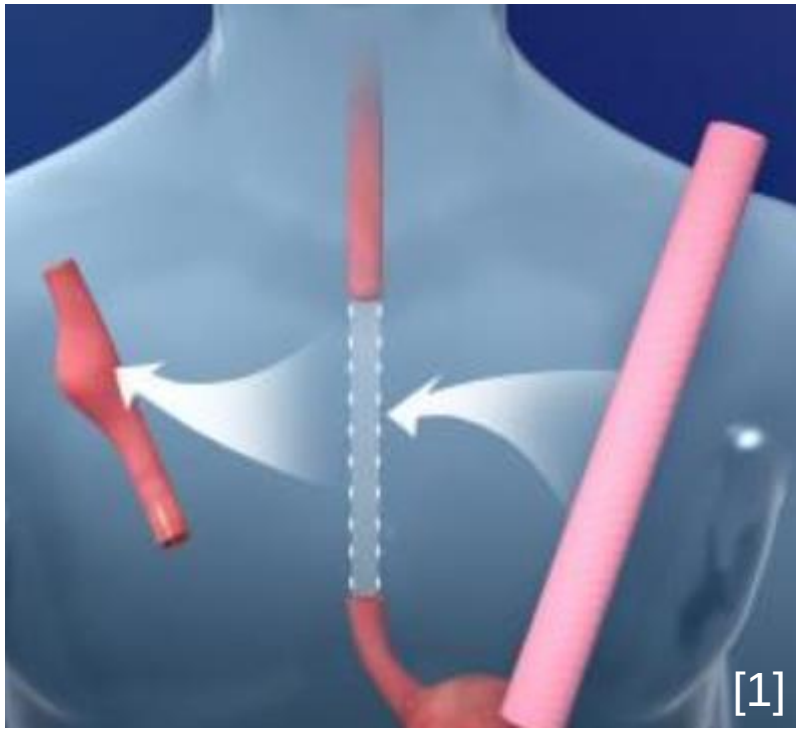
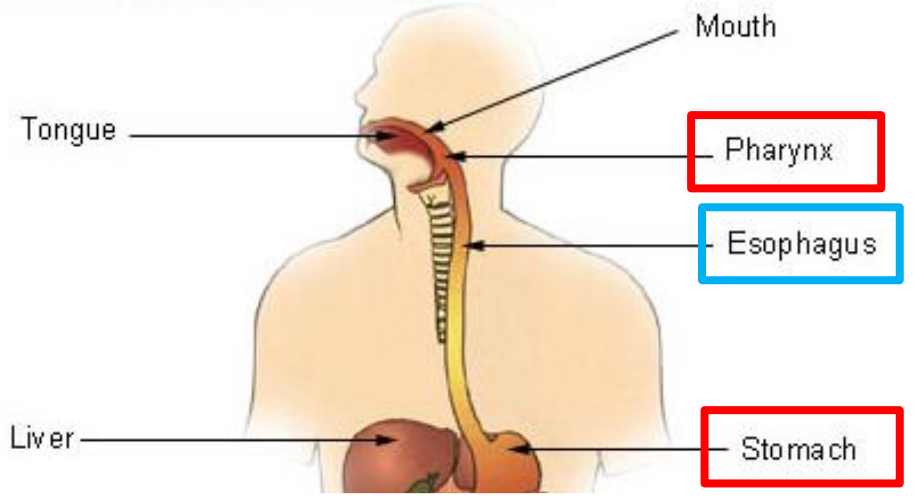
Cellspan Esophageal Implant


[1]

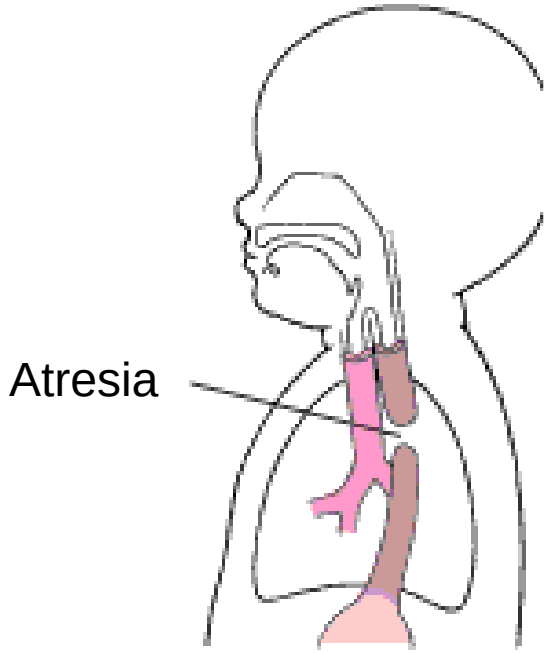
Final Project
EN.585.729.81
Julia Hand

Background & Problem Statement

- Esophagus [2]
  - Tube shaped
  - Striated & smooth muscle
  - Pharynx to stomach
- Diseases [4]
  - Esophageal atresia [5]
    - 1 : 4100 babies
  - Esophageal cancer [7]
    - 20,640 diagnosed
    - 16,410 die
- Patient needs & current market [5&7]



