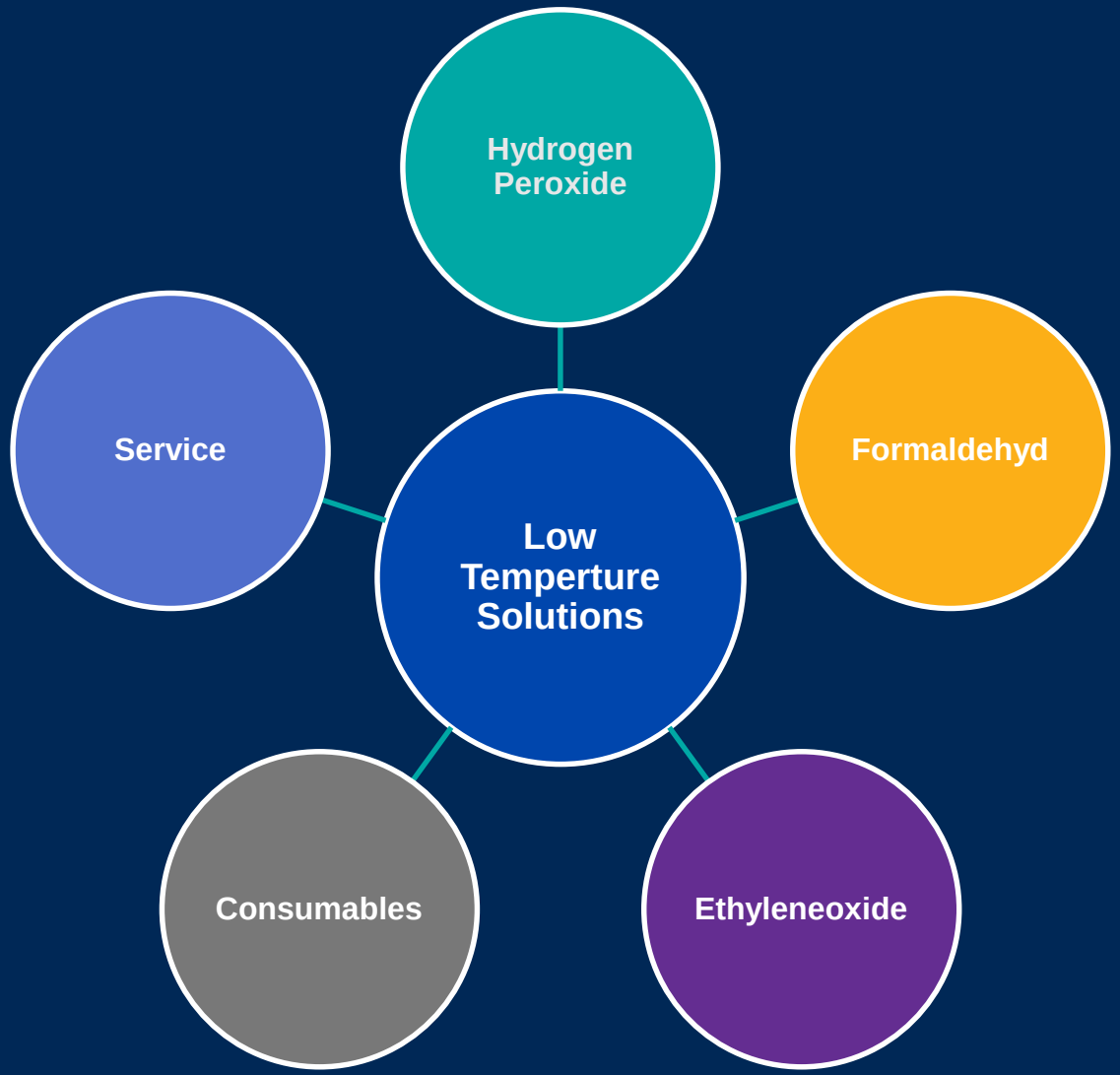

Low Temperature Sterilization

2018-02-02

Robert Tornberger

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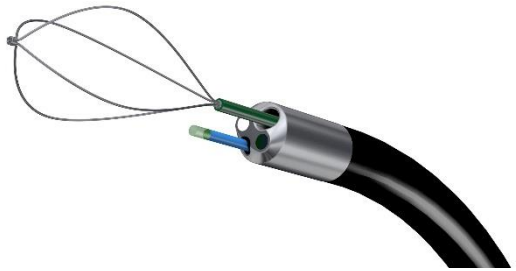
Back ground

- Instruments used in MIS are often sensitive to high temperature and pressure. This leads to a growing demand of Low Temperature Sterilizers.
- Customer requests on a higher through-put and production capacity.
- New trend and demands of low temperature sterilization for semi critical instruments that might be categorized as critical, i.e. Duodenoscopes.

Back ground



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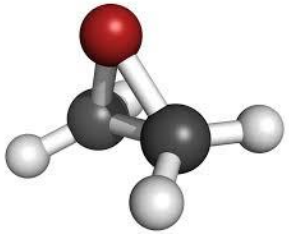
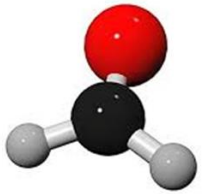
Sterilization Methods

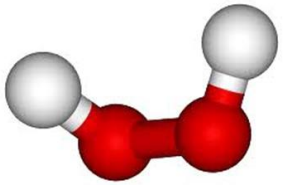
- Ethylene oxide



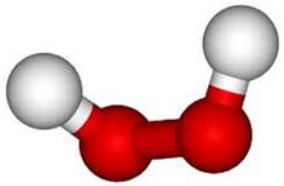
- Formaldehyde

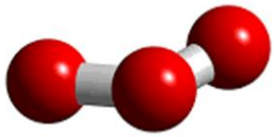


- Hydrogen peroxide



- Hydrogen peroxide/Ozone

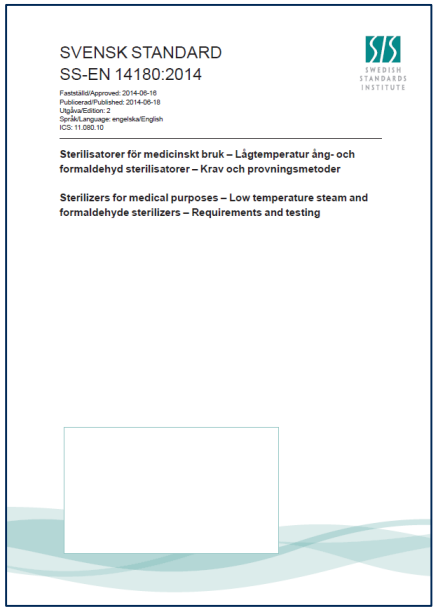




Standards

Standards – requirements, testing and acceptance criteria:

