NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

Plus Sutures for preventing surgical site infection

1 Technology

1.1 Description of the technology

Plus Sutures (Ethicon, Johnson & Johnson Medical Ltd) are a range of synthetic, absorbable sutures that are either impregnated with or coated with medical grade triclosan, depending on the suture type. Triclosan is a broad-spectrum antibacterial agent effective on most common organisms associated with surgical site infection (SSI). Plus Sutures are intended for wound closure in people after a surgical procedure and are designed to prevent bacterial colonisation of the suture for 7 days or more. Absorbable sutures are absorbed by tissue over a matter of days and don't need removing. The company claims Plus Sutures can reduce the incidence of SSI and result in fewer readmissions because of an SSI.

Plus sutures are available in 3 variations of suture polymers and are available in a range of sizes and designs. Each of the 3 varieties has different physical properties and absorption rates which affects which tissue types it is better suited to:

- Coated VICRYL Plus Antibacterial (polyglactin 910) Suture is a multifilament (multiple braided threads) with an absorption rate of between 57 and 70 days making it best suited for general soft tissue approximation and ligation (bringing together or tying of tissue edges).

- MONOCRYL Plus Antibacterial (poliglecaprone 25) Suture is a monofilament sutures (solid and smooth thread) with an absorption rate of between 91 and 119 days making it best suited for general soft tissue approximation and ligation. This suture is also available in a barbed design for knotless suturing.

- PDS Plus Antibacterial (polydioxanone) Suture is a monofilament suture (solid and smooth thread) with an absorption rate of between 182 and 238 days. This suture can be used for general soft tissue approximation, including use in paediatric cardiovascular surgery, and other surgery types that require up to 6 weeks wound support. This suture is also available in a barbed design for knotless suturing.

PDS Plus and MONOCRYL Plus contain no more than 2,360 micrograms/m triclosan. VICRYL Plus has a coating of copolymer, calcium stearate as well as up to 472 micrograms/m triclosan. The absorption rates and handling properties are the same as non-triclosan sutures.

1.2 Relevant indication

Plus Sutures are used for wound closure in people that have had a surgical procedure and need wound closure with an absorbable suture.

Surgical site infection is a type of healthcare-acquired infection in which a wound infection develops as a complication of 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 that is usually caused by contamination of an incision with microorganisms from the patient's own body at the time of surgery.

A surgical site infection surveillance programme conducted by Public Health England (PHE) reported cumulative SSI incidence between April 2015 and March 2020. The risk of SSI varies between surgery types with contaminated or clean-contaminated surgery procedures associated in particular with an increased risk of SSI. The PHE reported the highest SSI incidence to be in bile duct, liver or pancreatic surgery (9.1%) and large bowel surgery (8.3%).

The lowest SSI incidence was reported in hip and knee replacement surgery (0.5%). A table presenting SSI risk for all surgical types included in the analysis can be found in the surveillance of surgical site infection infections in NHS hospitals in England, April 2019 to March 2020 annual report. These data are based on the surveillance data of 133 contributing NHS trusts and may not be an accurate reflection the national incidence of SSI.

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. Preoperative measures include:

- Preoperative bathing with soap, preferably within a day of the planned surgical procedure and an antiseptic preparation immediately before the procedure.
- Nasal decolonisation, since Staphylococcus aureus is a likely potential cause of SSI.
- A preventative course of antibiotics (unless the surgery is considered clean, non-prosthetic and/or uncomplicated).

To close the wound, the guideline recommends considering antimicrobial triclosan-coated sutures. The wound is dressed with an appropriate dressing and changed using aseptic non-touch technique. Sterile saline is used to irrigate the wound up to 48 hours after surgery.

If SSI is suspected, an antibiotic is given that covers the likely organisms causing infection in line with NICE's guideline on antimicrobial stewardship: systems and processes for effective antimicrobial medicine use.

1.4 Regulatory status

- Coated VICRYL Plus Antibacterial (polyglactin 910) Suture received a CE mark in September 2004 as a class III device for wound closure. Its latest review of the CE mark was in September 2020.

- MONOCRYL Plus Antibacterial (poliglecaprone 25) Suture received a CE mark in May 2007 as a class III device for wound closure. Its latest review of the CE mark was in January 2020. The barbed designed version received CE mark in October 2016.

- PDS Plus Antibacterial (polydioxanone) Suture received a CE mark in March 2009 as a class III device for wound closure. Its latest review of the CE mark was in January 2020. The barbed designed version received CE mark in September 2016.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Reduced risk of SSI, independent of the type of surgery
- Reduced SSI associated length of stay
- Reduced antibiotics prescribed

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

- Cost savings as a result of reduced treatment of SSIs
- Reduced bed days associated with reduced treatment of SSIs

2 Decision problem

Population	Adults and children that need wound closure after a surgical procedure and in whom absorbable sutures are an appropriate option
Intervention	• PDS Plus Antibacterial (polydioxanone) Suture • MONOCRYL Plus Antibacterial (poliglecaprone 25) Suture • Coated VICRYL Plus Antibacterial (polyglactin 910) Suture
Comparator(s)	Sutures that do not contain an antibacterial agent
Outcomes	The outcome measures to consider include: • Incidence of SSI • Type of SSI • length of post-operative stay in hospital relating to SSI • readmission related to SSI • antibiotics use for SSI (including prescription, duration and dose)

	• Severity of SSI using validated scoring systems such as ASEPSIS (additional treatment, serous discharge, erythema, purulent exudate, separation of tissues, isolation of bacteria, stay duration as an inpatient) wound score. • incidence of wound dehiscence (wound opening) • patient reported pain or discomfort • 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 will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	
Subgroups to be considered	• Adults • Children • Clean wound procedures • Non-clean wound types	
Special considerations, including those related to equality	This technology should not be used in people with known allergies to triclosan. All absorbable sutures, including Plus Sutures, may not be appropriate for older people; age is a protected characteristic under the 2010 Equalities Act. The company's product information manual advises that the use of all absorbable sutures, including Plus Sutures, may also not be appropriate for people who are, malnourished, debilitated or people with conditions that may prevent wound healing. In some cases, these people may be classed as disabled; disability is a protected characteristic under the 2010 Equalities Act.	
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	Not applicable	

3 Related NICE guidance

Published

- Surgical site infection: prevention and treatment (2019) NICE guideline NG125.
- Prevention and control of healthcare associated infections (2019) NICE Pathway

In development

NICE is developing the following guidance:

- Leukomed Sorbact for preventing surgical site infection. NICE medical technology guidance. Publication expected February 2021.

4 External organisations

4.1 Professional

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

- Association for Clinical Microbiologists
- Association for Perioperative Practice
- Association of Breast Surgery
- Association of Clinical Biochemists - Microbiology Section
- Association of Surgeons of Great Britain and Ireland
- Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland
- British Association for Surgery of the Knee
- British Association of Aesthetic Plastic Surgeons
- British Association of Paediatric Surgeons
- British Association of Plastic Reconstructive and Aesthetic Surgeons
- British Obesity Surgery Society
- British Orthopaedic Association
- Healthcare Infection Society
- Infection Prevention Society
- Royal College of Nursing

- Royal College of Surgeons
- Society for Cardiothoracic Surgery of GB and Ireland
- Society for General Microbiology
- The Association for Perioperative Practice
- The Vascular Society of Great Britain & Ireland
- The Welsh Wound Innovation Centre