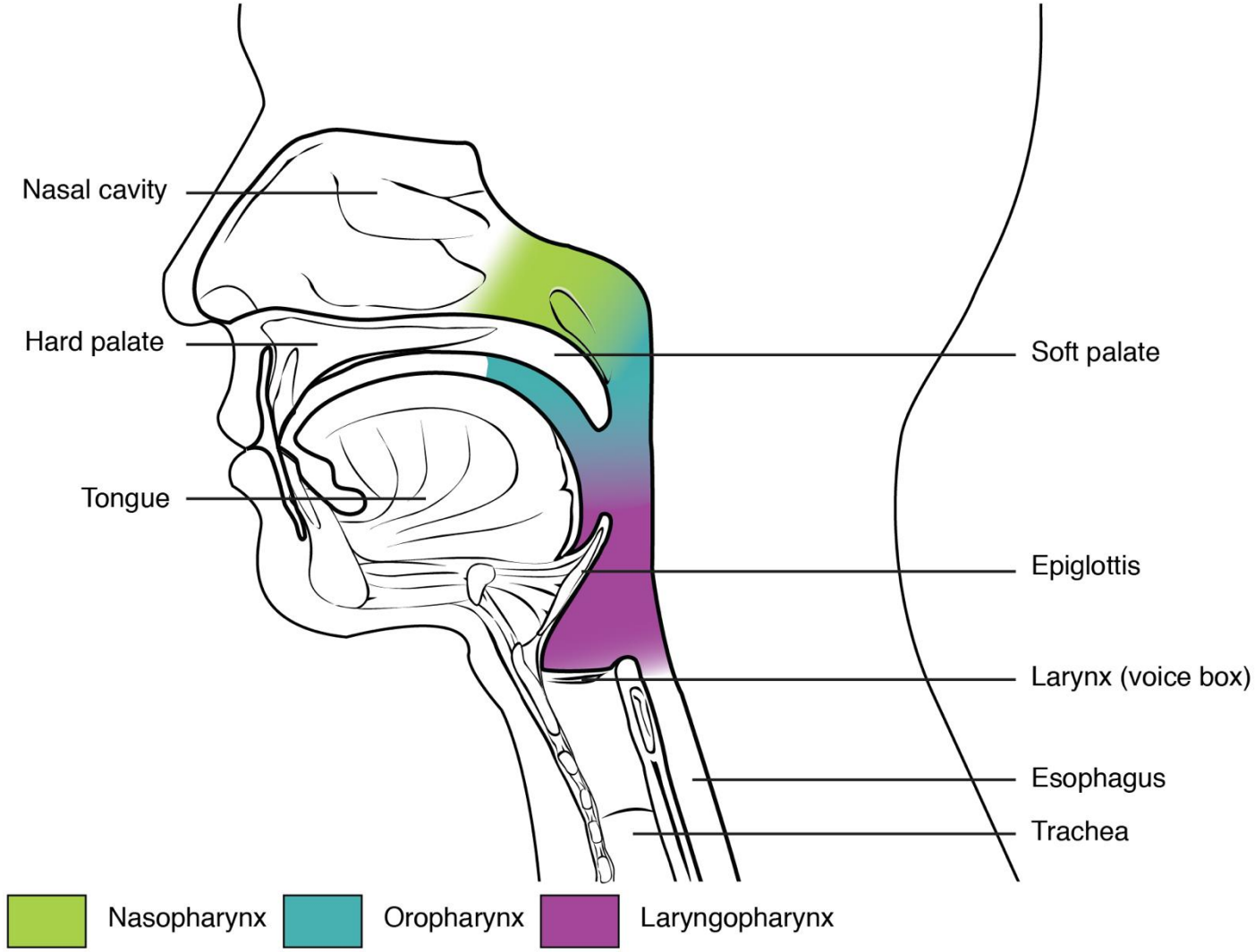
LARYNGOSCOPES – SUNMED PORTFOLIO

INTRO TO LARYNGOSCOPY

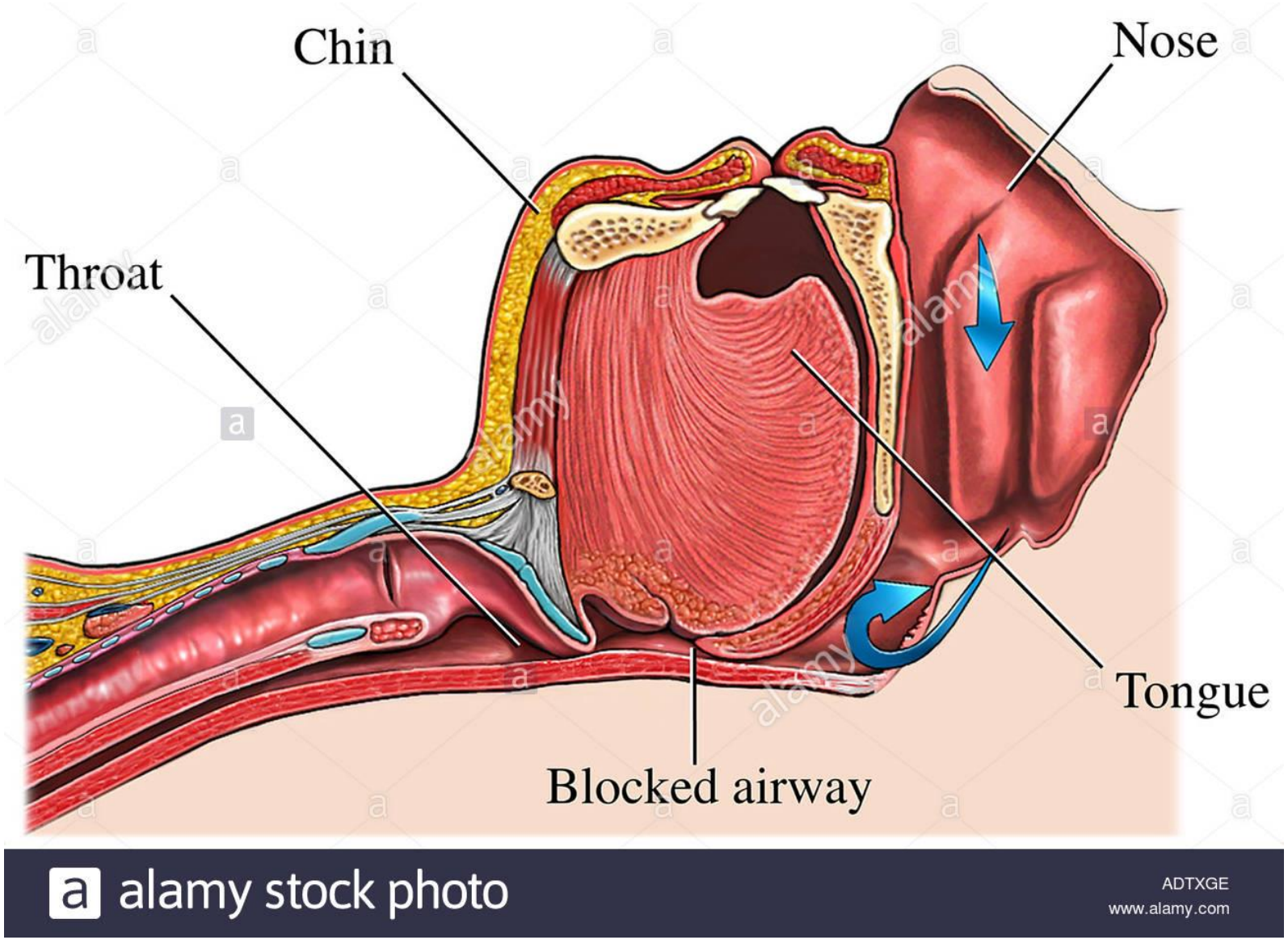
Laryngoscopy (la·ryn·go·sco·pi): Laryngoscopy is a term describing the visualization or examination of the larynx by distraction of the upper airway structures.

It is typically used to enable intubation and airway management in anesthesia, critical care, and trauma scenarios.

