





# 750K develop pneumonia due to stomach reflux/year due to ventilator (VAP)



# Cost of pneumonia (VAP)

48 K per patient

7 days of extended hospital stay

## Hospital Acquired Infections (HAI):

# Problem (VAP)

Eat into Hospital margin

Not covered by payers

Monitored by Medicare

# Problem (VAP)

Lying flat

Sedation- breathing tube

Muscle relaxant- help breathe with ventilator

Reflux of acid in esophagus and then into lungs to trigger pneumonia

Current feeding tubes don't restore normal emptying of esophagus and stomach

## Solution

Smart FeedT Every intubated patient needs a feeding tube

Restores esophageal and stomach motion: bioelectric stimulation

Detects & Clears saliva that pools at the back of throat that enters the lungs

Using resonant EM distribution

### FDA Approval Process

510K process

Class II device

Plastic & single use

Approval 3-6 months



## 750 K cases of pneumonia

## Savings

36 billion USD/year

5.25 million hospital days saved

# Hospital (Market size)

1 million feeding tubes in ICU patients

1.5 Million in hospitalized patients

2.5 to 5.0 million feeding tubes used (1-2 tubes per patient) (unit)/year

## 0.5 million long-term feeding tubes

## Community (Market size)

Tube changed every 6 weeks

10 tubes/year per patient

5 million feeding tubes (unit)

In hospital: Medicare part A

Reimbursement

Community: Medicare part B

Existing billing code(s)

## Revenue (ICU only)

1 million get feeding tube

Unit cost: \$50

50 million per year (100% penetration)

25 million per year (50% penetration)

5 million per year (10% penetration)

#### Founder & CEO

- Entrepreneur, physician and scientist
- Business & investment advisor: JSimple LLC
- Team: Greg Semenza:
   Nobel prize, 2019
- NIH: excellence award



#### Founder

- Thoracic surgeon-25 years
- Expert in reflux injury
- Pioneer in resonant EM transmission
- Bonde Innovations LLC (CoRISMA): 27 million for 22.2% stake
- FDA panel



Team (Engineering and R/D)

#### Jin Park

VP, Research and development

#### **Daniel Olsen**

Director, Quality assurance & production

#### **Egemen Tuzun**

Preclinical FDA Regulatory affairs

More than 20 years experience in pre-FDA GLP studies.



#### Investment and legal

John Visconti, Visconti and Associates

Corporate legal team:

**Khanna LLP** 



#### Regulatory experts

Jennifer Tomassello: Senior policy advisor, FDA and congressional contact

CardioMed device consultants,
Edgewater, MD

MCRA:
reimbursement
experts, Manchester,
CT

#### Science

This groundbreaking work: link between reflux and damage to lungs & esophagus

This work led to the invitation from Johns Hopkins for Dr. Bonde to continue his work.

