

Challenging the STERRAD 100NX Sterilizer under experimental “clean” and “dirty” conditions

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Medical equipment

A new very expensive hightech medical instrument for diagnostic or therapeutic purposes (wonderfull for the clinician - a nightmare for hospital hygienist) does it end up being a single use product because we cannot reprocess it?!

STERRAD®100NX™ Sterilizer



Why the STERRAD 100NX Sterilizer?

ONLY NEEDS

a power point

H₂O₂ cartridges provided by the manufacturer
to run

DOES NOT

leave any toxic residues nor
generates harmful waste

Cycle times are short

Working temperatures are low

>> "gentle" processing of thermo-labile instruments

Aim of the study

- Evaluate the efficacy of the Sterrad 100 NX under challenging conditions
- Challenges:
 1. Carrier materials (TIT, PU and PE)
 2. Wrappings (1 or 3 times)*
 3. Organic and inorganic burdens *

Working hypothesis

To verify that the Sterrad 100NX sterilizer in its present setting can consistently provide a minimum sterility assurance level (SAL) of 10^{-6} in presence of above mentioned challenges.

Carrier materials

Certain materials, particularly **polymers**, might not be compatible with H₂O₂. Depending on the type of polymer, different degrees of **polymer surface modifications** induced by H₂O₂ and other plasma-based sterilization techniques have been observed.

Carrier materials

Sterilant type and concentration as well as parameters such as:

- temperature,
 - pressure and of course
 - cycle time of a sterilization process
- will determine which materials can be safely processed.

Carrier materials

- Titanium (TIT)
- Polyethylene (PE)
- Polyurethane (PU)

Single versus threefold wrapping of inoculated carriers (sized 20 x 5 mm) with Tyvek® sterilization pouches.

Test organism

- Spores of *Geobacillus stearothermophilus* (ATCC 7953) were used as indicator organism (at least one million spores per carrier).
- Spore preparation was done following the method described by Pflug IJ. After harvesting and cleaning spore pellets were resuspended in either 5% FBS or in hard water.

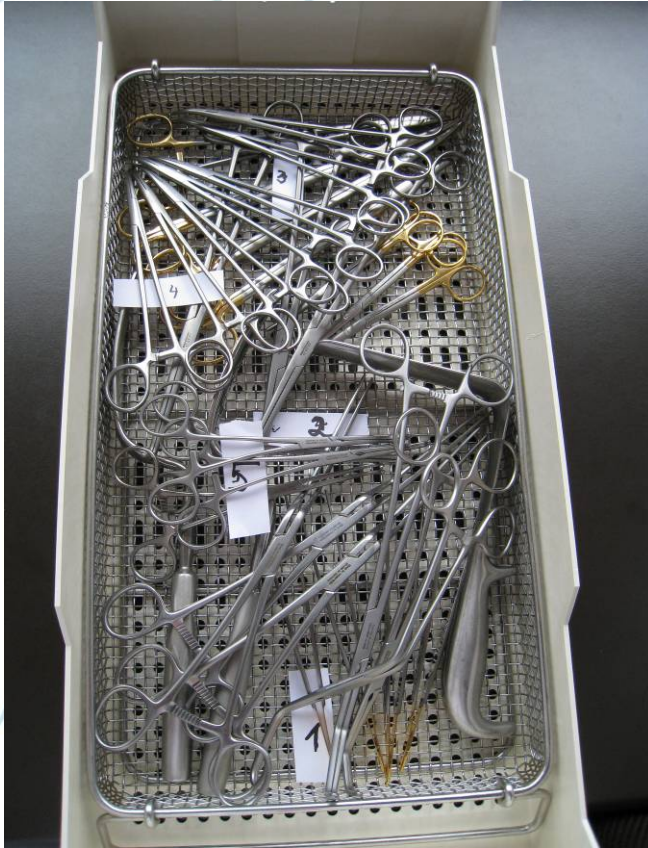
Test load

- Two perforated stainless steel baskets with a standardized load of surgical instruments without lumens such as forceps, scissors, clamps and retractors
- >> Total weight of the test load was 5 kg.

BI-Distribution

- In testing the efficacy of a sterilization process, the BIs should be placed in several places considered to be the most difficult sites in the sterilizer load to sterilize. We therefore distributed our BIs trying to reflect probable key positions.

