NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical Technologies Evaluation Programme

Sponsor submission of evidence:

Evaluation title: SecurAcath device for securing percutaneous catheters

Sponsor: Interrad Medical

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Instructions for sponsors

This is the template for submission of evidence to the National Institute for Health and Care Excellence (NICE) as part of the Medical Technologies Evaluation Programme process for developing NICE medical technologies guidance. Use of the submission template is mandatory.

The purpose of the submission is for the sponsor to collate, analyse and present all relevant evidence that supports the case for adoption of the technology into the NHS in England, within the scope defined by NICE. Failure to comply with the submission template and instructions could mean that the NICE cannot issue recommendations on use of the technology.

The submission should be completed after reading the 'Medical Technologies Evaluation Programme Methods guide' and the 'Medical Technologies Evaluation Programme Process guide' available at www.nice.org.uk/mt. After submission to, and acceptance by, NICE, the submission will be critically appraised by an External Assessment Centre appointed by NICE.

Under exceptional circumstances, unpublished evidence is accepted under agreement of confidentiality. Such evidence includes 'commercial in confidence' information and data that are awaiting publication ('academic in confidence'). When data are 'commercial in confidence' or 'academic in confidence', it is the sponsor's responsibility to highlight such data clearly. For further information on disclosure of information, submitting cost models and equality issues, users should see section 11 of this document 'Related procedures for evidence submission'.

The submission should be concise and informative. The main body of the submission should not exceed 100 pages (excluding the pages covered by the template and appendices). The submission should be sent to NICE electronically in Word or a compatible format, not as a PDF file.

The submission must be a stand-alone document. Additional appendices may only be used for supplementary explanatory information that exceeds the level

of detail requested, but that is considered to be relevant to the case for adoption. Appendices will not normally be presented to the Medical Technologies Advisory Committee when developing its recommendations. Any additional appendices should be clearly referenced in the body of the submission. Appendices should not be used for core information that has been requested in the specification. For example, it is not acceptable to attach a key study as an appendix and to complete the economic evidence section with 'see appendix X'.

All studies and data included in the submission must be referenced. Identify studies by the first author or trial ID, rather than by relying on numerical referencing alone (for example, 'Trial 123/Jones et al.[126], rather than 'one trial[126]').Please use a recognised referencing style, such as Harvard or Vancouver.

The sponsor should provide a PDF copy of full journal articles or reports – in electronic or hard copy form – included in the submission, if the sponsor is either the copyright owner or has adequate copyright clearance to permit the intended use by NICE. This clearance must be wide enough to allow NICE to make further copies, store the article electronically for a limited period of time on a shared drive to be accessed by a limited number of staff. Additionally, any full article obtained and submitted in electronic format must be done so in a manner compliant with the relevant contractual terms of use permitting the sponsor electronic access to the article. If the sponsor does not have sufficient copyright clearance, they are asked to submit references or links only, or details of contacts for unpublished research. NICE will then itself obtain full copies of all relevant papers or reports, paying a copyright fee where necessary. For unpublished studies for which a manuscript is not available, provide a structured abstract about future journal publication. If a structured abstract is not available, the sponsor must provide a statement from the authors to verify the data provided.

If a submission is based on preliminary regulatory recommendations, the sponsor must advise NICE immediately of any variation between the preliminary and final approval.

Document key

Boxed text with a grey background provides specific and/or important guidance for that section. This should not be removed.

Information in highlighted black italic is to help the user complete the submission and may be deleted.

The user should enter text at the point marked 'Response' or in the tables as appropriate. 'Response' text may be deleted.

List of tables and figures

Please include a list of all tables and figures here with page references.

Glossary of terms

If a glossary of terms is required to inform the submission of evidence include in the table. Delete if not required.

Term	Definition

Section A – Decision problem

Section A describes the decision problem, the technology and its clinical context. There is also information about ongoing studies, regulatory information and equality issues.

Sponsors should submit section A before the full submission (for details on timelines, see the NICE document 'Guide to the Medical Technologies Evaluation Programme process', available from www.nice.org.uk/mt

1 Statement of the decision problem

The decision problem is specified in the final scope issued by NICE. The decision problem states the key parameters that should be addressed by the information in the evidence submission. All statements should be evidence based and directly relevant to the decision problem.

Table A1 Statement of the decision problem

	Scope issued by NICE	Variation from scope	Rationale for variation
Population	People who require an intravascular catheter* for central venous access		
Intervention	The SecurAcath securement device		
Comparator(s)	• Adhesive catheter securement devices, such as StatLock or Grip-Lok, or other adhesives (such as steristrips) • Sutures (see also 'Cost analysis' below)		
Outcomes	The outcome measures to consider include: • Rates of catheter migration and dislodgement • Rates of catheter-related infection, including catheter-related bloodstream infection (CRBSI), local infection/inflammation and thrombophlebitis • Number of unplanned catheter removals and re-insertions • Time taken to secure catheter • Patient and clinician satisfaction scores • Pain while in situ and on insertion and removal • Quality of life measures • Device-related adverse events eg. catheter malfunction, thrombosis and vessel erosion	Add suture needle stick injuries	SecurAcath eliminates risk and costs associated with suture needlestick injury compared to suture for catheter securement

Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.		
Subgroups to be considered	• People who receive a PICC • People who receive a CVC • People with co-morbidities • Children and young people • People with a medium to long dwell time		

Special considerations, including issues related to equality		Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	Yes		
		Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No		
		Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No		

	The technology may be used by adults or children, but is most commonly used in older patients with chronic conditions who may be classed as disabled if their condition has a significant and long-standing adverse effect on activities of daily living. The technology may also be used regularly in people with cancer, who are protected under the Act from the point of diagnosis. The technology is not suitable for people with an allergy to nickel.		

2 Description of technology under assessment

2.1 Give the brand name, approved name and details of any different versions of the same device.

SecurAcath

2.2 What is the principal mechanism of action of the technology?

SecurAcath is a single use securement device used to hold percutaneous catheters in place. It consists of two components, a base and cover. The base contains two small, blunt, flexible securement feet which are placed beneath the skin; the cover snaps onto the base outside the body to hold the catheter shaft in place. It is designed to remain in situ throughout the period of catheter placement and does not need replacing.

3 Clinical context

3.1 Provide a brief overview of the disease or condition for which the technology is being considered in the scope issued by NICE.

SecurAcath is intended for use in adults and children who need a catheter for central venous access (peripherally inserted central catheter [PICC], non-tunnelled or tunnelled (e.g. Hickman) central venous catheter [CVC]). The technology can also be used for securing drainage catheters.

Indications for central venous catheterisation, including those inserted peripherally, include :

Access for therapy

- *Total parenteral nutrition*
- *Poor peripheral access*
- *Infusion of irritant drugs—for example, chemotherapy*
- *Long term drug therapy, such as antibiotics*

Access for extracorporeal blood circuits

- *Renal replacement therapy (short-term for severe kidney failure)*
- *Plasma exchange*

Monitoring or interventions

- *Central venous pressure*
- *Central venous blood oxygen saturation*
- *Pulmonary artery pressure*
- *Temporary transvenous pacing*
- *Targeted temperature management*
- *Repeated blood sampling.*

Estimates provided for the NICE guidance on the Tegaderm CHG securement dressing, based on expert advice and using 2012/13 hospital episodes statistics data indicated there were around 225,824 adult ICU episodes in England which required a central venous catheter, 88,074 of which involved a stay of over 48 hours.

3.2 Give details of any relevant NICE or other national guidance or expert guidelines for the condition for which the technology is being used. Specify whether the guidance identifies specific subgroups and make any recommendations for their treatment. If available, these should be UK based guidelines.

NICE has not produced any guidance on securing a catheter line.

Guidelines produced by the British Committee for Standards in Haematology on the insertion and management of central venous access devices in adults (Bishop et al. 2007) recommend, based on an evidence review, the use of securing devices such as StatLock (in preference to sutures), and that lines should not be sewn into or around the vein.

The European Council Directive 2010/32/EU known as the “Sharps Directive” was put in force in the UK on 11 May 2013. The directive states to “Avoid the use of medical sharps altogether, where there is a practicable alternative. The SecurAcath eliminates the use of suture needles when sutures are used for catheter securement.

The US Centers for Disease Control and Prevention guidelines for the prevention of intravascular catheter-related infections (2011) recommend the use of a sutureless securement device to reduce the risk of infection for intravascular catheters. This is a category II recommendation which is defined as ‘those practices where there is only suggestive or less definitive evidence’.

The US Infusion Nursing Society publishes the Infusion Therapy Standards of Practice. The latest revision released in January 2016 includes guidelines on Vascular Access Device (VAD) stabilization.

- Consider use of an engineered stabilization device (ESD) as inadequate stabilization and securement can cause unintentional dislodgement and complications requiring premature VAD removal

- ESDs promote consistent practice among all clinicians, reduce VAD motion that can lead to complications, reduce interruption of needed infusion therapy, and may decrease cost of care

- Avoid use of tape or sutures as they are not effective alternatives to an ESD

In the 2016 Standards, a new category called Subcutaneous Engineered Stabilization Devices (ESDs) has been added. SecurAcath is the only subcutaneous ESD available. The new Standards state; subcutaneous ESDs have been successful in stabilizing PICCs and CVADs, patient outcomes and patient and inserter satisfaction have been favorable; however, additional studies with other CVADs are needed.

A number of hospital trusts have produced internal guidance on the use of catheter securement devices including SecurAcath. An example is the Royal

Cornwall NHS Trust which has produced a clinical guideline for the use of intravascular catheters in adults. The guideline recommends that a securement device (e.g Statlock, Grip-lok) should be used to prevent catheter migration and dislodgement in patients with a PICC line or midline catheter.

The NICE guideline on infection control provides guidance on preventing infection for adults and children with vascular access devices in primary and community care settings. The guideline recommends that the skin at and around the catheter insertion site should be cleaned with chlorhexidine gluconate in 70% alcohol and allowed to air dry during dressing changes. The insertion site should be covered by a sterile transparent semipermeable membrane dressing which should be changed every 7 days or sooner if the dressing is no longer intact or moisture collects under it.

3.3 Describe the clinical pathway of care that includes the proposed use of the technology.

SecurAcath would be used in adult and paediatric patients needing central venous access via a PICC, a tunnelled or non-tunnelled CVC placed for therapy. It would be used in place of existing methods of catheter securement (e.g. steristrips, tape, sutures, or adhesive securement devices such as StatLock) to prevent catheter migration and dislodgement, in conjunction with an appropriate dressing to prevent catheter-related infection. The device can remain in place for the duration of the catheter placement and would not require changing when dressings are changed.

3.4 Describe any issues relating to current clinical practice, including any uncertainty about best practice.

Adhesive devices for securing catheters must be replaced at least weekly or as needed. The process of changing out the adhesive securement device presents a high likelihood of catheter movement, migration or accidental dislodgement. Adhesives can also cause medical adhesive-related skin injury (MARSI).

Sutures for catheter securement put the clinician at risk for suture needle stick injury. Sutures also create punctures in the skin which can increase risk of infection. Sutured down catheters cannot be lifted off the skin to allow for proper cleaning of the skin at the insertion site.

3.5 Describe the new pathway of care incorporating the new technology that would exist if the technology was adopted by the NHS in England.

SecurAcath would be used in place of existing methods of catheter securement (e.g. steristrips, tape, sutures, or adhesive securement devices such as StatLock) to prevent catheter migration and dislodgement.

3.6 Describe any changes to the way current services are organised or delivered as a result of introducing the technology.

When SecurAcath is used in place of adhesive securement devices the SecurAcath does not need to be changed out with each routine dressing change.

3.7 Describe any additional tests or investigations needed for selecting or monitoring patients, or particular administration requirements, associated with using this technology that are over and above usual clinical practice.

None

3.8 Describe any additional facilities, technologies or infrastructure that need to be used alongside the technology under evaluation for the claimed benefits to be realised.

None

3.9 Describe any tests, investigations, interventions, facilities or technologies that would no longer be needed with using this technology.

SecurAcath would be used in place of existing methods of catheter securement (e.g. steristrips, tape, sutures, or adhesive securement devices such as StatLock)

3.10 Describe how the NHS in England can disinvest from tests, investigations, interventions, facilities or technologies described in section 3.9 that would no longer be needed with using this technology.

NHS can eliminate the use of adhesive securement devices, sutures, and suture removal kits. NHS will also benefit from a decrease in catheter replacement procedures due to migration and dislodgement.

4 Regulatory information

4.1 Provide PDF copies of the following documents:

- Instructions for use
- CE mark certificate or equivalent UK regulatory approval such as EC declaration of conformity
- Quality systems (ISO 13485) certificate (if required).

PDF copies of these documents should be submitted at the same time as section A.

4.2 Does the technology have CE mark for the indication(s) specified in the scope issued by NICE? If so, give the date that authorisation was received. If not, state current UK regulatory status, with relevant dates (for example, date of application and/or expected approval dates).

Yes. Initial CE certification obtained Feb10, 2010

4.3 Does the technology have regulatory approval outside the UK? If so, please provide details.

Yes, the product has been approved in the following countries:

USA - Class II, First 510(k) clearance in July 2010, 510(k) K120935, K092306

Canada - Class II, License Number: 82108, Initial license date: 2010

Australia Class IIb, ARTG 235987, 9/04/2015

4.4 If the technology has not been launched in the UK provide the anticipated date of availability in the UK.

Not Applicable

4.5 If the technology has been launched in the UK provide information on the use in England.

The SecurAcath is currently being used routinely at 35 NHS hospitals in England. Evaluations are currently ongoing at another 6 hospitals.

5 Ongoing studies

5.1 Provide details of all completed and ongoing studies on the technology from which additional evidence relevant to the decision problem is likely to be available in the next 12 months.

