Testimony of

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Technology for Patient Safety at Veterans Hospitals

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Electro-Spec is a company engaged in the field of electroplating utilizing precious and semi-precious metal on devices and components in the aerospace, automotive, telecommunication, military and medical industries. Steriplate is a wholly owned subsidiary of Electro-Spec that is engaged in developing specialty metal alloys that have been shown to be antimicrobial in testing against specific types of bacteria known to cause Hospital Acquired Infections (HAI's). I would like to thank you for the invitation to present our exciting and potentially life-saving technology. In my testimony, I will address the following key points:

1.) The serious threat that is posed in the United States, concerning HAI's and the need for newer methods and technology to help combat the cost associated with treatment and prevention of the spread of infectious diseases.
2.) The ability of copper and copper alloys (**specifically Steriplate**) to provide a continuous antimicrobial surface to help prevent the spread of HAI's.
3.) The time, expense and complexity that exist in trying to engineer and develop new technologies that will address the ongoing issues in veterans hospitals and hospitals across the United States and the barriers associated with commercialization and market success.

A brief summary of the key points highlighted and emphasized in my testimony can be found at the end of this document.

My testimony today is based upon my metallurgical knowledge and background, as a business owner of Electro-Spec and Steriplate, and the infinite possibilities of utilizing metal as an antimicrobial finish in a variety of applications inside and outside the human body.

Electro-Spec (an Indiana company) specializes in high reliability and highly functional electroplating. Electro-Spec utilizes precious and semi-precious metal on ferrous and non-ferrous materials for the aerospace, military, medical, automotive and telecommunication industries. Electro-Spec utilizes state-of-the-art chemistries and equipment to electroplate some of the most demanding devices and components for its customers. Devices and components that go into space, military defense, implantable (life sustaining and life altering) or various telecommunication equipment, are just a few of the items that Electro-Spec is recognized as the preferred plating supplier for. With a customer base of Lockheed Martin, Raytheon, Boeing, Medtronic, Smiths Group, Energizer, Northrop Grumman, Honeywell and TRW, Electro-Spec is viewed as a strategic partner in the advancement of innovative equipment, devices and technologies.

Problem Statement

The United States is viewed as one of the most technologically advanced, innovative and forward thinking countries in the world. In fact, the United States is considered the global leader in medical innovation. Yet despite all of these advances in technology, the 4th leading cause of death in the United States is Hospital Acquired Infections (HAI's), something that plagues every nation in the world. The CDC reports in their most recent study that 1 out of every 20 patients treated in a hospital, will become infected with a Hospital Acquired Infection. Unfortunately, the most recent statistics of 183 hospitals showed 648,000 patients nationwide suffered 721,000 infections which lead to 75,000 deaths in 2011. This is equivalent to over 200 deaths per day (more than AIDS and Breast Cancer combined), associated to infection from various forms of bacteria, of which some are particularly resistant to antibiotic therapy and treatment. Hospital Acquired Infections result in a net increase in cost of $43,000 per patient and an additional 19 days of hospitalization and result in 2.5 x increased likelihood of readmission within 30 days. The financial impact to the nation is estimated at over $45 billion in trying to deal with infectious diseases.

HAI's are various types of infections that patients acquire while they are receiving care or treatment for another condition in a health care environment. HAI's can be spread or acquired anywhere care is being administered. The information referenced above through the CDC is specific to hospitals, but obviously HAI's can be acquired from inpatient acute care facilities, ambulatory surgical centers, outpatient centers, long term care facilities or even field hospitals. These infections are associated with various risk factors with the patient and the medical services rendered. Transmission of communicable diseases between patients and healthcare workers or even overuse of antibiotics, are other ways of acquiring HAI's. The U.S. Department of Health and Human Services (HHS) has identified the reduction of HAI's as an "Agency Priority Goal" for the Department. HHS has stated that it is committed to reducing the national rate of HAIs by demonstrating significant, quantitative and measureable reductions in hospital acquired central line-associated bloodstream infections and catheter-associated urinary tract infections. Newly established goals for the reduction of HAI's have a target date of 2020 (HAI National Action Plan) and these goals are being supported by the U.S. Department of Labor, U.S. Department of Defense and the U.S. Department of Veterans Affairs, along with scientists, clinicians and health leaders.

