



Stable Airway Management (SAM)



Safety • Comfort • Cost • Improved Outcomes



Stable Airway Management Device



COST EFFECTIVE
DEVICE



SAFE AND
EASY TO USE



INCREASED
PATIENT SAFETY



EXCELLENT
PATIENT EXPERIENCE



100% Made in the U.S.A.





SAM: Stable Airway Management



✓ 100% Made in the U.S.A.

- Manufactured, assembled, and packaged in Waynesboro, Virginia by Klann Plastics
- Constructed of medical grade, injection molded plastic
- Medical grade foam pads are attached using medical grade adhesives
- Low Cost



This device is patent protected under
U.S. Patent No. 11,523,961
U.S. Patent No. 11,806,285



Monitored Anesthesia Care (MAC) vs. General Anesthesia



General Anesthesia

- Greater depth of anesthesia
- Requires endotracheal tube placement and mechanical ventilation
- Endotracheal intubation associated with significant risks



Safety • Comfort • Cost • Improved Outcomes



Monitored Anesthesia Care (MAC) vs. General Anesthesia



General Anesthesia

- Greater depth of anesthesia
- Requires endotracheal tube placement and mechanical ventilation
- Endotracheal intubation associated with significant risks

Monitored Anesthesia Care (MAC)

- Lighter depth of sedation
- No need for endotracheal tube or mechanical ventilation
- Selected but numerous procedures can accommodate MAC



Safety • Comfort • Cost • Improved Outcomes



Rapid growth in non-operating room anesthesia (NORA)

Increased demands for NORA

- Growth of outpatient centers and ambulatory care facilities
- Innovations in procedural techniques that reduce need for general anesthesia
- NORA accounts for nearly 33% of all anesthetics in the United States

NORA Locations

- GI Endoscopy
- Interventional Radiology
- Interventional Cardiology
- Office Based Dental Surgery
- Office Based Plastic Surgery
- Electroconvulsive Therapy
- MRI

Safety • Comfort • Cost • Improved Outcomes



Rapid Growth in NORA and MAC

- Growth in non-invasive/non-surgical procedures
- Growing elderly population
- Environmental health care cost containment through the elimination of waste anesthetic gases (WAG's)

Review > [Curr Opin Anaesthesiol.](#) 2019 Aug;32(4):504-510.
doi: 10.1097/ACO.0000000000000751.

Safety in the nonoperating room anesthesia suite is not an accident: lessons from the National Transportation Safety Board

Jason D Walls¹, William J Bramble Jr², Mark S Weiss¹

Affiliations + expand

PMID: 31157626 DOI: [10.1097/ACO.0000000000000751](#)

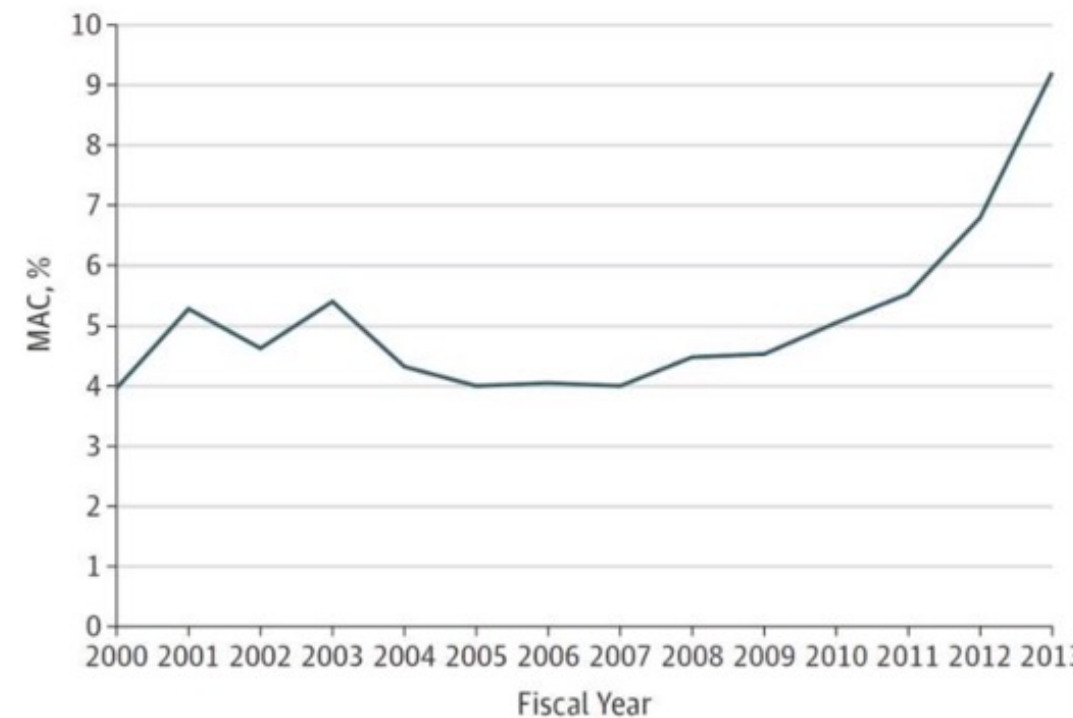
> [J Patient Saf.](#) 2018 Mar;14(1):9-16. doi: 10.1097/PTS.0000000000000156.