None

This should include unpublished and ongoing studies, and studies awaiting publication. Also include post-marketing surveillance and register data.

5.2 If the technology is, or is planned to be, subject to any other form of assessment in the UK, please give details of the assessment, organisation and expected timescale.

None

6 Equality

NICE is committed to promoting equality of opportunity and eliminating unlawful discrimination on the grounds of age, disability, gender reassignment, race, religion or belief, sex, and sexual orientation, and to comply fully with legal obligations on equality and human rights.

Equality issues require special attention because of NICE's duties to have due regard to the need to eliminate unlawful discrimination, promote equality and foster good relations between people with a characteristic protected by the equalities legislation and others.

Any issues relating to equality that are relevant to the technology under assessment should be described. This section should identify issues described in the scope and also any equality issues not captured in the final scope.

Further details on equality may be found in section 11.3 of this document.

6.1.1 Describe any equality issues relating to the patient population and condition for which the technology is being used.

None

6.1.2 Describe any equality issues relating to the assessment of the technology that may require special attention.

None

6.1.3 How will the submission address these issues and any equality issues raised in the scope?

Not Applicable

Section B – Clinical evidence

7 Published and unpublished clinical evidence

Section B requires sponsors to present published and unpublished clinical evidence for their technology.

Sponsors should read section 6 of the Medical Technologies Evaluation Programme methods guide on published and unpublished evidence, available from www.nice.org.uk/mt

All statements should be evidence-based and directly relevant to the scope. Reasons for deviating from the scope should be clearly stated and explained in table A1.

Sponsors are required to submit section B in advance of the full submission (for details on timelines, see the NICE document 'Guide to the Medical Technologies Evaluation Programme process', available from www.nice.org.uk/mt

7.1 Identification of studies

Published studies

7.1.1 Describe the strategies used to retrieve relevant clinical data from the published literature. Exact details of the search strategy used should be provided in section 10, appendix 1.

A literature search of Ovid MEDLINE, Ovid EMBASE, ClinicalTrials.gov, Google and Google Scholar was performed. A meta-analysis or systematic review were not possible due to scare literature. Published information is

included as well as published commentary, observational data on the “general topic” of securement.

Unpublished studies

7.1.2 Describe the strategies used to retrieve relevant clinical data from unpublished sources.

A literature search of Ovid MEDLINE, Ovid EMBASE, ClinicalTrials.gov, Google and Google Scholar was performed. A meta-analysis or systematic review were not possible due to scare literature. Searches conducted included Organisation meetings, conferences, same search criteria were used for both published and unpublished.

7.2 Study selection

Published studies

7.2.1 Complete table B1 to describe the inclusion and exclusion criteria used to select studies from the published literature. Suggested headings are listed in the table below. Other headings should be used if necessary.

Table B1 Selection criteria used for published studies

Inclusion criteria	
Population	Patients who require an intravascular catheter for central venous access
Interventions	The SecurAcath securement device
Outcomes	Successful deployment and removal of device without complication. Successful securement. General comment review publications of securement devices, technologies, PICC migration and reduction in this complication.
Study design	Observational, prospective observational, multi- centre. Editorial comment, review of available technology
Language restrictions	None
Search dates	2010- 2016
Exclusion criteria	
Population	First published studies in USA and Europe no direct comparison to described technology within the scope
Interventions	
Outcomes	
Study design	
Language restrictions	
Search dates	

7.2.2 Report the numbers of published studies included and excluded at each stage in an appropriate format.

Published studies - 3. Published commentary, editorial, review overall securement devices/technology - 4. Note PRISMA not included due to scarcity of available data

Unpublished studies

7.2.3 Complete table B2 to describe the inclusion and exclusion criteria used to select studies from the unpublished literature. Suggested headings are listed in the table below. Other headings should be used if necessary.

Table B2 Selection criteria used for unpublished studies

Inclusion criteria	
Population	Patients who require an intravascular catheter for central venous access
Interventions	Post market evaluations of SecurAcath catheter securement device
Outcomes	
Study design	observational
Language restrictions	none
Search dates	2010 - 2016
Exclusion criteria	
Population	
Interventions	
Outcomes	
Study design	
Language restrictions	
Search dates	

7.2.4 Report the numbers of unpublished studies included and excluded at each stage in an appropriate format.

Unpublished observational data - 10. Primary source poster presentations at vascular access conferences. Note PRISMA not included due to scarcity of available data.

7.3 Complete list of relevant studies

The sponsor should provide a PDF copy of all studies included in the submission if the sponsor is either the copyright owner or has adequate copyright clearance to permit the intended use by NICE. If the sponsor does not have sufficient copyright clearance, they are asked to submit references or links only, or details of contacts for unpublished studies. For unpublished studies for which a manuscript is not available, provide a structured abstract about future journal publication. If a structured abstract is not available, the

sponsor must provide a statement from the authors to verify the data provided.

7.3.1 Provide details of all published and unpublished studies identified using the selection criteria described in tables B1 and B2.

Table B3 List of relevant published studies

Primary study reference	Study name (acronym)	Population	Intervention	Comparator
Hughes 2014	NA	Oncology PICC Observational.	First utilisation of technology/ product	None
Egan 2013	NA	Prospective postmarket. Efficacy and safety	First utilisation of technology/ product	None
Cordovani 2013	NCT00903539	Multi-centre observational post-market	First utilisation of technology/ product	None
Published commentary / review				
Oliver. 2016	NA	Overview of available securement devices, technologies and their significance		All securement technologies
Alpenberg.2016	NA	Report patient experience		
Higginson. 2015	NA	Infection prevention editorial overview securement vascular catheters		
Egan.2012	NA	Overview of novel, new technologies including securement		

Table B4 List of relevant unpublished studies

Data source	Author	Population	Intervention	Primary outcome	Comparator
	McParlan	All PICCs placed in 2013 and 2015	Retrospective analysis of Statlock costs and SecurAcath costs	Replaced PICCs and cost of securement devices	Statlock
www.wocova.com/congress/lisbon-2016	Janssens 2016	Patients scheduled for PICC insertion,	Randomised to StatLock or SecurAcath	Time to perform dressing change, Secondary outcome catheter migration	Statlock
http://www.vascular-access.info/pub/wocova Presentation at WoCoVA	Zerla 2016	Oncology patients with chemo indicated for > 2 months	SecurAcath	Skin integrity, pain score, dislodgement	none
Organisation/ Association website http://cvaa.info/ Poster presentation	Djurcic–Jovan 2016	Elderly patients requiring PICC insertion. Quality improvement initiative	Education management of PICC migration inclusive SecurAcath intention to reduce costs	Reduction Chest X-Ray tip location confirmation	previous system not described
www.ava.org Presentation annual conference	Pittiruti 2015	A.Oncology PICC insertion B.Patients requiring PICC with high risk of dislodgement paediatric, elderly	SecurAcath	Cost reduction Migration reduction	Cost Statlock verses SecurAcath
www.wocova.com/congress/berlin-2014/	Hill 2014	Patient with PICC	SecurAcath	Cost. Time to change. Malposition PICC	previous costs, efficiency verses StatLock
PT Team report	Misericordia 2015	PICCs placed by team in 2014	SecurAcath	Reduction in PICC replacements	Previous use of adhesive device

www.ava.org	Sandeluss 2013	Haem-Oncology PICC insertion reduction migration	SecurAcath	Reduction migration Patient comfort	none
www.ava.org	Ballance 2013	Central venous catheters Intensive care	SecurAcath	reduce needlestick reduce migration ease of disinfection at site	suture
www.ava.org	Dougherty 2013	Oncology patients PICC	SecurAcath	Reduction skin reaction Reduction migration Reduction damaged catheters/ occulsion	StatLock
www.ava.org	Stone 2013	Paediatric PICC	SecurAcath	Reduction in skin reaction and catheter migration	none
www.ins1.org	Peveler 2013	Central venous catheters. Paediatrics Skin integrity	SecurAcath	Skin integrity Dwell time	none
www.ins1.org	Ballance 2012	Central venous catheters and PICC	SecurAcath	Patient comfort Ease of deployment reduction in migration	none

7.3.2 State the rationale behind excluding any of the published studies listed in tables B3 and B4.

No studies were excluded.

7.4 Summary of methodology of relevant studies

It is expected that all key aspects of the methodology will be in the public domain. If a sponsor wishes to submit aspects of the methodology in confidence, section 11.2 describes how to highlight confidential information.

7.4.1 Describe the study design and methodology for each of the published and unpublished studies using tables B5 and B6 as appropriate. A separate table should be completed for each study.

Table B5 Summary of methodology for published studies randomised controlled trials

Study name	**Janssens**
Objectives	SecurAcath vs. Statlock time to perform dressing changes
Location	University Hospital Leuven. Belgium
Design	Randomised NCT02311127
Duration of study	5 months
Sample size	105
Inclusion criteria	Patients older than 18 years old, able to give informed consent, speak and read Dutch, and were followed by University Hospital Leuven for their IV therapy
Exclusion criteria	Patients allergic to nickel or ethylene oxide
Method of randomisation	unknown
Method of blinding	none
Intervention(s) (n =) and comparator(s) (n =)	51 SecurAcath, 51 Statlock
Baseline differences	none
Duration of follow-up, lost to follow-up information	
Statistical tests	
Primary outcomes (including scoring methods and timings of assessments)	Time to perform dressing change
Secondary outcomes (including scoring methods and timings of assessments)	Catheter migration, Accidental dislodgement, Catheter related bloodstream infection, pain experiences

Table B6 Summary of methodology for observational studies

Study name	Hughes M (2014) Reducing PICC migrations and improving patient outcomes.
Objective	Successful deployment of device. Reduced malposition Reduce costs.

	Improved disinfection at catheter insertion site
Location	Velindre Cancer Centre, Whitchurch, Cardiff
Design	Observational product evaluation
Duration of study	June – November 2012
Patient population patient	Oncology requiring PICC insertion
Sample size	31
Inclusion criteria	none described
Exclusion criteria	none described
Intervention(s) (n =) and comparator(s) (n =)	31
Baseline differences	N/A
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up.	Until removal of PICC catheter. I device remaining in situ. Up to 200 days
Statistical tests	None
Primary outcomes (including scoring methods and timings of assessments)	None specified Primary goal to successfully deploy and removed device – without complication
Secondary outcomes (including scoring methods and timings of assessments)	None specified

Study name	Egan G (2013) A Prospective Postmarket Study to Evaluate the Safety and Efficacy of a New Peripherally Inserted Central Catheter Stabilization System
Objective	
Location	Albany Medical Center in Albany, New York; St Joseph's Hospital in St Paul, Minnesota; and St Luke's Hospital in Kansas City, Missouri.
Design Prospective	observational
Duration of study	August 2100 – December 2010

Patient population	PICC insertion required
Sample size	68
Inclusion criteria	18 years and over
Exclusion criteria	Unwilling or unable to sign ICF Known upper extremity venous thrombosis, occlusion, or flow-limiting stenosis within the desired catheter course with no other viable site for access in either arm Known hypersensitivity to nickel (the securement anchor is composed of nitinol, a nickel-titanium alloy) Previous mastectomy or axillary lymph-node dissection on the same side as catheter placement Skin integrity deemed unfavorable by the operator, eg, friable skin due to chronic steroid use, presence of cellulitis or rashes at the desired site of catheter insertion with no other viable site for access
Intervention(s) (n =) and comparator(s) (n =)	68
Baseline differences	NA
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Until PICC removed
Statistical tests	
Primary outcomes (including scoring methods and timings of assessments)	Device securement success (% of devices inserted and removed without device related malfunctions, complications or adverse events)
Secondary outcomes	Device success: 62 (91.2%). Unsuccessful: 2 catheter slippages (defined as a movement >0.5cm, without loss of catheter function); 1 unable to remove the anchor as designed at removal; 1 cellulitis infection at the securement site; 2 persistent pain at the anchor securement site that required medical intervention. Median time to place the device was 15 seconds (range 10 to 180 seconds). Mean time for securement was 31 +/- 38 seconds. All devices were placed successfully (without malfunction or placement failure).

	Mean catheter dwell time was 22.6 days (SD +/- 36 days. Unscheduled removal of the SecurAcath device for any reason occurred in 20.6% (14) of patients: 4 because of suspected or confirmed bloodstream infections, 4 patient removal of own catheter, 2 pain, 1 dislodgment, 1 catheter kinking, 1 a 7 Fr SecurAcath used in error with a 5 Fr catheter and 1 SecurAcath lid lost during home dressing change on the 140th day (the remaining SecurAcath base was later removed, but the catheter stayed in place). The mean pain score immediately after device removal in 57 (11 had no pain score recorded) patients was 1.5 (SD +/- 2.5). The mean pain score during device dwell time in the 57 patients available for responses was 0.7 (SD +/- 1.6). In terms of their overall satisfaction with SecurAcath, 91.2% (52) of 57 patients responding were neutral, satisfied, or very satisfied, and 84.2% (48) were either satisfied or very satisfied.

