

# SecurAcath for securing percutaneous catheters

Medical technologies guidance

Published: 5 June 2017

Last updated: 10 August 2022

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## Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

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Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should [assess and reduce the environmental impact of implementing NICE recommendations](#) wherever possible.

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# 1 Recommendations

- 1.1 SecurAcath is recommended as a cost-saving option for securing peripherally inserted central catheters (PICCs) with an anticipated medium- to long-term dwell time.

## **Why the committee made these recommendations**

The evidence shows that SecurAcath is at least as good as other devices for securing PICCs. It also has the benefit of not needing to be replaced at weekly dressing changes. It has a high rate of successful device placement and a low incidence of catheter-related complications.

Cost modelling shows that SecurAcath is cost saving compared with adhesive securement devices if the PICC remains in place for 21 days or longer. Cost savings result from shorter maintenance times and less need for device replacement when using SecurAcath.

## 2 The technology

### Description of the technology

- 2.1 SecurAcath (Interrad Medical) is a single-use device to secure percutaneous catheters in position on the skin. It is intended for use in adults and children who need a central venous catheter (CVC), a long, thin, flexible tube that is inserted into a vein through the skin. It is positioned so that the distal tip lies in a large central vein, usually the superior vena cava, right atrium or inferior vena cava.
- 2.2 CVCs are inserted using various access sites, including veins in the arm, chest, neck or groin; the choice in individual patients depends on a variety of factors such as anticipated duration of access needed (dwell time), reason for insertion and the quality and patency of venous sites available. There are 4 types of CVCs (Dougherty et al. 2015):
- Peripherally inserted central catheters (PICCs): CVCs inserted into a peripheral vein in the arm, rather than in the neck or chest. PICCs may be used for short-term access (7 to 10 days), but are more typically used in people needing intravenous access for several weeks or months. They are used in inpatient and outpatient settings.
  - Non-tunnelled CVCs (referred to in this guidance as 'CVCs'): Short-term CVCs placed into a large vein near the neck, chest, or groin. Non-tunnelled CVCs are indicated for short-term access (usually 7 to 10 days) when peripheral access is impractical or in acute, urgent situations. Non-tunnelled CVCs need securing at the site of insertion.
  - Tunnelled CVCs (also called Hickman lines): CVCs that are passed under the skin (tunnelled) from an insertion site near the neck or chest to a separate exit site, which helps to prevent infection and provides stability. Tunnelled CVCs are indicated for long-term access (more than 30 days). These long-term CVCs need securement for the first 2 to 4 weeks until tissue granulation around the 'cuff' of the tunnel, but after this, do not need additional securing.
  - Implanted ports: CVCs placed completely under the skin, which are used for

long-term therapies. Implanted ports have few complications, have minimal risk of infection and do not need securing.

- 2.3 SecurAcath has 2 parts, a base and cover. The base is made up of 2 foldable metal legs and 2 securement feet. The feet are placed under the skin at the catheter insertion site, and unfolded to make a subcutaneous anchor. The cover attaches to the catheter shaft and holds it in place when it is clipped onto the base. The device stays in place as long as the catheter is needed and can be lifted off the skin to allow cleaning of the insertion site.
- 2.4 SecurAcath is a class IIB device first CE marked in 2012. It is available in 6 different sizes (3 F to 8 F). The SecurAcath device is size-specific and the choice of device should be matched to the size of the catheter. The current size range for SecurAcath is not suitable for use with most renal dialysis catheters (a specific type of long-term tunnelled CVC). However, larger sizes (up to 12 F) are planned to be available in late 2017, which may be suitable for use with these type of CVCs.
- 2.5 The list price of SecurAcath stated in the company's submission is £16.00 excluding VAT. During development of the guidance, the company updated the UK list price of SecurAcath to £20.00. The cost of SecurAcath has been updated in the revised cost model to £18.00 excluding VAT. **[2022]**
- 2.6 The claimed benefits of SecurAcath in the case for adoption presented by the company are:
- no interruptions or delays in therapy because of improved catheter securement
  - fewer repeat procedures by improving vessel preservation and reducing reinsertions
  - fewer catheter complications (dislodgements, migration, thrombosis and infection)
  - a decrease in catheter replacement costs
  - a reduction in overall treatment costs because of fewer delays and complications.

