Avdeling for smittevern

Robotkirurgi
Rengjøring og sterilisering av utstyr

Smittevernforum 18. oktober 2022

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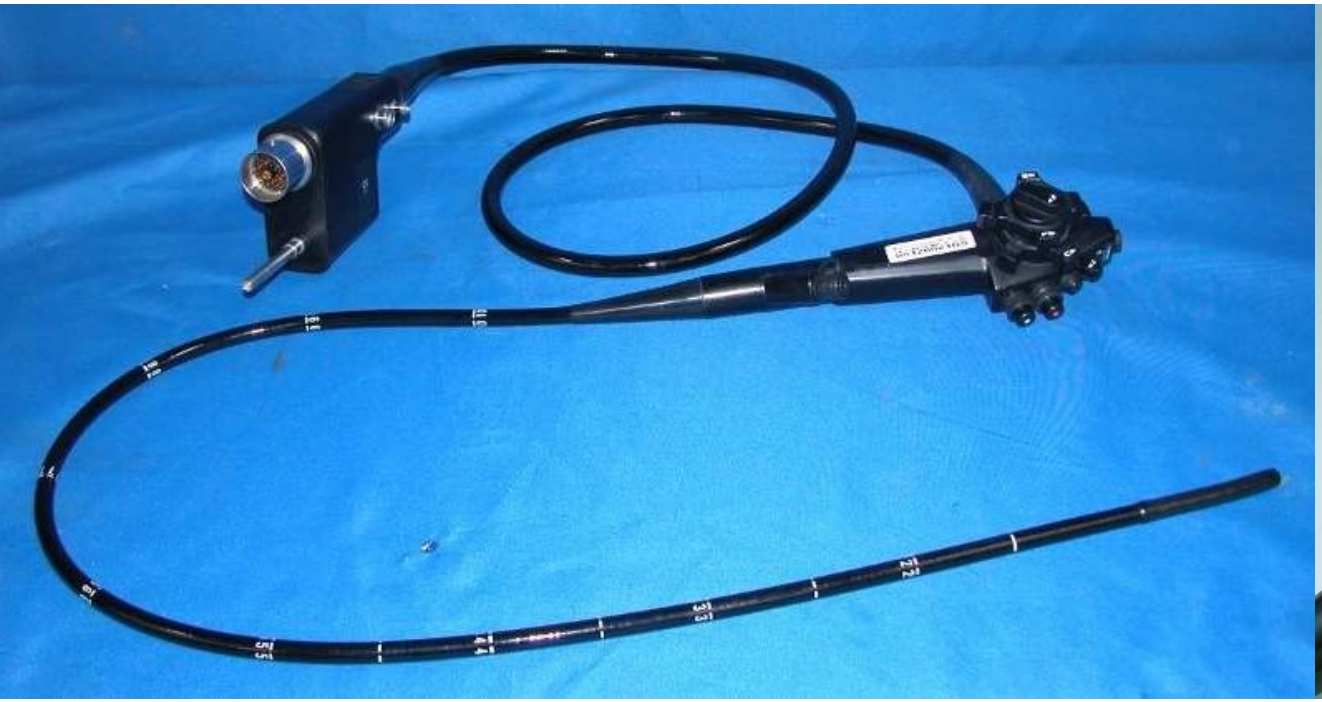
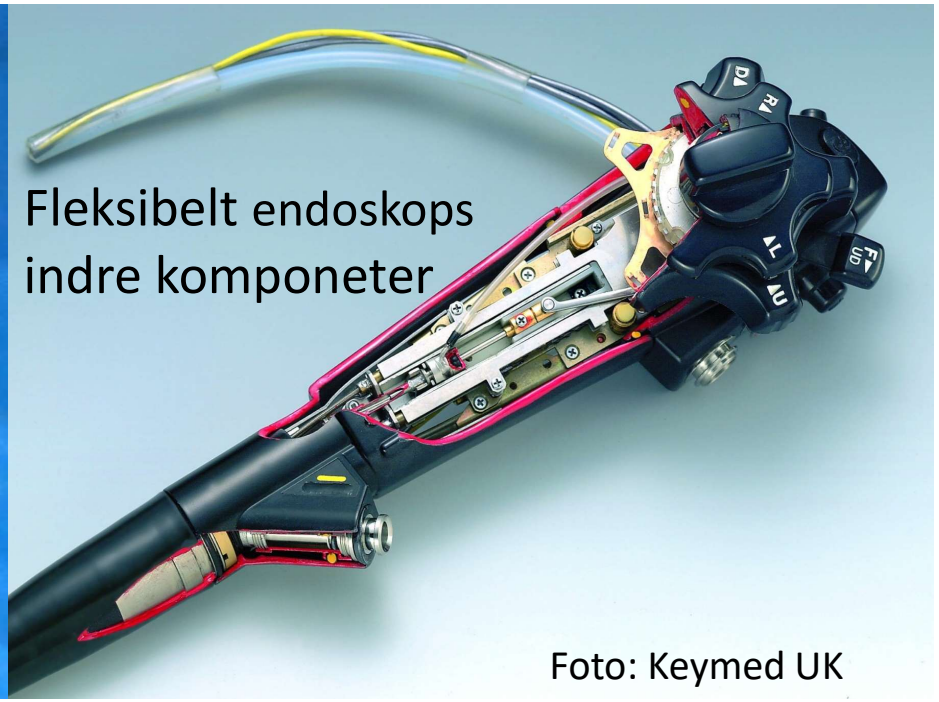
Avdeling for smittevern
Oslo universitetssykehus

