# Airway Bronchoscope

*The future of rigid bronchoscopy and minimally invasive airway surgery*

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# Airway Foreign Bodies

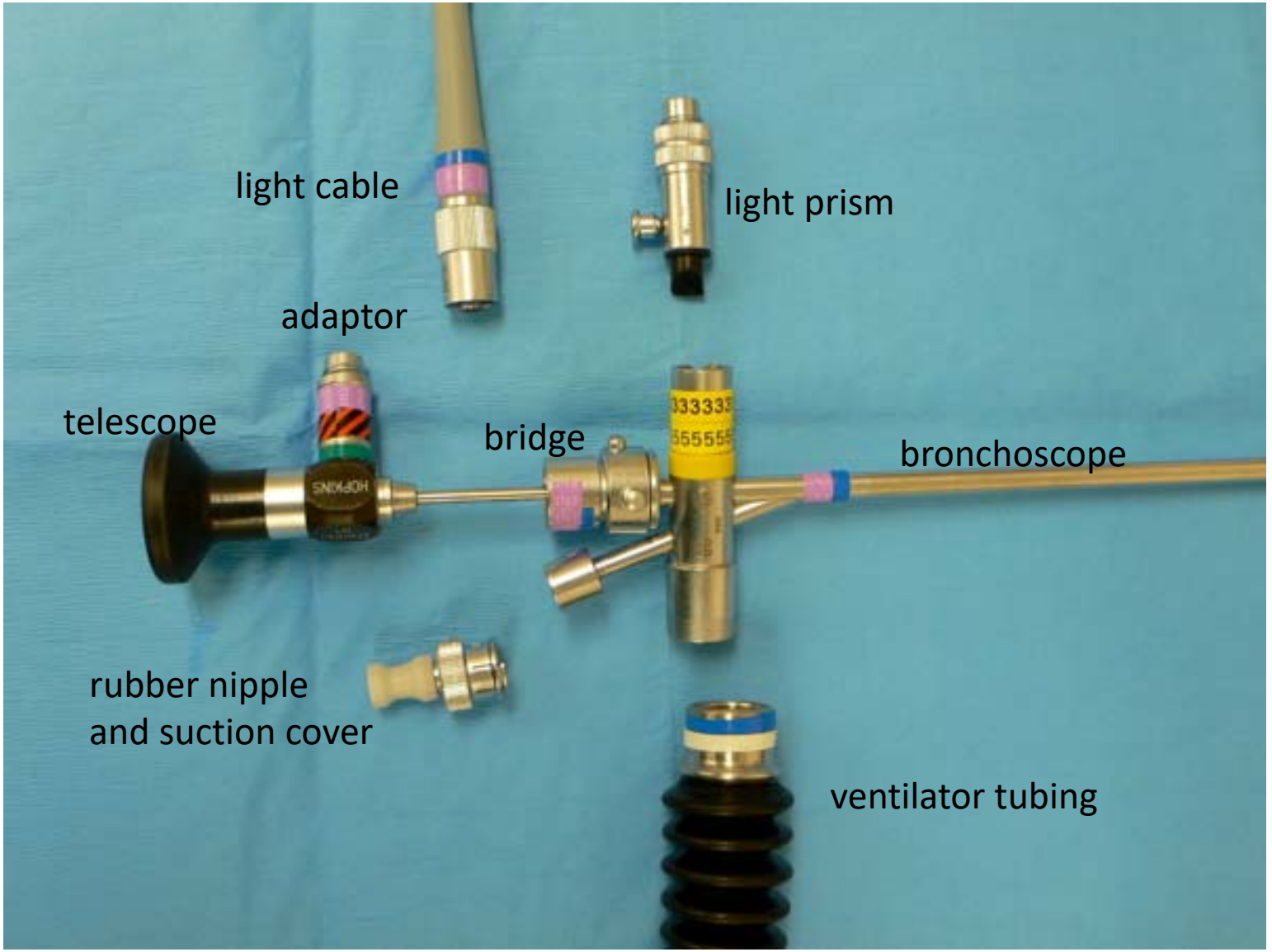
- **2.5 Million** foreign body aspirations per year in US[1]
- **3.4 % mortality** in pediatric hospitalizations for airway foreign bodies[2]
- **2000 deaths** per year in the United States[1]
- **3rd and 4th** leading cause of **accidental death** in ages 1-4 and 0-1, respectively[3]

