Conditions of FDA Pre-Market Approval

• For SEDASYS® Users
  – Patients ASA I and II, Greater than 18 Years Old
  – Procedures – Colonoscopy and EGD
  – Level of Sedation – Minimal to Moderate
    • ASA Continuum of Depth of Sedation
  – Approved Training in Device Use
Conditions of FDA Pre-Market Approval

• Involving Anesthesiologists
  – Used only in health care facilities where anesthesia professional is **Immediately available** on site to
    • Respond to emergency
    • Provide consultation
  – Meaning of “Immediate Availability” determined by the Facility
Conditions of FDA Pre-Market Approval

• For Ethicon Endo-Surgery - SEDASYS® Manufacturer
  – Post Marketing Studies
    • User Response to Alarm Systems
      – Multi-center study of 866 patients
      – Primary End Point – percentage of documented responses to alarms
        • Expectation – 100%
      – Secondary End Points – Sufficiency of Response, Hands-on Airway
        Rescue interventions by anesthesia professionals
  • Use in Routine Clinical Practice
    – 7,430 patients
    – Primary End Point – total anesthesia professional rescue interventions
      • 99% certainty that Anesthesiologist Interventions < 1/1,000 patients
    – Secondary End Points – Number of Patients Requiring Bag Mask
      Ventilation or Artificial Airway Interventions

– Determine whether the Pre-Market Approval condition of Immediate Anesthesiologist Availability can be Removed
Roles of Anesthesiologists Related to SEDASYS®

• Facility Administrators
  – Directors of Anesthesia Services
    • Centers for Medicare and Medicaid Services - Hospital Conditions of Participation Require that Facilities:
      – *must* provide these[anesthesia and analgesia] services *in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy*. The service is responsible for all anesthesia administered in the hospital.

• Clinicians in Endoscopy Suites
  – caring for patients before, during, or after using SEDASYS® in the GI Suite
ASA Initiatives – Introduction of SEDASYS® into the Market

- Meet with Other Organizations
  - FDA Representatives
    - Clarify Conditions of Pre-Market Approval for SEDASYS®
  - Ethicon Endo-Surgery to Safely and Efficiently Integrate SEDASYS® into Practice
- American Hospital Association
  - Meetings regarding ASA major initiatives – Perioperative Surgical Home
  - Discussing the Training program for SEDASYS®
  - Anesthesiologist availability
ASA Initiatives – Introduction of SEDASYS® into the Market

• Develop Guidance for Anesthesiologists and Directors of Anesthesia Services regarding SEDASYS® and Future CAPS Devices

• Member Input – SEDASYS@asahq.org
ASA Recommendations – Directors of Anesthesia Services (DAS)

Uniform Standard of Care

• That there be a uniform standard of care for sedation and anesthesia throughout any facility, including those contemplating the use of CAPS devices.
  – Based on the Level of Sedation
    • ASA Continuum of Depth of Sedation
  – SEDASYS® Adheres to Same Uniform Standards for Minimal/Moderate Sedation
  – SEDASYS® May Help to Establish Uniform Standards throughout Facility
ASA Recommendations – Directors of Anesthesia Services (DAS)

Device Labeling

• That the DAS and the Users of the device be familiar with the FDA Labeling Information on the Operation and Safe Use of the Device.

• Facility Policies and Practice regarding the operation of the device should be Consistent with the Manufacturer’s Recommendations and FDA Labeling Requirements.
ASA Recommendations – Directors of Anesthesia Services (DAS)

Quality Assurance-Performance Improvement

• That the DAS Revise the Facility Quality Management Program in Procedural Sedation to Include Collection of Data on CAPS devices.

• The Anesthesia Quality Institute has developed Quality Metrics for Procedural Sedation - Procedural Sedation Metrics.
  - Useful guide for the DAS
  - Instrumental in evaluating the safety and outcomes of all patients undergoing procedural moderate sedation.
Anesthesia Quality Institute
“Core Procedural Sedation Metrics”

Volume Metrics
• Type and number of procedures performed
• Number of patients receiving light or moderate sedation
  – Number receiving sedation via Computer-Assisted Personalized Sedation (CAPS)
• Number of patients receiving deep sedation
• Number of patients cared for by an anesthesia team

