NEXT STANDARD OF CARE IN HAI PREVENTION

CeraShield™

BIOFILM-RESISTANT ENDOTRACHEAL TUBE

Designed to reduce ventilator associated respiratory infections (VARI) and significantly lower overall cost of care

N8 BIOSCIENCES

The CeraShield™ ETT is approved for marketing in Canada and Belize with other approvals pending. The CeraShield™ ETT is an investigational device in the United States.

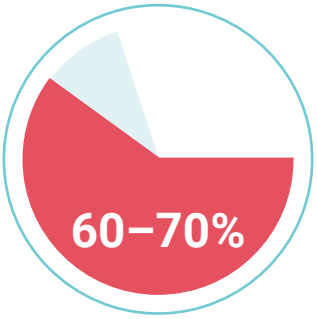
CeraShield™ ETT

MEDICAL DEVICE-ASSOCIATED BIOFILMS POSE A SERIOUS THREAT TO HUMAN HEALTH AND LEAD TO NOSOCOMIAL INFECTIONS

New strategies are urgently needed

Up to 80% of microbial infections in the human body involve biofilm formation, especially in hospital settings, which greatly promotes the incidence rate and mortality[1,2]

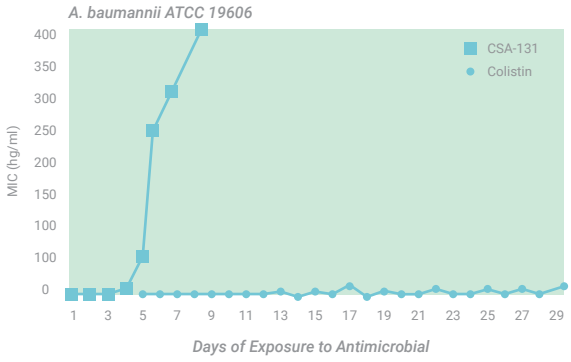
Over 6 million potential deaths from nosocomial infections worldwide each year[3]

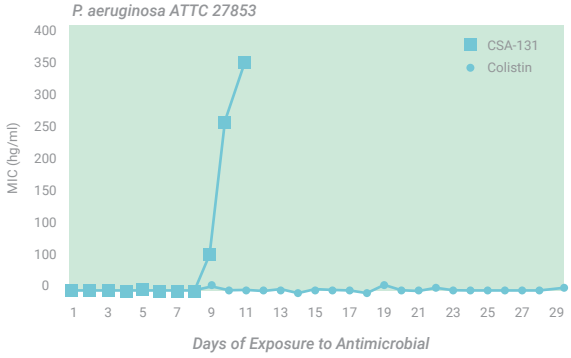


60–70% of nosocomial infections are associated with biomaterials or implants[4]

- **Ordinary medical devices allow millions of pathogenic CFUs to grow within hours and act as a reservoir of infectious agents, leading to inflammation and infection.**
- The resistance of bacteria in biofilms to antibiotics can be **10–1,000X** that of the corresponding planktonic cells.[5]
- The rates of horizontal plasmid transfer were **several orders of magnitude higher** in the biofilms than in liquid cultures of the same organisms.[6]