Emerging Technologies

Many emerging technologies to help control HAI's have been developed and implemented in recent years. Everything from bleach wipes, to UV Light Disinfection machines, to hydrogen peroxide vapor machines have been utilized to control the spread of infectious disease and cross contamination. However, these methods are used to "treat" the source of contamination and do not pose a permanent and continuous method to controlling the HAI's. In certain situations, the surfaces can become immediately re-contaminated through human contact or contact with contaminated equipment. Microbes have the ability to reproduce rapidly in the right environment and can exist on surfaces for days, weeks or even months in the right environment. However, in order for the microbe to transition to a pathogen, it must be able to survive on surfaces for a sufficient amount of time while retaining its ability to be virulent or colonize a susceptible host after removal from the surface it was contacted with – thus resulting in inadvertent transmission. Many current methods for the removal of these pathogens treat the surface once, but don't provide continuous treatment or prevention. To date, the only recognized method for permanent, continuous and sustainable reduction in the bacterial burden of surfaces is copper.

In 2008 the United States Environmental Protection Agency (EPA) registered five families of copper-containing alloys as antimicrobial, establishing that products manufactured from one of these registered alloys can make public health claims wherein the label indication states that the alloys kill 99.9% ($\log_{10}$ 3.0) of bacteria within two hours of exposure **(1).** It is anticipated that the solid antimicrobial copper surfaces will remain microbiocidal for the life of the product (>10 years). A variety of controlled studies have looked at the antimicrobial activity of copper surfaces against specific human pathogens **(2,3,4,5,6,7,8).** In fact solid copper surfaces have been found to be microbicidal to well over 30 bacteria, fungi and viruses. Of the microbes listed in Table 1**,** five were evaluated in the studies used to grant the public health registration by the United States EPA. The public health claims granted illustrate the robust nature of the antimicrobial activity **(9)**. Alloys granted registration contain greater than 60% metallic copper and were found to continuously kill greater than 99.9% of Gram-negative and Gram-positive bacteria within two hours of exposure even after repeated contamination illustrating how solid copper surfaces will inhibit the buildup of microorganisms between routine cleaning and sanitizing steps.

TABLE 1
MICROORGANISMS SENSITIVE TO THE ANTIMICROBIAL PROPERTIES INTRINSIC TO SOLID METALLIC COPPER

Microbe	***Reference(s)***	***EPA***

		Registered
Acinetobacter baumanii	(47)	
Aspergillus flavus	(96)	
Aspergillus fumigatus	(96)	
Aspergillus spp.	(96)	
Campylobacter jejuni	(28)	
Candida albicans	(47, 96)	
Clostridium difficile	(97)	
Clostridium difficile spores	(97)	
Carbapenem-Resistant *Enterobacteriaceae (CRE)*	(84)	
Enterobacter aerogenes	(87)	*
E. coli O157:H7	(87, 104)	*
Escherichia coli-NDM1	(93)	
Fusarium culmonium	(96)	
Fusarium oxysporium	(96)	
Fusarium solani	(10)	
Fusarium spp.	(96)	
Influenza A (including H1N1)	(53)	
Klebsiella pneumoniae	(47)	
Klebsiella pneumoniae-NDM-1	(93)	

