

# FORMA

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endoscopy

*Superior Solutions for  
Pediatric Surgery*

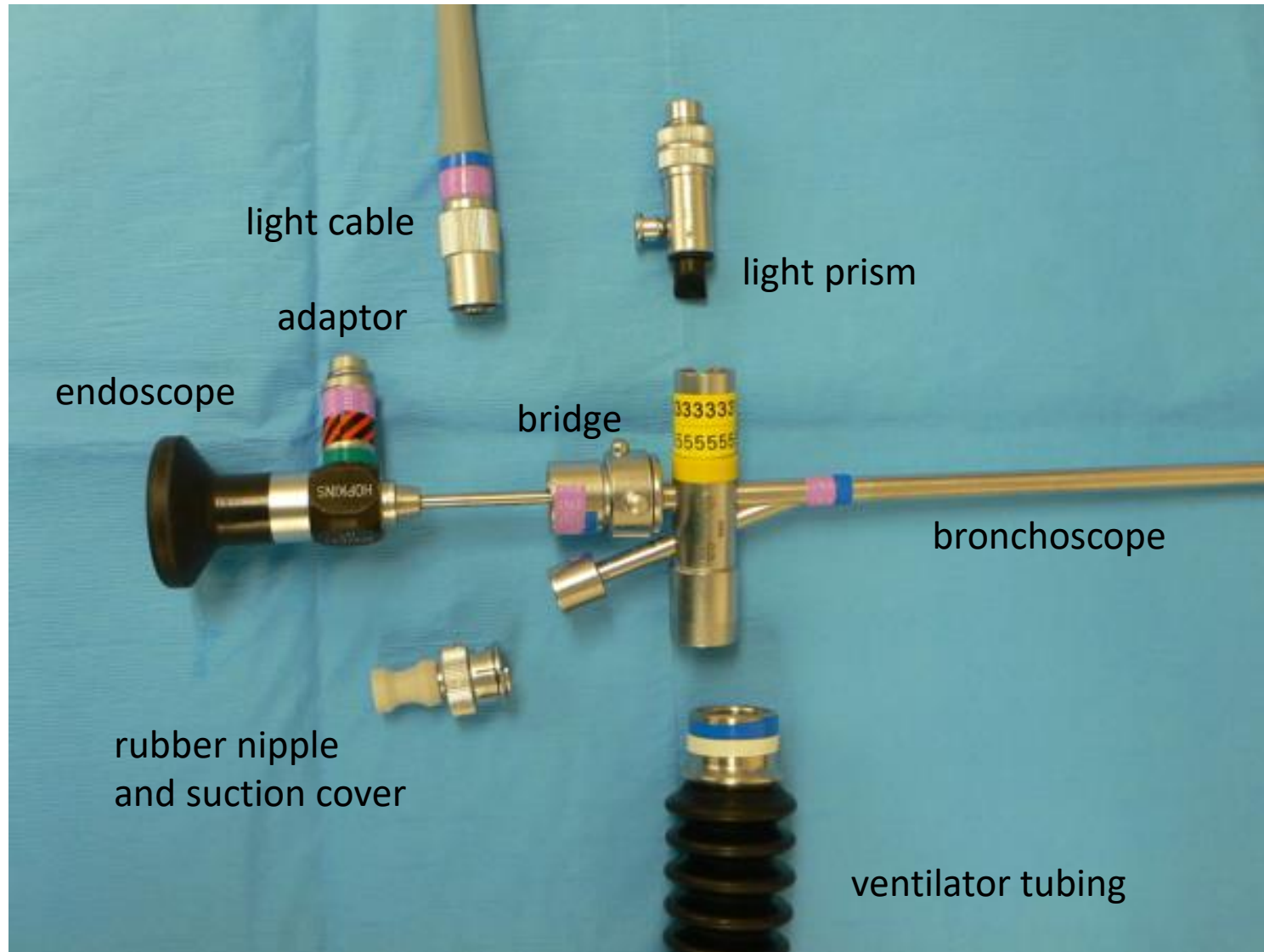
[www.FormaEndoscopy.com](http://www.FormaEndoscopy.com)