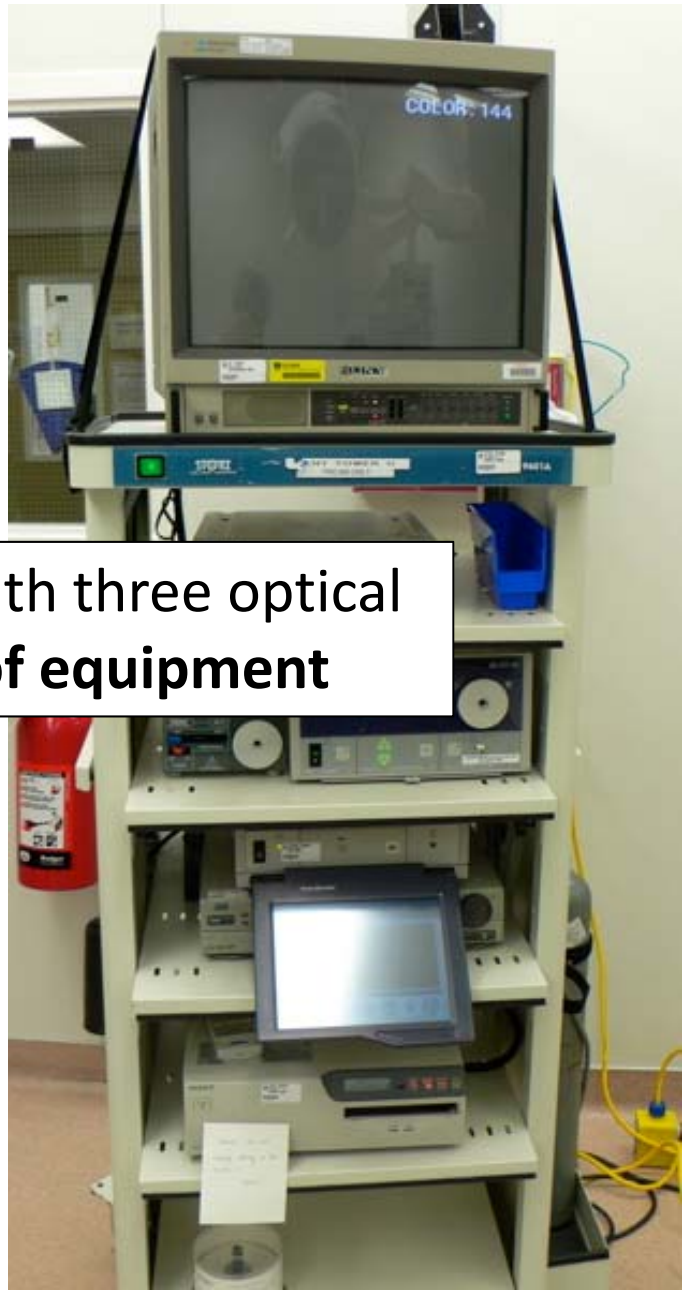

1 Karatzanis , Vardouniotis, Moschandreas et al. The risk of foreign body aspiration in children can be reduced with proper education of the general population. Int J Pediatr Otorhinolaryngol 2007;71 (2) 311- 315

2 Shah RK, Patel A, Lander L, Choi SS.Arch Management of foreign bodies obstructing the airway in children. Otolaryngol Head Neck Surg. 2010 Apr;136(4):373-9

3 Rodríguez H, Passali GC, Gregori D, Chinski A, Tiscornia C, Botto H, Nieto M, Zanetta A, Passali D, Cuestas G. Management of foreign bodies in the airway and oesophagus. *Int J Pediatr Otorhinolaryngol.* 2012 May 14;76 Suppl 1:S84-91. Epub 2012 Feb 24S

# The pediatric rigid bronchoscope






Two bronchoscopes used with three optical forceps requires **28 pieces of equipment**

# Would it make sense to assemble a fire extinguisher from 28 pieces?

# Complications During Anesthesia

- **Hypoxemia** (9.2-25.5)[1-3] and **hypercarbia** (24%)[1]
- **Surgeon** inhales **anesthetic gas**[5] (headache, dizziness, increased risk if surgeon has liver disease)
- **Hypoxemia** and **inability to ventilate** is most common cause for **intraoperative cardiopulmonary arrest** in children[6]
- **Mortality** 0.5-1.1%[7,8]
- **Overall 20% major complication rate, 5% prolonged anesthesia**[9]


1 Litman RS, Ponnuri J, Trogan I. Anesthesia for tracheal or bronchial foreign body removal in children: an analysis of ninety-four cases. Anesth Analg 2000;91:1389–91

2 Chen LH, Zhang X, Li SQ, Liu YQ, Zhang TY, Wu JZ The risk factors for hypoxemia in children younger than 5 years old undergoing rigid bronchoscopy for foreign body. Removal. Anesth Analg. 2009 Oct;109(4):1079-84.

