National Institute for Health and Care Excellence

External Assessment Centre correspondence

[SecurAcath]

The purpose of this table is to show where the External Assessment Centre relied in their assessment of the topic on information or evidence not included in the sponsors' original submission. This is normally where the External Assessment Centre:

a) become aware of additional relevant evidence not submitted by the sponsor
b) need to check "real world" assumptions with NICE's expert advisers, or
c) need to ask the sponsor for additional information or data not included in the original submission, or
d) need to correspond with an organisation or individual outside of NICE

These events are recorded in the table to ensure that all information relevant to the assessment of the topic is made available to MTAC. The table is presented to MTAC in the Assessment Report Overview, and is made available at public consultation.

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General assessment report	**Initial questions sent to manufacturer – 12.07.16** 1. The manufacturer has submitted clinical evidence from conference proceedings published as early as 2012. Why haven't these abstracts materialised in full-text publications? Is there an overlap between any of the submitted abstracts and the full texts included in the sponsor's submission?	**Response from manufacturer 13.07.2016 (in purple)** 12. The manufacturer has submitted clinical evidence from conference proceedings published as early as 2012. These clinical evidence are presentations & posters. Why haven't these abstracts materialised in full-text publications? Submitted abstracts do not routinely (in the vascular access arena translate into publication, many remain just as posters) Is there an overlap between any of the submitted abstracts and the full texts included in the sponsor's submission? No 13. Can the manufacturer provide the full outline of their search strategy for all the databases they searched? Currently, the	

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	2. Can the manufacturer provide the full outline of their search strategy for all the databases they searched? Currently, the submission only includes some of the free text and headings words but not the full search strategies. In addition, the sponsor lists Headings such as “PICC migration and “PICC replacement”, however, the EAC was unable to find these as search terms in MeSH or Emtree.	submission only includes some of the free text and headings words but not the full search strategies. In addition, the sponsor lists Headings such as “PICC migration and “PICC replacement”, however, the EAC was unable to find these as search terms in MeSH or Emtree. MeSH migration/ replacement not used, focus on securement, multiple variables for migration / replacement 14. In section 10.2.1 the sponsor lists only the MHRA and the MAUDE databases. Are these the only databases searched by the sponsor? Yes, specific to adverse events If not, can the sponsor please provide a full list of the databases they searched to collect the clinical evidence?	

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	3. In section 10.2.1 the sponsor lists only the MHRA and the MAUDE databases. Are these the only databases searched by the sponsor? If not, can the sponsor please provide a full list of the databases they searched to collect the clinical evidence? 4. In section 10.2.6 the sponsor lists only the inclusion criteria can the sponsor confirm that there no exclusion criteria were used?	15. In section 10.2.6 the sponsor lists only the inclusion criteria can the sponsor confirm that there no exclusion criteria were used? No exclusion criteria used 16. What is the nature of the Misericordia 2015 report? KiTEC assumes that these are unpublished data submitted to the manufacturer? Yes, the Misericordia data is unpublished data provided to us by the hospital. It is an internal report they used to highlight the quality improvement and cost savings they achieved by using the SecurAcath. We have asked them to try to publish the data, however, the key person at the hospital has since retired.	

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	5. What is the nature of the Misericordia 2015 report? KiTEC assumes that these are unpublished data submitted to the manufacturer? 6. Please provide access to the criteria used for methodological quality assessment of the studies included in the clinical evidence submission for both the RCT and the observational studies.	17. Please provide access to the criteria used for methodological quality assessment of the studies included in the clinical evidence submission for both the RCT and the observational studies. No substantive quality assessment due to observational prospective nature of date 18. In section 7.9.1 the sponsor mentions as comparative data for the dislodgement rate the results reported by Yamamoto 2002. Has the sponsor run a full systematic review for retrieving evidence for the comparators or this is a publication selected based on clinical expertise? Publication selected based on clinical expertise 19. Are there different versions of SecurAcath? If yes, can you please provide details including when they were first CE marked and the	

