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2024 WEBINAR SERIES #5
MEDICAL DEVICES BACK TO THE REPROCESSING: FUTURE

EVOLUTION OF URO-GENITAL MD REPROCESSING



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4th WEBINAR

INTRO

HISTORICALLY STANDARDS USED TO DECONTAMINATE FLEXIBLE ENDOSCOPES HAVE PROMOTED HIGH LEVEL DISINFECTION AS THE ACKNOWLEDGED LEVEL. THIS STANDARD HAS ALSO INCLUDED ENDOSCOPES AND MEDICAL DEVICES USED IN THE PROVISION OF DIAGNOSTIC SERVICES USED WITHIN URO-GENITAL HEALTHCARE. SHOULD WE BE LOOKING AT DIFFERENT LEVELS DEPENDENT ON THE HIERARCHY OF RISK? ARE RISKS APPROPRIATE AND WHERE IS THE EVIDENCE OF HARM WITHIN THE URO-GENITAL FIELD?

SHOULD WE DETERMINE THE LEVEL OF DECONTAMINATION BASED UPON CLINICAL CONSEQUENCE AND IS THE CURRENT GUIDANCE ILLUSTRATED WITHIN SPAULDING OUTDATED? SHOULD WE LOOK AT DIFFERING STANDARDS OF DECONTAMINATION FOR 'HIGHER RISK' DEVICES SUCH AS URETEROSCOPES AND CYSTOSCOPES?

Are we doing enough to overcome known issues utilising such devices for patient activity?

Does this knowledge make us more accountable?

SHOULD WE EVOLVE INTO UTOPIA, 'STERILIZATION OF ENDOSCOPES'? DO WE UNDERESTIMATE THE RISK WHEN DECONTAMINATING SUCH MEDICAL DEVICES.



ARE RISKS APPROPRIATE AND WHERE IS THE EVIDENCE OF HARM USING ENDOSCOPES WITHIN THE URO-GENITAL FIELD?



IMAGE SOURCE: https://www.olympus.com.au/medical/rmt/media/Content/-Content-MSD/Images/Product-Images/570-x-570/bronchovideoscope-bf-xt190-53214_ProductHero_GalleryThumb_352.png

POLICY FOR THE LOCAL DECONTAMINATION OF REUSABLE EQUIPMENT ACCORDING TO THE SPAULDING CLASSIFICATION

Risk category	Recommended level of decontamination	Examples of medical devices
HIGH (CRITICAL) ITEMS THAT ARE INVOLVED WITH A BREAK IN THE SKIN OR MUCOUS MEMBRANE OR ENTERING A STERILE BODY CAVITY	STERILIZATION	SURGICAL INSTRUMENTS, IMPLANTS/PROSTHESES, RIGID ENDOSCOPES, SYRINGES, NEEDLES
INTERMEDIATE (SEMI-CRITICAL) ITEMS IN CONTACT WITH MUCOUS MEMBRANES OR BODY FLUIDS	DISINFECTION (HIGH LEVEL)	RESPIRATORY EQUIPMENT, NON-INVASIVE, FLEXIBLE ENDOSCOPES, BEDPANS, URINE BOTTLES
LOW (NON-CRITICAL) ITEMS IN CONTACT WITH INTACT SKIN	CLEANING (VISIBLY CLEAN)	BLOOD PRESSURE CUFFS, STETHOSCOPES

