Assessment of novel antimicrobial material to prevent biofilm formation in critical in semi-critical medical devices

Authors

William Leiva MBA, MPH
Affiliation:
- Bucharest University Of Economic Studies
- EUIS LCC

Paulo Laranjeira PhD
Affiliation:
Orion CE

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- Introduction
- Research aims
- Experimental design
- Results and Discussion
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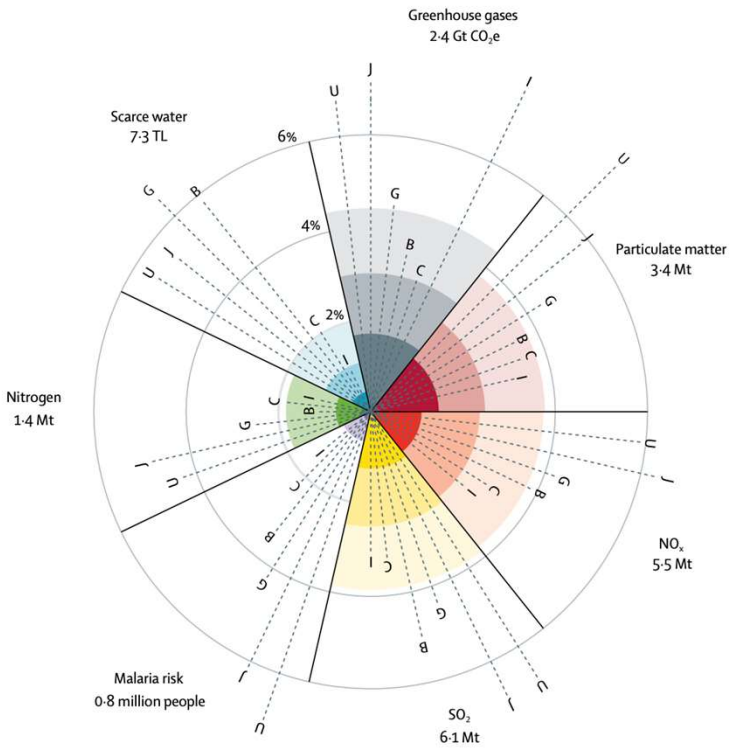
Disclosure

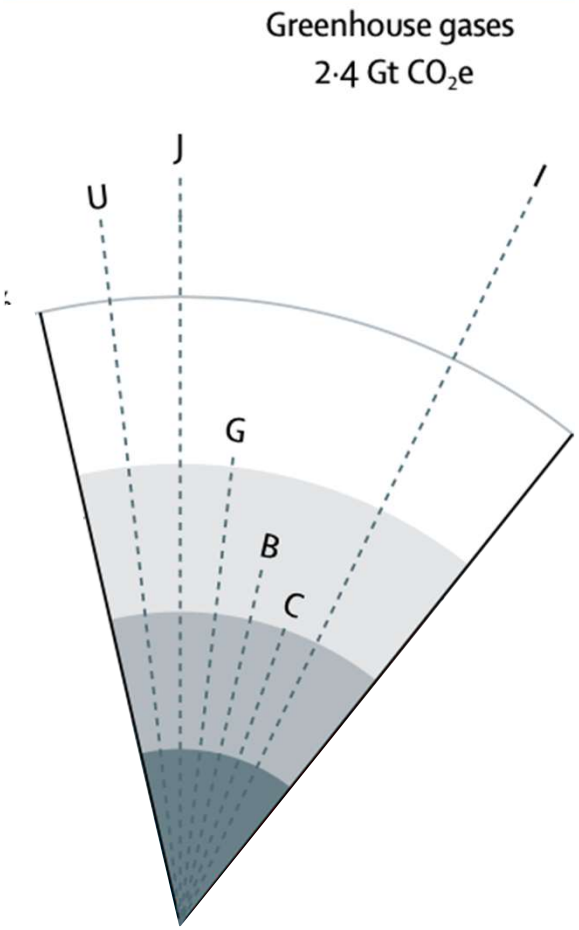
This research has been partially funded by a 2022 Kilmer Research Grant from the AAMI Foundation in the United States and it was conducted in collaboration with the Department of Biomechanics of the University of Nebraska at Omaha, USA.

Neither researcher have equity nor funding from the testing, manufacturing equipment nor PLA companies described.

Microbiological testing were conducted in an independent, ISO Accredited third-party facility.