Utstyret fra helvete ….





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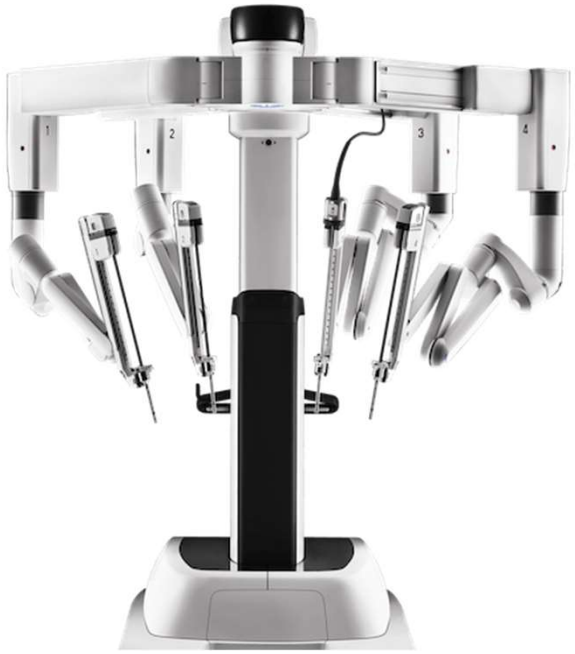