# Choking is the Leading Cause of Accidental Death in Toddlers!



- 2.5 million foreign body aspirations in US
- 3% death in airway aspiration

# Current Pediatric Rigid Bronchoscope System



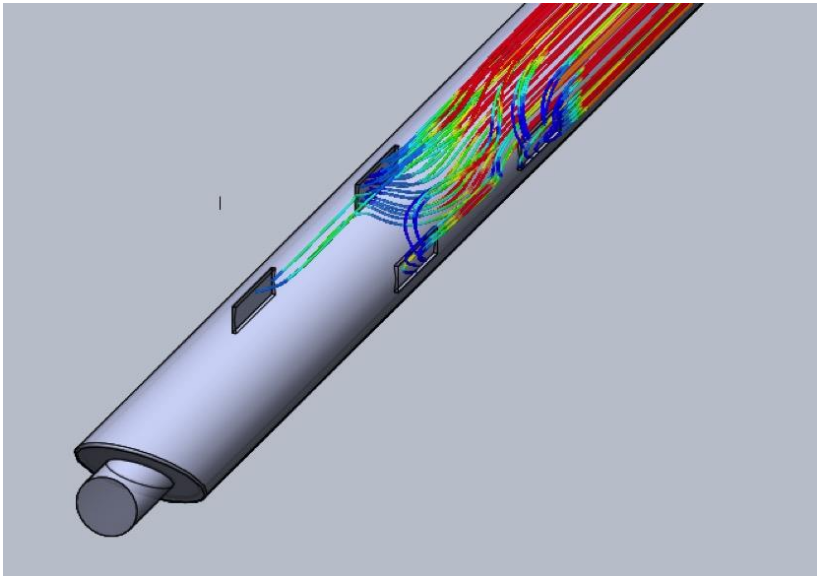
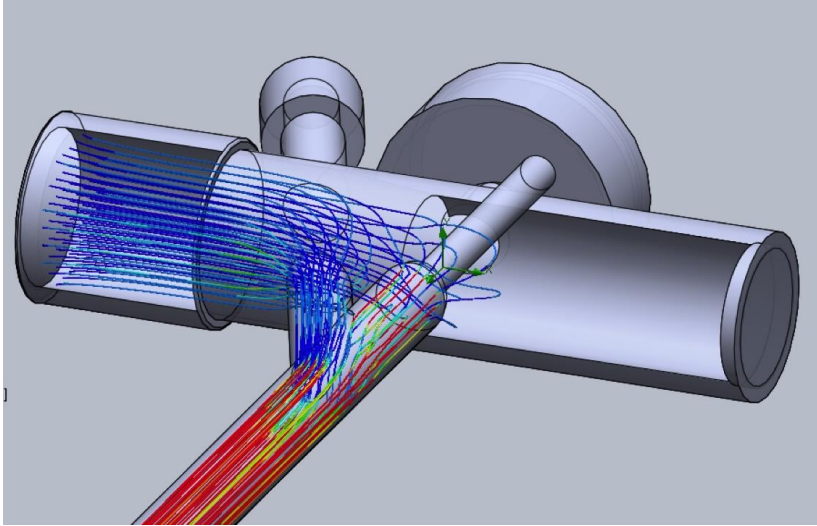
**Could you easily assemble this system?**

Would it make sense to assemble a fire extinguisher when a fire starts?



Time is critical!

