



WFHSS • 2016

17th WORLD STERILIZATION CONGRESS

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BRISBANE CONVENTION AND EXHIBITION CENTRE



PLACE OF LOW TEMPERATURE STERILIZATION IN EUROPE (Ex : France)



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WFHSS – 28 octobre 2016

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INTRODUCTION

Convection oven – dry heat : 180°C

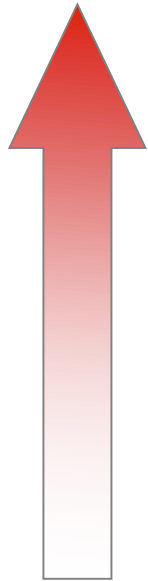
Autoclave – steam : 121 to 134°C

LTS :

Gas sterilizer - Ethylene Oxide & Formaldehyde : 55 to 80°C

Gas sterilizer - hydrogen peroxide : 40 to 55°C

Radioactivity – gamma ray : ambient temperature



ETHYLENE OXIDE / FORMALDEHYDE

No more in European Hospitals :

- Toxicity for patients, staff and Earth
- Complex installation
- Inactivity in PRION's inactivation

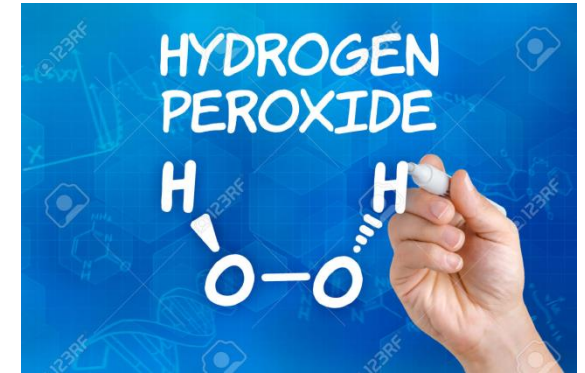
Ethylene oxide : Use in industry for Single use Medical device (MD)



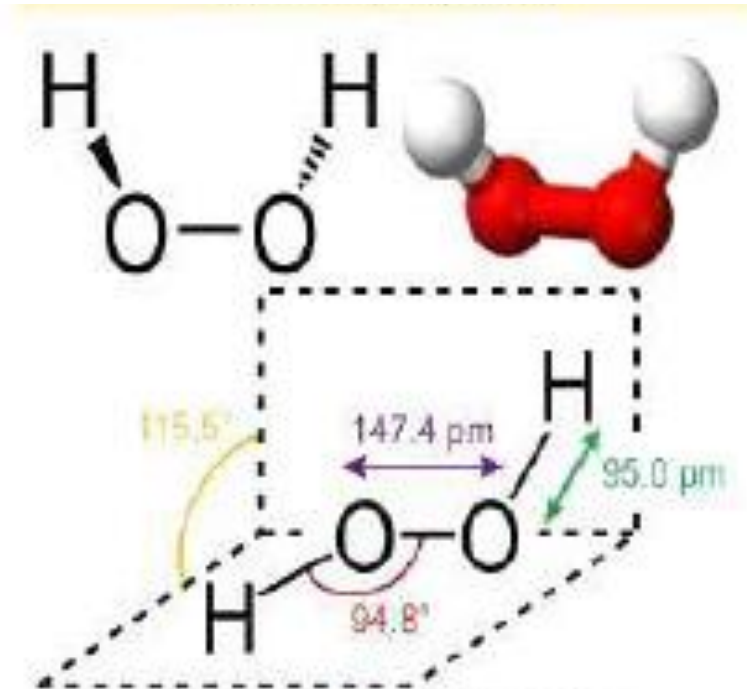
The image shows the packaging for the Euromedis EUROPERF S 3-way tap. The packaging is green and white. At the top left, the Euromedis logo is visible. To the right of the logo, the text 'Réf. 104108SD' is printed. Below this, the product name 'EUROPERF[®] S' is prominently displayed in green, with 'dist.' in smaller text above it. Underneath the product name, it says 'Set pour perfusion - STÉRILE' and 'robinet 3 voies 180 cm'. Further down, there are several lines of text in multiple languages: 'Apyrogène - Non toxique - Sans latex - Sans DEHP', 'Alimentation par gravité seulement', '20 gouttes d'eau = 1 ± 0,1 ml', and 'filtre : 22 µm'. Below this, there are seven circular icons with letters (GB, D, E, I, P, NL) and corresponding text in their respective languages. To the right of the text is a vertical diagram of the 3-way tap device. At the bottom of the packaging, there is a 'LOT' field with a barcode, a 'CODE EAN' field, and a 'STERILE EO' label. At the very bottom, it says 'Laboratoires Euromédic - Z.I. de la Tuilerie 60290 Netally-sous-Clermont - France' and 'Made in China'.