TYPES OF ENDOSCOPIC PROCEDURES

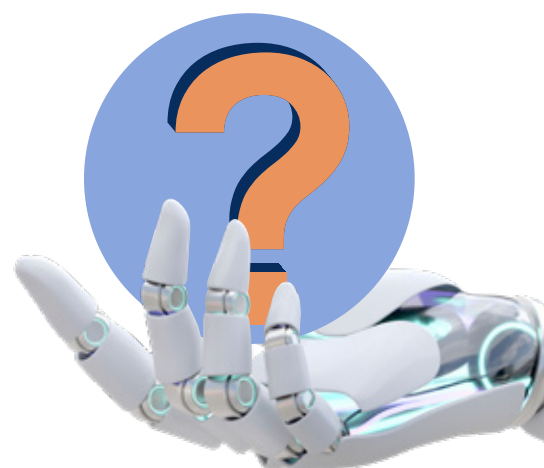
Types of endoscopes	Rigid endoscope example	Flexible endoscope example	Level of decontamination
INVASIVE - PASSED INTO NORMALLY STERILE BODY CAVITIES OR INTRODUCED INTO THE BODY THROUGH	ARTHROSCOPE LAPAROSCOPE CYSTOSCOPE	NEPHROSCOPE ANGIOSCOPE CHOLEDOCHOSCOPE	STERILIZATION BY STEAM OR A LOW TEMPERATURE METHOD E.G. GAS PLASMA
NON-INVASIVE -IN CONTACT BRONCHOSCOPE WITH INTACT MUCOUS MEMBRANE, BUT DOES NOT ENTER STERILE CAVITIES	BRONCHOSCOPE	GASTROSCOPE COLONOSCOPE BRONCHOSCOPE	HIGH-LEVEL DISINFECTION, E.G. IMMERSION IN GLUTARALDEHYDE, PERACETIC ACID, CHLORINE DIOXIDE

Source: WHO Guidelines for MD Decontamination & Reprocessing for Health-care Facilities (2016), Risk Assessment in Sterile Services, pag 22, Table 2

01. Endoscope, An everlasting problem?

HEALTHCARE HAS CHANGED SIGNIFICANTLY IN THE PERIOD SINCE SPAULDING WAS DEVELOPED, USE OF DIAGNOSTIC DEVICES, SUCH AS FLEXIBLE ENDOSCOPES, HAS BECOME A COMMON WHEN INVESTIGATING PATIENT AILMENTS. THE ABILITY TO VIEW AND TAKE BIOPSY RESULTS IN A FAST ASSESSMENT OF ILLNESS AND HOPEFULLY, RESULTING IN A BETTER PATIENT OUTCOME.

DEVICE MANUFACTURERS CONTINUE THE TECHNOLOGICAL EVOLUTION OF SUCH MEDICAL DEVICES. SUCH EVOLUTION PRESENTS BETTER PATIENT EXPERIENCES AND OUTCOMES, HOWEVER DO THEY COME WITH GREATER INFECTIONS RISKS? IS DECONTAMINATION CONSIDERED AS PART OF THIS DEVICE DESIGN? DO WE, AS AN INTERNATIONAL COMMUNITY, ADOPT INTERNATIONAL STANDARD OF PRACTISE OR DO WE INTERPRET RISKS TO DIFFERING LEVELS?



RISK

DIFFERENT TYPES OF FLEXIBLE ENDOSCOPES:

- OLONOSCOPES
- BRONCHOSCOPES
- GASTROSCOPES
- CHOLEDOCHOSCOPES
- DUODENOSCOPES
- URETEROSCOPES
- CYSTOSCOPES
- NEPHROSCOPE
- ENT SCOPES
- AND MORE!...

Image Ref -Flexible Ureterscopes
Olympus America
Medical – October 2024

SUCH EVOLUTION PRESENTS BETTER PATIENT EXPERIENCES AND OUTCOMES, HOWEVER DO THEY COME WITH GREATER INFECTIONS RISKS?



Are Device manufacturers instructions appropriate for decontamination or do they not promote the best practise?

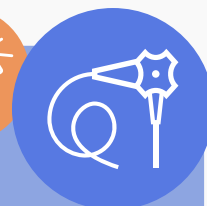
02.The evolution of Uro Genital Medical Devices

A UROLOGY ENDOSCOPY ALLOWS THE EXAMINATION OF THE URINARY TRACT USING A CAMERA ATTACHED TO A TUBE. THERE ARE TWO MAIN TYPES OF UROLOGIC ENDOSCOPY PROCEDURES:

- **Cystoscopy**
- **Ureteroscopy**

ONE OF THE MAJOR COMPLICATIONS OF A UROLOGIC ENDOSCOPY PROCEDURE CAN BE INFECTION. SUCH INFECTION CAN BE CAUSED BY MANY REASONS, BOTH EXOGENOUS AND ENDOGENOUS SOURCES. INAPPROPRIATE DECONTAMINATION CAN BE ONE OF THE PRIMARY SOURCES OF CROSS CONTAMINATION.