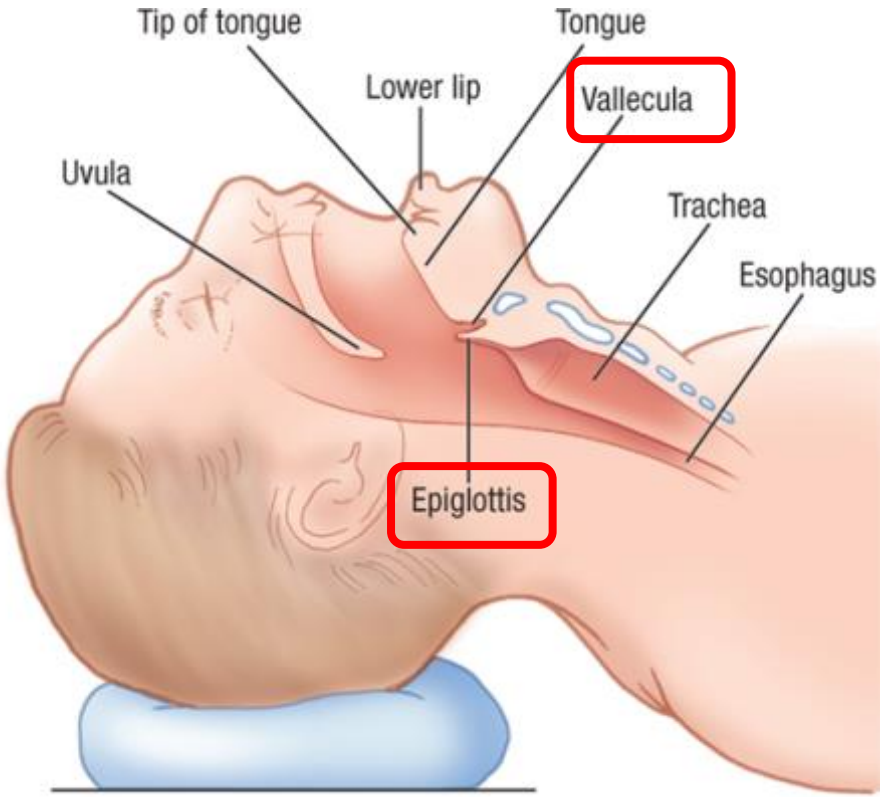
AIRWAY ANATOMY

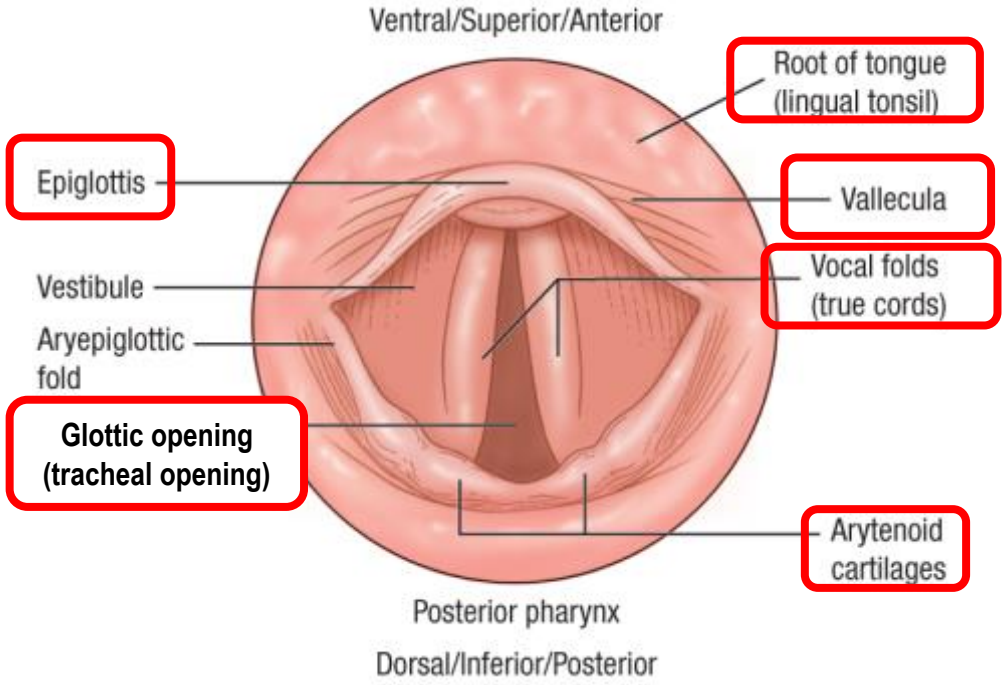


AIRWAY VIEW IN SUPINE POSITION



KEY AIRWAY ANATOMY FOR LARYNGOSCOPY:





Glottic opening: the opening between the vocal cords. This is the target for tracheal intubation.

Vallecula (val·lec·u·la): the space between the base of the tongue and the epiglottis

Arytenoid cartilages (ar·y·te·noid): A pair of small triangular cartilages in the larynx that help to move the vocal cords

INTRODUCTION TO LARYNGOSCOPES

A **laryngoscope** (la·ryn·go·scope) is used to lift the upper airway structures, such as the epiglottis, out of the way to allow visualization of the vocal cords (larynx) and enable intubation through the glottic opening.

Laryngoscopes are used where-ever tracheal intubations are performed, including OR, ED, ICU, NICU, PICU, EMS

OPTIONAL VIDEOS

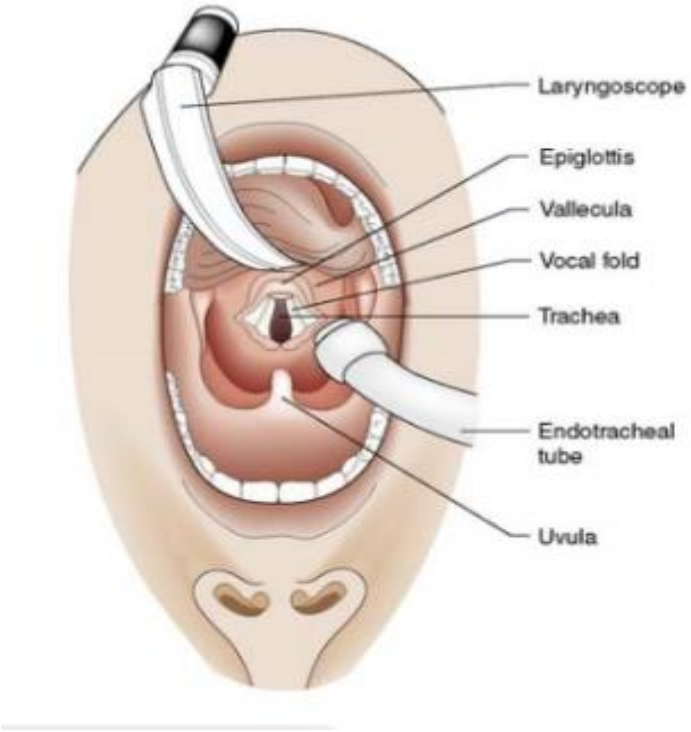
Good views from practioner's POV
https://www.youtube.com/watch?v=4V_poulbcnA

Direct Laryngoscopy https://www.youtube.com/watch?v=AZeBumPaj4g
Use of Mac and Miller blades for intubation

Anatomy and Intubation
https://youtu.be/iOPpSGbuYmQ
- Skip to the 6:30 min mark: @ 6:30 Anatomy; Great view of vallecula lift at 7:30 / Mallampati overview
- @ 8:30 Intubation Equipment; @ 12:00 Direct laryngoscopic intubation

The first 6.5 mins are pharmacology – double back to it if you can

Intubation using Direct and Indirect (Video) Laryngoscopes
https://www.youtube.com/watch?v=gnkYGRMaw7o
First 6 min shows use of different direct and video laryngoscopy devices