- EN 1422:2014 - Ethylene Oxide
- EN 14180:2014 – Formaldehyde
- draftEN XXXXX - Hydrogen peroxide TC 102 wg 6 (2019)


SVENSK STANDARD
SS-EN 14180:2014

Fastställd/Approved: 2014-06-18
Publicerad/Published: 2014-06-18
Utgåva/Edition: 2
Språk/Language: engelska/English
ICS: 11.080.10

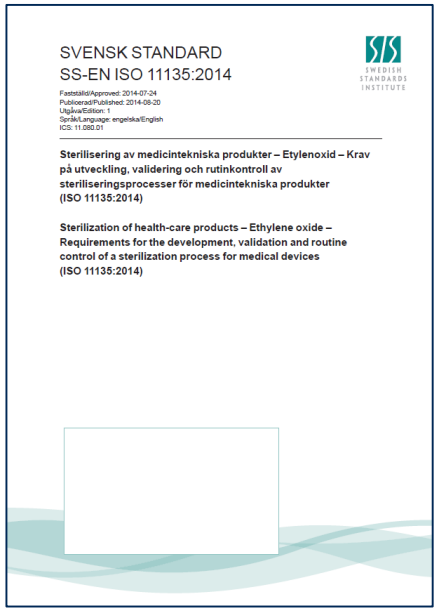
Sterilisatorer för medicinskt bruk – Lågtemperatur ång- och formaldehyd sterilisatorer – Krav och provningsmetoder

Sterilizers for medical purposes – Low temperature steam and formaldehyde sterilizers – Requirements and testing

Standards

Standards for development, validation and routine control:

- EN-ISO 11135:2014 - Ethylene Oxide
- EN-ISO 25424:2009 – Formaldehyde
- ISO/NP 22441 - Hydrogen peroxide (ISO/TC 198)


SVENSK STANDARD
SS-EN ISO 11135:2014

Fastställd/Approved: 2014-07-24
Publicerad/Published: 2014-08-20
Utgåva/Edition: 1
Språk/Language: engelska/English
ICS: 11.080.01

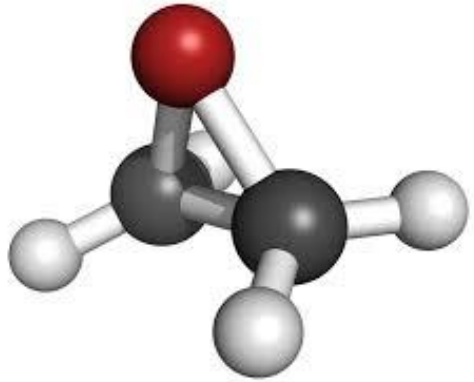
Sterilisering av medicintekniska produkter – Etylenoxid – Krav på utveckling, validering och rutinkontroll av steriliseringsprocesser för medicintekniska produkter (ISO 11135:2014)

Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)

Sterilization Methods – Ethylene oxide

Characteristics

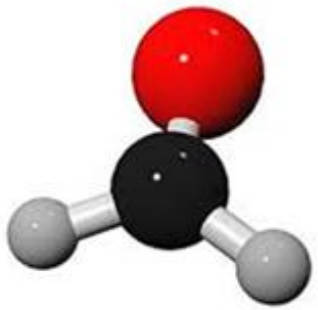
- Very effective sterilant
- Applied in gas/steam
- Good penetration in longer lumens
- Cancer Hazard and Reproductive Hazard
- Explosive
- Wrapping/porous material absorbs the sterilant
- Degassing required outside the chamber



Sterilization Methods – Formaldehyde

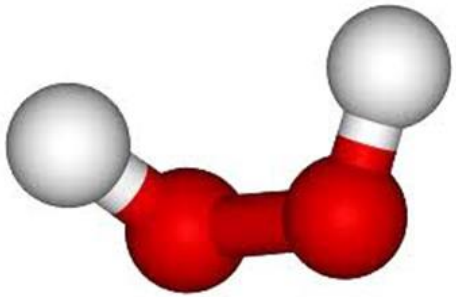
Characteristics

- Very effective sterilant
- Applied in gas/steam
- Good penetration in longer lumens
- Dangerous breathing in…
- Dissolves in water
- Wrapping/porous material absorbs the sterilant
- Degassing in-chamber



Sterilization Methods – Hydrogen peroxide

Characteristics

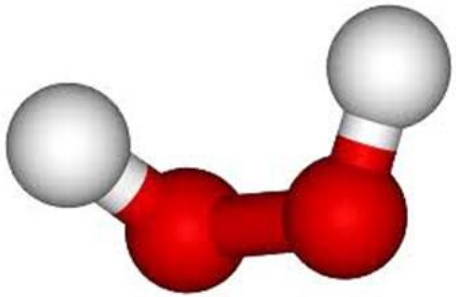


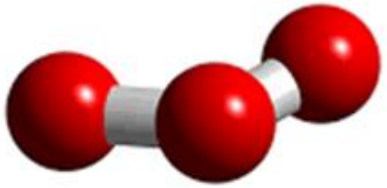
- Very effective sterilant
- Applied as vapor
- Good penetration in lumens
- Reactive/Corrosive
- Dissolves in water
- Transforms into water and oxygen with plasma and catalytic converter

