Moving Antimicrobial Copper from the Laboratory to the Clinical Setting

CSAT Kickoff Meeting - May 17, 2011

Wilton Moran

Project Engineer

Copper Development Association

Antimicrobial Copper Cu+

CDA Mission

The Copper Development Association, Inc. is a not-for-profit trade association that provides technical, market development, education and support services for the U.S. copper industry with a vision towards positively influencing the use of copper and its alloys in today's society.

Copper - Properties

Symbol: Cu
Atomic Number: 29
Atomic Weight: 63.546
Standard state: solid at 298 K
Color: copper, metallic
Properties:
Ductile
Malleable
High thermal Conductivity
High electrical Conductivity
Easily alloyed
Good corrosion resistance
Readily available
Highly recyclable
Antimicrobial

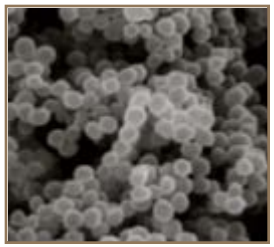
For additional information, go to: www.copper.org

Copper Alloys: Laboratory Effectiveness & Regulatory Approvals

Focus of CDA Research

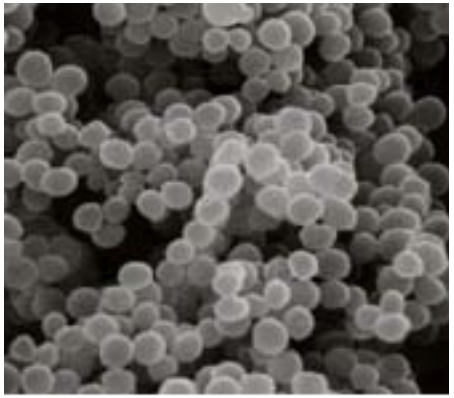
- Inhibitory effects of touch-surface materials on bacteria, including:
  - Wrought & cast copper-based alloys
  - Stainless steel, aluminum, plastics and more
  - Silver-containing coatings and other antimicrobial surfaces

- Effect on organisms that are known human pathogens and present a serious threat to society
  - MRSA
  - *Clostridium difficile*
  - H1N1
  - E. coli O157:H7
  - Black mold
  - And more...



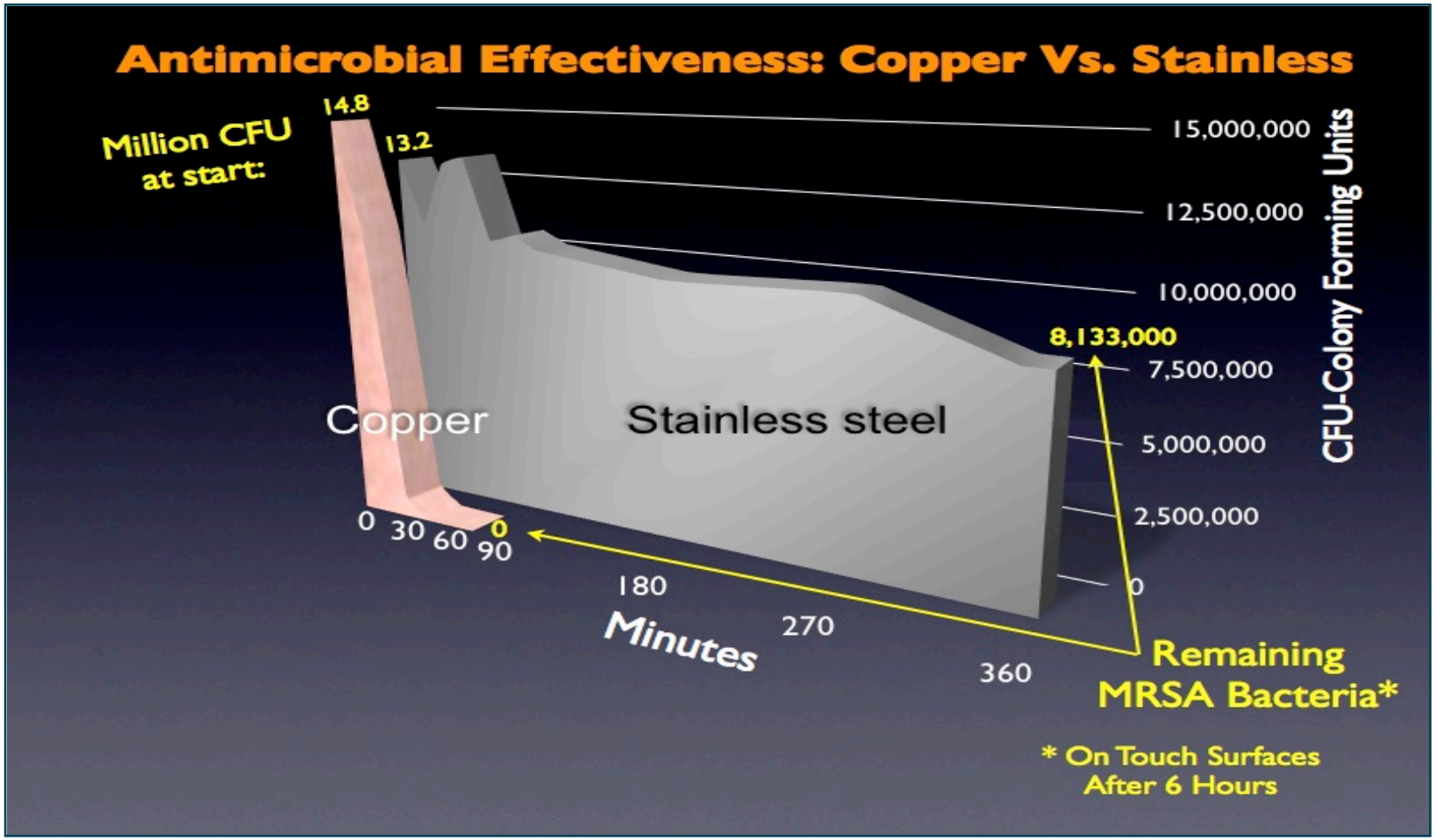
MRSA Methicillin-resistant *Staphylococcus aureus*

- An antibiotic-resistant “Superbug”
- One of the most serious and widespread hospital-acquired infections
- Following slide shows:
  - Copper alloys kill MRSA within two hours
  - In comparison, stainless steel shows little effect after 6 hours