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	7. In section 7.9.1 the sponsor mentions as comparative data for the dislodgement rate the results reported by Yamamoto 2002. Has the sponsor run a full systematic review for retrieving evidence for the comparators or this is a publication selected based on clinical expertise? 8. Are there different versions of SecurAcath? If yes, can you please provide details including when they were first CE marked and the main	main differences between them? Which versions are covered by the current CE mark? The SecurAcath was CE marked in 2010. The device has had some design iterations since then. The first version only had 2 sizes. The second design had a slightly different shape and added sizes. The current design has a different shape to improve cover removal. All of the design modifications are covered under the current CE certificate which was renewed in July 2015. 20. The sponsor has set the date limit for their search strategy from 2010 onwards. Can the sponsor please justify the choice of this cut-off? Was SecurAcath available prior to 2010? Not available prior to 2010	

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	differences between them? Which versions are covered by the current CE mark? 9. The sponsor has set the date limit for their search strategy from 2010 onwards. Can the sponsor please justify the choice of this cut-off? Was SecurAcath available prior to 2010? 10. What are the definitions used by the sponsor for short, medium and long-term dwell times?	21. What are the definitions used by the sponsor for short, medium and long-term dwell times? Short term: 1-7 days. Medium term: 8-29 days. Long term: over 30 days 22. Table B1 lists as an intervention the general term Securement. Can the sponsor please provide the rationale for choosing this general term and not the intervention as defined in the scope? SecurAcath is described as a securement device/ technology. Securement of the catheter is the function it provides. Can the sponsor please explain the context of this term in respect to SecurAcath and its comparators? SecurAcath is the only device available on the market that does not require routine replacement,	

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	11. Table B1 lists as an intervention the general term Securement. Can the sponsor please provide the rationale for choosing this general term and not the intervention as defined in the scope? Can the sponsor please explain the context of this term in respect to SecurAcath and its comparators?	remains in situ for the dwell/ insertion time of the catheter. All other comparators require replacement routinely (usually every seven days)	

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General assessment report	**Teleconference with the sponsor – 13.07.16**	Multiple questions. Teleconference notes included in Appendix 1.	
Assessment report: clinical evidence section	**E-mail from sponsor 19.07.16**	Our team has been developing the full outline of the search strategy for the databases we used. Our team is working with clinicians who have indicated they are preparing papers for publication. We hope to be able to provide drafts of the papers as soon as possible. We understand that a poster does not meet the same level of evidence of a published paper, however, we included them because they support the clinical benefits that the SecurAcath provides. It is typical with new vascular access devices like SecurAcath, that the initial use and much of the research is done by nurses. The nurses on vascular access teams may not have the time or funding needed to write a full paper and go through the publication process. In many cases a poster is as far as they can go with the time and resources they have. We believe they number of posters that have been presented on the SecurAcath and the cumulative positive results they show indicates clear enthusiasm and need for an improved catheter securement device. In addition, all of the posters have been done retrospectively and without the financial support or direct involvement of our company.	.

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		I have also attached a document that shows the SecurAcath design changes since the CE Mark was received. We hope this is helpful.	
Assessment report: clinical evidence section	**E-mail to study author (Lisa Dougherty) 22.07.2016** Would there be any other information about the study that you would be willing to send us (for example any quantitative data)? We assume that StatLock was the standard comparator in your study (please let us know if this is incorrect). Please let us know if the information should be treated confidentially.	**Response from author 26.07.2016** Hello – It was not a study but an evaluation of the product. We had been using Statlock. I can send you the evaluation we did in full but most of the information was on the poster. Let me know if you would like it and I can send it to you – the only part that remains confidential is the pricing and so I would remove the details of that.	
Assessment report: background / clinical evidence section	**E-mail to study author (Selena Sandeluss) 22.07.2016** The poster notes the findings that the rate of migration with SecurAcath was 2% as compared with previous rate of 7%. How were the catheters being secured prior to the introduction of SecurAcath (e.g. StatLock, steristrips)?	**Response from author 25.07.2016** I'm just talking to my manager about this and I will respond [no further responses were received]	