Study name	Cordovani D, Cooper R M A (2013) Prospective trial on a new sutureless securement device for central venous catheters. Study funded by the company Trial NCT00903539: Prospective SecurAcath Subcutaneous Securement Trial
Objective	
Location	Department of Anesthesia and Pain Management, Toronto General Hospital, Toronto, ON, Canada
Design	Multi centre observational post marketing
Duration of study	June 2010 – Jan 2011
Patient population	patients requiring 7fr central venous catheter
Sample size	74
Inclusion criteria	
Exclusion criteria	
Intervention(s) (n =) and comparator(s) (n =)	
Baseline differences	

How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Not stated
Statistical tests	
Primary outcomes (including scoring methods and timings of assessments) successful deployment securement	
Secondary outcomes (including scoring methods and timings of assessments) N/A	

Posters								
Name	McParlan	Janssens	Djurcic–Jovan	Sandeluss	Ballance	Dougherty	Stone	Pevelar
Date	2016	2016	2016	2013	2013	2013	2013	2013
Location	[redacted]	University Hospital Leuven. Belgium	Ottawa Hospital. Canada	University College Hospital UK	Wayne Memorial Hospital Goldsboro North Carolina.US	Royal Marsden Hospital. London. UK	Boston Children's Hospital.US	Cincinnati Children's Hospital. US
Design	[redacted]	Randomised NCT02311127	Quality improvement initiative	Retrospective audit	Post market evaluation	Product evaluation	Product evaluation	Product evaluation
Duration	[redacted]	5 months	13 months	not described	not described	1 month		not described
Sample size	[redacted] Statlock, SecurAcath	105	54	100	not described	30	42 paediatric	paediatric patient presenting with fragile skin
Follow up	[redacted]	6 months	not described	not described	Catheter removal	not described	Catheter removal	Catheter removal
Outcome 1.	[redacted]	Time to perform dressing change	Reduction in catheter migration	Reduction in catheter migration		Reduced catheter migration. Improved care of insertion site Resolved skin issue	Reduction, elimination skin issues related to securement device	Reduced catheter migration
Outcome 2.	[redacted]	Catheter migration. Accidental dislodgement. DIscomfort. Catheter related infection	Cost savings due to reduced transport and repeat X ray Cost saving on catheter replacement.	Patient / user experience	Reduce catheter migration One device for life of catheter	General improvement of care of PICC catheter site	Reduced migration	Reduce skin reaction

Comparator	[redacted]	StatLock	N/A	N/A	N/A	N/A	N/A	N/A
Summary	[redacted]	Mean time to perform each dressing change is [redacted] shorter in the SecurAcath group. User education is required.	An estimated $10, 149 saving on transport. No catheter migration occurred potential cost saving $20, 215.	Catheter migration reduced from 7% with adhesive device to less than 2% with SecurAcath. 88% of patients found SecurAcath tolerable and would have it again	ICU conversion from suturing to evaluated device for acute CVC catheter. PICC catheter use, reduced catheter migration. Improved disinfection at site achieved	Positive user feedback. Improved disinfection. Reduction in cost of changing securement device.	All catheters remained in place, completed therapy course with no complication or skin reaction	Patient A: 2PICCs lost to migration. Final PICC with SecurAcath device remained in place 57 days. Patient B: 4 catheters of various types lost due to migration, dislodgement Final catheter (PICC) with SecurAcath device remained in place 61 days
		Report	**Presentations**					
Name	Ballance	Misericordia	Zerla	Pittiruti	Pittiruti	Hill		
Date	2012	2015	2016	2015	2015	2014		
Location	Wayne Memorial Hospital Goldsboro North Carolina.US	Edmonton, Alberta Canada	Gorgonzola, Italy	Catholic University Hospital, Rome Italy	Catholic University Hospital, Rome Italy	St. Paul's Hospital – Vancouver, BC Canada		
	Product evaluation			Study A	Study B			
Design	4 months	Prospective	Prospective	prospective clinical oncology chemotherapy-PICC	prospective clinical specific patient groups	prospective clinical		
Duration	10	One year	Catheter removal	> 2 months	3 months	catheter removal		
Sample size	not described	542 placed, 485 follow-up	30 oncology patients chemo	48	47. total	60 PICC		

			indicated for >2 months		18 acute C VC.29 PIC			
Follow up	Reduction suturing/ needlestick injury Improved skin disinfection at catheter insertion site	PICC removal	Catheter removal	catheter removal	catheter removal	catheter removal		
Outcome 1.	Reduced migration	Reduction in PICC replacements	Skin integrity score, pain score at placement, maintenance and removal less than 2	safety and cost effectiveness of device	elderly group with high risk of dislodgement. Paediatric patients. Patient with skin issues	Cost saving and efficiency		
Outcome 2.	N/A		Zero catheters dislodged	N/A	N/A	N/A		
Comparator	No issues are described, all catheters remained in place for the required time period. Acute CVC now secured using device.	Adhesive device	NA	N/A	N/A	N/A		
Summary		542 PICCs placed in one year with SecurAcath. Previous replacement rate with adhesive device securement was 11%.	> 90% Skin integrity score of < 2 >90% pain score at insertion <2	dwell time 26 pts (2- 9 months) 18 pts (9months) 4 pts (2 months) 24 devices were also used with	100% effective in paediatric population, may not be as effective in	Zero malposition 2 accidental dislodgements by patient.		

		This was reduced to 1.66% with SecurAcath. Total cost savings of $37,692	98.7% pain score at maintenance <2 66.7% pain score at removal <2 0 catheters dislodged. Cost savings due to decrease in replaced PICCs.	glue. No complications reported, 100% effective. Reduced dislodgement 8-10% previous experience. $6 saved per week	elderly confused patient group. Cost effective, Previous dislodgement 50% - 2 patient initiated dislodgement.	Less time consuming.		

7.4.2 Provide details on data from any single study that have been drawn from more than one source (for example a poster and unpublished report) and/or when trials are linked this should be made clear (for example, an open-label extension to randomised controlled trial).

None

7.4.3 Highlight any differences between patient populations and methodology in all included studies.

Patient populations include adult, paediatric, patients with specific needs ie: restless, confused patients with high probability of accidental dislodgement. Including patient groups with specific fragile skin issues.

7.4.4 Provide details of any subgroup analyses that were undertaken in the studies included in section 7.4.1. Specify the rationale and state whether these analyses were pre-planned or post-hoc.

None

7.4.5 If applicable, provide details of the numbers of patients who were eligible to enter the study(s), randomised, and allocated to each treatment in an appropriate format.

None

7.4.6 If applicable provide details of and the rationale for, patients that were lost to follow-up or withdrew from the studies.

Not applicable.

7.5 Critical appraisal of relevant studies

7.5.1 Complete a separate quality assessment table for each study. A suggested format for the quality assessment results is shown in tables B7 and B8.

Table B7 Critical appraisal of randomised control trials

Study name	Janssens	
Study question	**Response (yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was randomisation carried out appropriately?	yes	Standard randomization procedure
Was the concealment of treatment allocation adequate?	yes	Standard randomization procedure
Were the groups similar at the outset of the study in terms of prognostic factors, for example, severity of disease?	yes	Standard randomization procedure
Were the care providers, participants and outcome assessors blind to treatment allocation? If any of these people were not blinded, what might be the likely impact on the risk of bias (for each outcome)?	no	Blinding not possible
Were there any unexpected imbalances in drop-outs between groups? If so, were they explained or adjusted for?	no	
Is there any evidence to suggest that the authors measured more outcomes than they reported?	no	
Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate methods used to	no	

account for missing data?		
Adapted from Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

Table B8 Critical appraisal of observational studies

The majority of the submitted data are observation studies, or product evaluation, a critical appraisal is difficult to describe. That notwithstanding, it is apparent regardless of the design methodology employed that clinicians are aware of a significant issue around the securement of various types of central venous catheters. Whilst the data presented may not have been submitted for peer review publication, all observational prospective clinical evaluations have had significant results to persuade clinicians to move forward with the device and incorporate it into their hospital routine practices. With subsequent cost savings to justify to procurement and purchasing departments that hospital costs and patient safety can be achieved.

Study name Hughes M.		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?		Evaluation of initial use of device. 31 uses evaluated
Was the exposure accurately measured to minimise bias?	no	observational review
Was the outcome accurately measured to minimise bias?	yes	initial measurement criteria well described
Have the authors identified all important confounding factors?	yes	
Have the authors taken account of the confounding factors in the	no	

design and/or analysis?		
Was the follow-up of patients complete?	yes	
How precise (for example, in terms of confidence interval and p values) are the results?	N/A	
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		
Study name Egan		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	yes	Written consent obtained. All personnel educated in insertion and use of device All patients were treated according to the institutional standard of care and according to the instructions contained in the SecurAcath device instructions for use. Study supplies were provided by the study sponsor, Interrad Medical Inc.
Was the exposure accurately measured to minimise bias?	Yes	prospective observational study
Was the outcome accurately measured to minimise bias?	Yes	
Have the authors identified all important confounding factors?	NA	
Have the authors taken account of the confounding factors in the design and/or analysis?	NA	
Was the follow-up of patients complete?	Yes	
How precise (for example, in terms	NA	

of confidence interval and p values) are the results?		
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		
Study name Cordovani 2013		
Study question	**Response** **yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Written consent obtained. All personnel educated in insertion and use of device All patients were treated according to the institutional standard of care and according to the instructions contained in the SecurAcath device instructions for use. Study supplies were provided by the study sponsor, Interrad Medical Inc.
Was the exposure accurately measured to minimise bias?	Yes	Prospective observational study
Was the outcome accurately measured to minimise bias?	Yes	Prospective observational study
Have the authors identified all important confounding factors?	NA	
Have the authors taken account of the confounding factors in the design and/or analysis?	NA	
Was the follow-up of patients complete?	Yes	
How precise (for example, in terms of confidence interval and p values) are the results?	NA	
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

7.6 Results of the relevant studies

All outcomes pertinent to the scope and the measures used to assess those outcomes should be presented.

7.6.1 Complete a results table for each study with all relevant outcome measures pertinent to the decision problem. A suggested format is given in table B9.

A separate table for each study must be completed. State N/A or unknown if appropriate. Any outcomes not tested statistically can be included in the comments section.

Table B9 Outcomes from published and unpublished studies

Study name		Janssens
Size of study groups	Treatment	51
	Control	51
Study duration	Time unit	5 months
Type of analysis	Intention-to-treat/per protocol	
Outcome	Name	Mean time spent for dressing change
	Unit	Minutes
Effect size	Value	[redacted] minutes SecurAcath, [redacted] minutes Statlock
	95% CI	[redacted] SecurAcath, [redacted] Statlock
Statistical test	Type	
	p value	
Other outcome	Name	Catheter migration
	Unit	cm
Effect size	Value	[redacted] cm SecurAcath, [redacted] cm Statlock
	95% CI	
Statistical test	Type	
	p value	
Comments		[redacted]

Study name		Hughes
Size of study groups	**Treatment**	31
	Control	none device evaluation
Study duration	**Time unit**	total dwell time
Type of analysis	**Intention-to-treat/per protocol**	observational study – reduced migration, evaluation pain, reduction in replacement, ease of use, reduced cost
Outcome	**Name**	
	Unit	Velindre Cancer Centre, Whitchurch, Cardiff
Effect size	**Value**	
	95% CI	
Statistical test	**Type**	NA
	p value	NA
Other outcome	**Name**	
	Unit	
Effect size	**Value**	
	95% CI	
Statistical test	**Type**	
	p value	

Comments		Though an observational study consideration should be given to the cost reduction highlighted. Any initial difficulties should be viewed in the light that operators after education were evaluating the device. As noted this is a commentary. Only one catheter moved, by 1 cm 83% of patients were very satisfied with the device. 3 patients were not satisfied and had the device removed 28 patients evaluated their pain score as zero (0-10 scale) throughout the dwell time. Five patients scored their pain to be over 5 and 3 had the device removed due to severe or unresolved pain. A number of patients reported some discomfort (picking) in the first few days, up to a week after placement, but for the majority this settled. Staff caring for patients reported prolonged bleeding (longer than previously) at the exit site post placement. Device removal caused the most dissatisfaction among staff, due to the distress it frequently caused for patients, and as a result a local algorithm was designed to minimise pain at removal. The author reports that the administration of local anaesthesia at the site proved effective when the device was difficult to remove, and that cutting the device in two was an easy and effective procedure to aid removal of the device. The author notes that the majority of patients experienced a swift removal of the device without any discomfort or pain.
Study name		**Egan**
Size of study groups	**Treatment**	68
	Control	none
Study duration	**Time unit**	Aug 2010 – Dec 2010
Type of analysis	**Intention-to-treat/per protocol**	prospective observational study
Outcome	**Name**	multi centre
	Unit	Albany Medical Center in Albany, New York; St Joseph's Hospital in St Paul, Minnesota; St Luke's Hospital Kansas City, Missouri.
Effect size	**Value**	
	95% CI	
Statistical test	**Type**	
	p value	
	Name	

Other outcome	**Unit**	
Effect size	**Value**	
	95% CI	
Statistical test	**Type**	
	p value	
Comments		Though an observational study this publication reviews the successful deployment of the device. Device success: 62 (91.2%). Unsuccessful: 2 catheter slippages (defined as a movement >0.5cm, without loss of catheter function); 1 unable to remove the anchor as designed at removal; 1 cellulitis infection at the securement site; 2 persistent pain at the anchor securement site that required medical intervention. Median time to place the device was 15 seconds (range 10 to 180 seconds). Mean time for securement was 31 +/- 38 seconds. All devices were placed successfully (without malfunction or placement failure). Mean catheter dwell time was 22.6 days (SD +/- 36 days. Unscheduled removal of the SecurAcath device for any reason occurred in 20.6% (14) of patients: 4 because of suspected or confirmed bloodstream infections, 4 patient removal of own catheter, 2 pain, 1 dislodgment, 1 catheter kinking, 1 a 7 Fr SecurAcath used in error with a 5 Fr catheter and 1 SecurAcath lid lost during home dressing change on the 140th day (the remaining SecurAcath base was later removed, but the catheter stayed in place).The mean pain score immediately after device removal in 57 (11 had no pain score recorded) patients was 1.5 (SD +/- 2.5). The mean pain score during device dwell time in the 57 patients available for responses was 0.7 (SD +/- 1.6).
Study name		**Cordovani**
Size of study groups	**Treatment**	74
	Control	none
Study duration	**Time unit**	
Type of analysis	**Intention-to-treat/per protocol**	Multi-centre observational post-market study central venous catheters
Outcome	**Name**	
	Unit	Department of Anesthesia and Pain Management, Toronto General Hospital, Toronto, ON, Canada
Effect size	**Value**	

	95% CI	
Statistical test	**Type**	
	p value	
Other outcome	**Name**	
	Unit	
Effect size	**Value**	
	95% CI	
Statistical test	**Type**	
	p value	
Comments		97% (72) patients successful securement was achieved. Two patients experienced catheter dislodgement, identified within 24 hrs of catheter placement and attributed to improper coupling of the 2 device components. No other device-related malfunctions occurred. The immediate procedural success rate was 100%. The mean (standard deviation) time to secure the catheter was 62.5 (97.3) sec, and 91% of the devices were deployed within 2.5 min. Mean catheter indwelling time was 3.1 (5.1) days. Discomfort analogue score (scale 1-10) during device use and at removal was 0.9 (1.6) and 1.6 (2.1), respectively. Fourteen of the 15 patients with previous CVC or peripherally inserted central catheter experience considered SecurAcath to be as or more comfortable than a sutured catheter. Six of the 8 healthcare professionals questioned thought that maintenance of the device site was somewhat or much easier than with a sutured catheter, and all stated they would recommend this device to other professional colleagues. Post market surveillance established successful use on the device except on 2 occasions, due to improper joining to 2 pieces of device.

