Advances in hydrogen peroxide gas plasma sterilization

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Topics of Discussion

- Development of sterilization technologies
- Hydrogen Peroxide Gas Plasma Technology
- STERRAD® 100NX™ System Overview
- Independent studies on prions inactivation
Trends Affecting Sterilization Methods

- Minimally Invasive Surgery
- Multi-Resistant Organisms
- Regulatory Climate changes
- Need for Safety and Speed
Sterilization Trends - Temperatures

- Steam
- Formaldehyde
- Ethylene Oxide
- Peracetic Acid Liquid
- Chlorine Dioxide
- H$_2$O$_2$ gas plasma
Sterilization trends - Time

- Ethylene Oxide
- Hydrogen Peroxide
- H$_2$O$_2$ gas plasma
- Ozone
- Peracetic Acid Liquid
Ideal Sterilization system attributes

- Terminal sterilization: packaged instruments
- Fast cycle time: Instruments/device turn-around
- Safety: No toxic dangers to humans and environment
- Safety for the instruments: Low temperature process, compatibility endorsed by Medical Device Manufacturers
- Availability to built in CSSD (double door option)
- Versatile to allow use in variety of locations
- Cost effective
- Simple to use by operators
- Broad spectrum of antimicrobial efficacy
Hydrogen Peroxide Gas Plasma Technology
Infection Control Innovation
History of Commitment

1880
First Antiseptic Surgical Dressing by J&J

1890
J&J pioneers Dry-Heat and Steam Pressure Sterilization

1963
J&J pioneers CIDEX® Activated Dialdehyde Solution for HLD

1980
Discovery of Hydrogen Peroxide as a Gas Plasma Precursor

1993
STERRAD® 100 System

1997
STERRAD® 50 System

1999
STERRAD® 200 System

2000
CIDEX® OPA

2004
Next Generation: STERRAD® NX™ System

2008
Next Generation: STERRAD® 100NX™ System
STERRAD® Systems worldwide

15 years of experience in health care market!

Over 12,000 STERRAD® Systems installed and over 32 million cycles run worldwide
STERRAD® Systems Features

- Low temperature and dry process
- Safe for heat- and moisture-sensitive items
- Short cycle time: Rapid instruments turnaround
- Non-toxic: safe for instruments, environment, healthcare workers
- No need for aeration of the instruments
- Easy to install: no plumbing or ventilation system needed
- Instruments are wrapped for use or storage
- Easy to use: simple push-button or touch screen operation
What is Plasma?

- It is the 4th state of matter
- 99% of all matter in the universe exists in the plasma state
How is Plasma Created?

• Plasma is created when energy is applied to a gas with enough force to strip electrons from atoms.

• The resulting mixture of free radicals, ultraviolet light, positive and negatively charged particles is known as plasma.

Aurora Borealis  Plasma TV  Neon Lights
What is Gas Plasma?

- Gas plasmas are highly ionized gases, composed of ions, electrons and neutral particles that produce a visible glow
- The benefit of low-temperature gas plasma is that it has the ability to efficiently eliminate traces of residual hydrogen peroxide from materials and devices
  - No toxic residue on instruments
  - Increased patient safety
STERRAD® Systems Sterilization Process

• A vacuum is created inside the chamber
• Hydrogen peroxide sterilant is injected into the chamber and allowed to surround and interact with devices to be sterilized
  - This is the phase of the process in which microorganisms are killed
• Applying a strong electrical field creates plasma
• Plasma breaks down the peroxide into a “cloud” of highly energized species (this produces the visible glow)
  - The primary purpose of plasma is to efficiently eliminate traces of residual hydrogen peroxide
When the electrical field is turned off, these species recombine, turning the hydrogen peroxide into water vapor and oxygen.

The divided hydrogen peroxide ($H_2O_2$)....