3 Shen X, Hu CB, Ye M, Chen YZ. Propofol-remifentanil intravenous anesthesia and spontaneous ventilation for airway foreign body removal in children with preoperative respiratory impairmentPaediatr Anaesth. 2012 Dec;22(12):1166-70.

4 Ostfeld E, Ovadia L. Bilateral tension pneumothorax during pediatric bronchoscopy (high-frequency jet injection ventilation). Int J Pediatr Otorhinolaryngol. 1984 Jul;7(3):301-4.

5 Westphal K, Lischke V, Aybeck T, Kessler. Exposure of the pediatric surgeon to inhalation-anesthetic during pediatric bronchoscopy, procedures. Pneumologie. 1997 Dec;51(12):1123-6.

6 Morray JP. Cardiac arrest in anesthetized children: recent advances and challenges for the future. Paediatr Anaesth. 2011 Jul;21(7):722-9.

7 Fidkowski CW, Zheng H, Firth PG. The anesthetic considerations of tracheobronchial foreign bodies in children: a literature review of 12,979 cases. Anesth Analg. 2010 Oct;111(4):1016-25

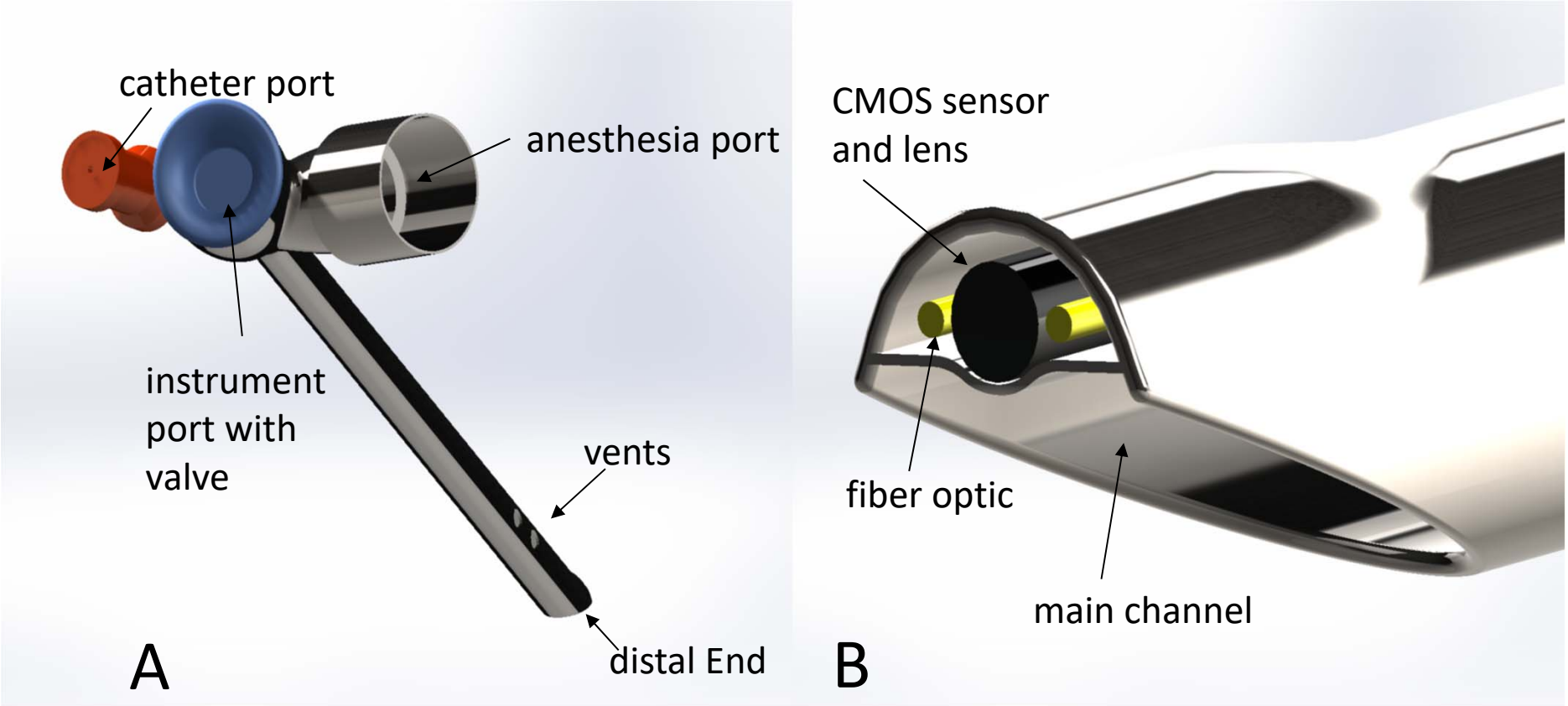
8 Latifi et al. Rigid tracheobronchoscopy in the management of airway foreign bodies: 10 years experience in Kosovo.*Int J Pediatr Otorhinolaryngol.* 2006;70:2055-9