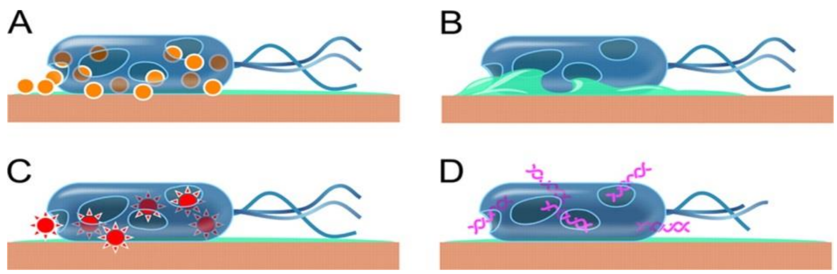
Legionella pneumonphila	(65, 66)	
Listeria monocytogenes	(105)	
Methicillin Resistant *Staphylococcus aureus* (*MRSA*)	(87)	*
Methylobacterium spp.	(76)	
Mycobacterium tuberculosis	(47)	
Norovirus	(94)	
Penicillium chrysogenum	(96)	
Penicillium spp.	(96)	
Pseudomonas aurginosa	(87, 96)	*
Rhinovirus	(11)	
Rotavirus	(11)	
Salmonella enterica	(28)	
Salmonella typhi	(79, 80)	
Spingomonoas spp.	(76)	
Staphylococcus auerus	(87)	*
Serratia marcescens	(11)	
Vancomycin Resistant Enterococci (VRE)	(87)	*
Vibrio cholerae	(79, 80)	

(9) Information provided by Michael Schmidt, Ph.D – Dept. of Microbiology and Immunology – Medical University of South Carolina

The public health claims attributed to solid copper have been evaluated to limit the bacterial burden found on commonly touched surfaces and objects in active healthcare environments.

What makes copper so effective?

The metal destroys bacteria by coaxing the organism to donate electrons to it, resulting in the production of free radicals within the cell. The result is damage to bacterial DNA and cell proteins. The metal is also effective against viral and fungal pathogens. The entire process occurs quickly resulting in the collapse of a population within minutes. **Thus, the likelihood that the population will develop resistance to this multifaceted mechanism of death is unlikely**.

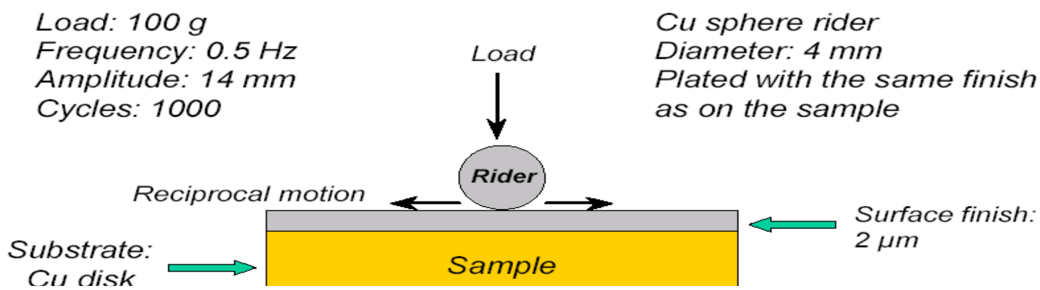


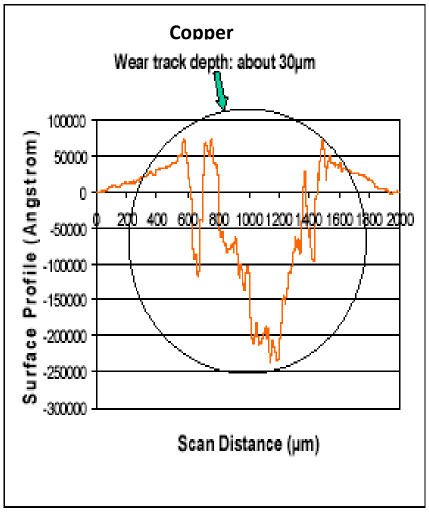
Antimicrobial Metal Technology

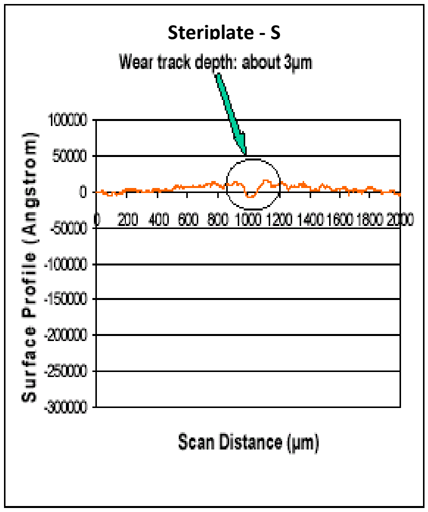
What is Steriplate and how has it been shown to be antimicrobial? Steriplate is a tertiary alloy specifically designed for medical applications. Comprised of three distinctly different metals, Steriplate is an electroplated alloy that can be plated on numerous types of surfaces to impart antimicrobial properties on the surface and shown to provide the same benefits of copper. At the same time it gives better wear, corrosion, and tarnish properties than conventional copper can provide.