Introduction





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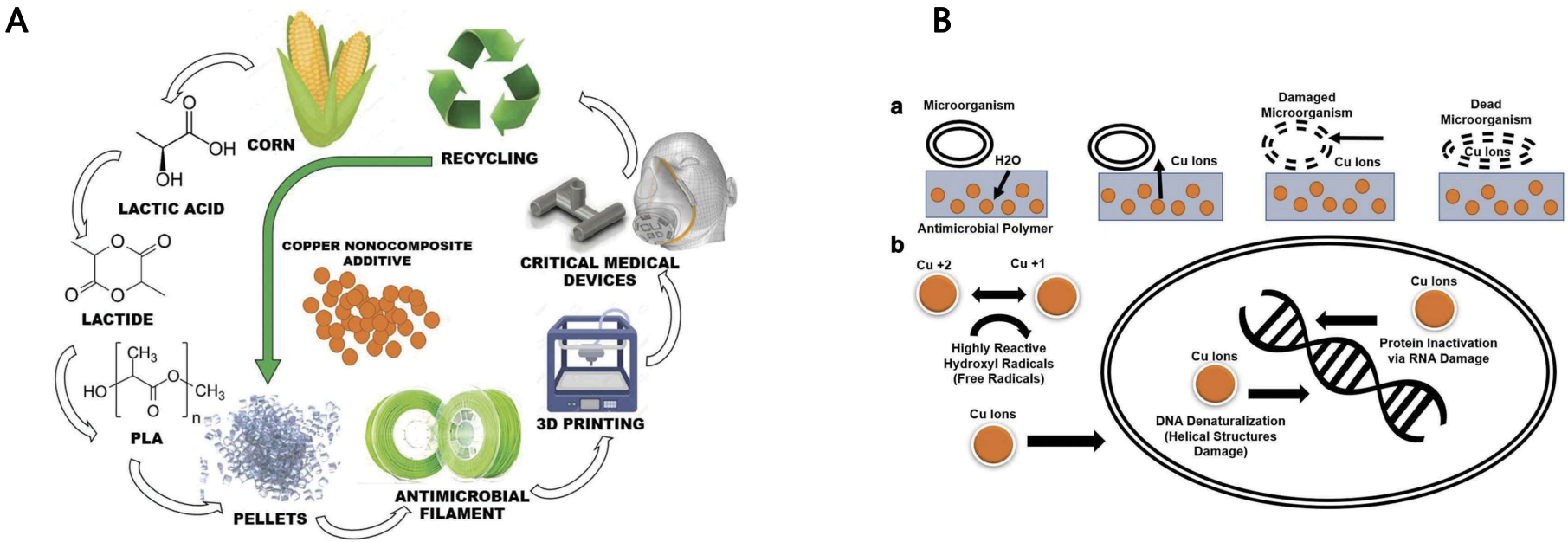

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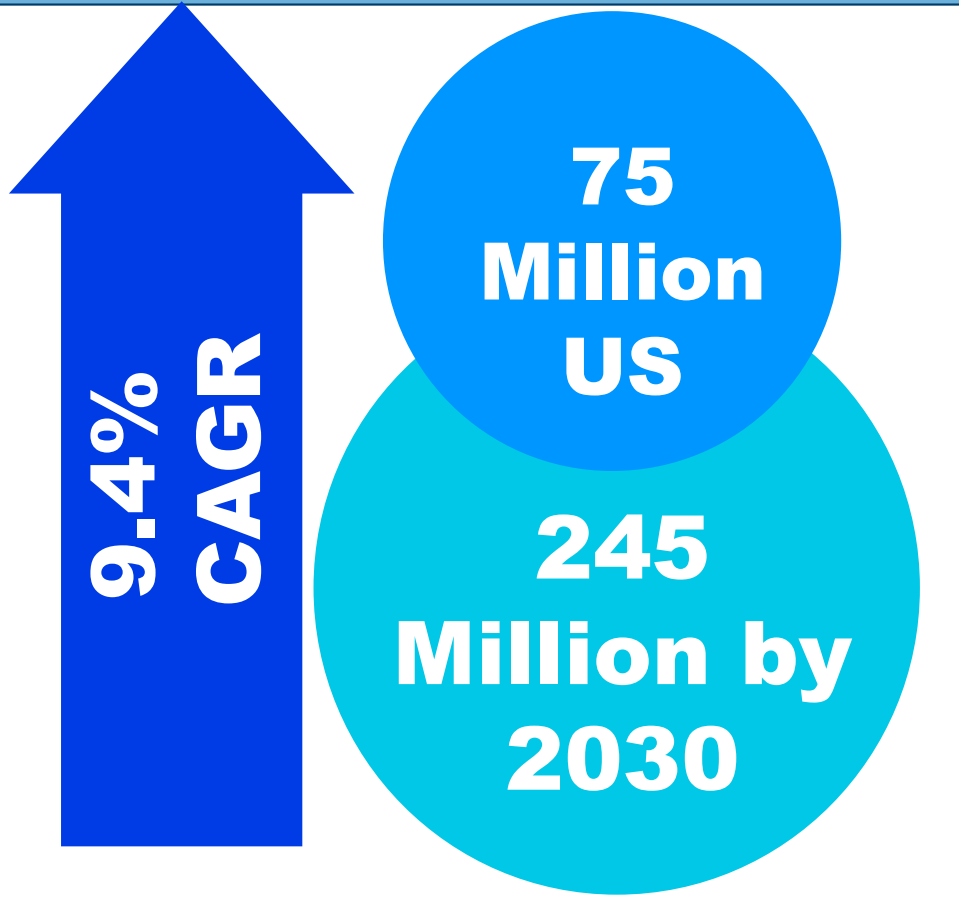