Staphylococcus aureus
Image courtesy of K Hiramatsu

MRSA Viability

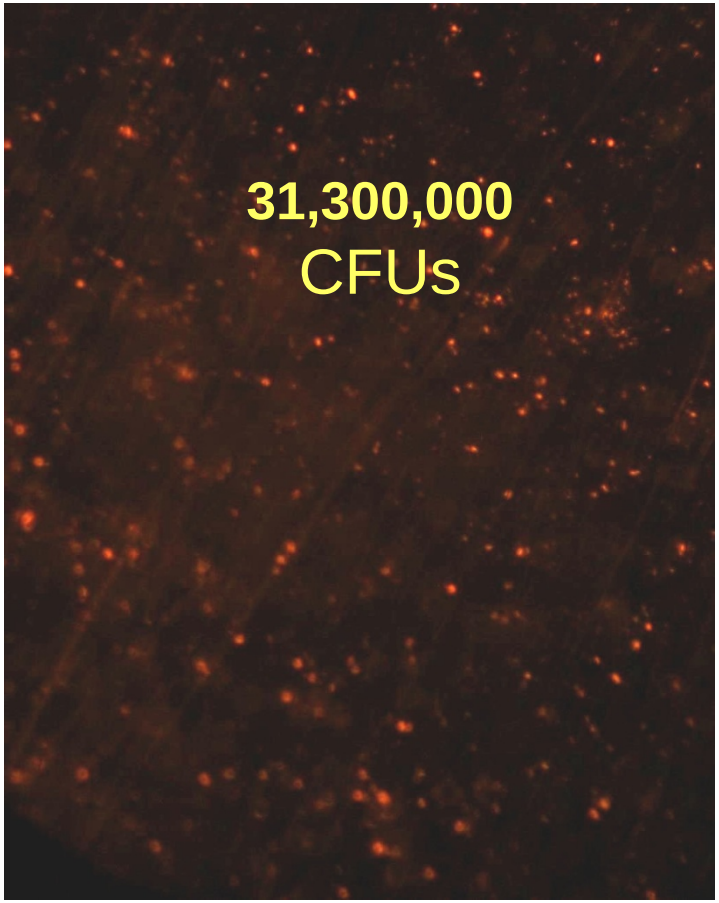


Antimicrobial Copper Cu+

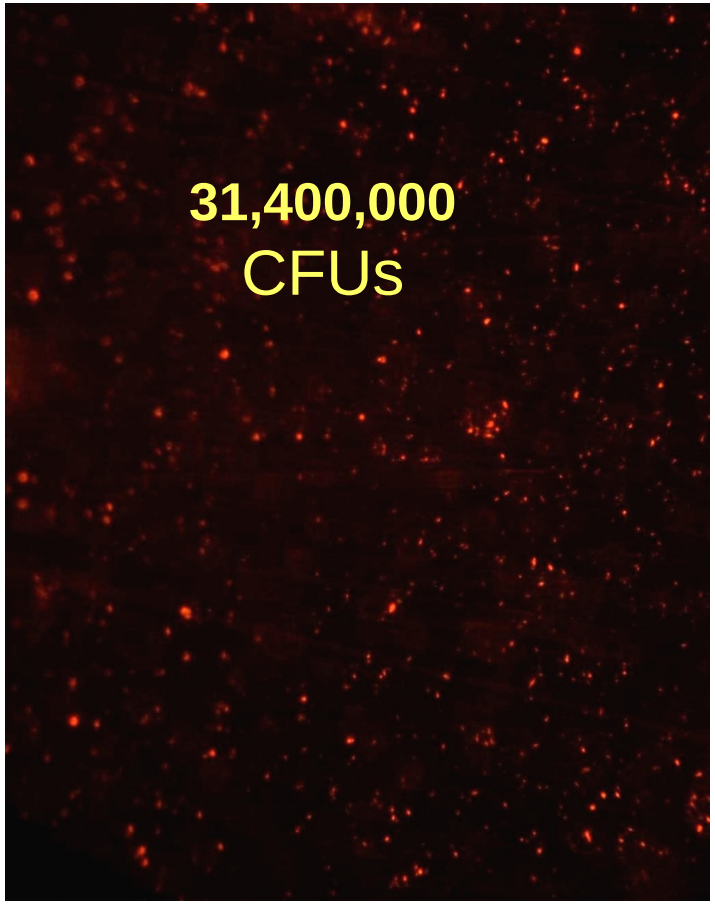
E. Coli O157:H7

Time
0 minutes

Stainless Steel



Copper



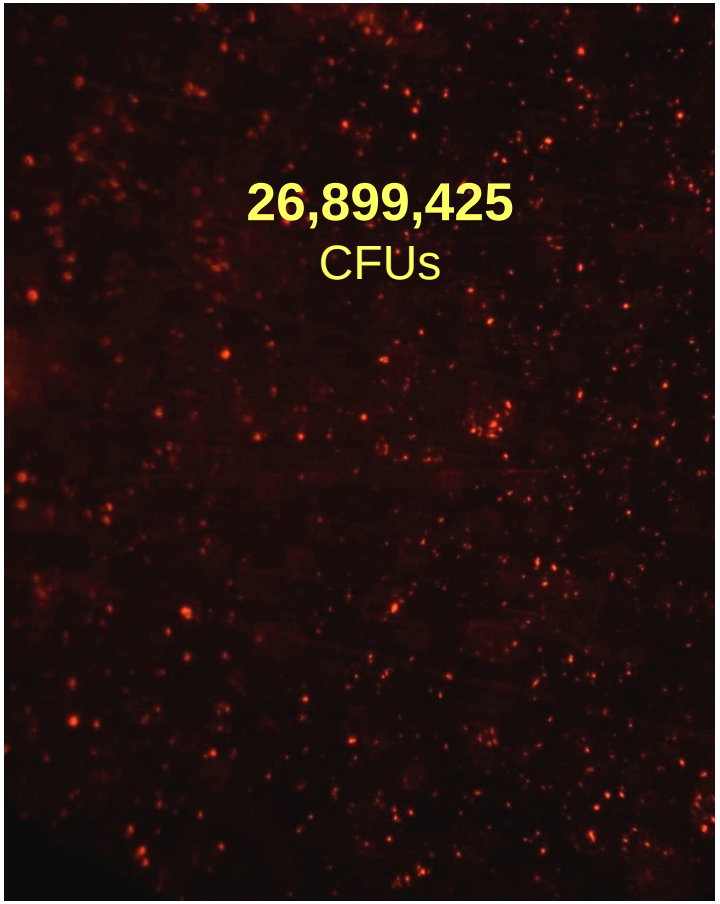
Epifluorescence Images after Staining with Viability Fluorophore CTC

