

# Advances in hydrogen peroxide gas plasma sterilization

**Tatiana Yermakova**

**International Product Manager LTS**

**Europe, Middle East and Africa**



# Topics of Discussion

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

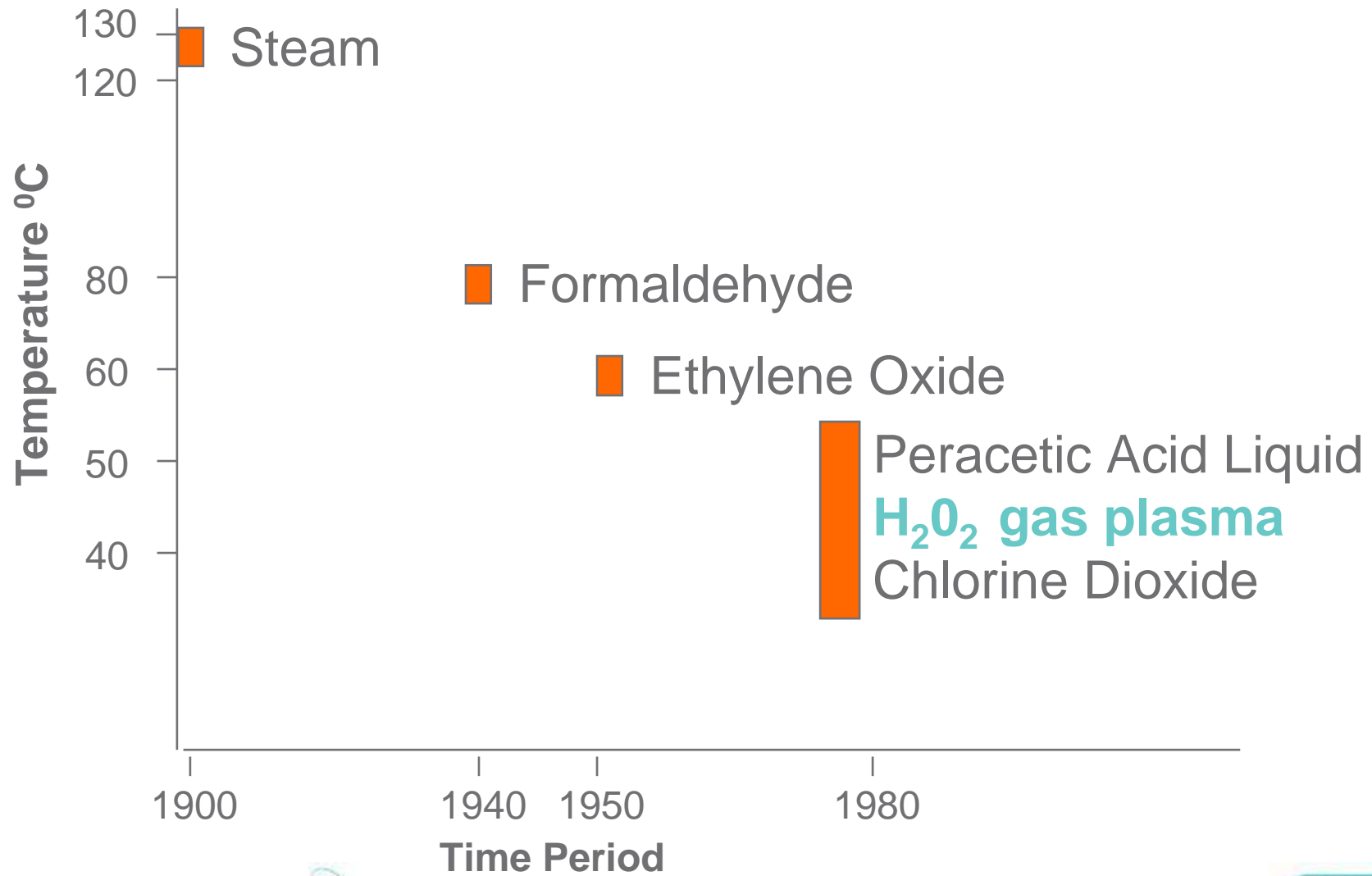


# Trends Affecting Sterilization Methods

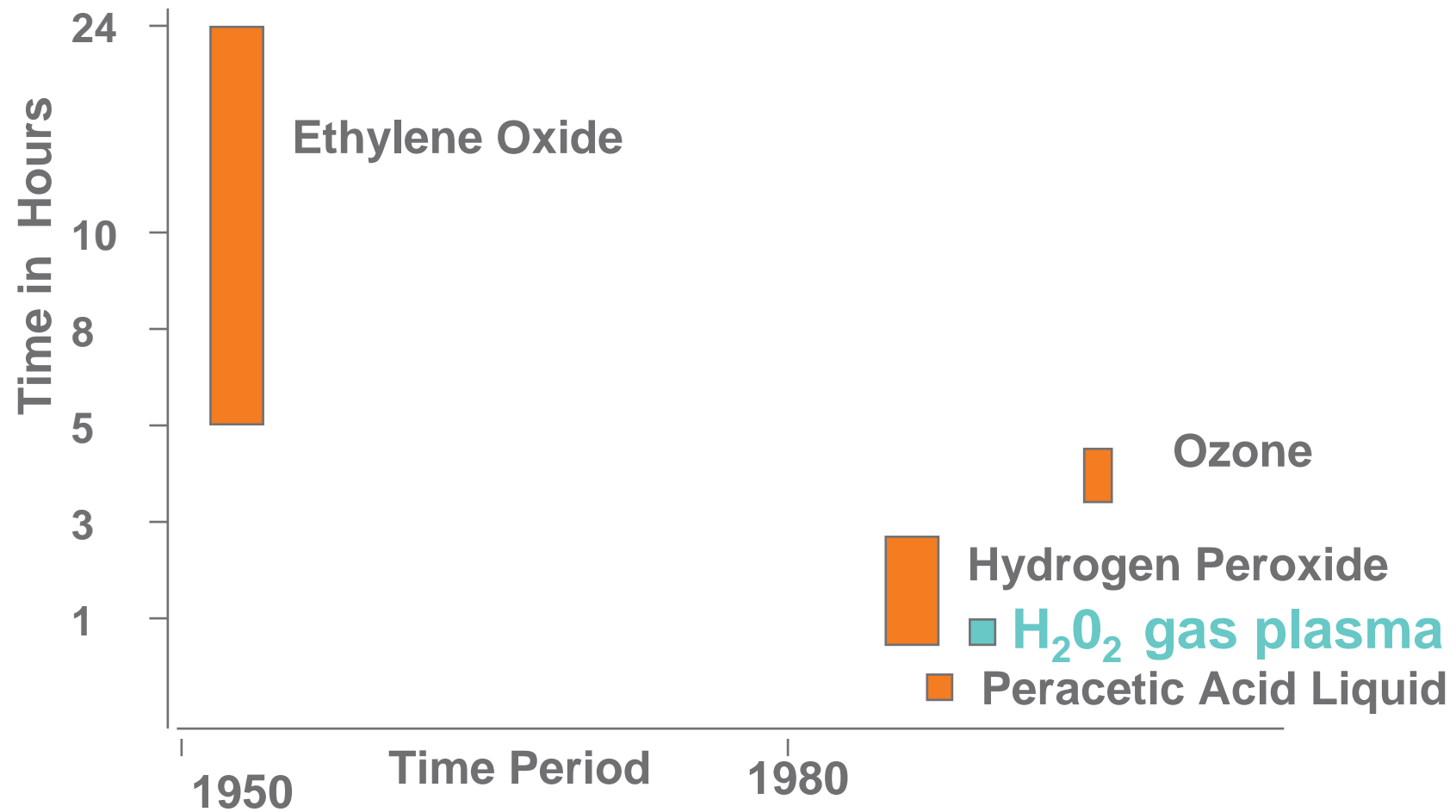
- Minimally Invasive Surgery
- Multi-Resistant Organisms
- Regulatory Climate changes
- Need for Safety and Speed