STERILANT

Hydrogen peroxide = H₂O₂



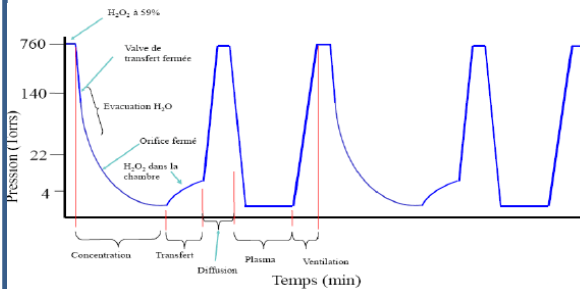
- Powerful oxidizer
- Concentrated gas : mini 59%
- Needs contact
- Broad spectrum of microorganism : cell killing by H₂O₂ gas exposur



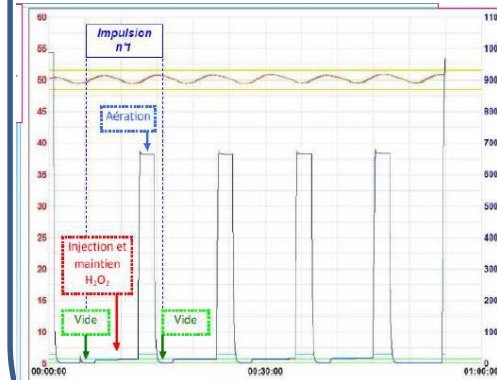
MAIN SUPPLIERS

- **ASP / Johnson & Johnson**
- Hydrogen Peroxide 85/95%
- with Plasma
- T°C < 55
- Time : 24-58 r

STERRAD 100NX[®]



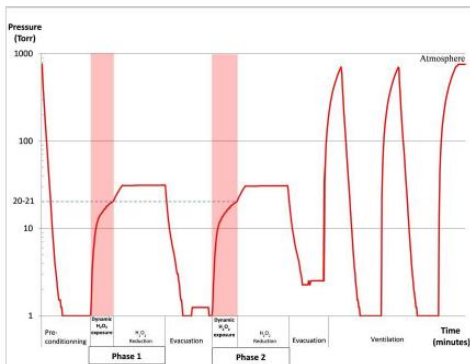
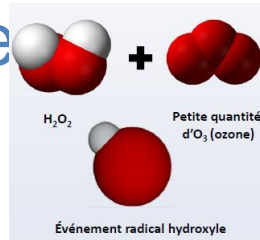
- **STERIS – VPRO max[®]**
- Hydrogen Peroxide 59%
- without Plasma (catalytic converter)
- T°C = 50
- Time < 55 min