Validation in extensive animal studies

Worlds first esophageal cancer vaccine developed by Dr Bonde based on this work



## National Institutes of Health



ROYAL COLLEGE OF PHYSICIANS AND SURGEONS OF GLASGOW

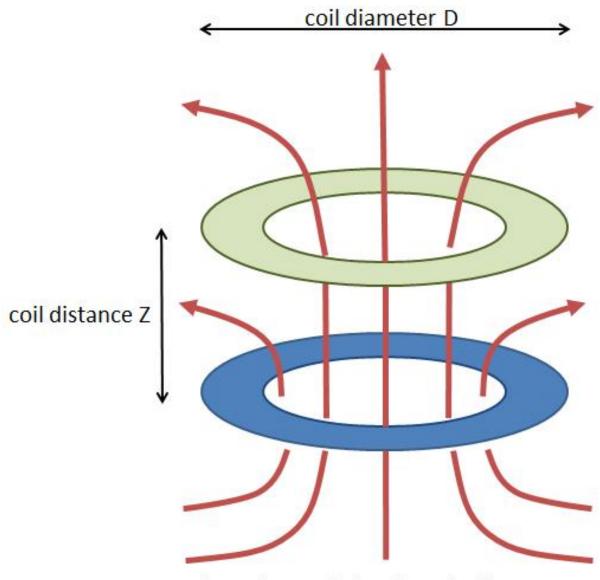




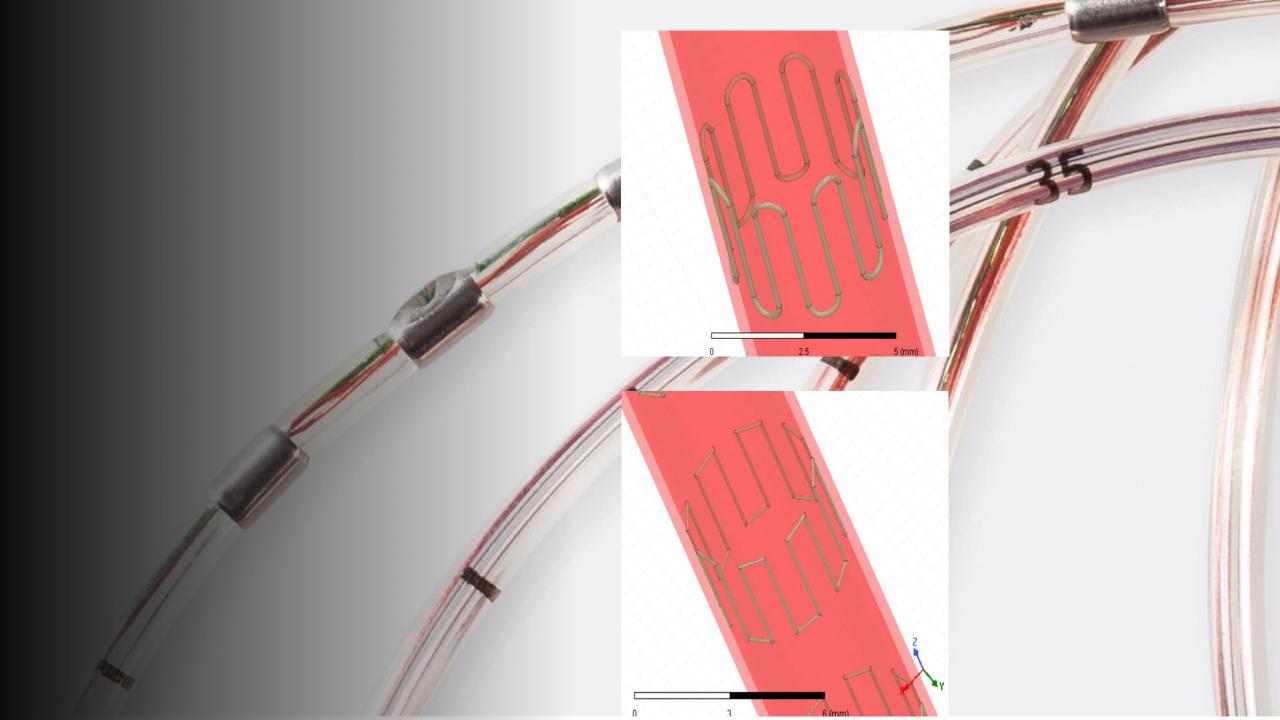


Funding and grants

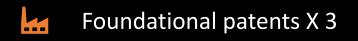
## Resonant EM transfer

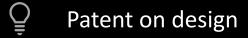


loosely coupled coils: Z similar to D



## IP portfolio (six identified and four in works)







Patent on AI backed monitoring

Design of smart controller

Telemetry unit design

## Market (expansion)

Dysphagia (Impaired Swallowing) with frequent aspiration	Narrowing in the esophagus or digestive tract (stricture)	Inability to take oral feedings due to head or neck trauma	Gastrointestinal cancer	Gastrointestinal complications due to trauma	Intestinal failure
Bowel Obstruction	Crohn's Disease(in severe cases)	Microscopic Colitis	Short bowel syndrome	Ulcerative Colitis	Prolonged anorexia
Bulimia	Severe protein- energy malnutrition	Coma or depressed sensorium	Liver failure	Critical illnesses (e.g., burns) causing metabolic stress	Dementia
		Neuro-Muscular Disorders	Pediatric Indications		

## KOL (over 100 from top 15 institutions)

Gastroenterology specialist

Thoracic surgeons-

esophagus, stomach& lung specialists

ICU specialists-

Intensivists

Pulmonologists-

lung specialists

ICU nurse managers

ICU nurses

Hospital administrators

Billing and coding specialist

Reimbursement specialists

### Current therapy for prevention of VAP

## Elevate head of bed-

doesn't
 happen 24/7:
 procedures,
 change of
 sheets,
 turning

#### Motility drugs-

 takes days to work

## Anti-acid drugs

 Not effective in reducing volume

#### Suction saliva-

only done
 when nurse
 hears
 "gurgling"-- patient
 drowning in
 own
 secretions!