# Sterilization Trends - Temperatures



# Sterilization trends - Time



# 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

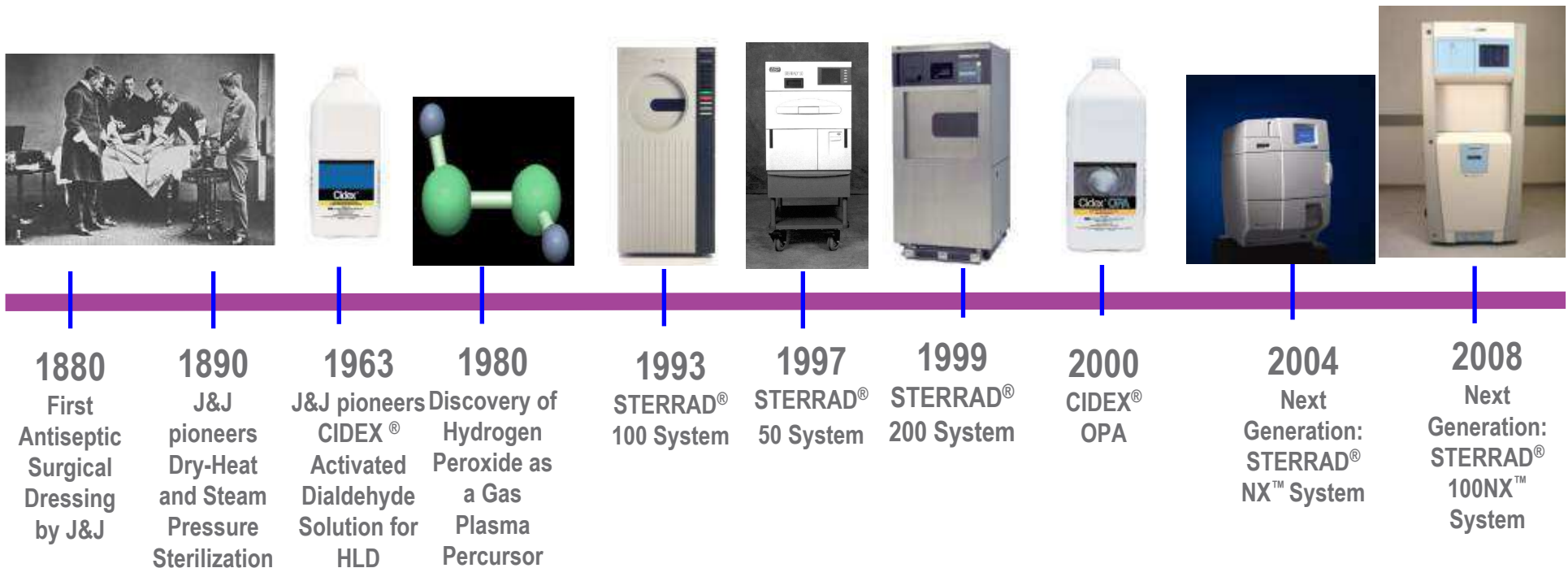


# Hydrogen Peroxide Gas Plasma Technology



# Infection Control Innovation

## History of Commitment





# STERRAD® Systems worldwide



15 years  
of experience in health  
care market!

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



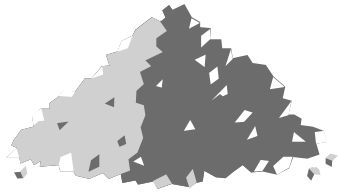
# STERRAD® Systems Features

- 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?

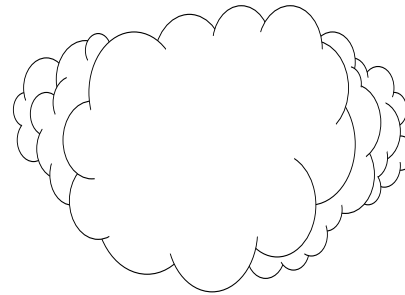
- It is the 4th state of matter
- 99% of all matter in the universe exists in the plasma state