Test load + BIs



Test load upper shelf



Test load lower shelf

Carrier type (PU, PE, TIT)

Untreated

300 ppm

600 ppm

1200 ppm

5% FBS

1

2

3

4

1

2

3

4

1

2

3

4

1

2

3

4

1

2

3

4

Standard half
Cycle #

Experimental setting

Standard half cycle #1: Quantitative evaluation
Standard half cycle #2-4: Qualitative evaluation

Cycles (full cycles)

- **Standard cycle**

for the sterilization of most surgical instruments >> about 47 min. cycle time

AND

- **Flex Scope cycle**

for the sterilization of flexible endoscopes >> about 42 min. cycle time.

Why use half cycles?

„overkill method“

- The principle of the half-cycle approach is to challenge a sterilization process with BIs (usually containing at least 10^6 spores per carrier) at sterilization times equal to half of the full cycle. Inactivating a BI with an initial population of 10^6 in the half-cycle means at least a 6-log reduction has been attained. Extrapolating the inactivation kinetics of a half-cycle which inactivated 10^6 spores will provide a 10^{-6} SAL for the full cycle.

Reference: EN ISO 14937

Worst-case conditions

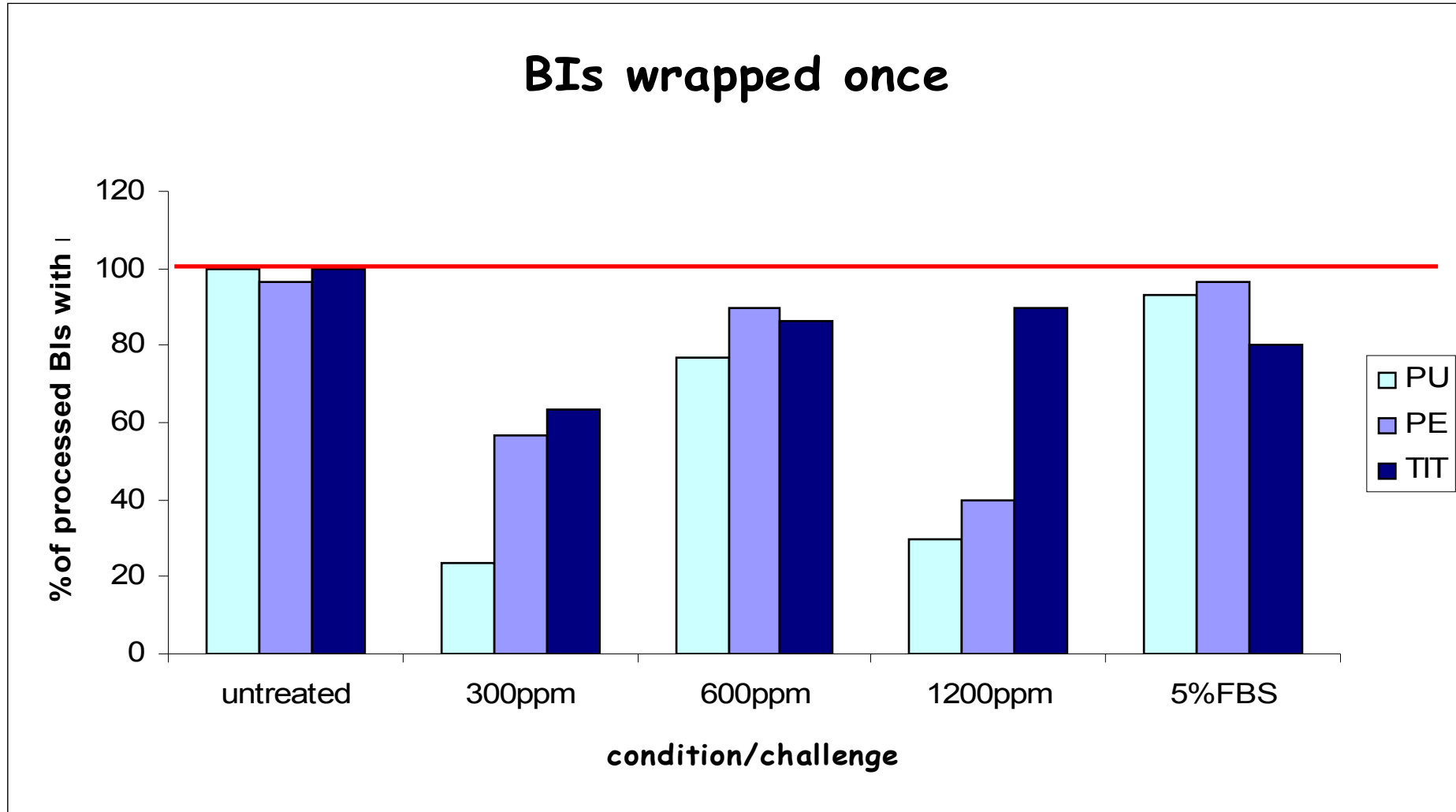
- Cleaning process not validated >> sub-standard washing or rinsing
- Human error >> Pushing the wrong button: Standard instead of Flex Scope cycle