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	Would there be any other information about the study that you would be willing to send us (for example reports, abstracts)? Please let us know if the information should be treated confidentially.		
Assessment report: background / clinical evidence section / economic evidence section	**E-mail to study author (Lieve Goossens [Janssens]) 22.07.16** NICE has asked us to carry out an independent assessment of the clinical and economic evidence for the SecurAcath catheter securement device. We have been sent the attached poster presentation for your completed randomised controlled trial (NCT02311127). I was wondering whether you intended to publish your RCT results in a journal? If so, when are you hoping to publish these results (for example, this summer)? Would there be any other information about the study that you would be willing to send	**Response from author 26.07.2016** Thank you for your interest in our study. We plan indeed to publish the study, but I think, to be realistic, it will be fall 2016. I'm willing to share more details as soon as they are available (if treated confidentially of course). **Second response on 05.06.2016 [draft of PDF study attached]** I worked very hard to make a version of the manuscript that is fairly OK. However I have to recheck some details. I added some comments on data I have to come back on in the discussion section, but it also can help you because there is some more clarification in it. I am still not decided how I best report the pain scores. I should appreciate if you could let me know if data were not clearly described so I can improve them, anyway if you have further questions, don't hesitate to contact me,	

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	us? Please let us know if you want any information treated confidentially. I would greatly appreciate any additional information you can provide. Please do let me know if you have any questions.	**Follow up email 09.08.2016** [redacted] Thank you again for your interest, I am fine with the use of the data in a confidential way!	
Assessment report: background / clinical evidence section	**E-mail to sponsor 26.07.16** We now understand that there are 6 sizes of SecurAcath, corresponding to the Fr size of the catheter. Does the body size of the device vary correspondingly (or just the size of the aperture for the catheter)? Are the anchors the same size for all 6 device sizes?	**Response 26.07.16** The size of the body of the SecurAcath device is the same for all 6 French sizes, the channel within the SecurAcath device varies to fit the appropriate French size catheter. The anchors are the same on all of the SecurAcath devices. Below is the search strategy used in the database searches:	

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	In addition, would you please send through the full outline of the search strategy for the databases you used?	Meshterms provided limited results. Text words search proved more productive. Search terms used: securement. peripherally inserted catheter. central venous catheter. securement device. novel securement. Most productive search – PubMed. Aim: To perform a narrative review of research literature about dressing and securement of ACs. Methods: A literature search of the Cochrane Central Register of Controlled Trials, Ovid MEDLINE, Ovid EMBASE, and EBSCO CINAHL, as well as Google and Google Scholar was performed. A meta-analysis or systematic review was not possible because of scarce literature.	
Assessment report: background / clinical evidence	**E-mail sent to expert advisers (Liz Dougherty) 09.08.16** I noticed that you are the Chair of the IV Therapy Forum in the RCN's "Standards for Infusion Therapy" (2010) report (found here : http://www.bbraun.it/documents/RCN-Guidlines-for-IV-therapy.pdf). I have, however, been unable to find the report on the RCN website. Is this still official guidance?	**Response from expert 09.08.2016** Hi – the RCN IV therapy forum no longer exists and hasn't done since 2009. We left RCN and set up an independent vascular access society called NIVAS – National Infusion and Vascular Access Society. I was the chair of that till 2014. The RCN has no IV group although I think there is an invited group that are reviewing and updating the Standards but until then the RCN have removed them from the website. So there are no up to date guidelines – many nurses still refer to the RMH Manual of Clinical Nursing Procedures for up to date information and guidance – the latest	