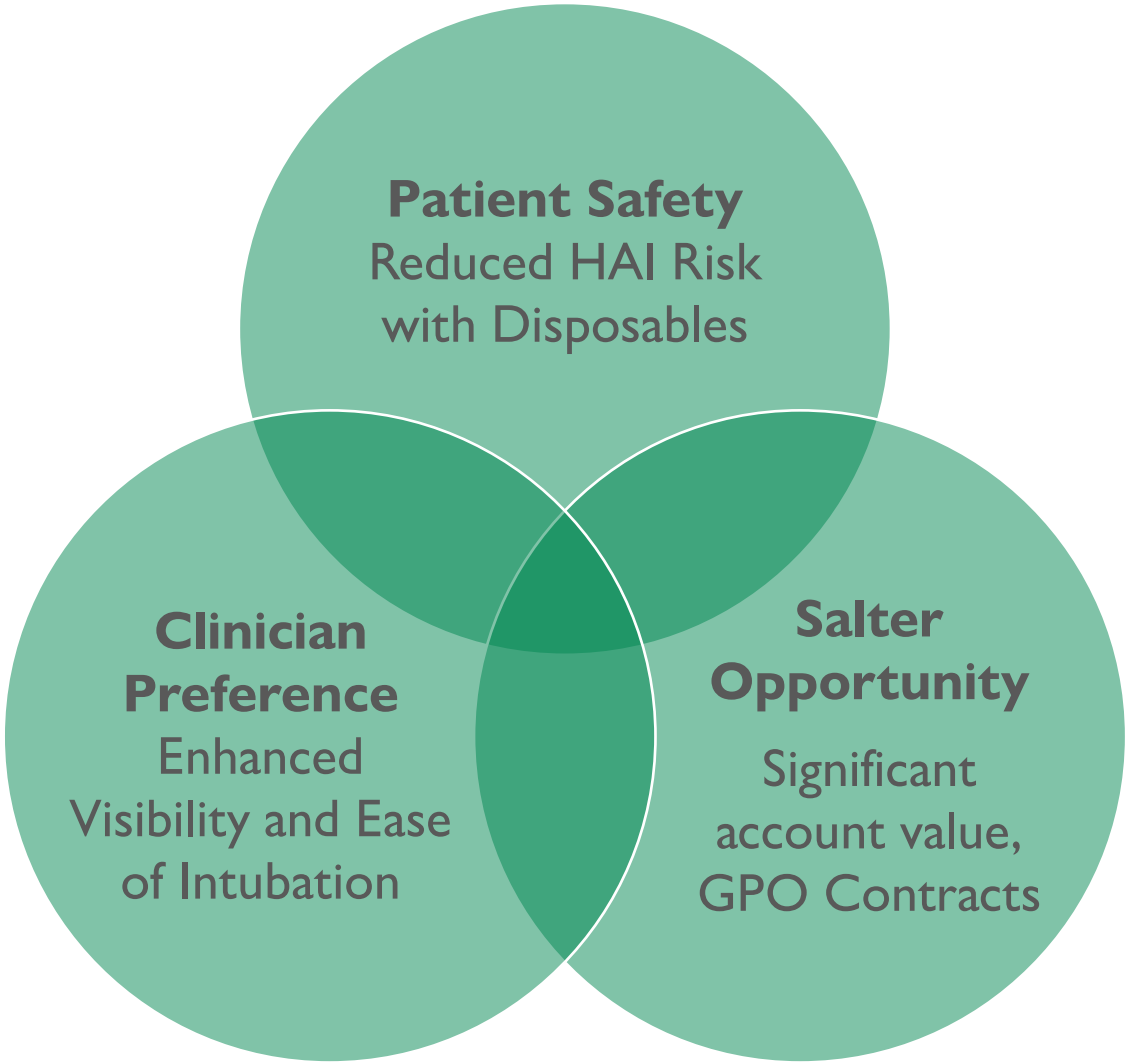


OBJECTIVES & CONTENT OUTLINE

You will have the knowledge, tools, support and target list to be successful with IntuBrite Day 1 post-NSM

Session	Deliverables
I. Laryngoscopy Intro	Review of Key Basics Market Overview
II. Product Details	IntuBrite Products Competitive Products
III. Sales Process	Clear sales process • Targeting • Detailed Talk Track • Evaluation planning & management • FAQs/ Objection Handling
IV. Planning Your Success	• Intubation training • Leading an Effective In-Service

WHY IS INTUBRITE SO EXCITING?



INTUBRITE®

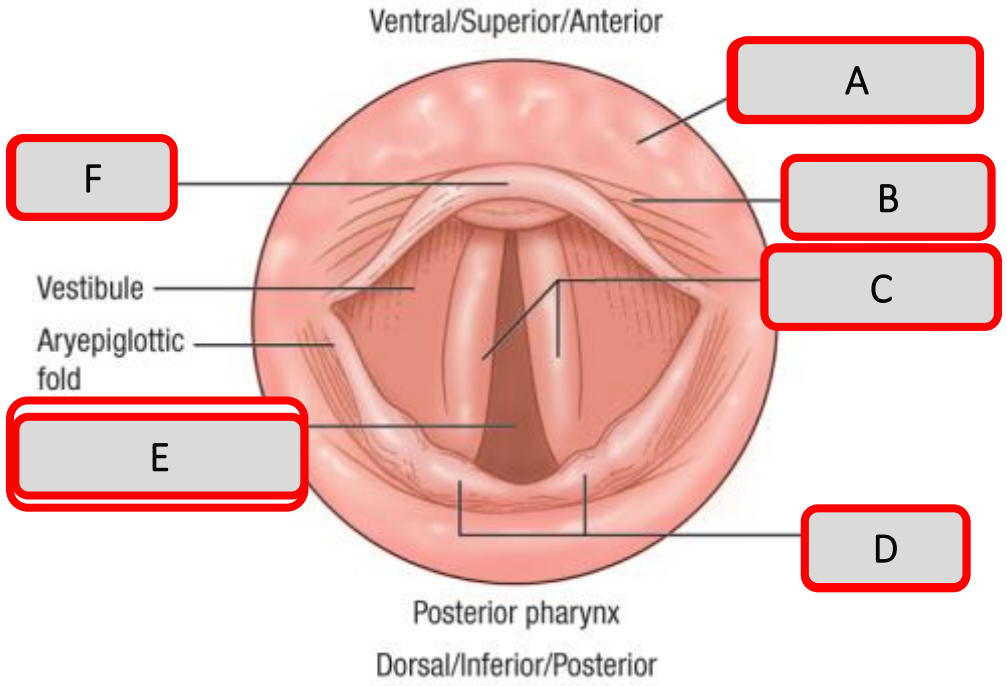
INTUBRITE DEMO KITS

Demo Kit Contents:

- **Dual LED Disposable** Handles & Blades
- **Greenlight Disposable** Handles & Blades
- **VLS Edge Video** Laryngoscope, Reusable Blades, Wands, Rigid Styles, Disposable Sheaths, Accessories
- **Competitive Disposable Samples**: Flexicare, Teleflex Rusch
- **Misc accessories:** Cases, PFHV & STLT, cloth

POP QUIZ

Name the Airway Anatomy



- *Glottic opening*: the opening between the vocal cords. This is the target for tracheal intubation.
- *Vallecula* (val·lec·u·la): the space between the base of the tongue and the epiglottis
- *Arytenoid cartilages* (ar·y·te·noid): A pair of small triangular cartilages in the larynx that help to move the vocal cords

POP QUIZ:

Which Blade is Mac Style & which is Miller Style?

A.

B.

Mac Blade

- The most common Curved blade design

- MaC

Miller Blade

- Most common straight blade design

- MiLLer

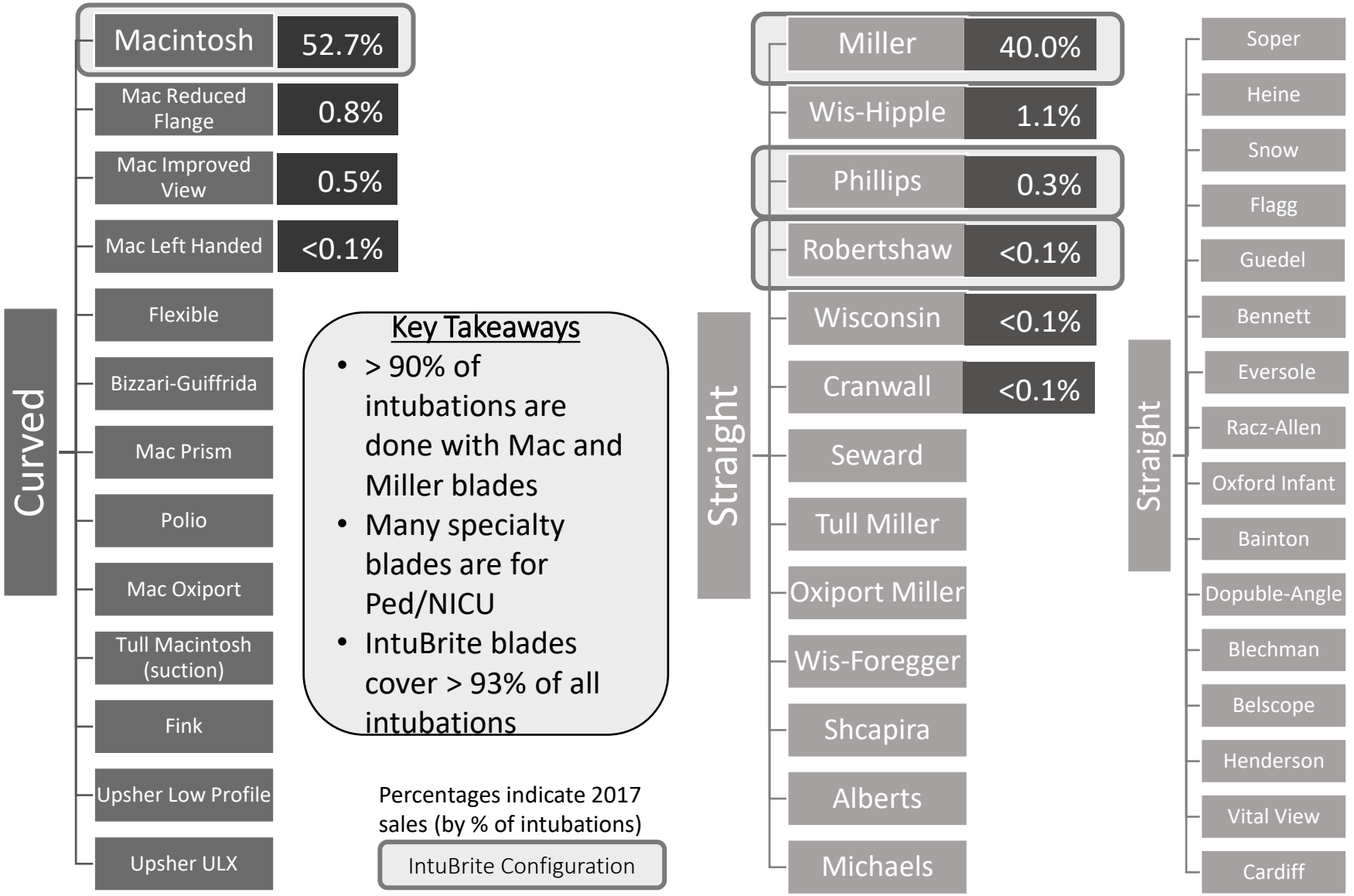
BLADE SIZES – MAC, MILLER SIZE RANGES

- Mac and Miller blades overlap in many, but not all size offerings
- Straight blades are preferred for NICU use – reflected in size range of Miller blades.

