LOW TEMPERATURE STERILIZATION AND HIGH TECH MEDICAL DEVICES

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A definition

- Sterilization:
  - validated process used to render a product free from viable microorganisms (ISO 14937)
- Low temperature:
  - relating to or carried out at very low or relatively low temperatures (Webster's)
- Low temperature sterilization
  - rendering a product free from viable microorganisms at relatively low temperatures But how low is low?

Why is a definition not helpful?

Necessary for devices…

… that can't tolerate steam

- … that can't withstand temperature
- … that can't withstand pressure variations

Important to know which are the limiting parameters!

Medical device compatibility

- For reusable medical devices, ‘compatibility’, is intended to demonstrate that the device will remain functional after repeated use and perform for a useful life.
- ‘Compatibility’ does not mean the same as ‘sterility’
- ‘Compatibility’ does not mean the device will function continuously at the same level, regardless of the cleaning or sterilization process chosen forever.
- A ‘compatible device’ list does not always mean the device has been validated by the device manufacturer. Checking with the device manufacturer is necessary to be sure of this if a process is not in the IFU’s

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Low temperature processes – a comparison of common EU available types

Process	3M 5XL	Matachana 130LF	TSO_3 125L	Andersen EOGas Series 4	ASP STERRAD 100NX	Steris V-PRO MAX
Temperature °C	37/55	52/60/78	30-36	30/50	55	50
Cycle time	3-5.5 Hrs +Aeration	1-3 Hrs	4.5 Hrs	3.5-24 Hrs	24-47 Mins	28 – 55 Mins
Agent	100% Ethylene Oxide	2% Formaldehyde + steam	Ozone	100% Ethylene Oxide	59% Hydrogen Peroxide vapour with Gas Plasma as a reduction agent	59% Hydrogen Peroxide vapour
Unpleasant odours?	No	Yes	Yes	No	No	No
Effect on humans	Toxic, Carcinogenic, Mutagenic	Toxic, Carcinogenic	Radiomimetic agent	Toxic, Carcinogenic, Mutagenic	Exposure limits set although not listed as a carcinogen	Exposure limits set although not listed as a carcinogen
Other limitations	Needs aeration. Sometimes ETO residue in items even after aeration	Paraformaldehyde formation. Protein fixative	Ozone concentration can be difficult to measure	Needs aeration. Sometimes ETO residue in items even after aeration	Material contraindications and non-cellulose wraps must be used.	Material contraindications and non-cellulose wraps must be used.

HIGH TECH DEVICES

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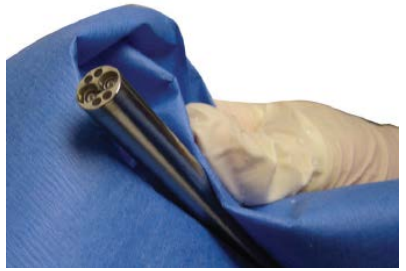
Robotic Surgery

DaVinci System – most common type in EU use:

- Approximately 570,000 da Vinci® procedures performed in 2014, up 9% from 2013 – First half 2015 procedures up approximately 13%
- 3,398 da Vinci® System installed base as of 6/30/15 with 573 in Europe
- Complex invasive devices requiring sterilization
- Some parts are heat labile and temp change sensitive



Robotic Surgery

THE LEAD: GOOGLE TO MAKE SURGICAL ROBOTS IN DEAL WITH J&J

Google's newest push into health care technology involves surgical robots, a partnership with a pharmaceutical giant and competition with one of Silicon Valley's largest medical-device companies.

Richard Juarez assembles a patient side manipulator that will be a component of a da Vinci Surgical System at the headquarters and manufacturing plant of Intuitive Surgical in Sunnyvale, Calif. on Friday, Aug.10, 2012. (Gary Reyes/Staff)

Google and a Johnson & Johnson unit announced Friday that they will be working together to make robots that can assist in surgeries, a strategic collaboration with no price tag announced. The aim of the project appears to be similar to the da Vinci robots manufactured and sold by Sunnyvale's Intuitive Surgical, the third largest public Silicon Valley company in the biotech/health care sector.