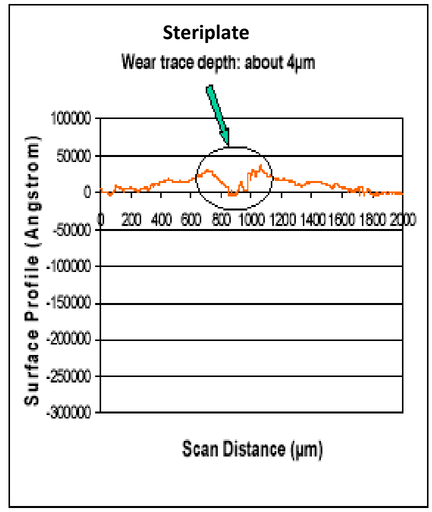
Wear Resistance: Steriplate exhibits excellent lubricity and wear properties

Sliding Wear Test Setup









Corrosion Resistance: Steriplate exhibits exceptional corrosion and tarnish resistance in a variety of environments

- ❑ **Artificial sweat (ISO 3160) :** < 24 h
- ❑ **Thioacetamide:** >24 h
- ❑ **NSS:** *Brass*: 48 H to white rust, >122 H
- ❑ **Humid atmosphere (85°C – 85% RH):** >72Hrs
- ❑ **Thermal Cycles:** -50°C/+85°C, RH=70% for 10 days (1000 cycles):no discoloration
- ❑ **Tarnish resistance:** no color change after 4 H exposure at 150°C.

Antimicrobial Testing: Steriplate demonstrated antimicrobial properties in various efficacy testing

E. coli (CRE)

ANTIMICROBIAL TEST LABORATORIES

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Study Update – NG4980
04APR2014

E. coli (CRE) BAA-2469 JIS Z 2801 Study Results

Test Microorganism	Contact Time	Carrier Type	CFU/Carrier	Percent Reduction Compared to Control at Contact Time	Log_{10} Reduction Compared to Control at Contact Time
E. coli (CRE) BAA-2469	Time Zero	ATL Control	2.25E+05	N/A	
	2 Hours	ATL Control	1.50E+05		
		Steriplate w/ SAM's – Nickel Base	4.35E+04	71.00%	0.54
	24 Hours	ATL Control	2.45E+06	N/A	
		Steriplate w/ SAM's – Nickel Base	<5.00E+00	>99.9998%	>5.69
		Steriplate w/o SAM's – Nickel Base	<5.00E+00	>99.9998%	>5.69

- **Results showed that Steriplate demonstrates antimicrobial functionality against E. coli (CRE) at greater than 99.9998% reduction in 24 hours.**

S. Aureus (MRSA):

***Staphylococcus aureus* 33592 (MRSA)**

This bacterium is a Gram-positive, spherical-shaped, facultative anaerobe. *Staphylococcus* species are known to demonstrate resistance to antibiotics such as methicillin. *S. aureus* pathogenicity can range from commensal skin colonization to more severe diseases such as pneumonia and toxic shock syndrome (TSS). *S. aureus* is commonly used in several test methods as a model for gram positive bacteria. It can be difficult to disinfect but does demonstrate susceptibility to low level disinfectants.