  000, 00 and 1.5 are important differentiators to NICU and children's facilities

Size	Patient Size	% of market	Mac	MIller
000	Small premature infant	Minimal		✓
00	Premature infant	1.2%		✓
0	Neonate	2.8%	✓	✓
1	Small Child	3.7%	✓	✓
1.5	Child	1.2%		✓
2	Child	19.2%	✓	✓
3	Adult	37.5%	✓	✓
3.5	Adult	1.8%	✓	
4	Large adult	22.6%	✓	✓
5	Extra-large adult	Minimal	✓	

MORE BLADE SHAPES



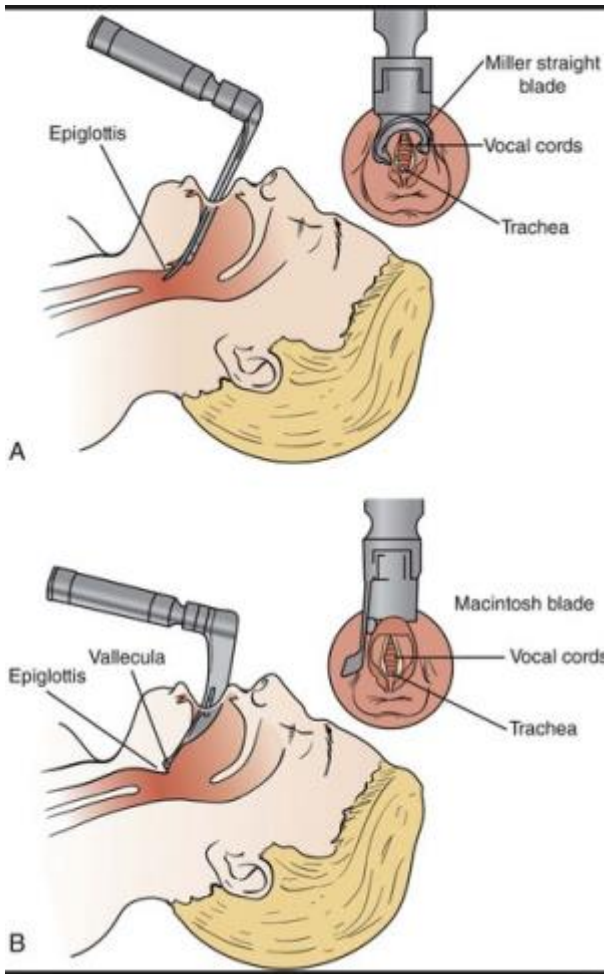
Key Takeaways

- > 90% of intubations are done with Mac and Miller blades
- Many specialty blades are for Ped/NICU
- IntuBrite blades cover > 93% of all intubations

Percentages indicate 2017 sales (by % of intubations)

IntuBrite Configuration

BLADE DESIGN IMPACTS TECHNIQUE



Straight blade: Tip goes *under the epiglottis* and lifts it directly

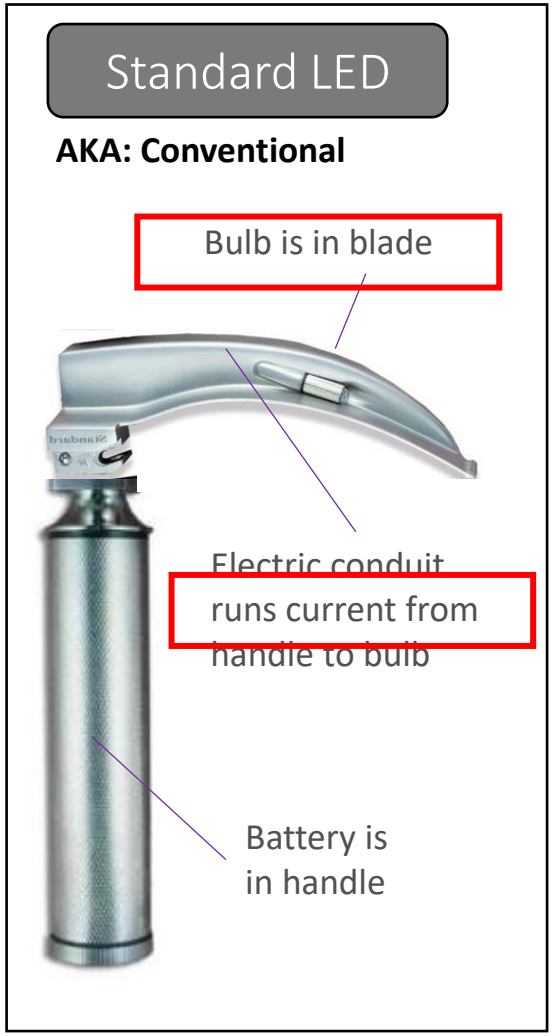
Curved blade: Tip fits *into the vallecula* and indirectly lifts the epiglottis

FIBER OPTIC (OR GREENLINE) LIGHTING SYSTEMS

- >90% of market
- Handles and blades built to the Green ISO Standard 7376 can use the term Green, Green System
- Indicated by green color coding on blade and handle
- Why is this important?
  - Indicates compatibility with any other handle or blade that is also "Green"
  - Can mix & match disposable & reusable

STANDARD LED LIGHTING SYSTEMS

- <10% of market
- Generally have a superior lighting system than fiberoptics
  - fiber optic pipe degrades light quality
- Not compatible with Green systems



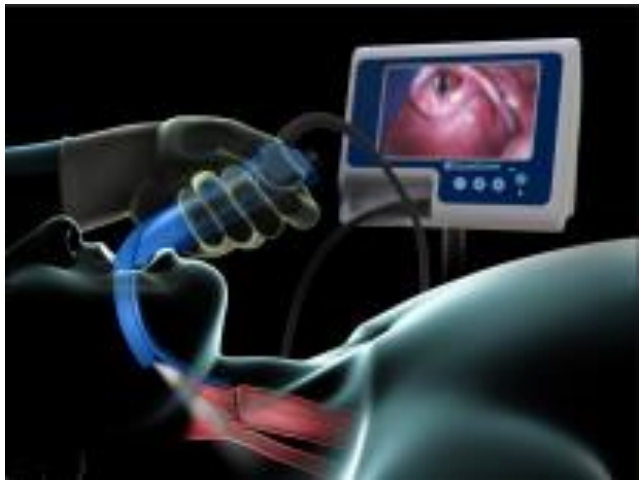
POP QUIZ

Which illustrates use of Direct Laryngoscopy _____?

A.

Direct Laryngoscopy

B.



