Review report of MTG34: SecurAcath for securing percutaneous catheters

This medical technology guidance was published in June 2017.

All medical technology guidance is usually reviewed 3 years after publication, unless NICE become aware of significant new information before the expected review date.

This review report summarises new evidence and information that has become available since this medical technology guidance was published, and that has been identified as relevant for the purposes of this report. This report will be used to inform NICE's decision on whether this guidance will be updated, amended, remain unchanged (static list) or withdrawn.

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1 Original objective of guidance

To assess the clinical and cost effectiveness of SecurAcath for securing percutaneous catheters.

2 Current guidance recommendations

1.1 The case for adopting SecurAcath for securing peripherally inserted central catheters (PICCs) is supported by the evidence. SecurAcath is easy to insert, well tolerated, associated with a low incidence of catheter-related complications and does not usually need removing while the catheter is in place.

1.2 SecurAcath should be considered for any PICC with an anticipated medium- to long-term dwell time (15 days or more).

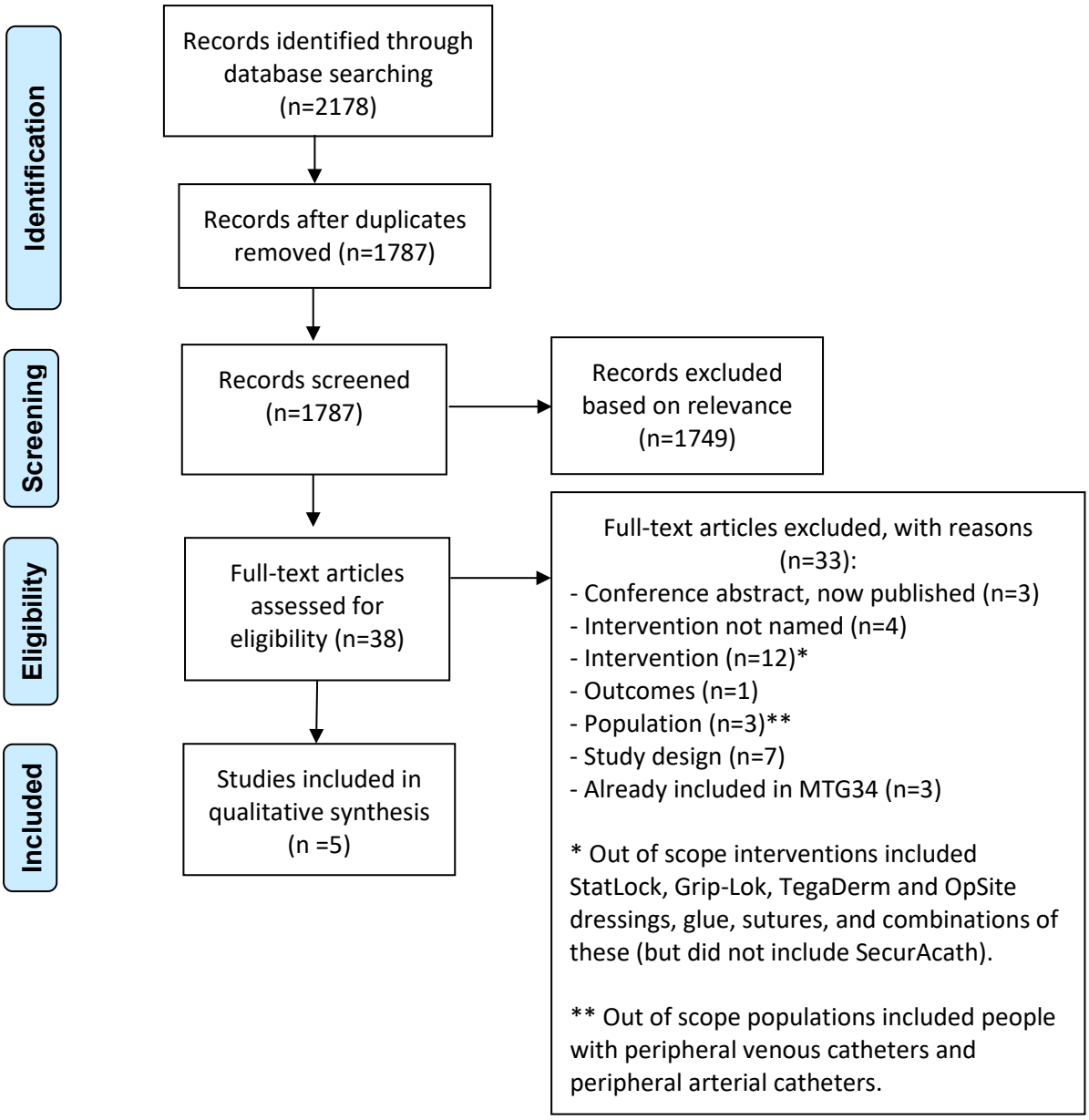
1.3 Cost modelling shows that SecurAcath is cost saving compared with adhesive securement devices if the PICC remains in place for 15 days or longer. Estimated cost savings range from £9 to £95 per patient for dwell times of 25 days and 120 days, respectively. Cost savings result from shorter maintenance times and less need for device replacement with SecurAcath. Annual savings across the NHS in England from using SecurAcath are estimated to be a minimum of £4.2 million.

3 Methods of review

The NICE guidance Information Services (gIS) identified 2178 potentially relevant studies from their literature search (detailed in Appendix A1). After de-duplication, 1787 titles and abstracts were provided. These studies were sifted by a single reviewer (RO) and 38 were found to be potentially within the scope of the original guidance (NICE MTG34 Scope, 2017). The full text articles for these studies were retrieved and assessed for inclusion against the scope (RO). Thirty-three of these were excluded on full text review, with five studies (including one conference abstract) remaining for further analysis.

A summary of the sifting and selection process of the EAC literature search is reported in Figure 1.

Figure 1: PRISMA diagram



The company provided a list of 15 completed studies, including a poster presentation, and 1 clinical expert provided a list of 4 studies. The company also provided details of ongoing trials (described in section 4.6). The results from two of these were available; one as a pre-publication abstract, and the other as a conference abstract. Of these additional 21 references, 11 had been identified by the gIS search and already sifted by the EAC. The remaining 10 were assessed for eligibility for inclusion (RO). Of these, two papers and one conference abstract were considered to be in scope.

Subsequent to project initiation, the company provided four more recently published studies, three were considered to be in scope.

From identified guidelines and reviews, the reference lists were checked for further relevant papers, and none were found.

From the gIS search, and the references provided by the company and clinical experts, a total of nine full papers, and two conference abstracts were considered in scope. The studies excluded are detailed in Appendix A2.

The EAC notes that one of the included conference abstracts (Pittiruti *et al.* 2016), and one of the excluded conference abstracts (Pittiruti *et al.* 2016b), excluded as SecurAcath is not explicitly named as the intervention, should have been available at the time of publishing the original MTG34 guidance (NICE MTG34, 2017). Only one reference to Pittiruti *et al.* was made in the Assessment Report by Kings Technology Evaluation Centre (KiTEC) EAC (NICE MTG34 Assessment Report, 2017), and it was to a presentation in 2015 (Pittiruti 2015). Newcastle EAC has cross-referenced this with the studies included in this review, and notes that this reported on two cohorts, which resemble those reported as studies A and B in Pittiruti *et al.* 2019. The poster was excluded from the original assessment, by KiTEC EAC, as the intervention included the use of glue to secure the catheter at the exit site, alongside SecurAcath. In the full text publication, no mention is made of the use of glue in studies A and B, only in study C. Following discussion with NICE, the EAC has not excluded studies using glue in addition to SecurAcath, as there is no indication that this is used only with SecurAcath and has not historically been used with other securement devices. Therefore this should not bias results in favour of SecurAcath. Additionally, the use of glue is reported exclusively in Italian studies, although not all of them, suggesting that its use may be determined by clinician or centre preference. However, this does mean the evidence currently available may not be generalisable to the UK population.

In its original assessment report for MTG34, KiTEC EAC also raised concerns regarding methodological quality and publication bias, in relation to a number of studies being published as abstracts and not going on to be published in peer-reviewed journals (NICE MTG34 Assessment Report, 2017). The EAC echoes this concern. The three studies reported in Pittiruti *et al.* 2019, although partially consistent with the presentation by Pittiruti (2015), as far as the EAC can tell, do not report on the cohorts reported in the Pittiruti *et al.* 2016 or Pittiruti *et al.* 2016b conference abstracts.

4 New evidence

4.1 Changes in technology

The company confirmed no changes to the technology, but stated that two new, larger sizes (10F and 12F) are now available. The technology is now available in eight sizes.

4.2 Changes in care pathways

The EAC did not identify any new care pathways or significant changes to clinical guidelines relating to SecurAcath, and none were identified by the clinical experts. The most relevant clinical guideline (CG139, 2017), Healthcare-associated infections: prevention and control in primary and community care, was updated in the same year as MTG34 was published. It makes no recommendations relating to catheter securement for the prevention of infection associated with vascular access devices. There is published NICE Guidance for other technologies relevant to placement and securement of catheters for central venous access, and relevant to infection prevention of access sites. These are listed in Appendix A3.

The Royal College of Nursing updated its standards for infusion therapy in 2016, removing specific guidance to use a manufactured securement device whenever feasible, and instead recommending that those placing "*CVCs, and particularly midlines and PICCs, consider use of an engineered stabilisation device*". Where the guidance previously provided an example of StatLock, no specific devices are named in the update.

4.3 Results from the MTEP research commissioning workstream

The EAC is not aware of any research commissioned by the MTEP to inform the guidance review. However, the EAC notes that SecurAcath is included on the MedTech Funding Mandate for 2021/21, which will lead to increased uptake and potential for further cohort studies. However, if SecurAcath is adopted according to the mandate for all eligible PICC lines, and remains in use beyond the end of the mandate, this may limit opportunities for randomised controlled trials (RCTs) with comparators in the scope, and limit the evidence available for guidance review in the future.