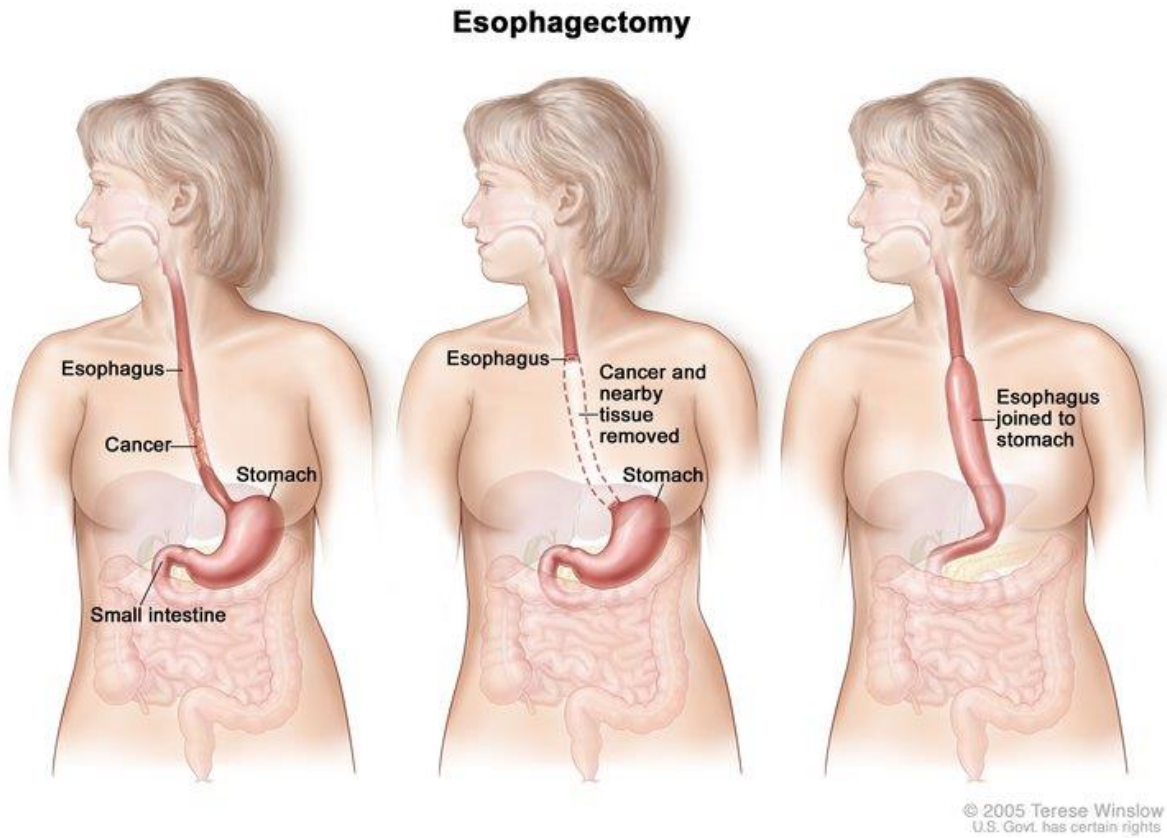
[3]



[6]

Existing Landscape

- Surgical reconnection [8]
- Gastric pull-up or transposition [9]
- Colon interposition [4]
- Jejunal interposition [11]
- Foker Process [12]



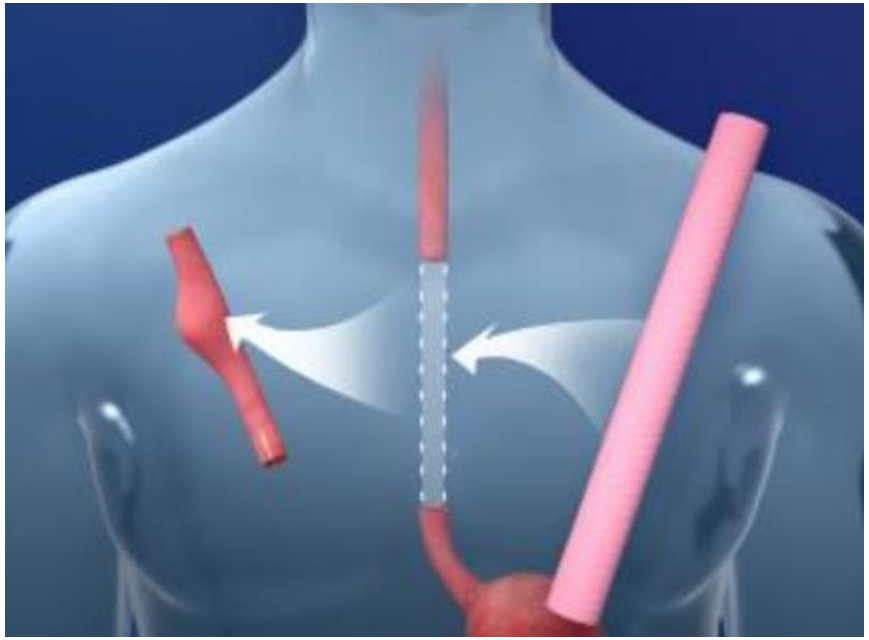
[10]

Engineered Solutions

- Biostage [13]
  - Patient stem cells
  - Cellspan scaffold

biostage™
REGENERATIONS AHEAD [1]

- Design Criteria
  - Size [14]
  - Invasiveness
  - Rejection
  - Application [15]
  - Manufacturability [16]
  - Strain properties [17]



[1]

Validation & Verification

- Native esophagus stain [17]
  - Longitudinal = 2.1MPa
  - Radial = 1.4MPa

Validation [18]

- Probe-burst pressure testing
  - 25.4mm/min
  - Native & new tissue
- Removed 5cm of native esophagus & inserted 6cm of Cellspan implant
- 3 timepoints (30, 90 & 365 days)
  - Removed implant & 4cm of tissue
- **Conclusion**
  - Longer post implant time, stronger tissues
  - Increase in average burst pressure

Verification

- 2017 first human implant [19]
- 90 days [19]
- Large animal trials [20]
- March 2020 [20]
- **Conclusion**
  - Implant met patient needs

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