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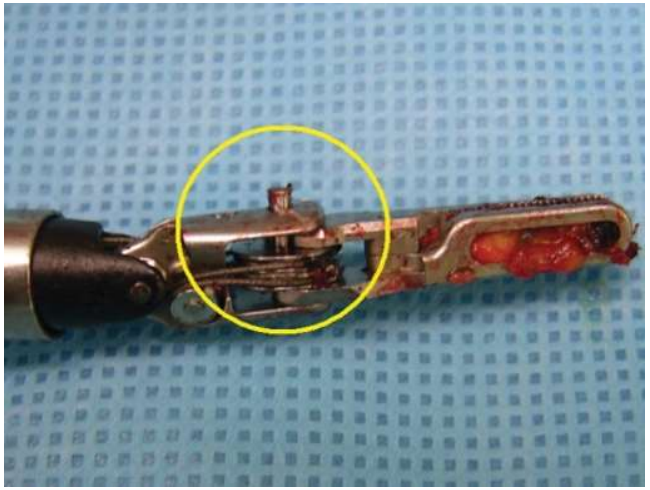
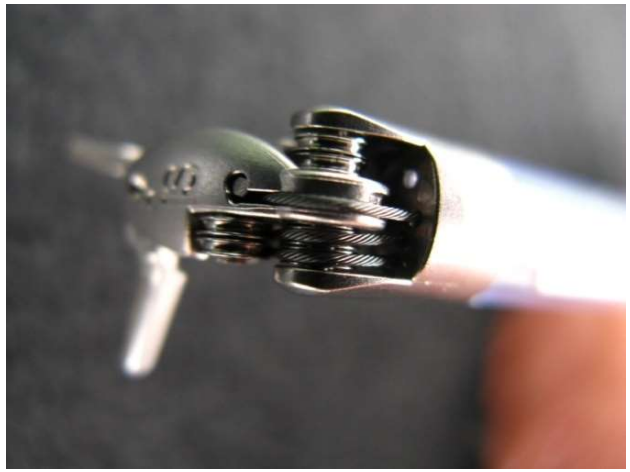
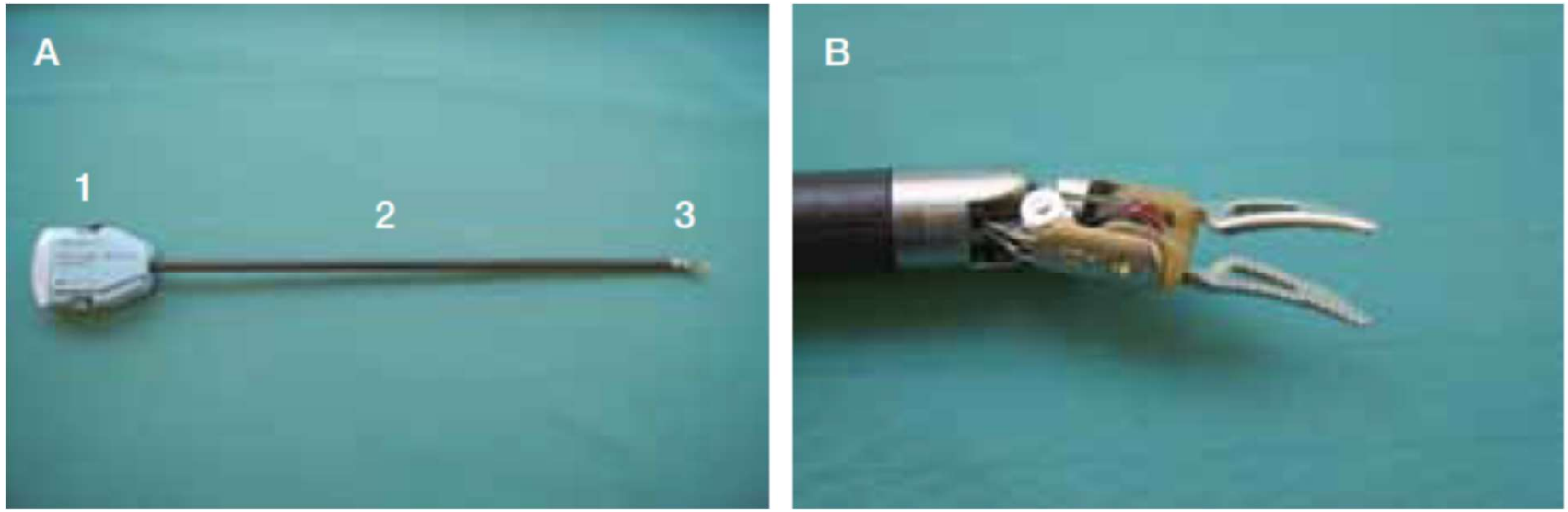


