Biofilm-Removing Urinary Catheter

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Team 3
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What is it?

- **Biofilm**
  - Microorganisms stuck together

- **Catheter**
  - Used to collect urine from bedridden patients
Current Issues

- Occlusion and Infections
  - CAUTIs

- Catheters must be replaced often
  - Time and Money
  - Pain and Discomfort
Demonstration
Mechanism

(a) Biofilm Forms
(b) Actuate
(c) Water injection, Biofilm removed in urine
(d) Lumen cleared

Repeat biofilm removal as necessary
Intellectual Property Protection

Two Possible Forms-

- **Trade Secret**
  - Little resources required
  - Not practical for this technology

- **Patent**
  - Long, expensive process
  - Most secure form of IP protection for this process
-Current patents exist for:
  ● Catheters
  ● Urinary Catheters
  ● Biofilm Removal Processes

-No current (patented) technology that
  ● removes biofilm in the same way as the one proposed
  ● involves biofilm removal on urinary catheters
Customer Segment

Identification and Analysis
Customer Identification and Segmentation

- **Hospitals***
  - Acute care vs Outpatient
  - Average Stay Time
- **Doctors**
  - Speciality
- **Nurses***
  - Administer Catheters
- **Patients**
  - Choose their own care
  - Long stay
- **Marine Shipping Companies***
  - Large Loads
  - Distance of Travel
- **Medical device companies**
  - Make biomaterials for in the body/bodily fluids
- **Municipal water works**
  - Size/Age of Network
Acute Care Hospitals

Job
- Treat patient pains

Gains
- Overall costs ↓
- Serve more patients

Pains
- Fewer infections
- Fewer deaths
Nurses (who administer catheters)

**Job**
- Care for sick and needy

**Gains**
- More time for other issues
- Happier patients

**Pains**
- Less hassle and upkeep
Large Marine Shipping Companies

Job
● Transport goods across the globe

Gains
● Rid bacteria and be environmentally-friendly
● Overall costs ↓

Pains
● Relieve corrosion and slow ship damage
Value Proposition

Hypothesis & Market Research Approach
Healthcare-Associated Infections (HAIs)

- What are they?
  - Bloodstream infections, pneumonia, surgical site infections, UTIs
- The Problem
  - 1.7 million HAIs in hospitals
  - 99,000 deaths per year
  - 4th leading cause of death in the US
- Plagues
  - Outpatient care, long-term care facilities, in-home patients

- Catheter-Associated Urinary Tract Infections (CAUTIs)
  - The most common type of HAI - from the use of Foley/indwelling catheters
  - 30% of infections in acute care hospitals
  - Accounts for up to 40% of all infections in healthcare settings
  - Received by 12% to 25% of hospitalized patients
VP Hypothesis - HCWs

- **Pain Relievers**
  - Prevent onset of CAUTI
  - Devastating mental and emotional pain for patients
  - Undesired costs (financial pain relief)

- **Gain Creators**
  - Method of effectively removing one of the main causes of CAUTIs (functional gain)
  - Peace of mind for both healthcare workers & patients
Market Research Approach

1. Detailed Market Segmentation
   a. Different types of healthcare workers

2. Assess Competitive Landscape
   a. Better solutions

3. Customized Value Proposition

4. Market Research
   a. Discuss, interview, survey segmented healthcare workers
      i. Feasibility and willingness to adopt technology
      ii. Current frustrations
      iii. Additional training/instruction
Competitive Analysis

Alternative 1: Constantly Replacing the Catheter

- costly for hospital and patient
- painful for patient
- time waste for nurse
- lack of efficiency
Competitive Analysis

Alternative 2: Antiseptic/Antibacterial Catheter
- vulnerable to breaks
- urine samples invalid
- doesn’t work against all types of bacteria
- could get clogged and would need to be replaced anyway
Competitive Analysis

Alternative 3: Non-stick/Hydrophobic Catheter

- still susceptible to breakage and leaks
- cannot remove biofilm once it’s formed
- more expensive
Regulatory Environment-Background

- Regulatory Body in the US is the FDA: Center for Devices and Radiological Health (CDRH)
- Catheters utilize both Class I and Class II medical devices, but the urinary catheter itself is a Class II device.
- FDA identifies a Urinary Catheter as
  “... a flexible tubular device that is inserted through the urethra and used to pass fluids to or from the urinary tract.”
- Identical to the main function of the Biofilm-Removing Urinary Catheter
  ○ Added benefit that the proposed catheter can now remove biofilm on demand.
Regulatory Environment-Assessment

Class II Medical Device Regulation Involves:

- Establishment registration
- Medical Device Listing
- Premarket Notification 510(k) (Unless Exempt)
- Investigational Device Exemption (IDE)
- Quality System (QS) regulation
- Labeling requirements
- Medical Device Reporting
Premarket Notification 510(k) -