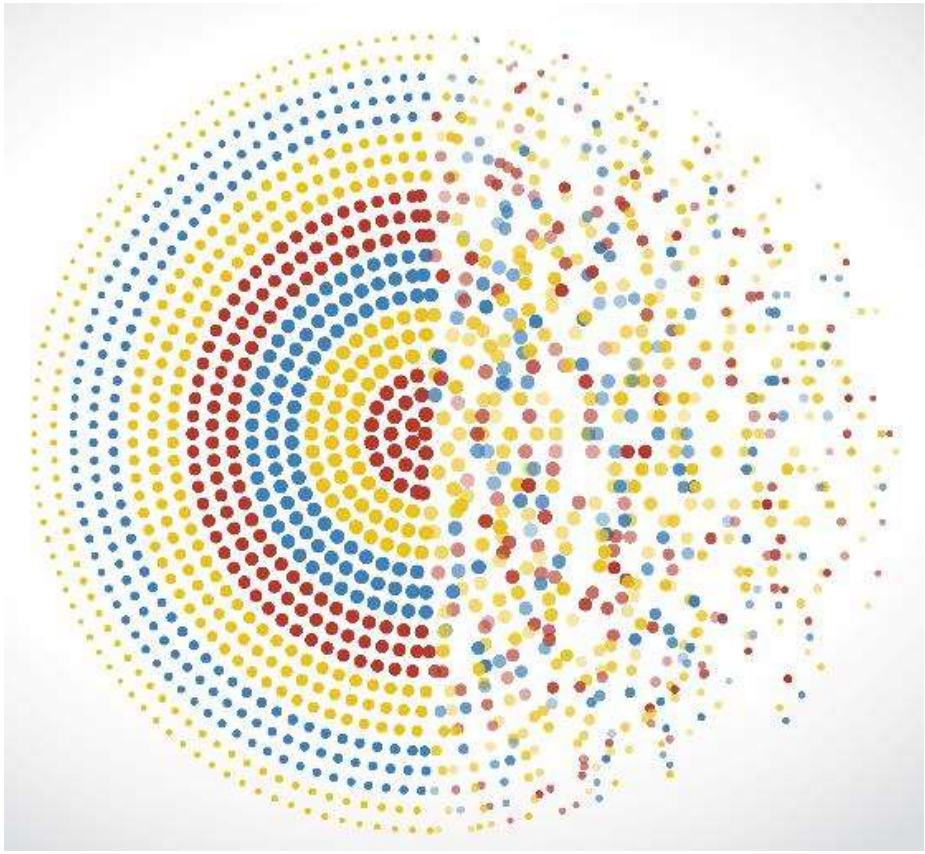

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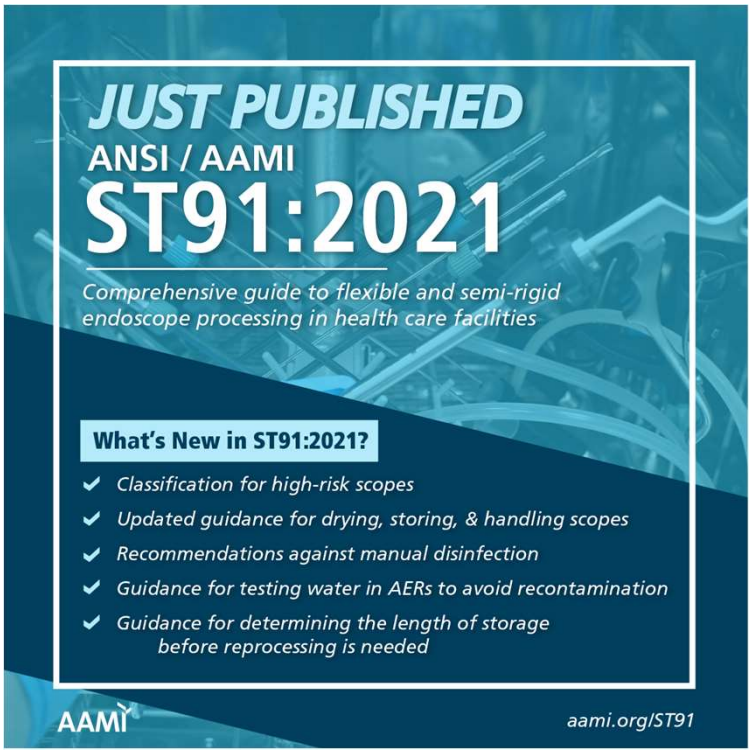
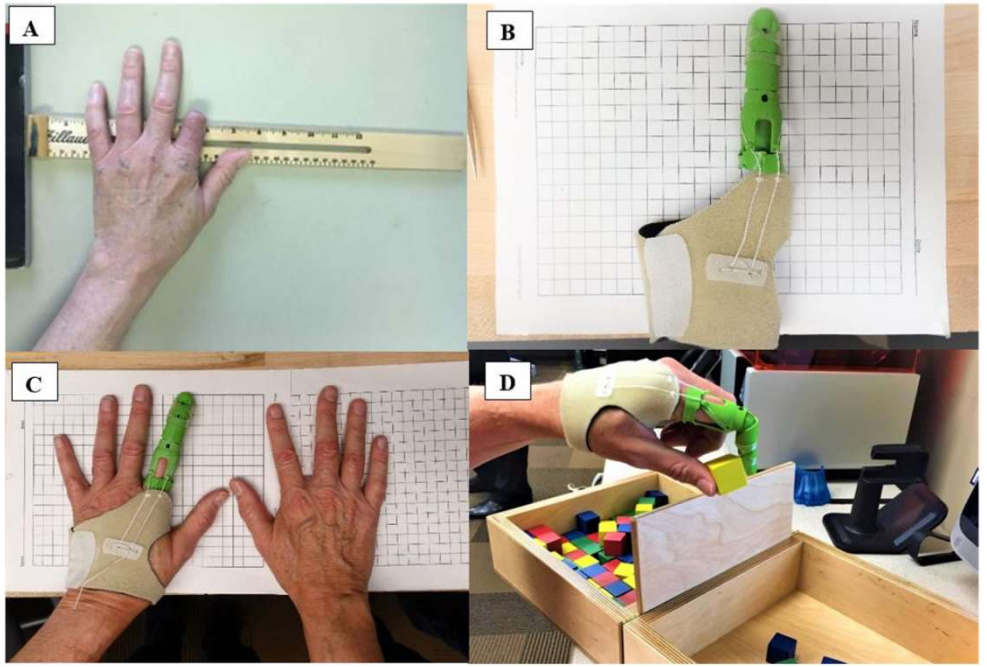


GI Societies Joint Statement on ANSI/AAMI ST91: GI societies vote No on AAMI revisions on endoscopic processing Published:March 11, 2022DOI:https://doi.org/10.1016/j.gie.2022.02.004

Introduction

Inoculum (Initial Load, *CFU/mL)	Log_{10} Reduction at 24 h	Reduction (%)
Methicillin-resistant *Staphylococcus aureus* (7.10E+9)	1.65	98.95
Escherichia coli (3.33E+9)	1.32	95.03
Staphylococcus aureus (6.3E+5)	5.7	99.99
Escherichia coli (9.3E+5)	4.6	99.99

* CFU: colony forming unit.



Zuniga JM. 3D Printed Antibacterial Prostheses. *Applied Sciences*. 2018; 8(9):1651. https://do i.org/10.3390/app8091651

Research aims

Primary

The primary aim of this research is to **assess the effectiveness of Active PLA** to reduce and/or prevent bacterial growth of microorganisms of concern that may lead to the formation of biofilms.

