

GUIDANCE FOR DIRECTORS OF ANESTHESIA SERVICE FOR COMPUTER-ASSISTED PERSONALIZED SEDATION (CAPS) DEVICES

Committee of Origin: Quality Management & Departmental Organization

On May 3, 2013, Ethicon Endo-Surgery, Inc., a subsidiary of Johnson & Johnson (EES), announced that the Food and Drug Administration (FDA) granted Premarket Approval for the SEDASYS® System, a computer-assisted personalized sedation (CAPS) system designed to achieve and maintain minimal-to-moderate sedation. The SEDASYS® System was introduced on a limited basis beginning in 2014 and is likely to be followed in the marketplace by other similar CAPS devices.

This guidance document will provide recommendations on specific clinical and administrative issues that Directors of Anesthesia Services (DAS) and practicing anesthesiologists should discuss with Directors of Gastroenterology Services in order to integrate CAPS devices into practice in the safest and most efficient fashion.

- 1. Uniform Standard of Care:** ASA recommends that there be a uniform standard of care for sedation and anesthesia, based on the level of sedation, throughout all facilities and all practice locations, including those contemplating the use of CAPS devices. This document seeks to clarify these standards of care as they apply to the utilization of CAPS. Consistent with a uniform standard of care for sedation and anesthesia, the Centers for Medicare and Medicaid Services hospital Conditions of Participation (CoP) (42CFR§482.52) and their applicable interpretive guidelines specifically define existing Federal requirements that a hospital furnishing anesthesia services, including anesthesia and analgesia, must provide these services in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy, the Director of Anesthesia Services. The Director of Anesthesia Services is responsible for all anesthesia administered in the hospital.
- 2. FDA Device Labeling:** ASA recommends that the health care facility, DAS and the users of the CAPS device be familiar with the FDA labeling information on the operation and safe use of the device. ASA **STRONGLY RECOMMENDS** that facility policies regarding the operation of the device should be entirely consistent with the manufacturer's recommendations and FDA labeling requirements.
 - **Indications:** The device label requires that the SEDASYS® System is indicated for "the intravenous administration of 1% (10 mg/mL) propofol injectable emulsion for the initiation and maintenance of **minimal-to-moderate sedation**, as defined by the American Society of Anesthesiologists (ASA) Continuum of Depth of Sedation, in ASA physical status I and II patients ≥ 18 years old undergoing colonoscopy and esophagogastroduodenoscopy (EGD) procedures." **Therefore, FDA approval of SEDASYS® is limited to ONLY minimal to moderate sedation and to ONLY these two procedures.**
 - **Restriction of Use:** The device labeling states that "[t]he SEDASYS® System must only be used in hospitals and/or health care facilities where an anesthesia professional is immediately available for assistance or consultation as needed. The definition of 'immediate availability of an anesthesia professional' will be determined by each individual facility." In order to implement this restriction, ASA **RECOMMENDS** that "immediate availability" as it relates to the FDA restriction on the use of CAPS devices could mean a code team or rapid response team, which includes an anesthesia professional as defined by CMS, at a minimum.

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Disclaimer: This document has been developed by the ASA's Ad Hoc Committee on SEDASYS®, but has not been reviewed or approved as a practice parameter or policy statement by the ASA House of Delegates. This document does not constitute an endorsement by ASA of the SEDASYS® System, nor does ASA make any assessment of, or representations regarding the safety of the SEDASYS® System. This document is not intended to provide operating instructions for use of the SEDASYS® System, the operation of which must be consistent with manufacturer and governmental guidelines. Variances from recommendations contained in this document may be acceptable based on the judgment of the responsible anesthesiologist. The recommendations are designed to encourage quality patient care and safety in the workplace, but cannot guarantee a specific outcome. They are subject to revision from time to time as warranted by the evolution of technology and practice. This document is not intended to provide legal advice. Federal and state laws and regulations referenced in this document are subject to change and there are considerable variations among state requirements. We strongly encourage consultation with legal counsel regarding specific laws and requirements applicable to your practice.

In March 2016, Johnson & Johnson, the manufacturer of SEDASYS®, announced they would be halting the sale of the device. However, this document serves to address any potential uses of a CAPS device in the future, including SEDASYS®.

