MEDICAL DEVICE ANODIZATION COMPATIBILITY WITH HYDROGEN PEROXIDE STERILIZATION

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Abstract

In order to achieve compatibility with sterilization processes, material selection is particularly important when designing medical devices.

In addition to the primary base materials used for the construction of common medical devices, consideration should also be given to secondary materials used to enhance the devices.

Specifically, **anodization** is a critical material components that can dictate device compatibility if incorrectly specified for the device design.

This material component was evaluated to better understand compatibility with the STERRAD® System sterilization process.

Please read and follow User's Guide prior to using for important information, including contraindications, warnings and proper directions.

Incompatible Materials Evaluated

Anodization[1]

- Organic colorants, or dyes, are by far the most widely used for decorative finishes.
- The porous anodized aluminum is simply dipped in a dye bath, and over time, dye is absorbed into the surface.
- All dyes fade to some degree, over time, as a result of bond cleavage within the organic molecule.
- This cleavage can occur as a result of UV irradiation, chemical oxidation or a combination of both.
- An oxidative environment—such as a STERRAD® sterilization cycle—can fade anodized coatings that are colored with organic dyes.

Examples of anodized metal surfaces

Original blue anodization color faded after 2 STERRAD® 100NX System standard cycles

[1] Source: "Anodizing that Withstands H_2O_2 Cleaning; Testing color anodized finishes in hydrogen peroxide gas plasma sterilization." written by Mark Jozefowicz of Reliant Aluminum Products; (Products Finishing Dec. 2013 – pfonline.com), accessed on 01/21/2019 (https://www.pfonline.com/articles/anodizing-that-withstands-h2o2-cleaning)

Organic Anodization Samples Processed in STERRAD® System

Aluminum alloy (AA6061) sheet stock coupons were colored with organic anodization methods using the conditions listed in this table, then processed in 100 STERRAD® 100NX Standard Cycles.[2]

Organic Dye[2]

Chemistry	Conc.	pH	Temp.	Immersion Time	Color
Sanodal Red B3LW	5 g/L	5.6	140°F	20 min	Red
Sanodye Blue G	3 g/L	5.6	140°F	20 min	Blue
Sanodal Green 3LW	3 g/L	5.6	140°F	20 min	Green
Sanodal Deep Black HBL	10 g/L	5.6	140°F	20 min	Black
Sanodye Yellow 3GL	3 g/L	5.6	140°F	20 min	Yellow
Sanodal Turquoise PLW	5 g/L	5.6	140°F	20 min	Turquoise

[2] Source: "Anodizing that Withstands H_2O_2 Cleaning; Testing color anodized finishes in hydrogen peroxide gas plasma sterilization." written by Mark Jozefowicz of Reliant Aluminum Products; (Products Finishing Dec. 2013 – pfonline.com), accessed on 01/21/2019 (https://www.pfonline.com/articles/anodizing-that-withstands-h2o2-cleaning)

Inorganic Anodization Samples Processed in STERRAD® System

Aluminum alloy (AA6061) sheet stock coupons were colored with inorganic anodization methods using the conditions listed in these tables, then processed in 100 STERRAD® 100NX System Standard Cycles.[3]

Inorganic Adsorption[3]

Chemistry	Con.	pH	Temp.	Immersion Time	Color
Sanodal Gold 4N	20 g/L	5	140°F	10 min	Gold
Step 1: $K_3Fe(CN)_6 \cdot 3H_2O$	10 g/L	n/a	70°F	2 min	n/a
Step 2: $FeNO_3$	10 g/L	n/a	70°F	2 min	Blue

Inorganic Electro-Deposition[3]

Chemistry	Voltage	Time	Color
30 g/L $CuSO_4 \cdot 5H_2O$ 10 g/L $MgSO_4 \cdot 7H_2O$ 6 g/L H_2SO_4	18V AC	5 min	Maroon
20 g/L Anodal Color TS-2 20 g/L H_2SO_4	18V AC	3 min	Bronze
20 g/L Anodal Color TS-2 20 g/L H_2SO_4	18V AC	12 min	Black

[3] Source: "Anodizing that Withstands H_2O_2 Cleaning; Testing color anodized finishes in hydrogen peroxide gas plasma sterilization." written by Mark Jozefowicz of Reliant Aluminum Products; (Products Finishing Dec. 2013 – pfonline.com), accessed on 01/21/2019 (https://www.pfonline.com/articles/anodizing-that-withstands-h2o2-cleaning)

Anodization Seals Processed in STERRAD® Systems

Aluminum alloy (AA6061) sheet stock coupons were colored using the organic and inorganic anodization conditions listed in the previous tables, sealed using the conditions listed in this table, then processed in 100 STERRAD® 100NX System Standard Cycles. In the case of the inorganic colors, only seals 1-7 were used.[4]

Seal Conditions[4]