### KOL- pressure points

#### Administrators:

 Hospital acquired infections- major drain on hospital margin

### Intensive care specialists:

 Mortality and extended ICU stay clogs system

#### ICU nurses:

 Not easy to timely suction, assess and avoid reflux

#### Surgeons/physicians:

 Disappointing to see successful procedure only to have patients succumb to pneumonia

### KOL- major ask

Restore natural motility

Help empty stomach

Prevent reflux

Measure reflux

• Time to intervene

Self propelled tube

Help position tube within body

Help with identifying and de-clogging tube

Automatic suction of saliva and throat

### Current feeding tubes

01

Passive conduit for carrying liquid food

02

Positioning within wrong structure a problem

03

De-clogging a problem-often needing change out

04

Actually exacerbates reflux due to mechanical presence across the valve

### Comparison

#### **Current feeding tubes**

Passive tubes to feed

Does not restore function

Does not prevent reflex of acid

Does not prevent pooling of saliva

Takes >24 -48hrs for accurate positioning

USD 30

#### **Smart FeedT**

Active: able to feed
Restores normal function
No reflux of acid
No saliva pooling
Accurate positioning
Self propulsion
USD 50

#### Silicon Valley Bank Exit Data

#### **Smart FeedT is FDA Class II Device**

	FDA Class II Devices		
Median Exit	\$350 Million		
Median Time to Exit	3.5 Years		
	41% Development Stage		
Stage at Exit	50% CE Mark only		
	9% FDA Approved		

Source: Silicon Valley Bank mid-year Report Healthcare Exits 2015-2018

**Disrupt Existing Market** 

Reflux a common problem afflicting >2.5 million hospitalized patients

**Expand Existing Market:** 

Nursing homes, post chemo patients, stroke patients account for 1.5 million

**Expand Indications** 

Patients after gut operation or major operation who need nutrition

**Expand Patient Eligibility** 

Hasten normal functioning of the esophagus and stomach with motility problems, "not just feed but treat"

Access Expanded Infrastructure

Skills, expertise already exists which can be leveraged

#### Opportunity

Major Market Opportunity

Multiple
Disruptive
Features

Proven & Experienced Management

Strong Investment Fundamentals

"What you have is truly transformative"

Leading Thoracic Surgeon,
Johns Hopkins School of Medicine

"HAI market is ripe for disruption"
Former VP Clinical Affairs Abbott Labs

"Major effect on hospital margin"

Leading Administrator, New York Presbyterian Hospital

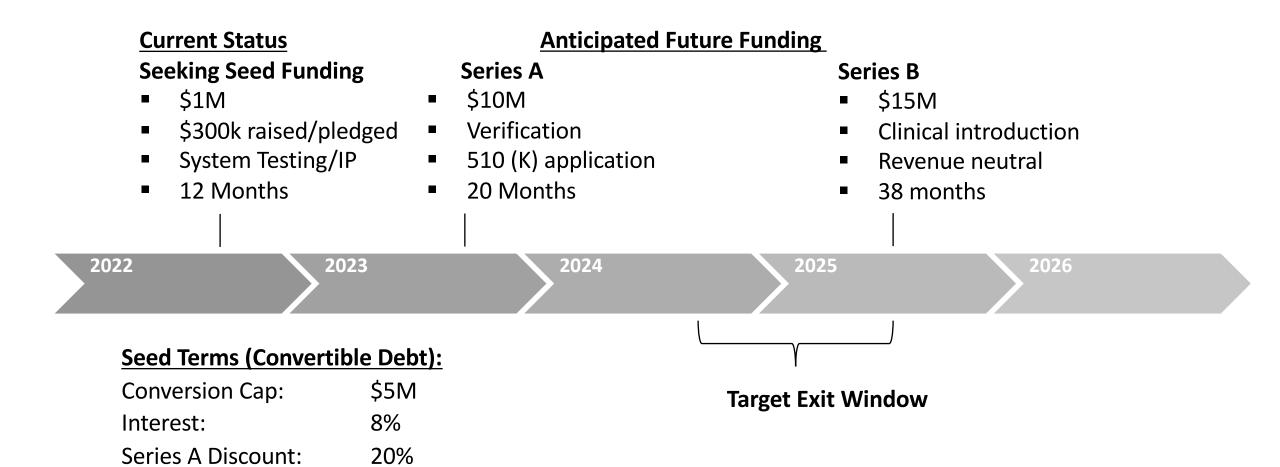
"This transformative device market is a fertile ground"

Former Chief Medical Officer Medtronic

"Everybody will want to buy this company"

Former Chief Editor, MDDI

### Funding and Milestones



#### **Current Device Market Size**







Projected market growth

2021-2028 : \$450 Billion - \$650 Billion CAGR: 5.4%