Interventional Procedures Outside of the Operating Room: Results From the National Anesthesia Clinical Outcomes Registry

Beverly Chang, Alan D Kaye, James H Diaz, Benjamin Westlake, Richard P Dutton, Richard D Urman

PMID: 29461406 DOI: [10.1097/PTS.0000000000000156](#)

A MAC Use in FY 2000-2013



Rapid Increase in NORA Cases

2010

28.3%

2014

35.9%

Demand for NORA is continuing to rapidly expand



Safety • Comfort • Cost • Improved Outcomes

Anesthesia Provider Challenges in MAC



Distractions



Increasing patient complexity

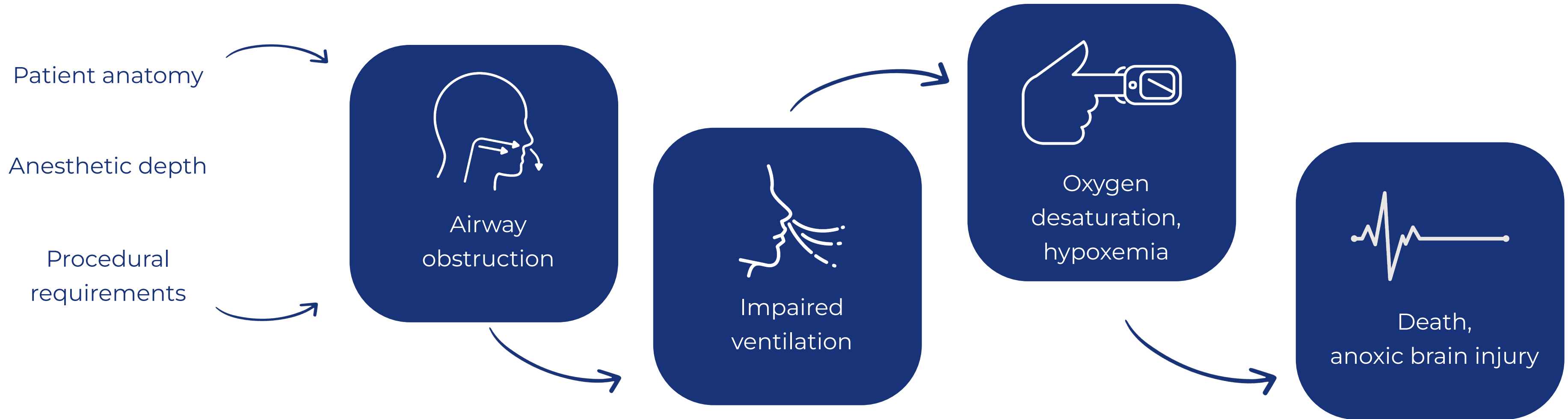


No existing standard of care for airway positioning

Safety • Comfort • Cost • Improved Outcomes



Complications of Monitored Anesthesia Care (MAC)



Safety • Comfort • Cost • Improved Outcomes



Stable Airway Management Device

SAM is a cost-efficient, non-metallic, plastic disposable device designed for positional support during monitored anesthesia care (MAC). It has been deemed a class I device by the FDA.

