STERIPLATE®

U.S. Patent 9,586,381 Executive Summary

Technology of Steriplate®

Using the natural ability of certain types of metals to be antimicrobial, Steriplate[®] is a super alloy that has the additional benefits of high corrosion resistance, wear resistance and hydrophobicity, providing another level of performance in a variety of devices and applications that have traditionally been susceptible to microbial contamination. Steriplate[®] has been proven to continuously reduce bacterial contamination or inhibit bacterial contamination, ultimately achieving a 99.9% reduction in less than 2 hours with



Steriplate[®] has properties that provide superior metallurgical performance, while still being biocompatible. By also providing a super hydrophobic surface, it enhances the ability to inhibit microbial colonization of surfaces inside and outside the body. Additionally, since Steriplate[®]

is an electrically conductive alloy, studies have shown significantly enhanced antimicrobial effect with micro-current stimulation.



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Mechanism of Action of Steriplate®

Steriplate[®] 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. Through cell lysis, Steriplate[®] can collapse the cell membrane instantly through contact. This continuous contact helps prevent the bacterial cell from developing resistance due to this multifaceted mechanism of action. Additionally, because Steriplate[®] is hydrophobic, the alloy is molecularly sealed and provides additional biofilm resistance while providing protection from the typical toxicity associated with antimicrobial metals.



Market Studies and Potential Applications for Steriplate®

The market opportunities are based upon Steriplate's[®] antimicrobial effects on E. coli, MRSA, C. difficile and B. atrophaeus bacteria (gram positive and gram negative bacteria). Available markets in semiimplantable, medical tools and testing devices or high touch surfaces could expand exponentially depending on other organisms to which the surface is resistant. Secondly, even though it takes time before the organisms die, the surface presents an additional benefit in ensuring the pathogenic micro-organisms do not multiply to thresholds that can cause



infection. Finally, properties of the surface material will influence the extent to which the product can be adapted to various environments. Biocompatibility through osteoblast studies, implant studies as well as a multitude of cytotoxicity tests, demonstrate Steriplate® is a unique application not currently on the market.



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While most competing technologies are biocompatible, not cytotoxic and leverage different methods for bacterial inhibition or antimicrobial effect, only Steriplate® can claim the use of antimicrobial metals on a hydrophobic surface,

that is wear resistant, non-oxidizing, electrically conductive, noneluting while offering continuous protection. Drug eluting technologies have a finite life cycle for therapy. Technologies utilizing Silver typically oxidize more readily and develop a patina that starts to restrict silver ion release. Steriplate® is a tertiary alloy of three metals, two of which are antimicrobial, electrically conductive, wear resistant, oxidation resistant, hydrophobic, nonleaching and proven biocompatible. Additionally, since Steriplate® does not use precious metal in its alloy unlike other technologies, the material cost is generally far less while providing a more robust alloy than gold, silver or palladium. Steriplate® can be electroplated on a variety of metallic surfaces and different geometries of medical and orthopedic devices and equipment as well.



Steriplate[®] FDA 510K Clearances

Steriplate® has received the following clearances from the FDA:

- **K190565** Cervical Plate (March 5, 2019)
 - o Registration Name: Spinal Intervertebral Body Fixation Orthosis
 - Intended for anterior screw fixation to the cervical spine (C2-C7) for immobilization and stabilization as an adjunct to fusion in skeletally mature patients
 - o Regulatory Class: Class II
- K192768 Temporary Fixation Pins (September 30, 2019)
 - o Registration Name: Smooth or Threaded Metallic Bone Fixation Fastener
 - Intended as a guide wire for osteosynthesis implants, external fixation (Steinmann Pins)
 - o Regulatory Class: Class II
- K231905 Electro-Spec Steri-Caps (June 29, 2023)
 - o Registration Name: Smooth or Threaded Metallic Bone Fixation Fastener
 - Intended for use in protection of protruding ends of wires in osteotomies or arthrodesis of fractures in the foot or hand
 - Regulatory Class: Class II

Steriplate[®] Manufacturing and Support

Steriplate LLC is a wholly owned subsidiary of Electro-Spec, Incorporated. Electro-Spec is regarded as one of the most technologically advanced plating companies in the world. Servicing customers in North America, Europe and Asia, Electro-Spec's name is synonymous with innovation. Electro-Spec specializes in utilizing precious and semi-precious metals for medical, automotive, aerospace and telecommunication devices and equipment. Through ongoing research and development of the antimicrobial benefits of metals in certain applications, Steriplate LLC was founded. Steriplate LLC is the principal research arm of Electro-Spec for antimicrobial coatings in a variety of applications. Steriplate processes include metal electroplating and unique surface treatments for environmental, semi-implantable and permanent implantable devices. With two facilities in the United States (Indiana and South Carolina), supply chain support is readily available to interested partners.