Sterilization Methods – Hydrogen peroxide & Ozone

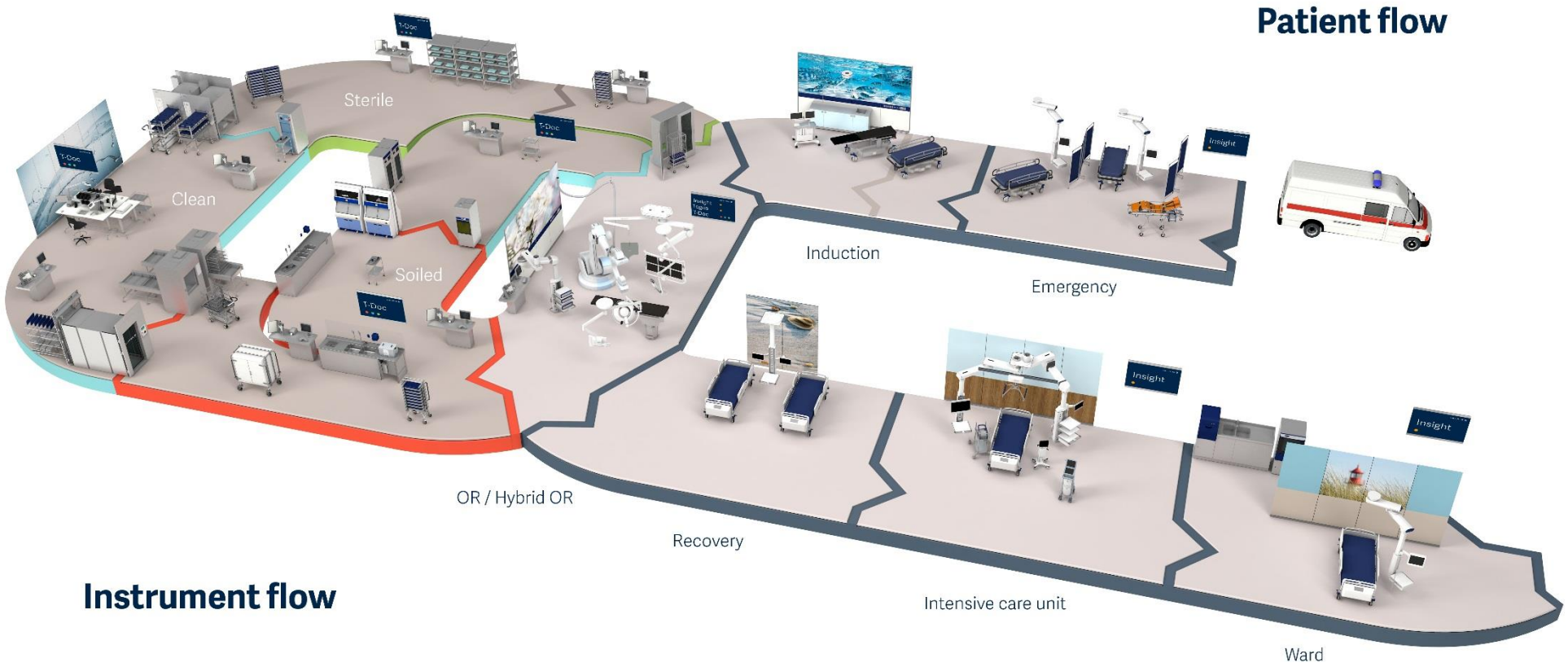
Characteristics

- Very effective sterilant combination
- Applied as vapor that condensates (micro layer)
- Good penetration in longer lumens
- Reactive/Corrosive
- Dissolves in water
- Hydrogen peroxide decomposes to water and oxygen with Ozone
- Ozone decomposes to water and oxygen with the hydrogen peroxide