## Current management

- 2.7 Current options for catheter securement include adhesive devices (such as StatLock and Grip-Lok), steri-strips, tape and sutures (stitches).
- 2.8 NICE has not produced guidance on securing catheters for central venous access. The [NICE guideline on healthcare-associated infections](#) recommends that the skin at and around the catheter insertion site is cleaned with chlorhexidine gluconate in 70% alcohol and allowed to air dry during dressing changes. The insertion site should be covered by a sterile transparent semipermeable membrane dressing which should be changed every 7 days or sooner if the dressing is no longer intact or moisture collects under it.
- 2.9 [British Committee for Standards in Haematology on the insertion and management of central venous access devices in adults](#) (Bishop et al. 2007) recommend using securing devices such as StatLock rather than sutures, and discourage the suturing of catheters to the skin. Several NHS trusts have produced local guidance on using catheter securement devices including SecurAcath.
- 2.10 The [US Infusion Nursing Society's Infusion Standards of Practice \(2016\)](#) refers to engineered stabilisation devices such as SecurAcath and StatLock. It suggests that these types of devices should be considered for securing catheters. It also says that engineered stabilisation devices promote consistent practice among clinicians, reduce catheter movement that can lead to complications, reduce the number of interruptions needed for infusion therapy, and may lower costs of care. The document suggests that tape or sutures should be avoided because they are not as effective as engineered stabilisation devices, based on good quality evidence from randomised controlled trials. The document also states that users should be aware of the risk of medical adhesive-related skin injury with the use of adhesive-based engineered stabilisation devices.

## 3 Clinical evidence

### Summary of clinical evidence

- 3.1 The key clinical outcomes for SecurAcath given in the decision problem were:
- rates of catheter migration and dislodgement
  - rates of catheter-related infection, including catheter-related bloodstream infection, local infection or inflammation and thrombophlebitis
  - number of unplanned catheter removals and reinsertions
  - time taken to secure the catheter
  - patient and clinician satisfaction scores
  - pain while in position and on insertion and removal
  - quality-of-life measures
  - device-related adverse events, for example catheter malfunction, thrombosis and vessel erosion.
- 3.2 The external assessment centre assessed 11 studies on SecurAcath, 9 submitted by the company and 2 identified independently. Three SecurAcath studies were published as peer-reviewed journal articles (Cordovani and Cooper 2013; Egan et al. 2013; Hughes et al. 2014), the remaining 8 studies were unpublished manuscripts, poster presentations, audit reports or conference abstracts (Janssens et al. 2016b; Djurcic-Jovan et al. 2016; Dougherty et al. 2013; Hill et al. 2014; Misericordia et al. 2015; Zerla et al. 2016; Stone et al. 2013; McParlan et al. 2016). The external assessment centre also identified 6 studies on a comparator, StatLock (Fang et al. 2011; Teichgräber et al. 2011; McMahan et al. 2002; Yamamoto et al. 2002; Zerla et al. 2016; Venturini et al. 2011). During the evaluation, Zerla et al. 2016 was published as a peer-reviewed article (Zerla et al. 2017).



## Published studies with SecurAcath

- 3.3 Cordovani and Cooper (2013) is a prospective multicentre cohort study done in Canada, which investigated 74 adults who had central venous catheters (CVCs) secured with SecurAcath. The primary outcome was device securement success, which was reported in 72 patients (97%). Mean catheter securement time was 62.5 seconds and the mean dwell time was 3.1 days. Discomfort was measured on a 1 to 10 scale (with 10 being most discomfort): mean scores were 0.9 in situ and 1.6 at removal. Of the 15 patients who had previously had a sutured catheter, 14 found SecurAcath 'as or more comfortable'. Six out of 8 healthcare professionals found maintenance 'somewhat' or 'much easier' than sutures.
- 3.4 Egan et al. (2013, and its earlier iteration Sansivero [2011]) investigated peripherally inserted central catheters (PICCs) secured with SecurAcath in 68 adults in intensive care units, transplant units or outpatient clinics at 3 centres in the US. The primary end point was device securement success, defined by the absence of device-related malfunctions and adverse events. Secondary end points included securement time, patient comfort and ease of maintenance. Mean dwell time was 22.6 days and mean securement time was 31 seconds. Securement-related malfunctions were seen in 6 patients (8.8%), with 20 (22.1%) adverse events reported. Pain scores were measured on a 0 to 10 scale: immediately after device removal, the mean pain score was 1.5. In situ mean pain score was 0.7 and 91.2% of patients were either neutral, satisfied or very satisfied with SecurAcath. Use of SecurAcath did not influence placement or maintenance techniques. The authors concluded that SecurAcath performed favourably when compared with StatLock (on the basis of historical data for StatLock reported by Yamamoto et al. [2002]: respective rates of migration and dislodgement of 2.9% and 0% for SecurAcath and 6% and 12% for StatLock).
- 3.5 Hughes et al. (2014) prospectively evaluated PICCs with SecurAcath in 31 adults at a single UK centre. Mean dwell time was over 30 days in 45% of patients. The study reported 100% successful device placement; 11% were placed with 'difficulty' and 19% with 'slight difficulty'. Staff reported difficulty with removal 'fairly frequently'. One patient experienced