4.4 Description of new studies

The nine peer-reviewed full papers all reported observational cohort studies, including:

- four comparative studies (prospective cohort study [N=1], prospective studies with retrospective data used as a comparator [N=2], retrospective cohort study [N=1])
- two prospective single arm cohort studies
- one paper reporting on three different prospective single arm cohort studies
- two single arm retrospective cohort studies.

The two conference abstracts reported a comparative service evaluation, and a single arm observational study. The studies reported were in patients with PICCs (N=5, including one abstract), central venous catheters (CVCs, N=3) and a mixture of both PICCs and CVCs (N=5, including one abstract). Four studies (D'Andrea *et al.* 2021, Crocoli *et al.* 2021, Pittiruti *et al.* 2019 [studies B and C]) also reported on femorally inserted central catheters (FICCs), but results were aggregated with those for CVCs and PICCs. All included studies are summarised in Appendix B1.

The EAC notes that when reporting outcomes, there are inconsistencies in the terminology used across studies. For example, migration may be referred to as partial dislodgement, and total dislodgement may be referred to as accidental removal. Dislocation is also used in the context of migration and dislodgement. In terms of migration, there are also inconsistencies in the distance a catheter needs to move to be considered migrated, ranging from more than 1cm (Fitzsimons *et al.* 2020) to more than 2cm (Culverwell *et al.* 2020), and some studies did not explicitly declare their criteria for migration. There are also differences in reporting of infection, with some studies reporting catheter-related bloodstream infections (CRBSI) and some reporting central line associated bloodstream infections (CLABSI). A CRBSI is a bloodstream infection that has been laboratory confirmed and identifies the catheter as the source of infection. A CLABSI is a bloodstream infection that occurs in a patient who has had a central line in the previous 48 hours, which is not related to an infection at another site (Centers for Disease Control and Prevention). Therefore, this terminology is not interchangeable.

4.4.1 Studies reporting on PICCs only

Five studies reported on the use of SecurAcath exclusively with PICC lines; two comparative cohort studies, two single-arm cohort studies, and one abstract describing a service evaluation.

Comparative studies

The Culverwell *et al.* (2020) study, described as a product evaluation, included 51 patients with PICCs secured with SecurAcath over a four month data collection period, beyond which no follow up was conducted. Comparative data was sourced retrospectively from two separate four-month periods, one year apart. The primary outcome reported was migration of the catheter by more than 2cm, without loss of function. Secondary outcomes of relevance included breaches in skin integrity, pain during placement and removal, staff ease and confidence in placing and removing the device, and changing dressings, dislodgement (defined as accidental removal resulting in loss of function), line kinking, difficulty flushing the line, allergic reaction to nickel, and duration of device placement. Excess costs relating to PICC replacement due to migration or dislodgement were also reported.

Another retrospective study (Rowe *et al*, 2020) took a convenience sample of 7,779 patients, of which 47 had CLABSI reportable infections (as per National Healthcare Safety Network [NHSN] guidelines). The two securement devices compared were SecurAcath (n=32 infections) and an adhesive securement device (n=15 infections). The only outcome considered was the incidence of CLABSI, and whilst the length of follow up was not defined, the EAC assumes minimum follow-up was 48 hours (in line with NHSN guidelines for CLABSI).

Single arm studies

Study A reported by Pittiruti *et al.* (2019) was a prospective single arm cohort study in 50 oncology patients requiring a PICC for at least eight weeks, with follow up until catheter removal. Reported outcomes included pain during placement or removal, total or partial dislodgement, removal of the catheter before the scheduled time, and inflammation.

Brescia *et al.* (2021) reported on a retrospective cohort of 639 adult cancer patients who had PICCs secured with SecurAcath over three years between 2018 and 2020. They reported on dislodgement of the catheter, requiring repositioning, and number of safety outcomes. These included incidence of difficulty placing the device, including pain, complications within 48 hours, including pain and local bleeding, and late complications including, pain, catheter malfunction, local or systemic infection, catheter occlusion, catheter-related thrombosis (CRT) or issues with the skin around the exit site (for example, lesions or pressure ulcers).

Abstract

The Kay *et al.* (2020) abstract was a service evaluation comparing SecurAcath (n=10) to sutures (n=10) for securement of PICCs with an intended dwell time of over two weeks. The evaluation took place over 5 months, and was exclusively in paediatric patients (age range between 5 weeks and 17 years). Reported outcomes include displacement and migration, infection, skin damage, pain at the securement site, and completion of treatment.

4.4.2 Studies reporting on CVCs only

Three studies reported on the use of SecurAcath exclusively with CVC lines, or on CVCs and FICCs; one comparative cohort study, and two single-arm cohort studies.

Comparative study

The Dolcino *et al.* (2017) study reported on a prospective cohort of 51 adult and paediatric patients undergoing ultrasound guided positioning of a cuffed tunnelled CVC secured with SecurAcath, over a 4 month period. Comparative

data included 122 CVCs secured with StatLock, Grip-Lok or sutures. The primary outcome was catheter dislodgement, and secondary outcomes were catheter related complications including infection, thrombosis and malfunction, with follow up taking place for at least 30 days.

Single arm studies

D'Andrea *et al.* (2021) reported on a prospective cohort of 70 neonates with 72 lines in total, including 62 CVCs and 10 FICCs, over a 12 month period. Outcomes reported were dislodgements, early removals, ease of removal and the use of sedatives or local anaesthetic.

Barone *et al.* (2020) reported on a prospective cohort study of 30 pre-term neonates admitted to a neonatal intensive care unit over a 12-month period. All patients received a CVC insertion bundle including SecurAcath for catheter securement; the feasibility of this bundle was the primary outcome of the study. Secondary outcomes were early and late complications, including catheter dislocation, CRBSI (according to the Infective Diseases Society of America criteria), venous thrombosis, malfunction and duration of placement.

4.4.3 Studies reporting on PICCs and CVCs

Four studies reported on the use of SecurAcath with PICC and CVC lines, including one comparative cohort study, three single-arm cohort studies (one available in abstract form only).

Comparative study

The Fitzsimons *et al.* (2020) study recruited 52 consecutive paediatric patients requiring a PICC (n=29) or non-cuffed tunnelled CVC (n=23) for a medium dwell time, secured with SecurAcath. Recruitment was over a 9-month period, and retrospective data was used as the comparator, although this was not defined. Patients were followed up until catheter removal, and the primary outcome was securement failure of either migration of greater than 1cm from the documented insertion length, or accidental removal. The secondary outcome was CLABSI, defined as infection developing within 48 hours of placement, or defined as maintenance-related if developing after 48 hours.

Single arm studies

Two of the studies (Study B and Study C) by Pittiruti *et al.* (2019) recruited prospective consecutive cohorts of 50 and 100 patients respectively, with non-cuffed PICCs, CVCs and FICCs secured by SecurAcath. Patients in both studies were followed up until catheter removal. Patients were enrolled in Study B if they were judged to have at least a 30% risk of partial (that is, greater than 2cm) or total catheter dislodgement. The study outcomes were difficulty placing the device, pain or discomfort during placement or removal,

duration of catheter placement, partial dislodgement, accidental removal, and inflammation. This study recruited people with comorbidities, including dementia and skin problems affecting the use of adhesive, and included both adult and paediatric patients. Study C enrolled only paediatric patients, aged under 18 years, and defined outcomes of duration of placement, partial dislodgement, total accidental removal, inflammation, pain or discomfort during dressing changes, and on removal.

A retrospective study by Crocoli *et al.* (2021) reported on 250 CVCs, 48 PICCs, and 10 FICCs from three paediatric oncology units; all were tunnelled and secured with SecurAcath. Reported outcomes included CRBSI, CRT, dislodgement of 2cm or more, occlusion, local inflammation, exit site infection, pain on removal, or any local discomfort whilst the catheter and SecurAcath were in situ.

Abstract

The Pittiruti *et al.* (2016) abstract reports on a single arm observational study of 60 neonates and children requiring central venous access for at least 10 days. All catheters were tunnelled and consisted of 27 PICCs, and 38 CVCs, all secured with SecurAcath. Outcomes included ease of placement and removal, duration of placement, and accidental removals.

4.5 Results from new studies

Full details of outcomes are given in Appendix B2. The scope for the original MTG34 guidance (NICE MTG34 Scope, 2017) listed eight outcomes, six of which are presented below. The exact outcomes reported differed across the included studies, and none reported on the fourth outcome from the scope, relating to time taken to secure the catheter, or the seventh outcome, relating to quality of life measures. These outcomes have been omitted from the narrative below and from the outcomes table (Appendix B2).

4.5.1 Studies reporting on PICCs only

Five studies reported on the use of SecurAcath exclusively for PICC securement (Culverwell *et al.* 2020, Rowe *et al.* 2020, Pittiruti *et al.* 2019 [Study A], Brescia *et al.* 2021, Kay *et al.* 2020 [abstract]).

Outcome 1: Catheter migration and dislodgement

Most studies reported on this outcome (N=4), with Rowe *et al.* (2020) being the only one that did not. Three studies reported zero migrations with SecurAcath, including the product evaluation by Culverwell *et al.* (2020), and Study A by Pittiruti *et al.* (2019). The abstract by Kay *et al.* (2020) reported zero migrations or displacements in the SecurAcath arm, and 2 (20%) migrations in the sutures arm. Culverwell *et al.* (2020) reported 2 dislodgements in 51 patients, and Brescia *et al.* (2021) reported 7/639 (1.1%)

dislodgements, both for SecurAcath. In the latter, the authors identified that four of the reported dislodgements were due to the catheter being smaller than its labelled size, and hence smaller than the corresponding SecurAcath device. Both the abstract by Kay *et al.* (2020) and Study A by Pittiruti *et al.* (2019) reported no dislodgements for SecurAcath. None of the comparative studies found statistically significant differences in migration or dislodgement between arms.