OTHER SUPPLIERS

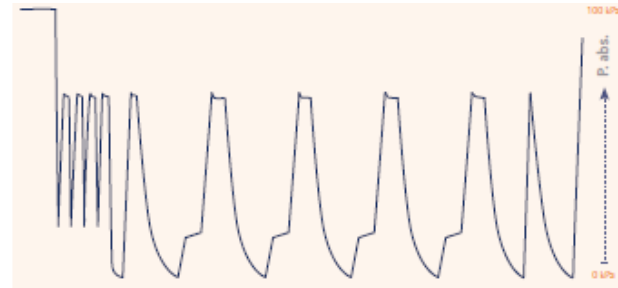
- **GETINGE – Sterizone VP4®**

- Hydrogen Peroxide
- Ozone : O_3
- $T^{\circ}C = 41$
- Time : 46-60



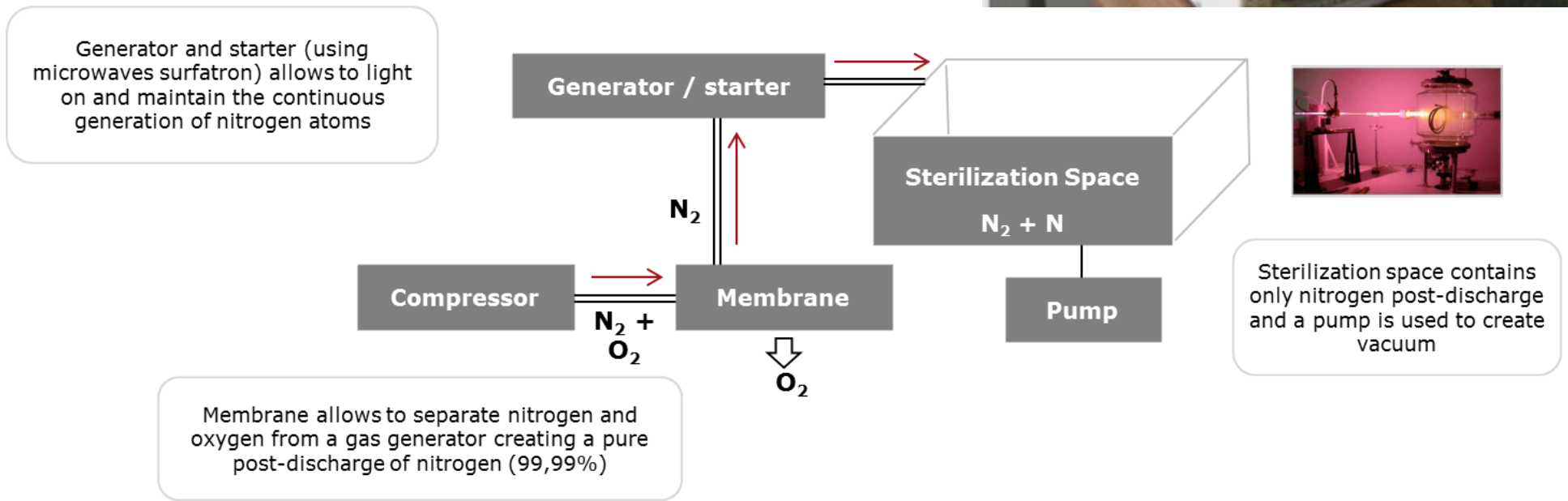
- **MATACHANA – 130HPO®**

- Hydrogen Peroxide 59%
- with Plasma
- Time : 25-48 min



IN PROCESS

- **ACTEON – Plasmalyse[®]**
 - Nitrogen plasma
 - $T^{\circ}\text{C} = 60$
 - Time = 133 min
- Under development



Two Types of Validation

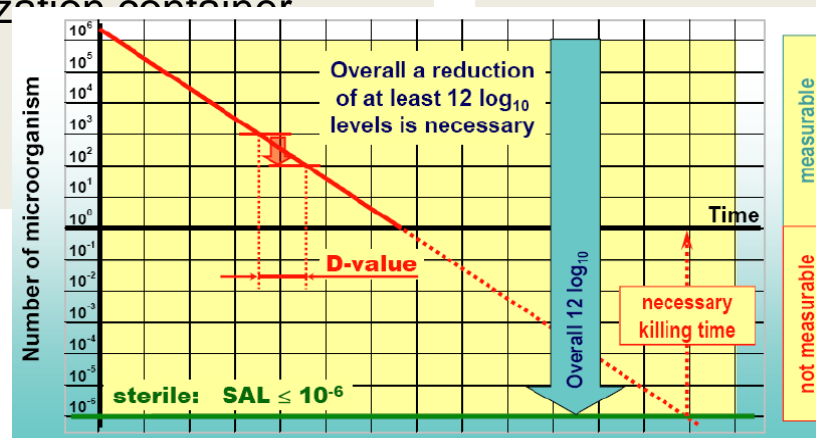
Sterility Assurance and Functional Compatibility