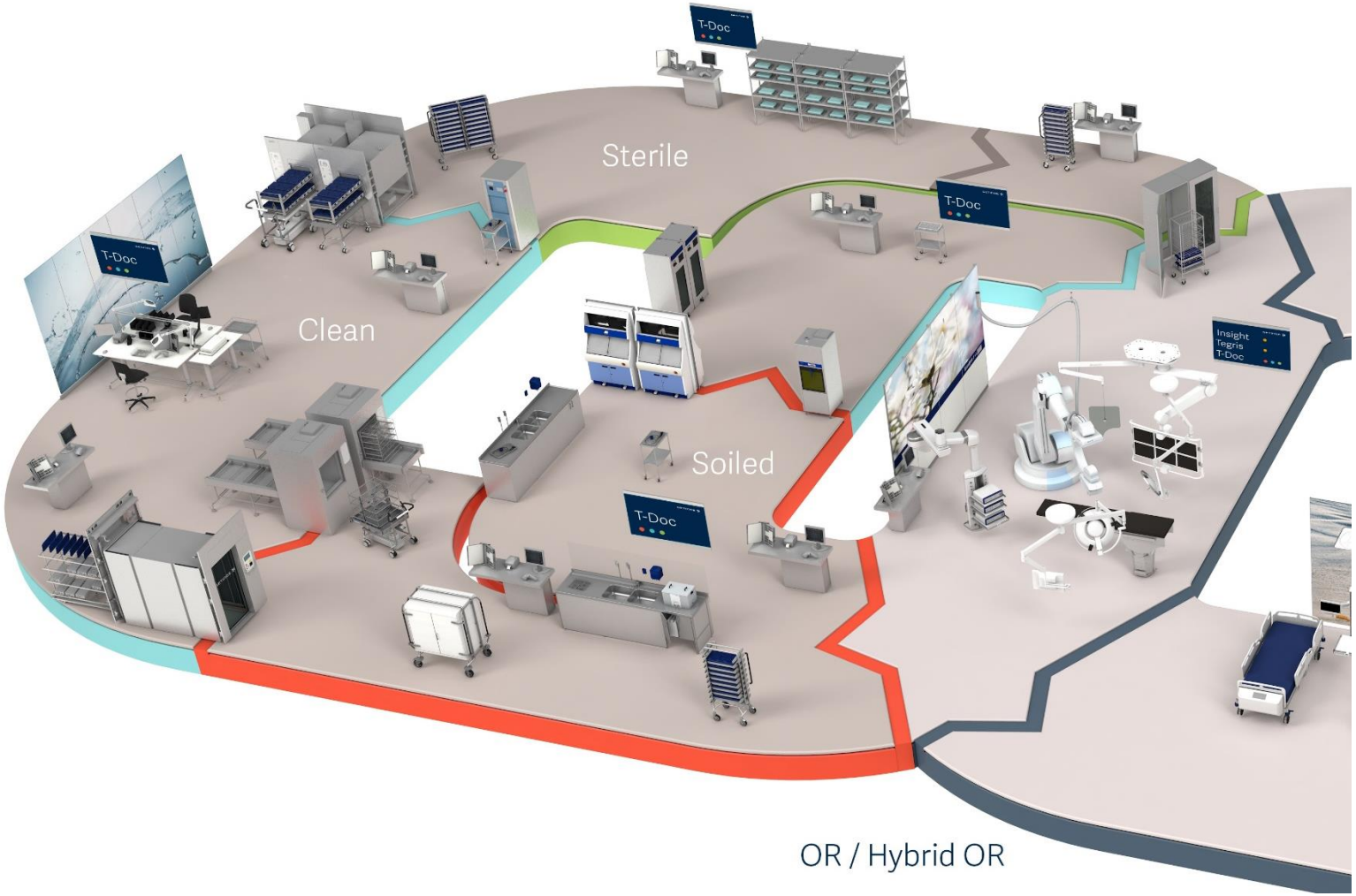




Instrument Flow and Production Solution



Production Solution



Low Temperature Sterilizers

Customer Requirements

Low temperature sterilization customer requirements

High instrument compatibility:
- Material
- Lumen length

Throughput:
- Cost effective
- High/Medium/Low/Peaks
- Type of instruments

Safety:
- User, patient & environment
- Validated cycles

High Quality:
- Quality assurance
- Notified bodies

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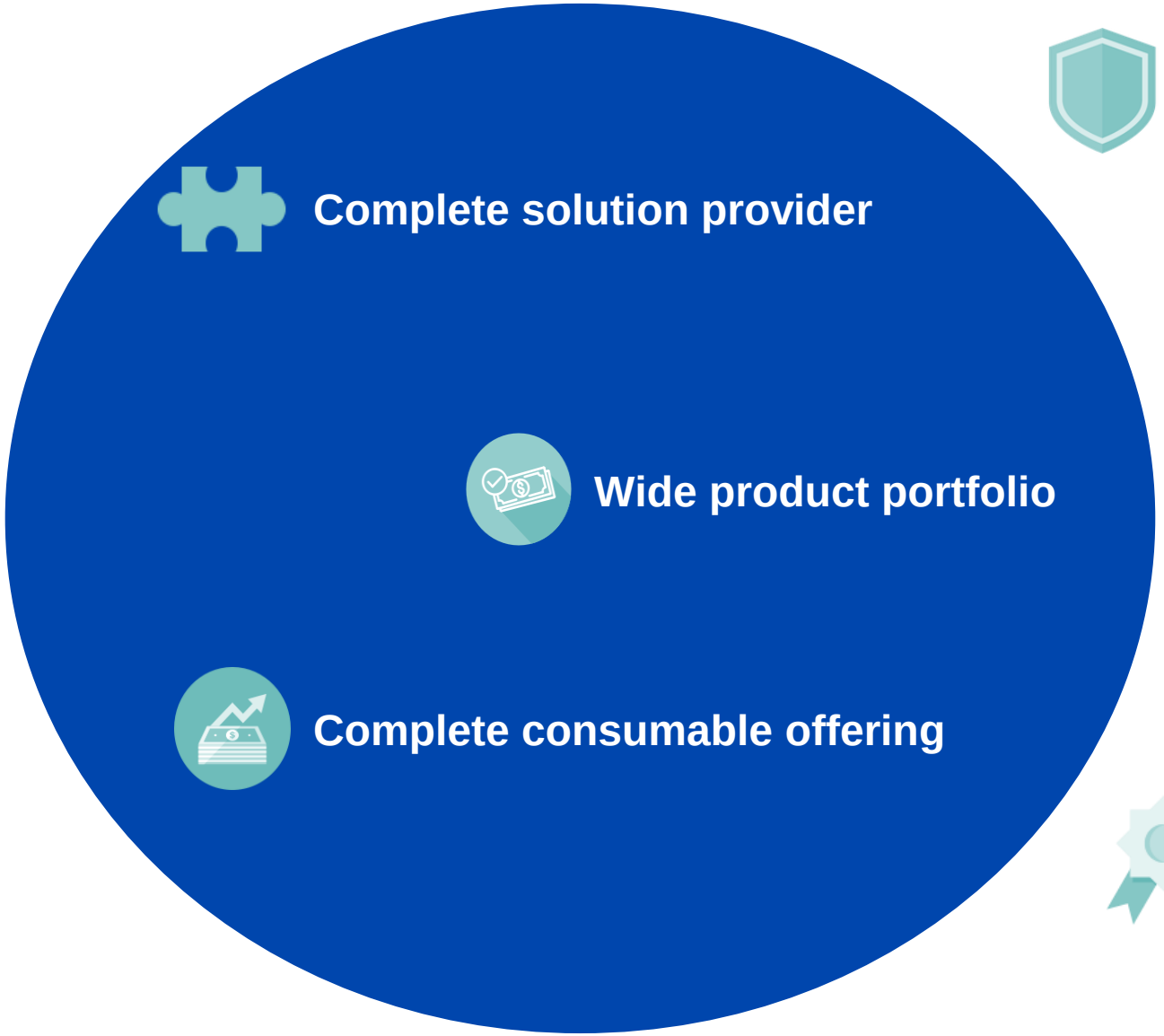
Low Temperature Sterilizers

Supplier Offer



High instrument compatibility:
- Material
- Lumen length

Throughput:
- Cost effective
- High/Medium/Low/Peaks
- Type of instruments

Safety:
- User, patient & environment
- Validated cycles

High Quality:
- Quality assurance
- Notified bodies

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Consumables - Low Temperature Sterilizers

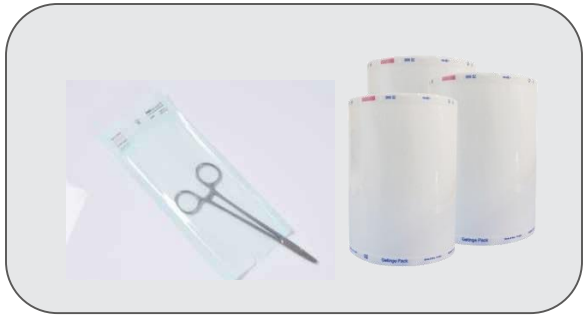
Total Consumable Offering

Sterilant

Routine Monitouring Kits

Chemical Indicators

Biologic Indicators



Packaging Materials

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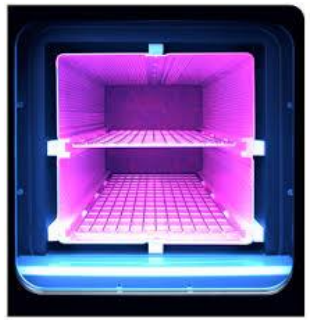
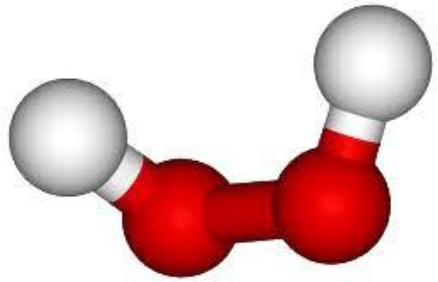
Hydrogen Peroxide & Plasma