Outcome 2: Rates of catheter-related infection, including CRBSI, local infection / inflammation and thrombophlebitis

Four studies reported on catheter related infection or inflammation, with two reporting on CRBSI or CLABSI rates, and two reporting on exit site infection or inflammation. Rowe *et al.* (2020) found from retrospective data, a CLABSI rate of 0.46% in those using SecurAcath, compared with a 1.79% CLABSI rate in those using an adhesive securement device. They calculated a relative risk of CLABSI of 3.88 (95% CI 2.11 to 7.14 [calculated by the EAC]) when using the adhesive securement device instead of SecurAcath. Brescia *et al.* (2021) found a CRBSI rate of 16/639 (2.5%) or 0.17 per 1,000 catheter days. Culverwell *et al.* (2020) was the only study to report no cases of exit site infection. Study A by Pittiruti *et al.* (2019) reported transient exit site inflammation in 2.1% of catheters secured with SecurAcath, during maintenance, and chronic inflammation in 4.2% at catheter removal.

Outcome 3: Number of unplanned catheter removals and reinsertions

The EAC has summarised securement failures and dislodgements under outcome 1, and this section summarises removals and reinsertions for other reasons. Culverwell *et al.* (2020) reported 3/51 elective catheter removals prior to the end of planned therapy, but it is noted that these were for clinical reasons not related to the catheter or securement device. The Kay *et al.* (2020) abstract reported 4/20 patients who did not complete treatment, nothing that one was in the sutures arm of the study and due to migration (as summarised in outcome 1), and the other three were for reasons including occlusion or breakage. It was not clear from the abstract which arm of the study these three cases were assigned to.

Outcome 5: Patient and clinician satisfaction scores

No studies reported on the satisfaction of patients, and two studies reported on the satisfaction of clinicians. Study A by Pittiruti *et al.* (2019) found that placement of SecurAcath was easy and uncomplicated in all cases. Culverwell *et al.* (2020) reported that staff experience was positive overall and that 3/31 (9.6%) found removal easy, 24/31 (77.4%) found it manageable, and only 4/31 (12.9%) found it difficult. All staff agreed that "*once they gained*

confidence, removal became easier", and it was reported that there was an initial learning curve of 1-2 weeks associated with inserting the device.

Outcome 6: Pain while in situ and on insertion and removal

Four studies reported on this outcome, with only the abstract by Kay *et al.* (2020) reporting no cases of pain. Both Culverwell *et al.* (2020) and Study A by Pittiruti *et al.* (2019) reported no cases of pain during insertion of SecurAcath, but reported the use of local anaesthetic. Both studies reported some pain on removal (NRS>0), ranging from 10.4% of patients (Pittiruti *et al.* 2019, Study A) to 41.2% of patients (Culverwell *et al.* 2020). Brescia *et al.* (2021) reported discomfort during catheter dwell time in 17/639 patients (2.7%).

Outcome 8: Device related adverse events, e.g. catheter malfunction, thrombosis and vessel erosion

Catheter related adverse events were reported in only two studies. Culverwell *et al.* reported exit site bleeding at insertion in all 16 of the haematology patients included in the study, although this was attributed to their haematological status. The general surgery patients experienced slight bleeding at insertion, and neither group experienced bleeding on removal. In 4/51 (7.8%) cases, the catheter became kinked and occluded, due to incorrect dressing technique, and there were difficulties flushing the PICC line in 2/51 (3.9%), which required the catheter to be repositioned correctly in the SecurAcath channel. Brescia *et al.* (2021) reported CRT in 12/639 (1.9%) and reversible catheter occlusion in 15/639 (2.3%).

4.5.2 Studies reporting on CVCs only

With only three studies reporting on patients with CVCs, or patients with CVCs or FICCs, evidence is limited. It should be noted that the D'Andrea *et al*. (2021) study, reporting on both CVCs and FICCs did not distinguish between them in the results reported.

The Dolcino *et al.* (2017) study reported significantly fewer dislodgements with SecurAcath than comparators (p=0.012 [calculated by the EAC]), and findings that were not statistically significant were rate of CVC related infection, thrombosis and catheter malfunction, which included occlusions. However, the quality of reporting of the study was considered poor, with many percentages (rates of dislodgement, thrombosis and malfunction for both SecurAcath and comparator) and their p-values presented incorrectly and corrected by the EAC in the outcomes table in Appendix B2.

The D'Andrea *et al.* (2021) study reported no cases of migration or dislodgement, and reported that SecurAcath removal was easy and

uneventful in all cases, and completed without sedation or local anaesthetic. Of 72 catheters (including 10 FICCs), only one was removed earlier than planned, due to an ulcer at the exit site.

The Barone *et al.* (2020) study considered the feasibility of using a bundle, which included SecurAcath, for insertion of CVCs in pre-term neonates in intensive care. No cases of CRBSI, thrombosis, or catheter malfunction were reported, and 28/30 catheters were successfully inserted on the first attempt, with no injuries or insertion related complications recorded. However, this represents a small sample size, in a niche population that is not generalisable to the population as a whole.

4.5.3 Studies reporting on PICCs and CVCs

Of the five studies reporting on the use of SecurAcath for PICCs and CVCs, only Fitzsimons *et al.* (2020) reported outcomes aggregated for both catheters, and for each type separately. However, findings reported for securement failure, CLABSI, and all-cause failure of the catheter, including one occlusion, were not statistically significant for all catheters aggregated or reported separately.

The Pittiruti *et al.* (2019) paper reporting on Study B and Study C found no cases of partial dislodgement, and total dislodgement in 2/47 (4.3%) and 1/95 (1.1%) cases respectively. Crocoli *et al.* (2021) reported dislodgement in 8/311 (2.6%), although it should be noted that this and other outcomes reported below from the same study may have included FICCs, as the authors did not distinguish between them.

Study B by Pittiruti *et al.* (2019) reported chronic exit site inflammation at removal in 2/47 (4.3%) patients, and in Study C there was exit site inflammation and erosion in 1 patient (1.1%). Crocoli *et al.* (2021) reported exit site infection in 2/311 (0.6%) and was the only study reporting on CVCs and PICCs to report incidence of CRBSI, at 42/311 (13.5%).

Clinicians experienced difficulty placing SecurAcath in 2/47 cases in Pittiruti *et al.* (2019) Study B, and placement was reported to be easy and uncomplicated in all cases in Study C. There were no pain cases reported on insertion in Study B, and 5/47 (4.3%) experienced pain on removal. In study C, no patients experienced pain on removal, but 4/95 (4.2%) experienced pain during dressing changes. Pain was also reported by Crocoli *et al.* during maintenance or removal, in 4/311 (1.3%). Catheter malfunctions were reported in 3/311 (0.9%), and no cases of CRT were detected.

The Pittiruti *et al.* (2016) abstract reported that all PICCs and CVCs were easy to place, and accidental removal occurred due to skin erosion in 1/65.

4.6 Ongoing trials

The NICE gIS search identified two studies, however both were completed, and both had been included in the clinical evidence for the original guidance. A top-level search of ClinicalTrials.gov by the EAC did not identify any further studies that had not already been considered.

The company provided a list of eight ongoing studies. The EAC excluded four that did not meet the decision problem (two incorrect population: ventricular drain, chest drain; one undefined population; one published as an abstract and included in clinical evidence). Of the remaining four studies, three were not included in a trial register and were shared as academic in confidence. A summary of all relevant ongoing trials is reported in Appendix C.

4.7 Changes in cost case

The following clinical parameters were included in the original company model, and have been reviewed in relation to the new evidence available.

Clinical parameter	EAC comment
Rate of migration (x per 1000 catheter days) for CVC and PICC	There were no significant findings for migration in either PICCs or CVCs, and therefore insufficient evidence to update this parameter.
Rate of dislodgement (x per 1000 catheter days) for CVC and PICC	There were no significant findings for dislodgement in PICCs, and therefore insufficient evidence to update this parameter for PICCs. Although Dolcino *et al.* 2017 reported significantly fewer CVC dislodgements with SecurAcath than comparators, the EAC did not consider the study to be of high enough quality to inform an update of this parameter for CVCs.
Rate of CRBSI & catheter-related thrombosis (CRT) (x per 1000 catheter days) for CVC and PICC	There were no significant findings for CRBSI, CLABSI or CRT for PICCs or CVCs, and therefore insufficient evidence to update this parameter.
Rate of occlusion (x per 1000 catheter days) for CVC and PICC	Occlusions were not well reported across studies, with many grouping them in with general catheter malfunctions. There is insufficient evidence to update this parameter for either PICCs or CVCs.
Rate of needlestick injury (x per 1000 catheter days) for CVC	Needlestick injuries were not reported in the included studies, so there is no evidence to update this parameter for CVCs.

Placement times (minutes) for SecurAcath, StatLock and Suture	Placement times were not reported in the included studies, so there is no evidence to update this for any securement device.
Maintenance time (minutes) for SecurAcath, StatLock and Suture	Maintenance times were not reported in the included studies, so there is no evidence to update this for any securement device.

In summary, there was either no evidence, or insufficient evidence to support updating any of the clinical parameters above, and therefore no changes were made to the cost case.

4.8 Other relevant information

The NICE gIS search identified 15 results from the FDA MAUDE database, detail provided in Appendix D. Six were related to catheter leak, two were line occlusions. Ten included the use of Bard catheters (67%), the manufacturers and models of the remaining five were not reported. The majority included PICC lines (67%). The gIS found no MHRA safety notices at the time of their search (14/01/2021), and nor did the EAC (searched 14/06/2021).