https://www.youtube.com/watch?v=-jm63JdTrp4

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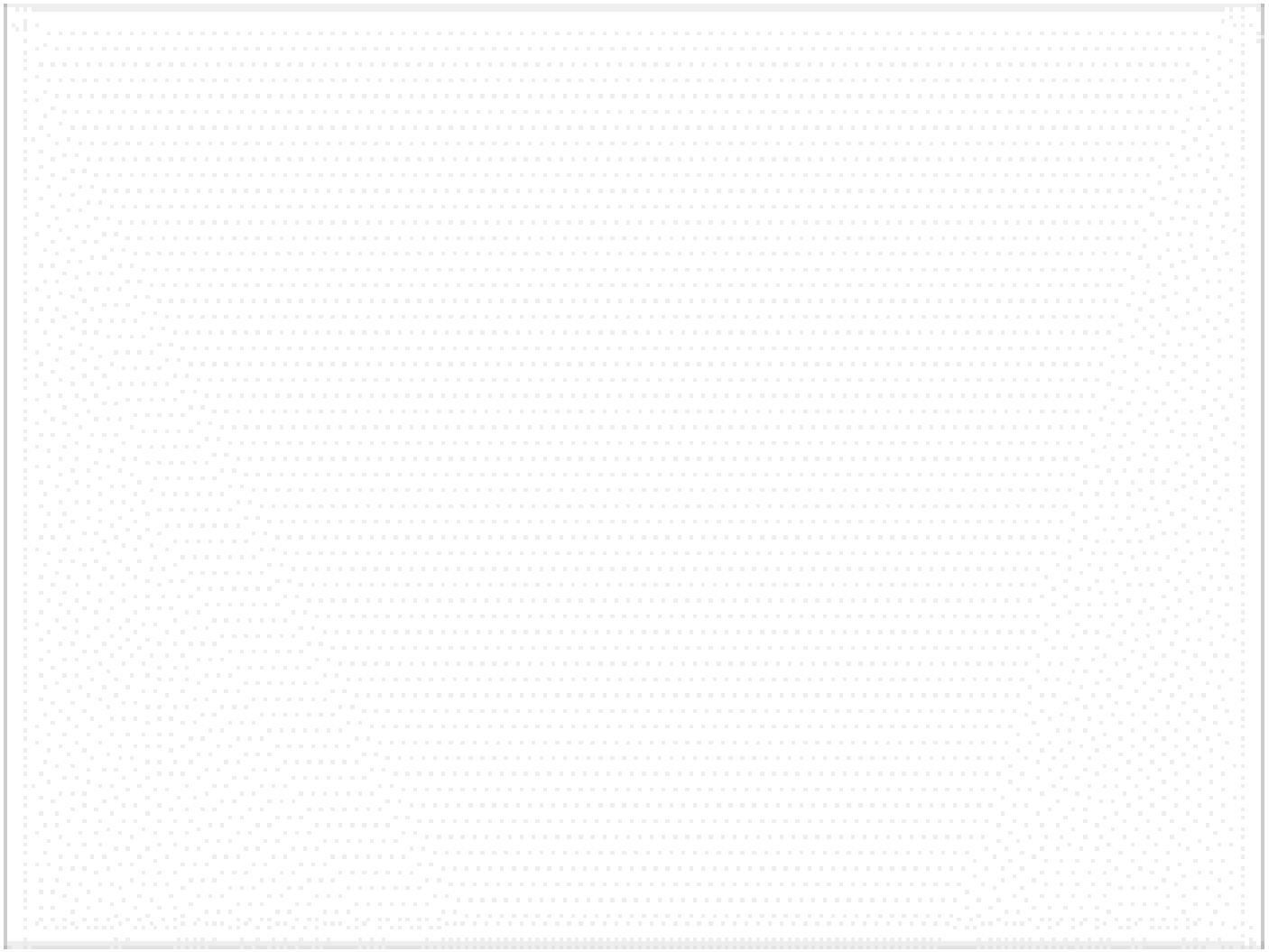
Robotic Single Entry Surgery



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Robotic Surgery

5.6.3 Wrap and Sterilize

Wrap the tray using a sterilization wrap that has appropriate regulatory approval for the sterilization parameters used in the STERRAD 100NX Express Cycle or the STERRAD 100S Short Cycle.

Select the packaging material according to BS EN ISO 11607-1:2009 or AAMI/ISO 11607-1:2006(R)2010.

The endoscope should be stored in a sterilized container with suitable retainers so that it is protected against shocks and slippage. The packaging must be approved according to BS EN ISO 11607-1:2009 or AAMI/ISO 11607-1:2006(R)2010.

⚠ **CAUTION:** Use only the indicated sterilization machines and cycles. Any other cycles have not been validated and may damage the endoscope.

⚠ **CAUTION:** Do not autoclave *Intuitive Surgical* endoscopes. Autoclave cycles introduce high temperatures and sudden temperature changes, which will damage the endoscope.

	 5 mm Endoscope	●		●	●†	●
da Vinci Si	 8.5 mm Endoscope		●	●	●†	●
	 12 mm Endoscope		●	●	●†	●

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BK Ultrasound ProART

Designed to be used in robotic-assisted surgery, ProART™ curved linear array drop-in transducer enables intra-operative imaging for faster kidney navigation and difficult-to-access tumours. Its specially-designed fin ensures maximum control and organ contact. Built for durability it has a Kevlar-reinforced cable.