Antimicrobial Copper Cu+

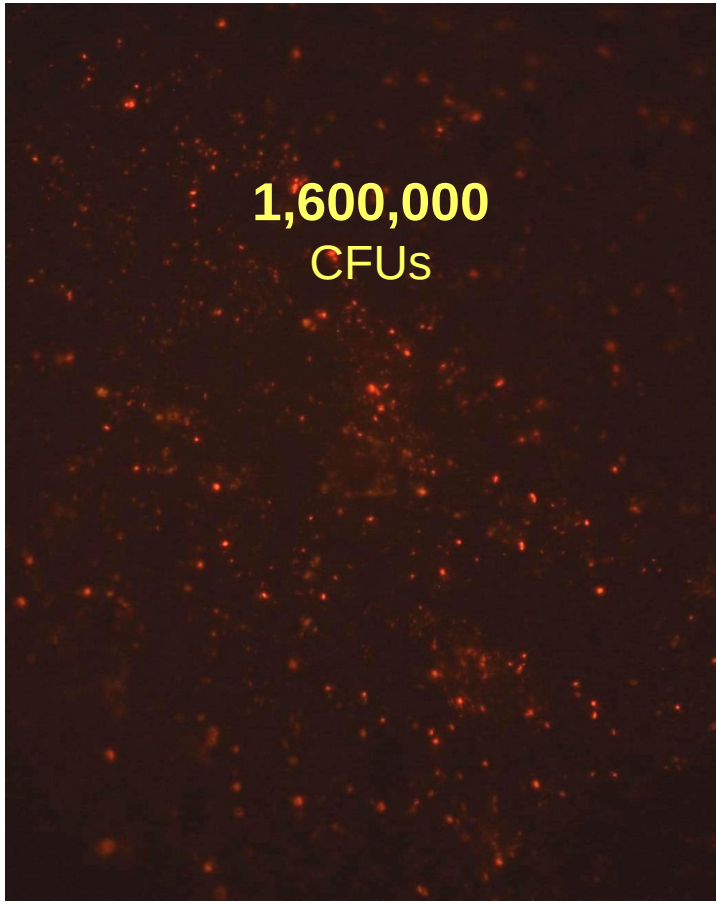
E. Coli O157:H7

Time
30 minutes

Stainless Steel



Copper

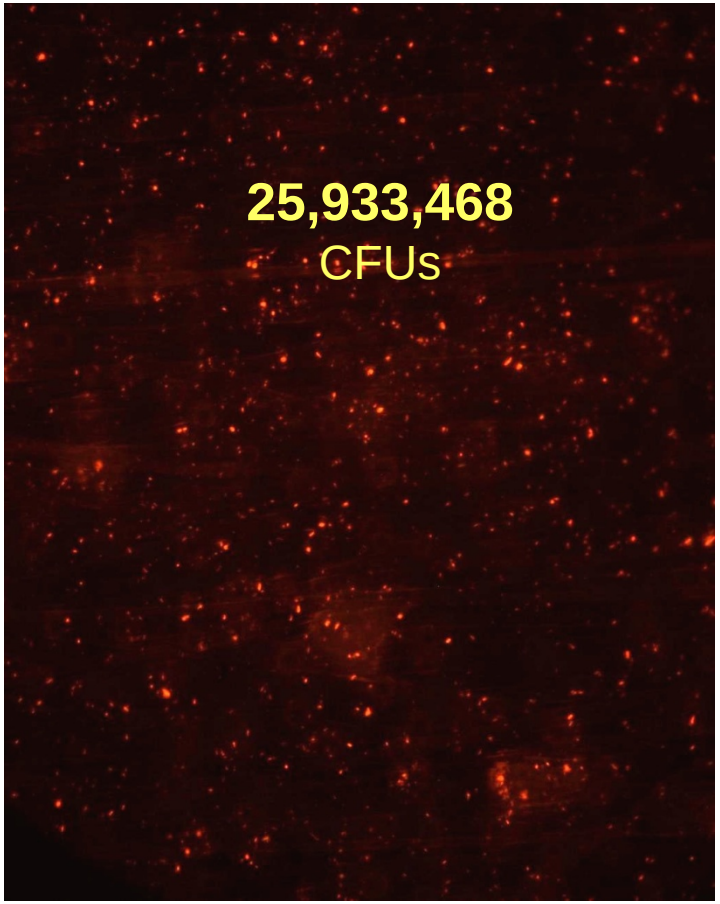


Epifluorescence Images after Staining with Viability Fluorophore CTC

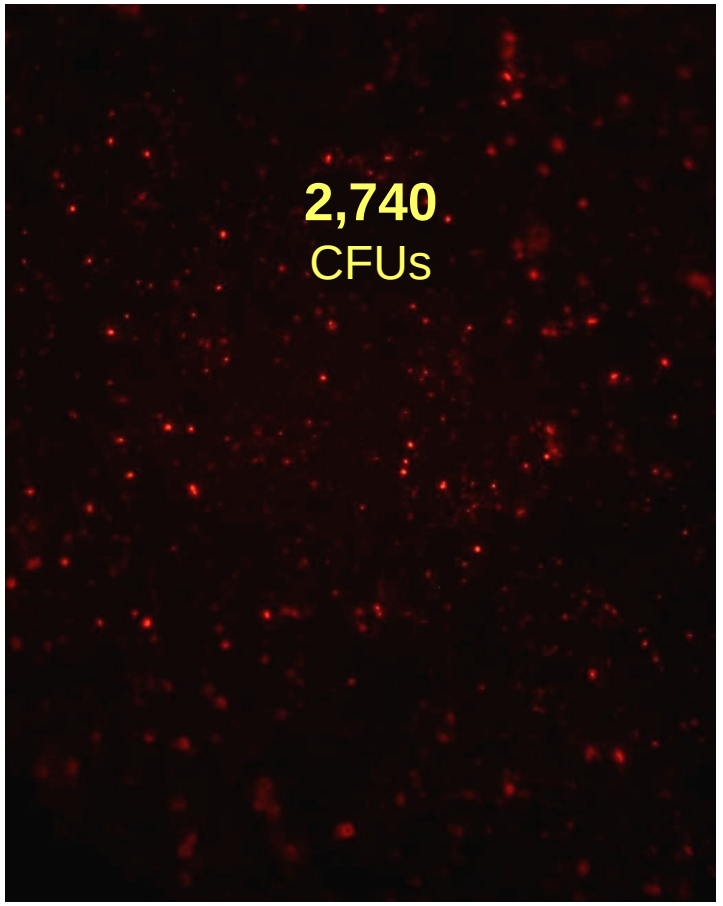
E. Coli O157:H7

Time
60 minutes

Stainless Steel



Copper

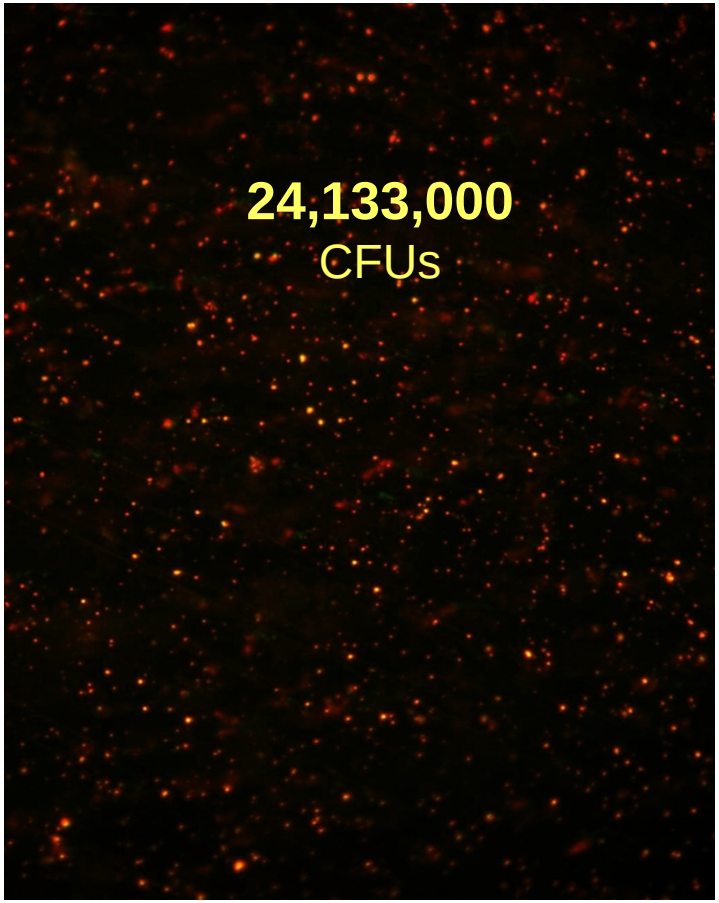


Epifluorescence Images after Staining with Viability Fluorophore CTC

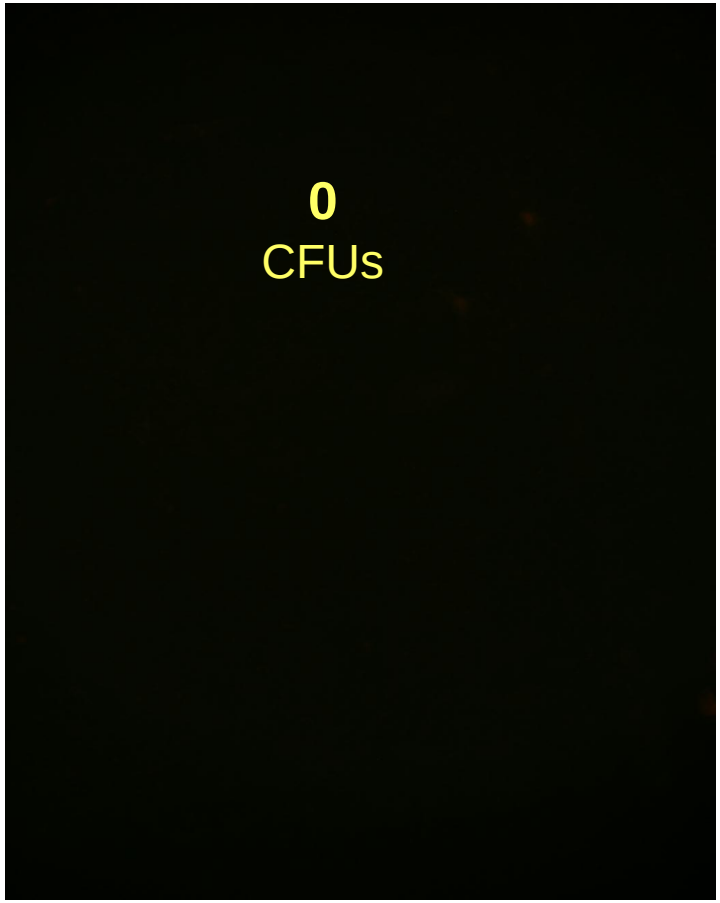
E. Coli O157:H7

Time
90 minutes

Stainless Steel



Copper

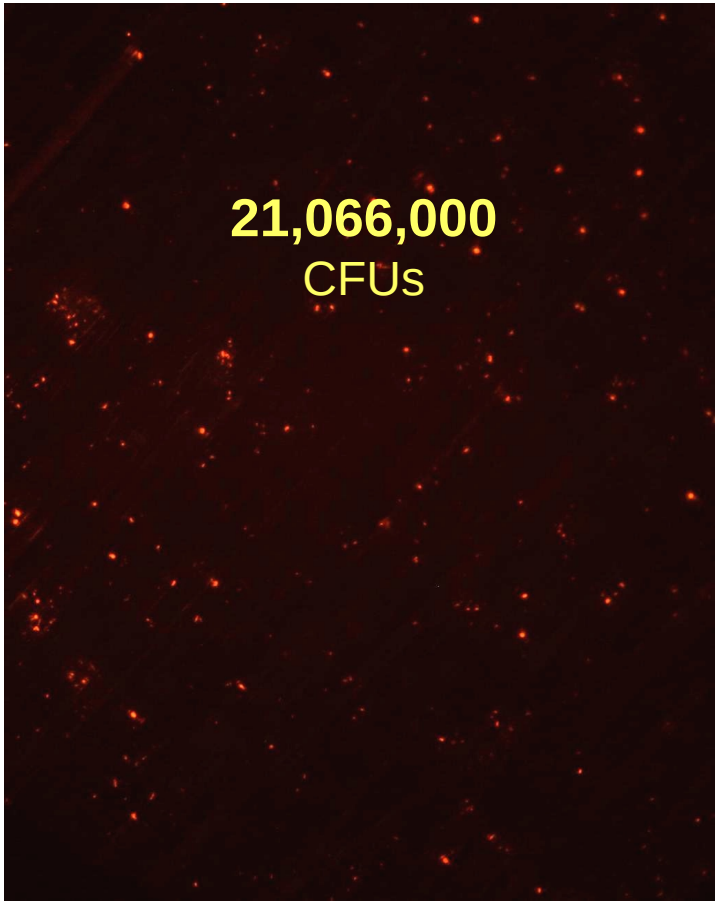


Epifluorescence Images after Staining with Viability Fluorophore CTC

E. Coli O157:H7

Time
120 minutes

Stainless Steel

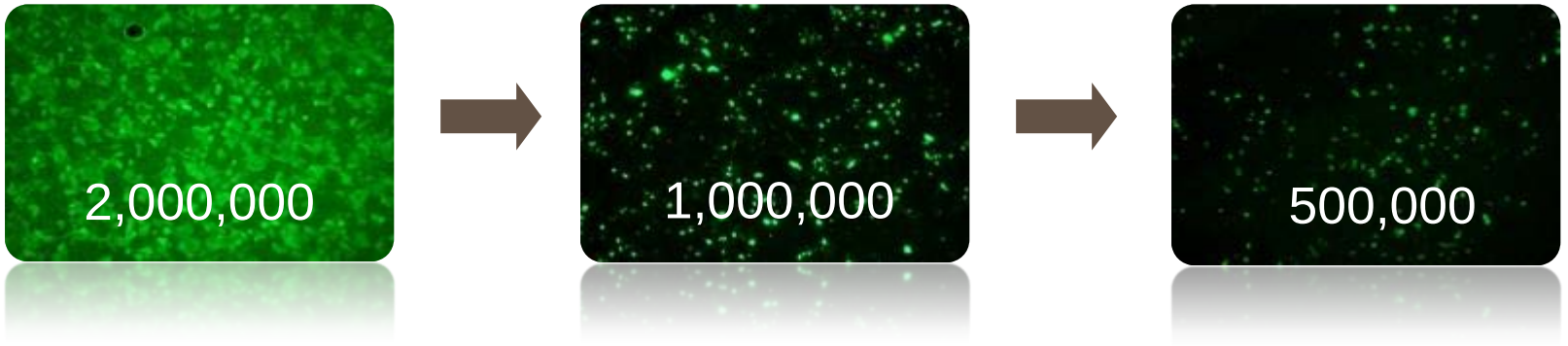


Copper

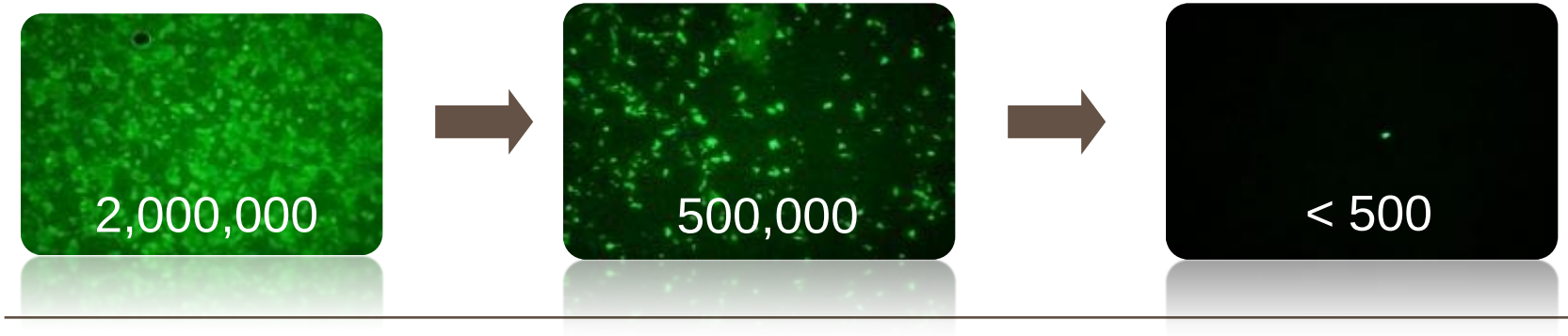
Epifluorescence Images after Staining with Viability Fluorophore CTC

Antimicrobial Copper efficacy: Influenza A

Stainless Steel Samples: 6 hours



Antimicrobial Copper (99.9%) Samples: 6 hours



Antimicrobial Claims in the United States

EPA Jurisdiction—FIFRA

What is FIFRA?

- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
- Federal control of pesticide distribution, sale and use
- US EPA studies the consequences of pesticide usage
- All pesticides must be
  - Registered
  - Properly labeled
  - Present no harm to environment
  - Demonstrate efficacy, **only** if related to human health

US EPA Good Laboratory Practice Tests

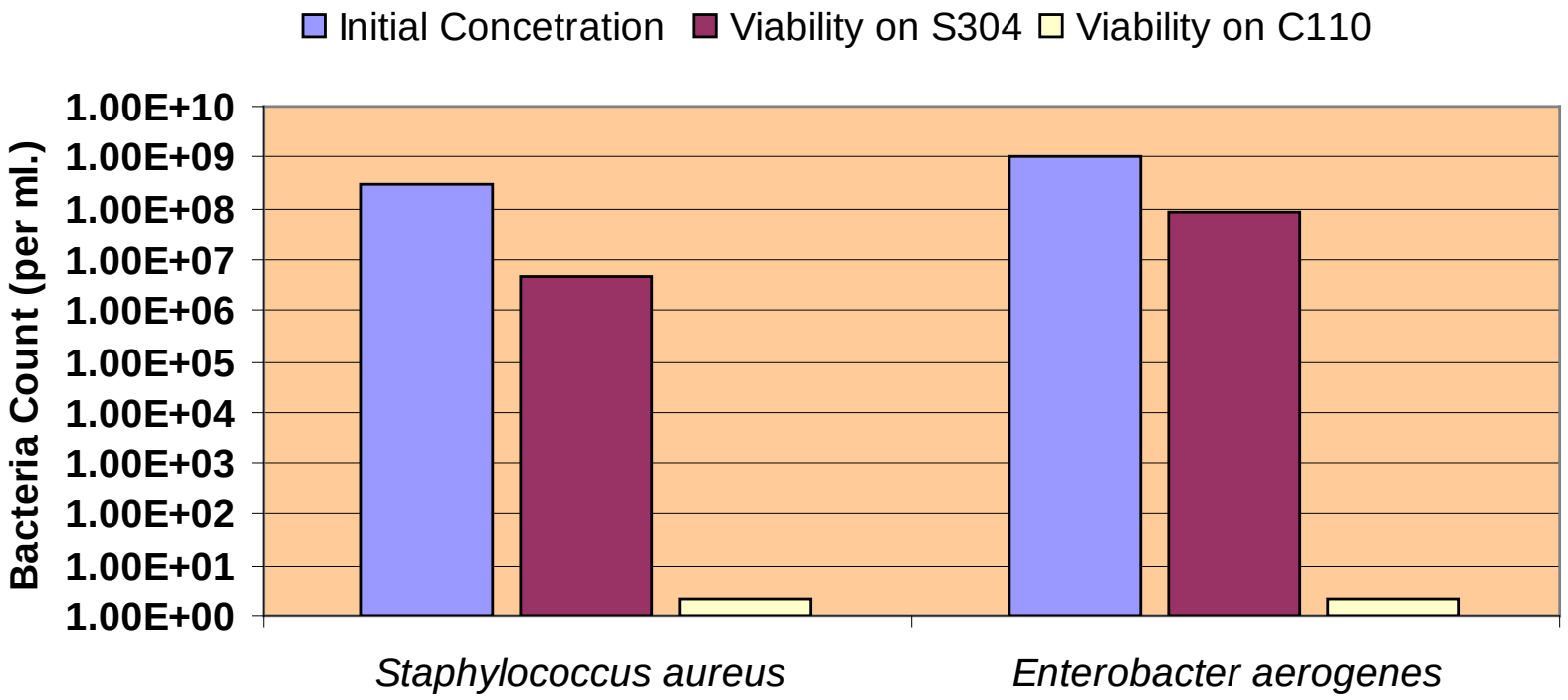
- Three US EPA Approved Test Protocols @ 20° C
  - Efficacy as a Sanitizer
  - Residual Self-Sanitizing Activity
  - Continuous Reduction of Bacterial Contaminants

- Six bacteria
  - *Staphylococcus aureus*
  - *Enterobacter aerogenes*
  - *Escherichia coli* O157:H7
  - *Pseudomonas aeruginosa*
  - Methicillin-Resistant *Staphylococcus aureus* (MRSA)
  - Vancomycin-Resistant *Enterococcus*

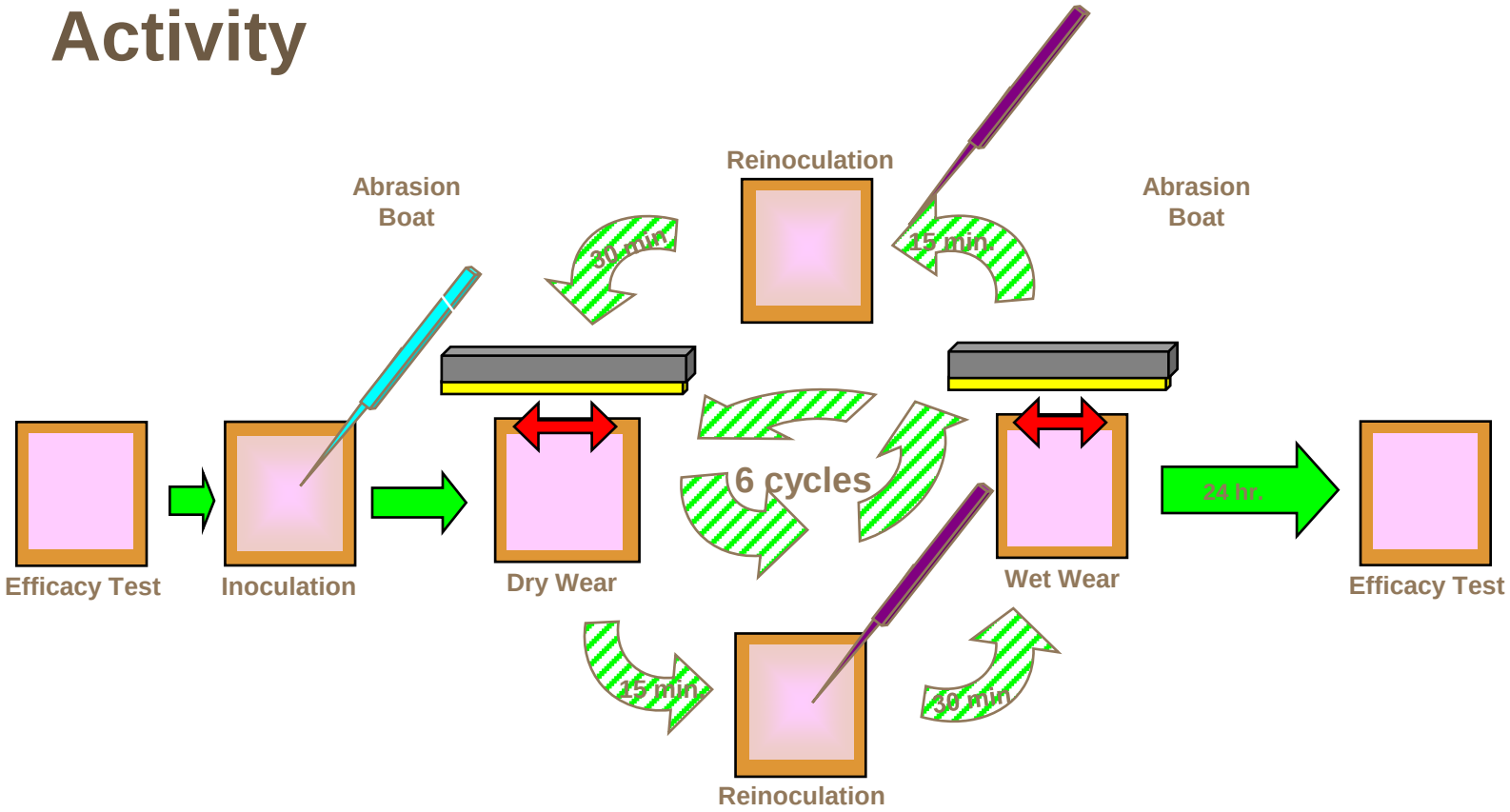
- Six Alloys
  - C11000, C26000, C28000, C51000, C70600, C75200
  - Two or three separately manufactured lots/heats of each alloy
  - Over 3000 samples

Test Protocol 1: Efficacy as a Sanitizer Results

- Label claim: This surface kills 99.9% of bacteria within 2 hours of exposure



Test Protocol 2 : Residual Self-Sanitizing Activity

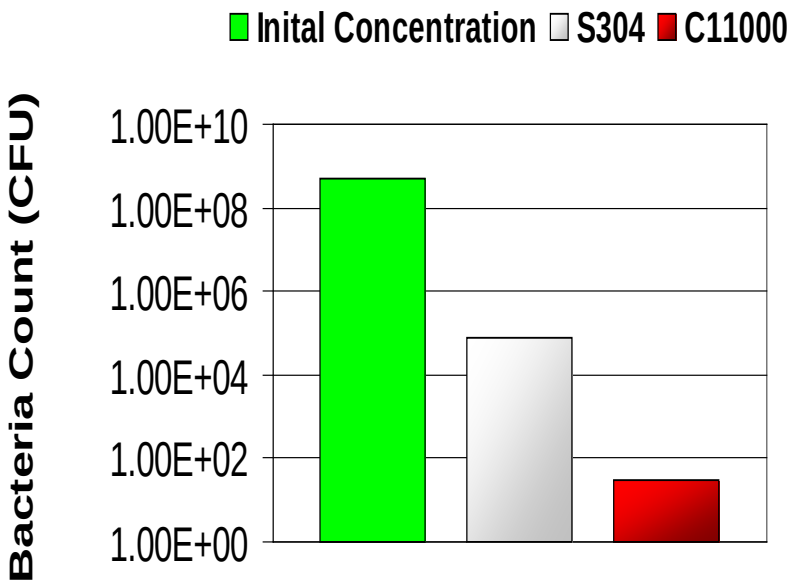


Test involves :