Resistance generation to colistin





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3. Gyawali B, Ramakrishna K, Dhamoon AS. Sepsis: The evolution in definition, pathophysiology, and management. SAGE Open Med. 2019;7:2050312119835043. Published 2019 Mar 21. doi:10.1177/2050312119835043.
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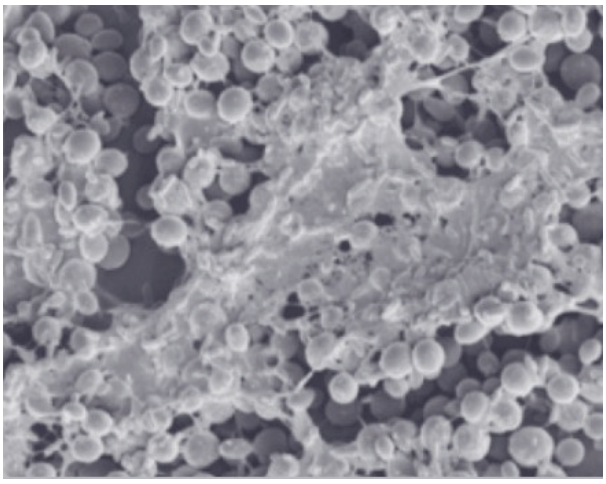
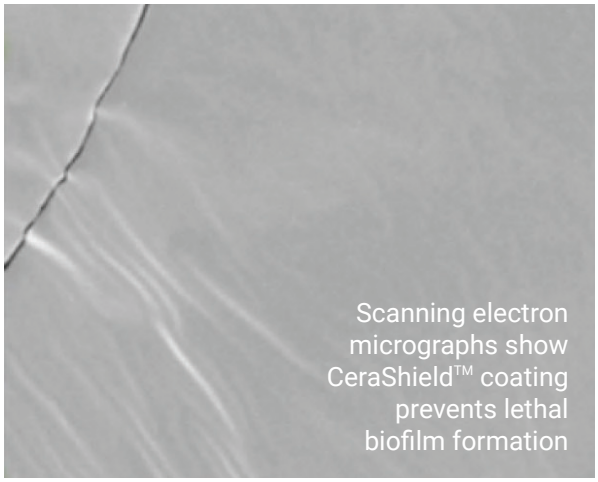
6. Rodney M. Donlan, Biofilm Formation: A Clinically Relevant Microbiological Process, Clinical Infectious Diseases, Volume 33, Issue 8, 15 October 2001, pages 1387–1392, https://doi.org/10.1086/322972.

CeraShield™ biofilm-resistant coating works to prevent infection and inflammation

Ordinary ETT



CeraShield™ Biofilm-Resistant ETT



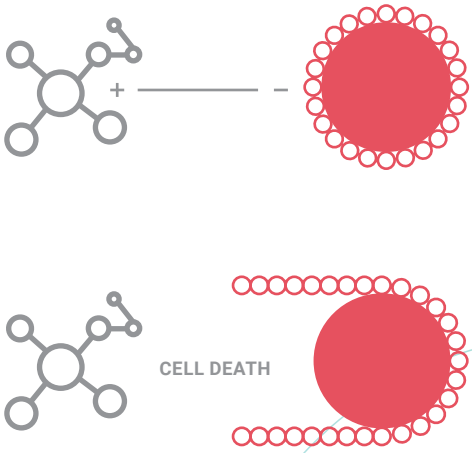
Scanning electron micrographs show CeraShield™ coating prevents lethal biofilm formation

CeraShield™ coating mimics the activity of the human body's innate immune system, which does not induce antimicrobial resistance (AMR).

1. Creates hydration layer that inhibits bacterial adhesion to the surface, creating a "moat" around the device.

2. The CeraShield™ coating's net positive charge attracts the negatively-charged membranes of certain viruses, fungi, and bacteria.

3. As the CeraShield™ coating and pathogen get closer together, the CeraShield™ coating begins to permeabilize and depolarize the cell membrane, **leading to rapid cell death.**



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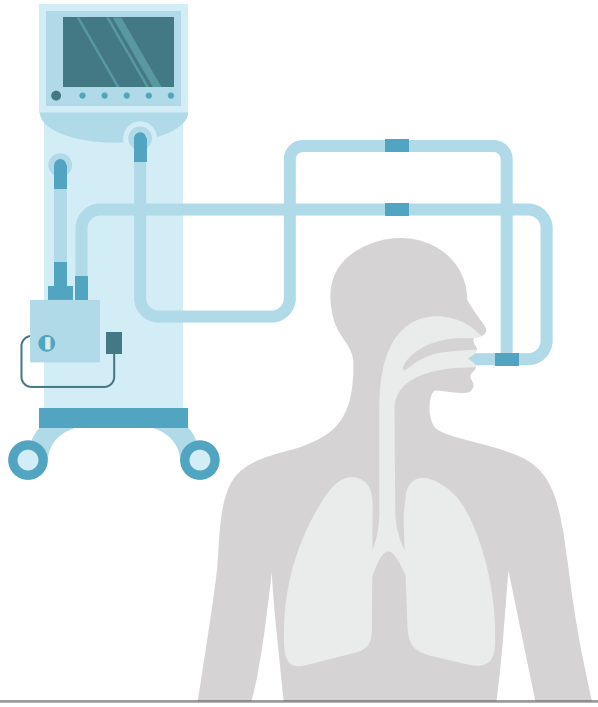
VENTILATOR-ASSOCIATED PNEUMONIA: WHAT IS THE REAL COST?