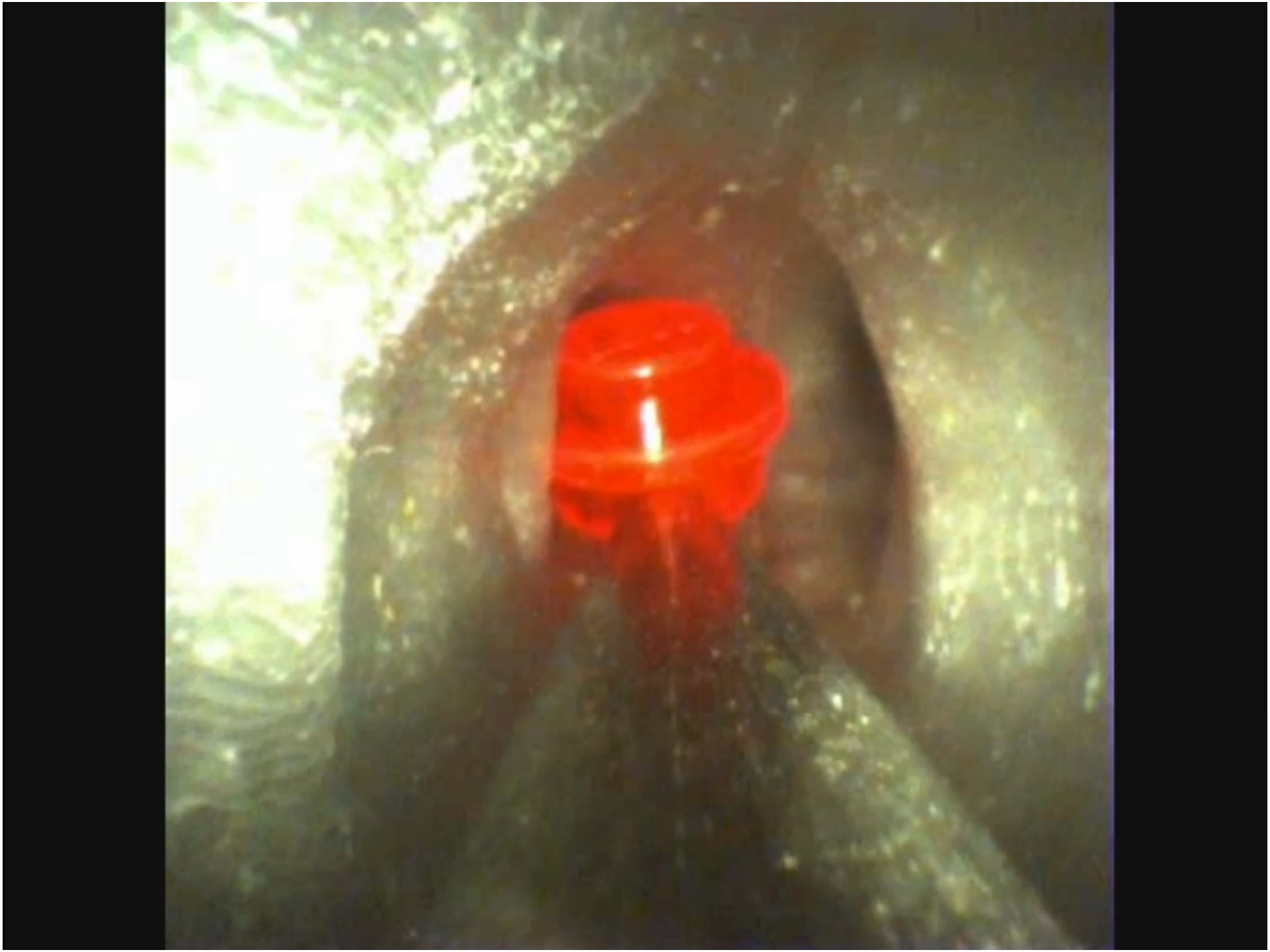
9 Sjogren, PP . . . Grimmer, JF. Predictors of Complicated Airway Foreign Body Extraction. *The Laryngoscope*. In Press.