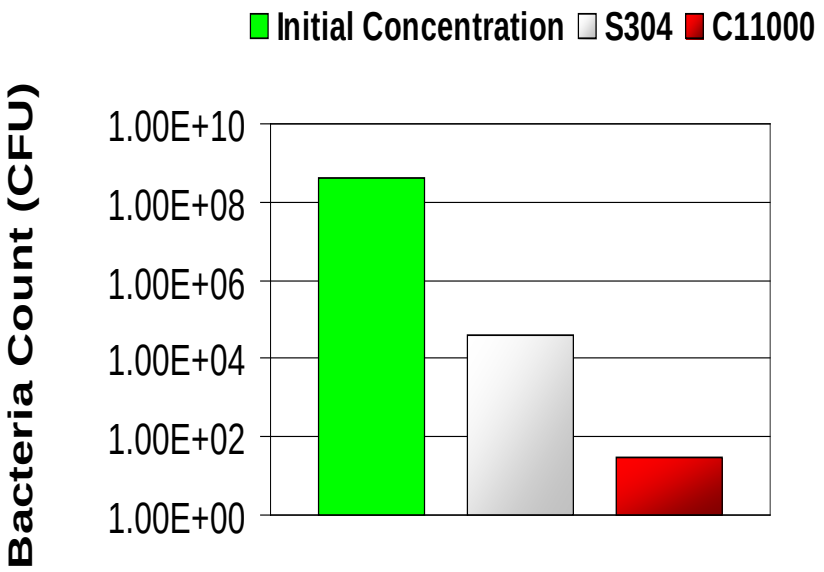
1) **Initial reading after 120 min.**
2) **Six 'reinoculation and wear' cycles (using Abrasion Boat), and**
3) **Final reading after 24 hours.**

Residual Self-Sanitizing Activity Results

E. coli O157:H7



Initial 120 min. efficacy test



After 6 wear and reinoculation cycles and at least 24 hrs

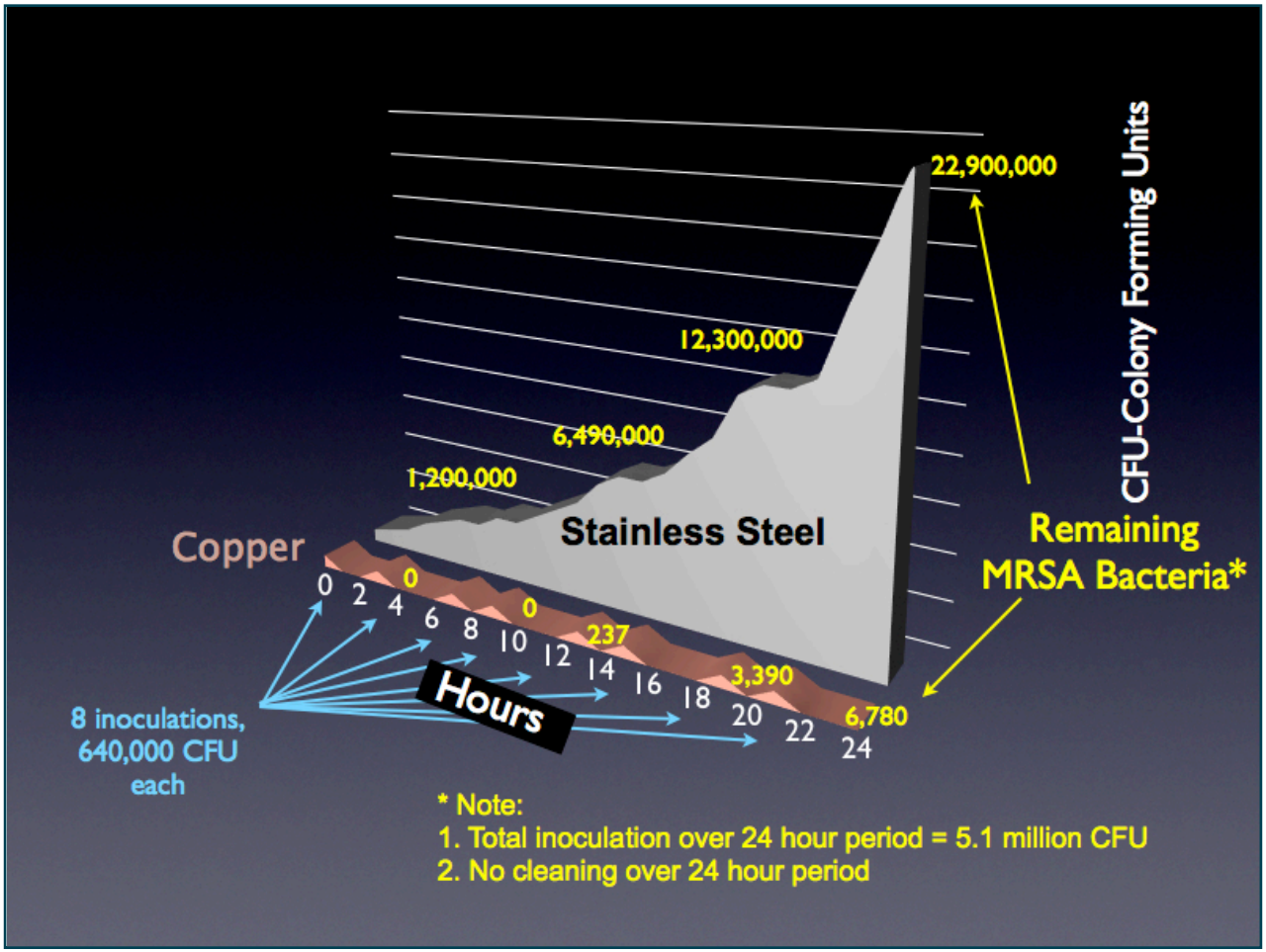
- - - Antimicrobial Properties of Copper are Still Fully Effective

Test Protocol 3: Continuous Reduction of Bacterial Contaminants

Test procedure

- Inoculate test samples every 3 hours for 21 hours, 8 total inoculations
- No cleaning in-between inoculations
- Continuously measure antimicrobial efficacy prior to each re-inoculation for 24 hours

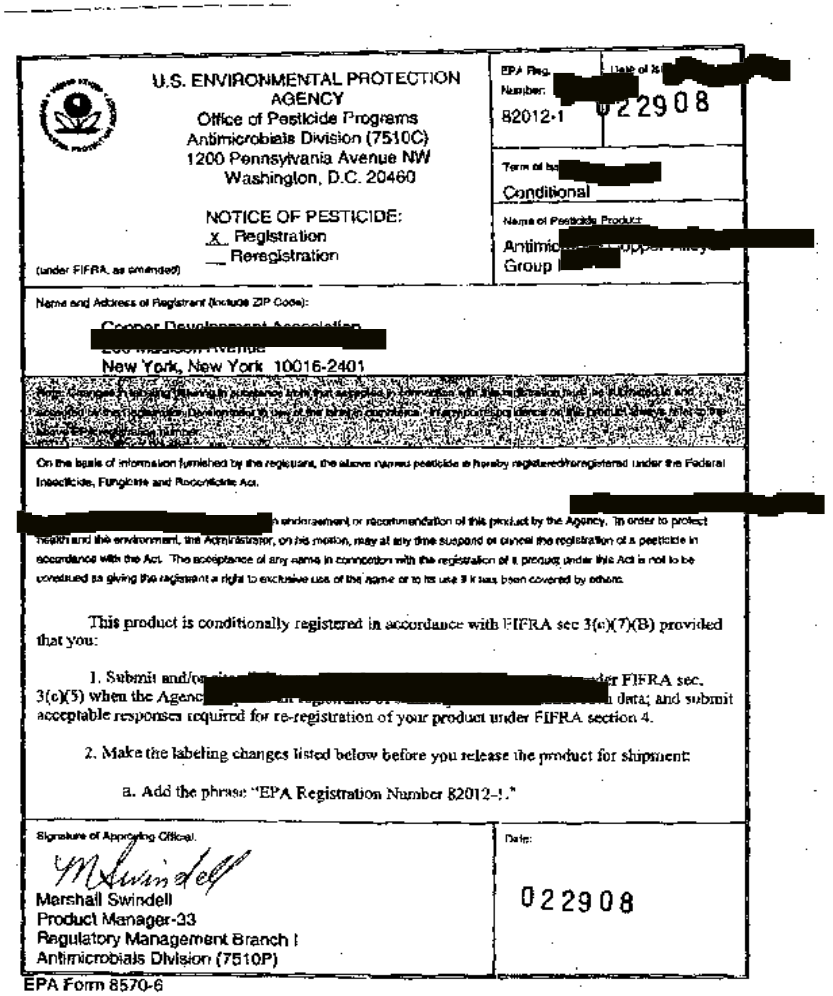
Continuous Reduction of MRSA on C110



Antimicrobial Copper Cu+

Six U.S. EPA Registrations

- Issued Feb 29, 2008 & July 12, 2009
- Antimicrobial Copper Alloys
- Six bacteria
- Public Health Claims
- EPA Reg. Numbers 82012-1 thru 82012-6
- 355 Registered Cu Alloys
- Minimum 60% Cu Content



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:
X Registration
__ Reregistration
(under FIFRA, as amended)

EPA Reg. Number: 82012-1
Date of Issuance: 022908
Term of Issuance: Conditional
Name of Pesticide Product: Antimicrobial Copper Alloy Group

Name and Address of Registrant (Include ZIP Code):
Copper Development Association
New York, New York 10016-2401

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(B) provided that you:

1. Submit and/or cite all data under FIFRA sec. 3(c)(5) when the Agency determines that data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Add the phrase "EPA Registration Number 82012-1."

Signature of Approving Official:
Marshall Swindell
Product Manager-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date: 022908

EPA Form 8570-6

Label claims

[Antimicrobial Copper Alloys continuously reduce bacterial* contamination, achieving 99.9% reduction within two hours of exposure.]

[Antimicrobial Copper Alloys surfaces kill greater than 99.9% of Gram-negative and Gram-positive bacteria* within two hours of exposure.]

[Antimicrobial Copper Alloy surfaces deliver continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within two hours, even after repeated wet and dry abrasion and re-contamination.]

[When cleaned regularly, Antimicrobial Copper Alloy surfaces kill 99.9% of bacteria* within two hours, and continue to kill more than 99% of bacteria* even after repeated contamination.]

[Antimicrobial Copper Alloy surfaces help inhibit the buildup and growth of bacteria* within two hours of exposure between routine cleaning and sanitizing steps.]

**Staphylococcus aureus, Enterobacter aerogenes, Escherichia coli O*157:H7, Methicillin -resistant *Staphylococcus aureus* (MRSA), *Pseudomonas aeruginosa ,* Vancomycin Resistant *Entercoccus*

Label claims(continued)

Required language:

The use of a Copper Alloy Surface is a supplement to and not a substitute for standard infectious control practices; users must continue to follow all current infection control practices related to cleaning and disinfecting environmental surfaces. The Copper Alloy surface material has been shown to reduce microbial contamination, but not necessarily prevent cross contamination.

