NICE advice

SecurePort IV tissue adhesive for use with percutaneous catheters

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is SecurePort IV. It is a tissue adhesive used for securing percutaneous catheters.
- The **innovative aspects** are that SecurePort IV combines the actions of multiple products to seal and secure catheter insertion sites and aims to reduce microbial infection. The technology also cures flexibly to act like a second layer of skin.
- The intended **place in therapy** would be as an alternative to standard care in people with percutaneous catheters.
- The **main points from the evidence** summarised in this briefing are from 1 non-randomised comparative study, 1 observational study and 1 retrospective study including a total of 107 adults and 1,842 newborn babies under 28 days old with peripherally inserted central catheters. They show that SecurePort IV is more effective than standard care in securing percutaneous catheters.

- **Key uncertainties** around the evidence or technology are that there are no published randomised controlled trials which compare SecurePort IV with other securement technologies for catheters. No studies have been done in an NHS context. Although there are larger studies of other cyanoacrylate tissue adhesives, the study populations for SecurePort IV have been relatively small.
- **Experts advised** that the technology could reduce the rates of catheter dislodgement and infection as well as reducing the need for more frequent dressing changes because of bleeding after insertion. No changes would be needed to existing clinical facilities, but they noted training would be needed because of the nature of the adhesive.
- The **cost** of SecurePort IV is £5 per unit (excluding VAT).

The technology

SecurePort IV (Adhezion Biomedical) is a cyanoacrylate tissue adhesive intended for use in people having a percutaneous catheter inserted. Percutaneous catheters are associated with complications such as migration or dislodgement of the catheter, bleeding around the insertion site and infection. Specifically, SecurePort IV is a 2-octyl-cyanoacrylate tissue adhesive, and the company claims the device offers enhanced properties for patients and clinicians. SecurePort IV seals and secures the insertion site and uses a formulation to reduce catheter-related infections. The formulation has antimicrobial properties, which the company claims reduces the ability of bacteria to migrate into the bloodstream and tissues. Each applicator holds 0.15 ml of SecurePort IV and can distribute controlled amounts of product. After placement of a line, 1 to 2 drops of SecurePort IV are applied at the insertion site, underneath catheter hubs and over any sutures to increase dressing adherence and reduce the risk of infection. The adhesive remains active for up to 7 days which limits the need for regular dressing changes. SecurePort IV has been tested for compatibility with a wide range of catheters and can be used alone as a securement device or in addition to currently available devices.

Innovations

The key innovative feature of SecurePort IV is that it combines the benefits of multiple products to seal and secure catheter insertion sites and prevent microbial infection. The technology is formulated to cure flexibly and act like a second skin.

Current care pathway

In current practice, multiple products may be applied to avoid potential complications after inserting a percutaneous catheter. These include pressure dressings to prevent bleeding, antimicrobial dressings to prevent infection and securement devices to prevent catheter dislodgement and migration.

The following publications have been identified as relevant to this care pathway:

- NICE medical technologies guidance on SecurAcath for securing percutaneous catheters
- NICE medical technologies guidance on Tegaderm CHG securement dressing for vascular access sites in critically ill adults.

Population, setting and intended user

SecurePort IV would be used in primary and secondary care settings in place of current securement methods for percutaneous catheters. The company claims that it can be used in people of all ages including newborn babies under 28 days old.

SecurePort IV would be applied by an anaesthetist or nurse when inserting a catheter or changing the dressing after 7 days.

Costs

Technology costs

The cost of SecurePort IV is £5 per unit (excluding VAT). One unit would be used per patient catheter insertion.

Costs of standard care

The costs of standard care vary widely between healthcare settings, from £5 to £90, depending on the dwell time of the catheter and combination of products that are used to secure the catheter and prevent microbial infection.

Resource consequences

The device has been used in the UK since 2020, with more than 20 sites using SecurePort IV with catheters on a regular basis. There are no practical difficulties or changes in facilities that are anticipated if the technology is adopted.

