

Advances in Low Temperature Sterilization

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Trends in Medical Devices

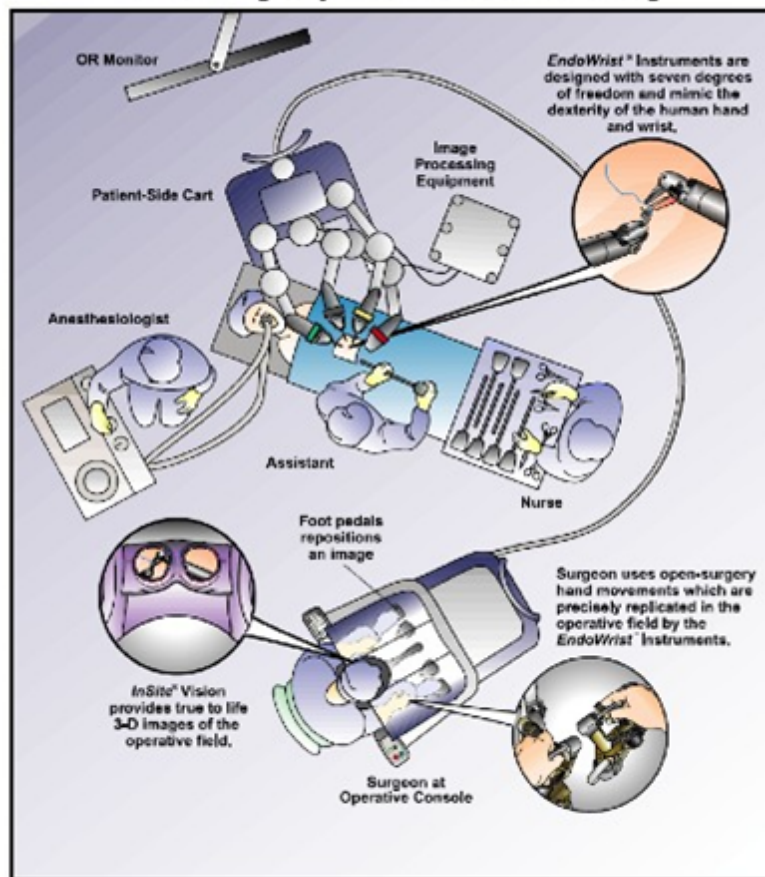
- **Inventory restrictions**
 - Cost management
- **Minimum Invasive Surgery (MIS)**
- **Increased complexity**
- **Integrated electronics**
- **Temperature-sensitive materials**
- **New technologies**
 - Drug-device combinations
 - Nanotechnology

Spine Assist Robot



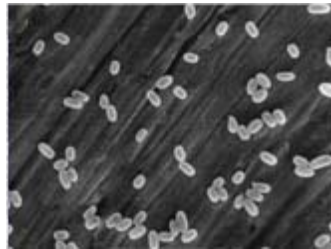


da Vinci® Surgical System in a General Procedure Setting



Trends in Sterilization

- **Sterilization standards**
 - ISO 17665 series (moist heat)
 - ISO 14937 (all sterilization processes)
- **Validation and record keeping requirements**
- **Increasing need for low temperature sterilization**
- **Faster turn-around time**
- **Reducing costs**
- **Environmental concerns**
- **New microbial concerns**
 - Toxins, including endotoxins
 - Prions
 - Parvoviruses



