

**FLORIDA ANODIZED SYSTEM & TECHNOLOGIES, INC.:  
EFFECT OF STERRAD® STERILIZATION ON ANODIZED  
ALUMINUM**

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**1.0 Purpose**

To determine the material compatibility of anodized aluminum prepared by Florida Anodized System & Technologies, Inc. (F.A.S.T.) in the STERRAD Sterilization System and to verify that the anodized coating from F.A.S.T. will not adversely affect the efficacy of the STERRAD Sterilization System.

**2.0 Background**

ASP received the various color anodized coated samples from F.A.S.T.

**3.0 Materials**

- 3.1 The various color coated samples prepared by F.A.S.T  
Green, Gold, Gold-M, Burgundy, Yellow, Blue, Blue Gray and Black
- 3.2 STERRAD 100 Sterilizer
- 3.3 STERRAD Instrument Trays (Product Code 13521), 10" x 21" x 3.5"
- 3.4 Spunguard Heavy Duty Sterilization Wrap
- 3.5 STERRAD 100 Cassettes (Product Code 10110)
- 3.6 STERRAD Chemical Indicator Tape (Product Code 14200)
- 3.7 TSB (C9CBKH Exp. 12/99) media & other supplies for aseptic transfer
- 3.8 Biological indicators with at least 10<sup>6</sup> spores (Titer to be verified by  
TP-0300-50-001). *B.stearothermophilus*, spore lot # STPA 0927, paper,  
1.6 x 106 cfu/strip, inoc. date: 4/2/97
- 3.9 STERRAD Chemical Indicators (Product Code 14100)
- 3.10 Stereo-microscope with 150X and Photographic Documentation  
Capability
- 3.11 ASP Sterilization Pouches
- 3.12 Heat Sealer
- 3.13 Nominal 59% H2O2
- 3.14 Micro Syringe

## 4.0 Experimental Evaluations

- 4.1 Material compatibility test
- 4.2 Efficacy test

## 5.0 Procedure

### 5.1 Material compatibility test

Before processing of the first cycle, the metal surface of each sample received was microscopically and photographically documented. The samples were placed in the STERRAD Instrument Trays without any overlapping of device parts. A STERRAD Chemical Indicator was placed inside of each tray. The tray was double wrapped with Heavy Duty Spunguard Sterilization wrap. The samples were processed through 100 full STERRAD Sterilization Cycles with standard cassette injection mechanism or equivalent. After every 10 cycles, the trays were removed from the sterilizer chamber and were allowed to reach room temperature (approximately 20 minutes) prior to handling. Cycle print outs were retained in the lab notebook. The samples were inspected visually for signs of change (loss of gloss, discoloration, degradation of metals). All material changes were documented by photography. This process was repeated 10 times for a total of 100 full STERRAD Sterilization Cycles.

### 5.2 Efficacy test

To ensure the metal coating materials will not affect sterilization efficacy by the decomposition of excessive amount of  $H_2O_2$ , the following experiments were carried out.

Each sample was placed individually within an ASP Sterilization pouch (total of 8 samples). Three BI strips and one CI strip were enclosed in each ASP pouch (one BI strip is above the plate, one is underneath the plate and one is on the side of the plate). The ASP pouches were placed into the STERRAD Trays with the Tyvek side facing down and the trays were double wrapped using Spunguard Heavy Duty Sterilization wrap. The samples were processed through half cycle (25 min. diffusion, 15 min. plasma) using STERRAD 100 Sterilizer and 1450  $\mu$ l of 59%  $H_2O_2$ . After cycle completion, BI strips were transferred into TSB tubes and the tested TSB tubes were incubated at 55°C. The tested BI spore strips were observed for bacterial growth from the 1st day to the 7th day and the 14th day. Color changes of CI strips were observed after the cycle was complete.

## 6.0 Results and Discussion

### 6.1 Material compatibility test

Upon completion of 100 cycles, the samples demonstrated no visual changes, none of them change color or even slight fading.

### 6.2 Efficacy test

Samples	Green	Gold	Gold-M	Burgundy	Yellow	Blue	Blue gray	Black
CI test	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed
BI test	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed

Upon completion of the efficacy test, all the samples showed no bacterial growth.

## 7.0 Conclusion

The color anodized coated samples from F.A.S.T are compatible with the STERRAD Sterilization System. They retained the original color after 100 cycles. In addition, the color anodized aluminum pieces did not affect the efficacy of the STERRAD Sterilization System.