The company states that minimal training is recommended to achieve maximum product effectiveness. Free of charge virtual training modules and videos for healthcare professionals are available on the manufacturer's website.

Regulatory information

SecurePort IV is a CE-marked class IIa 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.

No equality issues have been identified.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement for medtech innovation briefings. 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

Three studies are summarised in this briefing.

One non-randomised comparative study of 62 people (Webber et al. 2020), one observation study of 45 people (Nicholson and Hill, 2019) and one retrospective study of

1,842 newborn babies less than 28 days old (van Rens et al. 2021) are included.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

There are several studies which investigate using cyanoacrylate tissue adhesives for securing different types of catheters in adults, young people and newborn babies less than 28 days old. These studies predominantly include other tissue adhesives which have a similar formulation to SecurePort IV but not identical, because of the type of cyanoacrylate and the additional antimicrobial function of SecurePort IV. The number of studies specifically assessing the use of SecurePort IV is limited and the current literature recognises that larger, randomised trials are needed. One recent study and 1 ongoing study were identified as part of this briefing and are outlined below. Further studies are needed in people with percutaneous catheters to capture the potential benefits of the technology such as reduced rates of infection, reduced bleeding and longer time for dressing change.

The outcomes reported in the literature are relevant to the NHS, but none of the studies outlined have been done in an NHS context.

Webber et al. (2020)

Study size, design and location

A non-randomised comparative study in 62 people with peripherally inserted central catheters. The study was done in USA.

Intervention and comparator(s)

SecurePort IV, compared with chlorhexidine-impregnated disk and engineered stabilisation device.

Key outcomes

There were 31 people in the control group and 31 people in the intervention group, no

statistically significant differences were found between the 2 groups for baseline variables. In the control group, 6 observations of catheter migration happened which accounted for 19.35% of the study arm. In the intervention group, no migrations were seen. There was a statistically significant difference (p=0.010) in migration rates between the 2 groups, with the control group having a higher migration rate than the intervention group.

Strengths and limitations

The study time frame was 4 weeks, which is considerably lower than other studies that have assessed the use of tissue adhesives and other catheter securement devices. The study sample size was relatively small and inclusion criteria was limited to inpatients having surgery, which may not be generalisable to the broader population of people who have peripherally inserted central catheters. Also, the antimicrobial effect of SecurePort IV could have been assessed by recording the number of catheter-related infections. A strength of the study was that the technology was compared with the current standard of care for catheter stabilisation and securement, with a clear outcome employed to test efficacy of the intervention.

Nicholson and Hill (2019)

Study size, design and location

An observation study of 45 adults with peripherally inserted central catheters who received SecurePort IV. The study was done in Canada.

Intervention and comparator(s)

SecurePort IV, no comparator.

Key outcomes

All patients had the insertion site assessed at 3 timepoints: 24 hours, 96 hours and 7 days. The insertion site status was categorised based on the following observations: bleeding, not bleeding, dressing intact and dressing not intact. Of the 45 people included in the study, 42 (93%) had intact dressings and no bleeding observed at all 3 timepoints. Three people did not meet the criteria for tissue adhesive application as they could not achieve haemostasis after 6 minutes of direct manual pressure. They had the following clinical conditions: chronic kidney disease, post-cardiac surgery on high dose anticoagulants and

haemophilia dependent on factor product for coagulation. The study authors reported that from using SecurePort IV in this evaluation, they were able to eliminate the standard 24-hour dressing change, experienced savings on supplies and nursing time and increased patient satisfaction.

Strengths and limitations

A strength of the study is that resource use outcomes were observed in addition to clinical outcomes, which allows both cost and time saving benefits to be captured. Although there was no direct comparison of clinical efficacy with standard care or an alternative treatment, efficiency was compared before and after the implementation of SecurePort IV. A limitation of the study is that it was commissioned by the manufacturer. Also, a relatively small study population was included.

Van Rens et al. (2021)

Study size, design and location

A retrospective observational study of 867 neonates with peripherally inserted central catheters who received SecurePort IV compared with 975 neonates who did not receive catheter securement. The study was done in Qatar.