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	What would be the RCN's most up to date guidance on infusion therapy?	edition came out in 2015. The other document that nurses refer to are the American INS standards and these were updated earlier this year. Hope that helps	
Assessment report: background / clinical evidence section / economic evidence section	**E-mail to sponsor 10.08.16** 1. The NICE scope considers other securement devices (StatLock or Grip-Lok), adhesives (steristrips) and sutures as comparators but does not limit comparisons by type of catheter (PICC or CVC). What was the rationale for limiting comparison with SecurAcath to other adhesive devices for those receiving a PICC, and only sutures for those receiving a CVC? 2. Would you verify our understanding of the indication : SecurAcath may be used in tunnelled or nontunnelled CVCs, PICCs and in apheresis/dialysis CVCs. It is not used in port CVCs. Is this correct?	**Response from sponsor 10.08.16** 1. The rational for limiting comparison on PICCs to adhesive devices is the vast majority (over 90%) of PICCs are currently secured with adhesive devices. Sutures do not work well for mid to long term dwell because they are prone to clinical complications such as infection , erosion, and catheter related infections. The rational for limiting comparison on CVCs to sutures is the vast majority (over 90%) of CVCs are currently secured with sutures. CVCs are typically placed by physicians who have found adhesive devices do not work well in the neck area where skin oils, sweat, hair and anatomy do not allow adhesive devices to secure well. 2. Ports are implanted beneath the skin. The SecurAcath is indicated for percutaneous catheters that go through the skin. The indications for the SecurAcath are very broad. There are a number of percutaneous catheters used in patient care. The initial uses for the SecurAcath have been on PICCs, CVCs and some drainage catheters due to the sizes available. The intention for the	

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	According to the IFU, the SecurAcath Device is indicated for short or long term securement of percutaneous indwelling catheters to the access site by means of a subcutaneous anchor. SecurAcath is not solely for central use, but can also be used in midline or conventional peripheral intravenous catheters– is this correct? Are there other indications? 3. Would we be able to have a high resolution, technical image of the device for use in the assessment report?	device is to continue to expand uses and replace adhesive securement devices and sutures for all percutaneous catheters. There is not currently a SecurAcath device that can be used for peripheral IVs. 3. Yes, image is attached.	
Assessment report: background	**E-mail sent to expert advisers 10.08.16**	**Reply from Meinir Hughes 10.08.16**	

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/ clinical evidence section / economic evidence section	1. What are the main guidelines used in the UK for CVC insertion, management and removal? We are including PICC as a subset of CVC (as per British Committee for Standards in Haematology guidelines). Is practice standardised or is there local variation in the UK? What about non-UK countries? Is practice generally driven by the manufacturer (and therefore practice that uses certain devices such as StatLock does not significantly differ)? 2. Please would you provide us with your definitions for the following (please let us know if our understanding is correct): a. Catheter migration / dislodgement / malposition – Accidental removal or movement that resulted in the loss of function is defined as catheter	1. What are the main guidelines used in the UK for CVC insertion, management and removal? EPIC3; RCN Infusion guidelines. We are including PICC as a subset of CVC (as per British Committee for Standards in Haematology guidelines). Is practice standardised or is there local variation in the UK? Yes local variation with generic standardised practice according to EPIc3 etc. What about non-UK countries? Not known. Is practice generally driven by the manufacturer No by specialist practitioners (and therefore practice that uses certain devices such as StatLock does not significantly differ)? 2. Please would you provide us with your definitions for the following (please let us know if our understanding is correct): a. Agree b. Agree although in my opinion catheter-related infection can be diagnosed feom clinical signs without removal. c. Agree d. Agree e. Agree 3. Blood reflux within the internal space of the catheter. Agree	

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	dislodgment, whereas catheter migration is defined as movement greater than 0.5 cm without loss of function, even if the catheter tip is no longer in a central position (Yamamoto, 2002). Malposition refers to the catheter tip being in an incorrect position and can refer to either migration or dislodgement. b. Catheter related blood stream infection - Catheter-related bloodstream infections are confirmed upon isolation of identical organisms from both line and peripheral blood cultures or defervescence of symptoms after PICC removal (Centers for Disease Control guidelines). c. Local infection - A diagnosis of cellulitis established on the basis of skin tenderness, erythema, oedema, and purulent exudate that resolves with	4. No. Evidence not strong enough currently. 5. Poor venous access, ambulatory therapy, toxic infusate to the vein or painful infusate. Do not know this figure. Agree. 6. Landmark method for any type of CVC placement is now considered outdated practice although it is still possible to place a PICC in the AC fossa post vein palpation but since the use of ultrasound is not recommended and rarely used. The placement of a tunnelled catheter should always be ultrasound guided (NICE guidance) 7. I would suggest always. 8. Agree and catheter function whether is flushes and gives a blood return. 9. Agree, and prevent migration. 10. How would you manage the following complications (we have included our current understanding):	