AS HEALTHCARE PROVIDERS WE MUST DO ALL WE CAN TO ENSURE DEVICES ARE REPROCESSED TO THE CORRECT STANDARDS. MANUFACTURERS INSTRUCTIONS PRESENT THE BASIC RECOMMENDATIONS FOR DECONTAMINATION; HOWEVER, THEY OFTEN DO NOT CONSIDER NATIONAL VARIATIONS, INTERPRETATIONS AND REQUIREMENTS.



INAPPROPRIATE DECONTAMINATION CAN BE ONE OF THE PRIMARY SOURCES OF CROSS CONTAMINATION.



• Cystoscopy

CYSTOSCOPY IS A PROCEDURE THAT ALLOWS YOUR DOCTOR TO EXAMINE THE LINING OF YOUR BLADDER AND THE TUBE THAT CARRIES URINE OUT OF YOUR BODY (URETHRA). A HOLLOW TUBE (CYSTOSCOPE) EQUIPPED WITH A LENS IS INSERTED INTO YOUR URETHRA AND SLOWLY ADVANCED INTO YOUR BLADDER.

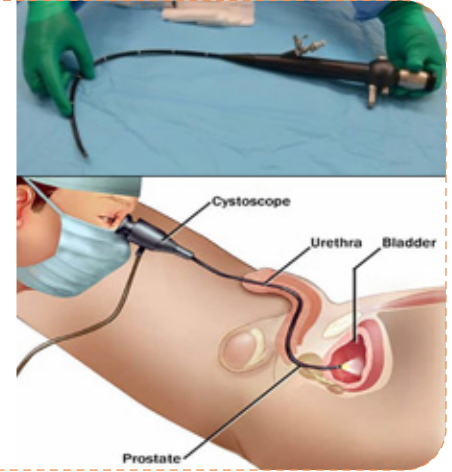
CYSTOSCOPY IS USED TO DIAGNOSE, MONITOR AND TREAT CONDITIONS AFFECTING THE BLADDER AND URETHRA. YOUR DOCTOR MIGHT RECOMMEND CYSTOSCOPY TO:

INVESTIGATE CAUSES OF SIGNS AND SYMPTOMS.

DIAGNOSE BLADDER DISEASES AND CONDITIONS.

TREAT BLADDER DISEASES AND CONDITIONS.

DIAGNOSE AN ENLARGED PROSTATE.



Source: 4 -Cystoscopy - Mayo Clinic (October 2024) - <https://www.mayoclinic.org/tests-procedures/cystoscopy/about/pac-20393694>, visited on 20241018

• Ureteroscopy

URETEROSCOPY IS A PROCEDURE TO ADDRESS KIDNEY STONES, AND INVOLVES THE PASSAGE OF A SMALL TELESCOPE, CALLED A URETEROSCOPE, THROUGH THE URETHRA AND BLADDER AND UP THE URETER TO THE POINT WHERE THE STONE IS LOCATED.

THE RATE OF INFECTIOUS COMPLICATIONS AFTER ENDOUROLOGICAL PROCEDURES IS STILL CONSIDERABLE AND ITS MANAGEMENT STILL CHALLENGING. **URINARY TRACT INFECTIONS (UTI) ARE NOW THE MOST COMMON COMPLICATIONS** AFTER URINARY STONE MANAGEMENT WITH SEVERAL SEVERE CLINICAL SCENARIOS, FROM POSTOPERATIVE FEVER (4.4%) TO UROSEPSIS (0.7%), **DESPITE ADEQUATE PERIOPERATIVE ANTIMICROBIAL PROPHYLAXIS.**

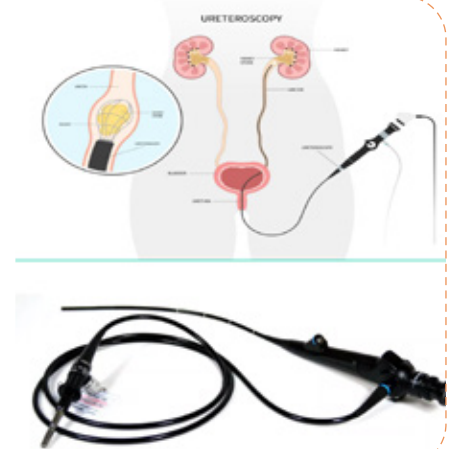


Image 1: <https://medical.lympusamerica.com/products/flexible-video-ureteroscopes>, visit on 2024/10/22

Image 2: Medfin (September 2024)

Source: Myths and realities: Infectious complications after endoscopic surgery of urinary stones, published on page 17 of the January/February 2020 edition of European Urology Today (EUT).