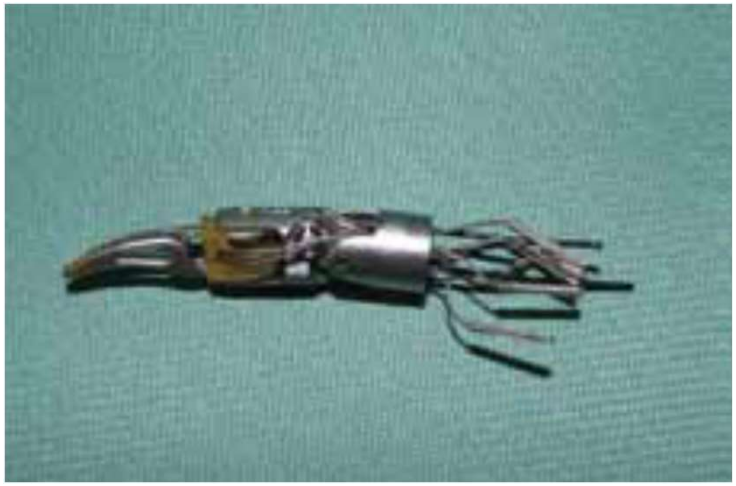

LARGE NEEDLE DRIVER
Validierung

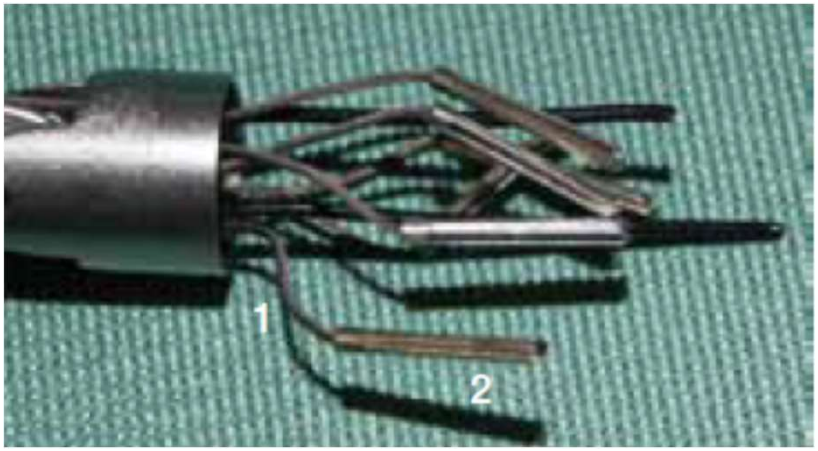




Maryland Bipolar Forceps (MBF) as an example of a robotic instrument.
1A: Overall view with 1: Casing, 2: Shaft, 3: Distal working end.
1B: Detailed shot of the distal end with soil on the guide rollers.

Wehrt M, Michels W. Zentral Service 2013




1
2

Problemet:

- Svært komplekse instrumenter
- Tynne vaiere som går over små trinser
- Trange lumen
- Begrenset mulighet for visuell inspeksjon
- Omfattende manuelle rengjøringstrinn
- Ikke alle proteinteter kan brukes (wolfram)

Kritiske punkter

- Nøyaktig etterlevelse av brukermanual for aktuelle modeller av utstyret
- Omhyggelig manuell forbehandling
- Holde instrumentene fuktige
- Validert vaskedekontaminator (for robotinstrumenter)
- Maks 60 minutter til start av maskinell dekontaminering
- Ultralyd

A method for testing the cleaning efficacy of MIS robotic instruments

M. Wehrl[1], W. Michels[2]

EndoWrist® Instrument and Accessory Cleaning and Sterilization Compatibility Matrix

NOTE: For complete cleaning and sterilization instructions, precautions and warnings, refer to the Reprocessing Instructions (PN 550875), of which this wall chart is a subset, or to the applicable Instructions for Use.

		Cleaning					Disinfection[5]		Sterilization				
		Enzymatic Cleaning (pH-Neutral)	Ultrasonic Bath[2]	*da Vinci SonicPro* (For U.S. only)	Medisafe SI PCF System	Medisafe Niagara SI System (Not available in the U.S.)	Thermal	Chemical	Autoclave (Pre-vacuum)	STERIS System 1E[6], V-PRO 1, V-PRO 1 Plus	STERRAD 50, 100S, 200	STERRAD 100NX Express Cycle[8]	EtO
Instrument Accessories	 *EndoWrist*® Instruments	●	●	●[3]	●[3]	8 mm instruments only	◆[4]		●				
	 Instrument Arm Cannula and Cannula with Outlet	●	●	●[3]			◆[4]		●				
	 Obturator/Reducer	●	●	●[3]			◆[4]		●				
	 Instrument Sterile Adapter[1]	●	●	●[3]			◆[4]		●				
	 Instrument Arm Cannula Holder[1]	●	●	●[3]			◆[4]		●				
	 PK Instrument Cords	●					◆[4]		●[7]		●[7]		
	 Wrench, Emergency Grip Release	●	●				◆[4]		●				
	 *Snap-Fit* Instrument Blade Protector and Reusable Insertion Tool	●	●				◆[4]		●				
	 *EndoPass* Delivery Instrument Blank Cartridge	●	●	●[3]			◆[4]		●				
Endoscopes	 *da Vinci* and *da Vinci S* 8.5 mm and 12 mm Endoscope	●						●		●	●	●[8]	●
	 *da Vinci* and *da Vinci S* 5 mm Endoscope	●						●	●		●	●[8]	●
	 *da Vinci SI* 8.5 and 12 mm Endoscope	●						●		●	●	●[8]	●
Vision Accessories	 *da Vinci* and *da Vinci S* Light Guide Cable	●					◆[4]		●				
	 *da Vinci* and *da Vinci S* Light Guide Cable Adapter	●	●				◆[4]		●				
	 *da Vinci* and *da Vinci S* Camera Arm Sterile Adapter	●	●	●[3]			◆[4]		●				
	 *da Vinci* and *da Vinci S* Camera Sterile Adapter	●	●	●[3]			◆[4]		●				
	 8.5 mm Endoscope Cannula	●	●	●[3]			◆[4]		●				
	 Endoscope Cannula Mount[1]	●	●	●[3]			◆[4]		●				
	 Endoscope Alignment Target	●	●	●[3]			◆[4]		●				

Equipment Parameters

Ultrasonic Bath

Power Density = 48 watts/gallon or greater (ultrasonic power output / internal tank volume)

Ultrasonic Frequency = 38kHz or greater

Sterilization Parameters

EtO Sterilization

Temperature: 55 ± 2 °C

Relative Humidity: 70 ± 5%

Set Pressure Point: 25.4 PSIA

Ethylene Oxide Concentration: 600 ± 30mg/L

Gas Exposure Time: 2 hrs.

