National Institute for Health and Care Excellence

Medical technologies evaluation programme

MT582 AnaConDa-S for sedation with volatile anaesthetics in intensive care

Consultation comments table

Final guidance MTAC date: 12 November 2021

There were 16 consultation comments from 2 consultees:

- 9 Comments from the manufacturer
- 7 Comments from the EAC

The comments are reproduced in full, arranged in the following groups

- Technology (comments 1 to 2)
- Inaccuracies (comments 3 to 16)

#	Consultee ID	Role	Section	Comments	NICE response
Technology					
1	1	Manufacturer		Product Name Change From October 1st 2021, AnaConDa will change name to Sedaconda ACD, where ACD is an abbreviation for Anaesthetic Conserving Device. The new name is part of a global unification of Sedana Medical's product brands and will not affect	Thank you for your comment. The name of the device will be updated in the final guidance.

				the appearance or function of the AnaConDa device in any way. For more than a decade, AnaConDa has enabled simple and efficient delivery of volatile anaesthetics to invasively ventilated patients. Sedaconda ACD will continue to support our vision to make inhaled anaesthetics available to critically ill patients everywhere.	
2	1	Manufacturer	2.5	Regulatory approval for isoflurane for sedation in ICU. update Section 2:5: "Volatile anaesthetics are not licenced" In July 2021 the company received a positive outcome for its European registration application for the drug Sedaconda (isoflurane) for inhaled sedation. Sedaconda is indicated for sedation of mechanically ventilated adult patients during intensive care and should only be administered via the medical device AnaConDa. (https://www.sedanamedical.com/?page_id=4760) Post Brexit, the UK process is separate. The company submitted its regulatory file to MHRA in Q1 2021, a decision is expected in 2022. We suggest draft MTAC notes 'regulatory approval for adults in UK is pending' until this date.	Thank you for your comment. Section 2.5 of the guidance has been amended to include that "regulatory approval for adults in the UK is pending".
Inaccuracies					
3	1	Manufacturer	2.2	Should anaesthesia be replaced with sedation depth?	Thank you for your comment. Section 2.2 of the guidance has been adapted to sedation terminology
4	2	EAC	2.2	Section 2.2. uses 'anaesthesia' (or derived words), where perhaps using 'sedation' (and derived words would be better.	Thank you for your comment. Section 2.2 of the guidance has been adapted to sedation terminology
5	1	Manufacturer	2.8	Should this be intravenous sedation?	Thank you for your comment. Section 2.8 of the guidance has been amended to 'intravenous sedation'

6	1	Manufacturer	4.10	Title – AnaConDA – typo	Thank you for your comment. Typo in section 4.10 of the guidance has been amended
7	1	Manufacturer	4.10	5th Bullet – Peoples	Thank you for your comment. Typo in section 4.10 of the guidance has been amended
8	1	Manufacturer	4.10	6th Bullet – Cardiac Attack – I think this should be post cardiac arrest?	Thank you for your comment. Section 4.10 of the guidance has been amended to include “post cardiac arrest”
9	1	Manufacturer	4.10	Whole section 4.10 should People be replaced with Patients?	Thank you for your comment. It is NICE style to use people instead of patients
10	1	Manufacturer	4.12	we have three training modules that have been independently accredited with CPD Points. Can this be added as well as the opinion of the clinical experts	Thank you for your comment. The 3 accredited online learning modules have been added to the guidance
11	2	EAC	2.7	AnaConDa-S is not the only technology allowing to use volatile sedation (point 2.7 and 4.1), both our assessment report and expert advice (MTG Medtech Guidance pp.11-12 | page 503-504 of consultation pack) state this (and this is also evident from the company’s submission), with the expert explicitly naming the MIRUS.	Thank you for your comment. Section 2.8 and 4.1 has been changed to omit the statement that Sedaconda ACD is the only device for delivery of volatile sedation.
12	2	EAC	2.9	Suggest wording change from 'likely' to 'predominantly' intensivists and intensive care nurses. The clinical experts have highlighted that technical staff might be involved.	Thank you for your comment. Section 2.10 has been amended to include “In the NHS this would likely be intensivists, intensive care nurses and other technical staff.”
13	2	EAC	3.1	This is inaccurate - 2 were cross-over, 12 were RCTs, 1 prospective, 5 retrospective and 1 with a prospective AnaConDa arm	Thank you for your comment. Section 3.1 of the guidance has been amended to “Twelve were randomised controlled trials, 2 cross-over studies, 5 retrospective studies, 1 prospective study, and

					1 study collected data prospectively for the AnaConDa-S arm”
14	2	EAC	3.8	Should be 8 publications, not studies, for neurological outcomes.	Thank you for your comment. Section 3.8 of the guidance has been amended to 8 publications
15	2	EAC	3.11	This statement is inaccurate 'AnaConDa-S was cost saving compared with intravenous propofol when the duration of non-ventilated intensive care days was in the region of 0.5 days to 0.6 days lower.' Following the corrections to the economic modelling, the sensitivity analysis suggests that AnaConDa remains cost saving even when duration of ICU stay is slightly longer (see Addendum)	Thank you for your comment. Section 4.15 of the guidance has been amended to reflect the EAC addendum: “Sedaconda ACD-S was cost saving when duration of non-ventilated days in intensive care was only a few hours shorter than that of intravenous sedation (2.5 hours to 5 hours).”
16	2	EAC	4.8	Typo (‘anaesthetia’)	Thank you for your comment. Typo in section 4.8 of the guidance has been amended