# Complications During Bronchoscopy



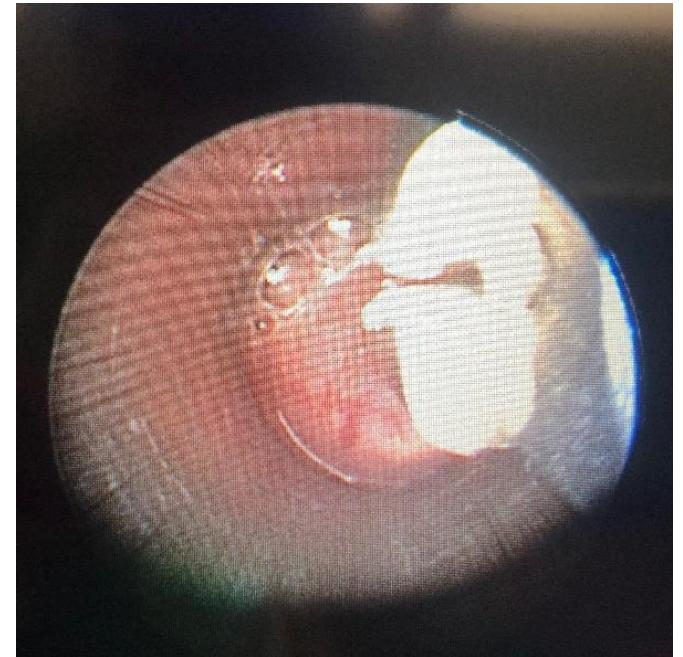
- Low oxygen and elevated CO<sub>2</sub> which can cause intraoperative cardiopulmonary arrest in children
- Mortality rate 0.5-1.1%, overall major complication rate 20%, prolonged anesthesia 5%
- Surgeon inhales anesthetic gas

(See Appendix 1)

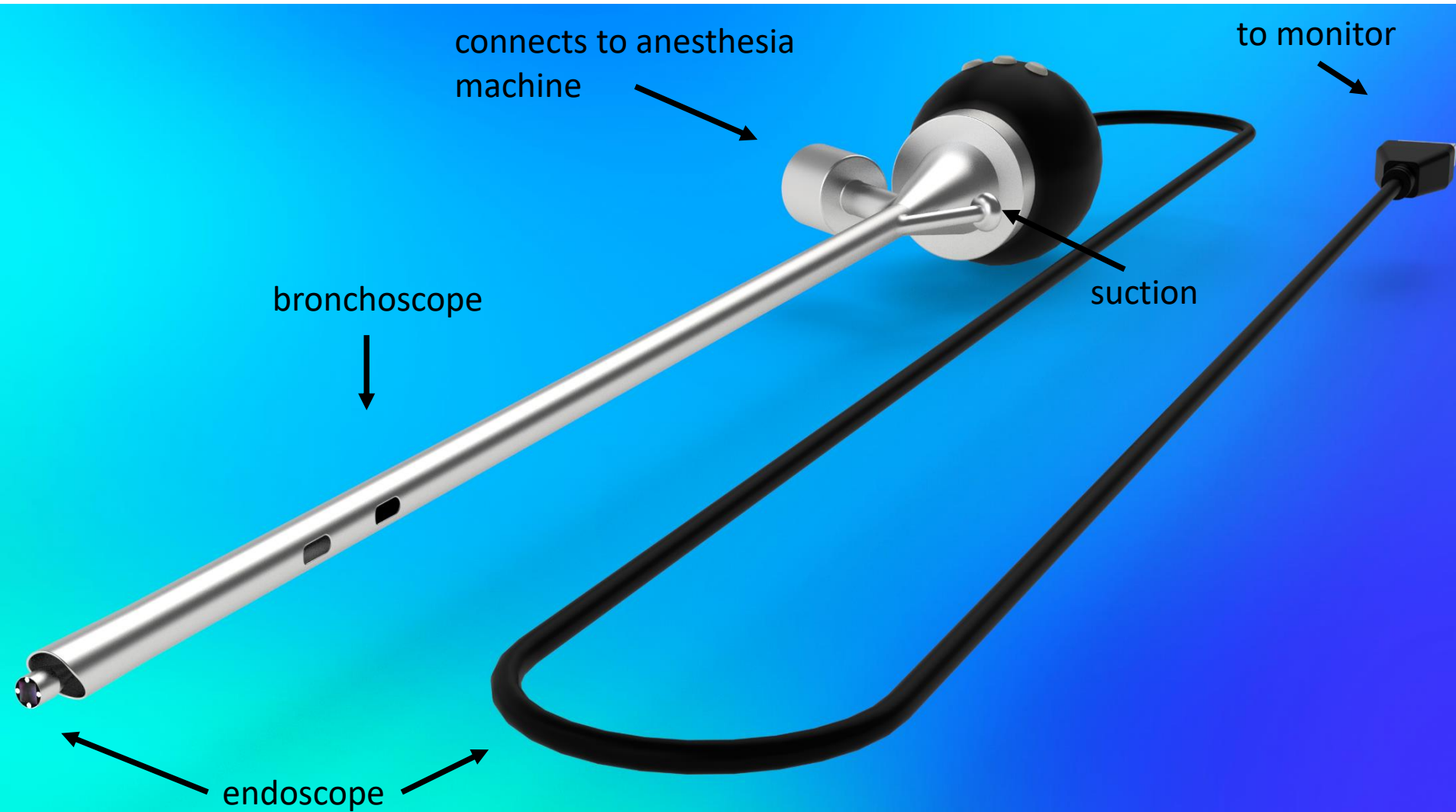
# Surgeons Agree!

