NICE advice

Plus Sutures for preventing surgical site infection

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is Plus Sutures. It is for wound closure in adults and children after surgical procedures.
- The **innovative aspect** is that the sutures contain the antimicrobial substance triclosan.
- The intended **place in therapy** would be as an alternative to standard care for people who need wound closure after a surgical procedure.
- The **main points from the evidence** summarised in this briefing are from 7 studies, including 3 meta-analyses, 1 systematic review and 3 randomised controlled trials including adults and children in a secondary care setting. Most studies found Plus Sutures more effective than standard care sutures in reducing surgical site infections.
- **Key uncertainties** around the evidence include the heterogeneity of studies included in the meta-analyses and the lack of systematic outcome measures reported.

- The **cost** of Plus Sutures depends on the size and features of the sutures and ranges from £3.63 to £4.94 depending on suture type, based on the most commonly used sutures codes within the NHS in England. The cost would be greater than non-antibacterial MONOCRYL, PDS II and VICYRL sutures used as standard care (£2.88 to £3.98). This may be offset if surgical site infections are reduced.

The technology

Plus Sutures (Ethicon, Johnson & Johnson Medical Ltd) are synthetic, absorbable sutures containing triclosan. Triclosan protects against most common organisms associated with surgical site infection (SSI).

The technology is available in 3 variations:

- PDS Plus Antibacterial (polydioxanone) Suture
- MONOCRYL Plus Antibacterial (poliglecaprone 25) Suture
- Coated VICRYL Plus Antibacterial (polyglactin 910) Suture.

PDS Plus and MONOCRYL Plus are monofilament sutures made from polyester and poliglecaprone 25 copolymer, respectively. Both contain no more than 2,360 micrograms/m triclosan. VICRYL Plus is a multifilament suture made from a copolymer of glycolide and lactide and contains no more than 472 micrograms/m triclosan. VICRYL Plus is also designed to further support the suture with a coating of copolymer, calcium stearate and triclosan. The absorption rate varies between versions. VICRYL Plus Sutures are absorbed between 56 and 70 days, MONOCRYL Plus Sutures are absorbed between 91 and 119 days and PD Plus Sutures are absorbed between 182 and 238 days. The absorption rates and handling properties are the same as non-triclosan sutures. The technology is designed to inhibit bacterial colonisation of the suture for 7 days or more.

This technology is for wound closure in adults and children. It should not be used in people with known allergies to triclosan. All absorbable sutures, including Plus Sutures, may not be appropriate for older people, or people who are malnourished, debilitated or have conditions that could delay wound healing.

Innovations

Plus Sutures differ from currently available sutures because they are coated with triclosan, an

antimicrobial. The company claims Plus Sutures can reduce the incidence of SSI and result in fewer readmissions because of an SSI.

Current care pathway

People having surgical intervention are at risk of SSIs. Appropriate measures for preventing SSIs can be found in NICE's guideline on surgical site infections: prevention and treatment.

In the NHS, standard preventative procedures include preoperative bathing with soap, preferably within a day of the planned surgical procedure. Nasal decolonisation is used when *Staphylococcus aureus* is a likely cause of SSI. In most surgical cases, people are given antibiotics to prevent bacterial infection. Skin at the surgical site is prepared with an antiseptic preparation immediately before the procedure. To close the wound, section 1.3.20 of NICE's guideline on surgical site infections recommends to consider antimicrobial triclosan-coated sutures. The wound is dressed with an appropriate dressing and changed using aseptic non-touch technique. Sterile saline is used to cleanse 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.

Population, setting and intended user

Plus Sutures are for wound closure in adults and children after a surgical procedure. The technology is used in secondary care by healthcare professionals, usually surgeons. No additional training is needed to use this technology.

Costs

Technology costs

The average costs of the most common sutures for each version of Plus Suture are:

- MONOCRYL Plus, £4.17
- PDS II Plus, £4.94
- VICRYL Plus, £3.63.

Plus Sutures can be purchased in boxes of 12, 24 and 36. They are available in a range of lengths and suture-needle combinations. Approximately 600 Plus Suture product codes are available in the

current NHS catalogue. No additional costs are needed to use the technology.