Secondary

The secondary aim is to **explore the potential of Active PLA to be used as component of critical and semi-critical medical devices** that pose challenges during the reprocessing and/or may benefit from a reduced bioburden after manufacturing.

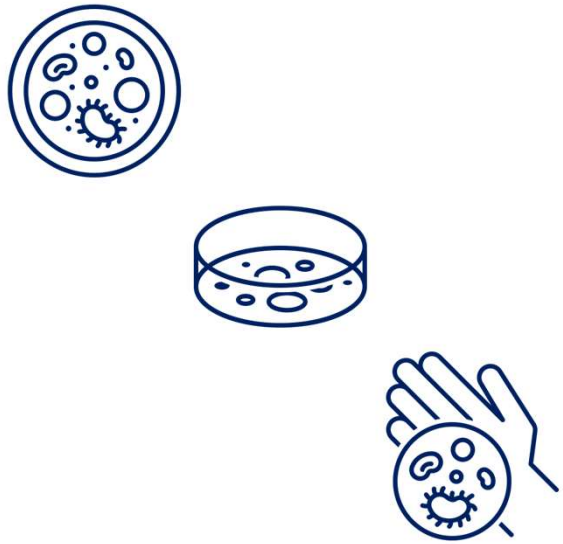
Specific Goals

Specific research aims are related to the specific antimicrobial performance of the test coupons when inoculated with 3 pathogens of concern often linked to infections where endoscopes have been vectors:

- **Pseudomona aeruginosa (9027)**
- **Escherichia coli (8739)**
- **Klebsiella pneumoniae (4352)**

Research aims

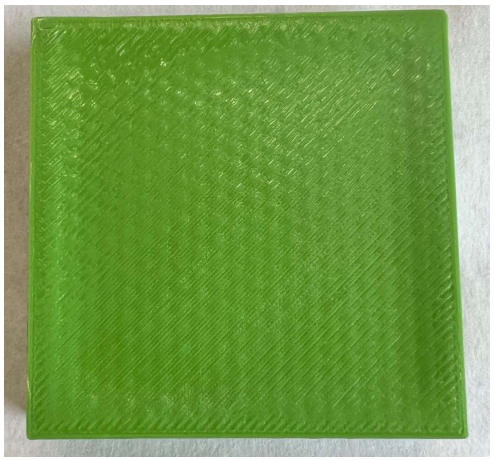
- Pseudomona aeruginosa (9027)
- Escherichia coli (8739)
- Klebsiella pneumoniae (4352)



Experimental design - Background

ISO 22196:2011

Measurement of antibacterial activity on plastics and other non-porous surfaces



PLA Active AN[1] is a trademark from Copper 3D, Santiago, Chile.
Ultimaker 2+ is a trademark from Ultimaker Holding BC, Utrecht, The Netherlands.