5 Conclusion

The EAC has found that, as when MTG34 was published, the majority of new evidence relating to SecurAcath is in the securement of peripherally inserted central catheters (PICCs). However, none of this evidence is a head-to-head comparison in the form of an RCT. When comparing an intervention cohort to a historical comparator, differences in outcomes cannot be assumed to be due to the intervention alone, as the delivery of care may have changed in other ways over time and there may be differences between the baseline characteristics of the groups. Therefore, given the lack of newly available robust and high quality evidence, updates to the clinical parameters in the economic model are not justified at this time, and the EAC considers there is insufficient evidence to inform an update of MTG34 in relation to PICCs.

Although evidence is beginning to emerge in CVCs, only three studies reported on CVCs without PICCs. Overall, the studies presented are poorly reported (Dolcino *et al.* 2017), in small populations with limited results and no generalisability to the majority of the population (Barone *et al.* 2020, D'Andrea *et al.* 2021), report no significant results for CVCs separate from PICCs (Fitzsimons *et al.* 2020) or do not distinguish between PICCs and CVCs at all in their reporting (Pittiruti *et al.* 2019 [Studies B and C], Crocoli *et al.* 2021). Furthermore, one clinical expert shared that they are aware of SecurAcath

being used to secure vascular access devices besides PICCs, but that their main use remains in PICC securement. Another expert indicated that they were not confident in the ability of SecurAcath to secure acute neck CVCs and stated that more trials and evidence would be needed to support this use case. The published evidence presented in this review supports this, and the EAC therefore considers there is insufficient published evidence to inform an update of MTG34 to include recommendations for securement of CVCs.

There is emerging evidence relating to the use of SecurAcath for the securement of FICCs, with two studies published recently (D'Andrea *et al.* 2021, Crocoli *et al.* 2021), but again, the EAC considers this insufficient to inform an update of MTG34 to include recommendations for SecurAcath to be used in this subgroup.

Appendix A1 – Literature search strategy

Search strategies

Database: Medline (MTG Review - SecurAcath - January 2021 - Medline)

Strategy used:

Database: Ovid MEDLINE(R) <1946 to January 15, 2021>
Search Strategy:
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1 exp Catheterization, Central Venous/ (15378)
2 exp Catheterization, Peripheral/ (11946)
3 exp Central Venous Catheters/ (2488)
4 ((central or venous or intravasc*) adj2 (catheter* or line or lines)).tw. (21886)
5 ((central or venous or intravasc*) adj2 (midline or midlines or line or lines)).tw. (5113)
6 (cvc or cvad).tw. (4076)
7 (peripherally adj4 inserted adj4 central catheter*).tw. (1199)
8 picc.tw. (989)
9 ((non tunnelled or non-tunnelled or tunnelled or hickman or broviac or cook) adj catheter*).tw. (812)
10 exp Catheters, Indwelling/ (18779)
11 ((indwell* or drain*) adj2 catheter*).tw. (9559)
12 (implantable vascular access device* or IAVD or PortACath).tw. (101)
13 or/1-12 (60067)
14 exp Sutures/ (17613)
15 (secure* or stabilis* or stabiliz* or non-mov* or dressing* or sutur* or steristrip* or adhesiv*).tw. (387223)
16 14 or 15 (392266)
17 13 and 16 (1918)
18 securacath.tw. (6)
19 statlock.tw. (23)
20 (griplok or grip-lok).tw. (2)
21 or/17-20 (1920)
22 Animals/ not Humans/ (4744333)
23 21 not 22 (1760)
24 limit 23 to ed=20160715-20210118 (371)

Notes:

Updated adjacency and standardised truncation. Changed field codes in clinical evidence strategy from mp to tw
Field codes in previous MTEP searching was done as .ti – will offer this to the analyst if unhappy with size of result

Line 11 taken from previous MTEP search

Reshaped lines 4 and 5 of EAC strategies – added “midline” as this was found in the scope document – shifted adjacency to lower amount to pinpoint more relevant material

Database: EMBASE

Strategy used:

Database: Embase <1974 to 2021 January 15>
Search Strategy:
---
1 exp central venous catheterization/ (9418)
2 exp central venous catheter/ (25312)
3 ((central or venous or intravasc*) adj2 (catheter* or line or lines)).tw. (37767)
4 ((central or venous or intravasc*) adj2 (midline or midlines or line or lines)).tw. (10714)
5 (cvc or cvad).tw. (8847)
6 (peripherally adj4 inserted adj4 central catheter*).tw. (2516)
7 picc.tw. (2891)
8 ((non tunnelled or non-tunnelled or tunnelled or hickman or broviac or cook) adj catheter*).tw. (1144)
9 exp indwelling catheter/ (17058)
10 ((indwell* or drain*) adj2 catheter*).tw. (15709)
11 (implantable vascular access device* or IAVD or PortACath).tw. (220)
12 or/1-11 (78146)
13 exp Sutures/ (63901)
14 (secure* or stabilis* or stabiliz* or non-mov* or dressing* or sutur* or steristrip* or adhesiv*).tw. (581264)
15 13 or 14 (604763)
16 12 and 15 (3758)
17 securacath.tw,dv. (23)
18 statlock.tw,dv. (77)
19 (griplok or grip-lok).tw,dv. (15)
20 or/16-19 (3803)
21 Nonhuman/ not Human/ (4744926)
22 20 not 21 (3647)
23 limit 22 to dc=20160715-20210118 (1373)
24 limit 23 to (conference abstract or conference paper or "conference review") (622)
25 23 not 24 (751)

Database: EconLit

Strategy used:

Database: Econlit <1886 to December 24, 2020>
Search Strategy:
---
1 ((central or venous or intravasc*) adj2 (catheter* or line or lines)).tw. (24)
2 ((central or venous or intravasc*) adj2 (midline or midlines or line or lines)).tw. (21)
3 (cvc or cvad).tw. (43)
4 (peripherally adj4 inserted adj4 central catheter*).tw. (2)
5 picc.tw. (2)
6 ((non tunnelled or non-tunnelled or tunnelled or hickman or broviac or cook) adj catheter*).tw. (0)
7 ((indwell* or drain*) adj2 catheter*).tw. (3)
8 (implantable vascular access device* or IAVD or PortACath).tw. (0)
9 or/1-8 (70)
10 (secure* or stabilis* or stabiliz* or non-mov* or dressing* or sutur* or steristrip* or adhesiv*).tw. (19485)
11 9 and 10 (2)
12 securacath.tw. (1)
13 statlock.tw. (1)
14 (griplok or grip-lok).tw. (0)
15 or/11-14 (2)

16	limit 15 to yr=2016-2021 (1)

Database: Cochrane (CDSR/CENTRAL)

Strategy used:

#1 MeSH descriptor: [Catheterization, Central Venous] explode all trees 819
#2 MeSH descriptor: [Catheterization, Peripheral] explode all trees 970
#3 MeSH descriptor: [Central Venous Catheters] explode all trees 142
#4 ((central or venous or intravasc*) near/2 (catheter* or line or lines)):ti,ab,kw 3784
#5 ((central or venous or intravasc*) near/2 (midline or midlines or line or lines)):ti,ab,kw 790
#6 (cvc or cvad):ti,ab,kw 912
#7 (peripherally near/4 inserted near/4 central catheter*):ti,ab,kw 354
#8 picc:ti,ab,kw 331
#9 ((non tunnelled or non-tunnelled or tunnelled or hickman or broviac or cook) near catheter*):ti,ab,kw 942
#10 MeSH descriptor: [Catheters, Indwelling] explode all trees 1026
#11 ((indwell* or drain*) near/2 catheter*):ti,ab,kw 2367
#12 (implantable vascular access device* or IAVD or PortACath):ti,ab,kw 68
#13 {OR #1-#12} 7498
#14 MeSH descriptor: [Sutures] explode all trees 994
#15 (secure* or stabilis* or stabiliz* or non-mov* or dressing* or sutur* or steristrip* or adhesiv*):ti,ab,kw 37874
#16 {OR #14-#15} 37943
#17 #13 and #16 550
#18 securacath:ti,ab,kw 7
#19 statlock:ti,ab,kw 20
#20 (griplok or grip-lok):ti,ab,kw 3
#21 {OR #17-#20} 555
#22 "conference":pt or (clinicaltrials or trialsearch):so 524840
#23 #21 NOT #22 334

Database: CRD (HTA – NHSEED and DARE not searched as ceased updates prior to search period

Strategy used:

1	MeSH DESCRIPTOR Catheterization, Central Venous EXPLODE ALL TREES IN HTA	18
2	MeSH DESCRIPTOR Catheterization, Peripheral EXPLODE ALL TREES IN HTA	14

3	MeSH DESCRIPTOR Central Venous Catheters EXPLODE ALL TREES IN HTA	2
4	(((central or venous or intravasc*) near2 (catheter* or line or lines))) IN HTA	52
5	(((central or venous or intravasc*) near2 (midline or midlines or line or lines))) IN HTA	14
6	((cvc or cvad)) IN HTA	5
7	((peripherally near4 inserted near4 central catheter*)) IN HTA	6
8	(picc) IN HTA	3
9	(((non tunnelled or non-tunnelled or tunnelled or hickman or broviac or cook) near catheter*)) IN HTA	1
10	MeSH DESCRIPTOR Catheters, Indwelling EXPLODE ALL TREES IN HTA	20
11	(((indwell* or drain*) near2 catheter*)) IN HTA	9
12	((implantable vascular access device* or IAVD or PortACath)) IN HTA	0
13	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12	80
14	MeSH DESCRIPTOR Sutures EXPLODE ALL TREES IN HTA	13
15	((secure* or stabilis* or stabiliz* or non-mov* or dressing* or sutur* or steristrip* or adhesiv*)) IN HTA	254
16	#14 OR #15	254
17	#13 AND #16	4
18	(securacath) IN HTA	0
19	(statlock) IN HTA	1
20	((griplok or grip-lok)) IN HTA	0
21	#17 OR #18 OR #19 OR #20	4
22	(#17 OR #18 OR #19 OR #20) IN HTA WHERE LPD FROM 15/07/2016 TO 18/01/2021	0