Posters								
Name	McParlan	Janssens	Djurcic–Jovan	Sandeluss	Ballance	Dougherty	Stone	Pevelar
Date	2016	2016	2016	2013	2013	2013	2013	2103
Location	[redacted]	University Hospital Leuven. Belgium	Ottowa Hospital. Canada	University College Hospital UK	Wayne Memorial Hospital Goldsboro North Carolina.US	Royal Marsden Hospital. London. UK	Boston Children's Hospital.US	Cincinnati Children's Hospital. US
Design	[redacted]	Randomised NCT02311127	Quality improvement initiative	Retrospective audit	Post market evaluation	Product evaluation	Product evaluation	Product evlaluation
Duration	[redacted]	5 months	13 months	not described	not described	1 month		not described
Sample size	[redacted] Statlock, SecurAcath	105	54	100	not described	30	42 paediatric	paediatric patient presenting with fragile skin
Follow up	[redacted]	6 months	not described	not described	Catheter removal	not described	Catheter removal	Catheter removal
Outcome 1.	[redacted]	Time to perform dressing change	Reduction in catheter migration	Reduction in catheter migration		Reduced catheter migration. Improved care of insertion site Resolved skin issue	Reduction, elimination skin issues related to securement device	Reduced catheter migration
Outcome 2.	[redacted]	Catheter migration. Accidental dislodgement. DIscomfort. Catheter related infection	Cost savings due to reduced transport and repeat X ray Cost saving on catheter replacement.	Patient / user experience	Reduce catheter migration One device for life of catheter	General improvement of care of PICC catheter site	Reduced migration	Reduce skin reaction

Comparator	[redacted]	StatLock	N/A	N/A	N/A	N/A	N/A	N/A
Summary	[redacted]	Mean time to perform each dressing change is 3 minutes shorter in the SecurAcath group. User education is required.	An estimated $10, 149 saving on transport. No catheter migration occurred potential cost saving $20,215.	Catheter migration reduced from 7% with adhesive device to less than 2% with SecurAcath. 88% of patients found SecurAcath tolerable and would have it again.	ICU conversion from suturing to evaluated device for acute CVC catheter. PICC catheter use, reduced catheter migration. Improved disinfection at site achieved	Positive user feedback. Improved disinfection. Reduction in cost of changing securement device.	All catheters remained in place, completed therapy course with no complication or skin reaction	Patient A: 2PICCs lost to migration. Final PICC with SecurAcath device remained in place 57 days. Patient B: 4 catheters of various types lost due to migration, dislodgement Final catheter (PICC) with SecurAcath device remained in place 61 days
		Report	**Presentations**					
Name	Ballance	Misericordia	Zerla	Pittiruti	Pittiruti	Hill		
Date	2012	2015	2016	2015	2015	2014		
Location	Wayne Memorial Hospital Goldsboro North Carolina.US	Edmonton, Alberta Canada	Gorgonzola, Italy	Catholic University Hospital, Rome Italy	Catholic University Hospital, Rome Italy	St. Paul's Hospital – Vancouver, BC Canada		
	Product evaluation			Study A	Study B			
Design	4 months	Prospective	Prospective	prospective clinical oncology chemotherapy-PICC	prospective clinical specific patient groups	prospective clinical		
Duration	10	One year	Catheter removal	> 2 months	3 months	catheter removal		

Sample size	not described	542 placed, 485 follow-up	30 oncology patients chemo indicated for >2 months	48	47. total 18 acute C VC.29 PIC	60 PICC		
Follow up	Reduction suturing/ needlestick injury Improved skin disinfection at catheter insertion site	PICC removal	Catheter removal	catheter removal	catheter removal	catheter removal		
Outcome 1.	Reduced migration	Reduction in PICC replacements	Skin integrity score, pain score at placement, maintenance and removal less than 2	safety and cost effectiveness of device	elderly group with high risk of dislodgement. Paediatric patients. Patient with skin issues	Cost saving and efficiency		
Outcome 2.	N/A		Zero catheters dislodged	N/A	N/A	N/A		
Comparator	No issues are described, all catheters remained in place for the required time period. Acute CVC now secured using device.	Adhesive device	NA	N/A	N/A	N/A		
Summary		542 PICCs placed in one year with SecurAcath. Previous replacement rate with adhesive	> 90% Skin integrity score of < 2	dwell time 26 pts (2- 9 months) 18 pts (9months) 4 pts (2 months)	100% effective in paediatric population,	Zero malposition 2 accidental dislodgements		

		device securement was 11%. This was reduced to 1.66% with SecurAcath. Total cost savings of $37,692	>90% pain score at insertion <2 98.7% pain score at maintenance <2 66.7% pain score at removal <2 0 catheters dislodged. Cost savings due to decrease in replaced PICCs	24 devices were also used with glue. No complications reported, 100% effective. Reduced dislodgement 8-10% compared to previous experience with adhesive device. $6 saved per week due to not changing adhesive device.	may not be as effective in elderly confused patient group. Cost effective, Previous dislodgement 50% - 2 patient initiated dislodgement.	by patient. Less time consuming.		

7.6.2 Justify the inclusion of outcomes in table B9 from any analyses other than intention-to-treat.

7.7 Adverse events

In section 7.7 the sponsor is required to provide information on the adverse events experienced with the technology being evaluated in relation to the scope.

For example, post-marketing surveillance data may demonstrate that the technology shows a relative lack of adverse events commonly associated with the comparator.

7.7.1 Using the previous instructions in sections 7.1 to 7.6, provide details of the identification of studies on adverse events, study selection, study methodologies, critical appraisal and results.

Exact details of the search strategy used should be provided in section 10 appendix 2.

7.7.2 Provide details of all important adverse events reported for each study. A suggested format is shown in table B10.

When providing details of important adverse events reported for each study, for each group, give the number of people with the adverse event, the total number of people in the group and the percentage with the event. Present the relative risk and risk difference and associated 95% confidence intervals for each adverse event.

Table B10 Adverse events across patient groups

Hughes	***Time period N/A***			***Time period 2 etc.***		
	Intervention **% of patients - 31 (n = *x*)**	***Comparator*** **% of patients (n = *x*)**	**Relative risk (95% CI)**	***Intervention*** **% of patients (n = *x*)**	***Comparator*** **% of patients (n = *x*)**	**Relative risk (95% CI)**
Class 1 (for example, nervous system disorders)						
Adverse Removal	Removal difficulties in 25%. above 3 (half pt's) 6 and above for 24% pain score 1- 10					
Adverse Infection	12% developed infection.8 months after the first use of SecurAcath, a separate audit was done with 100 patients which found 2 infections (a light growth of Staphylococcus aureus at the exit site, which resolved after oral antibiotics, and a systemic MRSA infection in a patient who had previously tested positive for MRSA).					
Class 2 (for example, vascular disorders)						
Adverse event 3						
Adverse event 4						
CI, confidence interval Adapted from European Public Assessment Reports published by the European Medicines Agency						
Egan	***Time period 1***			***Time period 2 etc.***		
	Intervention **% of patients (n = *x*)**	***Comparator*** **% of patients (n = *x*)**	**Relative risk (95% CI)**	***Intervention*** **% of patients (n = *x*)**	***Comparator*** **% of patients (n = *x*)**	**Relative risk (95% CI)**
Class 1 (for example, nervous system disorders)						
Adverse pain & infection	20 events .(22.1%) 4 AEs reported to be possibly (n = 3) or definitely (n = 1) related to the SecurAcath device include 1 patient who removed her PICC at home (the SecurAcath was removed the next day at the hospital), 2 patients who experienced catheter migration in spite of intact SecurAcath devices and properly applied dressings, and 1 catheter dislodgment due to a device lid not snapped on securely over the catheter. 3 events (death, cerebral hemorrhage, and methicillin-resistant staphylococcus aureus meningitis) were recorded as serious adverse events and were all felt to be unrelated to the procedure, device, or catheter.					
Adverse event 2						
Class 2 (for example, vascular disorders)						
Adverse event 3						
Adverse event 4						
CI, confidence interval Adapted from European Public Assessment Reports published by the European Medicines Agency						
Cordovani	***Time period 1***			***Time period 2 etc.***		
	Intervention **% of patients (n = *x*)**	***Comparator*** **% of patients (n = *x*)**	**Relative risk (95% CI)**	***Intervention*** **% of patients (n = *x*)**	***Comparator*** **% of patients (n = *x*)**	**Relative risk (95% CI)**
Class 1 (for example, nervous system disorders)						
Adverse event 1	None described					
Adverse event 2						
Class 2 (for example, vascular disorders)						
Adverse event 3						
Adverse event 4						

7.7.3 Describe all adverse events and outcomes associated with the technology in national regulatory databases such as those maintained by the MHRA and FDA (Maude).

A search of MHRA was performed, no results obtained. A similar search of Maude found the following:

Model Number SCR-1 Event Date 11/15/2013

The risk manager at (b)(6) reported that there were reports of difficulty in removing the anchor from patient's with tissue scar adhesion around the device. The nurse(s) were trying to remove the anchor gently to avoid hurting the patient resulting in difficulty removing the anchor and discomfort for the patient. There were no device malfunction an no adverse event. This incident occurred during the early implementation phase of the device, when many clinicians were just beginning to use the device. The company has found the removal process becomes easier once experience has been obtained. On some patients, especially with longer dwell times, the anchors become more embedded in the tissue. For these cases, the anchor needs to be pulled out using a swift, deliberate tug. The small, blunt anchors straighten when pulled out without damaging the skin. The removal of SecurAcath, when done correctly, can be equated to the removal of a huber needle from an implanted port in that some patients may experience momentary pain if any upon removal which quickly subsides upon completion of the removal procedure.

Manufacturer Narrative. There were no device malfunctions nor harm to the patient. Tissue growth around the anchor is normal and removal of the anchor under these conditions is described in the IFU. A rapid deliberate tug of the anchor is required to remove the anchor from the subcutaneous space if tissue growth is present. This generally results in little or no discomfort from the patient and is preferred to the gentle tentative anchor removal.

7.7.4 Provide a brief overview of the safety of the technology in relation to the scope.

The published and unpublished data give observational, post-marketing and evaluation results. Initial adverse events relate to operators having been educated and subsequently leaning to use the device and understand the functioning (deployment) of the device. The safe use of the device requires (as can be seen from the studies) requires education and learning. The device correct use and deployment of the device ensures its safety but more importantly provides securement of a variety of catheter types for the intended dwell time.

An additional note: The SecurAcath Instructions for Use include a warning not to use the device in patients with a known nickel allergy, also the standard contraindication: The patient is known or is suspected to be allergic to materials contained in the device.

It is important to understand the difference between Nitinol and other nickel containing alloys. The Nitinol in the SecurAcath undergoes a process called electropolishing during manufacturing. When electropolished, Nitinol forms a stable protective layer that acts as a barrier against ion exchange, protecting against nickel release, this is known as passivated nitinol. Electropolished nitinol has excellent biocompatibility, similar to that of stainless steel, which also contains nickel.[1]

Unpassivated metal alloys, like those used in inexpensive jewellery, have free nickel ions exposed on the surface which can cause a hypersensitivity response on the skin.

We do not recommend use of the SecurAcath on patients with a known nickel allergy. However, this information illustrates how the Nitinol in the SecurAcath device minimizes the associated risk to patients. It is advised to consider the risks and consequences of skin adhesive reactions, device migration, catheter tip malposition, and total dislodgement and the complications which are severe to the patient versus a potential reaction to nickel. The SecurAcath device can always be removed if hypersensitivity observed during dwell time.

7.8 Evidence synthesis and meta-analysis

When more than one study is available and the methodology is comparable, a meta-analysis should be considered.

Section 7.8 should be read in conjunction with the 'Medical Technologies Evaluation Programme Methods Guide', available from www.nice.org.uk/mt

7.8.1 Describe the technique used for evidence synthesis and/or meta-analysis. Include a rationale for the studies selected, details of the methodology used and the results of the analysis.

Paucity of published date excludes a synthesis or meta analysis

7.8.2 If evidence synthesis is not considered appropriate, give a rationale and provide a qualitative review. The review should summarise the overall results of the individual studies with reference to their critical appraisal.

