NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

The SecurAcath device for securing percutaneous catheters

1 Technology

1.1 Description of the technology

SecurAcath is a single use device used to secure round-shafted percutaneous catheters in place on the skin. There are 2 components, a base and cover. The base comprises two metal tips which form an anchor in the skin incision and two foldable arms. The cover holds the catheter shaft in place and clips into the base. The device is designed to remain in situ throughout the period of catheter residency and does not usually need replacement during this time. SecurAcath is available in 6 different sizes (3F to 8F) and the decision on which size device to select is determined by the catheter diameter. The closest smaller size of SecurAcath should be chosen, for example an 8F SecurAcath with an 8.5F catheter. SecurAcath is latex free and is MRI compatible (3 Tesla or less). The device can be lifted away from the skin to allow 360º cleaning of the insertion site.

1.2 Regulatory status

The SecurAcath device received a CE mark in December 2009 for the subcutaneous securement of implantable percutaneous medical devices.

1.3 Claimed benefits

The benefits to patients claimed by the company are:

- No interruptions or delays in therapy due to improved catheter securement
- Fewer repeat procedures by improving vessel preservation and reducing reinsertions

- Reduction in catheter complications (dislodgements, migration, thrombosis and infection)

The benefits to the healthcare system claimed by the company are:

- A decrease in catheter replacement costs
- A reduction in overall treatment costs through the avoidance of delays and complications

1.4 Relevant diseases and conditions

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 although this is outside the scope of this evaluation.

The target population for the device notified by the company is all patients receiving an intravascular catheter for central venous access.

Based on expert advice and using 2012/13 hospital episodes statistics data, it is estimated 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.

The technology is likely to be predominantly used in older, critically ill patients, who are likely to have a number of co-morbidities and in patients following major trauma, or those with conditions requiring long-term ongoing therapy such as cancer. In these individuals, catheters often need to remain in place for long periods of time. Central venous catheters are also used to deliver and remove blood, allow infusion of fluids and nutrition and medicines as well as to facilitate kidney dialysis. Current methods used to secure catheters such as the application of adhesive devices can interfere with the cleaning of the skin and need to be removed and replaced to allow this. This may predispose to infection. Failure to secure a catheter sufficiently, and changing the securement device, can lead to catheter migration resulting in complications such as malfunction of the catheter, erroneous measurement of central

venous pressure, catheter erosion leading to vessel rupture and cardiac tamponade as well as thrombophlebitis of large or central veins. In addition, the catheter may inadvertently fall out or be pulled out leading to loss of venous access. In its notification, the company stated that SecurAcath may be of particular benefit in patients for whom adhesive securement devices would not be suitable, such as those with skin burns or diaphoresis (profuse perspiration).

1.5 Current management

Current catheter securement options include adhesive devices such as StatLock and Grip-Lok and the use of steristrips and sutures.

NICE has not produced any guidance on securing intravascular catheters for central venous access

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 the use of securing devices such as StatLock in preference to stitches, and therefore discourage the suturing of catheters to the skin[1].

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 of intravascular catheters. This is a category II recommendation which is defined as 'those practices where there is only suggestive or less definitive evidence'[2].

A number of hospital trusts have produced local guidance on using 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

[1] Bishop L, Dougherty L, Bodenham A et al (2007) Guidelines on the insertion and management of central venous access devices in adults; International Journal of Laboratory Hematology 29 (4) 261-278

[2] Grady, N.P. et al (2011). Guidelines for the prevention of intravascular catheter-related infections

StatLock, Grip-Lok) should be used to prevent catheter migration and dislodgement in patients with a PICC or midline catheter.

The NICE guideline on infection control provides guidance on preventing infection in 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.

2 Reasons for developing guidance on SecurAcath for securing percutaneous catheters

The Committee concluded that SecurAcath may offer benefits to patients and the healthcare system when used to secure percutaneous catheters in a carefully selected group of patients.

The Committee was advised that SecurAcath is most suitable for use in adult patients who have a PICC placed with a medium to long dwell time expected at the time of insertion.

The Committee noted an ongoing trial comparing SecurAcath with StatLock in percutaneous catheter securement. It considered that the evidence from this study as well as the existence or emergence of further audit data about the use of SecurAcath would be potentially important to any evaluation, and should inform the scheduling of the assessment.

3 Statement of the decision problem

	Scope issued by NICE	
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	
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, specifically related to equality issues	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.
* includes peripherally inserted central catheter [PICC], non-tunnelled or tunnelled (e.g. Hickman) central venous catheter [CVC]	

4 Related NICE guidance

Published

- The Sherlock 3CG Tip Confirmation System for placement of peripherally inserted central catheters (2015) NICE medical technologies guidance 24
- The 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites (2015) NICE medical technologies guidance 25
- Guidance on the use of ultrasound locating devices for placing central venous catheters (2002) NICE technology appraisal guidance 49
- Healthcare-associated infections: prevention and control in primary and community care (2012) NICE guideline CG139
- Healthcare-associated infections: prevention and control (2011) NICE guideline PH36
- Surgical site infections: prevention and treatment (2008) NICE guideline CG74
- Prevention and control of healthcare-associated infections (2015) NICE pathway
- Infection prevention and control (2014) NICE quality standard 61
- Surgical site infection (2013) NICE quality standard 49

Evidence updates

- Infection: Evidence Update 64, September 2014. A summary of selected new evidence relevant to NICE clinical guideline 139 'Prevention and control of healthcare-associated infections in primary and community care' (2012). Available from: https://www.nice.org.uk/media/default/About/what-we-do/Evidence%20Services/Evidence-Updates-list.pdf

- Surgical site infection: Evidence Update 43, June 2013. *A summary of selected new evidence relevant to NICE clinical guideline 74 'Prevention and treatment of surgical site infection' (2008).* Available from: https://www.nice.org.uk/media/default/About/what-we-do/Evidence%20Services/Evidence-Updates-list.pdf

Under development

None identified:

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- Association of Surgeons in Primary Care
- British Cardiovascular Intervention Society
- Intensive Care Society
- Royal College of Nursing
- Royal College of Physicians
- British Association of Critical Care Nurses
- National Infusion and Vascular Access Society
- Infection Prevention Society

5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Association of Surgeons in Primary Care
- British Cardiovascular Intervention Society
- Intensive Care Society
- Royal College of Nursing

- Royal College of Physicians
- British Association of Critical Care Nurses
- National Infusion and Vascular Access Society
- Infection Prevention Society

5.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Critical Care Patient Liaison Committee (CritPaL)
- BME cancer.communities
- British Kidney Patient Association
- Cancer Black Care
- Cancer Equality
- Cancer of Unknown Primary (CUP) Foundation - Jo's Friends
- Cancer52
- Children with Cancer
- CLIC Sargent
- Crohn's and Colitis UK
- HAWC
- Helen Rollason Cancer Charity
- ICU Steps
- Independent Cancer Patients' Voice
- Macmillan Cancer Support
- Maggie's Centres
- Marie Curie Cancer Care
- MRSA Action UK
- National Kidney Federation (NKF)
- Kidney Research UK
- PINNT (Patients on Intravenous and Nasogastric Nutrition Therapy)
- Rare Disease UK
- Rarer Cancers Foundation

- Royal College of Surgeons of England (RCSeng)
- Sue Ryder
- Teenage Cancer Trust
- Tenovus Cancer Care
- Together for Short Lives
- Ulcerative Colitis UK.