Outcomes
• Cases completed as planned, without complication, versus:
• Cases cancelled due to patient discomfort or anxiety
• Cases with unplanned escalation in the continuum of sedation
• Patients receiving rescue medication: flumazenil or naloxone
• Unplanned respiratory support required in light or moderate sedation cases
  – Placement of nasal trumpet or oral airway
  – Placement of supraglottic airway (e.g. LMA) or endotracheal tube
  – Assisted ventilation with bag-valve-mask
  – Oxygen saturation < 85% for greater than 3 minutes
• Patients experiencing a serious adverse event (e.g. perforation, anaphylaxis, cardiac arrest)
• Unplanned admission of an outpatient within 24 hours
• Unplanned patient transfer to an Emergency Department
As the quality program matures and information technology capabilities advance, these data will enable further improvements in patient care:

- Patient demographics: age, sex, ASA Physical Status
- Procedure duration
- Medications used: doses and times
- PACU and facility length of stay
- Patient satisfaction: at PACU discharge and at 48 hours post-procedure
- Provider satisfaction: proceduralist and nursing staff
ASA Recommendations – Directors of Anesthesia Services (DAS)

Anesthesiologist Availability

- **SEDASYS® System** … used in hospitals and/or healthcare facilities where an anesthesia professional is immediately available for assistance or consultation as needed [Conditions of PreMarket Approval]
  
  – Definition of ‘immediate availability’ determined by each individual facility.” [Ethicon Users Guide]
ASA RECOMMENDS that hospitals and healthcare facilities outline a **specific expected role for anesthesiologists** as it relates to assistance or consultation.

ASA RECOMMENDS that the definition of “immediate availability” as it relates to rescue for CAPS devices means the level of a **code team or rapid response team**, which includes an anesthesia professional, at a minimum.
ASA RECOMMENDS Gastroenterology Services Formally Request a Consultation on any patient for whom they have Concerns about Sedation, including but not limited to, Patients who may not Meet Eligibility Requirements as specified by the device Manufacturer (e.g. determining the physical status of a patient).
Categories of Patients at Increased Risk

- Defined in SEDASYS® User’s Guide
  - Patients with a full stomach.
  - Patients using a fentanyl patch.
  - Patients with abnormal airway or diagnosed sleep apnea.
  - Patients with gastroparesis.
  - Patients with Body Mass Index ≥ 35.
  - Patients undergoing both colonoscopy and EGD during the same procedure.
  - Patients undergoing emergent procedure.
- Other Categories of Patients
  - Cannot Cooperate or Understand Instructions
  - Will likely need Deeper Level of Sedation
ASA Recommendations – Directors of Anesthesia Services (DAS)

Training Requirements

• **ASA STRONGLY RECOMMENDS** that the physician responsible for the sedation and operation of the CAPS device be required to receive this training
  – Often the physician performing the GI procedure
  – He/she is ultimately responsible for the proper use of the CAPS device.

• **ASA RECOMMENDS** DAS familiarize themselves with the training program to determine suitability for their environment.
  – Based on this review, the DAS may recommend additional education based on the local environment or the findings of the facility QAPI program.
ASA Recommendations – Directors of Anesthesia Services (DAS)
Co-Administration of Sedatives/Analgesics

• Device labeling “[t]he SEDASYS® System is designed to be used with a single premedication dose of fentanyl (25 to 100 mcg) given approximately 3 minutes before the start of propofol infusion.”
  – Important safety feature on which device design is based

• ASA RECOMMENDS that the operation of the device be consistent with this recommendation
ASA Recommendations – Directors of Anesthesia Services (DAS)

Alarm Conditions

DOSING IN RESPONSE TO ALARMS: ASA RECOMMENDS that when Drug Administration (either by PRN or infusion) is Stopped by the System during a Respiratory Alarm State, yellow or red, it should not be reinitiated by the user until the reason for the alarm state has been addressed and corrected.

For a cardiovascular red alarm, the infusion should be manually discontinued until the reason for the alarm has been addressed and corrected.
Summary of ASA Recommendations for Director of Anesthesia Services

- Uniform Standard of Care for Sedation and Anesthesia
- Facility Policies Follow Device Labeling
- Include SEDASYS® in Facility Sedation QA Program
- Anesthesiologist Availability
  - For Patient Rescue – Code or Rapid Response Team
  - Consultation – Planned Preoperatively for Patient Selection and Preparation
- Training
  - Responsible Physician be Trained
  - Training Program Tailored to Facility and Users
- Limited Co-Administration of Sedatives/Hypnotics
- Stop Propofol Administration Until Alarm State Addressed and Corrected
Working With SEDASYS®

To Allow Anesthesiologists

And SEDASYS®

To Deliver the Most Value

To the Most Patients

Most Safely and Effectively
Feedback on the ASA Recommendations to Directors of Anesthesia Services (DAS), SEDASYS Users, and Practicing Anesthesiologists

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Comment Period – Until October 28