WV Overcoats for Silicone: Long-Lasting, Broad Spectrum, Biocompatible Protection Against CAUTIs

WynnVision LLC
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NIDDK
National Institute of Diabetes and Digestive and Kidney Diseases
WV Overcoats for Silicone: Long-Lasting, Broad Spectrum, Biocompatible Protection Against CAUTIs

Outline
• Background: Imaging *Escherichia coli* cell disruption
• Challenge: translation of solution to a silicone catheter surface
• Progress: evidence for antimicrobial effectiveness with biocompatibility
• A pathway to FDA 510k clearance
The Company

WynnVision

- Founded in 2016 by Kenneth J. Wynne
  Commonwealth Professor
  Chemical and Life Science Engineering
  Virginia Commonwealth University

- Based on 20 years experience with antimicrobial technologies
- **Mission:** to generate ground breaking technologies for preventing infections from medical devices

Virginia Bio+Tech Research Park
800 East Leigh Street, Suite 57
Richmond, VA 23219-1551
Conceptual basis

- Learned about Nature’s **Antimicrobial Peptides** “AMPs”
- Create a water soluble chain molecule that is an AMP-mimic
- Atomic Force Microscopy to image biocidal action

- AFM images of *E. coli* in (PBS)
- *E. coli* cell wall disruption
- Cell dies
- Osmotic pressure inside cell
- Cell disruption like a pin in a balloon

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**Nano-bulge**

**Nano-pit**

How to translate from water soluble antimicrobial to antimicrobial surface?

- Basic AMP-like solution antimicrobials
- Fundamental knowledge about bacterial cell wall disruption

National Science Foundation, DMR

- Create a surface that disrupts bacterial cell walls on contact
- Solid state surface science
- Leap toward commercialization
- NIH NIDDK

NSF

NIH

WynnVision Biocompatible Antimicrobials
Implementation:
• A process for low cost overcoats on off-the-shelf silicone catheter segments
• “Simple is Good” for ready scaleup / manufacturing

Segments of a commercial, catheter with FDA clearance

Proprietary WV overcoat technology

WV overcoated catheter
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Most frequent pathogens associated with HAI CAUTIs cited by a CDC panel

<table>
<thead>
<tr>
<th>Time, 24 hr</th>
<th>Gram stain</th>
<th>Strain</th>
<th>% HAI CAUTIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASTM E2149 % kill</td>
<td>Kill</td>
<td>Strain</td>
<td>% HAI CAUTIs</td>
</tr>
<tr>
<td>99.999%</td>
<td>log 5</td>
<td>G(-)</td>
<td>Escherichia coli</td>
</tr>
<tr>
<td>99.999%</td>
<td>log 5</td>
<td>N/A</td>
<td>Candida albicans (spp)</td>
</tr>
<tr>
<td>99.96%</td>
<td>log 3.4</td>
<td>G(-)</td>
<td>Pseudomonas aeruginosa</td>
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<tr>
<td>99.999%</td>
<td>log 5</td>
<td>G(-)</td>
<td>Klebsiella pneumoniae</td>
</tr>
<tr>
<td>99.999%</td>
<td>Log 5</td>
<td>G(-)</td>
<td>Enterobacter spp</td>
</tr>
<tr>
<td>99.999%</td>
<td>Log 5</td>
<td>G(+)</td>
<td>Coagulase negative staphylococci (CoNS)</td>
</tr>
<tr>
<td>99.999%</td>
<td></td>
<td>G(+)</td>
<td>Staphylococcus aureus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G(-)</td>
<td>Acinetobacter baumannii</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G(-)</td>
<td>Klebsiella oxytoca</td>
</tr>
</tbody>
</table>

ISO 10993-5 test for toxicity of any leachate to human cells
• Human Dermal Fibroblast (HDF)
• Photomicrographs of HDFs after 48 h growth in medium extracts

- Untreated silicone tube
- WV-overcoated silicone tube
- Latex

- Cell viability was 0% for latex
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  ➢ *In vivo* tests: NAMSA
  ➢ Biologics Consulting: seeking 510k
Acknowledgement

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