- Training in the management of the cardiorespiratory effects of propofol: The device labeling provides that “[a]t a minimum, the member of the physician-led team who is administering sedation must have training in the management of the cardiorespiratory effects of propofol when administered using computer-assisted personalized sedation systems.” To be consistent with moderate sedation training and education requirements throughout the facility, ASA STRONGLY RECOMMENDS that the physician responsible for the sedation and operation of the CAPS device (i.e., the physician performing the procedure) be required to receive this training as he/she is ultimately responsible for the proper use of the CAPS device. Pursuant to the device label, this training must include:
 - Pharmacology of propofol.
 - Identification of high risk patients.
 - Recognition of progression of levels of sedation, and actions necessary to return a patient to intended levels of sedation.
 - Use of capnometry and the determination of adequate ventilation.
 - Management of airway obstruction and hypoventilation.
 - The moderate sedation training program developed and submitted to the FDA to meet this labeling requirement was reviewed and endorsed by the International Society for Anaesthetic Pharmacology (ISAP). ASA RECOMMENDS that DAS familiarize themselves with the program to determine suitability for their environment. Based on exposure to these materials, the DAS may choose to recommend additional education based on a variety of factors, including but not limited to, the local environment or the findings of the facility QAPI program.
 - Co-administration of sedative hypnotics: The device labeling provides that “The SEDASYS® System is designed to be used with a single premedication dose of fentanyl (25 to 100 mcgm) given approximately 3 minutes before the start of the propofol infusion.”
3. **Role of the DAS:** Consistent with CMS CoP (42CFR§482.52), the DAS has the authority and responsibility for directing the administration of all anesthesia services, including anesthesia and analgesia throughout the hospital (including all departments in all campuses and locations where anesthesia services are provided) and has the responsibility for evaluating the quality and appropriateness of the anesthesia patient care as part of the hospital’s Quality Assessment / Performance Improvement (QAPI) program. These DAS responsibilities include oversight of sedation provided by CAPS devices.
4. ASA recommends that the DAS revise the facility quality management program in procedural sedation to include data collection on all procedural sedation including CAPS in all hospitals and health care facilities where procedural sedation is performed.
- A recommended guide for the DAS on quality metrics and data collection is “Procedural Sedation Metrics,” which was developed by the Anesthesia Quality Institute. Various databases could be used for outcomes collection and analysis. These data will be instrumental in evaluating the safety and outcomes of all patients undergoing procedural moderate sedation.
5. **Need for anesthesiology consultation:** Health care facilities and the DAS should outline a specific expected role for anesthesiologists as it relates to assistance or consultation. More specifically, ASA RECOMMENDS Gastroenterology Services formally request a consultation on any patient for whom they have concerns about sedation, including but not limited to, patients for whom they have concerns about meeting eligibility requirements as specified by the device manufacturer (e.g., determining the physical status of a patient).

6. **Conduct of the medical procedure in response to alarms:** ASA RECOMMENDS during any alarm state, red or yellow, the conduct of the medical procedure should be stopped if doing so does not immediately and significantly compromise patient safety. If the medical procedure cannot be stopped and the physician remains committed to performing the procedure, the infusion should be stopped and the physician should immediately call for help.
- The care team should immediately and accurately assess the patient, equipment and the environment. The results of this assessment should be discussed verbally among all members of the care team, most principally between the physician and the nurse assigned to monitor the administration of sedation to determine the cause of the alarm state and to decide upon the appropriate therapeutic intervention. This guidance is outlined as follows:
 - **STOP:** the conduct of the medical procedure if doing so does not immediately and significantly compromise patient safety. If the medical procedure cannot be stopped and the physician remains committed to performing the procedure, the infusion should be stopped and the physician should immediately call for help.
 - **ASSESS:** the patient, equipment, and environment to determine the cause of the alarm state.
 - **DISCUSS:** involve the whole team to consider the differential diagnosis and therapeutic alternatives.
 - **MANAGE:** the patient's condition.
 - **INTERVENE:** as indicated, to correct the cause of the alarm state.
 - **MONITOR:** for resolution of the condition.