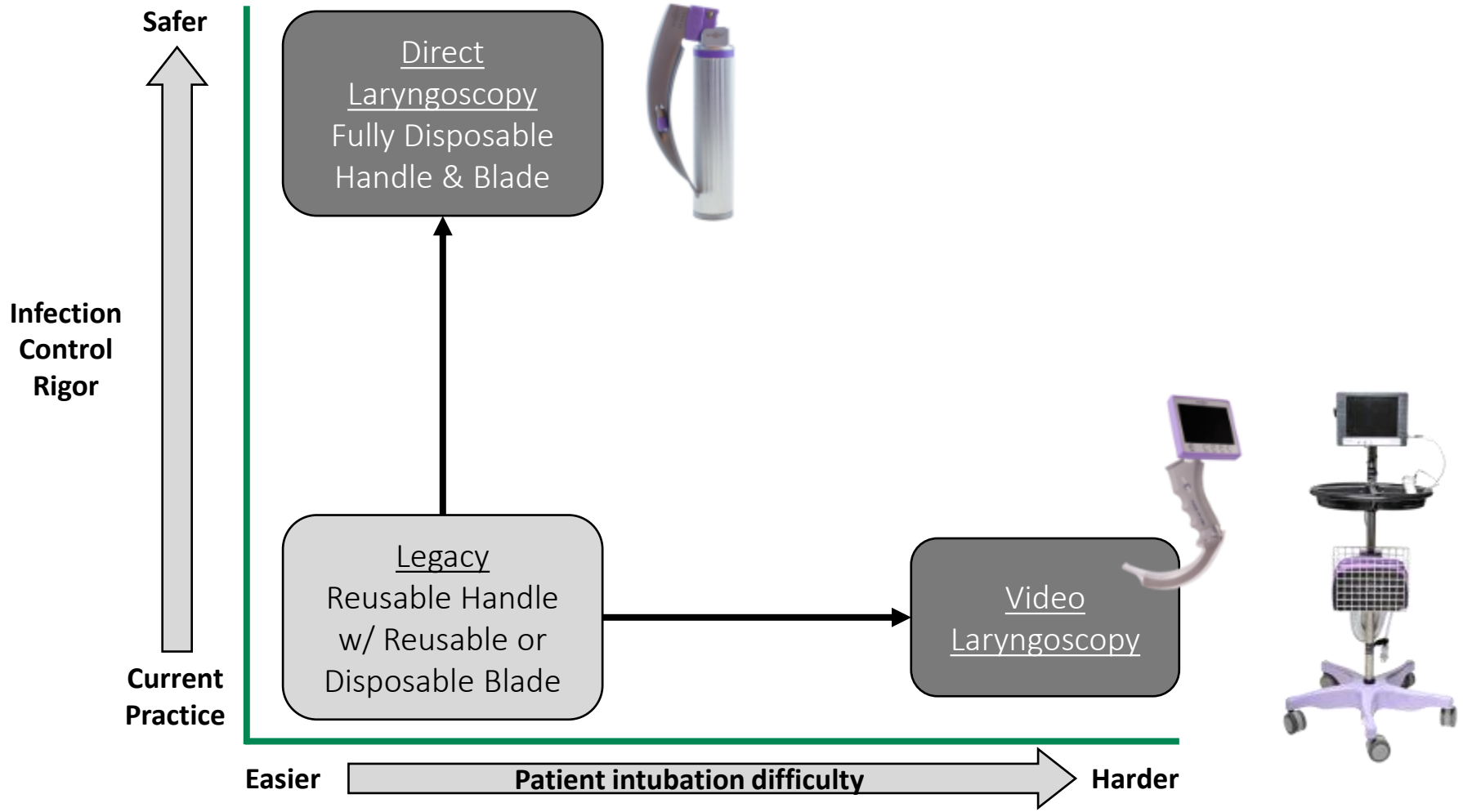
Indirect, or Video Laryngoscopy

LARYNGOSCOPY MARKET

MAJOR COMPETITOR PRODUCT OFFERINGS

	Direct				Video	
	Standard LED or Proprietary		Greenline (FiberOptic LED)		Handheld	Rollstand
	Reusable	Disposable	Reusable	Disposable		
IntuBrite	✓Handle	✓		✓	✓	✓
Flexicare		✓ *(new)*		✓		
Teleflex Rusch	✓	✓	✓	✓	✓	
SunMed	✓	✓Blade	✓	✓		
Vital Signs				✓		
Verathon	✓Handle	✓Blade		✓	✓ *(new)*	✓
Medtronic					✓	
Ambu					✓	
Karl Storz			✓	✓	✓	✓

SALTER IS POSITIONED TO TAKE ADVANTAGE OF LARYNGOSCOPE MARKET TRENDS



OUR GREATEST OPPORTUNITY IS HOSPITALS WITH DISPOSABLE HANDLES AND BLADES

Why Hospitals?

- Perform 19 out of 20 intubations annually
- Leverages our existing relationships
- Leverages our acute product portfolio

Why Disposable?

- 3x the unit growth rate of reusables
  - Driven by JCAHO guidelines
  - Increased focus on HAI
- Ongoing, consistent purchase, not a one time or infrequent purchase

REUSABLE → DISPOSABLE: JCAHO DRIVES CHANGE

FDA and JCAHO follow the Spaulding Classification…

Type	Contact	Req
Critical	Enters sterile tissue or blood flow	Sterilization
Semi-Critical	Contacts mucus membrane	High-level disinfection
Non-critical	No- or intact-skin contact	Low-level disinfection

…which results in citations when hospitals are only doing low-level disinfection on handles

Correct Practice: Typically, submerged in solution by central reprocessing

JCAHO citation

Current Practice: Wipe down between cases

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

Semicritical Items

Semicritical items contact mucous membranes or nonintact skin. This category includes respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades [24], esophageal manometry probes, cystoscopes [25], anorectal manometry catheters, and diaphragm fitting rings. These medical devices should be free from all microorganisms; however, small numbers of bacterial spores are permissible. Intact mucous membranes, such as those of the lungs and the gastrointestinal tract, generally are resistant to infection by common bacterial spores but susceptible to other organisms, such

JCAHO GUIDELINES

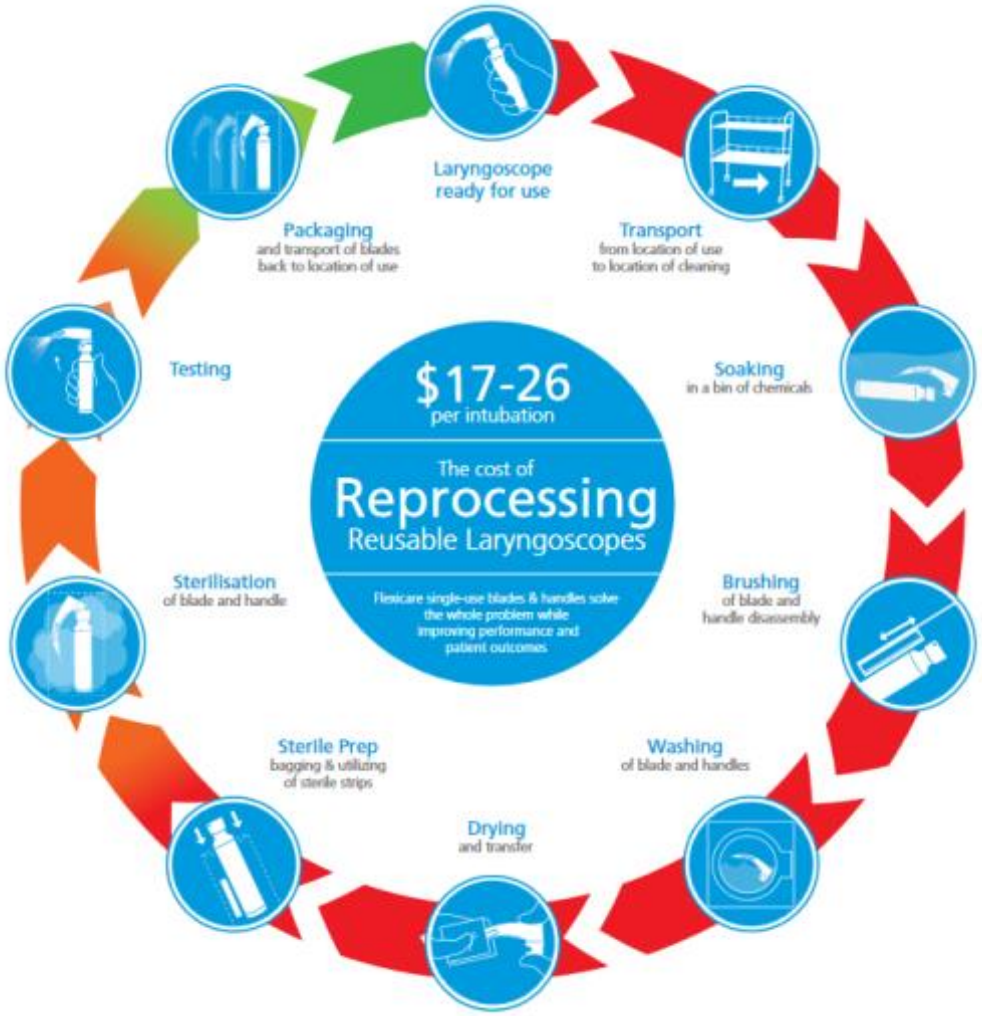
Laryngoscopes Blades and Handles - How to clean, disinfect and store these device
Laryngoscopes – Blades and Handles - How should we clean, disinfect and store these devices? How will the surveyors evaluate this process?

- **Laryngoscope blades** are processed via either **high-level disinfection or sterilization.**
- **Laryngoscope handles**, the organization is following the **manufacturer's instructions-for-use for cleaning/disinfection guidance.**
- **Packaged**
- **Stored in a way to prevent contamination**

https://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFaqId=1201&ProgramId=46

STERILIZATION STEPS & COST

- High cost per intubation: $17-$26
- Laryngoscope failure due to wear & tear, improper re-assembly
- Risk of cross-contamination resulting from poor cleaning or bacteria that remains
- Loss of product , replacement
- Time delays in product availability
- Diminished light quality over time



From ' Flexicare Cost of Reprocessing Brochure'
http://www.briteprosolo.com/images/downloads/Cost%20of%20Reprocessing.pdf