# Airway Designs, LLC

- Start up with two bioengineering students from the U
- $10,000 personal funds
- $25,000 in engine funding
- Jeremy Horton —> Engineering support
- Myriad Fiber —> Fiber options and CMOS (Omnivision)
- 3-D printed prototype with 3D systems

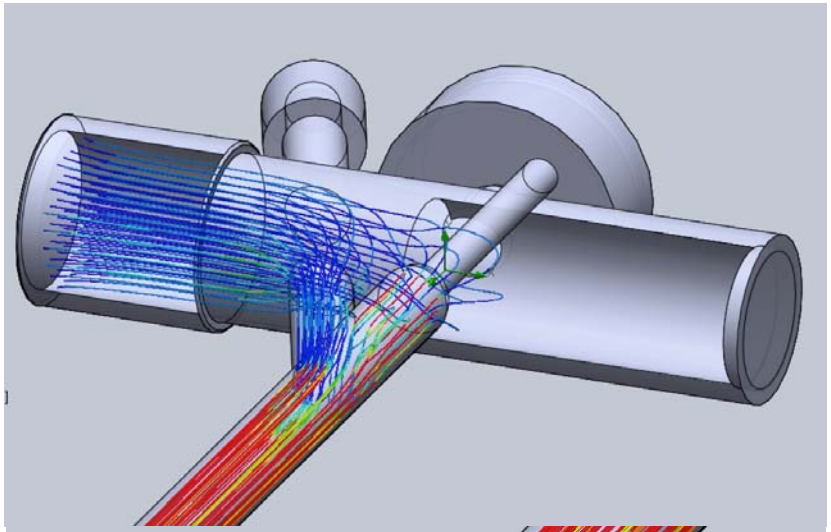
# Fully Integrated Rigid Bronchoscope

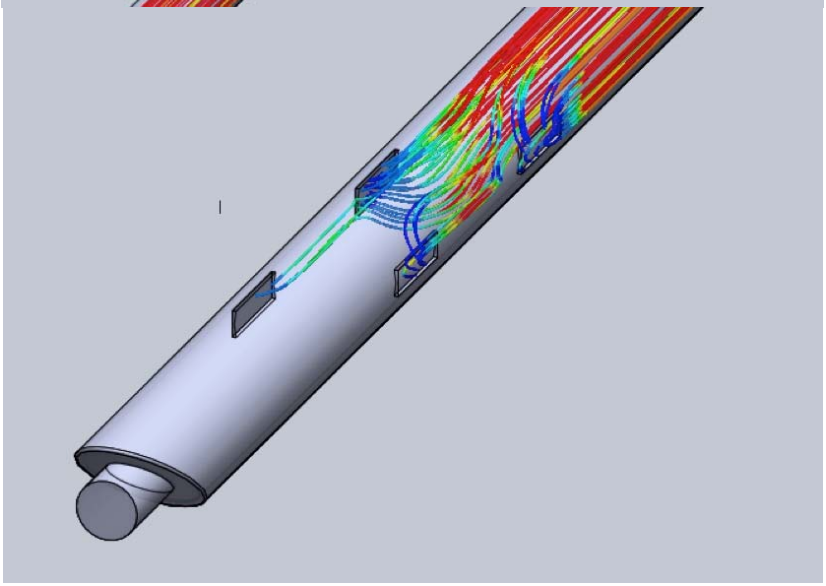




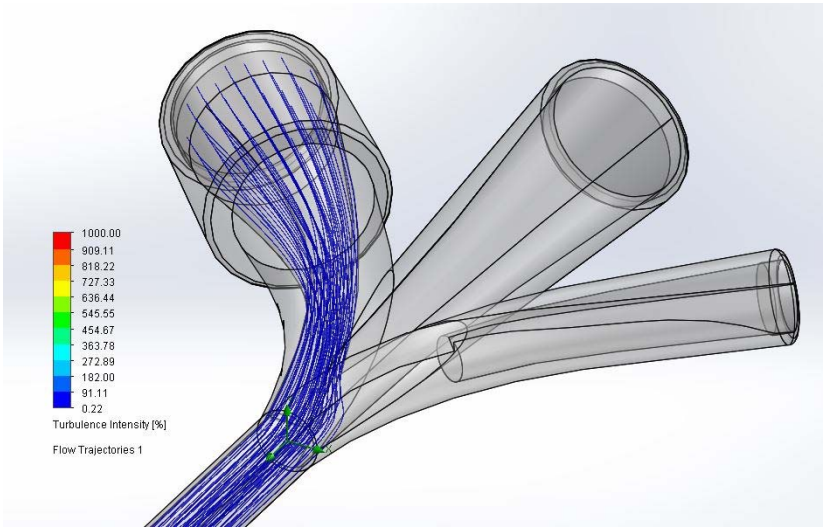
# Computational Fluid Dynamics

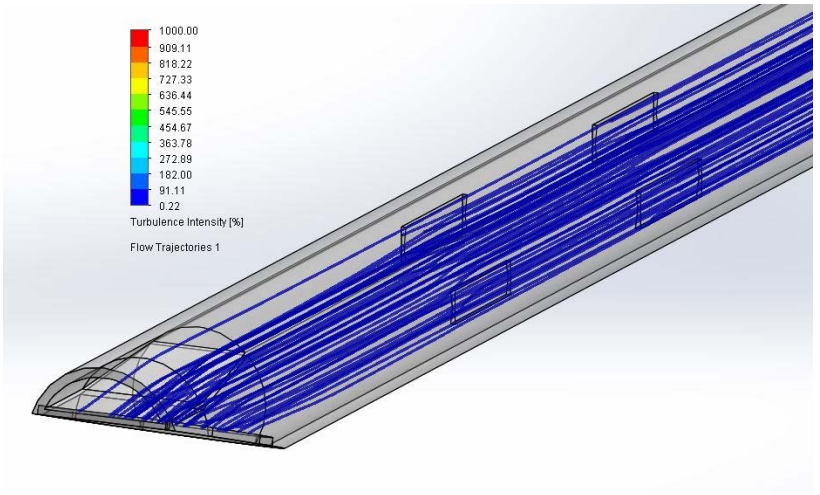
## Control



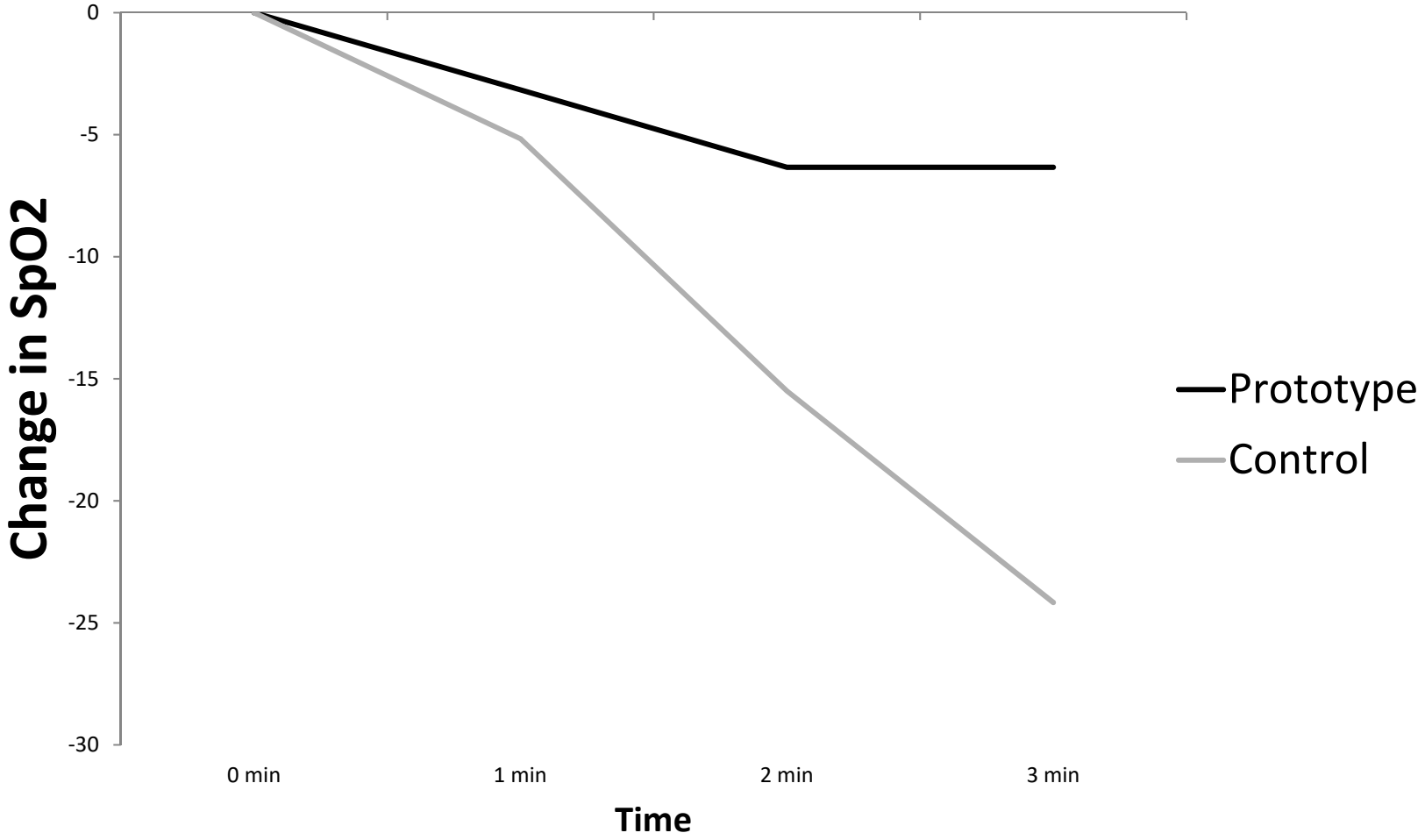


## Prototype



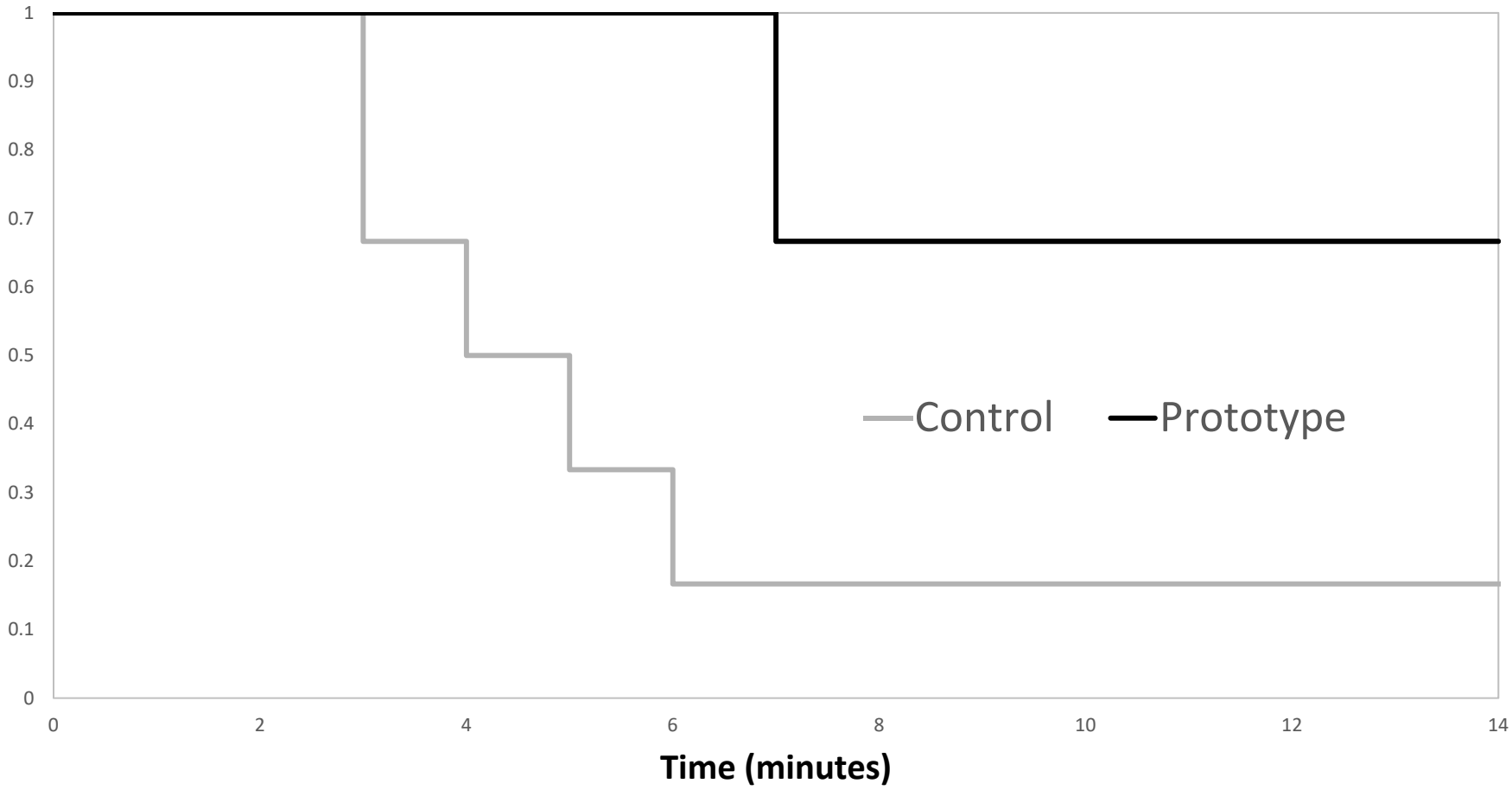



# Mean SpO2 during Bronchoscopy with Mechanical Ventilation in Lambs (n=6)




Mann Whitney U Test at 3 min ($P < 0.03$)

# Hemodynamically stable lambs during bronchoscopy with mechanical ventilation




Kaplan-Meier Curve with Log Rank Test (P<0.17)