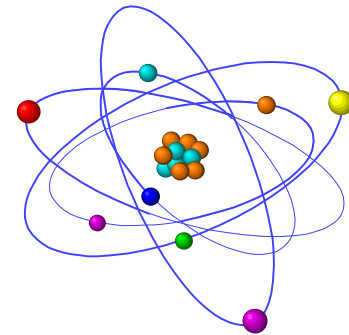
Solid



Liquid



Gas



Plasma

# 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



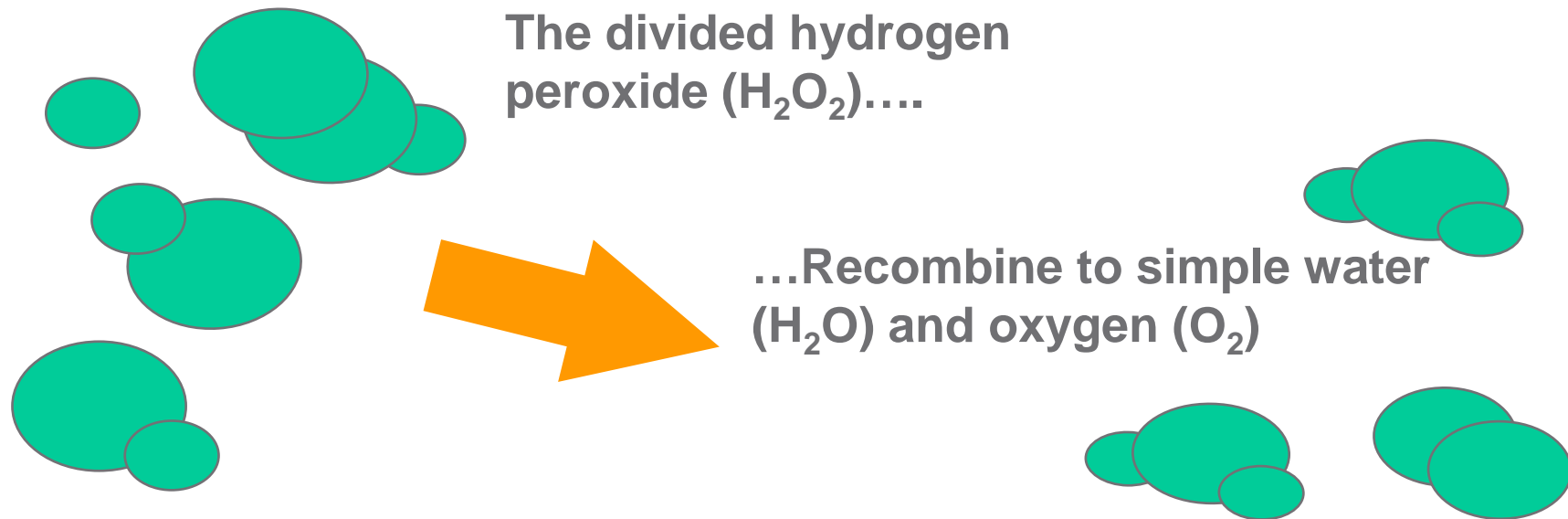
# STERRAD® Systems Sterilization Process

- 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



# STERRAD<sup>®</sup> Systems Sterilization Process

When the electrical field is turned off, these species recombine, turning the hydrogen peroxide into water vapor and oxygen



**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



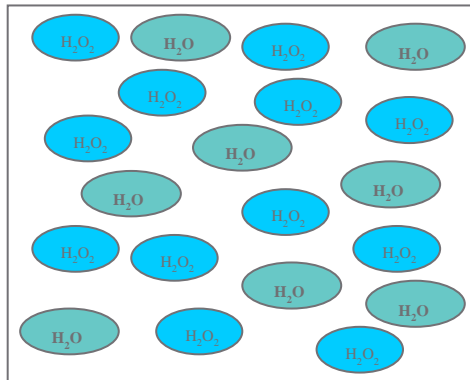
- STERRAD® Systems Cassettes
  - Sterilant in safe, easy-to-use cassettes
- CYCLESURE® 24 Biological Indicator
  - Provides evidence of proper sterilization in 24 hours
- Instrument Trays, Mats, and Holders
  - APTIMAX® Instrument Trays come in a variety of sizes and offer optimal protection for your instruments