Bacterial Spores ← *Clostridium*
Bacillus

↓
Mycobacteria ← *Mycobacterium*

↓
Non-enveloped, non-lipid viruses (hydrophilic) ← Parvoviruses

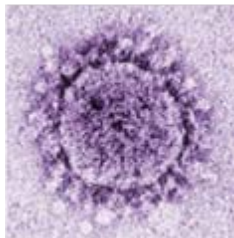


↓
Fungi ← *Aspergillus*
Stachybotrys

↓
Gram-negative vegetative bacteria ← *Escherichia*
Pseudomonas

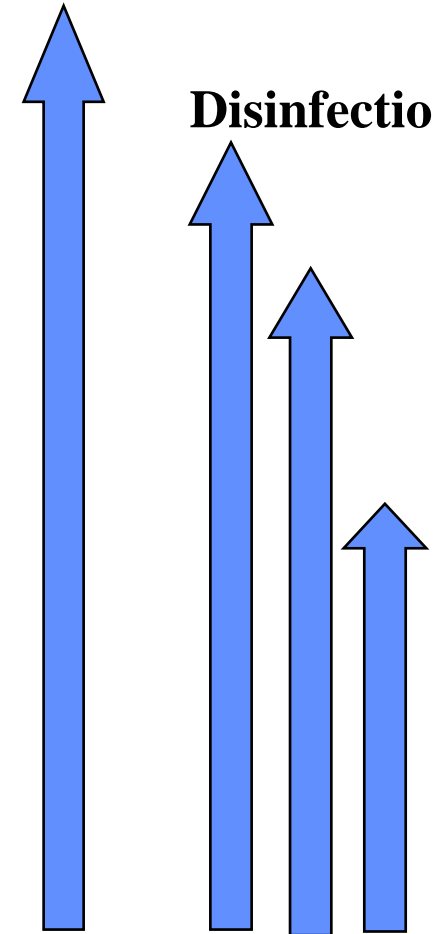
↓
Gram-positive bacteria ← *Enterococcus*
Legionella
Staphylococcus

↓
Enveloped, lipid viruses (lipophilic) ← Influenza



Sterilization

Disinfection



	Microorganism	Examples
<div>More Resistant</div> <div>↑</div> <div>Less Resistant</div>	Prions	Scrapie, Creutzfeld-Jakob disease, Chronic wasting disease
	Bacterial Spores	<i>Bacillus</i> , <i>Geobacillus</i> , <i>Clostridium</i>
	Protozoal Oocysts	<i>Cryptosporidium</i>
	Helminth Eggs	<i>Ascaris</i> , <i>Enterobius</i>
	Mycobacteria	<i>Mycobacterium tuberculosis</i> , <i>M. terrae</i> , <i>M. chelonae</i>
	Small, Non-Enveloped Viruses	Poliovirus, Parvoviruses, Papilloma viruses
	Protozoal Cysts	<i>Giardia</i> , <i>Acanthamoeba</i>
	Fungal Spores	<i>Aspergillus</i> , <i>Penicillium</i>
	Gram negative bacteria	<i>Pseudomonas</i> , <i>Providencia</i> , <i>Escherichia</i>
	Vegetative Fungi and Algae	<i>Aspergillus</i> , <i>Trichophyton</i> , <i>Candida</i> , <i>Chlamydomonas</i>
	Vegetative Helminths and Protozoa	<i>Ascaris</i> , <i>Cryptosporidium</i> , <i>Giardia</i>
	Large, non-enveloped viruses	Adenoviruses, Rotaviruses
	Gram positive bacteria	<i>Staphylococcus</i> , <i>Streptococcus</i> , <i>Enterococcus</i>
	Enveloped viruses	HIV, Hepatitis B virus, Herpes Simplex virus

Sterilization Technologies

● High Temperature

- Steam
- Dry Heat

● Low Temperature

- Ethylene oxide
- Low temperature steam/formaldehyde
- SYSTEM 1
- STERRAD
 - Plasma/Hydrogen Peroxide Gas
 - 100S (old process)
 - NX systems (new process)
- New
 - Hydrogen peroxide gas
 - Ozone
 - True Plasma processes



Ethylene Oxide



- **Advantages**

- Superior penetration and compatibility
- Capable of processing large volumes
- Sterile storage capability
- Easy-to-load (basket, few restrictions)
- International standard compliance

- **Disadvantages**

- Long cycles
 - Extended aeration
- Environment/personnel monitoring and record keeping

Low Temperature Steam/Formaldehyde

- Rarely used
- Advantages
 - Good compatibility and penetration
 - Capable of processing large volumes
 - Sterile storage capability
 - Combined high/low temperature systems (some designs)
- Disadvantages
 - Long cycle time
 - Can not sterilize liquids
 - May require extended aeration
 - Environment/personnel monitoring and record keeping
 - Toxicity
 - Irritating, mutagenic, carcinogenic and allergenic



SYSTEM 1 (Liquid Chemical PAA)



- **Advantages**

- Rapid cycle time
- No packaging required
- Broad range of devices
- Point-of-use
- No environmental monitoring
- International standard compliance (e.g., ISO 14937)