Costs of standard care

Non-antibacterial coated sutures such as MONOCRYL, PDS II and VICRYL Sutures are currently used as standard care for wound closure. The non-triclosan sutures costs are presented an as an average cost of the most common sutures in standard care. Non-triclosan MONOCRYL sutures cost £3.20, non-triclosan PDS II sutures cost £3.98 and VICRYL sutures cost £2.88.

Resource consequences

Plus Sutures are currently used in 140 UK NHS trusts. The technology will cost more than standard care. The company claims the technology can result in savings related to reduced SSIs and fewer associated readmissions.

Regulatory information

Plus Sutures are a CE-marked class 3 medical device.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Absorbable sutures, including Plus Sutures, may not be appropriate for older people; age is a protected characteristic under the 2010 Equalities Act. The use of absorbable sutures, including Plus Sutures, may also not be appropriate for people who are 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.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

There are 8 studies summarised in this briefing.

The 4 meta-analyses include 34, 29, 21 and 18 studies each. One systematic review includes 15 studies and 3 randomised controlled trials, which include a total of 2,233 patients.

Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The evidence base for this technology is extensive. Only a small number of the most relevant studies are reported in this briefing. The studies are high quality including meta-analyses, systematic reviews and blinded randomised controlled trials. Two studies included in this briefing were done in the UK. Most of the studies have been powered adequately and all studies report relevant outcome measures and compare the technology with an appropriate comparator. The evidence base would benefit from including outcome measures related to systematic impact, such as length of stay related to surgical site infections (SSIs), number of readmissions because of SSIs and a measure of antibiotic courses prescribed for SSIs.

Table 1 Summary of selected studies

Sukeik et al. (2019)	
Study size, design and location	RCT investigating the effect of triclosan-coated sutures, VICRYL Plus, on wound healing in 150 patients after hip and knee surgery. UK.
Intervention and comparator(s)	Plus Sutures, VICRYL Plus. Non-triclosan-coated sutures VICRYL.
Key outcomes	There was no significant difference between groups in the severity of SSIs, using ASEPSIS wound scoring system (p=0.75). Sensitivity analyses using Mann–Whitney U test found significant increase in wound complications in the VICRYL Plus cohort at 6 weeks' follow up (p=0.03).

Strengths and limitations	The study was double blinded and randomised with no significant differences between cohort demographics. However, the study was underpowered and factors affecting infection risk after patient discharge were not controlled for, which may confound the findings. The ASEPSIS scoring tool is not validated for use after orthopaedic surgery. The study used non-antibacterial staples in addition to Plus Sutures for skin closure, this may have impacted the effectiveness of the Plus Sutures in preventing SSIs. The study reviewed only patients who needed knee or hip surgery and may not be generalisable to other surgical procedures.
Onesti et al. (2018)	
Study size, design and location	Literature review of 15 RCTs comparing triclosan-coated sutures with conventional sutures to investigate their clinical effectiveness in reducing SSIs. Italy.
Intervention and comparator(s)	Plus Sutures. Non-triclosan-coated sutures.
Key outcomes	There were 7 RCTs that showed reduced rate of SSIs, 8 RCTs reported no significant differences. Reductions were more evident in single-centre trials compared with multicentre trials (6/10 single centre compared withs 1/5 multicentre).
Strengths and limitations	The RCTs included in this review included a range of sample sizes, procedures, triclosan-coated sutures and length of follow up. This heterogeneity is likely to confound the conclusions. Variables were reviewed separately but not analysed statistically. The quality of each of the studies was not reported.
Renko et al. (2017)	
Study size, design and location	RCT investigating the effect of triclosan-coated or -impregnated sutures on the incidence of SSIs in 1,633 children. Finland.
Intervention and comparator(s)	Plus Sutures. Sutures without triclosan.