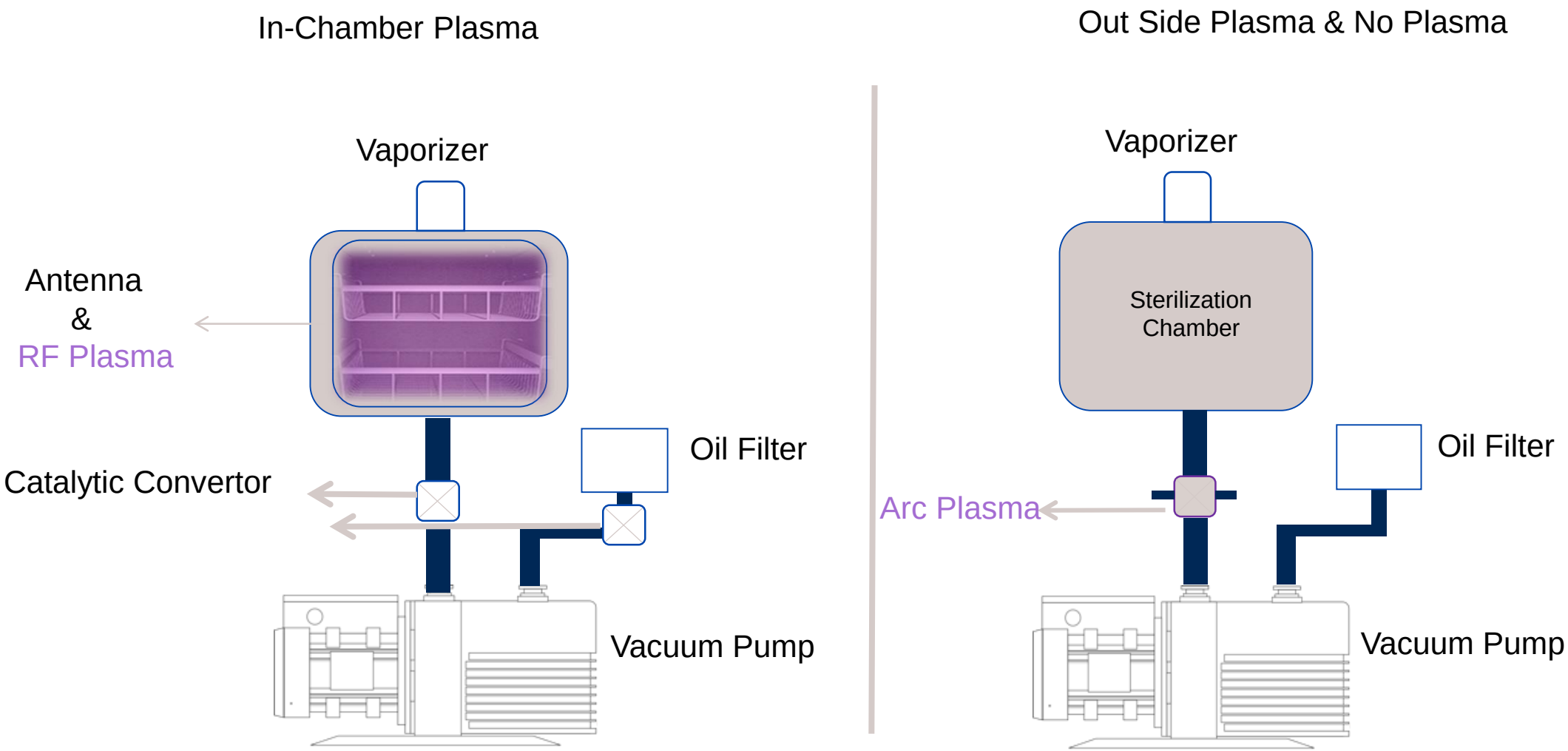
Hydrogen Peroxide & Plasma





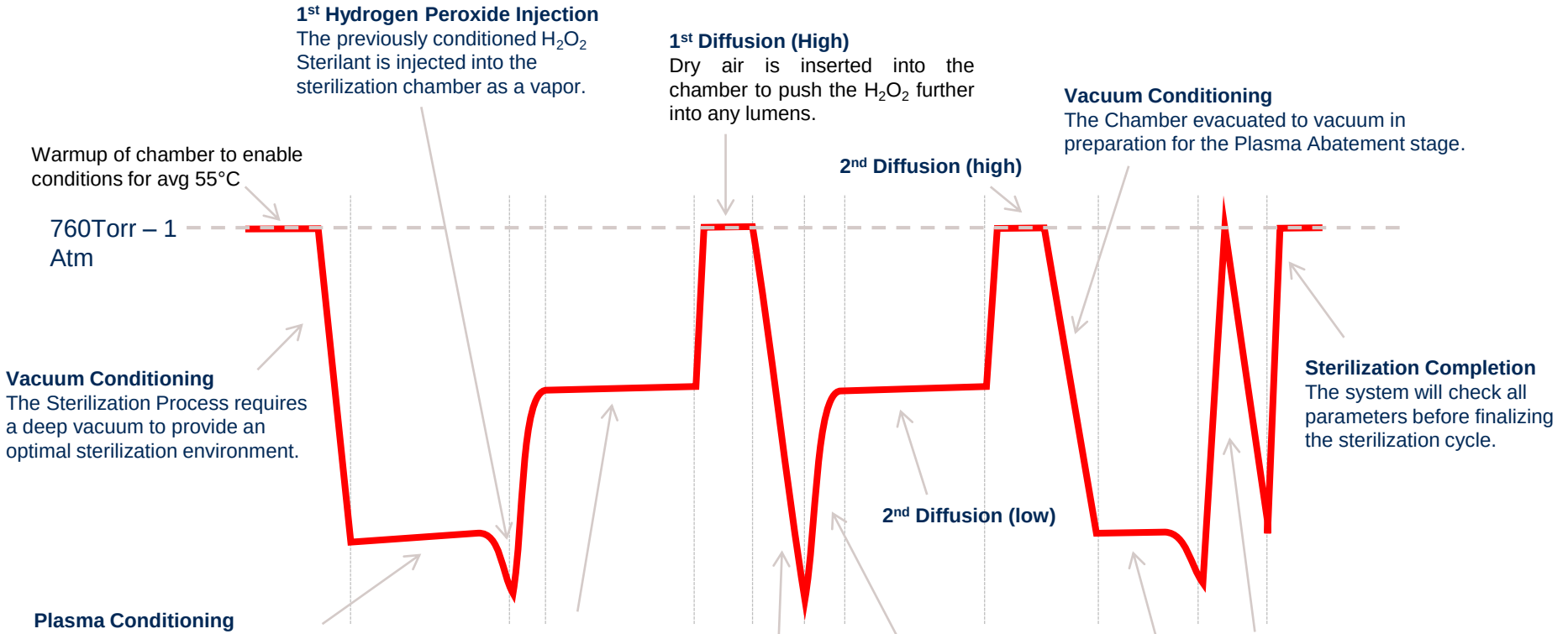
Low Temperature H2O2 Sterilizers

In-chamber Plasma vs. Out Side Plasma & No Plasma



Process

Fast cycle = 59% H_2O_2 2 injection
Standard = 80-82% H_2O_2 2 injections
Advanced = 90-92% H_2O_2 2 injections



Warmup of chamber to enable conditions for avg 55°C

Vacuum Conditioning
The Sterilization Process requires a deep vacuum to provide an optimal sterilization environment.

Plasma Conditioning
The Chamber is pre-conditioned with plasma in order to (i) remove moisture and (ii) enable homogenous heat distribution.

1st Hydrogen Peroxide Injection
The previously conditioned H_2O_2 Sterilant is injected into the sterilization chamber as a vapor.

1st Diffusion (low)
H_2O_2 is maintained as a vapor in order to enable homogenous and effective diffusion inside the lumens and cavities of the surgical instruments.

1st Diffusion (High)
Dry air is inserted into the chamber to push the H_2O_2 further into any lumens.

Vacuum Conditioning
The Chamber evacuated to vacuum in preparation for the 2nd Injection Phase.

2nd Diffusion (high)

2nd Diffusion (low)

2nd Hydrogen Peroxide Injection
Once again, conditioned H_2O_2 Sterilant is injected into the sterilization chamber as a vapor.

Vacuum Conditioning
The Chamber evacuated to vacuum in preparation for the Plasma Abatement stage.

Plasma Abatement
The plasma at the end of the cycle, ensures that all H_2O_2 is decomposed (to water vapor and oxygen) and to contributes to the sterilization via the UV and free radicals generated.

Optional Aeration
Sterilization cell is vented with purified dry air to provide further cleansing.

Sterilization Completion
The system will check all parameters before finalizing the sterilization cycle.

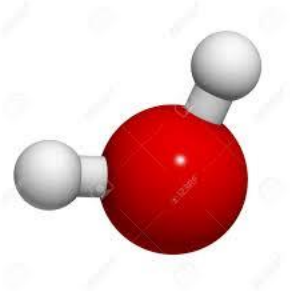
Low Temperature H_2O_2 Sterilizers

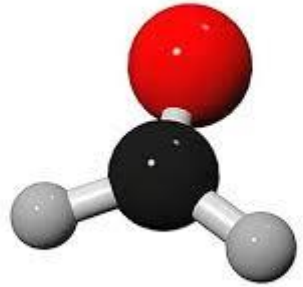
Lumen Claims

Cycle	Description	Inside Diameter	Length
Fast Cycle 29 min	Fast sterilization for surface instruments e.g. • General surface surgery instruments • Rechargeable batteries • Ophthalmic Instruments W/O lumens	Not Applicable	Not Applicable
Standard Cycle 42 min [Concentrated H_2O_2]	Sterilization of general surgical instruments with flexible and short rigid lumens e.g. • General surface surgery instruments • Single channel flexible scopes • Rigid lumens • Maximum 6 lumens per load	Flexi 1.0 mm 2.0 mm Rigid 1.0 mm	Flexi ≤ 850 mm ≤ 1200 mm Rigid ≤ 400 mm
Advanced Cycle 53 min [Concentrated H_2O_2]	Sterilization of general rigid (not flexible) surgical instruments with long lumens e.g. • General surface surgery metal instruments • Instruments which have long rigid lumens • Maximum 6 lumens per load	1.0 mm	≤ 500 mm

