Vascular Access Cap (VAC) Sterilizing Device

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Breakfast Club
The Problem

➢ 70% of hospital patients receive drugs, fluids, and nutrients administered intravenously or intra-arterially.

➢ Lines can remain in place for days or months.

➢ **Major complication of these lines is infection.**
The Problem

- 350,000 lost life years annually from blood stream infection (BSI) and associated premature death

- $20,000 to $30,000 per infection to the hospital

- Medicare not paying for hospital acquired infections

- Malpractice claims in the $billions
The Problem

- 140,000 to 560,000 infections/year
- CDC has reported 25,000 to 90,000 deaths each year
- Cost to hospital ranges from $500,000 to $2.8 million per year, *not* including potential for malpractice claims
Current Devices

Interlink® Components by BD

Interlink® Site by Baxter
Flow Rate** 10.3 L/hr
Flow Rate*** 16.7 L/hr

VersaSafe® by Alaris

SAFEline® by B. Braun

LifeShield® Prefilter by Hospira

Clearlink® by Baxter
Flow Rate* 7.3 L/hr

CLAVE® by Hospira/ICU Medical
Flow Rate* 8.0 L/hr

MicroCLAVE® by Hospira/ICU Medical
Flow Rate* 5.4 L/hr

InVision-Plus® by Rymed
Flow Rate* 7.9 L/hr

Smartsite® by Alaris
Flow Rate* 8.9 L/hr

Postflow™ by BD
Flow Rate* 3.2 L/hr

MaxPlus™ by Maximus
Flow Rate* 4.4 L/hr

CLC2000® by Hospira/ICU Medical
Flow Rate* 14.5 L/hr

ULTRASITE® by B. Braun
Flow Rate* 12.8 L/hr

SmartSite® Plus by Alaris
Flow Rate* 11.9 L/hr
First Pass Solution

www.excelsiormedical.com/swabcap.php
Swab Cap Highlights

- Study outlined on company website indicated bacterial growth was completely abolished using SwabCap
- One time use only
- Increased expense
- Increased work for multiple line access needs (ICU care)
Vascular Access Cap Device

Antibiotic solution (e.g. chlorhexidine)

Flip Cap

Sterile Needle entry

Snap or Screw Cap

Vascular Access Device

To Patient

****The CDC now is recommending that scrubbing for entering should be 15 sec, and then 10 sec wait, up from 10 and 10.
Vascular Access Cap Device

Advantages

- Immediate access to line
- NO wipe and wait
- Can use for multiple entries per day

**Pediatric CICU at Children’s - Doctors and nurses access a line once every 4 minutes. Current protocol recommended by CDC takes at least 30 seconds to sterilize and is not followed consistently.**
Current Status

- Patent application filed; professional prior art search completed and no problematic art discovered (notwithstanding SwabCap)

- In discussion with prototype development company to develop and test VAC prototype and start company around the technology
  - Startup company may need management team

- 510K route probably available because of competitive products
Future Work

- Most likely path forward includes *in vitro* lab testing of prototype, clinical trials, and design for manufacturing.

- Will require clinical data to support hypothesis that bloodstream infections are reduced.

- Technical hurdles: materials science, design for manufacturing, etc.
Potential Revenue

➢ From the CDC statistics, can estimate that 50-100 million vascular access units are used in the United States each year.

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<th></th>
<th>Conservative</th>
<th>Moderate</th>
<th>Aggressive</th>
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<tbody>
<tr>
<td>Market Penetration</td>
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<tr>
<td>Cost per device</td>
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<tr>
<td>Number of US units sold</td>
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