...Recombine to simple water ($H_2O$) and oxygen ($O_2$)

The result = No toxic residues
STERRAD® Systems Family

A System for Every Facility

- Family of versatile products
  - Designed to meet your specific needs
- Four different STERRAD® Systems
  - STERRAD® NX™ System
  - STERRAD® 100S System
  - STERRAD® 100NX™ System
  - STERRAD® 200 System
STERRAD® 100S System

Over 15 Years of Proven Performance

- Established industry standard in low temperature sterilization
  - The original with reliable, proven technology
- 55-minute Standard Cycle
  - Most general surgical instruments
- 72 minute cycle for Flexible scopes with use of boosters
STERRAD® 200 System

It Speaks Volumes

- 75-minute standard cycle
  - Most general surgical instruments
- 105 minute cycle for Flexible scopes with use of boosters
- Large chamber helps process more devices and allows for flexible load configurations
- 1 or 2 doors configuration
- Ideal for high volume Central sterilization Departments
STERRAD® Systems Consumables

Achieving and Maintaining Excellence in Sterilization

- **STERRAD® Systems Cassettes**
  - Sterilant in safe, easy-to-use cassettes

- **CYCLESURE® 24 Biological Indicator**
  - Provides evidence of proper sterilization in 24 hours

- **Instrument Trays, Mats, and Holders**
  - APTIMAX® Instrument Trays come in a variety of sizes and offer optimal protection for your instruments
Next Generation in hydrogen peroxide gas plasma sterilization
NX™ Technology

- Vaporization system concentrates hydrogen peroxide by removing most of the water
- Increased ability to penetrate lumens, including single-channel flexible endoscopes and other difficult to sterilize locations
- Overall sterilization cycle times are reduced
STERRAD® NX™ System

Sterilizer for all your department’s needs

- 28-minute Standard Cycle
  - Most general surgical instruments
- 38-minute Advanced Cycle
  - Single-channel flexible scopes
  - Longer-lumened devices
- Fast = Increased productivity
- Highest level of sterility at points of use assured
STERRAD® 100NX™
System overview
STERRAD® 100NX™ System Overview

The most advanced development from inventors of STERRAD®

- Designed to enhance the features and capabilities of the STERRAD® 100S System
- Incorporates NX™ technology in a larger system
- Expanded capabilities
  - Enhanced lumen claims (to 0.7 mm)
  - Standard cycle time of 47 minutes
  - Flex Cycle time of 42 minutes
  - Larger, rectangular chamber size
  - Network connectivity capabilities
  - 1 or 2 doors options
STERRAD® 100NX™ Sterilization Chamber

Rectangular Chamber

- Chamber shape is designed to accommodate multiple instrument sets in one cycle
- Useable chamber with double shelves maximizes productivity by enabling more instruments to be processed at once
- 27% greater usable volume than the STERRAD® 100S System
STERRAD® 100NX™ Fast Cycle Times

STANDARD Cycle: 47 minutes
FLEX Cycle: 42 minutes

• Provides exceptional instrument turnaround time
• Eliminates need for duplicate inventories
• Approximately 15% faster than the STERRAD® 100S System
STERRAD® 100NX™ RFID Cassette

Built-in RFID (Radio Frequency Identification) Tag

• RFID tag contains information the cassette expiration date, manufacturer, cell status and cycle completion

• A partially used cassette that has been ejected can be reinserted to avoid wasted sterilant, resulting in cost savings

• Five cycles per cassette
STERRAD® 100NX™ Ergonomic Foot Pad

Foot Pad

- Tapping the foot pad opens or closes the chamber door
- Convenience and safety – hands are not needed to open sterilizer doors
STERRAD® 100NX™ Network Connectivity

- Users have the option to connect their STERRAD® 100NX System to a remote PC or network via an Ethernet connection on the sterilizer.

- Users may also utilize the USB port.

- Ability to electronically maintain cycle records and download & view one-second cycle data.

- Allows for easy upload of instrument inventory to create menu for load entry data list. Eliminates need to hand-write load list.
Hydrogen Peroxide Monitoring

- Directly measures vaporized hydrogen peroxide concentration in the chamber every second
- Ensures that sufficient peroxide is available for sterilization to occur

Area under the peroxide-time curve

Decay rate constant
Sterilization Claims
Sterilization Claims

Metal and non-metal medical devices at low temperatures

Instruments that have diffusion-restricted spaces

• Hinged portion of forceps and scissors

Single-channel Polyethylene and Teflon® flexible endoscopes

Rigid and semi-rigid endoscopes

Polyethylene & Teflon tubing

All Claims validated for $10^{-6}$ SAL per ISO 14937 at half-cycle conditions.