Intervention and comparator(s)

SecurePort IV, compared with no catheter securement.

Key outcomes

The reason for catheter removal was recorded for each case. The most common reason was successful completion of therapy which showed a significant difference between both groups, with 78.0% in the SecurePort IV arm and 65.3% in the comparator arm ($p<0.001$). Therapy failure because of a complication or death was significantly lower in the tissue adhesive group compared with the no tissue adhesive group, 11.7% versus 27.9% ($p<0.001$). There was also a statistically significant reduction in the risk of central line-associated bloodstream infection in the SecurePort IV group (65% reduced risk, $p<0.001$).

Strengths and limitations

A strength of the study is that the patient population included newborn babies under 28 days old, which is one of the patient groups outlined by the company. The broad inclusion criteria allowed for a large sample size which was representative of the neonatal population that are typically treated with peripherally inserted central catheters. A limitation of the study was that it was done at a single centre using a retrospectively collected dataset. In contrast to randomised studies, this methodology can introduce the risk of selection bias.

Sustainability

The company claims the technology will reduce the use of single-use plastics, minimise waste and lower environmental impact through more efficient use of NHS resources. There is no published evidence to support these claims.

Recent and ongoing studies

- Evaluation of tissue glue on PICC and midline catheter insertion sites. ClinicalTrials.gov identifier: NCT04900740. Status: recruiting. Indication: people with mid-term or long-term venous access. Devices: SecurePort IV. Last update: 1 June 2021. Country: Czech Republic.
- Peripheral intravenous catheter securement with tissue adhesive. ClinicalTrials.gov identifier: NCT04086693. Status: completed, results published. Indication: people with vascular access device. Devices: SecurePort IV plus standard IV dressing (Adhezion). Last update: 6 December 2021. Country: USA.

Expert comments

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

Two out of 3 experts were familiar with or had used this technology before.

Level of innovation

Two of the experts considered this technology to be innovative compared with standard care. The other expert stated that using cyanoacrylate tissue adhesives is relatively established practice and that SecurePort is not chemically different compared with other cyanoacrylate tissue adhesives. The applicator itself was highlighted as the novel feature, because of its ease of use with vascular access devices.

Potential patient impact

All of the experts agreed that the technology may reduce the risk of infections at catheter insertion and exit sites. The securement properties of SecurePort IV also have the potential to reduce catheter dislodgement, which is a common issue with vascular access devices. The experts also commented that the technology could reduce the need for frequent dressing changes because of bleeding after insertion of a catheter.

Potential system impact

All of the experts noted that the technology has the potential to reduce reattendance to primary or secondary care shortly after the insertion of a vascular access device. This particularly relates to ambulatory care patients who need regular visits to have dressings changed. The reduced risks of line dislodgement and need for reinsertion also offer benefits to both patients and the healthcare system in terms of cost savings and improved health outcomes. Two of the experts suggested that the technology would cost more than current care because of frequent application. The other expert highlighted that the technology could decrease costs overall by reducing the need for dressing changes and saving nurse time.

General comments

All of the experts agreed that training would be needed to use the technology safely and effectively. This is important because of the adhesive properties of the technology, which mean both application of the SecurePort IV and weekly dressing changes should be considered. If the technology is adopted, the experts agreed that no change to existing clinical facilities would be needed and that it would be used in most or all general hospitals.

Expert commentators

The following clinicians contributed to this briefing:

- Ms Julie Godfrey, lead vascular access nurse consultant, Mid and South Essex Hospital Group. Did not declare any interests.
- Mr James Bitmead, senior infection control nurse, University College Hospitals NHS Foundation Trust. Did not declare any interests.
- Ms Dympna McParlan, vascular access lead nurse, Belfast Health and Social Care Trust. Did not declare any interests.

Development of this briefing

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

Update information

Minor changes since publication

July 2022: The CE mark classification of SecurePort IV has been changed from I to IIa.

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