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Validated Reprocessing Methods for the Fle Transducer Series

Validated Reprocessing Methods		Intraoperative									
		8666-RF	8809	8814	8815	8816	8824	8826	8836	8862	8863
Manual Cleaning[a]	3E-Zyme	•	•	•	•	•	•	•	•	•	•
Manual Disinfection[a]	Korsolex Basic	•	•	•	•	•	•	•	•	•	•
	Ethanol 70% (wiping)	•	•	•	•	•	•	•	•	•	•
	Revital-Ox Resert/Resert XL HLD			•	•	•		•	•	•	•
	Tristel Fuse For Instruments		•	•	•	•	•	•	•	•	•
Automated Disinfection[a]	Medivators Advantage Plus Intercept (detergent), Rapicide PA Disinfectant, flush: 70% isopropyl alcohol			•	•	•	•				•
Sterilization[a]	STERIS System 1[a], 1E, 1 Plus[a] and 1 Express1[b]	•	•	•	•	•	•	•	•	5	5
	STERIS V-Pro 1, 1 Plus, V-Pro maX *Standard cycle*	•		•	•	•	•	•	•	•	•
	STERIS V-Pro 60 *Non Lumen cycle*	•		•	•	•	•	•	•	•	•
	Sterrad NX & 100NX *Standard cycle*	1	2	3	3	3	3	•	•	4	4
	Sterrad 100S *Standard cycle (USA),* *Short cycle (rest of the world)*	•	•	•	•	•	•	•	•	•	•

fected before use. A transducer that is used
rilization is not possible, it must be
ion and then covered with a sterile
s of disinfection and sterilization in *Care,*

c surgery because the covers may be
r use in robotic surgery, the transducer

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Semi-rigid micro-endoscopy by PolyDiagnost

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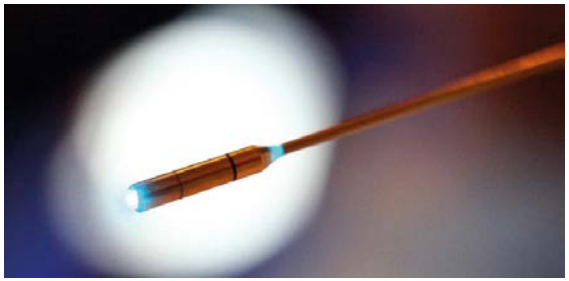
Semi-rigid micro-endoscopy by PolyDiagnost

	Semi-rigid optic with protective tube in the sterilisation tray	Handles, shifters
ETO gas sterilisation (55 °C to max. 60 °C)	X	X
Low-temperature plasma sterilisation: STERRAD® 100S	X	X
Steam sterilisation (autoclaving) 121 °C, 20 min (max. 124 °C)		X
Steam sterilisation (autoclaving) 132 / 134 °C, 5 min (max. 137 °C)		X

Cellvizio Miniprobe Microscope

- Area of interest is identified during endoscopic procedure. A Cellvizio miniprobe is introduced into the working channel of an endoscope
- The miniprobe appears on an endoscopic image and is positioned in contact with the mucosa
- A Cellvizio video is displayed in real-time. As many relevant Optical Biopsies as appropriate are recorded and saved



Published literature on cost savings

- Work undertaken by both Weber (Weber, 2009) and Schafer (Schafer, 2009) in Germany demonstrated savings in telescope repair costs
- Weber's stated that he was able to provide historical repair costs using two low temperature processes (ETO and STERRAD) versus steam
- Both low temperature processes showed considerably lower telescope repair costs than using steam, with the STERRAD system showing lowest of all
- The Schafer paper showed a 33% saving on repair costs when using a H_2O_2 process.
- Hospitals in the UK who have taken a similar approach to rigid endoscopes have anecdotally reported similar results.

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Benefits of LT Sterilization

- Terminal process so sterility can be maintained for extended storage periods near point of use (such as on airways trolleys) and beyond active storage cabinet limitations
- Practical aspects – devices that would otherwise be disinfected are available for use in emergency situations in the right state and are transportable without compromising sterility
- Some devices clearly indicate a need for sterilization due to the critical classification and we need that “sterility assurance” even if they cannot be steam sterilized
- Usually gentle processes in terms of thermal shock and pressure change
- Most have low services demand without the need for steam or air connections
- Some types (specifically H_2O_2 systems) have been shown to be “kinder” to telescopes with less frequent damage

But remember some wise words:

"We are stuck with technology when what we really want is just stuff that works."
Douglas Adams (Author)

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