Results of the Study

Test Microorganism	Contact Time	Carrier Type	CFU/Carrier	Percent Reduction Compared to Control at Contact Time	Log_{10} Reduction Compared to Control at Contact Time
S. aureus (MRSA) 33592	Time Zero	ATL Control	3.20E+05	N/A	
	6 Hours	ATL Control	4.60E+05		
		Steriplate w/ SAM's – Nickel Base	1.00E+01	99.998%	4.66
		Steriplate w/o SAM's – Nickel Base	2.00E+01	99.996%	4.36

- **Results showed that Steriplate demonstrates antimicrobial functionality against MRSA at an 99.99% reduction in just 6 hours of exposure**

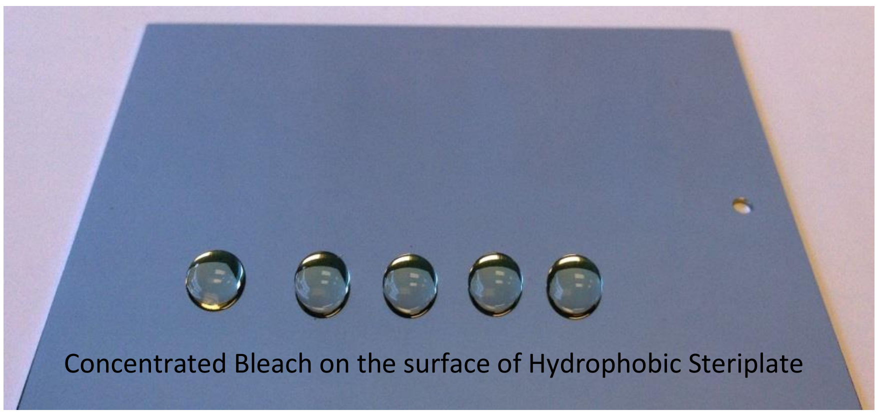
Biocompatibility Testing – Independent testing by a current medical customer

- Based upon the conservative assumption of patient exposure to a 2.5 gram component, these levels were below the levels of toxicological concern.
- MEM Cytotoxicity – Not cytotoxic

Not only does Steriplate have excellent metallurgical properties that can provide unique medical and environmental properties, the most unique property about Steriplate is that it can be made to be “hydrophobic” or “hydrophilic”. These properties provide a unique metallic surface that has antimicrobial properties, with even more unique capabilities outside or potentially inside the body.

One of the most critical aspects of making a surface resistant to microbial "loading", is to ensure that the surface is dry. By making Steriplate hydrophilic (readily absorbing liquid), the surface will have a propensity to dry quicker, rather than "pooling" in certain areas of the surface. Most surfaces will dry unevenly due to this pooling of liquid and result in continued loading of microbes in these areas. Outside the body, Steriplate is designed to provide maximum antimicrobial efficacy through its alloy composition and hydrophilic properties.

Steriplate with hydrophobic (repel liquid) surfaces, has been designed for clinical trials on devices that are short term or long term implantable or semi-implantable devices traditionally susceptible to infection.



Concentrated Bleach on the surface of Hydrophobic Steriplate

The additional benefit of having a hydrophobic surface that is antimicrobial, is the ability to repel blood, mucous, saliva, urine, perspiration and other contaminated "liquids" that obviously have the ability to transmit tremendous amounts of bacteria to various surfaces instantly. A secondary hypothesis that has not yet been trialed clinically, is that Steriplate in its hydrophobic state, may be able to act as an antimicrobial surface while imparting an additional benefit of being anticoagulant in preventing clotting and strokes. One of the current trials being discussed is to see if Steriplate can provide an antimicrobial surface that prevents thrombosis.

Electro-Spec and Steriplate are currently working with the IU School of Medicine on potential clinical trials on the following applications:

Application #1.)

Ventriculo-peritoneal shunts are commonly used devices in pediatric patients for hydrocephalus or interventricular hemorrhages. The shunts remain in place for prolonged periods, sometimes for life, and must be tapped periodically for a variety of reasons. A certain percentage of these patients develop an infection at the site where the shunts interface with the cerebrospinal fluid. If the valve at the interface is coated with Steriplate this should reduce the incidence of infection, especially since data shows excellent bactericidal results with organisms that commonly infect pediatric shunts.

Application #2.)