Database searches:

Databases*	Date searched	No retrieved	Version/files
MEDLINE (Ovid)	18/01/2021	371	1946 to January 15, 2021 (during reload – search for updates from start of December 2020)
MEDLINE In-Process (Ovid)	18/01/2021	78	1946 to January 15, 2021 (during reload – search for updates from start of December 2020)
MEDLINE ePub ahead of print (Ovid)	18/01/2021	24	January 15, 2021
EMBASE (Ovid)	18/01/2021	751	1974 to 2021 January 15
EMBASE conferences (Ovid)	18/01/2021	622	1974 to 2021 January 15
CDSR (Wiley)	18/01/2021	11	Issue 1 of 12, January 2021
CENTRAL (Wiley)	18/01/2021	320	Issue 1 of 12, January 2021
HTA database (CRD)	18/01/2021	0	n/a
Econlit (Ovid - for economic searches)	18/01/2021	1	1886 to December 24, 2020
Total		2178	
Total after de-duplication		1787	

Appendix A2 – Excluded study details

Study name and citation	Reason(s) for exclusion
Identified by NICE gIS literature search	
Ahmadnia E, Partington T (2016) Methods of Central venous catheter securement and chlorhexidine dressing use: A survey of practice across Southern England. Journal of the Intensive Care Society 17(4 Suppl. 1): 48-49	Outcomes
Biasucci DG, *et al.* (2018) Targeting zero catheter-related bloodstream infections in pediatric intensive care unit: a retrospective matched case-control study. The journal of vascular access 19(2): 119-124	Intervention not named
Blanchard D, Bourgeois S (2016) Securement and Dressing Devices for Central Venous Catheters. The American journal of nursing 116(6): 49	Study design
Chan RJ, *et al.* (2017) Central venous Access device SeCurement And Dressing Effectiveness for peripherally inserted central catheters in adult acute hospital patients (CASCADE): a pilot randomised controlled trial. Trials 18(1): 458	Intervention
Crowell J, *et al.* (2017) Project HANDS: A Bundled Approach to Increase Short Peripheral Catheter Dwell Time. Journal of infusion nursing : the official publication of the Infusion Nurses Society 40(5): 274-280	Intervention
Dang F-P, *et al.* (2019) Comparative efficacy of 13 antimicrobial dressings and different securement devices in reducing catheter-related bloodstream infections: A Bayesian network meta-analysis. Medicine 98(14): e14940	Study design
Edwards M, *et al.* (2014) A pilot trial of bordered polyurethane dressings, tissue adhesive and sutureless devices compared with standard polyurethane dressings for securing short-term arterial catheters. Critical Care and Resuscitation 16(3): 175-183	Intervention
Goossens GA, Grumiaux N, Janssens C, *et al.* (2018) SecurAstaP trial: securement with SecurAcath versus StatLock for peripherally inserted central catheters, a randomised open trial. BMJ Open 8(2): e016058	Already included in MTG
Holt D, *et al.* (2016) Subcutaneous securement of pediatric PICCS: One center's experience. JAVA - Journal of the Association for Vascular Access 21(4): 258	Intervention not named (abstract)

Study name and citation	Reason(s) for exclusion
Janssens C, *et al.* (2017) Securing peripherally inserted central catheters (PICCs), results of the SecurAstaP study: a randomized controlled trial comparing SecurAcath? and StatLock? Vascular access 11(2): 8-7	Conference abstract, now published
Karpanen TJ, *et al.* (2019) A clinical evaluation of two central venous catheter stabilization systems. Annals of Intensive Care 9(1): 49	Intervention
Kleidon TM, *et al.* (2017) A Pilot Randomized Controlled Trial of Novel Dressing and Securement Techniques in 101 Pediatric Patients. Journal of vascular and interventional radiology : JVIR 28(11): 1548-1556e1541	Intervention
Krenik KM, *et al.* (2016) Catheter Securement Systems for Peripherally Inserted and Nontunneled Central Vascular Access Devices: Clinical Evaluation of a Novel Sutureless Device. Journal of infusion nursing : the official publication of the Infusion Nurses Society 39(4): 210-217	Intervention
Liu W, *et al.* (2018) A New Way to Secure Internal Jugular Central Catheters. Journal of Cardiothoracic and Vascular Anesthesia 32(3): e70-e71	Intervention
McParlan D, Edgar L, Gault M, *et al.* (2020) Intravascular catheter migration: A cross-sectional and health-economic comparison of adhesive and subcutaneous engineered stabilisation devices for intravascular device securement. Journal of Vascular Access 21(1): 33-38	Already included in MTG
Macmillan T, *et al.* (2019) Assessing the effectiveness of a medical device with limited evidence. International Journal of Technology Assessment in Health Care 35 (Suppl. 1): 81	Study design
Macmillan T, *et al.* (2018) SecurAcath for Securing Peripherally Inserted Central Catheters: A NICE Medical Technology Guidance. Applied Health Economics and Health Policy 16(6): 779-791	Study design
Marsh N, *et al.* (2015) Securement methods for peripheral venous catheters to prevent failure: a randomised controlled pilot trial. Journal of Vascular Access 16(3): 237-244	Intervention
Marsh N, *et al.* (2015) Devices and dressings to secure peripheral venous catheters to prevent complications. Cochrane Database of Systematic Reviews 2015(6): cd011070	Population, study design

Study name and citation	Reason(s) for exclusion
Marsh N, *et al.* (2017) Devices and dressings to secure peripheral venous catheters: A Cochrane systematic review and meta-analysis. International Journal of Nursing Studies 67: 12-19	Population, study design
Mitchell ML, *et al.* (2020) Central venous access device Securement and dressing effectiveness: The CASCADE pilot randomised controlled trial in the adult intensive care. Australian Critical Care : Official Journal of the Confederation of Australian Critical Care Nurses 33(5): 441-451	Intervention
Oliver G, Jones M (2016) The importance of adequate CVC securement to prevent infection. British Journal of Nursing (Mark Allen Publishing) 25(8): 32-33	Study design
Pinelli, F, *et al.* (2020) GAVeCeLT-WoCoVA Consensus on subcutaneously anchored securement devices for the securement of venous catheters: Current evidence and recommendations for future research. Journal of Vascular Access	Study design
Pittiruti M and Emoli A (2016) Tunneling: The new frontier of central venous access devices. JAVA - Journal of the Association for Vascular Access 21(4): 261	Intervention not named (abstract)
Reynolds H, *et al.* (2015) Novel technologies can provide effective dressing and securement for peripheral arterial catheters: A pilot randomised controlled trial in the operating theatre and the intensive care unit. Australian Critical Care : Official Journal of the Confederation of Australian Critical Care Nurses 28(3): 140-148	Population
Rickard CM, *et al.* (2016) A 4-arm randomized controlled pilot trial of innovative solutions for jugular central venous access device securement in 221 cardiac surgical patients. Journal of Critical Care 36: 35-42	Intervention
Rickard CM, *et al.* (2015) Securing All intraVenous devices Effectively in hospitalised patients--the SAVE trial: study protocol for a multicentre randomised controlled trial. BMJ Open 5(9): e008689	Study design
Rickard CM, *et al.* (2018) Dressings and securements for the prevention of peripheral intravenous catheter failure in adults (SAVE): a pragmatic, randomised controlled, superiority trial. Lancet (London, England) 392(10145): 419-430	Intervention
Rowe MS (2019) Impact assessment of stabilization devices on CLABSI. Journal of Vascular Access 20(1): np15-np16	Conference abstract, now published

Study name and citation	Reason(s) for exclusion
Rowe MS, Spencer T (2019) Catheter securement impact on PICC-related CLABSI: Does securement effect risk? Antimicrobial Resistance and Infection Control 8 (Suppl. 1)	Conference abstract, now published
Ullman AJ, *et al.* (2015) Dressings and securement devices for central venous catheters (CVC). Cochrane Database of Systematic Reviews 2015(9): cd010367	Intervention not named
Ullman AJ, *et al.* (2017) Innovative dressing and securement of tunneled central venous access devices in pediatrics: a pilot randomized controlled trial. BMC Cancer 17(1): 595	Intervention
Zerla PA, *et al.* (2017) Evaluating safety, efficacy, and cost-effectiveness of PICC securement by subcutaneously anchored stabilization device. Journal of Vascular Access 18(3): 238-242	Already included in MTG
Identified by company and experts	
Cellini M, *et al.* (2020) Guidelines of the Italian Association of Pediatric Hematology and Oncology for the management of the central venous access devices in pediatric patients with onco-hematological disease. Journal of Vascular Access (Epub ahead of print)	Study design
Hawes ML (2021) Vascular access device securement for oncology patients and those with chronic diseases. British Journal of Nursing, 30(8, IV and Vascular Access Suppl.):S20-S25	Study design
Hughes P, *et al.* (2017) Assessment of the SecurAcath® device in reducing migration of drainage catheters in biliary and renal intervention. Poster presented at 2017 European Congress of Radiology, 1-5 March 2017, Vienna, Austria	Population
Marjanovic S, *et al.* (2020) Innovating for improved healthcare: policy and practice for a thriving NHS. Cambridge UK: The RAND Corporation	Study design
Pittiruti M, Pinelli F (2020) Recommendations for the use of vascular access in the COVID-19 patients: an Italian perspective. Critical Care, 28;24(1):269	Study design
Rodriguez Perez C, *et al.* (2020) Subcutaneously Anchored Sutureless Device for Securement of Chest Tubes in Neonates with Pleural Effusion: Three Case Reports. Case Reports in Pediatrics, 2020	Population