- **Disadvantages**

- No sterile storage
- Devices must be totally immersible
- Special connectors for devices with channels (flexible scopes)



STERRAD (Gas Plasma)



- **Two families, different processes**
 - 100S, 200, 50
 - NX, 100NX
- **Advantages**
 - Rapid cycle times
 - Sterile storage
 - No venting required
 - No personnel monitors
 - Non-toxic by-products
- **Disadvantages**
 - Moisture sensitivity
 - Limited penetration
 - Material compatibility concerns (flexible scopes)
 - Special loading considerations (plasma)
 - Cannot process cellulose materials or liquids

Amsco V-PRO 1 Low Temperature Sterilization System



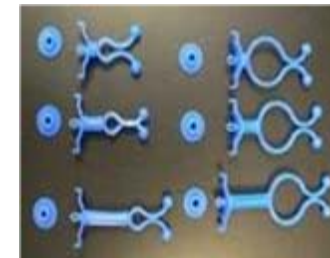
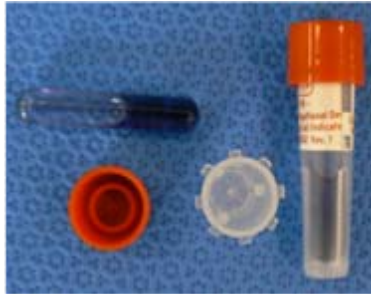
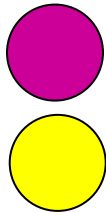
- **New sterilization process**
 - **Plastics**
 - **Metals**
 - **Lumens instruments**
- **Hydrogen Peroxide Gas**
- **NO PLASMA!**

Amsco® V-PRO™ 1

● Key Features

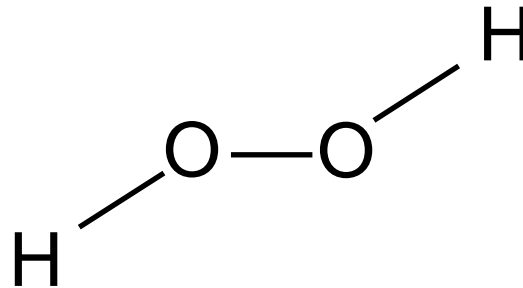
- Ease of installation
- Ease of use
- Productive
- Cost competitive
- Rapid cycle time (55 mins, complete)
- Antimicrobial efficacy
- Safety
- Compatibility
- Full range of consumables