For patients with severe scoliosis, the standard treatment is to install one or more metal rods in the spine for several months to years until the curvature is corrected. Sometimes the patient develops an infection around one of the rods. This type of infection can be very difficult to clear with a foreign body such as a rod in place and if it cannot be cleared, the only viable option may be to remove the rod. This may result in an incomplete fusion or instability of the spine and often creates further complication for the scoliosis treatment plan. If the rods were coated with Steriplate, this could reduce the incidence of infections, again with data that shows efficacy against the common organisms implicated in such infections.

Application #3.)

Baclofen pumps are used to administer Baclofen in a controlled dose to help patients suffering from spasticity from certain diagnoses like cerebral palsy. The pumps are implanted under the skin in a pocket in the abdominal area. Sometimes the pocket site around the pump becomes infected, necessitating surgical removal and prolonged antibiotic therapy. If the pump casing is coated with Steriplate, this could potentially reduce the incidence of infection in these patients.

Application #4.)

Adult dialysis patients are often fitted with a graft with an access port that is used to administer their hemodialysis treatment. Infection of these ports is quite common. The ports are currently made of plastic. If the grafts could be made of a metal and coated with Steriplate it could potentially cause a reduction in infections at the port site.

Where do we go from here?

In the United States, a high degree of statistical significance is needed to provide a convincing argument to U.S. federal government healthcare authorities, such as the Centers for Disease Control and Prevention (CDC), regarding the effectiveness of copper alloys in reducing microbial loads and cross infection in healthcare environments. For this reason, clinical trials at three major US hospitals were conducted between July 2010 and June 2011 with the intent of examining environmental bacterial loads, infection rates, and impacts on cross-contamination in intensive care unit (ICU) rooms retrofitted with copper touch surfaces versus rooms without copper surfaces **(10).**

The trials were funded by the U.S. Department of Defense (DOD) under the Telemedicine and Advanced Technology Research Center (TATRC), a subordinate element of the United States Army Medical Research and Materiel Command (USAMRMC). DOD has extraordinary interests in the potential for antimicrobial copper surfaces to reduce hospital-acquired infections because it wants to prevent hospital-acquired infections among thousands of its enlisted armed forces servicemen and servicewomen who have been injured in recent conflicts. TATRC, which funds a Military Infectious Disease Program was granted funds by the United States Congress to evaluate the antimicrobial effectiveness of copper, brass and bronze alloys. The studies were coordinated through the Advanced Technology Institute in Charleston, South Carolina **(10).**

Four-year clinical studies, published in 2013, were conducted at the intensive care units (ICUs) at Memorial Sloan-Kettering Cancer Center in New York City, one of the world's most prestigious cancer facilities, the Medical University of South Carolina, and the Ralph H. Johnson VA Medical Center in Charleston, South Carolina.

The studies revealed that the use of antimicrobial copper surfaces in the ICU's reduced the number of healthcare-acquired infections (HAIs) by 58% compared to patients treated in ICUs with non-copper touch surfaces. The antimicrobial copper surfaces were proved to work continuously.
(•US Army Medical Research and Materiel Command under Contract No. W81XWH-07-C-0053. The views, opinions and/or findings presented here are those of the author(s) and should not be construed as an official US Department of the Army position.)

Concluding Thoughts:

Every day over 200 people die due to hospital acquired infections. To borrow an analogy from Dr. Michael Schmidt (Director of Office of Special Programs and Professor and Vice Chair – Dept. of Microbiology and Immunology at The Medical University of South Carolina), if a jet plane carrying 200 passengers crash every single day of the year killing everyone on board, there would be public outrage. The entire fleet of planes throughout the country would be grounded and there would be significant investigations by the FAA, Aircraft manufacturers, Dept. of Defense and many more public and private entities. It would lead to questions of national security and would probably put the nation's economy in a tailspin. This is happening in a different manner and it is happening at an alarming pace. However, this is preventable and the technology is emerging to support the National Action Plan developed by the Dept. of Health and Human Services. Companies like Electro-Spec and Steriplate have the technology, but lack the financial resources necessary to further promote and market this technology. If we continue to invest wisely and work in a collaborative environment, where promotion and support of these emerging technologies is established at all levels (public and private), there is no doubt that the United States could not only save precious lives, but dramatically reduce the incidence of infectious disease and continue to lead the world in medical innovations. The time is now, however, as antibiotics are becoming less and less effective. Bacteria are continuing to mutate and become less and less resistant to antibiotics. Scientists worldwide continue to try and decode the defense mechanisms of various types of bacteria in an attempt to slow these mutations. Providing an environment where these bacteria are constantly being "attacked" and cannot reproduce and multiply, is the foundation of control in an effort to prevent the spread of HAI's. Copper and Copper alloys have been proven to be antimicrobial and provide a continuous way to control and limit the environmental burden, found in all medical facilities.