Sterility Assurance

- Must be performed on a production device, No simulation
- 6-log reduction in a half-cycle to demonstrate a full cycle of **SAL 10^{-6}** , under **ISO 14937**
 - Direct inoculation of relevant and resistant microorganisms, including bacterial spores
 - Placement of resistant microorganisms in lumens and within the sterilization container

Functional Compatibility

- Multiple cycle testing (100+) to assure functionality after continued reprocessing
- Verification from the MDM that all components of the device remain functional after repeated exposure to the sterilant
- Degradation or cosmetic affects captured to make customers aware of potential changes to observe during inspection
- publishes compatibility
- **CE Marking**

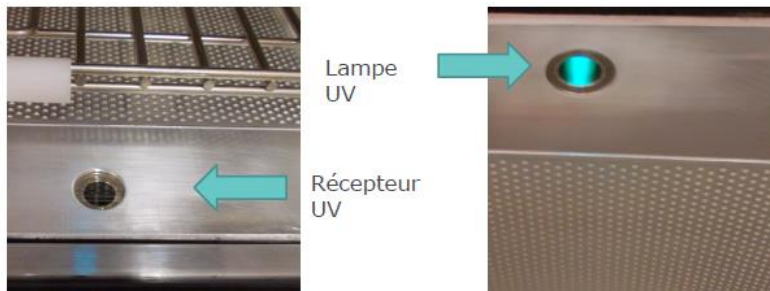


PARAMETRIC LOAD

Independent monitoring of the temperature and pressure

STERRAD NX[®]

- IMS system
- UV lamp allows measured the concentration of hydrogen peroxide in the chamber (254nm UV spectral analysis, 1-3mW)



VPRO Max[®]

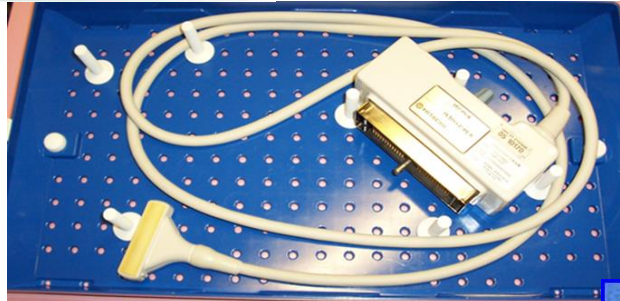
- measured injected volume
- indirect measured of the concentration of hydrogen peroxide during cycle by linear correlation with pressure.