ID	Type	Additive	Time	Temp.	pH
1	Boiling water	3 g/L Anodal SH-1	45 min	>205°F	5.7
2	Boiling nickel	7 g/L Anodal ASL	45 min	>205°F	5.5
3	Hot nickel	20 mL/L Anodal MS-1 New	20 min	180°F	5.8
4	Step 1: Cold seal	3 g/L Anodal CS-3	15 min	85°F	6
	Step 2: Hot water	3 g/L Anodal SH-1	15 min	160°F	5.7
5	Step 1: Cold seal	3 g/L Anodal CS-3	15 min	85°F	6
	Step 2: Hot nickel	7 g/L Anodal ASL	30 min	160°F	5.5
6	Step 1: Hot nickel	7 g/L Anodal ASL	10 min	160°F	5.5
	Step 2: Boiling water	3 g/L Anodal SH-1	45 min	>205°F	5.7
7	No seal - reference	n/a	n/a	n/a	n/a
8	Step 1: Hot nickel	7 g/L Anodal ASL	15 min	160°F	5.5
	Step 2: Boiling silicate	20 mL/L Anodal Si1000	15 min	> 205°F	11
9	Step 1: Cold seal	3 g/L Anodal CS-3	15 min	85°F	6
	Step 2: Boiling silicate	20 mL/L Anodal Si1000	15 min	> 205°F	11
10	Step 1: Cold seal	3 g/L Anodal CS-3	15 min	85°F	6
	Step 2: Hot nickel	7 g/L Anodal ASL	15 min	180°F	5.5
	Step 3: Boiling silicate	20 mL/L Anodal Si1000	15 min	> 205°F	11

[4] Source: "Anodizing that Withstands H_2O_2 Cleaning; Testing color anodized finishes in hydrogen peroxide gas plasma sterilization." written by Mark Jozefowicz of Reliant Aluminum Products; (Products Finishing Dec. 2013 – pfonline.com), accessed on 01/21/2019 (https://www.pfonline.com/articles/anodizing-that-withstands-h2o2-cleaning)

Anodization Compatibility Results with STERRAD® System

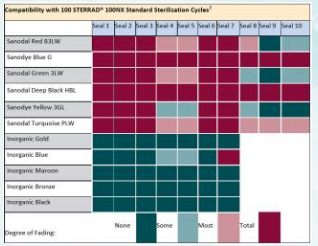
A comparative visual assessment of each of the colored finishes before and after undergoing sterilization cycles is shown;

✓Samples that survived the treatment without notable fading are identified by a dark green box

✓Samples that completely faded are indicated in red.[5]

Most of the seals failed to protect the anodization, but seal 9 clearly proved to be the best performer, allowing virtually no color deterioration of the red, green and yellow dyed coatings.[5]

For the most part, this study showed that inorganic colors were unaffected by STERRAD® Systems.[5]



[5] Source: "Anodizing that Withstands H_2O_2 Cleaning; Testing color anodized finishes in hydrogen peroxide gas plasma sterilization." written by Mark Jozefowicz of Reliant Aluminum Products; (Products Finishing Dec. 2013 – pfonline.com), accessed on 01/21/2019 (https://www.pfonline.com/articles/anodizing-that-withstands-h2o2-cleaning)

Alternative Compatible Materials

Anodization

To address the issue of fading with some anodized aluminum products, electrocoloring techniques were evaluated.[6]

Electrocoloring differs from conventional type II anodization processes in that instead of dying the component and then sealing the dye in the porous anodized oxide layer that is electrochemically grown on the aluminum, the part is immersed in a second electrolysis tank following initial clear anodization.[6]

The second electrolysis tank typically contains specific metal salts, such as stannous sulfate, for coloring. The coloring effect is believed to be due to the deposit of extremely small crystals or particles, such as metal or oxides, in the pores of the electrolytic oxide film. Such deposits can lead to coloring or shading due to the optical effects of absorption.[6]

In repeated testing this type of electrocoloring resists oxidation and bleaching for a minimum of 500 cycles.[6]

Examples of anodized metal surfaces

[6] Source: "Anodizing that Withstands H_2O_2 Cleaning; Testing color anodized finishes in hydrogen peroxide gas plasma sterilization." written by Mark Jozefowicz of Reliant Aluminum Products; (Products Finishing Dec. 2013 – pfonline.com), accessed on 01/21/2019 (https://www.pfonline.com/articles/anodizing-that-withstands-h2o2-cleaning)

In Summary

In addition to the STERRAD® System, there is an increasing number of sterilization processes and systems, that are either on the market or being developed, which utilize oxidization processes or strong oxidizers for sterilization, including:

- ozone
- chlorine dioxide
- hydrogen peroxide
- peracetic acid

These oxidizing sterilants are expected to react similarly with **anodization**.

While this testing was performed in a STERRAD® 100NX System, because of the similarity of technology between all STERRAD® systems, we would expect comparable results with anodized surfaces throughout the STERRAD® System family due to hydrogen peroxide use.

Therefore, medical device manufacturers should use care in selecting materials and designing components and devices, remaining aware of how materials may interact with various sterilizing processes. This concern with compatibility will, in turn, ensure longer life cycles and better cost-effectiveness for users in today's managed-care market.

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