- Due to the fact that product is identical in function to that of the already approved urinary catheter, only need to apply for a 510(k)
- Requires written proof that device is similar to existing device, along with processing fees
- Some parts of Urinary Catheter are exempt from this process, but technology as a whole needs to be approved.
## Go-to Market Strategy - Market Focus

- Focus on urinary catheters
- Expand into other medical applications
- Expand into marine, energy and other sectors

<table>
<thead>
<tr>
<th>Medical Devices (Core Sector)</th>
<th>Marine Transportation (Adjacent Sector)</th>
<th>Energy (Adjacent Sector)</th>
<th>Other (Adjacent Sector)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary catheters (core market)</td>
<td>Maritime / Ship hulls*</td>
<td>Jet-fuel*</td>
<td>City drinking water*</td>
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<tr>
<td>Implanted sensors*</td>
<td>Sea water filtration*</td>
<td>Petroleum transport*</td>
<td>Heat exchangers*</td>
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<tr>
<td>Peptic ulcers*</td>
<td>Sea water handling pipes*</td>
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<td>Dairy processing*</td>
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<td>Contact lenses*</td>
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<tr>
<td>Central venous catheters*</td>
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<td>Orthopedic devices*</td>
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<tr>
<td>Hemodialysis*</td>
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<td>Endotracheal tubes*</td>
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<tr>
<td>Dental Water supply*</td>
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* Adjacent markets
Go-to Market Strategy - Geographical Focus
Go-to Market Strategy - Direct Sales

- Direct Sales
  - In person
  - Phone

- Target: hospitals, clinics and medical insurance providers

- Emphasis:
  - Biofilm removal capability
  - Compatibility
  - Cheap pricing (+$0.50 / catheter estimate)
**Funding - Value Inflection Points**

**Point 1 (#2):**
IP Validation and Key Team Hires

**Point 2 (#1):**
Validation from our first hospital clients

**Point 3 (#3):**
Achieving scaling feasibility

**Point 4: (#4)**
Securing monopolistic market share in the Triangle

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**Round 1**
Preferred: Gov. Funding

Government / Angel / VC

$50+ mln*  
- Product development  
- Patent Exp.

**Round 2**
Preferred: Bank Debt

Banks

$20+ mln  
- Product & R&D improvements and evaluation

**Round 3**
Preferred: Convertible Debt Offerings

Angel Investors / VC

$50+ mln  
- Factory ramp-up  
- Working Capital

**Round 4**
Preferred: Convertible Debt / Equity Offerings

VC / Growth Equity

$50+ mln  
- Direct Sales Exp.  
- Marketing Exp.

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* Required funding amount is preliminary and illustrative; # indicates order of importance of value inflection points
Market Assessment

- 15-25% of hospital patients use them
- 75% of doctors don’t monitor how long catheters are being used
- 100% of patients that undergo catheterization longer than 28 days suffer a CAUTI
- 30 million urinary catheters used annually that will benefit from our technology
Market Assessment: Customer

- Biofilm removing catheter reduces infection
  - CAUTI causes 13,000 deaths each year
- Cheap: (approx +$.50 extra)

Incentive:
- 449,334 CAUTI cases each year
- **Saves patient extra $896**
- **cost to treat CAUTI**
- leads to $402 million dollar savings per year
Market Assessment: Supplier

- Size of Industry: 30 million urinary catheters
- Simple to manufacture: implement new shape of catheter
- New concept and not widely implemented
- Market Trend: Catheter usage will always remain
Market Assessment: Threats

Substitutes:
- Replace Catheter
- Antiseptic Catheter
- Nonstick/Hydrophobic

New Entrants:
- IP protected
- hard to compete with already low prices
- general advertisement not necessary.
Market Assessment: Top-Down

Pros:
● easy to implement
● cheap and solves issue
● catheters widely used

Cons:
● growth is unknown
● opportunity can not be fully estimated
Market Assessment: Bottom-Up

<table>
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<tr>
<th>Assumption</th>
<th>Estimate</th>
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<tr>
<td>Price of Catheter</td>
<td>$5.25</td>
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<td>Price w/ technology</td>
<td>$5.75</td>
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<tr>
<td>Units Used</td>
<td>30,000,000</td>
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<tr>
<td>Market Value</td>
<td>$172,500,000.00</td>
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<td>Share</td>
<td>45%</td>
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<td>Revenue</td>
<td>$77,625,000.00</td>
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Patient who would have gotten CAUTI saves: ~$868.50
Conclusion

Strengths
- Huge potential
- Large benefits in time, money, and happiness
- Solid research behind tech

Weaknesses
- Only proof of concept in lab
- New technologies take time to get used to
Questions to Seek Answers To

1. How well would this catheter work inside a human patient?
2. Is the process of removing the biofilm while it is inside a patient, relatively not uncomfortable, and is also reliable/efficient?
3. Will hospitals/nurses be willing to adopt a new model?
4. How viable are expansions into various external markets?