Qualitative Results

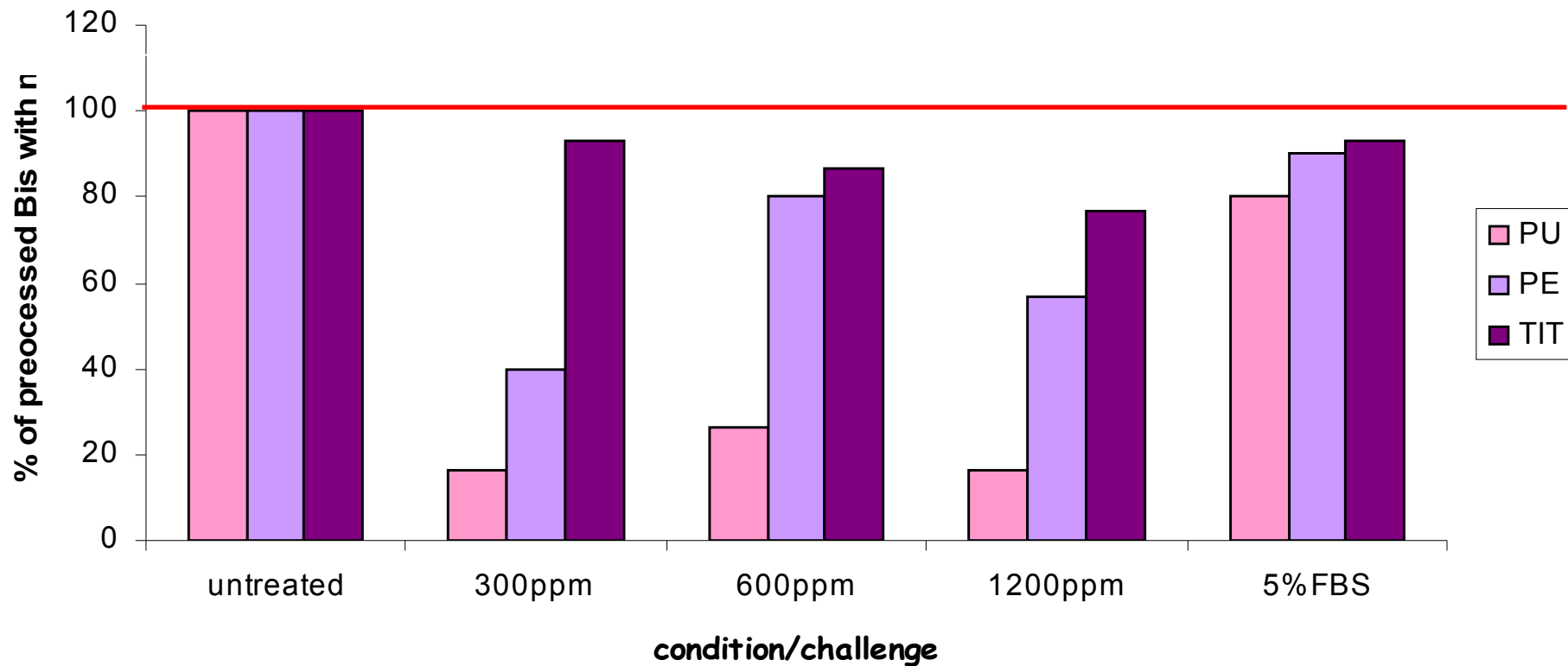
	Percentage of BIs with no growth					
	BIs wrapped once			BIs wrapped three times		
Condition/ challenge	<i>PU</i>	<i>PE</i>	<i>TIT</i>	<i>PU</i>	<i>PE</i>	<i>TIT</i>
<i>Untreated</i>	100%	96.6%	100%	100%	100%	100%
<i>300ppm</i>	23.3%	56.6%	63.5%	16.6%	40%	93.3%
<i>600ppm</i>	76.6%	90%	86.6%	26.6%	80%	86.6%
<i>1200ppm</i>	30%	40%	90%	16.6%	56.6%	76.6%
<i>5% FBS</i>	93.3%	96.6%	80%	80%	90%	93.3%