Detoxification Time: 0 hrs.

Aeration: 12 hrs. at 55 ± 2 °C

Autoclave

Cycle: Pre-vacuum

Temperature: 270–272 °F (132–134 °C)

Minimum Exposure Time for the U.S.: 4 min.

Minimum Exposure Time for countries following European guidelines: 3 min.

Dry Time: 20 min.

WARNING: The use of "flash" sterilization is not recommended.

WARNING: Do not sterilize at temperatures over 285 °F or 140 °C.

Disinfection Parameters

Chemical

The following methods are compatible with endoscope disinfection:

Cidex®	Helpur® H plus N
Cidex® OPA	Gigasept® FF

NOTE: The methods of sterilization and the parameters listed are the manufacturers' recommendations. Sterility is the responsibility of the person/institution performing sterilization.

Legend

- ● Validated for efficacy (i.e. process achieves expected cleaning/sterilization results) AND compatibility (i.e. process doesn't damage the product).
- ◆ Only validated for compatibility (i.e. process doesn't damage the product). Efficacy is not established.

1 For *da Vinci* System only.
2 Refer to Ultrasonic Bath Equipment Parameters listed at upper right.
3 Refer to the validated list of instruments for *da Vinci SonicPro* and Medisafe SI PCF/Niagara SI System on www.intuitivesurgical.com.
4 Thermal disinfection through washer/disinfector system *only*.
5 This is an optional step. All Intuitive Surgical reusable product must be sterilized prior to patient use. The hospital policy and regional guidelines should dictate whether the product must be disinfected after cleaning and prior to sterilization.
6 STERIS system 1E is a liquid chemical sterilant processing system cleared by FDA under special usage guidelines. Please contact STERIS Inc. for complete details.
7 Not validated with STERRAD 50 or 200. Refer to specific sterilization parameters for PK instrument cords in Reprocessing Manual (P/N 550875) for complete details.
8 Contact Advanced Sterilization Products (ASP) for availability in your region.

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 550721-03 Rev B

Hva er kravene i andre land?

- Storbritannia

Retningslinjer og krav til renhet

Europeisk og internasjonal standard

NS-EN ISO 15883-5:2021

Grenseverdiene er beregnet på dokumentasjon av rengjøringseffekten til en vaskedekontaminator for invasivt utstyr:

Alarmgrense: < 3 µg /cm^2

Aksjonsnivå: > 6.4 µg /cm^2

Tyskland

- **Robert-Koch Institut (RKI)** fra 2012 anbefaler en øvre grenseverdi på 100 µg protein per instrument (teoretisk risikoanalyse)

Retningslinjer forts.

Storbritannia

- **Health Technical Memorandum 01-01 (HTM)**, kravet er 5µg BSA (Bovint serum albumin) ekvivalent per instrumentside.
- For nevrokirurgiske instrumenter er kravet lavere, uten at dette er nærmere angitt.

Danmark

- **Nationale infektionshygiejniske retningslinjer (NIR)** for genbehandling af steriliserbart medicinsk utstyr 2019, angir grenseverdi for proteiner på rengjorte kirurgiske instrumenter: max. 100 µg per instrument».

Østerrike

- Etter manuell rengjøring I henhold til produsentens anbafalinger skal proteinmengden på den distale enden av hvert eneste instrument før vask i vaskedekontaminator
- Grenseverdi etter manuell rengjøring: **50 µg/ tupp**
- Hvis over grenseverdi: manuell omvask

Østerrike

- Deretter umiddelbar vasking i vaskedekontaminator med spesifikk innsats for robotinstrumenter
- Akseptkriterier etter vaskedekontaminator (før sterilisering): **20 µg/ tupp** (skal sjekkes ukentlig)

Norge

Ingen nasjonal retningslinje

Produsentens anbefalinger følges

Pilotprosjekt på OUS
(Eivind Espeland, Line Nateland, Linda Ashurst)