Please refer to User guide for more detailed processing information.
Sterilization Claims – STANDARD Cycle

STANDARD Cycle – 47 minutes

Single channel stainless steel lumens with

• Inside diameter of 0.7 mm or larger

• Length of 500 mm or shorter

• Maximum 10 lumens per load; 5 lumens per tray

Polyethylene and Teflon® tubing with

• Inside diameter of 1 mm or larger

• Length of 1000 mm or shorter

• Up to 20 pieces of tubing at one time

Flexible endoscopes are excluded

Please refer to User Guide for more detailed processing information
Sterilization Claims – FLEX Cycle

FLEX Cycle – 42 minutes

Single-channel Polyethylene and Teflon® endoscopes with

• Inside diameter of 1 mm or larger

• Length of 850 mm or shorter

• One or two single-channel flexible endoscopes may be processed in a single cycle

Please refer to User Guide for more detailed processing information
Clinical & Service Support
Clinical Education & Service Support

Clinical Education Consultants

• Provide on site in-service training (OR, GI, CSSD, Surgery Centers) to help standardize in all areas of the hospital

• Provide Consultative Services to Customers in all procedure departments to offer best practice solutions in sterilization and HLD

Service Engineers

• Assure validation & configuration kits are ordered

• Installation and validation process

• FSE will discuss the validation process with customer and follow up to assure success
Independent studies on prions inactivation
Prion: Unconventional Transmissible Agent

Unlike conventional diseases
• No virus or microorganism
• No immune reaction
• No inflammation
• Degeneration of the Central Nervous System (CNS) with lesions identified in the CNS only (spongiosis)

Transmissible (e.g. food, blood transfusion, surgery), but not contagious

Always fatal
• Suspected agent is a protein (Prion protein)
• Long asymptomatic period (several years before signs of disease appear)

Extreme resistance to conventional sterilization/disinfection processes. With dry heat infectivity is still detectable after:
• 180°C during 24 hours
• 320°C during 1 hour
• 600°C during 15 minutes
Prions diseases

ANIMALS

1732: Natural Scrapie / Sheep – Europa

1985: Bovine Spongiform Encephalopathy (180,000 cases – more than 900,000 contaminated bovine in food) – UK

1990: Cat SE (Switzerland)

Transmissible Mink Encephalopathy – (TME)

Chronic Wasting Disease (CWD)

HUMANS

1951: Kuru – New Guinea

1920: Creutzfeld-Jakob Disease (CJD) – Europa

Gerstmann-Sträussler-Scheinker Syndrome (GSS)

Fatal Familial Insomnia (FFI)

1995: Variant of CJD (vCJD)
Inactivation Studies Supported by ASP

INACTIVATION COMPARISON

Efficacy comparison of high-temperature steam versus different generations of low-temperature sterilizer systems

Three STERRAD® systems tested against steam

- STERRAD® 100S
- STERRAD® NX™
- STERRAD® 100NX™
Laboratories Conducting the Studies

**IN VIVO STUDY**

Directed by Klaus Roth, SMP GmbH (Tübingen, Germany) in collaboration with: University of Tübingen, Federal Reference Center for Virus Diseases of Animals


**IN VITRO STUDY**

Directed by Pascal Clayette, PhD, SPI-BIO, Neurovirology Laboratory (Fontenay aux-Roses, France)

SPI BIO is a spin-off of CEA, one of the reference research centers for Prion diseases in France.

Pascal Clayette was a close collaborator of the late Dr. Dominique Dormont, a scientist involved in Prions research and expert for Afssaps.
Phases of the Study

2002 – 2005 *IN VIVO TESTS—STERRAD® 100S / REFERENCE METHODS*

Steam (134°C, 18’) and steam plus NaOH (1N, 1h at RT)

**STERRAD® 100S long cycle** (1 cycle and 2 consecutive cycles)

Steam or **STERRAD® 100S** plus alkaline (A and B, at 55°C and 70°C) or enzymatic (37°C) detergents

