications (SSI, dehiscence, seroma, hematoma, delayed healing and abnormal scarring) • length of hospital stay as a result of surgical complications • time to heal • number of dressing changes • staff time to apply device • amount of wound exudate • rates of re-operation for wound complications • ease of use of the device by the patient • device-related adverse events
Cost analysis	Comparator(s): Costs will be considered from an NHS and personal social services perspective. Hospital and community settings should be considered. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.
Sub-groups to be considered	• individual surgical specialities* • wounds with low to moderate exudate • hard to heal wounds * including but not limited to obstetric, colorectal, abdominal, orthopaedic, cardiothoracic, gynaecology etc.

Special considerations, including those related to equality	The device may be beneficial to women who have had obstetric and gynaecology and breast surgery. Certain ethnic groups are more prone to poor wound healing due to increased risk of diabetes or keloid formation. Older people are also more at risk of poor wound healing. Sex, race and age are protected characteristic under the equality act 2010.	
Special considerations, specifically related to equality issues	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 characteristics?	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 MTAC will have relevant information to consider equality issues when developing guidance?	No

3 Related NICE guidance

Published

- NICE clinical guideline 74(2008, last updated 2017) Surgical site infections: prevention and treatment
- NICE clinical guideline 65 (2008, last updated 2016) Hypothermia: prevention and management in adults having surgery

Under development

None

4 External organisations

4.1 Professional organisations

4.1.1 Professional organisations invited to participate in the evaluation

The following societies have been have been invited to register as stakeholders:

- Arthritis and Musculoskeletal Alliance (ARMA)
- Association of Breast Surgery

- Association of Surgeons of Great Britain and Ireland
- British Association for Nursing Cardiovascular Care
- British Association for Surgery of the Knee
- British Association of Paediatric Surgeons
- British Association of Plastic Reconstructive and Aesthetic Surgeons
- British Obesity and Metabolic Surgery Society
- British Obesity Surgery Patients Association (BOSPA)
- British Obesity Surgery Society
- Colostomy Association
- National Rheumatoid Arthritis Society
- Royal College of Emergency Medicine
- Royal College of General Practitioners
- Royal College of Midwives
- Royal College of Nursing
- Royal College of Obstetricians and Gynaecologists
- Royal College of Surgeons
- Royal College of Surgeons of Edinburgh
- Royal College of Surgeons of England
- Society for Cardiothoracic Surgery of GB and Ireland
- Society of Vascular Nurses
- Surgical Dressing Manufacturers Association

4.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Age Related Diseases and Health Trust
- Arthritis Action
- Arthritis and Musculoskeletal Alliance (ARMA)
- Arthritis Research UK
- British Obesity Surgery Patients Association (BOSPA)
- British Skin Foundation (BSF)

- Cardiovascular Care Partnership (UK)
- Children's Burn Trust (CBT)
- Colostomy Association
- Core (Digestive Disorders Foundation)
- Crohn’s and Colitis UK (NACC)
- Dan's Fund for Burns
- Diabetes UK
- Foot in Diabetes UK
- IA (Ileostomy and Internal Pouch Support Group)
- Independent Age
- InDependent Diabetes Trust
- National Childbirth Trust (NCT)
- National Rheumatoid Arthritis Society
- Pressure Ulcers UK
- Pumping Marvellous Foundation
- Scleroderma and Raynaud's UK
- Short Bowel Survivors and Friends
- The Relatives and Residents Association
- Trauma Care
- Ulcerative Colitis UK
- Your Turn