$P^{\circ} H_2O_2 \leftrightarrow C^{\circ} H_2O_2 \leftrightarrow A$

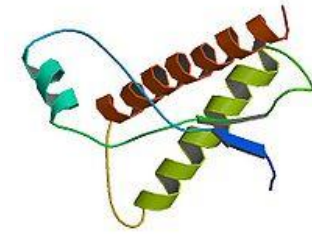
Biocide activity

MAIN INDICATIONS

Robot Da Vinci® / Probes / Endoscopes / Sonicision® / Cables / Glasses



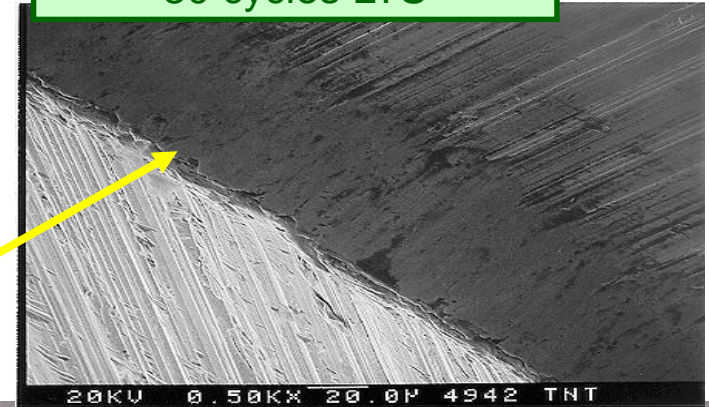
OTHER INDICATION



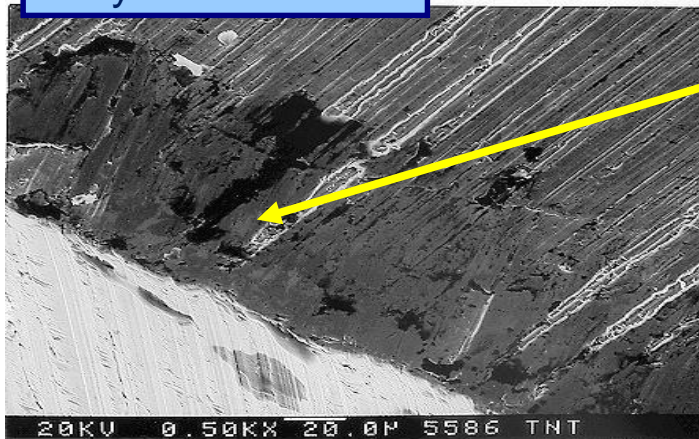
INACTIVATE PRION (PROteinaceous INfectious particle)