2005 – 2007 *IN VIVO TESTS - STERRAD® NX™ versus STERRAD® 100S*

**STERRAD® NX™ Advanced cycle** (1 cycle and 2 consecutive cycles)

**STERRAD® 100S or NX™** plus alkaline detergents

2007 *IN VITRO TESTS - VARIOUS STRAINS PLUS SUPPORT MATERIALS*

**STERRAD® 100S, NX™ and STERRAD® 100NX™** versus steam

**STERRAD® 100NX™ Standard and Flex cycles**

**STERRAD® NX™ Advanced cycle**
## Results 1: Alkaline Detergent Combined with STERRAD® 100S

<table>
<thead>
<tr>
<th></th>
<th>Transmission Rate (%)</th>
<th>Incubation Period (Days)</th>
<th>Incubation Delay (Days)</th>
<th>Reduction Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1% alkaline detergent A (55°C, 10 min)</td>
<td>11%</td>
<td>446 ± 153</td>
<td>363</td>
<td>≥ 5-6</td>
</tr>
<tr>
<td>1% alkaline detergent A (55°C, 10 min) plus STERRAD® 100S 1 long cycle</td>
<td>0%</td>
<td>540 ± 14</td>
<td>457</td>
<td>≥ 5-6</td>
</tr>
<tr>
<td>1% alkaline detergent A (55°C, 10 min) plus STERRAD® 100S 2 cons. long cycles</td>
<td>0%</td>
<td>540 ± 30</td>
<td>457</td>
<td>≥ 5-6</td>
</tr>
<tr>
<td>1% alkaline detergent B (55°C, 10 min)</td>
<td>0%</td>
<td>524 ± 42</td>
<td>441</td>
<td>≥ 5-6</td>
</tr>
<tr>
<td>1% alkaline detergent B (55°C, 10 min) plus STERRAD® 100S 1 long cycle</td>
<td>0%</td>
<td>540 ± 13</td>
<td>457</td>
<td>≥ 5-6</td>
</tr>
<tr>
<td>1% alkaline detergent B (55°C, 10 min) plus STERRAD® 100S 2 cons. long cycles</td>
<td>0%</td>
<td>552 ± 0</td>
<td>469</td>
<td>≥ 5-6</td>
</tr>
</tbody>
</table>

**Transmission Rate:** Number of sick animals / total number of animals in group (usually 10 animals/group).

**Incubation period:** Number of days between contamination.

**Incubation delay:** Additional survival period obtained by processing of wire (= incubation time - # of days of survival for hamster contaminated with a non-processed wire).

**Reduction Factor:** Estimated reduction of initial contamination load expressed on a logarithmic scale. Twelve additional days of survival correspond approximately to 1 log reduction of infection load. Experimental method does not allow to make statement above 5-6 log.

Alkaline detergents plus STERRAD® 100S, 1 or 2 long cycles: significant effects with no detected infectivity.
Results 2: STERRAD® NX™ with and without pre-treatment

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Transmission Rate (%)</th>
<th>Incubation Period (Days)</th>
<th>Incubation Delay (Days)</th>
<th>Reduction Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>STERRAD® NX™ 1 Advanced cycle</td>
<td>0%</td>
<td>570 ± 18</td>
<td>487</td>
<td>≥ 5-6</td>
</tr>
<tr>
<td>STERRAD® NX™ 2 cons. Advanced cycle</td>
<td>0%</td>
<td>574 ± 0</td>
<td>491</td>
<td>≥ 5-6</td>
</tr>
<tr>
<td>1% alkaline detergent A (55°C, 10 min) plus STERRAD® NX™ 1 Advanced cycle</td>
<td>0%</td>
<td>559 ± 22</td>
<td>476</td>
<td>≥ 5-6</td>
</tr>
<tr>
<td>1% alkaline detergent B (55°C, 10 min) plus STERRAD® NX™ 1 Advanced cycle</td>
<td>0%</td>
<td>562 ± 16</td>
<td>479</td>
<td>≥ 5-6</td>
</tr>
<tr>
<td>Steam 134°C 18 min</td>
<td>50%</td>
<td>428 ± 103</td>
<td>345</td>
<td>≥ 5-6</td>
</tr>
<tr>
<td>NaOH 1N 1h RT + Steam 134°C 18 min</td>
<td>28%</td>
<td>574 ± 197</td>
<td>471</td>
<td>≥ 5-6</td>
</tr>
</tbody>
</table>

**Transmission Rate:** Number of sick animals / total number of animals in group (usually 10 animals/group).

**Incubation period:** Number of days between contamination.

**Incubation delay:** Additional survival period obtained by processing of wire (= incubation time - # of days of survival for hamster contaminated with a non-processed wire).