Link: <https://uroweb.org/news/myths-and-realities-infectious-complications-after-endoscopic-surgery-of-urinary-stones>, visited on 20241018

03. Show me the Evidence?

ARE OUR ASSUMPTION OF THE RISKS A REALITY? THAT'S AN ARGUMENT THAT IS OFTEN RAISED FROM CLINICAL TEAMS THAT MAY HAVE DIFFERING PRIORITIES (PATIENT RELATED MANAGEMENT). SHOW US THE EVIDENCE? ETHICALLY, IS IT INCORRECT NOT TO USE THE HIGHEST STANDARD OF DECONTAMINATION POSSIBLE?

THIS STUDY LOOKS AT SEVERAL HISTORICAL INCIDENTS THAT HAVE BEEN LINKED TO TRANSMISSION OF MICRO-ORGANISMS BETWEEN PATIENTS USING URO-GENITAL SCOPES. IN THESE INCIDENTS THERE ARE PROVEN LINKS TO DEVICES AS THE PRIMARY SOURCE OF THIS TRANSMISSION. SUCH INCIDENTS ARE PREVALENT ACROSS THE GLOBE, AND WE ASK, IS THE EVIDENCE PRESENTED THE TIP OF THE ICEBERG?

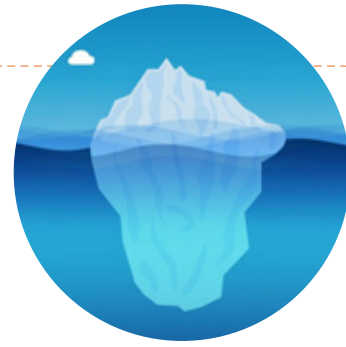
DO WE UNDERSTAND THE TRUE RISK AND THE CORRECT RATIO OF INFECTIONS BECAUSE OF DECONTAMINATION ACTIVITIES NOT BEING COMPLETED CORRECTLY?

DO WE UNDERTAKE ROUTINE SURVEILLANCE OF PATIENTS POST PROCEDURES?
DO WE MONITOR INTERNAL CONTAMINATION WITHIN SCOPES?



NEVER SAY
“
THAT WON'T
HAPPEN TO ME.
”

LIFE
HAS A FUNNY WAY OF
PROVING US WRONG.



Holistic strategy!
Can you see what is
under the tip of the
iceberg?

Source: <https://www.linkedin.com/pulse/holistic-strategy-can-you-see-what-under-tip-iceberg-nordahl>



ARE OUR ASSUMPTION
OF THE RISKS A REALITY?

*Is the Genie out of the
bottle? Evidence is
available to confirm the
infection risks, are we
doing enough to control?*

04. Developing New Systems:

SHOULD WE LOOK TO REDEVELOP OUR DECONTAMINATION SYSTEMS IN THE SAME WAY WE HAVE ADAPTED TO ROBOTIC SURGERY? MUST THE DEVICE MANUFACTURERS CONSIDER THE PRINCIPLES OF DECONTAMINATION AND PUT GREATER EMPHASIS ON DECONTAMINATION PROTOCOLS?

SHOULD WE WORK TOWARDS STERILIZATION, WHICH INCLUDES URO-GENITAL ENDOSCOPES? IS STERILIZATION ACHIEVABLE? WHAT ARE THE OBSTACLES, AND CAN WE OVERCOME OR IS IT A CULTURE?

ARE SINGLE USE DEVICES AN OPTION? WOULD THIS CONTRADICT NATIONAL SUSTAINABILITY DIRECTIVES?

*What do you want as a patient?
Single Use/Sterilized or Disinfected Device?*



Source: SE, 2019. Health Service Executive Standards and Recommended Practices for Operational Management of Endoscope Decontamination Facilities.
<https://www.hse.ie/eng/about/who/nqpsd/qps-improvement/hse-s-standards-and-recommended-practices-for-the-operational-management-of-edu-s-qpsd-d-082-1-v1.pdf>



SHOULD WE WORK TOWARDS STERILIZATION, WHICH INCLUDES
URO-GENITAL ENDOSCOPES?