Whilst the majority of the data provided falls under the description of product evaluation, review, and observational clinical prospective study there are several examples of testing the technology that results in significant reduction of catheter migration and avoidance of catheter replacement, indicating a noteworthy reduction in replacement costs.

The objective of the presented data are attempts on the part of practicing clinicians to improve patient safety and outcomes. The intention also includes endeavors by clinicians to comply and adhere to published guidance, recommendations on securement, reduction in needle stick injury, and use of engineered catheter stabilization device.

Taken as a whole the data has been substantial enough for clinicians to implement the device into their standards and policies of practice.

7.9 Interpretation of clinical evidence

7.9.1 Provide a statement of principal findings from the clinical evidence highlighting the clinical benefit and any risks relating to adverse events from the technology.

Published data and unpublished observational evaluations overall show a significant clinical benefit for this device. The primary clinical benefit being securement of various types of catheters in various patient groups enabling patients to receive prescribed intravenous therapy without interruption or additional procedures to replace catheters that have become malpositioned due to ineffective securement. The SecurAcath studies consistently show very low rates of catheter dislodgement and migration. A key published randomized study of the Statlock vs. sutures for securing PICCs shows a dislodgement rate for the Statlock of 12% and for sutures of 14% (Yamamoto 2002).

A significant additional benefit (presented in 2 studies) is the elimination of the need for suturing catheters in place and subsequently reducing the potential for suture needlestick injury.

7.9.2 Provide a summary of the strengths and limitations of the clinical-evidence base of the technology.

The studies presented are mainly observational evaluations of a new technology. This notwithstanding the willingness of operators to perform observational evaluations of the technology speaks significantly to the ongoing problem of securement of catheters. It should be noted that there may well be a consideration that there is a direct comparator in the market today, this is not the cause due to this technology being the first of its kind. Comparing adhesive devices against this new technology is comparing a device that requires changing routinely as opposed to a device that remains in situ for the lifetime of the catheter.

7.9.3 Provide a brief statement on the relevance of the evidence base to the scope. This should focus on the claimed patient- and system-benefits described in the scope.

Assured securement for the required dwell time of the catheter is supported by all published data as is a reduction in repeat procedures due to malposition or dislodgement of the catheter, this includes the listed reduced complications. Benefits are also addressed in described reduced costs of treatment and therapy delays.

7.9.4 Identify any factors that may influence the external validity of study results to patients in routine clinical practice.

Level of clinical evidence includes one only one randomised controlled study. However, there is considerable observational data to support this device as a safe effective alternative to comparators.

7.9.5 Based on external validity factors identified in 7.9.4 describe any criteria that would be used in clinical practice to select patients for whom the technology would be suitable.

Given the presented data, the majority of patients requiring catheter placement would be suitable. Studies presented include patient groups outside the original scope. Anecdotal evidence describes clinicians utilising the device when tunnelling a catheter without an implanted cuff to great effect.

Section C – Economic evidence

8 Existing economic evaluations

8.1 Identification of studies

8.1.1 Describe the strategies used to retrieve relevant health economics studies from the published literature and to identify all unpublished data. The search strategy used should be provided as in section 10, Appendix 3.

There are very few articles focused on the cost consequences or cost effectiveness of catheter securement methods, and no existing studies of the economics of SecurAcath. We conducted a systematic search of PubMed and Embase using the following search logic: (PICC or CVC) and (economic# or cost#) and (securement device). The overall search objective was to retrieve and review research articles that assessed the cost impact or cost effectiveness (or budget impact) of alternative central catheter securement devices.

8.1.2 Describe the inclusion and exclusion criteria used to select studies from the published and unpublished literature. Suggested headings are listed in the table below. Other headings should be used if necessary.

In addition to addressing this main search objective, the other inclusion requirement was that articles had to exhibit the following attributes: (1) English language; (2) Abstract present; (3) contain an empirical assessment of costs, in the form of cost minimization, cost consequence (or impact), cost effectiveness, or budget impact; and (4) contain a comparison of at least two catheter securement options. See Table C1.

Table C1 Selection criteria used for health economic studies

Inclusion criteria
Population: Patients who require an intravascular catheter for central venous access (PICC or CVC) and have had catheter securement devices in place
Interventions: Catheter securement device; must be comparative
Outcomes: Costs and expected costs of PICC and CVC with various catheter securement approaches; comparative
Study design: Cost-Effective Analysis, Meta-Analysis, Economic Analysis, Cost-Impact Analysis, Cost Consequences, Cost Minimization
Language restriction English
Search dates: 07/19/2016-07/20/2016
Exclusion criteria
Population: None
Interventions: None
Outcomes: Studies without costs reported; must be comparative

Study design: Clinical
Language restriction
Search dates: 07/19/2016-07/20/2016

8.2 Description of identified studies

8.2.1 Provide a brief review of each study, stating the methods, results and relevance to the scope. A suggested format is provided in table C2.

This search yielded a total of 2 articles. Using PubMed's "Related Articles"[1] feature for these 2 articles, we identified another 297 articles. The abstracts of each of these articles was searched for relevance to the search objective. Only 3 articles were deemed to be relevant to the main search objective and satisfied the four inclusion criteria. All of the 294 excluded articles were excluded due to failure to meet inclusion criteria #3 or #4. The citations and abstracts for the three selected articles are below:

1. Bausone-Gazda, D., et al. (2010). "A randomized controlled trial to compare the complications of 2 peripheral intravenous catheter-stabilization systems." J Infus Nurs **33**(6): 371-384.(1) "An open-label, prospective, randomized, non-inferiority study was conducted at a large academic, Magnet-designated, Level I trauma center to compare the peripheral intravenous catheter securement-related complication rates of 2 different stabilization systems. The control stabilization system included the StatLock device with a non-winged catheter, and the investigational stabilization system included a closed catheter system with a specially designed Tegaderm dressing. Data from 302 subjects indicated that the investigational stabilization system was non-inferior or similar to the control stabilization system with respect to the overall securement-related complications. The cost of the investigational stabilization system was approximately 75% of the cost for the control stabilization system."

2. Reynolds, H., et al. (2015).(2) "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." Aust Crit Care **28**(3): 140-148. "BACKGROUND: Peripheral arterial catheters are widely used in the care of intensive care patients for continuous blood pressure monitoring and blood sampling, yet failure - from dislodgement, accidental removal, and complications of phlebitis, pain, occlusion and infection - is common. While appropriate methods of dressing and securement are required to reduce these complications that cause failure, few studies have been conducted in this area. OBJECTIVES: To determine initial effectiveness of one dressing and two securement methods versus usual care, in minimising failure in peripheral arterial catheters. Feasibility objectives were considered successful if 90/120 patients (75%) received the study intervention and protocol correctly, and had ease and satisfaction scores for the study dressing and securement devices of >/= 7 on Numerical Rating Scale scores 1-10.

[1] See generally http://www.ncbi.nlm.nih.gov/books/NBK3827/#pubmedhelp.Computation_of_Similar_Articl.

METHODS: In this single-site, four-arm, parallel, pilot randomised controlled trial, patients with arterial catheters, inserted in the operating theatre and admitted to the intensive care unit postoperatively, were randomly assigned to either one of the three treatment groups (bordered polyurethane dressing (n=30); a sutureless securement device (n=31); tissue adhesive (n=32)), or a control group (usual practice polyurethane dressing (not bordered) (n=30)). RESULTS: One hundred and twenty-three patients completed the trial. The primary outcome of catheter failure was 2/32 (6.3%) for tissue adhesive, 4/30 (13.3%) for bordered polyurethane, 5/31 (16.1%) for the sutureless securement device, and 6/30 (20%) for the control usual care polyurethane. Feasibility criteria were fulfilled. Cost analysis suggested that tissue adhesive was the most cost effective. CONCLUSIONS: The pilot trial showed that the novel technologies were at least as effective as the present method of a polyurethane dressing for dressing and securement of arterial catheters, and may be cost effective. The trial also provided evidence that a larger, multicentre trial would be feasible."

3. Tuffaha, H. W., et al. (2014).(3) "Value of information analysis optimizing future trial design from a pilot study on catheter securement devices." Clin Trials **11**(6): 648-656. "BACKGROUND: Value of information analysis has been proposed as an alternative to the standard hypothesis testing approach, which is based on type I and type II errors, in determining sample sizes for randomized clinical trials. However, in addition to sample size calculation, value of information analysis can optimize other aspects of research design such as possible comparator arms and alternative follow-up times, by considering trial designs that maximize the expected net benefit of research, which is the difference between the expected cost of the trial and the expected value of additional information. PURPOSE: To apply value of information methods to the results of a pilot study on catheter securement devices to determine the optimal design of a future larger clinical trial. METHODS: An economic evaluation was performed using data from a multi-arm randomized controlled pilot study comparing the efficacy of four types of catheter securement devices: standard polyurethane, tissue adhesive, bordered polyurethane and sutureless securement device. Probabilistic Monte Carlo simulation was used to characterize uncertainty surrounding the study results and to calculate the expected value of additional information. To guide the optimal future trial design, the expected costs and benefits of the alternative trial designs were estimated and compared. RESULTS: Analysis of the value of further information indicated that a randomized controlled trial on catheter securement devices is potentially worthwhile. Among the possible designs for the future trial, a four-arm study with 220 patients/arm would provide the highest expected net benefit corresponding to 130% return-on-investment. The initially considered design of 388 patients/arm, based on hypothesis testing calculations, would provide lower net benefit with return-on-investment of 79%. LIMITATIONS: Cost-effectiveness and value of information analyses were based on the data from a single pilot trial which might affect the accuracy of our uncertainty estimation. Another limitation was that different follow-up durations for the larger trial were not evaluated. CONCLUSION: The value of information approach allows efficient trial design by maximizing the expected net benefit of

additional research. This approach should be considered early in the design of randomized clinical trials."

8.2.2 Provide a complete quality assessment for each health economic study identified. A suggested format is shown in table C3.

Table C3 Quality assessment of health economic studies

Study name: Bausone-Gazda, D., et al. (2010)		
Study design:		
Study question	**Response (yes/no/not clear/N/A)**	**Comments**
1. Was the research question stated?	Yes	
2. Was the economic importance of the research question stated?	Yes	
3. Was/were the viewpoint(s) of the analysis clearly stated and justified?	Yes	
4. Was a rationale reported for the choice of the alternative programmes or interventions compared?	Yes	
5. Were the alternatives being compared clearly described?	Yes	
6. Was the form of economic evaluation stated?	Yes	
7. Was the choice of form of economic evaluation justified in relation to the questions addressed?	Yes	
8. Was/were the source(s) of effectiveness estimates used stated?	Yes	
9. Were details of the design and results of the effectiveness study given (if based on a single study)?	Yes	
10. Were details of the methods of synthesis or meta-analysis of estimates given (if based on an overview of a number of effectiveness studies)?	Yes	

11. Were the primary outcome measure(s) for the economic evaluation clearly stated?	Yes	
12. Were the methods used to value health states and other benefits stated?	Yes	

13. Were the details of the subjects from whom valuations were obtained given?	Yes	
14. Were productivity changes (if included) reported separately?	Yes	
15. Was the relevance of productivity changes to the study question discussed?	Yes	
16. Were quantities of resources reported separately from their unit cost?	No	
17. Were the methods for the estimation of quantities and unit costs described?	Yes	
18. Were currency and price data recorded?	Yes	
19. Were details of price adjustments for inflation or currency conversion given?	No	
20. Were details of any model used given?	Yes	
21. Was there a justification for the choice of model used and the key parameters on which it was based?	No	
22. Was the time horizon of cost and benefits stated?	Yes	
23. Was the discount rate stated?	No	
24. Was the choice of rate justified?	No	
25. Was an explanation given if cost or benefits were not discounted?	No	
26. Were the details of statistical test(s) and confidence intervals given for stochastic data?	Yes	

27. Was the approach to sensitivity analysis described?	Yes	
28. Was the choice of variables for sensitivity analysis justified?	Yes	
29. Were the ranges over which the parameters were varied stated?	Yes	
30. Were relevant alternatives compared? (That is, were appropriate comparisons made when conducting the incremental analysis?)	Yes	

31. Was an incremental analysis reported?	Yes	
32. Were major outcomes presented in a disaggregated as well as aggregated form?	No	
33. Was the answer to the study question given?	Yes	
34. Did conclusions follow from the data reported?	Yes	
35. Were conclusions accompanied by the appropriate caveats?	Yes	
36. Were generalisability issues addressed?	Yes	
Adapted from Drummond MF, Jefferson TO (1996) Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. British Medical Journal 313 (7052): 275–83. Cited in Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

Study name: Reynolds, H., et al. (2015)		
Study design:		
Study question	**Response (yes/no/not clear/N/A)**	**Comments**
1. Was the research question stated?	Yes	
2. Was the economic importance of the research question stated?	Yes	

3. Was/were the viewpoint(s) of the analysis clearly stated and justified?	Yes	
4. Was a rationale reported for the choice of the alternative programmes or interventions compared?	Yes	
5. Were the alternatives being compared clearly described?	No	
6. Was the form of economic evaluation stated?	Yes	
7. Was the choice of form of economic evaluation justified in relation to the questions addressed?	Yes	
8. Was/were the source(s) of effectiveness estimates used stated?	Yes	
9. Were details of the design and results of the effectiveness study given (if based on a single study)?	Yes	
10. Were details of the methods of synthesis or meta-analysis of estimates given (if based on an overview of a number of effectiveness studies)?	Yes	
11. Were the primary outcome measure(s) for the economic evaluation clearly stated?	Yes	
12. Were the methods used to value health states and other benefits stated?	Yes	

