

# STERIPLATE®

U.S. Patent 9,586,381

## Executive Summary



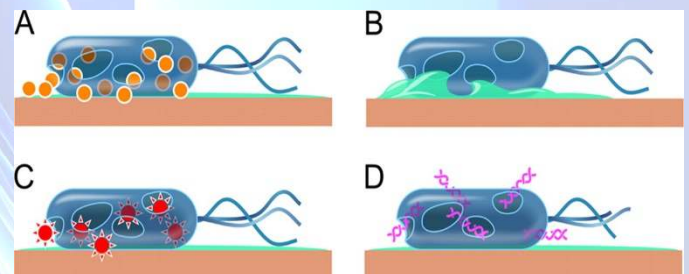
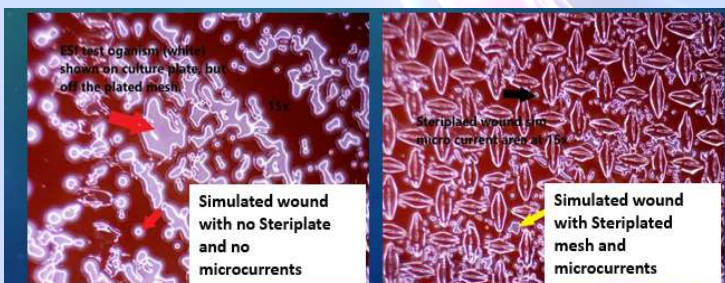
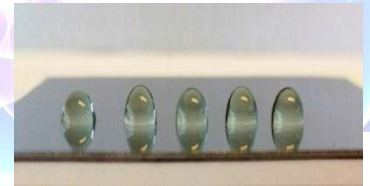
### Technology of Steriplate®

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 both gram positive and gram negative bacteria. More importantly, because Steriplate® is a metal finish, it provides continuous and ongoing antimicrobial effect as compared to other technologies that are drug eluting and wear off after time or in certain environments.



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.



### 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.





## Steriplate® FDA 510K Clearances

Steriplate® has received the following clearances from the FDA:

- **K190565** – Cervical Plate (March 5, 2019)
  - 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
  - Regulatory Class: Class II
- **K192768** – Temporary Fixation Pins (September 30, 2019)
  - Registration Name: Smooth or Threaded Metallic Bone Fixation Fastener
    - Intended as a guide wire for osteosynthesis implants, external fixation (Steinmann Pins)
  - Regulatory Class: Class II
- **K231905** – Electro-Spec Steri-Caps (June 29, 2023)
  - 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.