Thank you for your interest and support in this exciting and life-changing technology to address HAI's. I welcome your comments and questions.

Summary of Testimony:

- The United States is the unquestioned leader in the world in terms of medical innovation and technology. This is predominantly due to a system that rewards innovation and fosters collaboration to facilitate life-changing, life-sustaining and life-altering technologies to improve our lives. Unfortunately, one of the leading causes of death in the United States and one of the most expensive to treat, are hospital acquired infections. The U.S. Department of Health and Human Services (HHS) has identified the reduction of HAI's as an "Agency Priority Goal" for the Department. HHS has stated that it is committed to reducing the national rate of HAIs by demonstrating significant, quantitative and measureable reductions in hospital acquired central line-associated bloodstream infections and catheter-associated urinary tract infections. A new National Action Plan has been established this past year with significant goals to achieve by the year 2020. Federal and private funding will be necessary to meet these goals. The task will be difficult, but innovation is the backbone of small businesses, research institutions and the American people.
- Many emerging technologies to help control HAI's have been developed and implemented in recent years. Everything from bleach wipes, to UV Light Disinfection machines, to hydrogen peroxide vapor machines have been utilized to control the spread of infectious disease and cross contamination. However, these methods are used to "treat" the source of contamination and do not pose a permanent and continuous method to controlling the HAI's. In certain situations, the surfaces can become immediately re-contaminated through human contact or contact with contaminated equipment. Microbes have the ability to reproduce rapidly in the right environment and can exist on surfaces for days, weeks or even months in the right environment. However, in order for the microbe to transition to a pathogen, it must be able to survive on surfaces for a sufficient amount of time while retaining its ability to be virulent or colonize a susceptible host after removal from the surface it was contacted with – thus resulting in inadvertent transmission. Many current methods for the removal of these pathogens treat the surface once, but don't provide continuous treatment or prevention. To date, the only recognized method for permanent, continuous and sustainable reduction in the bacterial burden of surfaces is copper. In 2008 the United States Environmental Protection Agency (EPA) registered five families of copper-containing alloys as antimicrobial, establishing that products manufactured from one of these registered alloys can make public health claims wherein the label indication states that the alloys kill 99.9% ($\log_{10}$ 3.0) of bacteria within two hours of exposure**(1).** It is anticipated that the solid antimicrobial copper surfaces will remain microbiocidal for the life of the product (>10 years).
- Steriplate is a tertiary alloy specifically designed for medical applications. Comprised of three distinctly different metals, Steriplate is an electroplated alloy that can be plated on numerous types of surfaces to impart antimicrobial properties on the surface and provide the same benefits of copper. It provides better wear, corrosion, and tarnish properties than conventional copper. Additionally, Steriplate can be made to be hydrophobic or hydrophilic to impart additional properties to a variety of surfaces, devices and products (inside or outside the body).

- Antimicrobial surfaces offer a continuous way to control the environmental burden associated with various types of pathogens. Through the Surgical Care Improvement Project and the National Action Plan through HHS, hospitals and medical facilities have increased their level of hygiene and adopted best practices to levels previously unseen. However, it is intuitive to argue that any process or technology that augments or supplements the effectiveness of patient hygiene and routine cleaning will most definitely lead to lower rates of HAI's. The continuous antimicrobial effect of copper and copper alloys only enhance and complement the best cleaning practices required of medical facilities.

End Notes:

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