catheter migration of 1 cm. Pain scores were measured on a 0 to 10 scale. At placement, pain scores were 0 in all patients; in situ, 5 patients' scores were over 5, and at removal over half of patients' scores were over 3. PICCs were removed in 3 patients because of severe or unresolved pain. The study reported a PICC-related infection rate of 12% (n=31), which was reduced to 2% in a subsequent cohort (n=100).

- 3.6 Zerla et al. (2017; and the earlier unpublished extract Zerla et al. 2016) is a single-centre prospective study done in Italy without a comparator. It investigated 30 adults needing chemotherapy who had a PICC in place for over 2 months, secured with SecurAcath. The median dwell time was 145 days. Skin integrity issues were reported in 32.2% of patients. Pain scores were measured on a 0 to 10 scale: at placement, pain scores were less than or equal to 2 in 90% of patients, in situ they were less than or equal to 2 in 95% of patients and at removal they were less than or equal to 2 in 43.33% of patients. The authors report a median insertion site maintenance time of 10 minutes for SecurAcath, which compared favourably with a median of 20 minutes maintenance time for an adhesive device in a historical cohort of patients. No cases of dislodgment, infection and thrombotic episodes were reported. There were 2 unplanned catheter removals. The authors concluded that, after effective training, SecurAcath is comfortable for the patient, reduces catheter movements, and is more effective in comparison to adhesive devices in oncology patients with long-term catheterisation and ambulatory maintenance.

## **Unpublished studies and conference abstracts with SecurAcath**

- 3.7 Janssens (2016b) is a Belgian-based, single-centre, prospective, unblinded, randomised controlled trial comparing PICCs secured with SecurAcath and PICCs secured with StatLock in adults. The outcomes included time spent on dressing changes, catheter migration, accidental dislodgement and laboratory-confirmed catheter-related bloodstream infection. The study was submitted as an unpublished manuscript which was available to the committee as academic in confidence.
- 3.8 Djurcic-Jovan et al. (2016) is a single-centre retrospective, observational, comparative, longitudinal study done in Canada comparing PICCs placed

with and without SecurAcath in 54 patients needing complex continuing care. The primary outcome measure was unplanned catheter reinsertion. Mean dwell time was over 31 days. There were 60 unplanned catheter reinsertions reported without using SecurAcath compared with 3 unplanned reinsertions with SecurAcath. There was no catheter migration reported. The authors saw substantial time savings for nurses and clinicians after the introduction of SecurAcath. Qualitative outcomes were collected retrospectively. For SecurAcath, catheter migration was rated 'very good' or 'good' in 88% of cases, and catheter stability while doing insertion site maintenance, ease of dressing, and overall use of the device were rated as 'very good' or 'good' in 95% of cases.

- 3.9 Dougherty et al. (2013) is a UK-based single-centre prospective study without a comparator which evaluated PICCs secured with SecurAcath over 1 month in 30 patients. Qualitative data were gathered from nurses and patients. There was a reduction in malposition and catheter damage compared with previous practice and no skin reactions were seen. Nurses reported increased confidence in doing insertion site maintenance but also reported some difficulty removing the device. Patients reported pain at insertion ('if incorrectly placed and the anchor was too superficial') and pain at removal.
- 3.10 Hill (2014) is a Canadian-based single-centre pilot evaluation of PICCs secured with SecurAcath in 60 patients without a comparator. The author reported no malpositions but accidental dislodgement in 2 agitated patients. The author described dressing changes as being done by 'general unit staff, not IV team staff': SecurAcath gave staff increased confidence, fewer anxieties and increased efficiencies. The author described the successful use of SecurAcath in patients with skin integrity issues, when the device was used without adhesive dressing. The author concluded that overall patient satisfaction was achieved.
- 3.11 Misericordia et al. (2015, reported as Anonymous 2015 in the assessment report) is an unpublished report provided by the company. This is a retrospective, comparative audit done by the parenteral therapy team at the Misericordia Community hospital in Canada which evaluated 164 unanchored PICCs placed during 2013 and 542 PICCs placed during 2014 and secured with SecurAcath. The average dwell time was 29 days.