Study name and citation	Reason(s) for exclusion
Vailati D, *et al.* (2020) Choice and management of vascular access in the context of COVID-19 outbreak in Italy: Recommendations from clinical practice. Journal of Vascular Access (Epub ahead of print)	Study design

Appendix A3 – Relevant guidance

NICE guidance – published

NICE guidelines (clinical, public health, social care, medicine practice guidelines, safe staffing)

Surgical site infections: prevention and treatment (2019, updated 2020) NICE guideline NG125

Healthcare-associated infections: prevention and control in primary and community care (2012, updated 2017) NICE guideline CG139

All other NICE guidance and advice products

Tegaderm CHG securement dressing for vascular access sites (2020) NICE medtech innovation briefing 231

Plus Sutures for preventing surgical site infection (2020) NICE medtech innovation briefing 204

Leukomed Sorbact for preventing surgical site infection (2021) NICE medical technologies guidance 55

The Sherlock 3CG Tip Confirmation System for placement of peripherally inserted central catheters (2015, updated 2019) NICE medical technologies guidance 24

The 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites (2015, updated 2019) NICE medical technologies guidance 25

Biopatch for venous or arterial catheter sites (2017) NICE medtech innovation briefing 117

NICE pathways

Prevention and control of healthcare-associated infections (2020) NICE pathway

NICE guidance – in development

NICE guidelines (clinical, public health, social care, medicine practice guidelines, safe staffing)

Nothing found

All other NICE guidance and advice products

MT507 Plus Sutures for preventing surgical site infection (MIB204). NICE medical technologies guidance. Publication expected 28 June 2021.

Guidance from other professional bodies

The following guidance, identified by KiTEC EAC in the assessment report for MTG34, may still be relevant:

Royal Marsden Manual for Clinical Nursing Procedures

American Infusion Nurses Society (INS) Infusion Therapy Standards of Practice

British Committee Standards in Haematology guidance

Epic-3 guidelines (issued by the Healthcare Infection Society)

The Association of Anaesthetists of Great Britain and Ireland (AAGBI) guidelines on Safe vascular access

British Association of Perinatal Medicine

European Council Directive 2010/32/EU (the Sharps Directive)

KiTEC EAC also identified local guidelines from the following organisations: Great Ormond Street Hospital for Children NHS Foundation Trust, London Cancer Care. Bradford and Airedale NHS Trust, Doncaster and Bassetlaw Hospitals NHS Foundation Trust.

Appendix B1 - Characteristics of included studies

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAC comments
Dolcino *et al.* 2017 Italy	Prospective cohort study Intervention (n=51): SecurAcath and cyanoacrylate glue Comparators (n=122): StatLock, Grip-Lok or sutures, and cyanoacrylate glue	Recruitment between 1 May 2015 and 31 August 2016. Patients undergoing percutaneous ultrasound guided positioning of tunnelled-cuffed CVCs. Setting: University hospital (single-centre)	Primary: Catheter dislodgement Secondary: Catheter related complications including infection, thrombosis, malfunction. Follow-up: Patients were followed for at least 30 days after CVC placement during daily in-patient assistance, home-delivered care, and scheduled out-patient visits.	CVCs Adults and paediatric Mean length of CVC duration was 188±143 days.

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAC comments
Fitzsimons *et al.* 2020 Australia	Single-arm observational study with retrospective comparator Consecutive recruitment Intervention: SecurAcath for PICCs (n=29), and non-cuffed tunnelled CVCs (n=23) Comparator: historical (not defined)	Paediatric patients over a 9-month period in 2019 (exact dates not reported) who required medium term CVAD insertion under care of paediatric anaesthetic lines service. Retrospective comparator group taken from 2015-2018. Setting: children's hospital, mixture of medical and surgical cases	Primary: Securement failure, defined as migration greater than 1 cm from documented insertion length, or accidental removal. Secondary: CLABSI (infection developing within 48 hours of placement and maintenance-related if developing after 48 hours). Follow-up: until catheter removal	PICCs and CVCs (Cook, Bioflo) Paediatric only Total catheter days 1494 (range 4-86) days.

Culverwell *et al.* 2020 New Zealand	Product evaluation with retrospective comparator. Recruitment not described Intervention (n=51): SecurAcath	Data collection between June and October 2015. Retrospective comparator data obtained from two 4 month periods: between January and May 2014, between June and October 2015. Settings: haematology unit (n=16), and general surgical ward (n=35)	<u>Primary</u>: migration (movement >2 cm without loss of function), <u>Secondary</u>: Patient outcomes: breaches in skin integrity, pain during placement, pain during removal, bleeding. Staff outcomes: ease of placement, confidence and ease of changing dressings and cleaning, ease of removal. Product outcomes: dislodgement (accidental removal resulting in loss of function), line kinking, difficulty flushing line, exit site infection, allergic reaction to nickel, duration of placement. Excess costs relating to PICC re-placement due to migration or dislodgement. Follow-up: until end of 4-month product evaluation period.	PICCs

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAC comments
Rowe *et al.* 2020 US	Retrospective cohort study Convenience sample of 7,779 patients, including 47 with CLABSI reportable infections. Intervention (n=32): Subcutaneous engineered securement device Comparator (n=15): Adhesive engineered securement device	Patients aged 18 years and older in hospital setting who received a peripherally inserted central venous catheter between January 2015 and December 2018. Setting: general surgical, medical, oncology wards, and critical care areas (single-centre)	Primary: CLABSI (as per NHSN guidelines) Follow-up: Not defined	PICCs

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAC comments
D'Andrea *et al.* 2021 Italy	Cohort study Recruitment not described Intervention (n=70 patients, with 72 lines: 62 CVC, 10 FICC): insertion bundle including: pre-procedural ultrasound evaluation of all veins; skin antisepsis with 2% chlorhexidine; maximal barrier precautions; real-time ultrasound puncture and cannulation of the vein using micro-introduction kits; ultrasound guided tip navigation of the catheter; intra-procedural assessment of the location of the tip by intracavitary ECG and/or echocardiography; tunneling of the catheter so to move the exit site far from the puncture site (to the mid-thigh for FICCs and to the infraclavicular area for CICCs); SecurAcath; placement of cyanoacrylate glue over the puncture site and at the exit site; coverage of the exit site with transparent semipermeable dressing.	All neonates having central venous catheters inserted via ultrasound-guided cannulation either of the brachio-cephalic vein (CVC) or femoral vein (FICC) during 12 months of clinical practice. Setting: neonatal intensive care unit	Dislodgements, early removal and reasons for early removal, ease of removal and use of sedatives or local anaesthetics.	CVCs and FICCs Indwelling time of 39 ± 25 days

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAC comments
Pittiruti *et al.* 2019 (Study A) Italy	Prospective cohort study Consecutive recruitment Intervention (n=50): SecurAcath	Oncology patients requiring PICCs for at least 8 weeks for chemotherapy, in 2015-2016 (exact dates not reported). Setting: oncology outpatients (single-centre)	Pain during placement, dislodgement (total or partial), duration of placement, removal before scheduled time, inflammation, pain or discomfort during removal. Follow-up: until catheter removal	PICCs This study had previously been reported as a presentation (Pittiruti 2015), but mentioned the use of glue to seal the exit site. It was excluded from KiTEC's assessment report for MTG34 for this reason. The full paper does not mention the use of glue for studies A and B, only for study C.
Pittiruti *et al.* 2019 (Study B) Italy	Prospective cohort study Consecutive recruitment Intervention (n=50): SecurAcath	Patients requiring non-cuffed central venous access device, either PICC, CVC or FICC, in 2015-2016 (exact dates not reported), with an expected 30% risk of partial (>2cm) or total catheter dislodgement. Setting: not reported	Difficulty placing the device, pain during placement, duration of placement, partial dislodgement, total accidental removal, pain or discomfort during removal, inflammation. Follow-up: until catheter removal	PICCs, CVCs and FICCs People with comorbidities, including dementia, and skin problems affecting use of adhesive. Adults and paediatric. This study had previously been reported as a presentation (Pittiruti 2015), but mentioned the use of glue to seal the exit site. It was excluded from KiTEC's assessment report for MTG34 for this reason. The full paper does not mention the use of glue for studies A and B, only for study C.