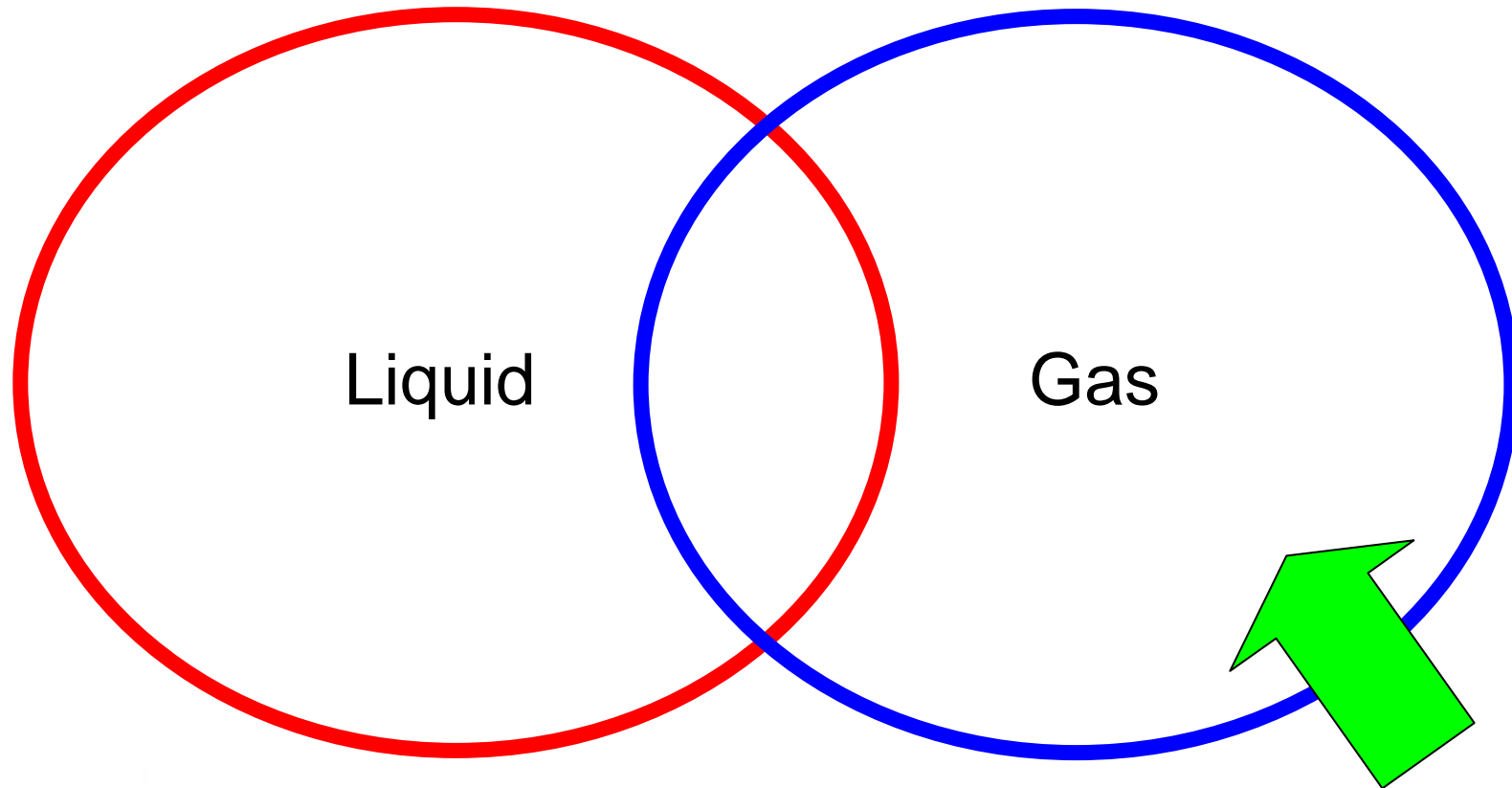
The Antimicrobial Used

Hydrogen Peroxide (H₂O₂)