The report also evaluated using a PICC designed to reduce catheter-related thrombosis. Six different operators took part in the evaluation. The primary outcomes were catheter-related thrombosis, PICC occlusion, catheter malposition, local infection and catheter-related bloodstream infection. In the SecurAcath cohort, there were no confirmed catheter-related bloodstream infections. From 2013 to 2014, the rate of catheter-related thrombosis decreased from 3.75% to 3.69%, PICC occlusion increased from 14.35% to 16.97%, and malposition decreased from 10.98% to 1.66%. The authors concluded that without using SecurAcath, around 60 of the 542 patients would have otherwise needed catheter replacements.

- 3.12 Stone et al. (2013) is a prospective, single-centre study done in the US which included PICCs secured with SecurAcath in 42 children with previous skin problems, irritation or allergic reactions to standard dressings. The authors compared outcomes with historical data on 17 patients with catheter migration in the same centre (undefined cohort). In the SecurAcath cohort, there were no catheter migrations, complications or unplanned catheter removals. The authors concluded that further research was needed to optimise dressings in patients with skin integrity issues.
- 3.13 McParlan et al. (2016) is a single-centre, UK prospective cohort study comparing PICCs secured with SecurAcath and with StatLock in haematology and oncology patients, published as a conference abstract. The full study was submitted as an unpublished poster which was available to the committee as academic in confidence. The abstract states that, during the study, there were no reported incidences of migration or PICC removal. This was associated with a reduction in chest X-rays to verify the location of migrated catheter tips (and therefore decreased exposure to radiation). There was also a reduced need for reinsertions, and reduced delays to therapy. The study reported significant financial benefits because of fewer PICC reinsertions and more efficient dressing changes. Additional benefits include reduced skin reactions, improved cleaning of the catheter site and greater user satisfaction. The abstract authors concluded that using SecurAcath had prevented PICC migration and improved patient outcomes.

## Additional work by the external assessment centre

- 3.14 The external assessment centre noted the lack of comparative published evidence between SecurAcath and its comparators. It considered the unpublished randomised controlled trial (Janssens et al. 2016b) to be the most relevant evidence to inform the decision problem.
- 3.15 The external assessment centre did a meta-analysis using data from 16 studies on 5 clinical outcomes that it considered appropriate: migration, dislodgement, catheter-related infection, catheter-related bloodstream infection and unplanned removals/reinsertions. Because of the limited evidence base, there was significant uncertainty in the results, reflected in wide 95% confidence intervals (95% CI). The meta-analysis reported the following results comparing SecurAcath with StatLock: migration: 4.00% (95% CI: 1.48 to 8.50) and 4.72% (95% CI: 2.28 to 8.50); dislodgment: 0.59% (95% CI: 0.3 to 1.03) and 4.07% (95% CI: 3.29 to 4.97); catheter-related infection: 0.77% (95% CI: 0.28 to 1.66) and 1.64% (95% CI: 1.10 to 2.35); catheter-related bloodstream infection: 1.68% (95% CI: 0.20 to 5.94) and 1.47% (95% CI: 0.18 to 5.21). The external assessment centre considered the meta-analysis to be supportive of the results of Janssens et al. 2016b (except dislodgement, where the meta-analysis showed a difference in dislodgement rates), with similar clinical outcomes between devices. The external assessment centre concluded that there is not enough evidence to show that SecurAcath is clinically superior in effectiveness and adverse events to StatLock, but there is some evidence that SecurAcath is non-inferior to StatLock.

## Committee considerations

- 3.16 The committee considered that the available evidence, despite its limitations, was enough to conclude that SecurAcath was associated with a high rate of successful device placement, a low incidence of catheter-related complications and does not usually need replacing while the catheter is in place. The committee also considered that the emerging comparative evidence suggested that SecurAcath is at least as effective as other devices for securing PICCs, with the added benefit of not needing to be replaced at weekly dressing changes.