Key outcomes	In the intention-to-treat group, SSIs happened in 3% of patients (20/778). In the control group, SSIs were seen in 5% of patients (42/779; proportional difference 2.8%, 95% CI 0.9 to 4.9; RR 0.48, 95% CI 0.28 to 0.80; p=0.004). In the per protocol analysis, SSIs were seen in 3% of the triclosan group (18/636) and 6% in the control group (39/651; proportional difference 3.2%, 95% CI 0.9 to 5.5; RR 0.47, 95% CI 0.27 to 0.81; p=0.005). Patients in the triclosan group had less need for revision of the wound, fewer visits to the physician or readmission to hospital and fewer antimicrobial courses.
Strengths and limitations	This is a large well-designed double-blinded and randomised study. Power calculations and randomisation methods were reported. A range of clean and clean-contaminated surgical procedures were included in the study increasing the generalisability of these data. CDC criteria were used to report SSIs and patients were followed up for 30 days. Cohort demographic data are comparable, but these data have not been compared statistically. The study is single-centre but included 69 surgeons.
Leaper et al. (2017)	
Study size, design and location	A meta-analysis of 34 studies investigating the effects of Plus Sutures compared with conventional sutures and modelling the economic impact based on the findings. UK.
Intervention and comparator(s)	Plus Sutures. Non-triclosan-coated sutures.
Key outcomes	The odds ratio for SSIs in the Plus Sutures group compared with the non-triclosan-coated sutures was 0.61 (95% CI 0.52 to 0.73; p<0.001). A significant degree of heterogeneity in the studies was reported (I^2=49%). Mean cost savings per operation ranged from £56.59 (90% CI 17.20 to 104.93) for clean wound procedures to £248.23 (90% CI 62.71 to 470.45) for contaminated or dirty wounds. Overall savings per operation are estimated to be £91.25 (90% CI 49.62 to 142.76).

Strengths and limitations	The outcome measures reported in the study are both clinically and systematically relevant. Costs analysis used UK health episode statistics public data to model the cost-saving estimation, making these data generalisable to the NHS. The modelled cost of an inpatient with an SSI was based on 2015/16 HES cost data, which are likely to now be outdated. Company employees were involved in writing the manuscript and data quality control, including a named author.
de Jonge et al. (2017)	
Study size, design and location	Meta-analysis of 21 RCTs investigating the efficacy of Plus Sutures in preventing SSIs.
Intervention and comparator(s)	Plus Sutures. Non-triclosan-coated sutures.
Key outcomes	Pooled relative risk was 0.72 (95% CI 0.6 to 0.86; p<0.001) for all publications. At a risk of 138 SSIs per 1,000 procedures, using Plus Sutures resulted in 39% fewer SSIs per 1,000 and a number needed to treat of 25. This could not be replicated after selection of high-quality studies only. Studies included in the analysis were found to have a serious risk of bias.
Strengths and limitations	The study includes a large sample size of 6,462 patients. Heterogeneity was low to moderate. Evidence was assessed using the GRADE system. The study is limited by the evidence quality, which is reported to be moderate, but subgroup analysis of high-quality evidence failed to replicate results. A range of definitions outside of the widely accepted CDC criteria are used for outcome definitions.
Wu et al. (2017)	
Study size, design and location	A systematic review and meta-analysis of 13 RCTs and 5 observational studies to investigate the effectiveness of triclosan-coated sutures compared with non-triclosan-coated sutures in reducing SSIs.
Intervention and comparator(s)	Plus Sutures. Non-triclosan-coated sutures.

Key outcomes	Triclosan-coated sutures significantly reduced SSI risk (RCTs, odds ratio 0.72, 95% CI 0.59 to 0.88, p=0.001; for observational studies, odds ratio 0.58, 95% CI 0.40 to 0.83, p=0.0003). The effect of triclosan-coated sutures was similar between different suture, wound and procedure type, although the VICRYL Plus compared with VICRYL revealed the most consistent favourable findings for triclosan-coated sutures.
Strengths and limitations	Quality of studies included in this systematic review and meta-analysis ranged from moderate to very low. Many of the included studies had conflicted interests.
Apisarnthanarak et al. (2015)	
Study size, design and location	A systematic review and meta-analysis of 22 RCTs and 7 non-RCTs comparing the use of triclosan-coated sutures and non-triclosan-coated sutures for the reduction of SSIs. Thailand.
Intervention and comparator(s)	Plus Sutures. Non-triclosan-coated sutures.
Key outcomes	The pooled RR of acquiring an SSI was 0.65 (95% CI 0.55 to 0.77) in favour of triclosan-coated sutures. Subgroup analyses found RR for RCTs to be 0.74 (95% CI 0.61 to 0.89) and non-RCTs to be 0.53 (95% CI 0.42 to 0.66), both in favour of triclosan-coated sutures. Compared with other procedures, abdominal surgery had the lowest RR of 0.56 (95% CI 0.41 to 0.77).
Strengths and limitations	This was a large meta-analysis including a large number of RCTs. The study used 95% CIs, subgroup analyses and sensitivity analyses to analyse the data. However, heterogeneity of the studies included may have confounded the results and quality of evidence was low in the non-RCTs. The analysis includes a duplicate of a previously included study, which limits the validity of the results.
Galal and El-Hindawy (2011)	
Study size, design and location	RCT investigating the effect of triclosan-coated or -impregnated sutures on the incidence of SSIs in 450 adults. Egypt.