Formaldehyde & Steam

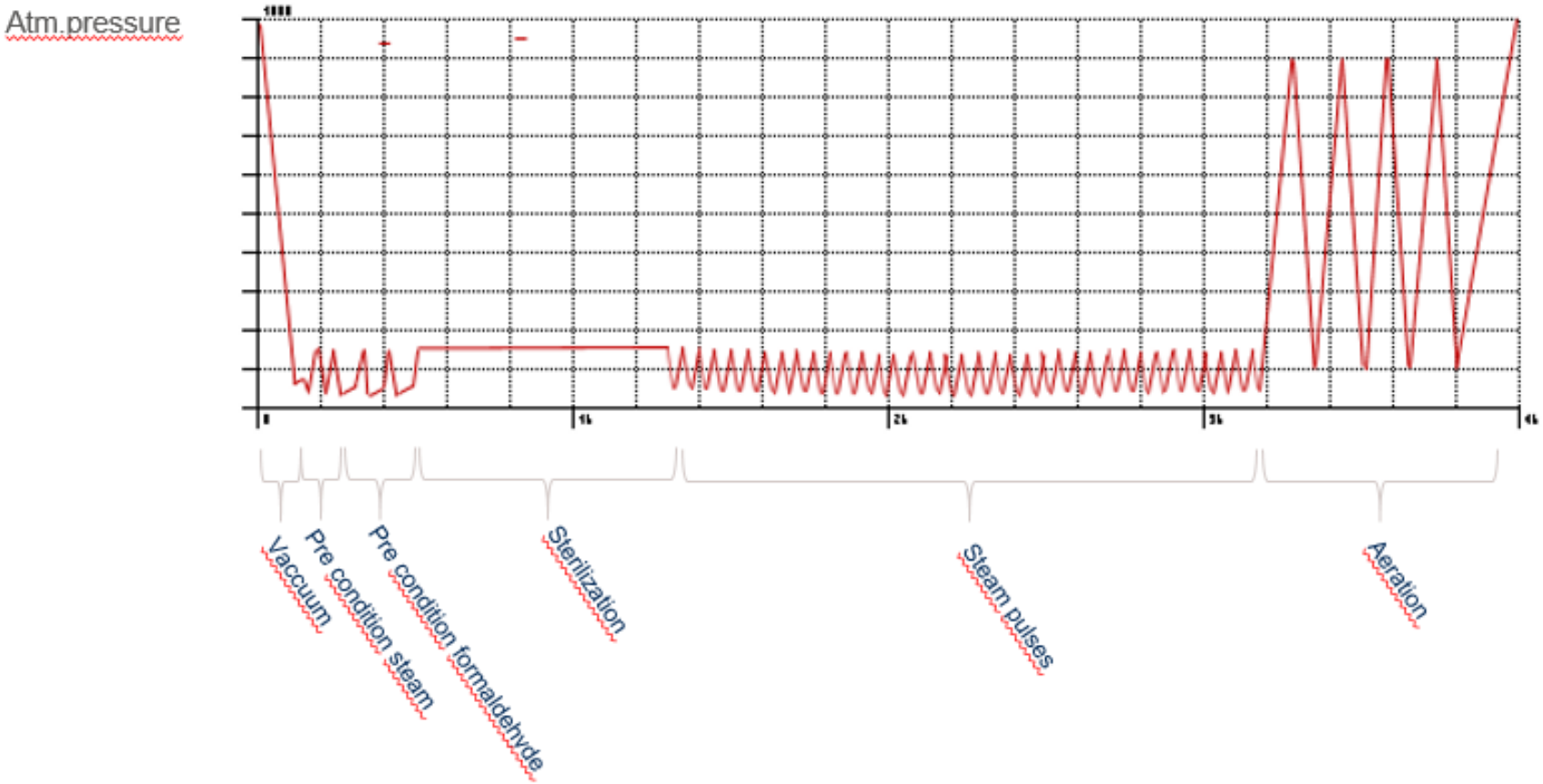
Formaldehyde & Steam





Formaldehyde & Steam

Formaldehyde Process (55º-80º)



Low Temperature Steam Formaldehyde

2 in

Low temp & high temp

134°C Steam
121°C
80°C Steam/FO
65°C
55°C

Safety

Typetested acc. to FO sterilizer norms

EN14180 Building and testing

EN25424 Development, validation and routine control

Material compatibility

Long lumen penetration & Non oxidizing

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Low Temperature Steam Formaldehyde