13. Were the details of the subjects from whom valuations were obtained given?	Yes	
14. Were productivity changes (if included) reported separately?	Yes	
15. Was the relevance of productivity changes to the study question discussed?	Yes	
16. Were quantities of resources reported separately from their unit cost?	No	
17. Were the methods for the estimation of quantities and unit costs described?	No	
18. Were currency and price data recorded?	No	
19. Were details of price adjustments for inflation or currency conversion given?	No	
20. Were details of any model used given?	Yes	
21. Was there a justification for the choice of model used and the key parameters on which it was based?	No	
22. Was the time horizon of cost and benefits stated?	Yes	
23. Was the discount rate stated?	No	
24. Was the choice of rate justified?	No	
25. Was an explanation given if cost or benefits were not discounted?	No	
26. Were the details of statistical test(s) and confidence intervals given for stochastic data?	Yes	
27. Was the approach to sensitivity analysis described?	N/A	
28. Was the choice of variables for sensitivity analysis justified?	N/A	

29. Were the ranges over which the parameters were varied stated?	N/A	
30. Were relevant alternatives compared? (That is, were appropriate comparisons made when conducting the incremental analysis?)	Yes	

31. Was an incremental analysis reported?	No	
32. Were major outcomes presented in a disaggregated as well as aggregated form?	No	
33. Was the answer to the study question given?	Yes	Very briefly
34. Did conclusions follow from the data reported?	Yes	
35. Were conclusions accompanied by the appropriate caveats?	Yes	
36. Were generalisability issues addressed?	No	
Adapted from Drummond MF, Jefferson TO (1996) Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. British Medical Journal 313 (7052): 275–83. Cited in Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

Study name: Tuffaha, H. W., et al. (2014)		
Study design:		
Study question	**Response (yes/no/not clear/N/A)**	**Comments**
1. Was the research question stated?	Yes	
2. Was the economic importance of the research question stated?	Yes	
3. Was/were the viewpoint(s) of the analysis clearly stated and justified?	Yes	

4. Was a rationale reported for the choice of the alternative programmes or interventions compared?	Yes	
5. Were the alternatives being compared clearly described?	No	
6. Was the form of economic evaluation stated?	Yes	
7. Was the choice of form of economic evaluation justified in relation to the questions addressed?	Yes	
8. Was/were the source(s) of effectiveness estimates used stated?	Yes	
9. Were details of the design and results of the effectiveness study given (if based on a single study)?	Yes	
10. Were details of the methods of synthesis or meta-analysis of estimates given (if based on an overview of a number of effectiveness studies)?	Yes	
11. Were the primary outcome measure(s) for the economic evaluation clearly stated?	Yes	
12. Were the methods used to value health states and other benefits stated?	Yes	

13. Were the details of the subjects from whom valuations were obtained given?	Yes	
14. Were productivity changes (if included) reported separately?	Yes	
15. Was the relevance of productivity changes to the study question discussed?	Yes	
16. Were quantities of resources reported separately from their unit cost?	No	

17. Were the methods for the estimation of quantities and unit costs described?	No	
18. Were currency and price data recorded?	No	
19. Were details of price adjustments for inflation or currency conversion given?	No	
20. Were details of any model used given?	Yes	
21. Was there a justification for the choice of model used and the key parameters on which it was based?	No	
22. Was the time horizon of cost and benefits stated?	Yes	
23. Was the discount rate stated?	No	
24. Was the choice of rate justified?	No	
25. Was an explanation given if cost or benefits were not discounted?	No	
26. Were the details of statistical test(s) and confidence intervals given for stochastic data?	Yes	
27. Was the approach to sensitivity analysis described?	N/A	
28. Was the choice of variables for sensitivity analysis justified?	N/A	
29. Were the ranges over which the parameters were varied stated?	N/A	
30. Were relevant alternatives compared? (That is, were appropriate comparisons made when conducting the incremental analysis?)	Yes	

31. Was an incremental analysis reported?	No	
32. Were major outcomes presented in a disaggregated as well as aggregated form?	No	

33. Was the answer to the study question given?	Yes	
34. Did conclusions follow from the data reported?	Yes	
35. Were conclusions accompanied by the appropriate caveats?	Yes	
36. Were generalisability issues addressed?	No	
Adapted from Drummond MF, Jefferson TO (1996) Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. British Medical Journal 313 (7052): 275–83. Cited in Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

9 De novo cost analysis

9.1 Description of the de novo cost analysis

9.1.1 Provide the rationale for undertaking further cost analysis in relation to the scope.

The NICE Medical Technology guidance scope concluded that SecurAcath may offer benefits to patients and the healthcare system when used to secure percutaneous catheters in adult patients who have a PICC or CVC placed with a medium to long dwell time expected at the time of insertion. Existing published economic and cost literature found in the literature search did not quantify SecurAcath benefits in comparison to existing catheter securement devices such as adhesive devices or sutures. Preliminary cost studies performed by company using the clinical outcomes from SecurAcath trials showed potential cost savings for NHS.

Patients

9.1.2 What patient group(s) is (are) included in the cost analysis?

The cost-analysis included all critically ill patients with intravenous catheters implanted, who are likely to have a number of co-morbidities and patients following major trauma, or those with conditions requiring long-term ongoing therapy such as cancer. In these individuals, catheter often need to remain in place for long periods of time. NICE has estimated there were approximately 225,824 adult ICU episodes in England in 2012/2013 whom required at least

one central venous catheter. For the same period, there were 88,074 ICU episodes involved a stay of over 48 hours. Thus, the cost analysis uses patient population of 88,074. Cost analysis included subgroups of PICC and CVC patients as suggested by scope. The model assumed half of ICU patients to receive PICC and the other half CVC lines.

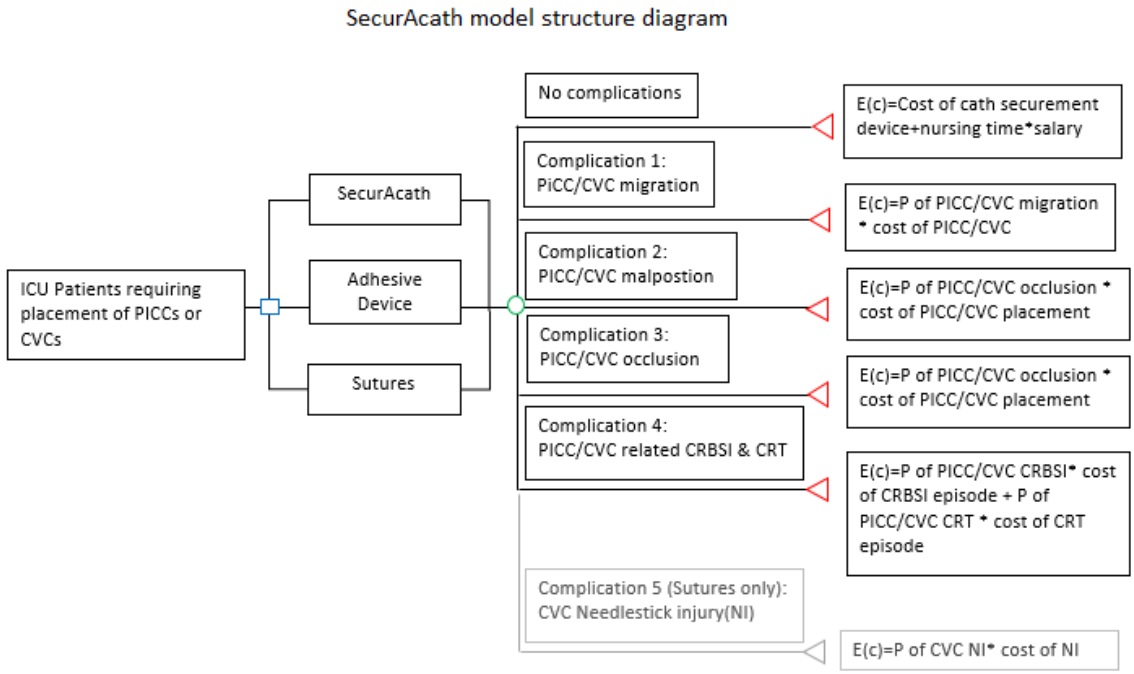
Technology and comparator

9.1.3 Provide a justification if the comparator used in the cost analysis is different from the scope.

The two comparators used in the cost analysis were adhesive devices (such as StatLock and/or GripLock) and sutures. This is as per the scope.

Model structure

9.1.4 Provide a diagram of the model structure you have chosen.



9.1.5 Justify the chosen structure in line with the clinical pathway of care identified in response to question 3.3.

The model adopts a simple cost-consequence model structure that uses expected cost [E(c)] calculations where expected costs are the product of probabilities (p) and costs (C), where $E(c)_i = p_i \times C_i$ for the i^{th} cost component. The decision tree is very straightforward. The model has one decision node

with three choices (SecurAcath, adhesive, or sutures) leading directly to terminal nodes wherein expected costs are calculated. The model is repeated for two types of central catheters: PICC and CVC.

The model compares the intervention SecurAcath catheter securement device to adhesive devices for securing the PICC line and sutures for securing the CVC line. After a patient receives a PICC or CVC line, a catheter securement device is implemented to prevent catheter migration and dislodgment, malposition, occlusion, catheter related bloodstream infections, thrombosis and needle-stick injury in the case of CVC sutures. The model investigates the costs associated with using catheter securement devices and any potential complications as well as the benefits of using SecurAcath in relation to adhesive devices and sutures. Benefits are measured as cost savings to the UK NHS.

9.1.6 Provide a list of all assumptions in the cost model and a justification for each assumption.

- Assumption 1: The model assumes an average of 25 PICC indwelling days and 3 CVC indwelling days. (4-6) 25 indwelling days are a reported mean for patients in the US.(7) When comparing SecurAcath to adhesive device, for 25 PICC indwelling days a patient will need one SecurAcath device and four adhesive devices. When comparing SecurAcath to sutures, for 3 CVC indwelling days, patients will need one of each of the securement devices. This is accounted for in the model. The model assumption is very conservative given that cancer patients in England have average catheter indwell time of 6 months as reported in study by Parker et al.(8) 6 and 3 months indwell time costs are explored in the sensitivity analysis part of this report.

- Assumption 2: The model assumes adhesive devices and SecurAcath are applied by nurses, whereas sutures are applied by physicians.(4)

- Assumption 3: The model assumes no additional resource use for placing catheter securement devices. The catheter securement device placement occurs while patients are already in the physician's office or clinic, with the necessity of a PICC or CVC placement already established prior to the securement method decision.

- Assumption 4: The model assumes four different types of adverse events/complications in the model diagram. The assumptions are supported by the published literature and unpublished Interrad clinical literature and include catheter migration, catheter malposition, catheter occlusion, infection such as CRBSI and CRT.(4, 9-11) CRBSI and CRT probabilities are assumed to be lower for PICC placements as the catheter securement devices are placed on the surface of the skin.(9) Suture is assumed to have a higher probability of CRBSI when securing a CVC in a patient.(12) Sutures are also assumed to bring a risk of needle-stick injury as supported by comparative clinical trial studies.(12)

- Assumption 5: We assume that the literature on the relationship between CVC suturing and CRBSI [including the findings that CVC CRBSI is reduced when sutureless securement devices (SSD) are used; see generally (13-16)] is applicable by logical extension to SecurAcath. SecurAcath uses a different securement technology than other SSDs (e.g., StatLock) but its securement properties (described above in this document) are assumed to imbue SecurAcath with similar CRBSI control attributes.

9.1.7 Define what the model's health states are intended to capture.

N/A

9.1.8 Describe any key features of the cost model not previously reported. A suggested format is presented below.

Table C4 Key features of model not previously reported

Factor	Chosen values	Justification	Reference
Time horizon of model	Annual cohort/episode of care	Annual cohort suggested by scope was used. Time horizon in the model is	
Discount of 3.5% for costs	0	Model time horizon is one year; future discounts are not applicable.	
Perspective (NHS/PSS)	NHS/PSS	Scope	Scope by NICE
Cycle length	Episode of care		
NHS, National Health Service; PSS, Personal Social Services			

9.2 Clinical parameters and variables

9.2.1 Describe how the data from the clinical evidence were used in the cost analysis.

The clinical data pertaining to the SecurAcath device used in the cost analysis comes from SecurAcath clinical trials.(4, 9, 10) Some of the SecurAcath clinical trials data were published (see Clinical section above) and this is indicated in the description of variable sources. In addition, there were some clinical outcomes data used in the model which have not yet been published. These variables are noted in the model variable sources as well. Clinical data is used for analyzing the probability (and costs) of adverse event outcomes such as catheter migration, malposition, occlusion and catheter related bloodstream infections and thrombosis.

9.2.2 Are costs and clinical outcomes extrapolated beyond the study follow-up period(s)? If so, what are the assumptions that underpin this extrapolation and how are they justified?

Costs and clinical outcomes are not extrapolated beyond the study follow-up period. The reason for not extrapolating costs and clinical outcomes beyond the study follow-up period is because all reported outcomes are of short-term time horizon (i.e., episode of care).

9.2.3 Were intermediate outcome measures linked to final outcomes (for example, was a change in a surrogate outcome linked to a final clinical outcome)? If so, how was this relationship estimated, what sources of evidence were used and what other evidence is there to support it?

Intermediate outcome measures are not used in the cost analysis.

9.2.4 Were adverse events such as those described in Section 7.7 included in the cost analysis? If appropriate, provide a rationale for the calculation of the risk of each adverse event.

Catheter related complications such as migration and dislodgment, malposition, occlusion, catheter related bloodstream infection and thrombosis, and needle-stick injury resulting from suturing were included as adverse events resulting from using any of the three catheter securement devices. The probabilities of adverse event occurrence were sourced from published papers and SecurAcath clinical trials as seen in table C5a. Data sources are indicated in the analysis table C5.