Welch Allyn®

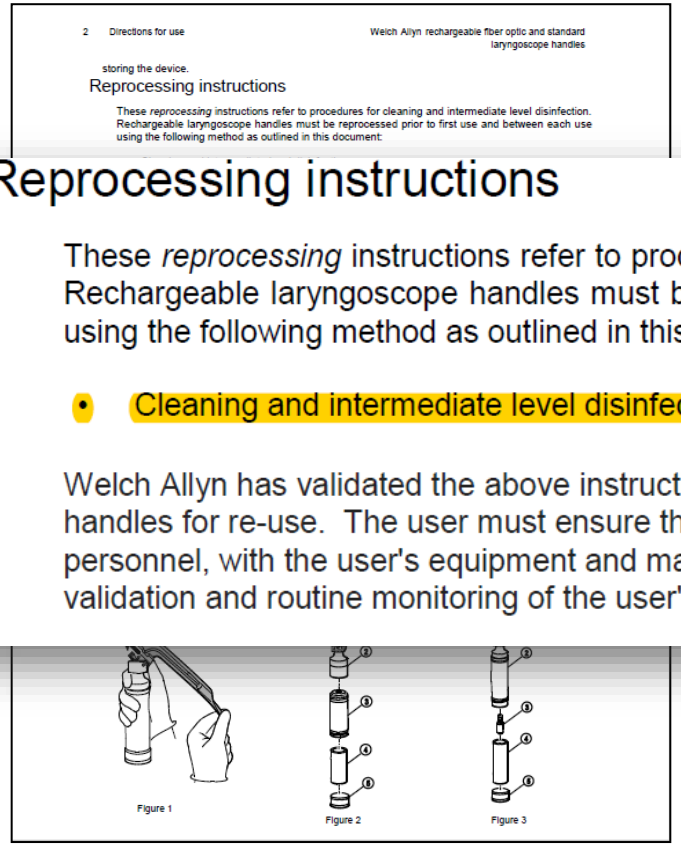
REF 901038 LARYNGOSCOPE
DIR 80021285 Ver. A

Revision date: 2016-02

℞ ONLY

Fiber optic laryngoscope handles Directions for use

ACCESSED 9/20/2017
HTTPS://WWW.WELCHALLYN.COM/CONTENT/DAM/WELCHALLYN/DOCUMENTS/SAP-DOCUMENTS/LIT/80021/80021285LITPDF.PDF

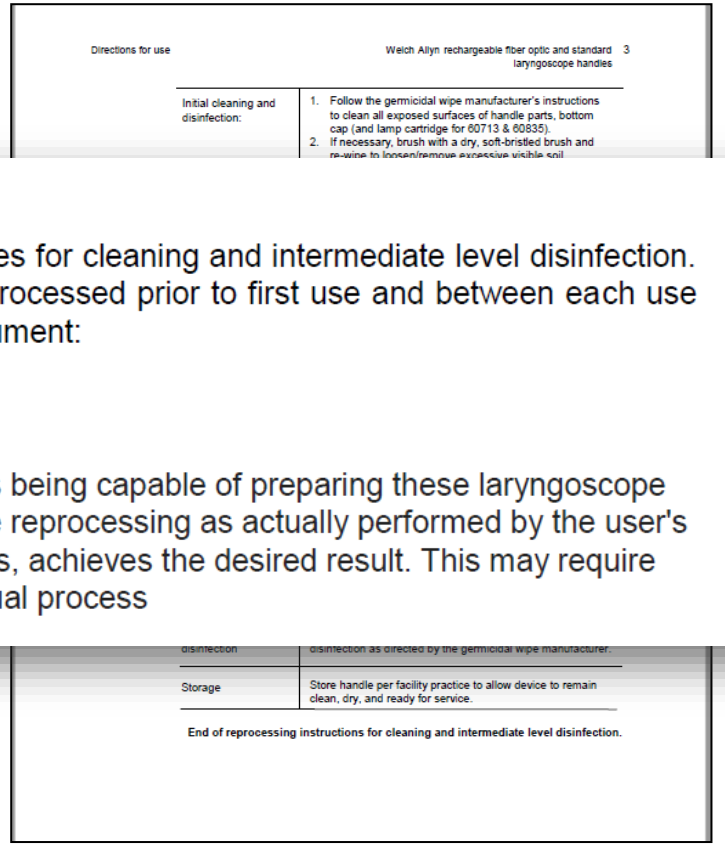

2 Directions for use Welch Allyn rechargeable fiber optic and standard laryngoscope handles

storing the device.

Reprocessing instructions

These *reprocessing* instructions refer to procedures for cleaning and intermediate level disinfection. Rechargeable laryngoscope handles must be reprocessed prior to first use and between each use using the following method as outlined in this document:

Figure 1 Figure 2 Figure 3


Directions for use Welch Allyn rechargeable fiber optic and standard laryngoscope handles 3

Initial cleaning and disinfection:	1. Follow the germicidal wipe manufacturer's instructions to clean all exposed surfaces of handle parts, bottom cap (and lamp cartridge for 60713 & 60835). 2. If necessary, brush with a dry, soft-bristled brush and re-wipe to loosen/remove excessive visible soil.
disinfection	disinfection as directed by the germicidal wipe manufacturer.
Storage	Store handle per facility practice to allow device to remain clean, dry, and ready for service.

End of reprocessing instructions for cleaning and intermediate level disinfection.

Reprocessing instructions

These *reprocessing* instructions refer to procedures for cleaning and intermediate level disinfection. Rechargeable laryngoscope handles must be reprocessed prior to first use and between each use using the following method as outlined in this document:

- Cleaning and intermediate level disinfection

Welch Allyn has validated the above instruction as being capable of preparing these laryngoscope handles for re-use. The user must ensure that the reprocessing as actually performed by the user's personnel, with the user's equipment and materials, achieves the desired result. This may require validation and routine monitoring of the user's actual process

Welch Allyn®

REF 901038 LARYNGOSCOPE
DIR 80021285 Ver. A

Revision date: 2016-02

Rx ONLY

Fiber optic laryngoscope handles Directions for use

ACCESSED 9/20/2017
HTTPS://WWW.WELCHALLYN.COM/CONTENT/DAM/WELCHALLYN/DOCUMENTS/SAP-DOCUMENTS/LIT/80021/80021285LITPDF.PDF

Clean and Intermediate Level Disinfection:

Prepare for Cleaning

- Separate blade from handle
- Prevent handle from drying

Initial Cleaning

- Remove the battery
- Clean with germicidal wipe
- Brush to remove any visible soil
- Re-wipe with germicidal wipe and let sit per germicidal wipe instructions

Air dry

Inspect parts and reassemble

Test by attaching to a clean and disinfected blade

Re-wipe all surfaces with germicidal wipe and let sit per germicidal wipe instructions

Store per facility practice

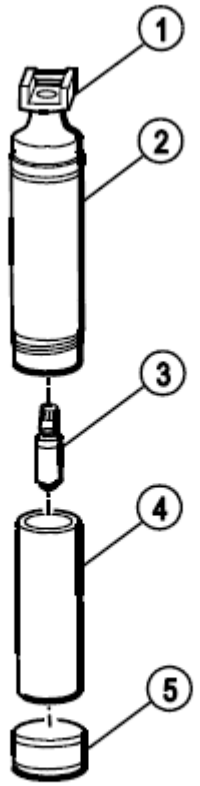


Figure 3

SIMPLEST WAY TO KEEP JCAHO COMPLAINT

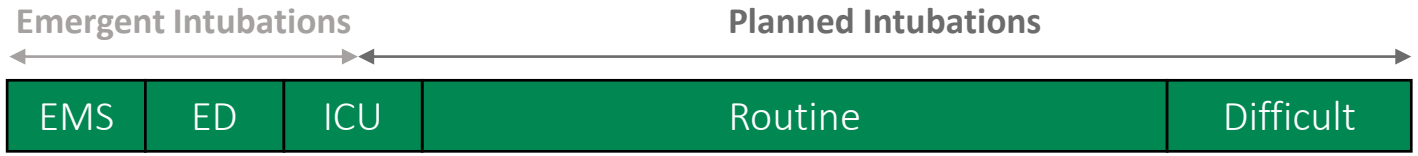
"We use disposable handles and blades"

DIRECT LARYNGOSCOPY → VIDEO LARYNGOSCOPY

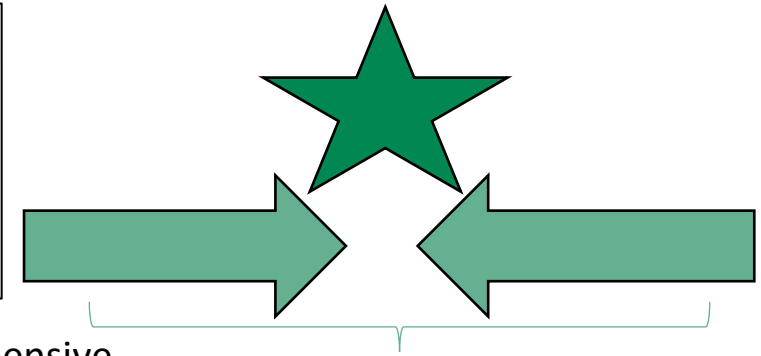
Drivers of conversion to Video

1. Clinical advantage of video
   - More compelling for less skilled intubationists
   - Strong for EMS, ED, ICU
   - Less for anesthesiologists
2. Clinical advantage for difficult cases
3. Seen as best, newest technology
4. More affordable technology options

VIDEO LARYNGOSCOPY COMPETITION FOR 'ROUTINE'



Two video Approaches



Portable, simple, inexpensive device with standard blades for field and unexpected intubations.

Video manufacturers trying to capture the big prize: routine use for all OR intubations.