Each added case of ventilator respiratory infection adds between $10,000–$50,000 (US).[7]

The total preventable cost worldwide is >$10 billion.[8]

9–13%
attributable risk of **death**[9]



Approximately 50% **of all critical care antibiotics** are for treatment for VAP[9,11]

up to **25** days prolonged **ICU** stay[10]

up to **22** days prolonged **hospital** stay[12]

7. Tejerina E, Frutos-Vivar F, Restrepo MI, et al. Incidence, risk factors, and outcome of ventilator-associated pneumonia. J Crit Care 2006 Mar;21(1):56-65. 16616625.
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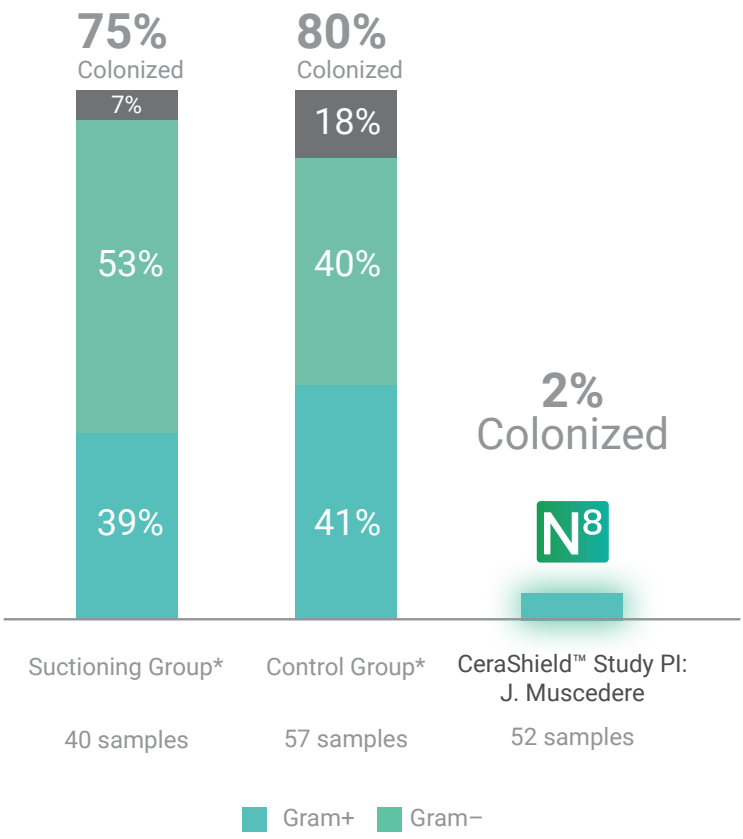
11. Petrosillo N, Capone A, Di Bella S, Taglietti F. Management of antibiotic resistance in the intensive care unit setting. Expert Rev Anti Infect Ther. 2010 Mar;8(3):289-302. doi: 10.1586/eri.10.7. PMID: 20192683.
12. Temsah MA, Al-Eyadhy AA, Al-Sohime FM, et al. Long-stay patients in pediatric intensive care units. Five-years, 2-points, cross-sectional study. Saudi Med J. 2020;41(11):1187-1196. doi:10.15537/smj.2020.11.25450.

INTRODUCING THE PROPRIETARY CERASHIELD™ COATED BACTERIA-RESISTANT ENDOTRACHEAL TUBE

By preventing biofilm, we can significantly prevent VAP and other adverse outcomes

Designated as **"breakthrough device"** by FDA

Comparison of Endotracheal Tube Aspirates



*Girou, E., Buu-Hoi, A., Stephen, F. et al. Airway colonization in long-term mechanically ventilated patients. Intensive Care Med 30, 225-233 (2004). https://doi.org/10.1007/s00134-003-2077-4.

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ENDOTRACHEAL TUBE SIZE	N8 PRODUCT CODE
7.0 mm	18170
7.5 mm	18175
8.0 mm	18180
8.5 mm	18185

INDICATION

The CeraShield™ endotracheal tube is to be used for airway management in adult patients expected to be intubated ≥ 24 hours.

The CeraShield™ ETT consists of:

- A standard adult cuffed ETT manufactured and sourced from Flexicare offered in sizes 7.0mm–8.5mm
- A hydrophilic anti-fouling coating on the inner and outer lumens, and the inflatable cuff

FOR MORE INFORMATION, CONTACT

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