Copper Alloys: Effective in the lab…
EPA Registered

Do they work in the hospital environment?

"Infections acquired during hospital stays kill more people than breast cancer, auto accidents and AIDS combined"

-Dan Childs, ABC News, Medical Unit

Healthcare-Associated Infections in the U.S.

2,000,000 Infections per Year

Healthcare-Associated Infections in the U.S.

100,000 Deaths per Year

Healthcare-Associated Infections in the U.S.

~$35-45 Billion per Year

March 2009 report by Centers for Disease Control and Prevention

Healthcare-Associated Infections in the U.S.

Medicare to stop payments for preventable infections

U.S. Clinical Trials

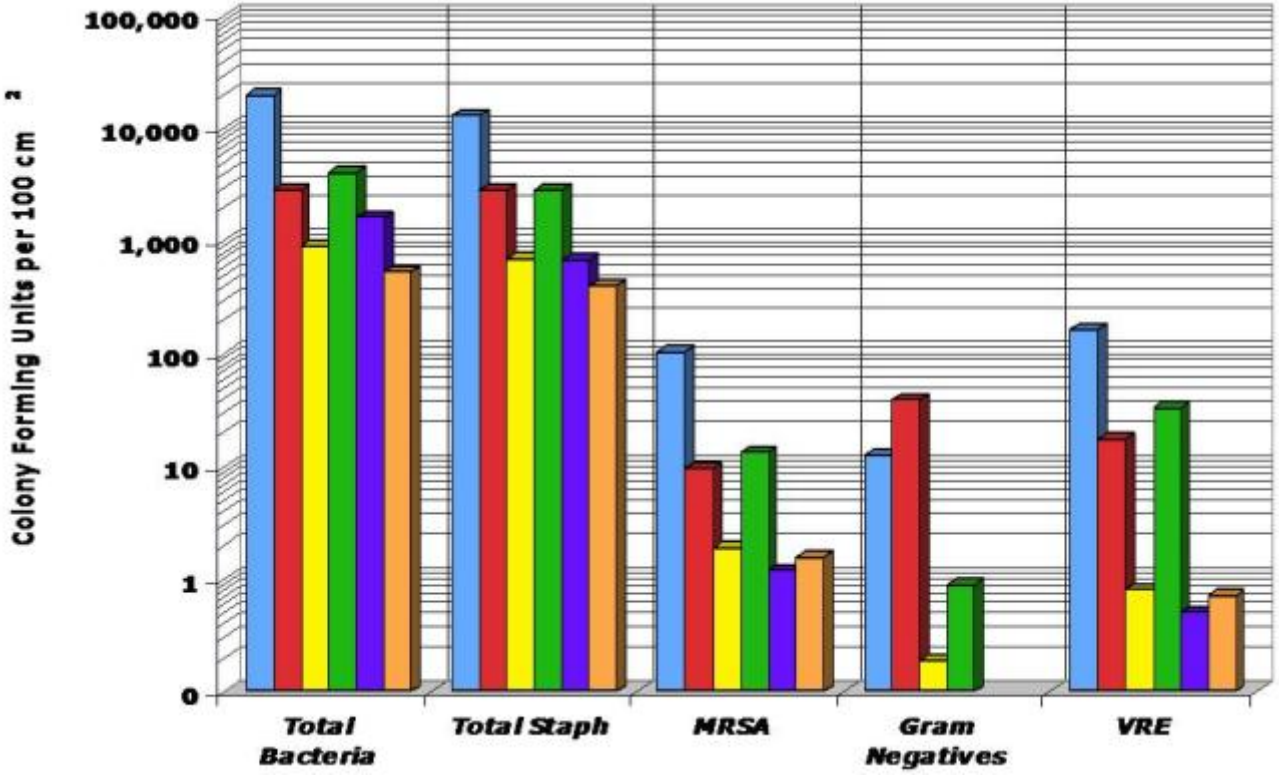
- Funded by The U.S. Department of Defense
- Trials at three sites:
  - Memorial Sloan-Kettering Cancer Center
  - Medical University of South Carolina
  - Ralph H. Johnson VA Medical Center

Bacteria that cause infections can be found in administrative areas and patient wards (after cleaning)

2,320 | 51 | 175 | 4,224 | 526 | 8,400 | 18,000 | 170 | 3,338

Bacterial Count: CFU/100cm2

Phase 1 results: objects closest to patient most contaminated

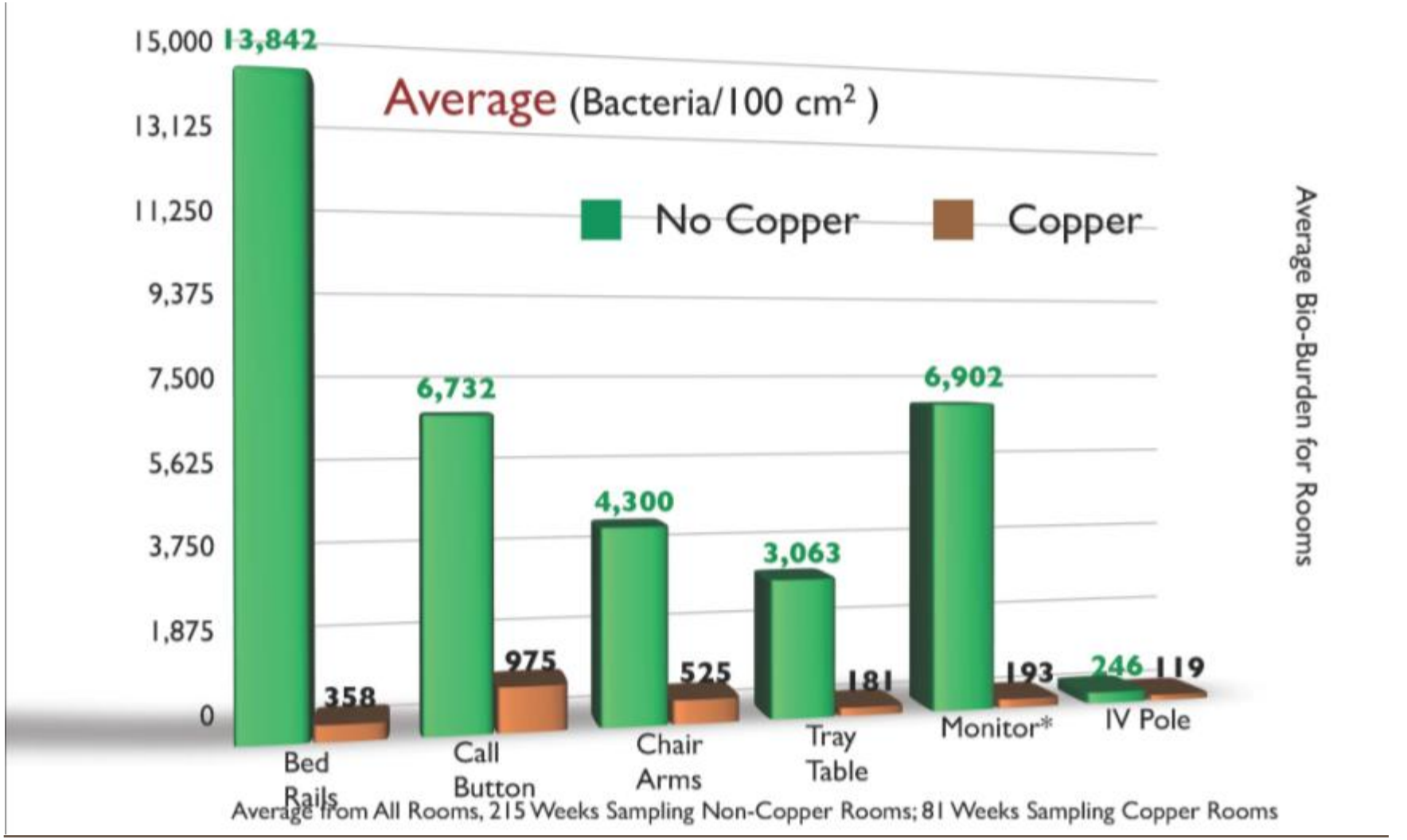


Bedrail , Chair , Over-bed Tray Table , Nurse's Call Button , Data Input Device , IV Pole

Salgado et al. "Microbial Burden of Objects in ICU rooms." Poster presentation, Interscience Conference for Antimicrobial Agents in Chemotherapy (ICAAC), October, 2008.