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	antibiotic treatment and/or catheter removal (Yamamoto, 2002). d. Unplanned removal - Unscheduled (i.e., unplanned) removal is defined as unexpected removal for any reason, with no restrictions applied (Egan 2013). e. Thrombosis - Suspected central venous thrombosis that is confirmed by duplex ultrasound or venography (Yamamoto, 2002). 3. Catheter occlusion – what is the primary cause of CVC occlusion? We understand that this mostly occurs due to thrombosis, but non-thrombotic causes can include precipitates, malpositioning, and mechanical obstructions. 4. Are anti-coagulants commonly administered to patients before CVC insertion? Some studies appear to	a. Migration: For catheter malfunctions such as migration, Bishop (2007) outlines that plain X-ray or a catheter contrast study may be helpful in confirming the diagnosis yes plus ECG now. A migrated catheter may be repositioned without being removed rarely. If the tip moves further out than the patient's shoulder area, there is a higher risk of thromboembolism and the line needs completely changing yes due to reduction in blood volume. b. Dislodgement: If a catheter becomes dislodged the line is usually removed and replaced (Jones, 1998). c. Agree d. Oral antibiotics e. Thrombosis: Anticoagulation is instituted and clinical symptoms monitored closely for signs of improvement for as long as the catheter is present anticoagulants used for 3 - 6 months regardless of catheter removal . Worsening of symptoms while anticoagulated indicates a need to remove the line agree and also an extensive thrombus diagnosed may indicate catheter removal. 11. If this is a general question re suturing then yes. Usually or could be a band 6 depending on the procedure.	

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	have used an anticoagulant catheter (Arrow Chlorag+ard) – is this used as standard? 5. In chemotherapy, which types of situation would require a PICC rather than an IV? 6. 6. Approximately what proportion of all chemotherapy patients will use a PICC? We assume this occurs in cases where there is a toxic regime for veins or very long term treatment. 6. How reliable is the 'landmark method' to insert a CVC? Is this only used in tunnelled catheters? 7. How often is anaesthetic used for catheter insertion or removal? We assume that it is typically used for both. 8. What are the main issues relative to current CVC practice? Examples of our assumptions are issues such as weekly dressing/securement device changes	12. Very rarely for PICCs. Yes sutures may be used for other types of catheters such as tunnelled CVC's and ports. **Reply from Lisa Dougherty 11.08.16** 1. UK. There are competency standards from NIVAS for insertion of CVADs. EPIC 3 guidelines 2016. RCN 2010 Standards for infusion therapy. AAGBU clinical Guidelines safer vascular access. Outside UK. INS standards of infusion therapy 2016. Gavecelt (Italian) – would need to find paper for title. There is local variation but it is not driven by manufacturers. 2. I would refer to EPIC 3 for this one (question 2b). 3. No thrombosis is between the vein and the catheter – occlusion is within the lumen of the catheter - cause is thrombotic as in blood reflux is commonest cause 4. No. No I believe it is being evaluated in the UK in a few hospitals	