# Next Generation in hydrogen peroxide gas plasma sterilization

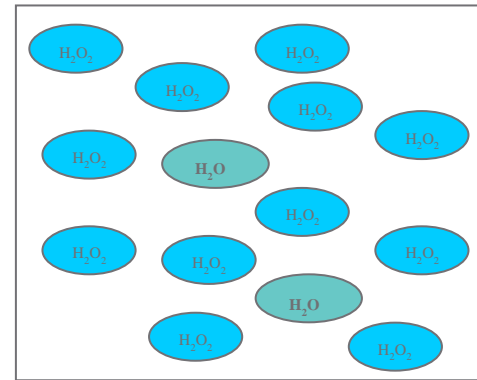


# NX™ Technology

- 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



Typical STERRAD® System  
Vapor Mixture



NX™ System  
Vapor Mixture

# 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



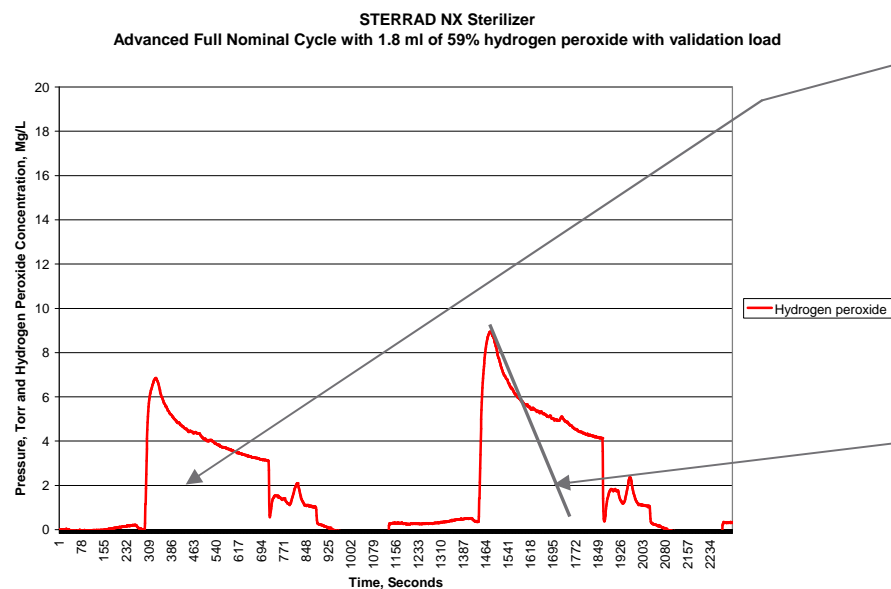
# STERRAD® 100NX™ Network Connectivity

- 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<sup>®</sup> 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<sup>®</sup> systems tested against steam

- STERRAD<sup>®</sup> 100S
- STERRAD<sup>®</sup> NX<sup>™</sup>
- STERRAD<sup>®</sup> 100NX<sup>™</sup>





# 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

Publication : "Low-Temperature Inactivation of Prion Protein on Surgical Steel Surfaces with Hydrogen Gas Plasma Sterilization." Z.X. Yan, L. Stitz, P. Heeg, K. Roth, P.-S. Mauz. "Zentral Sterilisation," Volume 16, 2008.

## 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

**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) .

	TRANSMISSION RATE (%)	INCUBATION PERIOD (DAYS)	INCUBATION DELAY (DAYS)	REDUCTION FACTOR
1% alkaline detergent A (55°C, 10 min)	<b>11%</b>	<b>446 ± 153</b>	<b>363</b>	<b>≥ 5-6</b>
1% alkaline detergent A (55°C, 10 min) plus STERRAD® 100S 1 long cycle	<b>0%</b>	<b>540 ± 14</b>	<b>457</b>	<b>≥ 5-6</b>
1% alkaline detergent A (55°C, 10 min) plus STERRAD® 100S 2 cons. long cycles	<b>0%</b>	<b>540 ± 30</b>	<b>457</b>	<b>≥ 5-6</b>
1% alkaline detergent B (55°C, 10 min)	<b>0%</b>	<b>524 ± 42</b>	<b>441</b>	<b>≥ 5-6</b>
1% alkaline detergent B (55°C, 10 min) plus STERRAD® 100S 1 long cycle	<b>0%</b>	<b>540 ± 13</b>	<b>457</b>	<b>≥ 5-6</b>
1% alkaline detergent B (55°C, 10 min) plus STERRAD® 100S 2 cons. long cycles	<b>0%</b>	<b>552 ± 0</b>	<b>469</b>	<b>≥ 5-6</b>

**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.

**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

**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) .

	TRANSMISSION RATE (%)	INCUBATION PERIOD (DAYS)	INCUBATION DELAY (DAYS)	REDUCTION FACTOR
STERRAD® NX™ 1 Advanced cycle	0%	570 ± 18	487	≥ 5-6
STERRAD® NX™ 2 cons. Advanced cycle	0%	574 ± 0	491	≥ 5-6
1% alkaline detergent A (55°C, 10 min) plus STERRAD® NX™ 1 Advanced cycle	0%	559 ± 22	476	≥ 5-6
1% alkaline detergent B (55°C, 10 min) plus STERRAD® NX™ 1 Advanced cycle	0%	562 ± 16	479	≥ 5-6
Steam 134°C 18 min	50%	428 ± 103	345	≥ 5-6
NaOH 1N 1h RT + Steam 134°C 18min	28%	574 ± 197	471	≥ 5-6

**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

TYPE OF STRAINS AND PLATES		STEAM 134°C, 18'	100S LONG CYCLE	NX™ ADVANCED CYCLE	100NX™	
					STANDARD CYCLE	FLEX CYCLE
263 K Strain	Stainless steel plates	≥ 5 log	2.5 log IL: 5 log (* )	≥ 5 log	≥ 5.5 log	≥ 5.5 log
	Polyethylene plates	-	-	≥ 6.5 log	-	-
	Polypropylene plates	-	-	≥ 6.5 log	-	-
6PB1 strain		≥ 4.5 log	≥ 4.5 log	≥ 4.5 log	-	-
vCJD strain		≥ 2.5 log	≥ 2.5 log	≥ 2.5 log	-	-

(\*) 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*):  $\geq 5-6$  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



## Innovative Infection Prevention Solutions

- 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!