Copper hospital components

90% reduction of Bacteria on Copper Surfaces

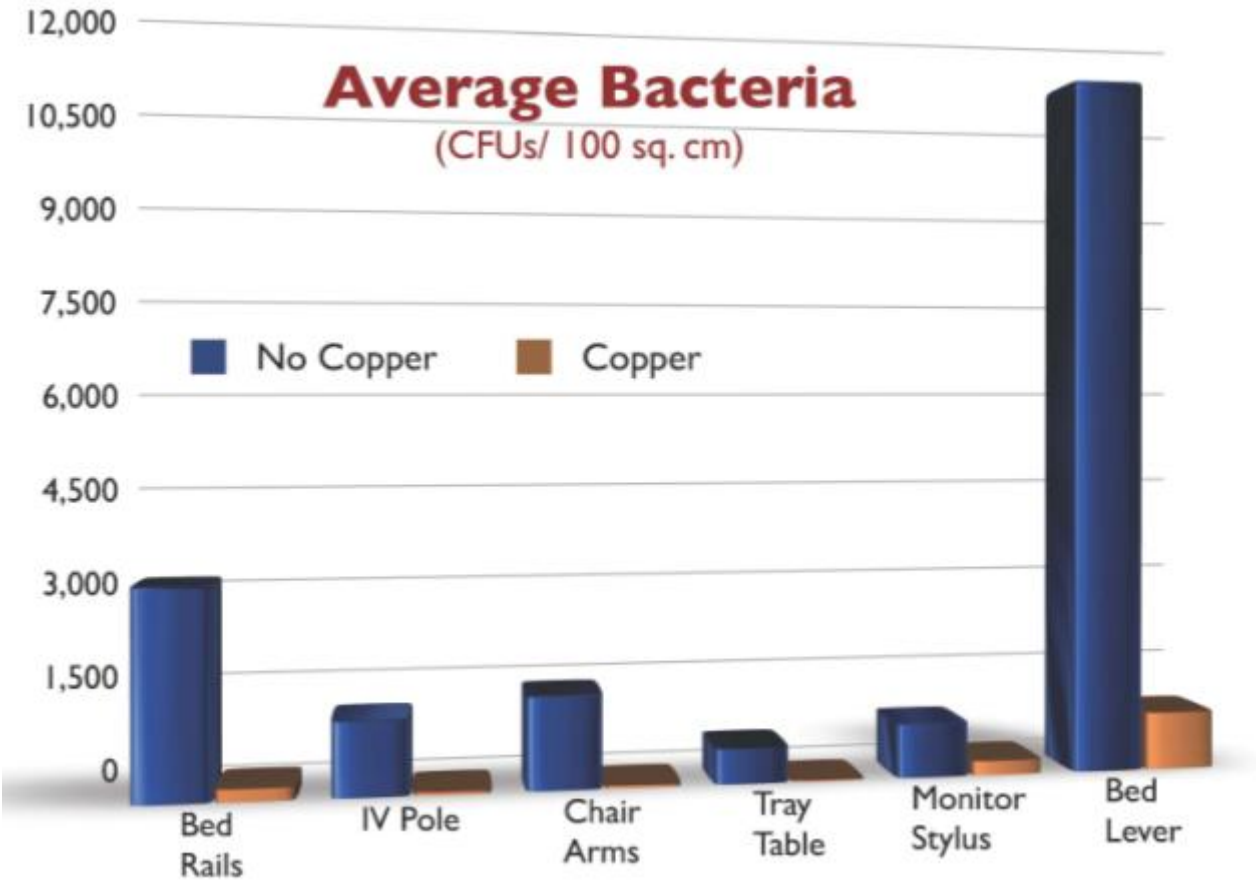


Salgado et al, Poster Presentation, 5th Decennial International Conference on Hospital Acquired Infections, 2010

Hospital de Calama, Chile

- Calama, Chile – very dry environment
- Demonstrates copper surfaces work despite low humidity

Chilean trials results:
~90% reduction on copper surfaces



Prado et al, Poster Presentation, 14th International Conference on Infectious Diseases, 2010

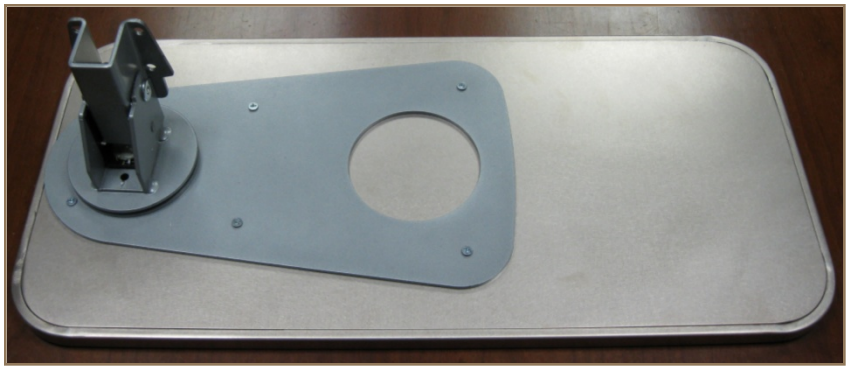
Northshore Hospital clinical trials
Manhasset, NY

- Measure/compare bioburden on phlebotomy chairs
  - Arms and tray tables copperized
- Compliments existing clinical data
  - Outpatient clinic
  - High percentage HIV positive

La Z Boy
Phlebotomy Chair

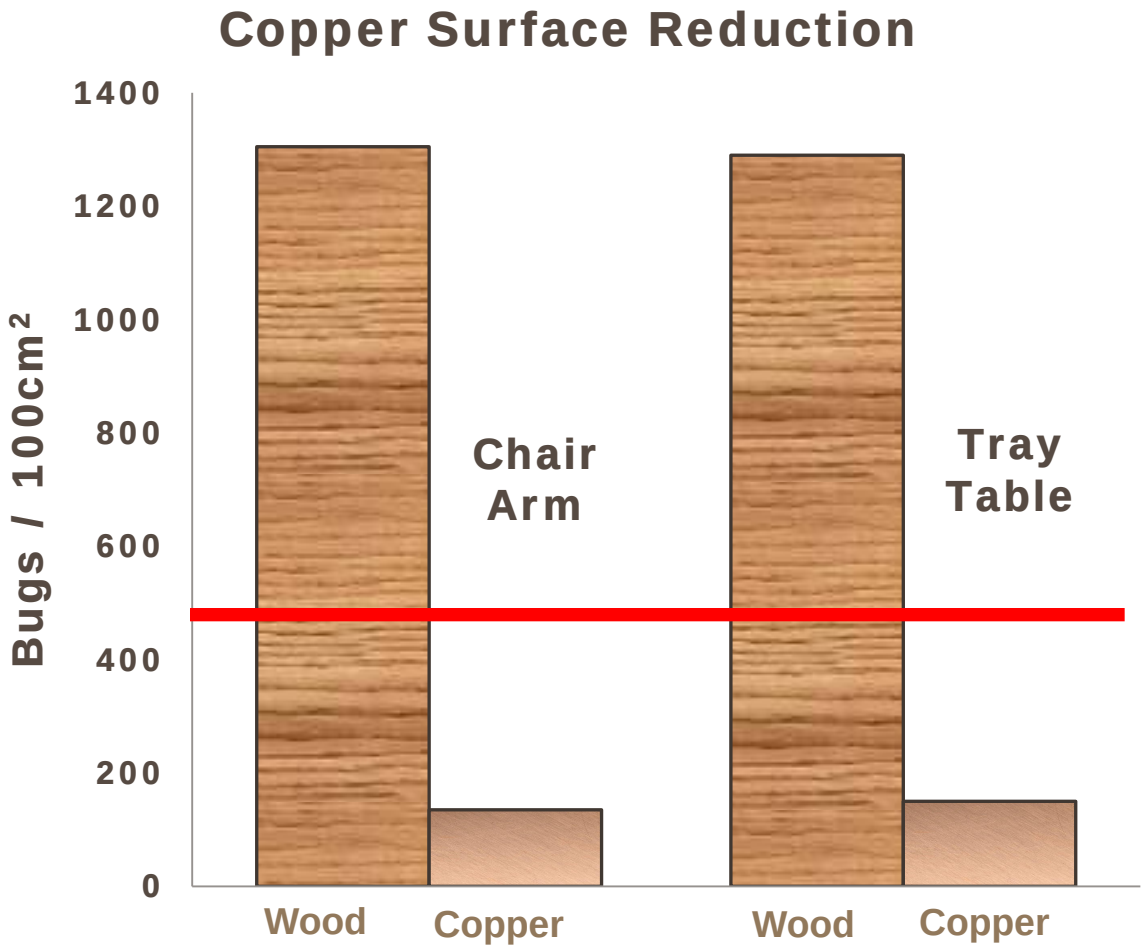
North Shore LIJ North Shore-Long Island Jewish Health System