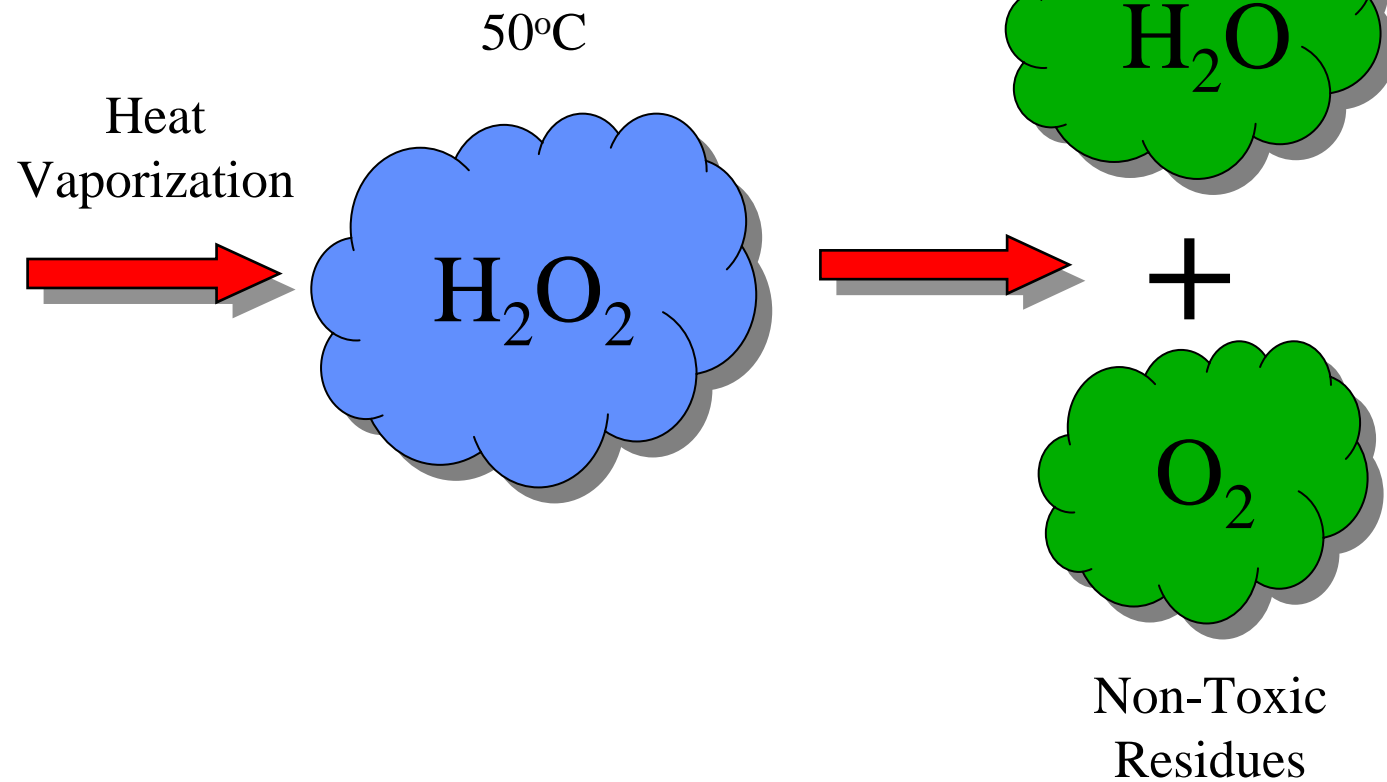
...but in gas phase

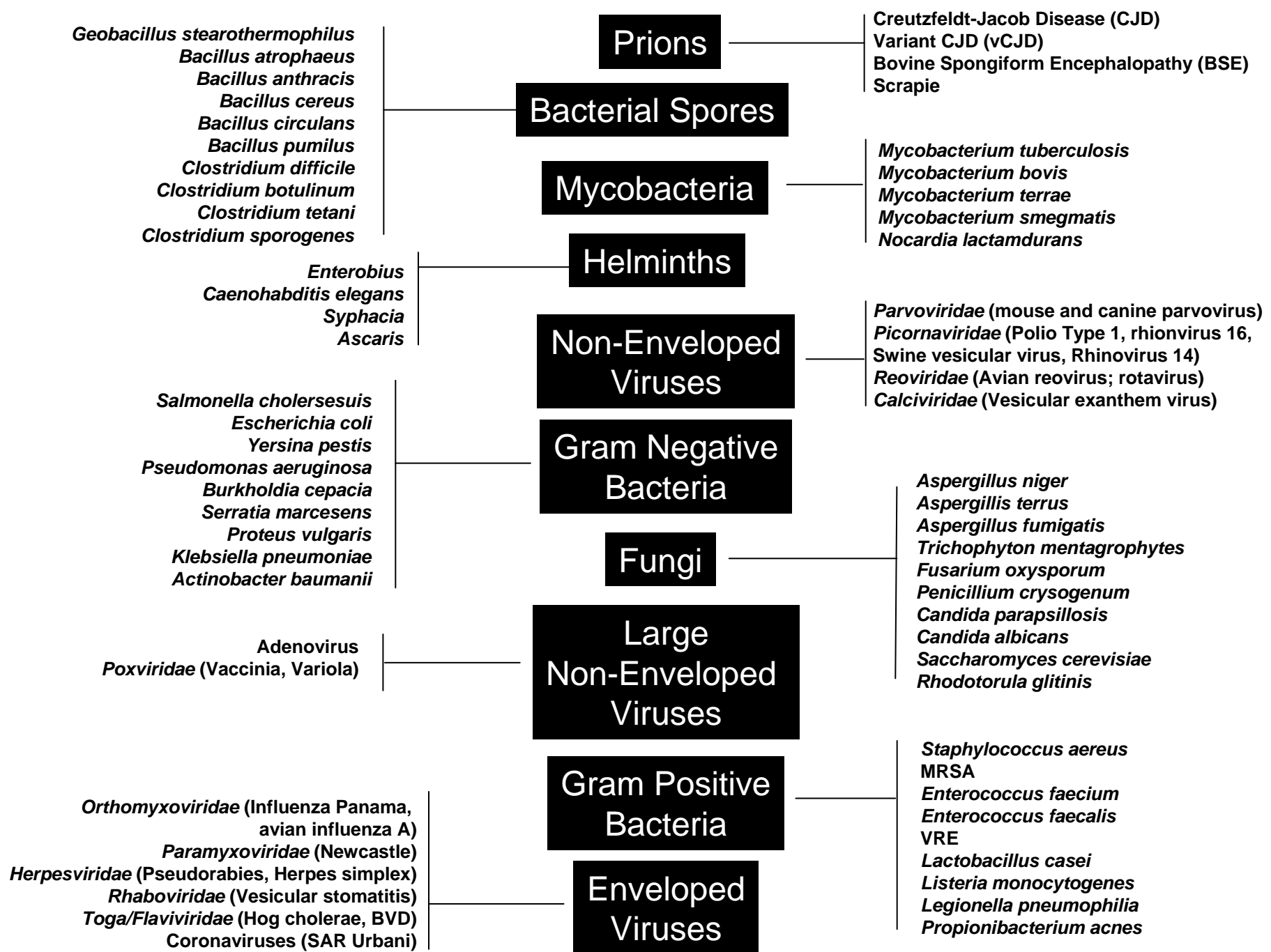
How Hydrogen Peroxide is Used





Vaprox® HC
Hydrogen
Peroxide
59%

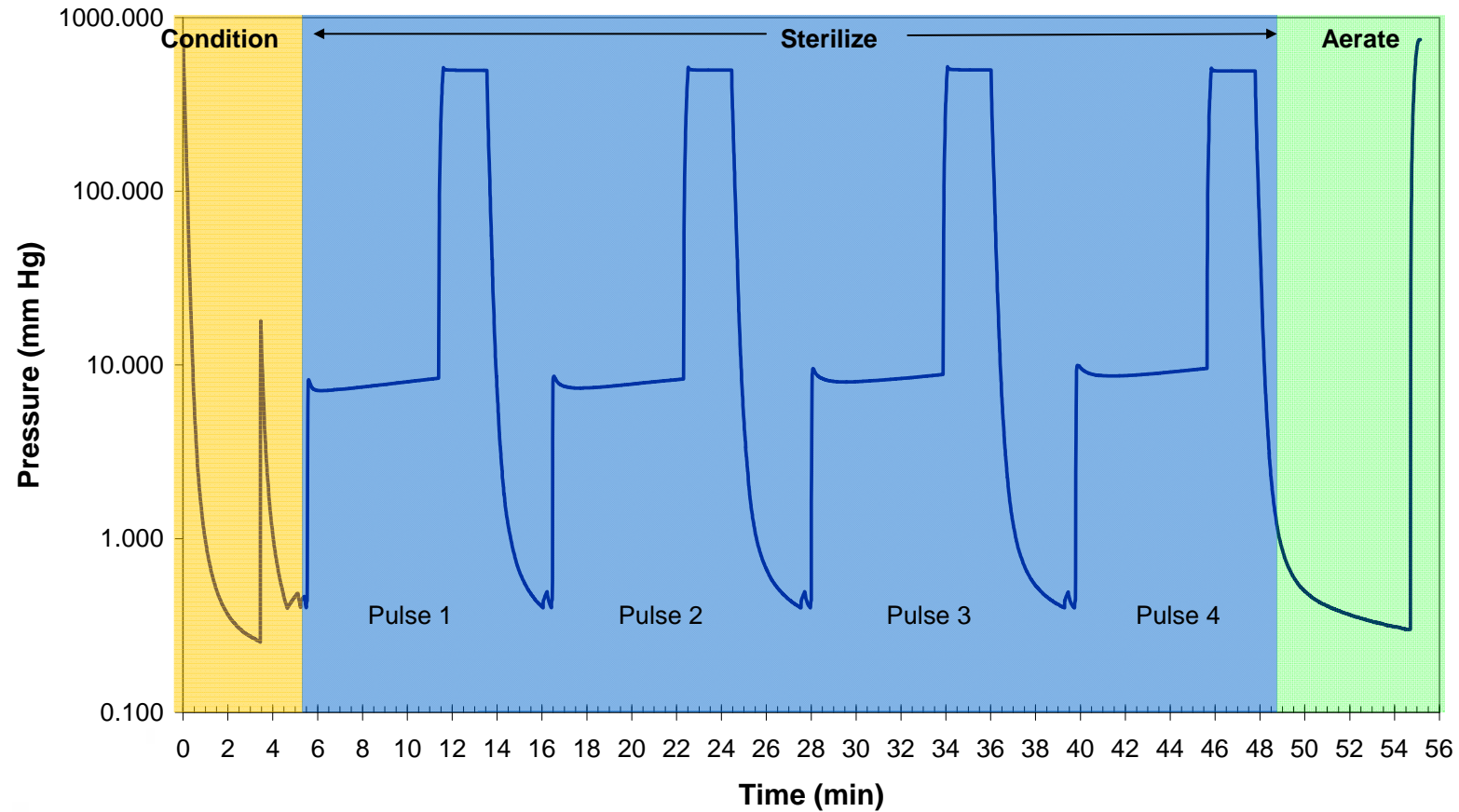






The V-PRO Process

V-PRO 1 Sterilization Cycle



ISO EN 14937: 2007

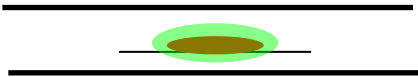
***STERILIZATION OF HEALTH CARE PRODUCTS —
GENERAL REQUIREMENTS FOR CHARACTERIZATION OF
A STERILIZING AGENT AND THE DEVELOPMENT,
VALIDATION AND ROUTINE CONTROL OF A
STERILIZATION PROCESS***

Fully Compliant, including demonstrated SAL of 10^{-6}

Examples...Surface Studies

Challenge Organism	# Sterile*	Log Reduction
<i>Acinetobacter baumannii</i>	10/10	6.61
<i>Burkholderia cepacia</i>	10/10	6.92
<i>Clostridium difficile</i> spores	10/10	6.13
<i>Escherichia coli</i>	10/10	6.36
<i>Enterococcus faecium</i> (VRE)	10/10	6.63
<i>Klebsiella pneumoniae</i>	10/10	6.32