- 3.17 The committee received advice from experts who use SecurAcath to secure PICCs in haematology and oncology patients in both inpatient and outpatient settings. The experts highlighted that PICCs in these patients have long dwell times of at least 6 months, and can be in place for up to 1 year.
- 3.18 The committee was advised by the experts that SecurAcath is well tolerated by patients when placed by an experienced healthcare professional. Pain on insertion is rare, because local anaesthetic is used anyway during the initial PICC placement. Pain is also rare while the device is in place, as long as it has been placed correctly. SecurAcath removal involves using scissors to cut the device in half and local anaesthetic administration is rarely needed. One expert stated that any discomfort patients experienced with using SecurAcath was countered by a reduction in anxiety linked with a lower likelihood of catheter displacement during dressing changes.
- 3.19 The committee was told by the experts that it is routine practice to anticipate the likely dwell time of PICCs at the time of insertion, based on the individual patient and clinical circumstances. It is possible that this consideration would inform the securement method selected in normal clinical practice. Although PICCs are sometimes in place for less time than anticipated, this is usually because of unexpected complications that necessitate early removal or replacement.

## 4 NHS considerations

### System impact

- 4.1 The company claimed that SecurAcath could lower costs by avoiding delays in treatment and reducing catheter-related complications.
- 4.2 Experts considered that specialist training was needed for the insertion, maintenance and removal of SecurAcath. Removal of the device was identified as the most challenging element in its use, but this becomes easier with more experience.
- 4.3 NICE has produced an [adoption resource about using SecurAcath](#) for the securement of peripherally inserted central catheters (PICCs).

### Committee considerations

- 4.4 The committee was advised by the experts that dressing changes are needed at the catheter insertion site on a weekly basis. They also said that a considerable amount of time is saved by using SecurAcath compared with StatLock for the maintenance of long-term PICCs. Dressing changes are much quicker and easier and there is a reduced risk of catheter dislodgement with SecurAcath.
- 4.5 The committee concluded that training was essential for the correct insertion, maintenance and removal of SecurAcath. Experts advised that proficiency improves quickly with experience and that there is a short learning curve. Training is provided free of charge by the company. This includes face-to-face instruction by clinical nurse advisers as well as online support from a downloadable mobile application.
- 4.6 SecurAcath is contraindicated in people with nickel allergy. One expert stated that, in their experience, true nickel allergy is rare and they had not encountered an allergic reaction to SecurAcath in their practice. It was also stated by the experts that patients may experience sensitivity to adhesive dressings.

- 4.7 The experts stated that they had no experience of using SecurAcath in young children (who tend to have tunnelled central venous catheters), but 1 had used it successfully with older children (aged 12 years and over) having chemotherapy.
- 4.8 One expert stated that bleeding can occur after SecurAcath placement, so more dressings may be needed.



## 5 Cost considerations

### Cost evidence

- 5.1 The company identified 3 published economic studies, but the external assessment centre considered them to be outside the scope. It did not identify any further economic studies.
- 5.2 The company presented a de novo cost model that compared the cost consequences of using SecurAcath in people with peripherally inserted central catheters (PICCs) compared with StatLock, and in people with central venous catheters (CVCs) compared with sutures.
- 5.3 The model used a decision-tree structure where people entered the model at the point of having a securement device (either SecurAcath, StatLock or sutures). Both trees contained 5 outcomes after securement: no complications; catheter migration; catheter malposition; catheter occlusion; or catheter-related infection (catheter-related bloodstream infection or catheter-related thrombosis). There was an additional outcome of needlestick injuries for health professionals in the suture group.
- 5.4 The model was constructed with a time horizon of 25 days for PICCs and 3 days for CVCs. Other clinical parameters such as the probability of migration, malposition, occlusion, infection and thrombosis were derived from published and unpublished literature. Device and resource costs relating to the cost of placement (such as nurse time) and complications were also from published and unpublished sources.
- 5.5 The results of the company's base case found cost savings with SecurAcath of £41.40 per patient for PICCs compared with StatLock and £1,005.60 per patient for SecurAcath with other CVCs compared with sutures. The main reasons for StatLock's greater costs as compared with SecurAcath were device costs and differences in catheter migration rates. For sutures, the main reasons for the greater costs were differences in the rates of catheter-related bloodstream infection or

catheter-related thrombosis.