Northshore Hospital clinical trials
Copper components fabricated



Northshore Hospital trials
Copperized chairs installed

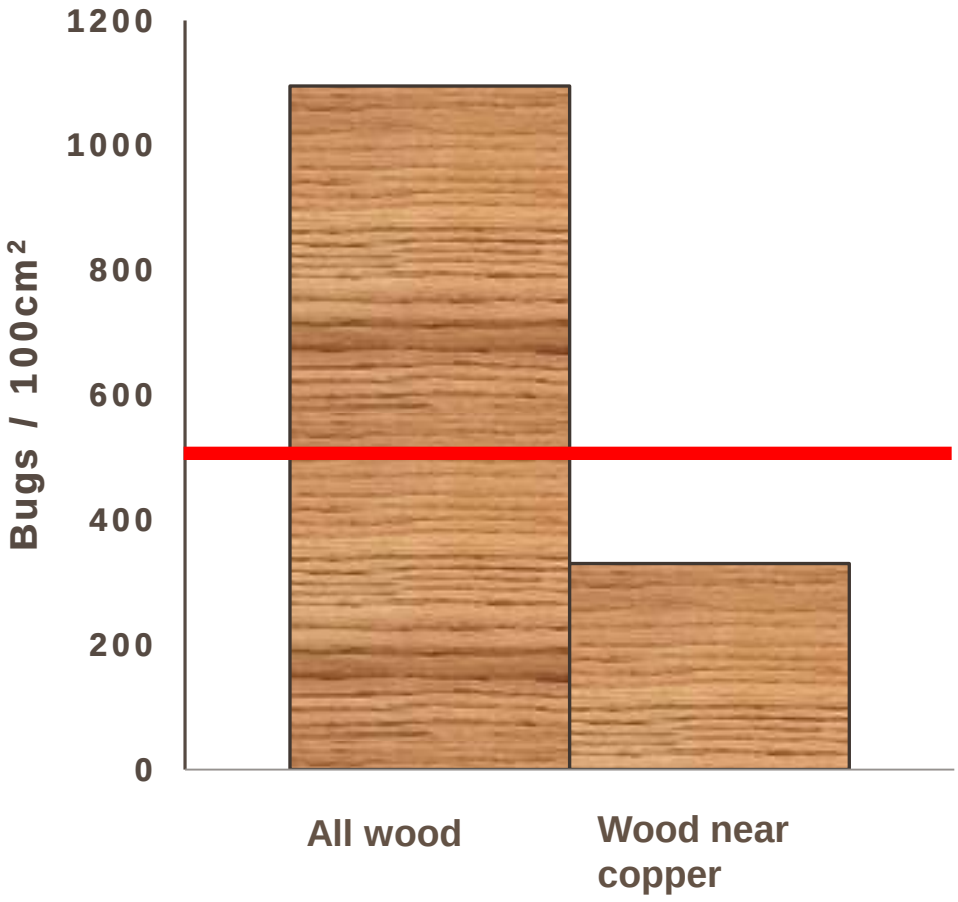
Compelling Performance Data

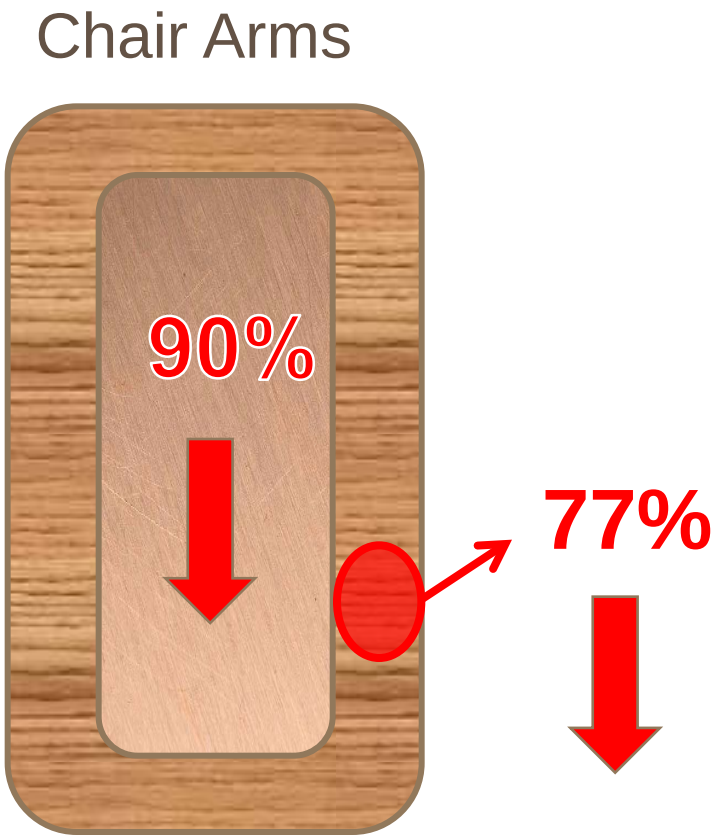


90%

Antimicrobial Copper Cu+

Halo Effect





Hirsch, B.E. et al, Poster Presentation, 50th Interscience Conference on Antimicrobial Agents in Chemotherapy, Boston, September 2010.

Antimicrobial Copper Cu+

Clinical trials are currently in operation around the world

Additional Activities

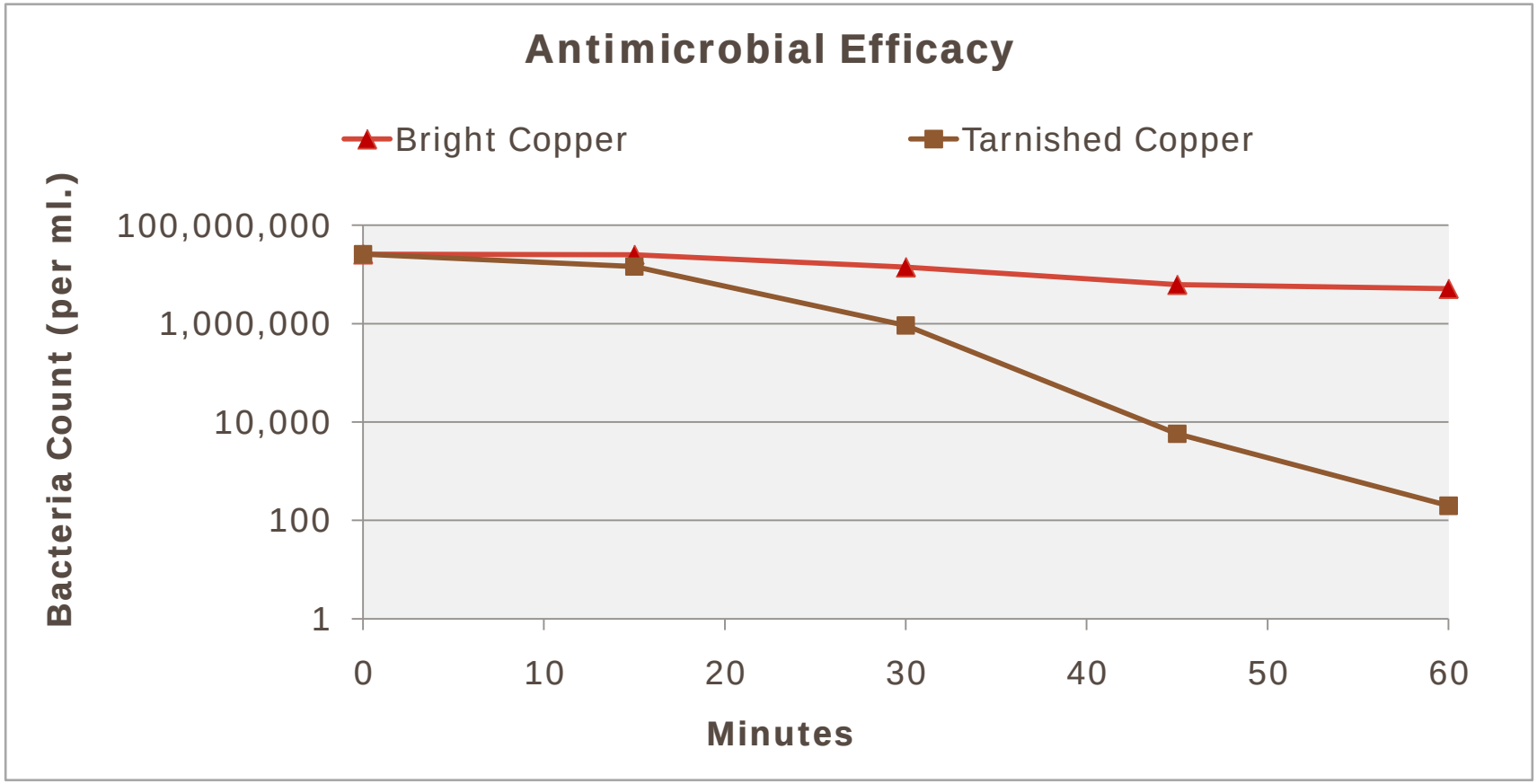
Antimicrobial Copper Cu+

Antimicrobial Copper Brand

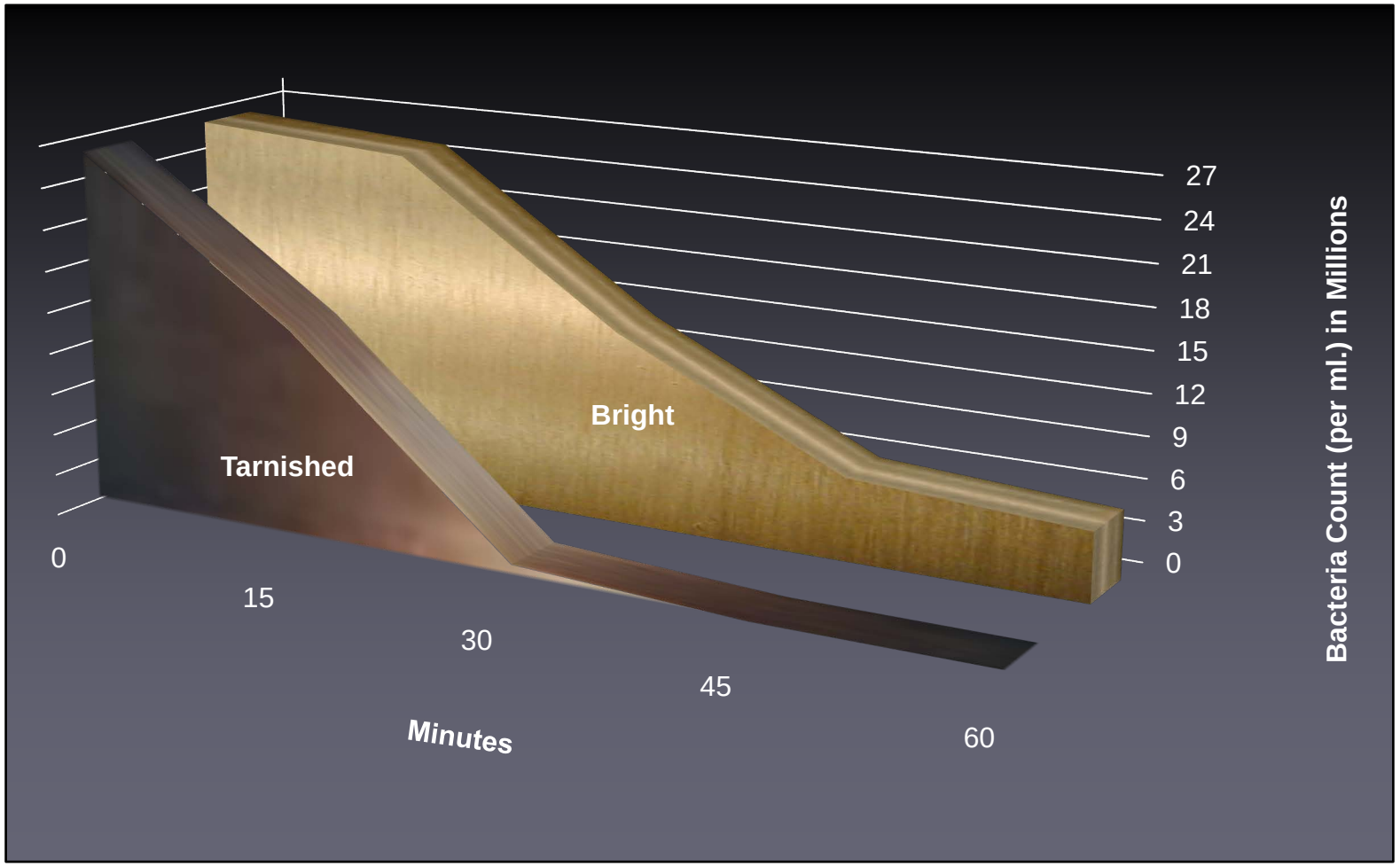
Effect of Tarnishing

Tarnishing Does Not Reduce Antimicrobial Effectiveness of Copper Alloys!

Effect of Tarnishing



E. Coli O157:H7 Viability: Bright vs. Tarnished



Thank You

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www.antiicrobialcopper.com

Antimicrobial Copper Cu+