9.2.5 Provide details of the process used when the sponsor's clinical advisers assessed the applicability of available or estimated clinical model parameter and inputs used in the analysis.

N/A

9.2.6 Summarise all the variables included in the cost analysis. Provide cross-references to other parts of the submission. A suggested format is provided in table C5 below.

Table C5a Summary of variables applied in the cost model

Variable	**Value** (*)	**Source**
PICC related variables		
Cost of SecurAcath	£16	(11)
SecurAcath nurse time	20.5 min	(10, 17)

Nurse wage per min	£0.60	NHS
Cost of PICC placement	£250	(11)
Cost of CRBSI episode	£9,900	(18, 19)
Cost of CRT episode	£250	(19, 20)
Cost of AD for PICC	£3.47	(11)
Adhesive device nurse time	40.8 min	(17)
Probability of PICC migration w/SecurAcath	[redacted]	(4, 8)
Probability of PICC malposition w/SecurAcath	0.0166	(9)
Probability of PICC occlusion w/SecurAcath	0.1435	(9)
Probability of CRT	0.0369	(9)
Probability of CRBSI w/SecurAcath (PICC)	0.0036	(9)
Probability of PICC migration w/AD	[redacted]	(8, 9)
Probability of PICC malposition w/AD	0.1098	(9)
Probability of PICC occlusion w/AD	0.12	(21)
Probability of CRBSI w/AD (PICC)	0.00369	(22)
CVC related variables		
Cost of sutures (per CVC)	£5	(17)
Cost of CVC placement	£450	(23)
Cost of Needle-stick injury episode (NI)	£312	(24)
Doctor wage per min	£1.47	(25)
Doctor time for suture placement	4.7min	(17)
Probability of CVC migration w/SecurAcath	0	(4)
Probability of CVC malposition w/SecurAcath	0.03	(4)
Probability of CVC occlusion w/SecurAcath	0	(4)
Probability of CRBSI w/SecurAcath (CVC)	0.00369	(22)
Probability of CRBSI w/SecurAcath (CVC)	0.04	(12)
Probability of CVC migration w/sutures	0	(12)
Probability of CVC malposition w/sutures	0.03	(4, 23)
Probability of CVC occlusion w/sutures	0.06	(21)
Probability of Needle-stick injury (NI)	0.02	(12)
Probability of CRBSI w/sutures	0.14	(21)

Notes: CRBSI = catheter related blood stream infection; CRT = catheter related thrombosis; AD = adhesive device; *-cited studies did not report confidence intervals

Model average cost component variables			
SecurAcath PICC outcomes			
No Complications	Cost of SecurAcath	SecurAcath nurse time	Nurse wage/min
Complication 1	Cost of PICC placement	Probability of PICC migration w/SecurAcath	
Complication 2	Cost of PICC placement	Probability of PICC malposition w/SecurAcath	
Complication 3	Cost of PICC placement	Probability of PICC occlusion w/SecurAcath	
Complication 4	Cost of CRBSI episode	Probability of CRBSI w/SecurAcath (PICC)	
	Cost of CRT episode	Probability of CRT w/SecurAcath & AD (PICC)	
Adhesive device PICC outcomes			
No Complications	Cost of AD for PICC	Adhesive device nurse time	Nurse wage/min
Complication 1	Cost of PICC placement	Probability of PICC migration w/AD	
Complication 2	Cost of PICC placement	Probability of PICC malposition w/AD	
Complication 3	Cost of PICC placement	Probability of PICC occlusion w/AD	
Complication 4	Cost of CRBSI episode	Probability of CRBSI w/AD (PICC)	
	Cost of CRT episode	Probability of CRT w/SecurAcath & AD (PICC)	
SecurAcath CVC outcomes			
No Complications	Cost of SecurAcath	SecurAcath nurse time	Nurse wage per min
Complication 1	Cost of CVC placement	Probability of CVC migration w/SecurAcath	
Complication 2	Cost of CVC placement	Probability of CVC malposition w/SecurAcath	
Complication 3	Cost of CVC placement	Probability of CVC occlusion w/SecurAcath	
Complication 4	Cost of CRBSI episode	Probability of CRBSI w/SecurAcath (CVC)	
	Cost of CRT episode	Probability of CRT	
Sutures CVC outcomes			
No Complications	Cost of sutures	Suture doctor time for CVC	Doctor wage per min

Complication 1	Cost of CVC placement	Probability of CVC migration w/sutures	
Complication 2	Cost of CVC placement	Probability of CVC malposition w/sutures	
Complication 3	Cost of CVC placement	Probability of CVC occlusion w/sutures	
Complication 4	Cost of CRBSI episode	Probability of CRBSI w/sutures	
	Cost of CRT episode	Probability of CRT	
Complication 5	Cost of NI episode	Probability of NI	

9.3 Resource identification, measurement and valuation

NHS costs

9.3.1 Describe how the clinical management of the condition is currently costed in the NHS

Catheter securement is not considered a clinical condition. Therefore, it is not specifically associated with HRG and PbR codes.

9.3.2 State the Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures (OPCS) codes for the operations, procedures and interventions relevant to the use of the technology for the clinical management of the condition.

N/A

Resource identification, measurement and valuation studies

9.3.3 Provide a systematic search of relevant resource data for the NHS in England. Include a search strategy and inclusion criteria, and consider published and unpublished studies.

To identify resources used in management of PICC and CVC insertions a literature search on clinical management guidelines for central venous access devices in short and long term care in various clinical settings was performed. To identify measurement data on catheter securement devices literature search criteria included current management for securing PICC and CVC lines in the UK. In order to quantify resource use for the NHS in England literature search looked for costs reported in the published studies in relation to PICC and CVC line securement with any of the intervention or comparator

devices. A literature search included Medline, PubMed, Embase, Medline, NHS EED, Google and Google Scholar.

9.3.4 Provide details of the process used when clinical advisers assessed the applicability of the resources used in the model[2].

N/A

Technology and comparators' costs

9.3.5 Provide the list price for the technology.

The list price of SecurAcath is £16.00.

9.3.6 If the list price is not used in the de novo cost model, provide the alternative price and a justification.
N/A

9.3.7 Summarise the annual costs associated with the technology and the comparator technology (if applicable) applied in the cost model. A suggested format is provided in tables C6 and C7. Table C7 should only be completed when the most relevant UK comparator for the cost analysis refers to another technology.

Table C6a Costs per treatment/patient associated with the technology in the cost model for PICC - SecurAcath

Items	Value	Source
Price of the technology per treatment/patient	£16.00	(11, 17)
Consumables (if applicable)	£12.00	(17)
Maintenance cost	N/A	
Training cost	N/A	
Other costs (total complications costs)	£85.88	(4, 9, 11, 17, 19)
Total cost per treatment/patient	£114.18	

Table C6b Costs per treatment/patient associated with the technology in the cost model for CVC SecurAcath

Items	Value	Source

Price of the technology per treatment/patient	£16.00	(11, 17)
Consumables (if applicable)	£12.00	(17)
Maintenance cost	N/A	
Training cost	N/A	
Other costs (total complications costs)	£418.7	(4, 9, 12, 22, 23)
Total cost per treatment/patient	£447.0	

Table C7a Costs per treatment/patient associated with the comparator technology in the cost model for PICC-Adhesive Device

Items	Value	Source
Cost of the comparator per treatment/patient	£12	(11, 17)
Consumables (if applicable)	£24	(17)
Maintenance cost	N/A	
Training cost	N/A	
Other costs (total complications costs)	£118.01	(9, 11, 19, 21-23)
Total cost per treatment/patient	£154.53	

Table C7b Costs per treatment/patient associated with the comparator technology in the cost model for CVC-Sutures

Items	Value	Source
Cost of the comparator per treatment/patient	£5	(17)
Consumables (if applicable)	£24	(17)
Maintenance cost	N/A	
Training cost	N/A	
Other costs (total complications costs)	£1400.7	(4, 9, 12, 21, 23, 24, 26)
Total cost per treatment/patient	£1452.6	

Health-state costs

9.3.8 If the cost model presents health states, the costs related to each health state should be presented in table C8. The health states should refer to the states in section 9.1.7. Provide a rationale for the choice of values used in the cost model.

N/A

Adverse-event costs

9.3.9 Complete table C9 with details of the costs associated with each adverse event referred to in 9.2.4 included in the cost model. Include all adverse events and complication costs, both during and after longer-term use of the technology.

Table C9 List of adverse events and summary of costs included in the cost model

Adverse events	Items*	Value	Source
PICC migration	Episode of care	£250	(19)
PICC malposition	Episode of care	£250	(19)
PICC occlusion	Episode of care	£250	(19)
CVC migration	Episode of care	£450	(23)
CVC malposition	Episode of care	£450	(23)
CVC occlusion	Episode of care	£450	(23)
CRBIS infection	Episode of care	£9,900	(19)
CRT infection	Episode of care	£250	(19)
NI	Episode of care	£321	(24)
Notes: *-Includes technology and staff costs			

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Miscellaneous costs

9.3.10 Describe any additional costs and cost savings that have not been covered anywhere else (for example, PSS costs, and patient and caregiver costs). If none, please state.

Cost analysis does not account for any other costs and cost savings that were not included in the previous cost parameters sections.

9.3.11 Are there any other opportunities for resource savings or redirection of resources that it has not been possible to quantify?

No other resource savings are considered.

9.4 Approach to sensitivity analysis

9.4.1 Has the uncertainty around structural assumptions been investigated? State the types of sensitivity analysis that have been carried out in the cost analysis.

The structural assumptions are relatively straightforward for this model, and generally supported by the literature on the value of improvement in catheter securement.(4, 12, 16, 27-37) Thus, we believe that the uncertainties surrounding the structural assumptions are minimal. As for uncertainty in the input data parameters, we performed one-way deterministic sensitivity analysis on cost of SecurAcath technology and on the probability of complications.

SecurAcath parameters varied include lower and upper bound values for device cost, catheter migration, catheter malposition and catheter occlusion.

9.4.2 Was a deterministic and/or probabilistic sensitivity analysis undertaken? If not, why not? How were variables varied and what was the rationale for this? If relevant, the distributions and their sources should be clearly stated.

Deterministic sensitivity analysis was undertaken. Cost of SecurAcath technology was varied using lower and upper bound values of £12, £20, £32 per device. The rationale behind varying costs supports potential different pricing of the technology that individual health systems may encounter when purchasing the device. Sensitivity analysis was also performed on the probabilities of complications, which are the key outcomes variables.

9.4.3 Complete table C10.1, C10.2 and/or C10.3 as appropriate to summarise the variables used in the sensitivity analysis.

Table C10.1a Variables used in one-way scenario-based deterministic sensitivity analysis for PICC

PICC	Baseline value	SC cost	Sens: -20%	SC cost	SC-AD	Sens: +20%	SC cost	SC-AD
SC Device cost	£16.0	£114.2	£12.8	£111.0	-£43.6	£19.2	£117.4	-£37.2
Migration	0	£114.2	0	£114.2	-£40.3	0.05	£126.7	-£27.9
Malposition	0.0166	£114.2	0.0133	£113.4	-£41.2	0.0199	£115.0	-£39.5
Occlusion	0.1435	£114.2	0.1148	£107.0	-£47.5	0.1722	£121.4	-£33.2
Notes: SC = SecurAcath; AD = Adhesive Device								

Table C10.1b PICC indwell time variable used in one-way scenario-based deterministic sensitivity analysis for adhesive device

Patient type & country (reference)	PICC indwell time	AD average cost	SC average cost	Cost Savings using SC
Cancer patients, US (mean) (7)	25 days	£154.5	£114.2	£40.3
Cancer patients, US (max) (7)	3 months	£187.6	£114.2	£73.4
Cancer patients UK (8)	6 months	£229.3	£114.2	£115.1
Notes: SC = SecurAcath; AD = Adhesive				

Table C10.1c Variables used in one-way scenario-based deterministic sensitivity analysis for CVC

CVC	Baseline value	SC cost	Sens: -20%	SC cost	SC-SU	Sens: +20%	SC cost	SC-SU
SC device cost	£16.0	£447.0	£12.8	£443.8	-£1008.8	£19.2	£450.2	-£1002.4
Migration	0.0	£447.0	0.0	£447.0	-£1005.6	0.05	£469.5	-£983.1
Malposition	0.03	£447.0	0.024	£444.3	-£1008.3	0.036	£449.7	-£1002.9
Occlusion	0.0	£447.0	0.0	£447.0	-£1005.6	0.05	£469.5	-£983.1
CRBSI	0.04	£447.0	0.032	£367.8	-£1084.8	0.048	£526.2	-£926.4
Notes: SC = SecurAcath; SU = Sutures								

Table C10.2a Variables used in multi-way scenario-based sensitivity analysis for PICC

Variable	SC Device cost	Migration	Malposition	Occlusion
Baseline	£16.0	0	0.0166	0.1435
-20%	£12.8	0	0.0133	0.1148
+20%	£19.2	0.05	0.0199	0.1722
Notes: SC = SecurAcath; AD = Adhesive				

Table C10.2b Variables used in multi-way scenario-based sensitivity analysis for CVC

Variable	SC Device cost	Migration	Malposition	Occlusion	CRBSI
Baseline	£16.0	0.000	0.030	0.000	0.04
-20%	£12.8	0.000	0.024	0.000	0.032
+20%	£19.2	0.050	0.036	0.050	0.048
Notes: SC = SecurAcath; SU = sutures					

9.4.4 If any parameters or variables listed in section 9.2.6 were omitted from the sensitivity analysis, provide the rationale.

N/A

9.5 Results of de novo cost analysis

Base-case analysis

9.5.1 Report the total costs associated with use of the technology and the comparator(s) in the base-case analysis. A suggested format is presented in table C11.