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	(and the risk increase for dislodgement/migration when the catheter is temporarily unsecured), the effect of length of dwell on patient satisfaction and pain experienced, and different risk levels (in terms of catheter related complication) for different CVC types (e.g. PICCs or nontunnelled). 9. Would the introduction of the SecurAcath device produce changes to the clinical pathway? Our assumption is that the main change is that SecurAcath will not require changing when dressings are changed (unlike adhesive securement devices). 10. How would you manage the following complications (we have included our current understanding): a. Migration: For catheter malfunctions such as migration, Bishop (2007) outlines that plain X-ray or a catheter	5. All IV – do you mean a peripheral cannula?Poor venous access. Infusional chemotherapy. Irritant/vesicant drugs. Supportive therapy e.g blood transfusion or blood sampling when on clinical trials. As above and very hard to state how many we place almost 2000 CVADs a year, not all for chemo 6. Shouldn't be used following NICE 2002 recommendation for jugular placements and it can be used for all CVAD insertions although landmark not used for PICCs. 7. Local anaesthetic for all CVAD insertions, ports and tunnelled need local anaesthetic on removal, PICCs and CVCs removal not required. 11. A and B are similar as if you have a dislodgement then you have catheter tip malposition. Question 11b. - Would depend on where tip was – might leave overnight and it may correct itself, could be repositioned by IR. If pulled out cannot be reinserted so could be removed completely or a new catheter exchanged over a guidewire. Question 11c. - Yes we would follow this. Question 11d. - May also get oral antibiotics. Question 11e. – We would follow this.	

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	contrast study may be helpful in confirming the diagnosis. A migrated catheter may be repositioned without being removed. If the tip moves further out than the patient's shoulder area, there is a higher risk of thromboembolism and the line needs completely changing. b. Dislodgement: If a catheter becomes dislodged the line is usually removed and replaced (Jones, 1998). c. Blood stream infection: Catheter related blood stream infections (CRBSIs) often require catheter removal for effective treatment, however in some patients, who have a continued need for an intravenous catheter, and in whom there are limited options for future lines, catheter salvage may be attempted (Snaterse et al. 2010). The decision to salvage or remove a catheter should	12. Only if they were inserting the CVC but most would choose to use a securing device of some type rather than sutures. Might be a band 6 13. Rarely for PICCs although some centres do suture them. Very common for CVC in critical care setting and theatres. Often varies with practitioners – anaesthetists more likely to suture. **Reply from Jackie Nicholson 19.08.16** **1.** Main England guidelines are epic3, practice would be fairly standardised in line with epic3. Fairly standard in USA and some European countries – USA use CDC guidelines and infusion nurses society guidelines. Practice aligned with type of securement that is used and would be fairly standard for each device. **2.** Please would you provide us with your definitions for the following (please let us know if our understanding is correct): a. I would agree with these definitions	

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	be made following discussion with the microbiologist and after consideration of the patient's clinical status and his position on the treatment pathway (Bishop et al. 2007). d. Local infection: Swabs from the entry site of the catheter, before local treatment with an antiseptic, are used to identify a pathogen in local infections. These can be treated with more frequent dressing changes and local antiseptic. e. Thrombosis: Anticoagulation is instituted and clinical symptoms monitored closely for signs of improvement for as long as the catheter is present. Worsening of symptoms while anticoagulated indicates a need to remove the line. 11. Would suturing normally be performed by a nurse in the UK? And	b. I would support CDC definition c. I would say local infection is not necessarily cellulitis which is a specific condition. Local infection would be suspected by the above symptoms and confirmed by culture of the site. d. I would agree e. This would be the process not the definition – the definition is more scientific. 3. Clot formation within the catheter. Thrombosis is really clot formation within a blood vessel rather than within a catheter. Agree 4. There is a difference between systemic anticoagulant administration (a medication into a vein) and a catheter as above that is coated with an anticoagulant. Anticoagulation medication is not administered to patients before CVC insertion (British Standards in Haematology 2006). Some operators would choose an anticoagulant coated CVC. 5. Lots of factors – length of treatment, need to give into a central vein, failure of cannulas, patient preference. You would have to ask cancer centres for this kind of data – it would vary depending on the speciality. Not necessarily.	

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	would this be a senior nurse - i.e band 7? 12. How widely used are sutures for intravascular catheter (PICC or CVC) securement in current clinical practice? And does use vary by type of intravascular catheter – i.e. by PICC or CVC?	6. If you mean not using ultrasound this is not recommended (epic3) 7. Always for insertion, rarely for removal but sometimes if a Securacath is uncomfortable to remove. 8. This is too broad a question for me to answer. 9. Agree this is the main advantage 10. How would you manage the following complications(we have included our current understanding): a. No – risk of infection as you cannot advance a migrated catheter. Generally yes but if treatment were about to finish it would be acceptable to leave for a few days b. Agree c. Agree d. Probably not – once an infection is identified then appropriate antibiotics would be prescribed. If no bacteria were cultured from the swab then the more frequent dressing changes and local antiseptic could be considered.	