MAJOR PLAYERS BY SEGMENT

Reusable	
Vyaire	19%
Teleflex	16%
Sun-Med	10%
Tri-Anim	8%
Welch-Allyn	7%
Heine	6%
Propper	5%
Flexicare	5%
All Others Armstrong, Mercury, Medline, Sharn, Anesthesia Service, > 30 others	24%

Fully Disposable	
Flexicare	65%
Teleflex	21%
IntuBrite	12%
All Others (Heine, Welch Allyn, OPB, Sun-Med, Tri-Anim, Vyaire)	2%

Video	
Verathon	#1
Karl-Storz	#2
Medtronic	#3
Ambu	#4
Others Teleflex, Venner, McGaw, DRE, Pentax	Minimal

* Reusable includes disposable blades used with reusable handles

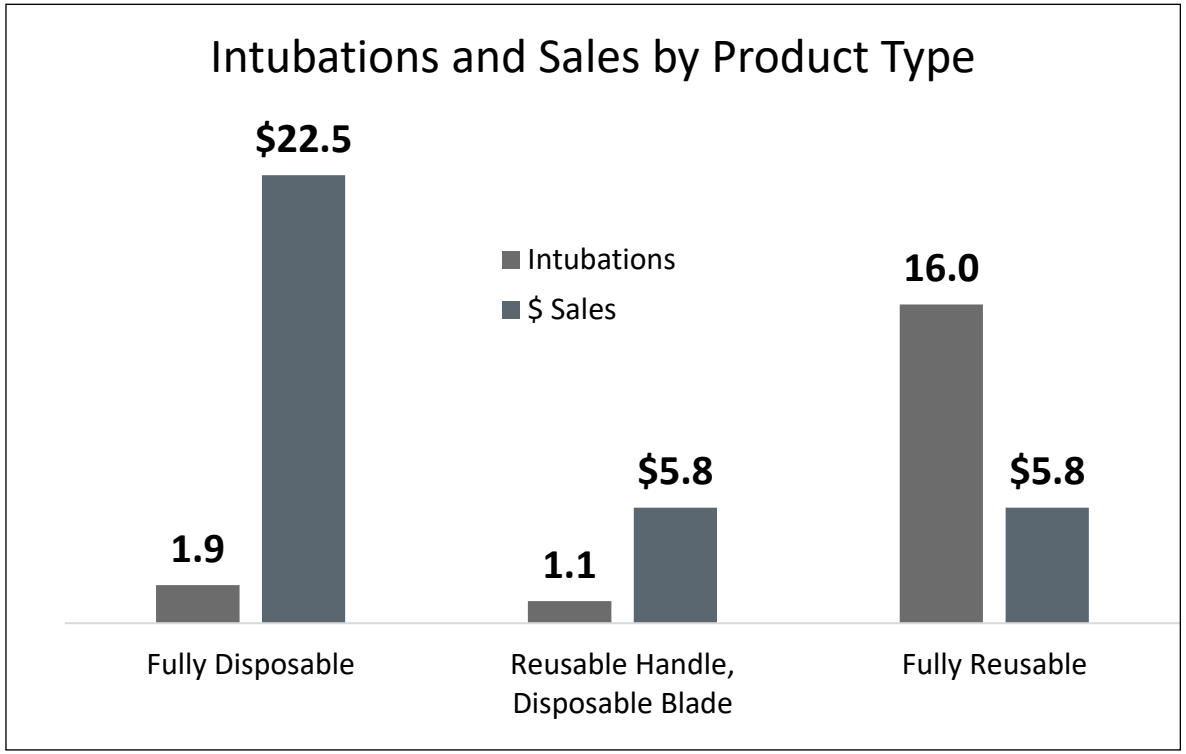
REUSABILITY

Reusable

Reusable items are designed to withstand reprocessing (high-level disinfection or sterilization). Most are guaranteed for duration (e.g. 5-7 years) and/or a defined number of autoclave cycles (e.g.) 4,000. Often, the electronic parts (bulb, battery, etc.) can be replaced when broken

Disposable

Disposable items are designed for single-patient use.



Key Takeaways

- All the money is in disposables.
- Winning disposable blades only to use with current reusable handles is a pot. wedge
- Winning reusables is unlikely. Don't devote time here.

REUSABLE VS DISPOSABLE: TRADE OFFS

	Reusable Handle & Blade	Disposable Handle & Blade
Benefits	• High quality weight and feel • What most physicians are accustomed to using – viewed as the gold standard	• Fresh battery and light for each use • No maintenance or reprocessing resources • Single patient use – no risk of cross-contamination
Drawbacks	• **Performance failure/variability due to reprocessing wear & tear** – **Light quality degrades/ flicker** – **Battery failure, incorrect reinstallation** – **Component failure** • High initial capital investment • Maintenance & replacement • Reprocessing time & costs (chemicals, time, labor, supplies)	• Not perceived to have the quality of a reusable • Cost is more 'tangible' to department • Environmental impact perceived to be more than reusable

REUSABLE → DISPOSABLE: COMPLIANCE CHALLENGES

Customers are reluctant to believe this

Switching to high-level disinfection of handles is expensive

$

Cost of high-level disinfection
- Cleaning solution and sterile water
- Labor costs

$

Must invest in many more reusable scopes
- Go from 1 set per OR to multiple sets per OR to cover time while being cleaned
- Higher breakage and loss rates during cleaning

$17-$26 per intubation for reprocessing handle and blade

Compliance to high-level disinfection is impractical

- Staff are frequently non-compliant
- Unanticipated breakage due to
  - Leaving batteries in handle during cleaning or incorrect insertion
  - Losing scopes during transport
  - Faster wear-and-tear due to reprocessing

Going disposable is the simplest way to stay compliant

COST OF REPROCESSING REUSABLE LARYNGOSCOPES

Outcome

As a result of the study, it was found that Glendale Adventist Hospital is incurring $129,854 in reprocessing costs directly associated with reusable laryngoscope blades and handles annually. With an estimated 5,000 intubations per year, this results in an average cost/intubation of $25.97. Table 1 on the following page shows a breakdown of the costs found within this study.

Furthermore, this does not include the potential impact from reducing the occurrence of hospital acquired infections. In addition to patient care issues, this financial liability has been conservatively estimated at $40,000 per hospital acquired infection occurrence. Assuming that even one reduction in hospital acquired infection is prevented by utilizing single-use laryngoscopes, this offers an additional savings of $8 per intubation for Glendale Adventist Hospital.

Glendale Adventist Hospital

Glendale, CA

- Reprocessing cost $25.97/intubation
- If 1 HAI: Add'l $8/intubation

Total Reusable Costs

	Re-Usable
Yearly costs of sterilization in CS (labor & supplies)	$ 44,035
Yearly costs of cleaning in Anesthesia room and OR Checking(labor & supplies)	$ 14,826
Purchase cost of new handles and blades	$ 7,688
Total Annual Cost	**$ 66,548**
Cost/Intubation	**$ 17.12**

Cost of Reusable Laryngoscope System if incurring only 1 Hospital Acquired Infection Per Year

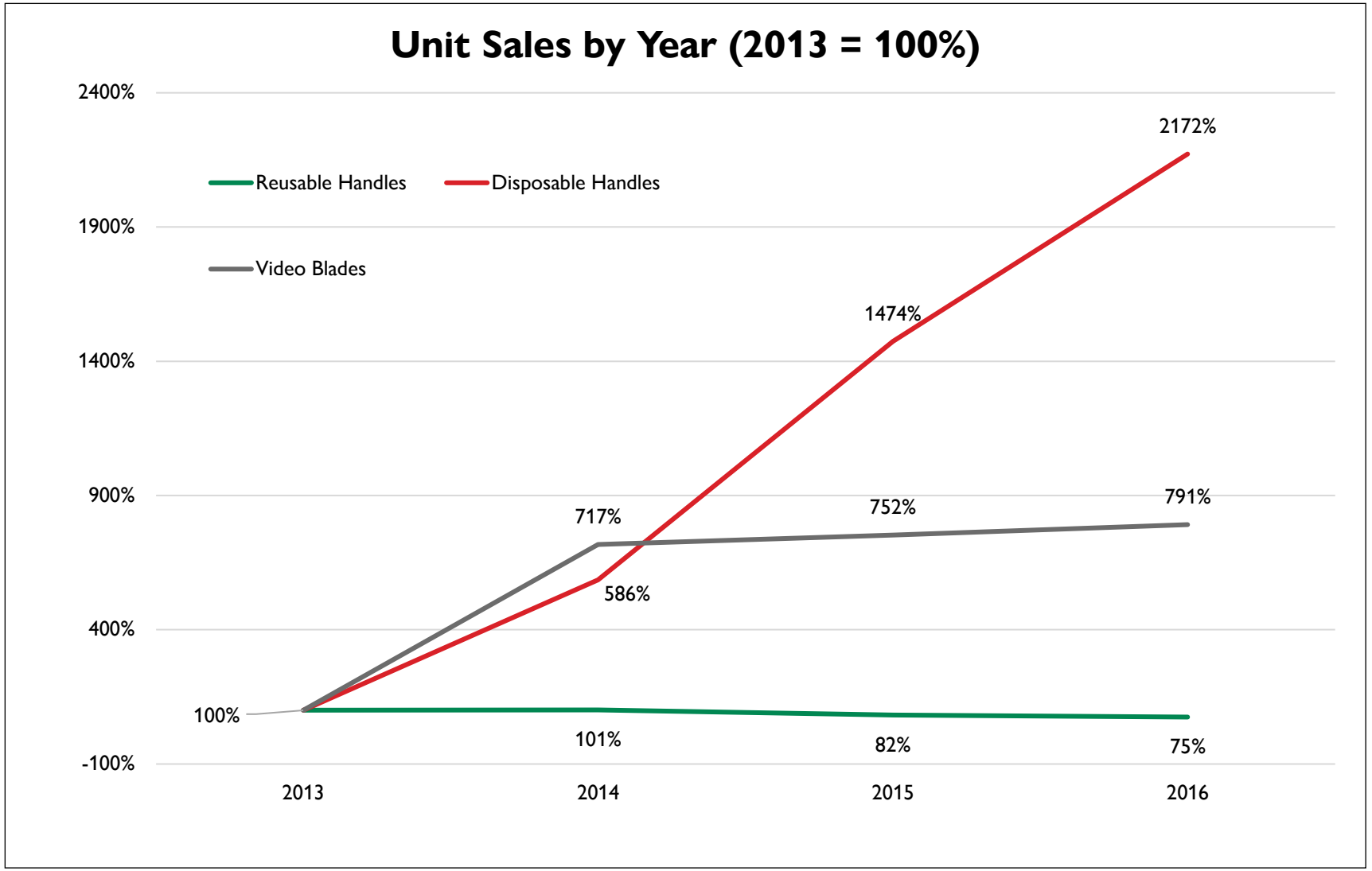
Estimated Cost of One Hospital Acqired Infection	$ 40,000
Total Annual Cost	**$ 106,548**
Cost/Intubation	**$ 27.40**