Resume

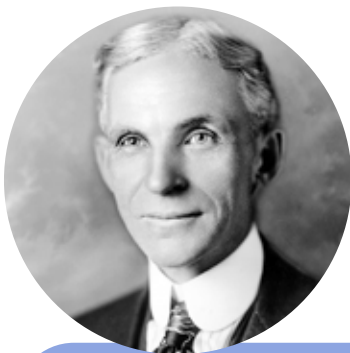
WE NEED TO DETERMINE THE RISK AND REACT APPROPRIATELY WITH PROCEDURE AND BIOBURDEN PRESENT WHEN USING URO-GENITAL ENDOSCOPES.

ADVANCEMENT IN URO GENITAL ENDOSCOPE TECHNOLOGY MUST INCLUDE BETTER DESIGNS (ROBUST) AND ENSURE DECONTAMINATION IS CONSIDERED AS PART OF DESIGN INNOVATION.

ADVANCEMENT IN REPROCESSING TECHNIQUES MUST BE CONSIDERED AND CHANGES ACCEPTED IN ACCORDANCE WITH EQUIPMENT AVAILABLE AND DEVELOPMENTS – EVOLUTION TOWARDS STERILIZATION MUST BE A PRIMARY CONSIDERATION.

USE OF SINGLE USE URO-GENITAL SCOPES SOLVE MANY OF THE ISSUES DISCUSSED IN CERTAIN AREAS OF HEALTHCARE, SINGLE USE DEVICE HAS MANY ADVANTAGES OVER RE-USABLE.

DOES SUSTAINABILITY DIRECTIVES PROVIDE AN OBSTACLE WHEN CHOOSING THE BETTER PATIENT OPTIONS? DECISION MAKING MUST BE BALANCED, AND ALL FACTS MUST BE ASSESSED WHEN CONSIDERING.

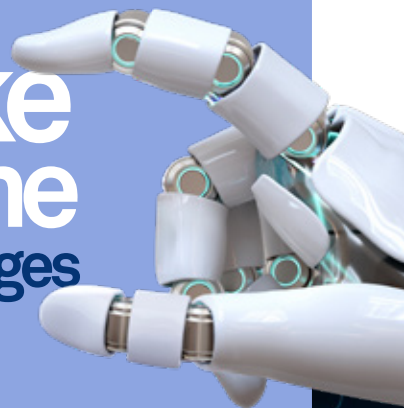


“If you always do what you’ve always done, you’ll always get what you’ve always got.”

Henry Ford

- 1 To conclude there are a combination of factors that can help reduce risks associated with Uro Genital endoscopic procedures (plus other types of endoscope).
- 2 Industry experts are now discussing whether Spaulding is appropriate within 2024.
- 3 We need to determine the risk and react appropriately with procedure and bioburden present.
- 4 Advancement in Uro Genital endoscope technology must include better designs (robust) and ensure decontamination is considered as part of design innovation.
- 5 Advancement in reprocessing techniques must be considered and changes accepted in accordance with equipment available and developments – Sterilization of reusables??
- 6 Sustainability and other factors are significant but must not be detrimental to patient safety.

**Take
home
messages**



References:

1. Dr. William Rutala, USA APIC 2016, SGNA 2017, AAMI 2017 | APIC Professional Advancement; Chapter 10 Review: Cleaning, Sterilization, Disinfection & Asepsis 2. Flexible ureteroscopes: a single centre evaluation of the durability and function of the new endoscopes smaller than 9Fr - PubMed (nih.gov) <https://pubmed.ncbi.nlm.nih.gov/10992358/>, visited on 20241018 3. Myths and realities: Infectious complications after endoscopic surgery of urinary stones, published on page 17 of the January/February 2020 edition of European Urology Today (EUT). Link: <https://uroweb.org/news/myths-and-realities-infectious-complications-after-endoscopic-surgery-of-urinary-stones>, visited on 20241018 4. Cystoscopy - Mayo Clinic (October 2024) - <https://www.mayoclinic.org/tests-procedures/cystoscopy/about/pac-20393694>, visited on 20241018 5. Dr. William Rutala, USA SGNA 2017 - Duodenoscopy and Endoscope Reprocessing: A need to shift from disinfection and sterilization

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