Less Corrosion ex. Microchirurgie

30 cycles LTS



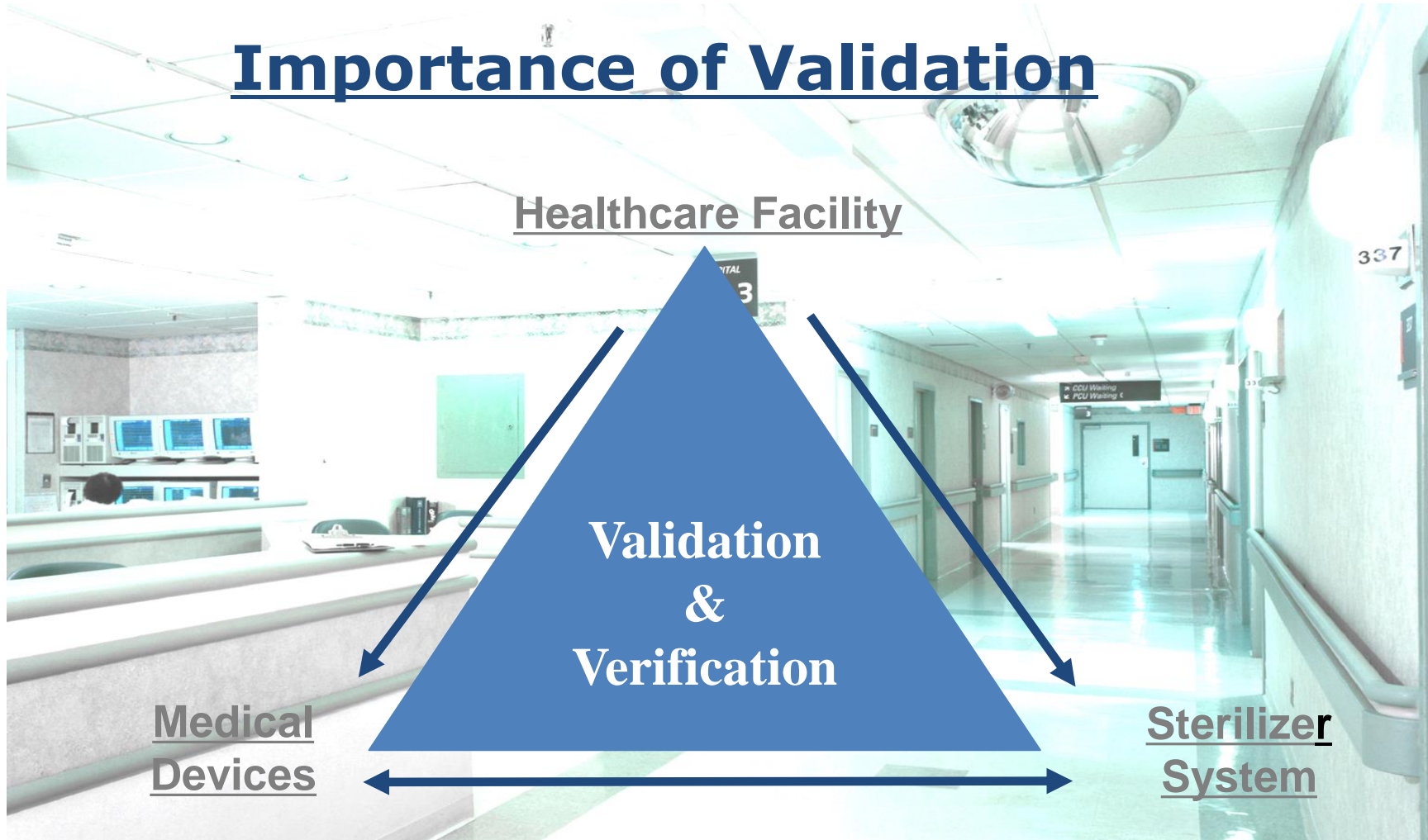
30 cycles STEAM



Dr V. DUBOIS

Manufacturer's Instructions For Use

Importance of Validation





Welcome to the STERRAD® Sterility Guide

Advanced Sterilization Products Division of Ethicon, Inc., an industry leader in infection prevention, is dedicated to helping you work more efficiently and effectively. The STERRAD® Sterility Guide is an easy-to-use, innovative online tool designed to provide STERRAD® Systems customers with an up to date list of devices that fall within STERRAD® System claims for sterility.

Benefits of registering:

- ✓ Personalized experience
- ✓ Manage a device inventory for easy searching
- ✓ Access to resources such as training videos, wall charts
- ✓ Helpful hints and so much more!

Register

[See how it works! Click here to view a demo of the new site ▶](#)

Recent Additions:

[Flexible Video Uretero-Renoscope, Flex-XC 11278VU](#)

KARL STORZ-ENDOSKOPE

[da Vinci Xi Endoscope with Camera, 8mm, 0° 470026](#)

Intuitive Surgical



V-PRO Device Compatibility Wizard

V-PRO Device Compatibility Wizard

Step 1: Please read and accept the Terms of Use

The V-PROSM Device Guide is intended for use with the V-PRO Sterilization Systems. This Device Guide represents devices that are both made of materials and have dimensional characteristics that have been cleared for sterilizing in the V-PRO Sterilization System. Such devices will be sterile if processed in a V-PRO Sterilization System in accordance with the appropriate V-PRO Sterilization System owner's manual.

This site updates frequently; this Device Guide is current

I accept the Terms of use

Next

V-PRO Device Matrix Home

- Terms
- Manufacturer
- Part Number
- Results

PLEASE READ CAREFULLY!

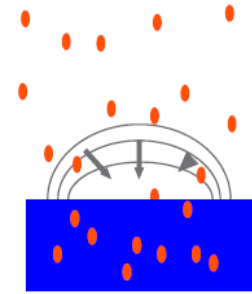
The following information identifies those cleaned, critical, semi-critical, heat-stable and heat-sensitive medical devices that have been validated by STERIS Corporation for processing in the STERIS[®] V-PRO[®] Sterilizer. STERIS' device validation program often includes working directly with device manufacturers to validate devices that can be processed in the V-PRO Sterilizer; due to the time it takes to update device Instructions for Use (IFU) and other labeling, the Device Matrix may contain devices prior to their appearance in the device IFU. Do NOT process any device in the V-PRO Sterilizer that the manufacturer has labeled as not suitable for processing in the STERIS[®] V-PRO[®] Sterilizer or in vaporized hydrogen peroxide sterilization systems. This site updates frequently. Consult and follow the device manufacturer's labeling and instructions for use for all processing, cleaning, handling and maintenance instructions. Consult and follow all product labeling and instructions for use for the V-PRO[®] Sterilizer.