Qualitative Results



Qualitative Results

BIIs wrapped three times



Untreated condition

- Our qualitative results show that irrespective of the number of wrappings (1 or 3) in the **untreated condition** sterilization by the Sterrad 100NX was equally effective on all three carrier materials, reaching a log₁₀ reduction rate of ≥ 6 under Standard half cycle conditions.

Organic/inorganic challenge

- When an organic or inorganic challenge was added to our spore carriers, with none of the three carrier materials a log₁₀ reduction rate of 6 could consistently be achieved under Standard half cycle conditions.

Carrier materials

- Sterilization by the Sterrad 100NX was least effective on the PU carriers (considering organic and inorganic challenge as well as once and three times wrapping).

Influence of wrapping (single/tripple)

- Threefold wrapping was beneficial for TIT in certain conditions (organic challenge and 300ppm qualitative results), while it impaired the sterilizing ability of H₂O₂ for PU and PE (wrapped three times with organic and inorganic challenge).

Influence of wrapping (single/tripple): Hypothesis

H₂O₂ trapped by the three layers of wrapping

>> had therefore longer time to act as sterilant.

Beneficial effect for an inert material (TIT) / Adverse effect for material incompatible with H₂O₂ sterilization:

The surplus of H₂O₂ might be absorbed by such materials and might thus be prevented from reaching relevant surfaces in sufficient concentrations.

Valid explanation for PU (a material known to absorb H₂O₂ varying with its micro-structure) it does not apply to PE known to be inert regarding H₂O₂ resorption.

Quantitative Results

Condition/ challenge	Reduction factor (mean from 10 positions)					
	BIs wrapped once			BIs wrapped three times		
	<i>PU</i>	<i>PE</i>	<i>TIT</i>	<i>PU</i>	<i>PE</i>	<i>TIT</i>
<i>Untreated</i>	5.60	5.26	5.73	5.67	5.81	5.19
<i>300ppm</i>	3.65	5.13	5.24	3.89	4.95	4.82
<i>600ppm</i>	5.06	5.62	5.09	3.84	5.41	5.53
<i>1200ppm</i>	5.07	4.74	6.17	5.60	4.56	6.12
<i>5% FBS</i>	5.57	4.37	5.29	5.01	4.47	4.72

Quantitative Results

Positions where a log reduction rate of ≥ 6 was reached

Condition	BIs wrapped once	BIs wrapped three times
untreated	PU position 2	PE position 1-3, 6,7
	TIT position 1,8-10	PU position 3,7,10
300ppm	none	none
600ppm	PE position 3,6,9,10	none
1200ppm	TIT position 1-10	TIT all positions except 8
5% FBS	PU position 1	none
	TIT position 4	none

Carrier positions

- Sometimes big variations in log₁₀ reduction rates found for our BIs under one specified condition:
 - >> uneven repartition of the spore preparation on the carrier material.
 - >> non-uniform distribution of H₂O₂ vapor in the sterilization chamber, therefore a limited ability of the vapor to reach different positions within the test load equally well.
- **Question:** Is hydrogen peroxide vapor distributed homogenously within the sterilization chamber? No sensors positioned within the test load.

Recommendations regarding the STERRAD®100NX™

- Low temperature hydrogen peroxide plasma offers a very promising sterilization technology.
- Significance of a **thorough and validated cleaning** of contaminated items before being exposed to sterilization in the STERRAD®100NX™ Sterilizer was clearly demonstrated.
- We also recommend to strictly **adhering to the manufacturers recommendations** specified in their User's Guide regarding the correct cycle and permitted materials of medical devices for their processing in the Sterrad 100NX sterilizer.

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Thank you for your attention!