- 5.6 The company did a 1-way deterministic sensitivity analysis, increasing SecurAcath device costs by up to 200%. It also did multiway deterministic sensitivity analyses, changing the values for each economic and clinical parameter simultaneously by  $\pm 20\%$ . In all cases, SecurAcath remained cost saving compared with its comparator. When PICC dwell time was increased to 6 months (reflecting a typical clinical situation of a patient having cancer treatment), the cost saving with SecurAcath increased to £115.00 per patient.
- 5.7 During the evaluation, a new peer-reviewed article was published that provided a simple cost analysis (Zerla et al. 2017). The published cost comparison of SecurAcath with StatLock only included the cost of the devices. Few details on the analysis are given, but the 30 patients having SecurAcath were compared with a historic control population (Zerla et al. 2015) of 793 patients who had PICCs secured with StatLock. Devices were assumed to cost €30 for SecurAcath and €6 for StatLock, giving a total device cost of €900 for SecurAcath and €4,254 for StatLock. The authors concluded that SecurAcath is cost saving. The authors also report no dislodgments with SecurAcath and compare this with results from Zerla et al. (2015) in which 63 dislodgements were seen. An overall cost for reinsertion for all 63 dislodgements is estimated to be €18,710.
- 5.8 The NICE adoption and impact scoping report (included in the assessment report overview) describes a single centre's experience of real-world total cost savings of up to £59,000 with SecurAcath when compared with StatLock when placing 1,100 PICCs over 6 months.
- 5.9 NICE has published a [resource impact template on SecurAcath](#), which can be used to calculate the local resource impact of implementing the guidance.

## Additional work by the external assessment centre

- 5.10 Overall, the external assessment centre considered the company's model to be appropriate given the limited evidence base available, but noted some errors in the model. These included figures wrongly quoted,

applying probabilities as rates and a lack of clarity on some sources of evidence. It queried several assumptions in the model: dwell times; the differential impact of securement device placement by nurses or doctors; that no extra resources are needed to place securement devices and the clinical outcomes chosen. It also queried the significant assumption in the model that outcomes were independent of time and were collected over similar dwell times. It noted there was a risk of study heterogeneity and uncertainty about variations in clinical practice and outcome measurements.

- 5.11 The external assessment centre regarded Yamamoto et al. (2002) as the best evidence available on the incidence of complications, because it reported rates rather than probabilities. Yamamoto et al. (2002) is a single-centre, US-based, prospective randomised controlled trial, comparing StatLock with sutures in patients with PICCs (n=170). The primary end point was catheter-related complications. Mean dwell times were 33 days for StatLock and 35 days for sutures. The risk of total complications was 49.4% and 71.7% for StatLock and sutures, respectively (p=not significant). There was no statistically significant difference in dislodgement or migration rates between the 2 groups, but a significant reduction in infections with StatLock was seen (p=0.032).
- 5.12 Using this evidence and the updated list price of SecurAcath, the external assessment centre revised the model base case. It assumed clinical equivalence for all outcomes between SecurAcath and comparators, except for needlestick injury, where a reduced risk without sutures was highly likely. Therefore, base-case costs related to placement and maintenance costs over the relevant dwell time only, with needlestick injury costs included where relevant. It also considered 3 dwell times for both CVCs and PICCs: 5 days (short), 25 days (medium), and 120 days (long). Other amendments included: adding StatLock as a comparator for CVCs; varying placement and maintenance times; suturing being done by a band 6 nurse; sutures remaining throughout the dwell time and updating resource costs.
- 5.13 The revised base case found that StatLock was the cheapest option for PICCs for short dwell times (5 days), but that SecurAcath was cost saving for medium to long dwell times (25 days and over). For CVCs,

StatLock was the cheapest securement option for short dwell times and sutures was the cheapest for medium to long dwell times. After the increase in the SecurAcath list price to £20, the external assessment centre reran the model, which increased SecurAcath costs in all analyses by £4 (see table 1 for a summary of external assessment centre results). The external assessment centre concluded that the impact of the list price change was minimal. StatLock remained the cheapest option for dwell times of 5 days and SecurAcath remained cheaper than StatLock for dwell times of 25 days and 120 days.