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAC comments
Pittiruti *et al.* 2019 (Study C) Italy	Prospective cohort study Consecutive recruitment Intervention (n=100): SecurAcath and paediatric insertion bundle, including pre-procedural ultrasound evaluation of the veins, ultrasound-guided venepuncture; ultrasound-based tip navigation, no fluoroscopy, tip location by intracavitary electrocardiography or echocardiography; placement of cyanoacrylate glue on the puncture site and/or exit site, covered with transparent membrane	Patients aged under 18 years who were candidates for elective placement of a non-cuffed PICC, CVC, or FICC, in 2016-2017 (exact dates not reported). Setting: not reported	Duration of placement, partial dislodgement, total accidental removal, inflammation, pain or discomfort during dressing changes, pain during removal. Follow-up: until catheter removal	PICCs, CVCs and FICCs Paediatric only

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAC comments
Barone *et al.* 2020 Italy	Prospective cohort study Recruitment not described Intervention (n=30): Insertion bundle including: ultrasound pre-puncture evaluation of central veins, hand hygiene and maximal barrier precautions, skin antisepsis with 2% chlorhexidine in alcohol, ultrasound-guided venipuncture, tip location by intracavitary echocardiography and/or echocardiography, tunnelling catheter to obtain exit site in infraclavicular area, SecurAcath, sealing exit site glue, coverage with transparent semipermeable dressing.	Preterm neonates admitted to NICUs over 12 months (exact dates not reported) and meeting one of the following criteria: expected duration of parenteral nutrition > 14 days; impending emergency surgery; acute respiratory insufficiency defined as the need for mechanical ventilation at day 7 of life; complex malformations; gastrointestinal emergencies; hemodynamic instability; and other severe acute conditions requiring a central catheter appropriate for high flow infusions, blood withdrawal, hemodynamic monitoring, and blood transfusions. Setting: neonatal intensive care units of three hospitals	Primary: Feasibility of insertion bundle for CVC. Secondary: Number of early and late complications, including dislocation, CRBSI (criteria of Infective Diseases Society of America, venous thrombosis, malfunction, and duration of placement.	CVCs Neonates Median dwell time of 37 (2-95) days

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAC comments
Brescia *et al.* 2021 Italy	Retrospective cohort study Intervention (n=639): PICCs secured with SecurAcath.	All cancer patients aged over 18, and who had given consent to the use of their data for clinical and epidemiological research, with PICCs secured with SecurAcath during a three year period (2018-2020). Setting: cancer institute	Primary: dislocation (dislodgement) requiring repositioning. Secondary: safety including incidence of difficulties with placement (difficulty, pain), complications within 48 hours (pain, local bleeding) and late complications (pain, catheter malfunction, local or systemic infection, occlusion, CRT, skin issues (lesions or ulcers).	PICCs (Vygon and Plan-1-Health) Average 154 (32-657) catheter days per patient

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAC comments
Crocoli *et al.* 2021 Italy	Retrospective cohort study All tunnelled catheters secured by SecurAcath Intervention (n=311: 250 CVC, 48 PICC, 13 FICC): SecurAcath	All children suffering from oncological or haematological diseases, who required the insertion of any external CVAD for short term, medium term, or long-term venous access. Only tunnelled catheters (either cuffed or non-cuffed) were considered. Setting: three paediatric oncology units	CRBSI, CRT, dislodgment (2cm or more), catheter malfunction (occlusion), local inflammation, exit site infection, pain at SAS removal or any local discomfort.	CVCs, PICCs, and FICCs Median dwell time of 24.9 (0.1-113) weeks
Kay *et al.* 2020 (abstract only) UK	Service evaluation Intervention (n=10): SecurAcath Comparator (n=10): Sutures	Evaluation carried out over five months (exact dates not reported). Paediatric patients with PICCs with an intended dwell time of over two weeks. Setting: tertiary paediatric centre	Displacement, migration, infection, skin damage, pain at site, line occlusion, completion of treatment.	PICCs Paediatric patients

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAC comments
Pittiruti *et al.* 2016 (abstract only) Italy (assumed)	Single arm observational study Recruitment not described Intervention (n=60 patients, with 65 lines: 27 PICC, 38 CVC): insertion bundle including ultrasound guidance, modified Seldinger technique by micro-introducer, tip location by intracavitary ECG, SecurAcath, glue for closure of the puncture site.	Paediatric patients, securement of tunnelled central line (both CVC and PICC) in neonates and children requiring central venous access for at least 10 days. Setting: unknown (single-centre)	Ease of placement, duration of placement, accidental removals, ease of removal.	PICCs and CVCs Paediatric patients

Abbreviations: CRBSI, catheter-related bloodstream infection; CLABSI, central line associated bloodstream infection; CRT, catheter-related thrombosis; CVC, central venous catheter; FICC, femorally inserted central catheter; NHSN, National Healthcare Safety Network; PICC, peripherally inserted central catheter; RCT, randomised controlled trial.

Appendix B2 – Study outcomes

Study name	Outcome 1: Catheter migration and dislodgement	Outcome 2: Catheter related infection	Outcome 3: Unplanned removals and reinsertions	Outcome 5: Patient and clinician satisfaction scores	Outcome 6: Pain while in situ and on insertion and removal	Outcome 8: Device related adverse events
Dolcino *et al.* 2017	**Dislodgement** SecurAcath: 2/51 (3.9%*) Comparators: 25/122 (20.5%*) (p=0.012*)	**CVC related infection** SecurAcath: 3/51 (5.9%) Comparators: 10/122 (8.2%) (NS)	*Not reported*	*Not reported*	*Not reported*	**Thrombosis** SecurAcath: 1/51 (2.0%*) Comparators: 3/122 (2.5%*) (NS*) **Malfunction** SecurAcath: 1/51 (2.0%*) Comparators: 5/122 (4.1%*) (NS*)
Fitzsimons *et al.* 2020	**Securement failure** SecurAcath: 3/52 (5.8%); 2.01 per 1000 catheter days. Non-SecurAcath: 11/158 (7.0%); 2.58 per 1000 catheter days (NS*) **Securement failure (PICC):** SecurAcath: 3/29 (10.3%)	**CLABSI** SecurAcath: 1/52 (1.9%); 0.67 per 1000 catheter days Non-SecurAcath: 2/158 (1.3%); 0.47 per 1000 catheter days (NS*) **CLABSI (PICC):** SecurAcath: 1/29 (3.4%) Non-SecurAcath:	*Not reported*	*Not reported*	*Not reported*	**All cause failure:** SecurAcath: 11/52 (21.2%); 7.36 per 1000 catheter days Non-SecurAcath: 22/158 (13.9%); 5.17 per 1000 catheter days (NS*) **All-cause failure (PICC)** SecurAcath: 6/29 (20.7%)

Study name	Outcome 1: Catheter migration and dislodgement	Outcome 2: Catheter related infection	Outcome 3: Unplanned removals and reinsertions	Outcome 5: Patient and clinician satisfaction scores	Outcome 6: Pain while in situ and on insertion and removal	Outcome 8: Device related adverse events
	Non-SecurAcath: 4/111 (3.6%) (NS*) **Securement failure (CVC):** SecurAcath: 0/23 (0%) Non-SecurAcath: 7/47 (14.9%) (NS*)	2/111 (1.8%) (NS*) **CLABSI (CVC):** SecurAcath: 0/23 (0%) Non-SecurAcath: 0/47 (0%)				Non-SecurAcath: 11/111 (9.9%) (NS*) **All-cause failure (CVC)** SecurAcath: 5/23 (21.7%) Non-SecurAcath: 11/47 (23.4%) (NS*)
Culverwell *et al.* 2020	**Migration** No cases reported **Dislodgement** 2/51 (3.9%)	**Exit site infection** No cases reported	**Unplanned removal** 3/51 removed electively prior to end of therapy for clinical reasons (unrelated to catheter or securement)	The overall experience of the staff using the SESD was positive. **Removal** 3/31 (9.6%) staff found it easy, 24/31 (77.4%) manageable, 4/31 (12.9%) difficult	**Insertion** No cases (local anaesthesia used) **Removal** No pain (NRS=0): 30/51 (58.8%) Pain (NRS>0): 21/51 (41.2%)	**Bleeding** Exit site bleeding at insertion observed in all 16 haematology patients. Slight bleeding during insertion but no ongoing bleeding in general surgery patients. No bleeding on removal in either group. **Catheter kinked** 4/51 (7.8%); incorrect dressing application

Study name	Outcome 1: Catheter migration and dislodgement	Outcome 2: Catheter related infection	Outcome 3: Unplanned removals and reinsertions	Outcome 5: Patient and clinician satisfaction scores	Outcome 6: Pain while in situ and on insertion and removal	Outcome 8: Device related adverse events
						Difficulty flushing 2/51 (3.9%); required reposition PICC in SecurAcath channel
Rowe *et al.* 2020	*Not reported*	**CLABSI** SESD: 32/6941 (0.46%) AESD: 15/838 (1.79%) Risk ratio: 3.88 [95%CI 2.11 to 7.14]*	*Not reported*	*Not reported*	*Not reported*	*Not reported*
D'Andrea *et al.* 2021	No cases	*Not reported*	**Early removal** 1/72 (1.4%)	In all patients, SAS removal was easy and uneventful, and it did not require any sedation or local anaesthetics.	*Not reported*	*Not reported*
Pittiruti *et al.* 2019 (Study A)	No cases of partial or total dislodgement.	**During maintenance** Transient exit site inflammation in 1/48 (2.1%) **At removal**	*Not reported*	Placement was easy and uncomplicated in all cases.	**Insertion** No cases of pain during placement **Pain / discomfort at removal** 5/48 (10.4%)	*Not reported*

Study name	Outcome 1: Catheter migration and dislodgement	Outcome 2: Catheter related infection	Outcome 3: Unplanned removals and reinsertions	Outcome 5: Patient and clinician satisfaction scores	Outcome 6: Pain while in situ and on insertion and removal	Outcome 8: Device related adverse events
		Chronic exit site inflammation in 2/48 (4.2%)				
Pittiruti *et al.* 2019 (Study B)	No cases of partial dislodgement. **Total dislodgement** 2/47 (4.3%)	**At removal** Chronic exit site inflammation in 2/47 (4.3%)	*Not reported*	Difficulty placing SecurAcath in two cases	**Insertion** No cases of pain during placement **Removal** 5/47 (4.3%)	*Not reported*
Pittiruti *et al.* 2019 (Study C)	No cases of partial dislodgement. **Total dislodgement** 1/95 (1.1%)	Exit site inflammation / erosion in 1/95	*Not reported*	Placement was easy and uncomplicated in all cases	**During dressing change** 4/95 (4.2%), all PICC **Removal** No patient experienced pain during removal	*Not reported*
Barone *et al.* 2020	*Not reported*	**CRBSI** No cases	Elective removal: 30/30 (100%)	Twenty-eight catheters were successfully inserted at the first venipuncture. Only two infants required a second attempt performed on the same vein. No cases of accidental arterial	*Not reported*	**Catheter-related thrombosis** No cases **Catheter malfunction** No cases