Confirmed by data collection series

- Difficult assembly
- Cumbersome
- Poor imaging/viewing
- Suctioning problems
- Poor patient ventilation



# FormaVue



# Advantages

- **Easier to assemble** (3 pieces)
- **Easier to handle**
- **Improved flow of vital gases**
- **Larger suction catheter**
- **HD imaging**

**Improved Outcomes!**



# Additional ENT Opportunities








Ear



Sinus

- Versatile device enables our design to readily gain acceptance in the sinus and ear markets
- Substantially larger market size

# Competition/Acquisition Partners

Manufacturer	Easy to Assemble	Improved Flow	Easy to Handle	Improved Suction	HD Imaging
	Yes	Yes	Yes	Yes	Yes
	No	No	No	No	No
	No	No	No	No	No
	No	No	No	No	No
	No	No	No	No	No

## **J. Fredrik Grimmer, MD**

*Founder, CMO, Director*

Professor of Surgery in pediatric otolaryngology at the University of Utah School of Medicine with expertise in airway problems.



## **Mike Russell, MBA**

*Founder, CEO, Director*

Over 30 years experience in the medical device industry developing and bringing to market novel, new med tech for early stage and start-up companies.



## **Timmy Chou**

*CFO*

Over 25 years experience includes CFO, Controller, and other management consultant responsibilities for numerous companies including medical device and pharma start-ups.



## **Joseph Nowoslowski, MD**

*Director*

Retired emergency medicine physician involved in angel funding and early seed biotech and med tech startups.



# Traction

- \$ ASPO grant, \$400k non-diluted funds invested
- 4 prototypes, design fine tuned
- Lamb ventilations study
- 3 podium presentations, 1<sup>st</sup> place basic science award
- 3 peer-reviewed publications
- 2 utility patents pending

(detailed time-line see Appendix 6)

# Opportunity

- \$1.5 M will get us 510k (Class II) FDA approval and full market launch in the US
- Targeting leading US children's hospitals and key opinion leaders
- Commitments gained from 20+ US surgeons
- Securing 10 hospitals would obtain 10% market share in the US

# Unique ADVANTAGES

- A **very low risk, inexpensive engineering** and technical development pathway with going to market in < \$1.5M financing
- A **very low risk regulatory** pathway (Class II, 510K) with a predicate
- **Well-defined influencers** (pediatric & adult ENT, general surgeon, hospital risk management & administration)
- **High-margin product** (ASP \$12,000/system) (COGS <\$1,000)
- Numerous **well-aligned** manufacturing, distribution, licensing and acquisition partners

# Summary

- Experienced, dedicated team
- Substantial technology improvement
- Traction building
- Sizable, well-defined total market
- Favorable valuation/investment terms

# Questions

Mike Russell

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