- 5.14 A one-way sensitivity analysis, reducing SecurAcath placement time to 30 seconds (as reported by the company), made SecurAcath slightly more cost saving and sutures slightly less cost saving, but did not change the base-case results (see table 1 for a summary of external assessment centre results). Another one-way sensitivity analysis assumed an insertion site maintenance time of 7.3 minutes for sutures, equivalent to the time reported for StatLock in Janssens (2016b). This changed the results for CVCs such that SecurAcath was cheaper than sutures for both PICCs and CVCs with a medium and long dwell time (see table 1).
- 5.15 The external assessment centre did a multivariate sensitivity analysis including differential risks of migration, dislodgement and catheter-related bloodstream infections, based on the figures reported in Yamamoto et al. (2002) and its meta-analysis. This found that StatLock was the cheapest option for short dwell times for both PICCs and CVCs, but for medium and long dwell times, SecurAcath was the most cost saving (see table 1).

**Table 1 Cheapest (cost saving) device in each of external assessment centre's 5 scenario analyses**

Scenario	1	2	3	4	5
CVC (central venous catheter): 5 days	StatLock (£5)	StatLock (£5)	StatLock (£5)	StatLock (£15)	StatLock (£5)
PICC (peripherally inserted central catheter): 5 days	StatLock (£16)	StatLock (£11)	StatLock (£16)	StatLock (£18)	StatLock (£16)

Scenario	1	2	3	4	5
CVC: 25 days	Sutures (£11)	Sutures (£6)	SecurAcath (£8)	SecurAcath (£21)	Sutures (£6)
PICC: 25 days	SecurAcath (£13)	SecurAcath (£18)	SecurAcath (£13)	SecurAcath (£9)	SecurAcath (£13)
CVC: 120 days (not clinically relevant: non-tunnelled CVCs only used short term)	Sutures (£11)	Sutures (£6)	SecurAcath (£90)	SecurAcath (£112)	Sutures (£6)
PICC: 120 days	SecurAcath (£90)	SecurAcath (£95)	SecurAcath (£90)	SecurAcath (£64)	SecurAcath (£90)

Scenarios:

1. Base case (placement and maintenance costs only; no differences in complication rates across devices).
2. One-way sensitivity analysis: assumes a SecurAcath placement time of 30 seconds.
3. One-way sensitivity analysis: assumes a suture maintenance time of 7.3 minutes.
4. Multiway sensitivity analysis including complication rates.
5. Suturing done by a consultant anaesthetist.

5.16 A threshold sensitivity analysis for dwell times using the base case indicated that SecurAcath was the cheapest option for securing PICCs for 15 days or more. For CVCs, the costs of sutures dropped below those of StatLock for dwell times of 8 days or more, but SecurAcath remained more expensive than sutures for securing CVCs over any dwell time. The increased list price of SecurAcath did not affect the threshold analysis.

5.17 For PICCs, the external assessment centre agreed with the company's conclusion that SecurAcath appears to be cheaper than StatLock over medium and long dwell times (25 days and over). Cost savings arise from shorter maintenance times with SecurAcath and the need to replace

StatLock weekly. It concluded that these cost savings were robust: it found smaller savings in the base case excluding complications, but similar results in sensitivity analyses including complications.

- 5.18 For CVCs, the external assessment centre agreed with the company's conclusion that SecurAcath was cost saving compared with sutures over short dwell times, but disagreed with the exclusion of StatLock as a comparator. Additional analysis including StatLock concluded that it was the cheapest for CVCs with short dwell times in all scenarios. For medium to long dwell times, suturing was cheaper than SecurAcath or StatLock in the base case (excluding complications). However, evidence suggested an increased risk of infection with suturing. Sensitivity analyses including complications found SecurAcath to be cheaper than suturing and StatLock over 25- and 120-day dwell times. This led the external assessment centre to conclude that SecurAcath is likely to be the cheapest option for securing CVCs over medium and long dwell times.
- 5.19 The external assessment centre reviewed the cost analysis in Zerla et al. (2017). The authors report shorter maintenance time for SecurAcath than StatLock, but do not include this in the cost comparison. They report median maintenance times of 10 minutes for SecurAcath and 20 minutes for StatLock, but the methodology for these estimates is unclear. Although the times reported are longer than the estimates of 4.3 minutes for SecurAcath and 7.3 minutes for StatLock reported by Janssen et al. (2016b; used in the external assessment centre cost analysis), they were in about the same ratio (that is, 1:2). The external assessment centre noted that the estimated cost of PICC reinsertion is similar to the cost of PICC dislodgement used in its cost analysis. In summary, the external assessment centre concluded that this study does not significantly change the findings of its cost analysis.
- 5.20 The external assessment centre used the increased maintenance times from Zerla et al. (2017) in an updated threshold analysis. The results reduced the cost-saving threshold for SecurAcath to a dwell time of 8 days or more. The external assessment centre noted that the use of maintenance times from this study instead of Janssen et al. (2016b) would not change the conclusions of its cost comparison (that is,