LIMITS

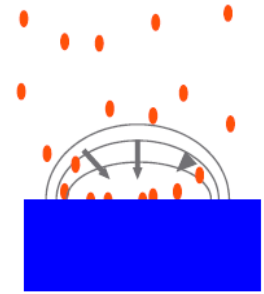
- Adsorption / Absorption



Reflection



Absorption



Adsorption

- Access to entire surface of MD
- Chemical indicator on each packaging (TYVEK® or SMS)
- Number / diameter and length of each lumen
- Water, cellulose

STERRAD® 100NX™ SYSTEM CYCLE SELECTION



The Next Generation Sterilization System.

All instruments must be cleaned and thoroughly dried prior to being packaged for sterilization in the STERRAD® 100NX™ Sterilizer.

Approved packaging includes ASP SteriTite® Containers, wrapped or pouched APTIMAX® Trays or Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator Strip. For rigid containers, verify that they are cleared for use in each cycle.

ADVANCED STERILIZATION PRODUCTS

Division of Medco International GmbH
a Johnson & Johnson company

*Please refer to the STERRAD® 100NX™ Sterilization System User's Guide for important information prior to use. Consult with the medical device manufacturer of instruments or endoscopes you intend to sterilize with any questions regarding materials compatibility.

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Tyvek and Teflon are registered trademarks of E.I. du Pont de Nemours and Company.
da Vinci is a registered trademark of Intuitive Surgical, Inc.

STANDARD CYCLE: 47 MINUTES

The STANDARD Cycle should be selected for instruments that meet the criteria below:

- General medical instruments (metal and nonmetal, including hinged devices)
- Instruments with single-channel stainless steel lumens
 - Internal diameter 0.7 mm or larger and length 500 mm or shorter
- Polyethylene and Teflon lumen tubing with an internal diameter of 1 mm or larger and length of 1000 mm or shorter.
 - These items must be sterilized without any additional load items
 - Limit of 20 pieces of tubing per cycle

Instrument sets that can be sterilized in the STANDARD Cycle include but are not limited to*:

- Arthroscopy and laparoscopic instrument sets
- Eye instruments
- Cystoscopy instruments
- Rigid or semi-rigid ureteroscopes
- Cameras and light cords
- Rechargeable batteries
- Doppler cords and defibrillator paddles
- Orthopedic drills and saws
- Ultrasound probes/transducers



STANDARD

Load Preparation: Two shelves (total weight: 21.4 lbs or 9.7 kg)

FLEX CYCLE: 42 MINUTES

The FLEX Cycle should be selected for flexible endoscopes that meet the criteria below:

- Single channel
- Internal lumen diameter of 1 mm or larger and length of 850 mm or shorter
- A maximum of two single-channel flexible endoscopes may be processed at one time
- No additional items may be processed in the cycle with the flexible endoscopes
- Place venting caps on flexible scopes according to the manufacturer's instructions

Flexible endoscopes that can be sterilized in the FLEX Cycle include but are not limited to*:

- Bronchoscopes
- Cystoscopes
- Hysteroscopes
- Choledochoscopes
- Flexible ureteroscopes
- Thoroscopes
- Intubation fiberscopes



FLEX

Load Preparation: A maximum of two single-channel flexible endoscopes

EXPRESS CYCLE: 24 MINUTES

The EXPRESS Cycle should be selected for instruments that meet the criteria below:

- General metal medical devices requiring surface sterilization, or sterilization of mated stainless steel and titanium surfaces
- Rigid or semi-rigid endoscopes without lumens
- Rechargeable batteries

Materials that should not be processed in the EXPRESS Cycle, even though they can be processed in the STANDARD and FLEX Cycles, are:

- Items made of nylon, polyurethane, or Kraton®
- Items with mated Delrin®, mated Ultem®, mated Radel®, or mated aluminum surfaces

Instruments that can be sterilized in the EXPRESS Cycle include but are not limited to*:

- da Vinci® endoscopes
- Rigid or semi-rigid endoscopes without lumens
- General surgery metal devices without lumens
- Rechargeable batteries
- Eye Instruments without lumens