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		e. This is a grey area – some remove the line, some treat with the line in situ. 11. Band 6 and above probably 12. Should never be used for PICCs, quite commonly used for acute CVCs and tunnelled CVCs. Yes.	
Assessment report: background / clinical evidence section	**E-mail sent to sponsor 11.08.16** We have a query with regard to the technical image of the device you sent across. Could you advise if there are any intellectual property restrictions with regard to our re-use of the image in the assessment report?	**Response from sponsor 11.08.16** There are no restrictions on the use of the image for your report.	

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Assessment report: background / clinical evidence section / economic evidence section	**E-mail sent to study author (Liz Simcock) 12.08.16** a) In the study you mention that "a secondary fixation device was needed to prevent dislodgement of the PICC for patients at high risk of tugging hard on the PICC" – could you provide a bit more information on the secondary fixation device? For example, were sutures, tape or glue used? b) Thanks for getting back to me so promptly. Just to be clear, in the high risk patients you used Securacath and Statlock? We are looking at data from lots of different studies on Securacath, Statlock, tape and sutures, and we need to know we are comparing like with like.	**Response from author 12.08.16** a) We use Statlock dressing for those patients which is what we used to use for all patients before we started using SecurAcath. There are some other dedicated dressings on the marked too but we have found this the best so far. c) Yes that's right.	

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Assessment report: background / clinical evidence section	**E-mail sent to study author (Antonio Canelli) 12.08.16** In the study you mention that Securacath is indicated “for ambulatory maintenance” – could you give me a bit more detail on what you mean by ambulatory maintenance?	**Response from author 25.08.16** We realized that "ambulatory maintenance" is improperly translated from the Italian phrase. To reply to your question, based on our clinical evaluation, the maintenance critical factor is the number of steps to perform the maintenance (5 Steps with Securacath and 8 with standard adhesive securement device) and this leads to saving time in patient nursing and improve patient compliance. Regarding the device safety, the Securacath reduced the mechanical complications due to extra lumen dislodgement, with consequent reduction in catheter replacements and reduction in therapy interruptions due to new PICC implant, with cost improvement. The above considerations lead to nursing improvement in patients treated at home (total parenteral nutrition, etc). In our experience introducing this new securement device and the evaluation of results in our clinical organization push the caregiver to change is background, with improved training and active discussion.	

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		In our opinion the Securacath, since is a new and advanced device for catheter securement, can be used successfully both in hospital nursing and home care nursing.	
Assessment report: background / clinical evidence section / economic evidence section	**E-mail sent to expert advisors (Meinir Hughes, Lisa Dougherty and Dympna McParlan) 16.08.16** Theoretically, do you think that there would be a difference in rates of thrombosis in patients using the SecurAcath securement device compared with those using StatLock?	**Reply from Meinir Hughes 17.08.16** Yes possibly. This would be due to the tip being in a sub-optimal location which theoretically increases the risk of thrombosis. Therefore securement with securacath is better as it tends to keep the tip in the correct position. **Reply from Dympna McParlan 18.08.16** Theoretically, I would think that there would be a difference in rates of thrombosis in patients using the SecurAcath securement device compared with those using StatLock as the rate of migration is dramatically reduced, a complication commonly associated with thrombosis. While our data demonstrates a marked reduction in migration since the introduction of SecurAcath we can not prove that thrombosis has reduced as we have been unable to capture this complication reliably.	