StatLock is cheaper than SecurAcath over short dwell times and SecurAcath is cheaper than StatLock over medium and long dwell times). The external assessment centre highlighted that Janssen et al. (2016b) provides higher quality evidence than Zerla et al. (2017) on maintenance times.

## Committee considerations

- 5.21 The committee noted that the experts disagreed with the external assessment centre's assumption that nurses would place sutures in the NHS, because they considered it would usually be done by a doctor in an operating theatre environment. Furthermore, the committee noted that when the external assessment centre had recalculated the CVC costs for using a consultant anaesthetist to place sutures, there were only minor differences in the results of the cost modelling (see [table 1](#)), with sutures becoming slightly less cost saving compared with SecurAcath in the base case.
- 5.22 The committee was advised by the experts that a 25-day dwell time for PICCs was an underestimate of routine clinical practice, because haematology and oncology patients usually have PICCs in place for 4 to 6 months, and even up to 1 year.
- 5.23 The committee concluded that while SecurAcath may take a few minutes longer than StatLock to place and remove (although the experts indicated that this difference reduces with increased experience), maintenance times with SecurAcath are a lot shorter than with StatLock.
- 5.24 The committee concluded that SecurAcath would not usually be used for tunnelled (Hickman) CVCs or implanted ports, but may be used for non-tunnelled CVCs. However, the committee also noted that non-tunnelled CVCs are used for short-term vascular access (usually less than 10 days). Furthermore, if SecurAcath is used for non-tunnelled CVCs, experts advised that in their experience, an adhesive device would also be placed on top of SecurAcath as an additional measure to prevent potential dislodgement. For all these reasons, the committee concluded that the cost-modelling results for non-PICC CVCs (with dwell times for up to 120 days) are unlikely to be clinically relevant.

## 2022 guidance review

- 5.25 For the guidance review, the EAC revised the model to reflect 2021 costs. Further details of the revised model are in the cost update in the [review decision from July 2022](#).
- 5.26 During the review, the original economic model was corrected so that the model accounted for the weekly replacement of StatLock devices. This meant that in the original guidance, SecurAcath should have been cost saving by £12.60 to £148.54 for PICCs with medium- to long-term dwell times, respectively.
- 5.27 Based on the 2022 guidance review updated cost model, the EAC updated the costs included in the original model. It found that SecurAcath was still cost saving for medium- and long-term dwell times of PICC lines but that the extent of cost saving was reduced compared with the original guidance. Cost savings result from shorter maintenance times and less need for device replacement with SecurAcath.



## 6 Conclusions

- 6.1 The committee concluded that there is evidence that SecurAcath is effective for securing peripherally inserted central catheters (PICCs). Using SecurAcath avoids the need for securement device replacement and is associated with a low incidence of catheter-associated complications, such as migration, occlusion, thrombosis and infection.
- 6.2 The committee concluded that SecurAcath is easy to use and is well tolerated by people with PICCs, provided that device placement is done by staff with appropriate training and experience.
- 6.3 The committee concluded that the adoption of SecurAcath for the securement of PICCs is likely to be cost saving compared with StatLock, with cost savings resulting from a reduction in the time taken during weekly dressing changes and from avoiding securement device replacement. Cost savings are greater with longer PICC dwell times, with cost modelling indicating that using SecurAcath becomes cost saving when the catheter is expected to be in place for 15 days or more.

## 7 Committee members and NICE project team

### Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

### NICE project team

Each medical technology guidance topic is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal) and a senior technical lead. Other key contributors are listed in the assessment report overview.

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## Update information

**August 2022:** We updated this guidance to reflect 2021 costs and revise cost-saving estimates. These are marked **[2022]**. Details of the changes are explained in the [review decision from July 2022](#).

ISBN: 978-1-4731-2513-1