Experimental design – Testing Conditions

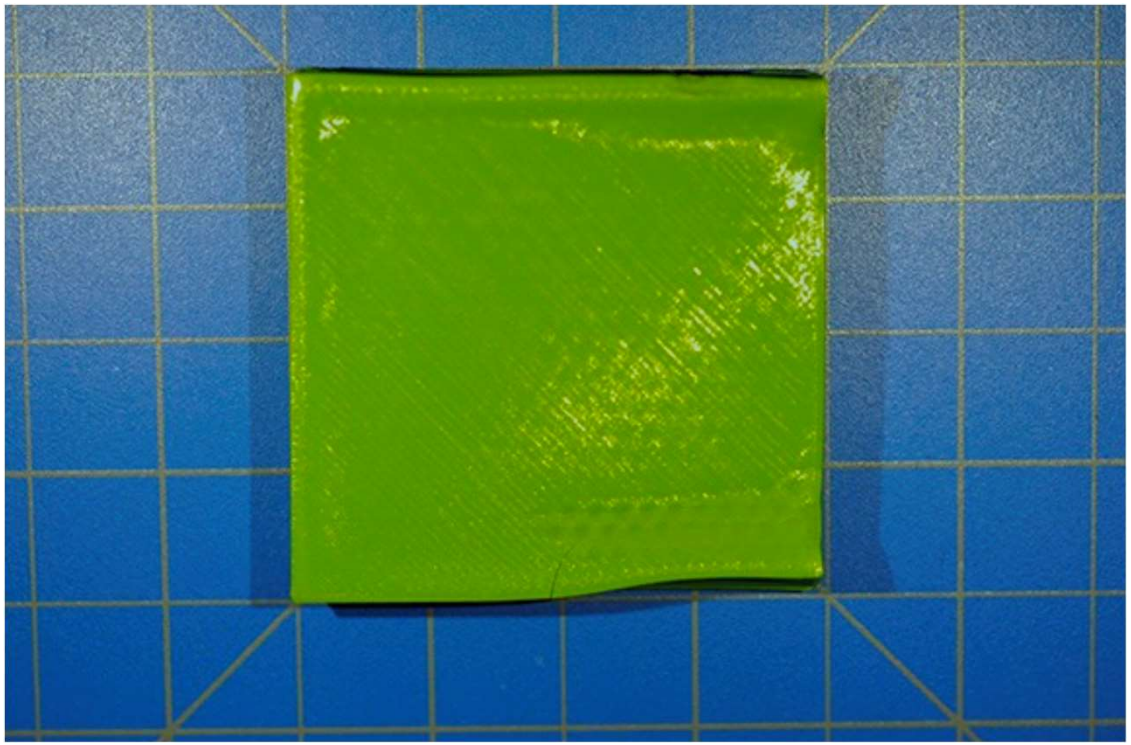
Microorganism	Control			Experimental samples		
	Coupon #1	Coupon #2	Coupon #3	Coupon #1	Coupon #2	Coupon #3
Pseudomona aeruginosa (9027)	a1	a2	a3	a1''	a2'	a3'
Escherichia coli (8739)	b1	b2	b3	b1'	b2'	b3'
Klebsiella pneumoniae (4352)	c1	c2	c3	c1'	c2'	c3'

Sample designation is based on laboratory recommendations.

Experimental design – Test Conditions

Testing variable	Criteria
Uncertainty	95% Confidence level of $Log_{10}(0.136)$
Test conditions	3 equal conditions must be satisfied for a test to be valid
Recovered bacteria	$6.2e^3$ /cm^2 – $2.5e^4$ / cm^2
Reduction Reported	Log_{10} Reduction
Population reported	CFU / cm^2
Incubation Time	24 hours
Incubation Temperature	37+/-1C°

Experimental design – Test Conditions



Sample partially retracted during steam sterilization, ready to be inoculated.

Results and Discussion

M.O.	Sample	Inoculum CFU/cm²	Population at 24 h CFU/cm²
Pseudomona aeruginosa (9027)	Control	$4.1e^4$	$3.2e^5$
Escherichia coli (8739)	Control	$4.2e^4$	$3.9e^6$
Klebsiella pneumoniae (4352)	Control	$5.5Ee^4$	$3.5Ee^6$

Results and Discussion

M.O.	Sample	Log_{10} Reduction at 24 h	Reduction (%)
Pseudomona aeruginosa (9027)	Experimental	5.1 Log_{10}	99.99% N.R.
Escherichia coli (8739)	Experimental	5.2 Log_{10}	99.99% N. R
Klebsiella pneumoniae (4352)	Experimental	3.9 Log_{10}	99.99%

Results

Pre Test

- Manufacturing settings.
- Visual testing.
- Sterilization conditions.

Effectiveness

- Pseudomona aeruginosa (9027)
- Escherichia coli (8739)
- Klebsiella pneumoniae (4352)

Variation

- Population growth and reduction was observed.

Discussion

Sustainability

- Evidence around sustainability.
- Upcycling and recycling.
- Reduction of waste.

Further research

- Economic and financial impact.
- Cost of replacement.
- Mechanical testing and specific requirements.
- Durability assessment.

Next Steps

- Phase II of the project.
- Coupons compliant with current design.
- Expansion to 10+ microorganism of concern.

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- Lenzen, M. (2020, July 1). *The environmental footprint of health care: a global assessment*. The Lancet Planetary Health. Retrieved October 23, 2022, from https://www.thelancet.com/journals/lanplh/article/PIIS2542-5196(20)30121-2/fulltext
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- ISO Standard 22196:2011 "Measurement of antibacterial activity on plastics and other non-porous surfaces"

wfhss World Federation for Hospital Sterilisation Sciences

Correspondence

William Leiva MBA, MPH
William.leiva@gmail.com

Paulo Laranjeira PhD
prlaranjeira@gmail.com

Thank you