Table C11 Base-case results

Securement Method	Total per patient cost (£)
SecurAcath (PICC)	£114.2
Adhesive Device (PICC)	£155.6
SecurAcath (CVC)	£447.0
Sutures (CVC)	£1452.6

9.5.2 Report the total difference in costs between the technology and comparator(s).

The total difference in NHS costs per PICC placement episode with an average of 25 indwelling days is £40 cost savings when utilizing SecurAcath instead of an adhesive device. The total difference in NHS costs for CVC placement episode with an average of 3 indwell days is £1005.6 when utilizing SecurAcath in place of sutures.

For cancer patients in the UK with PICC indwelling days of 6 months NHS cost saving is £115 per patient.

9.5.3 Provide details of the costs for the technology and its comparator by category of cost. A suggested format is presented in table C12.

Table C12a Summary of costs by category of cost per patient for PICC

Item	SC Cost	AD Cost	Increment	Absolute increment	% absolute increment
Technology cost	£28.3	£36.5	-£8.2	£8.2	20.3%
Other technology related costs	£85.9	£118.1	-£32.2	£32.2	79.7%
Total	£114.2	£154.6	-£40.4	£40.4	100%
Notes: SC = SecurAcath; AD = Adhesive. Source: Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee					

Table C12b Summary of costs by category of cost per patient for CVC

Item	SC Cost	SU Cost	Increment	Absolute increment	% absolute increment
Technology cost	£28.3	£11.9	£16.4	£16.4	1.58%
Complications related costs	£418.7	£1440.7	-£1002	£1002	98.42%
Total	£447	£1452.6	-£1005.6	£1005.6	100.0%
Notes: SC = SecurAcath; SU = sutures. Source: Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee					

9.5.4 If appropriate, provide details of the costs for the technology and its comparator by health state. A suggested format is presented in table C13.

N/A

9.5.5 If appropriate, provide details of the costs for the technology and its comparator by adverse event. A suggested format is provided in table C14.

Table C14a Summary of costs by adverse events per patient for PICC

Adverse event	SC Cost	AD Cost	Increment	Absolute increment	% absolute increment
Migration	£0	£14.9	-£14.9	£14.9	20.9%
Malposition	£4.2	£27.5	-£23.3	£23.3	32.7%
Occlusion	£35.8	£30	-£5.8	£5.8	8.1%
CRBSI	£36.5	£36.5	-£27.2	£27.2	32.2%
CRT	£9.2	£9.2	£0	£0	0%
Total	£85.7	£118.1	-£59.6	£59.6	100%
Notes: SC = SecurAcath; AD = Adhesive. Source: Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee					

Table C14b Summary of costs by adverse events per patient for CVC

Adverse event	SC Cost	SU Cost	Increment	Absolute increment	% absolute increment
Migration	£0	£0	£0	0	0.0%
Malposition	£13.5	£13.5	£0	0	0.0%
Occlusion	£0	£27	-£27	£27	2.64%
CRBSI	£396	£1,386	-£990	£990	96.87%
CRT	£9.2	£9.2	£0	£0	0.0%
NI (Sutures only)	£0	£5	-£5	£5	0.49%
Total	£418.7	£1,440.7	-£1022	£1022	100%
Notes: SC = SecurAcath; SU = sutures. Source: Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee					

Sensitivity analysis results

9.5.6 Present results of deterministic one-way sensitivity analysis of the variables described in table C10.1.

Results of deterministic one-way sensitivity analysis in relation to C10.1			
Scenarios	SC Device Cost	Total cost of SC PICC episode	Total cost of SC CVC episode
Base case	£16.0	£114.2	£447.0
-25%	£12.0	£110.2	£443.0
+25%	£20.0	£118.2	£451.0
+200%	£32.0	£ 130.2	£463.0
Notes: SC = SecurAcath			

9.5.7 Present results of deterministic multi-way scenario sensitivity analysis described in table C10.2.

Results of deterministic multi way sensitivity analysis in relation to C10.2a for PICC						
PICC	SC Device cost	Migration	Malposition	Occlusion	SC cost	Saving with SC (SC-AD)
Baseline	£16.0	0	0.0166	0.1435	£114.2	£40.3
-20%	£12.8	0	0.0133	0.1148	£102.0	£52.5
+20%	£19.2	0.05	0.0199	0.1722	£137.9	£16.6
Notes: SC = SecurAcath; AD = Adhesive						

Results of deterministic multi way sensitivity analysis in relation to C10.2b for CVC							
CVC	SC Device cost	Migration	Malposition	Occlusion	CRBSI	SC cost	Saving with SC (SC-SU)
Baseline	£16.0	0.000	0.030	0.000	0.04	£447	£1005.6
-20%	£12.8	0.000	0.024	0.000	0.032	£361.9	£1090.7
+20%	£19.2	0.050	0.036	0.050	0.048	£577.1	£875.5
Notes: SC = SecurAcath; SU = sutures							

9.5.8 Present results of the probabilistic sensitivity analysis described in table C10.3.

N/A

9.5.9 What were the main findings of each of the sensitivity analyses?

The results remain robust in sensitivity analyses. SecurAcath is the least expensive of the three options in all iterations of sensitivity analyses.

9.5.10 What are the key drivers of the cost results?

In the PICC model the key drivers of the cost results for SecurAcath are reduced costs of catheter securement devices as adhesive devices require replacement every 7 days and reduced probability of catheter migration. Occlusion rate yields high costs in the SecurAcath group, however, as noted in the clinical findings occlusion rate variable depends on the nurse team experience level. Key cost drivers for the Adhesive device group are device costs and high catheter migration rate. Key cost driver for the CVC sutures group is a high CRBSI rate which includes catheter related thrombosis and catheter related blood stream infection.

Miscellaneous results

9.5.11 Describe any additional results that have not been specifically requested in this template. If none, please state.

No other miscellaneous results were found in the cost analysis model.

9.6 Subgroup Analysis

9.6.1 Specify whether analysis of subgroups was undertaken and how these subgroups were identified. Cross-reference the response to the decision problem in table A1 and sections 3.2 and 7.4.4.

Subgroups suggested by the scope document included PICC and CVC patients. The cost model accounted for both subgroups and throughout, and results have been presented separately for each of these groups. The model assumed that half of patient population was receiving PICCs and the other half was receiving CVCs in ICU units. These groups were identified based on the cost differences of the catheter placement procedures.

9.6.2 Define the characteristics of patients in the subgroup(s).

Patients who received a PICC and had SecurAcath or adhesive devices applied

to secure the catheter were considered a part of the PICC group. In the cost analysis for PICC patients the model assumes nurses place both catheter securement devices. Patients who received a CVC line and had SecurAcath or sutures applied to secure the catheter were considered to be part of the CVC group. In the cost analysis for CVC patients, the model assumes a nurse places the SecurAcath device whereas a surgeon was assumed to place sutures for catheter securement.

9.6.3 Describe how the subgroups were included in the cost analysis.

There were two cost analysis performed to capture the findings for both PICC and CVC subgroups of patients. Subgroups results were reported through the report.

9.6.4 What were the results of the subgroup analysis/analyses, if conducted? The results should be presented in a table similar to that in section 9.5.1 (base-case analysis).

Subgroup results were presented in the 9.5.1. section as the two separate analyses.

9.6.5 Were any subgroups not included in the submission? If so, which ones, and why were they not considered?

People with comorbidities and people with a medium to long indwell time were assumed to be a part of the PICC and CVC patient groups.

9.7 Validation

9.7.1 Describe the methods used to validate and cross-validate (for example with external evidence sources) and quality-assure the model. Provide references to the results produced and cross- reference to evidence identified in the clinical and resources sections.

Investigators used various published literature referenced in the report to cross check clinical and economic data variables. The results are generally consistent with what would be expected given the clinical performance differential of the SecurAcath device compared to adhesives and sutures.

9.8 Interpretation of economic evidence

9.8.1 Are the results from this cost analysis consistent with the published economic literature? If not, why do the results from this evaluation differ, and why should the results in the submission be given more credence than those in the published literature?

Results of the cost model are consistent with the published literature. Using sutures as a catheter securement option is the costliest option with the highest complication rates as reported in the published literature.(4, 19, 21) Consistent with the clinical findings, SecurAcath shows greater cost savings when used on the patients with medium to long indwell catheter times.(9) Overall SecurAcath would have the largest cost savings to NHS when compared to either adhesive devices or sutures.

9.8.2 Is the cost analysis relevant to all groups of patients and NHS settings in England that could potentially use the technology as identified in the scope?

The cost analysis focused on 4 out of 5 groups of patient identified by scope. The fifth group, children and young people, are assumed to be a part of the patient cohort. All of the clinical studies used in the cost analysis did not distinguish between adults and children in their patient cohorts

9.8.3 What are the main strengths and weaknesses of the analysis? How might these affect the interpretation of the results?

There are two main strengths of the cost study. First, the clinical effectiveness evidence for SecurAcath is strong and consistent. Second, the model relies on a very straightforward and transparent approach to estimating the expected total costs of the intervention and each comparator. The results of the sensitivity analysis further imply that the model is robust to changes in key variables.

9.8.4 What further analyses could be undertaken to enhance the robustness/completeness of the results?

N/A

References

Please use a recognised referencing style, such as Harvard or Vancouver.

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10 Appendices

10.1 Appendix 1: Search strategy for clinical evidence (section 7.1.1)

The following information should be provided:

10.1.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline
- Embase
- Medline (R) In-Process
- The Cochrane Library.

Databases searched include OVID, Medline, Embase, Google, Google Scholar and ClinicalTrials.

10.1.2 The date on which the search was conducted.

June 13th 2016

10.1.3 The date span of the search.

2010 - 2016

10.1.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean).

Free text search terms included securement, stabilisation, central venous catheter, peripherally inserted catheter, PICC, StatLock, replacement, migration, SecurAcath. Headings included PICC migration, replacement. PICC stabilisation. Central venous catheter securement.

10.1.5 Details of any additional searches, such as searches of company or professional organisation databases (include a description of each database).

Additional searches included the company database (repository of published and unpublished data)i.e inclusive of posters presented at vascular access conferences. Additional search of Association Vascular Access Journal, Infusion Nursing Society, British Journal Nursing.

10.1.6 The inclusion and exclusion criteria.

As described in the scope there is no other comparable technology available to date, subsequently publications including either the name of the technology or accurate descriptor were included.

10.1.7 The data abstraction strategy.

No

10.2 Appendix 2: Search strategy for adverse events (section 7.7.1)

The following information should be provided.

10.2.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline

- Embase
- Medline (R) In-Process
- The Cochrane Library.

Two searches were completed, Medicines and Healthcare products Regulatory Agency (MHRA) and Manufacturer and User Facility Device Experience (MAUDE)

10.2.2 The date on which the search was conducted.

June 13th 2016

10.2.3 The date span of the search.

2010 - 2016

10.2.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean).

SecurAcath

10.2.5 Details of any additional searches (for example, searches of company databases [include a description of each database]).

None

10.2.6 The inclusion and exclusion criteria.

Included all data related to the text SecurAcath

10.2.7 The data abstraction strategy.

None

10.3 Appendix 3: Search strategy for economic evidence (section 8.1.1)

There are very few articles focused on the cost consequences or cost

effectiveness of catheter securement methods. We conducted a systematic search of PubMed and Embase using the following search logic: (PICC or CVC) and (economic# or cost#) and (securement device). The overall search objective was to retrieve and review research articles that assessed the cost impact or cost effectiveness (or budget impact) of alternative central catheter securement devices. In addition to addressing this main search objective, the other inclusion requirement was that articles had to exhibit the following attributes: (1) English language; (2) Abstract present; (3) contain an empirical assessment of costs, in the form of cost minimization, cost consequence (or impact), cost effectiveness, or budget impact; and (4) contain a comparison of at least two catheter securement options.

This search yielded a total of 2 articles. Using PubMed's "Related Articles" feature for these 2 articles, we identified another 297 articles. The abstracts of each of these articles was searched for relevance to the search objective. Only 3 articles were deemed to be relevant to the main search objective and satisfied the four inclusion criteria. All of the 294 excluded articles were excluded due to failure to meet inclusion criteria #3 or #4.

10.4 Appendix 4: Resource identification, measurement and valuation (section 9.3.2)

The following information should be provided.

10.4.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline
- Embase
- Medline (R) In-Process
- NHS EED
- EconLIT.

The specific databases searched and the service provider used included:

- Medline
- Embase
- Medline (R) In-Process
- NHS EED

10.4.2 The date on which the search was conducted.

Investigators finished the search on 07/27/2016

10.4.3 The date span of the search.

Investigators conducted the search from 07/01/2016-07/28/2016

10.4.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean).

- PICC or CVC
  AND:
- Complications
- Catheter
- Securement
- Device
- Phlebitis
- Occlusion
- Infiltration
- Dislodgement
- Adherence
- Leakage

The complete search strategies used, including all the search terms: text words (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean).

10.4.5 Details of any additional searches (for example, searches of company databases [include a description of each database]).

Some clinical information was also supplied by the company

10.4.6 The inclusion and exclusion criteria.

Studies had to include explicit estimates or measures of rates and probabilities for central catheter complications, disaggregated by type of securement device

10.4.7 The data abstraction strategy.

Data was abstracted from the studies that met inclusion criteria. It was not possible to conduct meta-analysis (e.g., inverse variance weighting) based on the selected studies within each complication area. This was due mainly to heterogeneity in populations, securement technology, dwelling times, etc. Thus, we based the probabilities used in the model on studies meeting two basic criteria: (1) relevance of populations; and (2) relevance of data reported.

11 Related procedures for evidence submission

11.1 Cost models

Attached

11.2 Disclosure of information

N/A

11.3 Equality

N/A