- ✓ **Maintain airway patency**

SAM maintains the patient in the "sniffing position" - neck flexion with upper cervical extension

- ✓ **Non-Significant Risk Device**

Investigational Device Exemption (IDE) in place

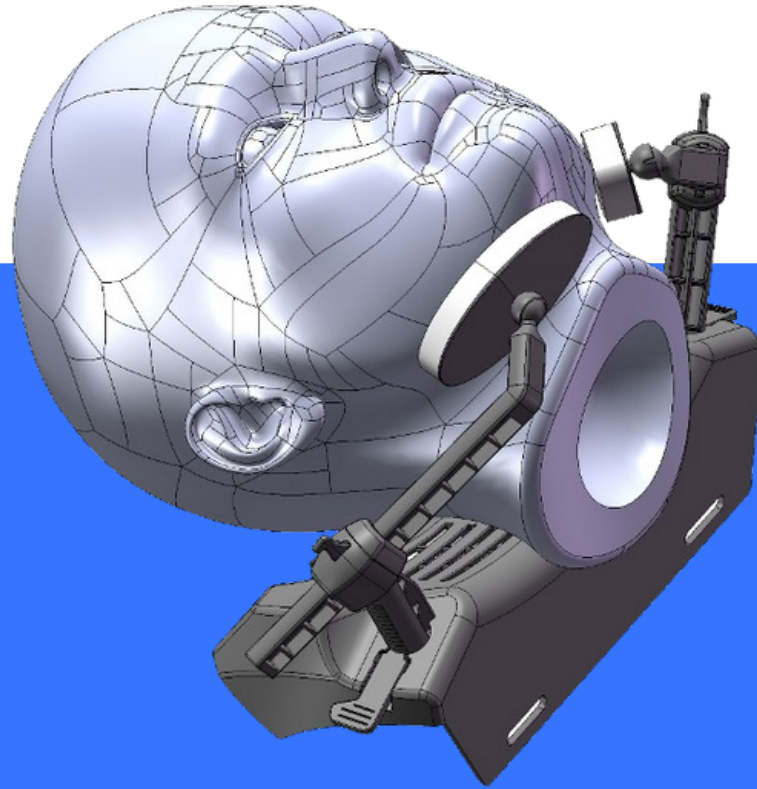


This device is patent protected under
U.S. Patent No. 11,523,961
U.S. Patent No. 11,806,285



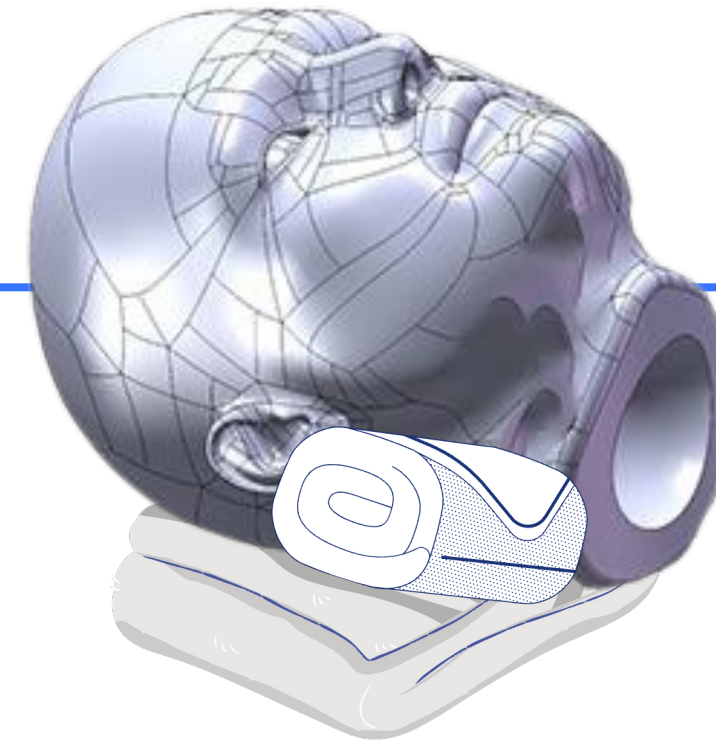


SAM vs. SOC



Stable Airway Management (SAM)

- Stable position
- Can be used in MRI
- User-friendly
- Single use
- No need for sterilization



Standard of Care (SOC)

- High variability
- Challenges with positioning
- May require more frequent adjustment



Safety • Comfort • Cost • Improved Outcomes



Clinical Trial Objectives

Study conducted at:

- Virginia Commonwealth University Medical Center
- Quaternary Care Center in Richmond, VA



1

Determine if the use of the SAM device during MAC reduces the need for providers to adjust patients during procedures compared to SOC.