Study name	Outcome 1: Catheter migration and dislodgement	Outcome 2: Catheter related infection	Outcome 3: Unplanned removals and reinsertions	Outcome 5: Patient and clinician satisfaction scores	Outcome 6: Pain while in situ and on insertion and removal	Outcome 8: Device related adverse events
				puncture or of pleural injury were registered during the study period. There were no insertion-related complications.		
Brescia *et al.* 2021	**Dislodgement** 7/639 (1.1%), 4/7 were due to catheter being smaller than the labelled size	**Early infection (within 48h)** No cases **CRBSI** 16/639 (2.5%), 0.17 per 1000 catheter days	*Not reported*	*Not reported*	**Local pain at exit-site (within 48h)** No cases **Discomfort (pressure ulcers and painful inflammation)** 17/639 (2.7%)	**Bleeding or hematoma at the exit-site (within 48h):** No cases **Skin ecchymosis** 24/639 (3.8%) **CRT** 12/639 (1.9%) **Reversible occlusion** 15/639 (2.3%) **Irreversible occlusion** No cases
Crocoli *et al.* 2021	**Dislodgement** 8/311 (2.6%)	**CRBSI** 42/311 (13.5%) **Exit site infection**	*Not reported*	*Not reported*	**Pain / discomfort at maintenance or removal** 4/311 (1.3%)	**Catheter malfunction (occlusion)** 3/311 (0.9%)

Study name	Outcome 1: Catheter migration and dislodgement	Outcome 2: Catheter related infection	Outcome 3: Unplanned removals and reinsertions	Outcome 5: Patient and clinician satisfaction scores	Outcome 6: Pain while in situ and on insertion and removal	Outcome 8: Device related adverse events
		2/311 (0.6%)				**CRT** No cases
Kay *et al.* 2020 (abstract only)	**Migration** SecurAcath: No cases **Migration and displacement combined** Sutures: 2/10 (see outcome 3)	*Not reported*	**Incomplete treatment** 4/20 (1 with migration in sutures arm, 3 for reasons including occlusion or breakage, unclear which arm these 3 were from)	*Not reported*	No cases	*Not reported*
Pittiruti *et al.* 2016 (abstract only)	*Not reported*	*Not reported*	**Accidental removal** 1/65 (due to skin erosion)	All were easy to place.	*Not reported*	*Not reported*

* Calculated by the EAC
Abbreviations: AESD, adhesive engineered securement device; CRBSI, catheter-related bloodstream infection; CLABSI, central line associated bloodstream infection; CRT, catheter-related thrombosis; CVC, central venous catheter; NRS, numerical rating scale; NS, not significant; PICC, peripherally inserted central catheter; SAS, subcutaneously anchored sutureless device; SESD, subcutaneous engineered securement device.

Appendix C – Details of studies and ongoing trials

Study identification	Study design	Population	Intervention Comparator	Outcomes	Status
Securing Central venous catheters to prevent catheter Dislodgment in children: the SECURED trial (ACTRN12620000783921) Australia	RCT feasibility study (n=60, 30 in each arm)	Children (neonate up to 18 years of age) requiring PICC insertion presenting with altered skin integrity and/or insertion of tunnelled non-cuffed CVC.	I: SecurAcath (delivered on catheter duration and remain in place for duration of catheter) C: sutureless securement devices (delivered on catheter insertion and replaced weekly for duration of the catheter)	Primary: Ability to demonstrate proportion eligible at screening, agreement to enrol, receive allocate treatment, loss to follow-up, missing data, satisfaction and acceptability with the study intervention. Catheter dislodgement. Secondary: Central venous access device-associated skin injury, dwell time of devices, patient/parent acceptability and satisfaction for catheter securement and experience during dressing change, staff satisfaction during dressing change, staff satisfaction with ease of application of securement devices, healthcare costs.	Recruiting Date of last data collection: not reported
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Study identification	Study design	Population	Intervention Comparator	Outcomes	Status

Abbreviations: C, comparator; CICC, centrally inserted central catheter; CVAD, central venous access device; CVC, central venous catheter; I, intervention; ICU, intensive care unit; RCT, randomised controlled trial.

Appendix D – Safety reports from MAUDE

Report date	Event description	Catheter used	Type	Manufacturer narrative
14/08/2020	Catheter leaking near/at SecurAcath	Bard PowerPICC HF	PICC	Likely related to catheter construction and not caused by SecurAcath
16/07/2020	Catheter leaking near/at SecurAcath; Impact on flow	Bard PowerPICC	PICC	Likely related to catheter construction and not caused by SecurAcath
06/12/2018	Catheter leaking near/at SecurAcath	Bard PowerPICC HF	PICC	SecurAcath device not returned; Likely related to catheter construction and not caused by SecurAcath
06/12/2018	Catheter leaking near/at SecurAcath	Bard PowerPICC HF	PICC	SecurAcath device not returned; Likely related to catheter construction and not caused by SecurAcath
01/12/2018	Catheter leaking near/at SecurAcath	Bard PowerPICC SV	PICC	SecurAcath device not returned; Likely related to catheter construction and not caused by SecurAcath
19/11/2018	Catheter leaking near/at SecurAcath	Bard PowerPICC HF	PICC	SecurAcath device not returned; Likely related to catheter construction and not caused by SecurAcath
21/06/2019	Line occlusion	Bard 7F DL	Hickman	Incorrect SecurAcath size selected (related to different outer diameter at distal and proximal ends of catheter)
28/03/2019	Line occlusion	Make and model not reported	CVC	Not reported
02/10/2019	Catheter was pulled out completely, SecurAcath still in place	Make and model not reported	CVC	Dislodgement most likely due to excessive tensile force to line during patient movement

12/06/2019	Cover could not be snapped on	Make and model not reported	Midline	Likely user error; misallignment of catheter within SecurAcath base.
07/03/2019; 27/02/2019	Anchor failed to lock down	Make and model not reported	Midline	Not reported
17/01/2019	Two PICC lines with holes, one near to SecurAcath location	Bard PowerPICC SOLO	PICC	No device returned; likely caused by extrusion/material defects in the catheter or misuse of the catheter
08/06/2018	Catheter kinked (n=3)	BARD PICC line	PICC	Likely related to catheter construction and not caused by SecurAcath
30/05/2018	Catheter snapped	BARD PICC line	PICC	The catheter break most likely happened between the strain relief and the securacath device, completely outside the securacath device itself.
20/05/2017	Anchor foot snapped	Make and model not reported	PICC	Unusual torsion load most likely cause of nitinol 'foot' to separate from SecurAcath.

Appendix E – References

Barone G, Pittiruti M, Ancora G, *et al.* (2020) Centrally inserted central catheters in preterm neonates with weight below 1500 g by ultrasound-guided access to the brachio-cephalic vein. Journal of Vascular Access (Epub ahead of print)

Brescia F, Pittiruti M, Roveredo L, Zanier C, *et al.* (2021) Subcutaneously anchored securement for peripherally inserted central catheters: Immediate, early, and late complications. Journal of Vascular Access (Epub ahead of print)

Crocoli A, Martucci C, Sidro L, Donne DD, *et al.* (2021) Safety and effectiveness of subcutaneously anchored securement for tunneled central catheters in oncological pediatric patients: A retrospective study. Journal of Vascular Access (Epub ahead of print)

Culverwell EA, Jar WM, Barratt R *et al.* (2020) Do subcutaneously engineered stabilisation devices reduce PICC migration? A product evaluation report. Australian Journal of Cancer Nursing 21(2): 15-20

D'Andrea V, Barone G, Pezza L, Prontera G, *et al.* (2021) Securement of central venous catheters by subcutaneously anchored suturless devices in neonates. The Journal of Maternal-Fetal & Neonatal Medicine, DOI: 10.1080/14767058.2021.1922377.

Dolcino A, Salsano A, Dato A, *et al.* (2017) Potential role of a subcutaneously anchored securement device in preventing dislodgment of tunneled-cuffed central venous devices in pediatric patients. Journal of Vascular Access 18(6): 540-545

Fitzsimons KM, Speekman J, Senior T, *et al.* (2020) An observational study of the securement of central venous access devices with a subcutaneous anchor device in a paediatric population at a tertiary level hospital. Journal of Vascular Access 21(6): 959-962

Kay H, Milton R, Diacono J, Sutton R (2020) Evaluation of a sutureless securement device (SecurAcath) for PICCs compared with sutures at a tertiary pediatric center [abstract]. In: Abstracts from the postponed 6th World Congress on Vascular Access (WoCoVA), 17-19 June 2020: Journal of Vascular Access; p66.Abstract PP15

Pittiruti M (2015) Defining the indications of subcutaneously anchored securement devices: a European point of view. Poster presented at the Association for Vascular Access Annual Scientific Meeting, 26-29 September 2015, Dallas, Texas, USA

Pittiruti M, Celentano D (2016) Our experience with subcutaneously anchored sutureless devices in pediatric patients [abstract]. JAVA - Journal of the Association for Vascular Access 21(4): 255

Pittiruti M, Emoli A (2016b) Tunneling: The new frontier of central venous access devices [abstract]. JAVA - Journal of the Association for Vascular Access 21(4): 261.

Pittiruti M, Scoppettuolo G, Dolcetti L, *et al.* (2019) Clinical experience of a subcutaneously anchored sutureless system for securing central venous catheters. British Journal of Nursing 28(2): 4-s14

Rowe MS, Arnold K, Spencer TR, *et al.* (2020) Catheter securement impact on PICC-related CLABSI: A university hospital perspective. American Journal of Infection Control 48(12): 1497-1500