**Reduction Factor:** Estimated reduction of initial contamination load expressed on a logarithmic scale. Twelve additional days of survival correspond approx. to 1 log reduction of infection load. Experimental method does not allow to make statement above 5-6 log.

- STERRAD® NX™: Infectivity not detected
- STERRAD® NX™: 1 Advanced cycle = 2 consecutive Advanced cycles
- Alkaline detergents plus STERRAD® NX™: no antagonism
## Results 3: *in vitro* study

<table>
<thead>
<tr>
<th>TYPE OF STRAINS AND PLATES</th>
<th>STEAM 134°C, 18’</th>
<th>100S LONG CYCLE</th>
<th>NX™ ADVANCED CYCLE</th>
<th>100NX™</th>
</tr>
</thead>
<tbody>
<tr>
<td>263 K Strain</td>
<td></td>
<td>≥ 5 log</td>
<td>≥ 5 log</td>
<td>≥ 5.5 log  ≥ 5.5 log</td>
</tr>
<tr>
<td>Stainless steel plates</td>
<td></td>
<td>≥ 5 log</td>
<td>IL: 5 log</td>
<td></td>
</tr>
<tr>
<td>Polyethylene plates</td>
<td>-</td>
<td>-</td>
<td>≥ 6.5 log</td>
<td>-</td>
</tr>
<tr>
<td>Polypropylene plates</td>
<td>-</td>
<td>-</td>
<td>≥ 6.5 log</td>
<td>-</td>
</tr>
<tr>
<td>6PB1 strain</td>
<td>≥ 4.5 log</td>
<td>≥ 4.5 log</td>
<td>≥ 4.5 log</td>
<td>-</td>
</tr>
<tr>
<td>vCJD strain</td>
<td>≥ 2.5 log</td>
<td>≥ 2.5 log</td>
<td>≥ 2.5 log</td>
<td>-</td>
</tr>
</tbody>
</table>

(*) IL = Initial Load (i.e. level of PrPres on plates before processing). Initial load depends on availability of contaminated brain homogenates. vCJD strain is more difficult to obtain than 263K. Except for 100 S Long cycle, reduction factor equals Initial Load (i.e. no PrPres was detected after processing).

- **263 K strain**
  - Coherent with *in vivo* results - STERRAD® NX™ > STERRAD® 100S
  - Identical efficiency of STERRAD® NX™ on the different surfaces
  - STERRAD® 100NX™ = STERRAD® NX™

- **“Human” strains**
  - Steam: no PrPres detected (≥ 4.5 log)
  - STERRAD® 100S and NX™: no PrPres detected
Conclusions

Efficacy comparison of high-temperature steam versus different generations of low-temperature sterilizer systems: three STERRAD® systems tested against steam

- **STERRAD® 100S**
- **STERRAD® NX™**
- **STERRAD® 100NX™**

*In vivo* German laboratory study showed STERRAD® NX™ sterilization system is effective in inactivating Prions and just as effective as high temperature steam sterilization.

*In vitro* study in French laboratory showed the STERRAD® 100 NX™ sterilization system is effective against Prions and just as effective as high temperature steam sterilization.
Prion Inactivation studies

**STERRAD® NX™ (alone or combined with alkaline detergent)**

No infectivity detected (*in-vivo*): $\geq 5-6 \text{ log}$

Efficiency (*in vitro*) against 263K strain & “human” strains

**STERRAD® 100NX™**

Identical efficiency (*in vitro*) against the 263K strain as compared to STERRAD® NX™
Summary

The STERRAD® 100NX™

- The most advanced development from Inventors of STERRAD® technology
- Utilizes the time proven hydrogen peroxide gas plasma technology
- Incorporated NX™ technology
- Incorporates up to date features:
  - Double door option
  - Hydrogen peroxide monitoring
  - IMS capability
  - Network connectivity
  - User friendly (foot pad, touch screen)
  - Two cycles option for flexibility
- Validated per ISO 14937
- Independent studies on Prions inactivation & Performance verified by independent sterilization experts
Advanced Sterilization Products

- Proven track record
- Pioneering technology
- Leader in the market with thousands of customers worldwide
- Allows customers to focus on what they do best - preventing infection and saving lives
Thank You!