<i>Pseudomonas aeruginosa</i>	10/10	6.92
<i>Staphylococcus aureus</i> (MRSA)	10/10	6.86
<i>Streptococcus pneumoniae</i>	10/10	6.61
<i>Enterococcus faecalis</i> (VRE)	10/10	6.90

Hospital Clinico De San Carlos, Madrid, Spain



		<i>Enterococcus faecium</i>	<i>Bacillus subtilis</i> spores
STERRAD	No soil/No Lumen	>6	5.9
	No soil/Lumen	4.7	4.6
	Soil/Lumen	4.4	3.9
VPro1	No soil/No Lumen	>6	>6
	No soil/Lumen	>6	>6
	Soil/Lumen	>6	>6





Prion inactivation using a new gaseous hydrogen peroxide sterilisation process

Human and Animal Strains

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Received 19 January 2007; accepted 23 August 2007

Fichet et al (2007) Journal of Hospital Infection **47**: 279-287

Examples...Safety

- **Safety for the patient**
 - ISO 10993-17
 - No toxicity
- **Safety for devices**
 - Material, component and device testing
- **Safety for staff**
 - Significantly below safety levels
- **Safety for the environment**
 - Degrades into water and oxygen

V-PRO™ 1 Sterilization

● Advantages

- Rapid cycle times
- Sterile storage
- No plasma necessary
- No venting required
- No personnel monitors
- Non-toxic by-products

● Disadvantages

- Cannot sterilize wet materials
- Limited penetration
- Limited life for some types of Nylon
- Cannot process cellulose materials



In the Future...

- **Increased use of temperature and process sensitive devices**
- **More complex and electronic devices**
- **Greater turn around times on device reprocessing**
- **Tighter control on reprocessing standards**
 - **Water quality**
 - **Cleaning verification**
 - **Tracking and traceability**
 - **Evidence-based verification of processes**

In the Future...

- **Low temperature sterilization processes**
 - **Safety and efficacy**
- **Microbial concerns**
 - **Living**
 - **Non-living**