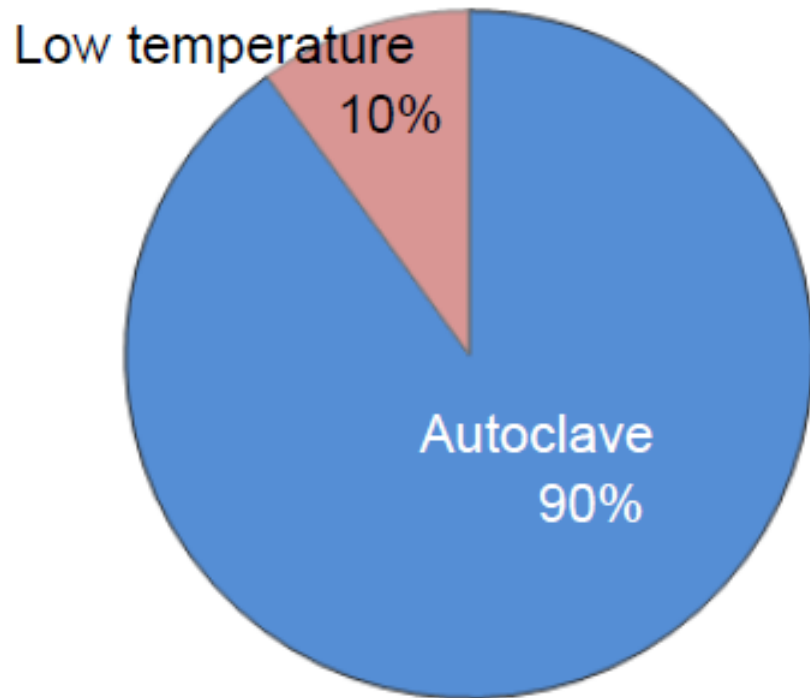


EXPRESS

Load Preparation: Bottom shelf only (10.7 lbs or 4.85 kg)



Market EU / France



France is still beyond rest of Europe in term of HPO - LTS :

- law makes mandatory to use steam sterilization for all suitable items

- higher cost than steam sterilization

Hydrogen peroxide sterilizers in Europe



In summary

	Process	Trend	Toxicity	Prion *	International standards	Costs
	Saturated steam	N°1 ^a	None	134°C, 18 min. ^d	EN ISO 17 665-1 and -2	Take into account
	Dry heat	⊘	None	No efficacy Fixative		
Low Temperature Sterilization	EtO	↘	Yes ^b	No efficacy	EN ISO 11 135-1 and -2 EN 30 993-7-2	<ul style="list-style-type: none"> • Hidden costs • Infrastructure • Safety procedure • Instrument damage
	LTSF	?	Yes ^c	No efficacy Fixative	EN ISO 25424 Check ! ^f	
	H ₂ O ₂	↗	None	Check ! ^e	EN ISO 14 937 Check ! ^f	

a) Vacuum and not gravity

b) EO carcinogenic - Requires desorption (EO sterilization residues)

c) Formol – carcinogenic

d) Not total inactivation. Total inactivation in combination with detergent (high alkaline pH)

e) Ask for data – some STERRAD® cycles approved for total inactivation – other process approved in combination with detergents only

INTERNATIONAL STANDARD

Functionality

Sterility

Processing

EN ISO 17664 /TIR 12

EN ISO 14937

Healthcare Institution

**Medical Device
Manufacturer
(MDM)**



Sterilization Supplier

⇒ Evaluates products for sterile efficacy based on the approved materials & lumen claims for a specific System

**Health Care
Provider**

⇒ Receives information through manufacturer's MD or the sterilizer for assurance in terminal sterilization

⇒ The MDM determines the functional compatibility in a Low T° Sterization System

**Sterility
Assurance**

CONCLUSION



- **HPO**
- **MD Compatibility, safety, time, cost,.....**
- **Trained team**
- **Responsability : France = Pharmacist**



**THANKS
FOR YOUR ATTENTION**

International Standards Harmonized in EU

Standards for the Manufacturer of a Medical Device

EN ISO 13485:2003 - Medical devices - Facilitate harmonized medical device regulatory standards for quality management systems

EN ISO 14971:2007 -Medical devices - Application of risk management to medical devices

EN ISO 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

EN ISO 14937:2009 - Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (also see: AAMI TIR 12)

EN ISO 14937:2009 ANNEX E – Application to be applied by healthcare facilities