Southeast Health

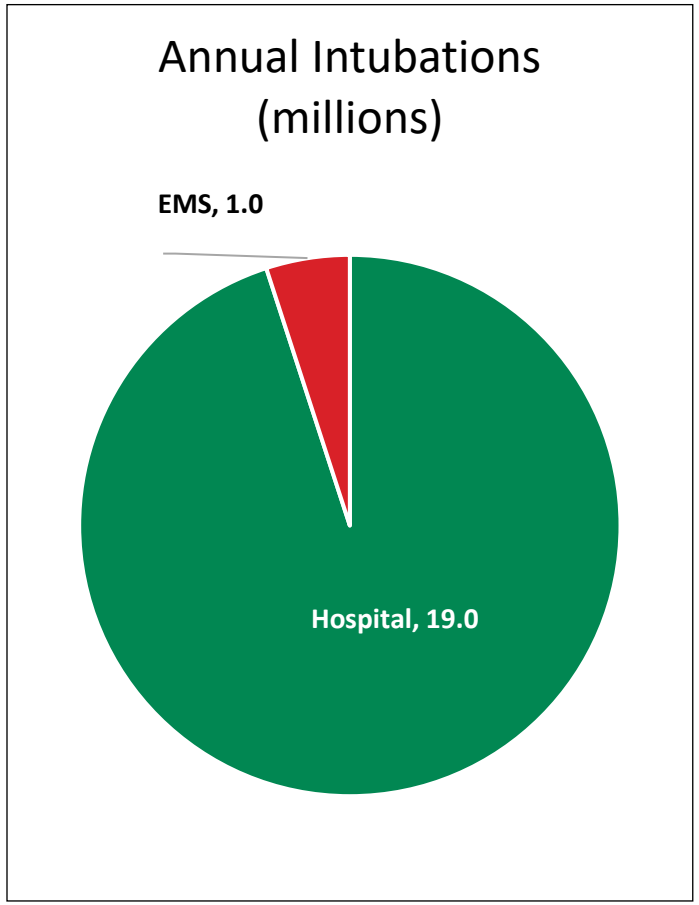
Cape Girardeau, Missouri

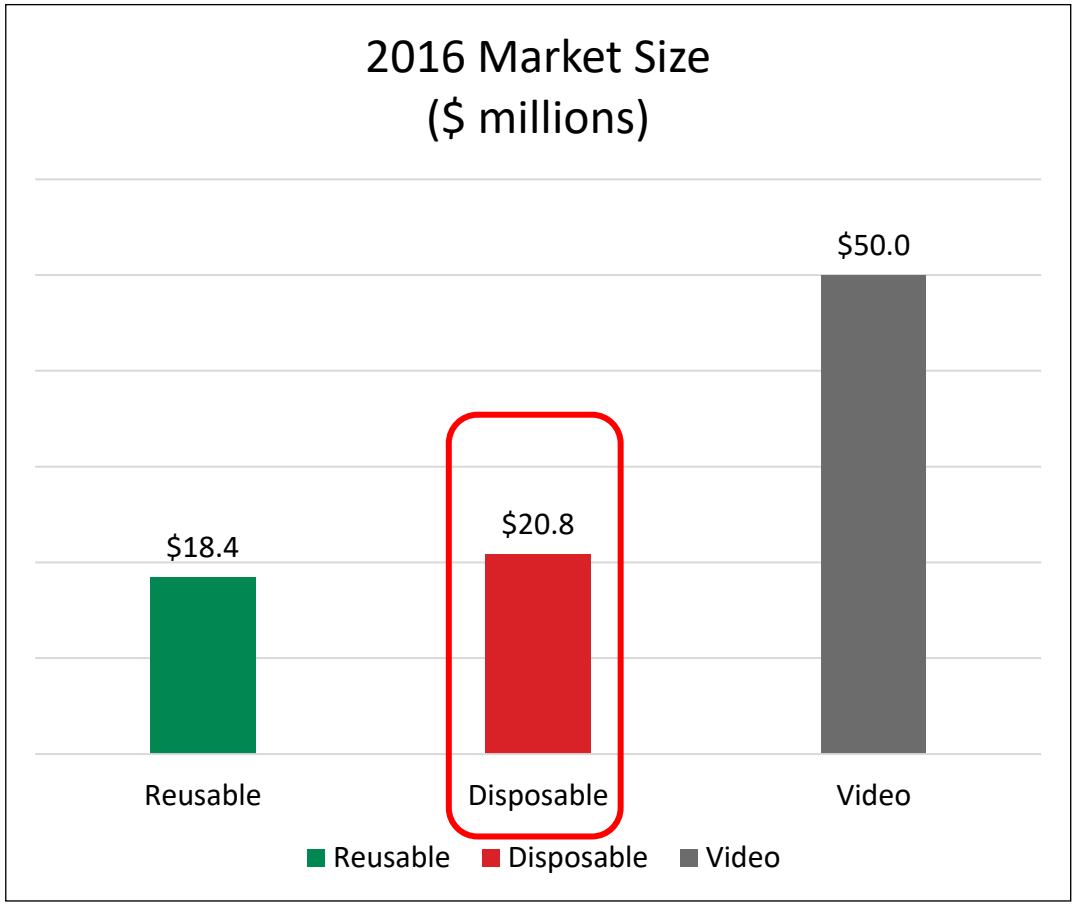
- Reprocessing cost $17.12/intubation
- If 1 HAI: Add'l $10.28/intubation

MARKET SEGMENT SIZES AND GROWTH



MARKET SIZE





Salter's greatest opportunity is in the Hospital market with Disposable handles & blades

* Reusable includes disposable blades used with reusable handles

MAJOR PRODUCTS, PRICING, STRENGTHS AND DRAWBACKS: DISPOSABLE

	ASP	Strengths	Weaknesses
 **Flexicare BritePro**	$10-15	• Recycling program • Contracts	• Reliability • Handle-blade give
 **Teleflex DispoLED**	$10-15	• None	• Reliability • Light quality • Handle-blade give
 **Intubrite**	$11-12	• UV light • Light quality • Metal construction • Reliability, strength, and quality	

Smaller Players (not comprehensive)

Heine XP

Sunmed SunOne

Storz Laryngobloc

OBP Surescope

MAJOR PRODUCTS AND PRICING: VIDEO

			Reusable Config			
			Monitor	Blades	Cable	Wands	Blades
ROLLSTAND		Verathon Glidescope	~$5k	$2-3k	~$5-$6k	~$4k	~$20-30
		Karl-Storz C-MAC	Over $5k	~$4k	~$500	unknown	unknown
		Intubrite VLS 8800	$4-$5k	$1k	N/A	~$1k	$8-10
HANDHELD		Ambu King Vision	$1.0-$1.5k	N/A	N/A	included	$8-10
		Medtronic McGrath MAC	$1.6-$2.6k Sometimes free	N/A	N/A	included	$12-20
		Intubrite 6600 Edge	$1.5 - $2.5k	$1k		~$1k	$8-10

Smaller Players (not comprehensive)

Venner APA dist. by Vyaire

Airtraq Dist. by TFX 

Magaw Co-Pilot 

Karl Storz C-MAC PM

Verathon Glidescope Go (NEW)

QUESTIONS?