Intervention and comparator(s)	Plus Sutures. Non-triclosan-coated sutures.
Key outcomes	SSI was 7% in the triclosan group and 15% in the control group (p=0.01). The mean extended stay as a result of infection was 3.71 days.
Strengths and limitations	The study reports relevant systematic outcomes. The study does not report demographic data or the method for diagnosing and reporting SSIs. The study was done in the US and so healthcare resource data are not generalisable to the NHS.
Abbreviations: CDC, Centers for Disease Control and Prevention; CI, confidence interval; HES, hospital episode statistics; RCT, randomised controlled trial; RR, risk ratio; SSI, surgical site infection.	

Recent and ongoing studies

Antibacterial-coated sutures at time of caesarean (ASTC). ClinicalTrials.gov identifier: NCT03386240. Status: recruiting. Indication: caesarean repair. Devices: Plus Sutures. Expected completion date: January 2021. Texas, USA.

Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Three specialists were familiar with Plus Sutures, 2 had used the technology before.

Level of innovation

Two of the 3 specialists considered the technology to be a novel design. Two considered the technology to be a minor adaptation to surgical equipment used in the NHS. None were aware of any competing technologies.

Potential patient impact

All 3 specialists believed the technology could reduce the incidence of surgical site infection (SSI).

Two believed the technology was most suitable in those with wounds at a higher risk of SSI infection such as after colorectal surgery or people having chemotherapy. All 3 believed the technology could impact the care pathway because of reduced length of stay for patients. All specialists commented that the technology may result in fewer readmissions for the patient. Two acknowledged the technology could improve patients' experience.

Potential system impact

All 3 specialists considered that the technology could have systematic benefits related to reducing SSIs. These include a reduced burden on primary care resources, reduced costs related to treating SSIs and reduced readmissions. All 3 believed the technology would have a small initial increase in cost that would be offset by savings related to reducing the incidence of SSIs.

General comments

Two specialists believed the technology would replace standard care sutures, whereas 1 believed the technology would be used in addition to standard care sutures and only used when suitable for patients. One believed research on Plus Sutures in all layers of wound closure would be beneficial. One believed improved auditing of SSIs and subgroup analysis of the effectiveness of Plus Sutures across all specialities would be beneficial.

Specialist commentators

The following clinicians contributed to this briefing:

- Mr Andrew Miller, consultant colorectal surgeon, University Hospitals of Leicester NHS Trust. Mr Miller received an honorarium for involvement in the consensus meeting held at Royal College of Surgeons in 2016 and co-authored a published paper reporting a consensus meeting reviewing Plus Sutures in 2016 and 2017.
- Ms Anne Pullyblank, consultant surgeon and medical director, North Bristol NHS Trust and West of England Academic Health Science Network, did not declare any interests.

- Mr Giles Bond-Smith, consultant surgeon, clinical lead for emergency general surgery and clinical lead for surgical site infection reduction, Oxford University Hospital NHS Foundation Trust. Mr Bond-Smith has been a speaker at 3 Ethicon events in 2019. Mr Bond-Smith also received an honorarium for involvement in the consensus meeting held at Royal College of Surgeons in 2016 and co-authored a published paper reporting a consensus meeting reviewing Plus Sutures in 2016 and 2017.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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