2

Determine if patient body mass index (BMI) moderates the effect of the SAM device on the need to adjust patients during a procedure.

3

Assess patient safety during SAM device use, as measured by the frequency with the patient is switched from mac to general anesthesia.



Safety • Comfort • Cost • Improved Outcomes



Study

Single-blinded, randomized controlled trial



40 Patients



20 Patients SOC

Median Age: 61

Median BMI: 29.2 kg/m²

Gender: 65% female, 35% male

20 Patients SAM

Median Age: 61

Median BMI: 28.8 kg/m²

Gender: 55% female, 45% male



RISK OF
AIRWAY MANIPULATION

BMI ASSOCIATION
PREDICTION

MAC TO GENERAL ANESTHESIA
CONVERSION



PATIENT SURVEY
3-DAYS
POST-OPERATIVELY



Results

Patient Characteristic	Value	SAM	SOC	Overall
Age (years)	Median (Range)	61.00(26.00-78.00)	61.00(38.00-84.00)	61.00(26.00-84.00)
Sex	Male	7(35.00%)	8(40.00%)	15(37.50%)
	Female	13(65.00%)	11(55.00%)	24(60.00%)
	Unknown	0(0.00%)	1(5.00%)	1(2.50%)
BMI (kg/m ²)	Median (Range)	29.20(17.90-54.50)	28.80(20.00-39.70)	29.15(17.90-54.50)
Duration of Anesthesia (minutes)	Median (Range)	127.00(29.00-245.00)	128.00(28.00-227.00)	127.50(28.00-245.00)
Mallampati Score	I	1(5.00%)	4(20.00%)	5(12.50%)
	II	13(65.00%)	11(55.00%)	24(60.00%)
	III	5(25.00%)	5(25.00%)	10(25.00%)
	IV	0(0.00%)	0(0.00%)	0(0.00%)
	Unknown	1(5.00%)	0(0.00%)	1(2.50%)
ASA Classification	ASA I	0(0.00%)	0(0.00%)	0(0.00%)
	ASA II	10(50.00%)	10(50.00%)	20(50.00%)
	ASA III	10(50.00%)	9(45.00%)	19(47.50%)
	ASA IV	0(0.00%)	1(5.00%)	1(2.50%)
	ASA V	0(0.00%)	0(0.00%)	0(0.00%)
	ASA VI	0(0.00%)	0(0.00%)	0(0.00%)
Respiratory Disorder	Yes	2(10.00%)	4(20.00%)	6(15.00%)
	No	18(90.00%)	16(80.00%)	34(85.00%)
Hypopneic/Apneic Events	Median (Range)	2.00(0.00-10.00)	1.00(0.00-11.00)	1.50(0.00-11.00)
Airway Manipulation	Median (Range)	2.00(0.00-10.00)	1.00(0.00-11.00)	1.50(0.00-11.00)
Conversion from MAC to General Anesthesia	Yes	1(5.00%)	0(0.00%)	1(2.50%)
	No	19(95.00%)	20(100.00%)	39(97.50%)

Safety • Comfort • Cost • Improved Outcomes



Study Conclusions

SAFETY

SAM was not significantly associated with a higher risk of airway manipulation.

APPLICABLE PATIENT POPULATION

No increase in number of airway manipulations, regardless of BMI.

CONVERSION FROM MAC TO GENERAL ANESTHESIA

No association between SAM use and conversion from MAC to general anesthesia.

PATIENT USER EXPERIENCE

No reports of neck or jaw pain or stiffness post-operatively.

Safety • Comfort • Cost • Improved Outcomes



SAM: Stable Airway Management

➤ Klann Plastics

- Located in Waynesboro, VA, in the Shenandoah Valley
- A family-owned business
- Injection molding plastics to manufacture medical equipment and devices since the 1950s



Safety • Comfort • Cost • Improved Outcomes



+

- **Safety**
- **Comfort**
- **Cost**
- **Improved Outcomes**

+

+