NICE National Institute for Health and Care Excellence

National Institute for Health and Care Excellence
Centre for Health Technology Evaluation

Pro-forma Response

External Assessment Centre Report factual check

The SecurAcath device for securing percutaneous catheters

Please find enclosed the assessment report prepared for this assessment by the External Assessment Centre (EAC).

You are asked to check the assessment report from Newcastle and York to ensure there are no factual inaccuracies contained within it. If you do identify any factual inaccuracies you must inform NICE by 2pm, **08 September 2016** using the below proforma comments table. All your comments on factual inaccuracies will receive a response from the EAC and when appropriate, will be amended in the EAC report. This table, including EAC responses will be presented to the Medical Technologies Advisory Committee and will subsequently be published on the NICE website with the Assessment report.

5 September 2016

NICE National Institute for Health and Care Excellence

Issue 1

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Pg. 6, 39 and 50 - sponsor's claim that the technology is likely to be predominantly used in older, critically ill patients	Remove sponsor's claim that the technology is likely to be predominantly used in older, critically ill patients	Sponsor did not make this claim. Technology is for any patient that requires a catheter	We would like to thank the sponsor for their comment. Although the sponsor did not use the word 'claim', in their economic submission page 23, section 9.1.2 they write '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.' The EAC therefore believes that within their submission the sponsor supports the assumption that the technology will be predominantly be used for this population. Based on the above we changed the wording (changes in red and strikethrough) of the section as follows: 'to support the assumption included in the sponsor's ~~claim~~ cost analysis that 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.

Issue 2

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Pg. 24 - SecurAcath is a single use securement device indicated for short or long term securement of percutaneous indwelling catheters for intravenous use to the access site by means of a subcutaneous anchor at the insertion site. Once in place it secures the catheter for the duration of therapy. It is not currently indicated for conventional peripheral intravenous catheters	SecurAcath is a single use securement device indicated for short or long term securement of percutaneous indwelling catheters to the access site by means of a subcutaneous anchor at the insertion site. Once in place it secures the catheter for the duration of therapy. The SecurAcath is not currently available for conventional peripheral intravenous catheters.	Correct indications for CE mark are for percutaneous indwelling catheters, not intravenous specific. The peripheral IV design is covered under the indications, it is just not available yet.	We would like to thank the sponsor for the extra information provided regarding the SecurAcath CE mark. We have implemented the suggested changes into the assessment report.

Issue 3

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Pg. 115 - EAC concludes that there is insufficient evidence to determine that SecurAcath is clinically superior in effectiveness and adverse events to StatLock.	EAC concludes that the SecurAcath is clinically superior in effectiveness and adverse events to StatLock with regard to catheter dislodgements.	SecurAcath dislodgement rate of 1.03% compared to StatLock rate of 4.97%	The conclusions drawn from the evidence included in the assessment report is based not only on the numbers reported, such as the confidence interval of the dislodgment rate, but also the clinical and statistical significance and the methodological quality of the assessed studies. The numbers quoted by the manufacturer represent the confidence intervals reported by the EAC's meta-analysis. It is noted, that the studies included in the meta-analysis have potentially many sources of bias which unfortunately cannot be assessed due to the majority of the evidence being presented as conference proceedings. As a result, the EAC does not consider the results of the meta-analysis in isolation but in comparison with the results reported by the RCT which did not show superiority of SecurAcath in respect to the dislodgment rates. In addition, the majority of the studies included in the

			meta-analysis did not directly compare SecurAcath with StatLock. Based on the above reasoning the EAC concludes that there is insufficient evidence that SecurAcath is clinically superior in effectiveness and adverse events to StatLock. The EAC does not accept the sponsor's proposed amendment.

Issue 4

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Pg. 122, 154 and 156 - submission had not fully addressed the specified scope in failing to include adhesive devices in particular as a comparator to SecurAcath for the securement of CVC lines	Adhesive devices were not included as a comparator for securing of CVCs because adhesives have not been accepted or adopted in clinical practice or CVC securement.	Approximately 90% of CVCs are currently secured with sutures. It is reasonable to use suture as the only comparator.	The EAC understands that the traditional method of attachment of CVC lines is suturing and practice remains overwhelmingly in favour of suturing. However, the EAC believes that both adhesive devices (StatLock) and SecurAcath are clinically acceptable alternatives to suturing. For example, a number of NHS Trust guidelines included in the assessment report (please see page 33 of our assessment report) propose sutures or StatLock as appropriate alternatives to the securement of CVCs. In light of this and the available evidence on the use of both StatLock and

			SecurAcath for securing CVC lines the EAC regards StatLock as a relevant comparator to suturing for CVC lines.