Steam

Formaldehyde

Steam & formaldehyde

1 2 in

Low Temperature Sterilizers

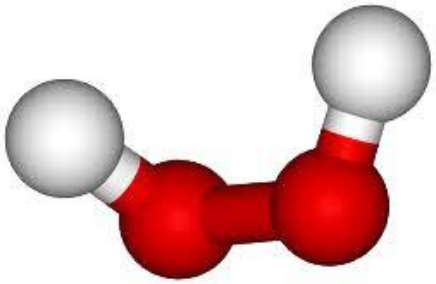
Hydrogen Peroxide & Plasma

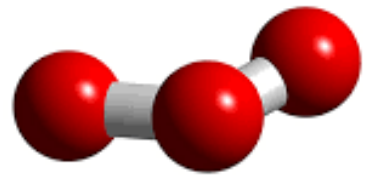
Hydrogen Peroxide & Ozone

Formaldehyde & Steam

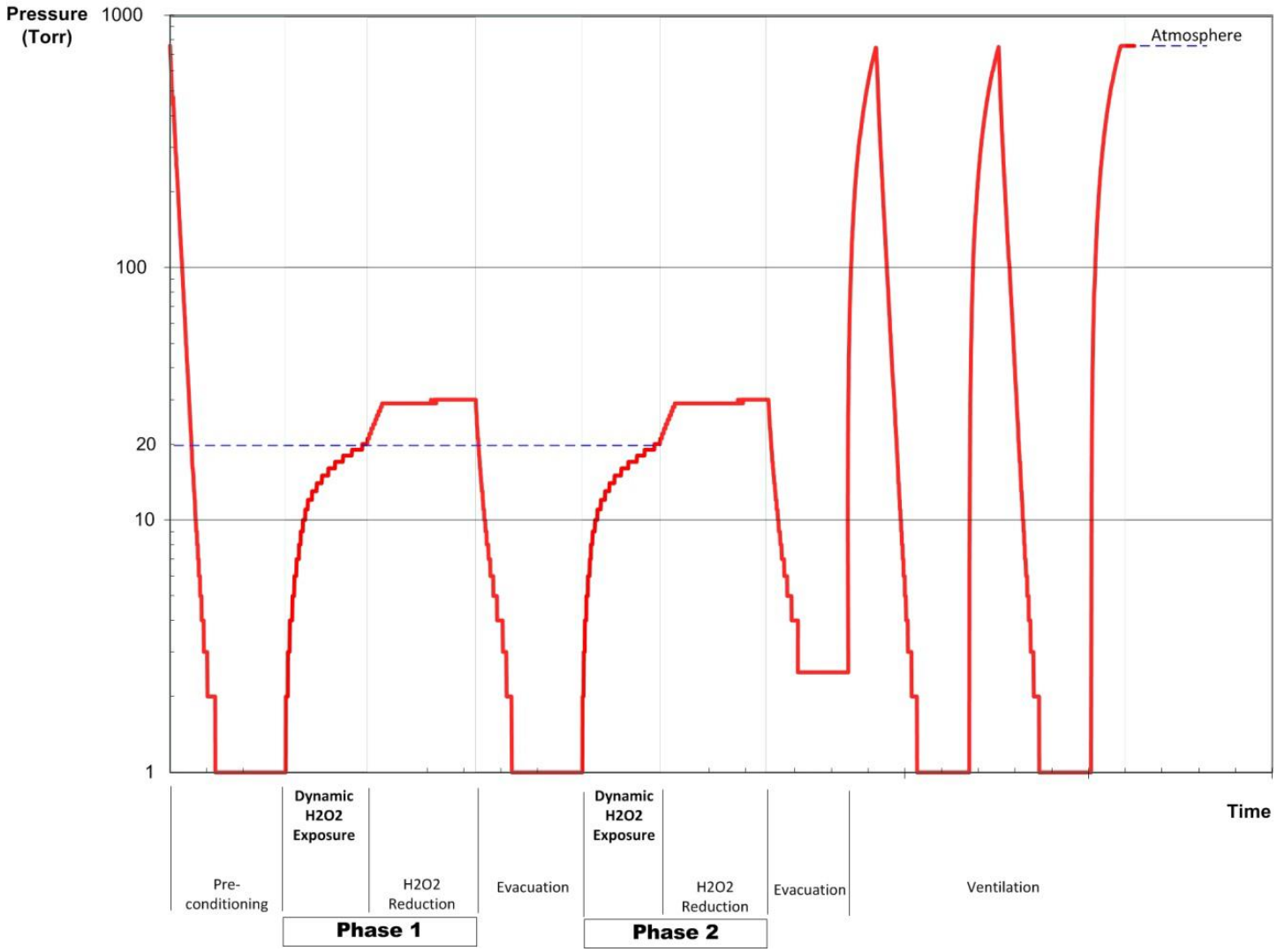
Hydrogen Peroxide & Ozone

Hydrogen Peroxide and Ozone





Process


Pressure (Torr)
1000
100
20
10
1
Atmosphere
Time
Dynamic H2O2 Exposure
H2O2 Reduction
Evacuation
Dynamic H2O2 Exposure
H2O2 Reduction
Evacuation
Ventilation
Pre-conditioning
Phase 1
Phase 2

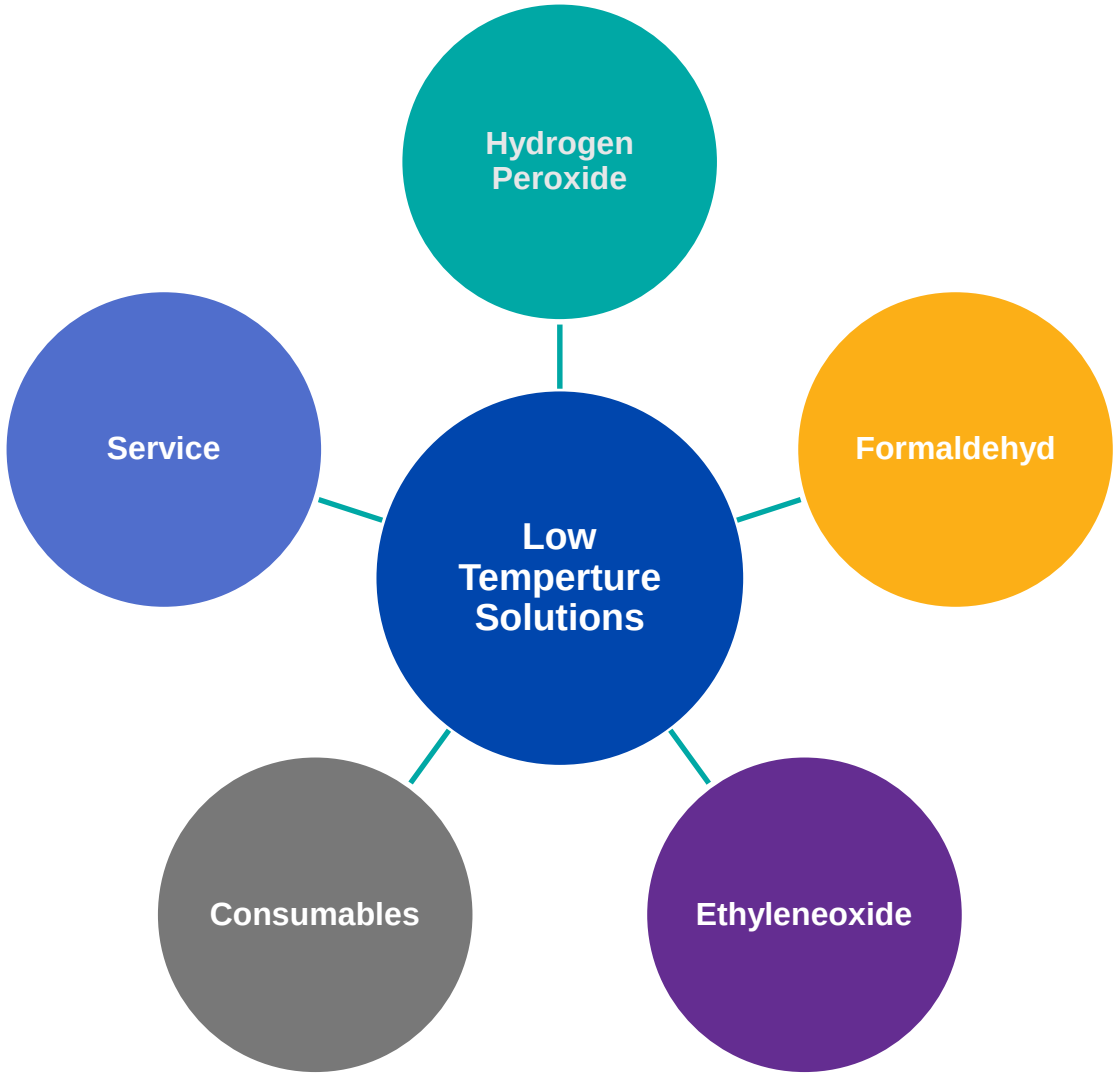
Low Temperature Sterilizers – TSO3

- ✓ First low temperature sterilizer with a “load sensing” Dynamic Sterilant Delivery System.
- ✓ First low temperature sterilizer with micro-condensation layer on device surfaces
- ✓ First “single cycle” low temperature sterilizer cleared to process a 34 kg load consisting of:
  - ✓General instruments
  - ✓Batteries, drills, cables, cameras
  - ✓Single channel flexible endoscopes
  - ✓Rigid and semi-rigid single and dual channeled devices including endoscopes.

**Note: long/multi-channel scopes are dedicated load, 1/cycle*

Low Temperature Sterilizers – TSO3

Cycle	Description	Inside Diameter	Length
Single Cycle (Cycle 1)	General surface surgery metal instruments, batteries, drills, cables, cameras, etc.	NA	NA
	Single channel flexible endoscopes	≥ 1.0 mm	≤ 850 mm
	Single & double channel flexible endoscope	≥ 1.0 mm	≤ 989 mm
	Rigid channel devices including single channel and double rigid channel endoscopes	≥ 0.7 mm ≥ 2.0 mm	≤ 500 mm ≤ 575 mm
	Multi-Channel flexible endoscope (Video colonoscope or gastroscope 4 channels total)*	≥ 1.2 mm ≥ 1.45 mm	≤ 1955 mm ≤ 3500 mm


Hydrogen Peroxide
Service
Low Temperture Solutions
Formaldehyd
Consumables
Ethyleneoxide

Questions & Answers

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PASSION FOR LIFE