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		Reply from Lisa Dougherty 30.08.16 Without data that is hard to say - in theory it should be – we certainly didn't see any increase and have seen a gradual decrease in our rates over the last few years.	
Assessment report: background / economic evidence section	**E-mail sent to expert advisors (Meinir Hughes and Dympna MacParlan) 17.08.16** In your experience what is a typical/average number of days for both short and medium term CVCs? For example 3 or 5 days for short term or 15 or 25 days for medium term. We understand there may be a lot of variation, but an approximate number based on your experience would be very helpful for our health economic analysis. We are assuming that any indwelling CVC over 30 days is classed as long term?	**Reply from Meinir Hughes 17.08.16** To be honest I would go with documented guide myself as you have done. We don't have any experience here of any short term catheters only PICCs. **Reply from Dympna McParlan 18.08.16** It would be very rare that we would insert a CVC for 3-5 days. it would only be in exceptional cases when we would insert a PICC when we have exhausted all means of peripheral access and we needed access for one treatment. In my experience 3-5 days would be associated with non tunnelled catheters (neck lines) associated with acute ICU care.	

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		We would associate short term insertion period with weeks to 2 months and medium term with 2-4 months. We would class long term with 3-9 months. These are very approximate estimates and I know that they are not in keeping with the literature.	
Assessment report: background / economic evidence section	**Question sent to expert advisors (Meinir Hughes and Dympna McParlan) 19.08.16** Would suturing (of CVC lines) be undertaken with a straight needle, a curved needle or a blunt needle?	**Reply from Meinir Hughes 19.08.16** Sorry I have not sutured any CVC's in situ. **Reply from Dympna McParlan 19.08.16** We use a curved needle.	
	Question sent to expert advisors (Meinir Hughes and Dympna McParlan) 23.08.16 How many curved needles would be used to suture a CVC line?	**Reply from Dympna McParlan 23.08.16** We only use one needle to suture on Tunnelled catheter removal as the exit site is not sutured following removal. The medics insert the catheters and I	

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		presume they use 2 needles as both the entry and exit site are both sutured on insertion. **Reply from Meinir Hughes 24.08.16** I don't suture my catheters sorry.	
Assessment report: background / economic evidence section	**Question sent to expert advisors (Meinir Hughes and Dympna McParlan) 25.08.16** How long on average would sutures last before requiring replacement in the securement of a catheter line?	**Reply from Meinir Hughes 25.08.16** I'm sorry, I have no experience of suturing catheters therefore this is something I have not looked into. **Reply from Dympna McParlan 26.08.16** The sutures that are inserted for a CVC are removed intentionally and not replaced. The entrance sutures at 1 week and the exit suture at 3 weeks when the dacron cuff has adhered.	

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Assessment report: background / clinical evidence section	**Question sent to expert (Lisa Dougherty) 30.08.2016** We are currently writing up the section on relevant clinical guidelines for the SecurAcath assessment report for NICE. I just wanted to make sure you were happy for us to reference the RMH Manual of Clinical Nursing Procedures in the report?	**Response from expert 30.08.2016** Yes – that is fine	
Assessment report: background / clinical evidence section	**Question sent to expert (Lisa Gorski) 30.08.2016** NICE has asked us to carry out an independent assessment of the clinical and economic evidence for the SecurAcath catheter securement device. As part of our report we need to give an overview of relevant clinical guidelines. The INS standards are commonly used in the NHS as gold standard guidelines. We just wanted to ensure that you were	**Response from expert 30.08.2016** Thank you for your question and it is acceptable to us to cite the Standards. Good luck in your assessment - I would be curious about your findings. This product is not widely used in the US, is interesting in concept although I have a number of questions/concerns about it.	

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	happy for us to refer to the Standards in the report, in particular the section about Vascular Access Device Stabilization (Section 6, standard 37) – would this be acceptable to you?		

Appendix 1

Notes from meeting with internal expert (Jane Hodson) 12.07.16

Notes from meeting with Jane Hodson.d

Notes from meeting with sponsor 13.07.16

Notes from meeting with manufacturer 1

Appendix 2 [Insert additional appendices as required]

Attachment received in e-mail from sponsor dated 19.07.16.

SecurAcath Designs.pdf

Attachment received in e-mail from sponsor dated 10.08.16

SecurAcath illustration.jpg