# Advantages

- **Faster response time and fewer technology failures**
  - 3 piece assembly compared to 10
  - No need to switch-out camera head and re-focus image during procedure
- **Improved patient ventilation**
  - Improved laminar flow
  - maintain a sealed airway circuit
- **Less accidental trauma**
  - Continuous viewing during suction
- **Shorter procedure time**
  - Few steps to complete a task
  - Easier Instrument insertion
- **Better control of instruments**
  - Easier to handle and insert
  - Greater variety of instruments
  - 2 instruments simultaneously

# Market Research

- LEAN Cohort Analysis
  - 6 week course through the University of Utah
  - Developed objective survey to identify “pain points” with current technology
  - Interviewed pediatric surgeons and pediatric otolaryngologists in Utah and Colorado
  - Most commonly cited “pain points”
    - **Complicated assemble (unanimous)**
    - **Lack of viewing during suctioning**
    - **Poor ventilation**

# Marketing Research

- Primary Children's Hospital represents about 1% of US market
- 600 pediatric rigid bronchoscopies per year
  - 90% diagnostic
  - 10% Foreign Body removal
- Maintain inventory of 80 bronchoscopes replaced every 5 years
- Cost per unit is $11,664

# Market for Pediatric Bronchoscopy

| | Number of children (<15 yo) | Number of scopes needed | Market to replace current inventory ($10,000/scope) | Annual Addressable Market ( 5 year life) |
|---|---|---|---|---|
| Primary Children's | | 80 | $800,000 | $160,000 |
| Utah | 653,344 | 100 | 1,000,000 | $200,000 |
| United States | 62,771,600 | 9,615 | $96,153,000 | $19,230,000 |
| North America | 66,281,101 | 10,144 | $101,144,900 | $20,288,000 |
| Europe | 118,417,680 | 18, 124 | $181,240,000 | $36,248,000 |

http://www.prb.org/DataFinder/Geography/Data.aspx?loc=412

# Challenges

- Keep imaging components clean *in situ*
- Small market
- Disruptive design

# Future

- $727k to obtain 510k (Class II) FDA approval
- **Myriad Fiber** to manufacture imaging system
- Low and high volume manufacturing plans being developed
- Target thought-leading Children's Hospitals
- Only need contracts with 8-10 Children's Hospitals to obtain 10% market share in the US
- With 10% market share, US annual addressable market 1.9-3.8 million

# Praise at ASPO Meeting, Austin, TX, May 2017

- Michael Rutter, MD (Cincinnati Children's Hospital)
- Robert Rubin, MD (Albert Einstein College of Med.)
- Reza Rahbar, DDS, MD (Boston Children's Hospital)
- Karen Zur, MD (Children's Hospital of Philadelphia)
- Margaret Kenna, MD (Boston Children's Hospital)
- Glenn Green, MD (University of Michigan)
- David Zopf, MD (University of Michigan)
- Bob Weatherly, MD (Children's Mercy, Kansas City)