REPROCESSING ENDOSCOPES

In the Urology Unit

ASP Advanced Sterilization Products

IS IT Time For A Change?

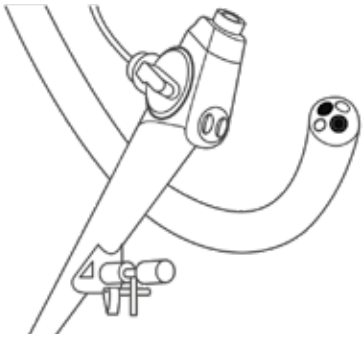
Urological endoscopic devices are used both semi-critically and critically (according to the Spalding Classification) and as such this can lead to confusion about the correct method of reprocessing

Sterilization would provide the highest standard of patient care, offer a more convenient reprocessing method, and can reduce the financial burden of healthcare-associated infections (HAIs) that can occur when disinfected devices are used critically

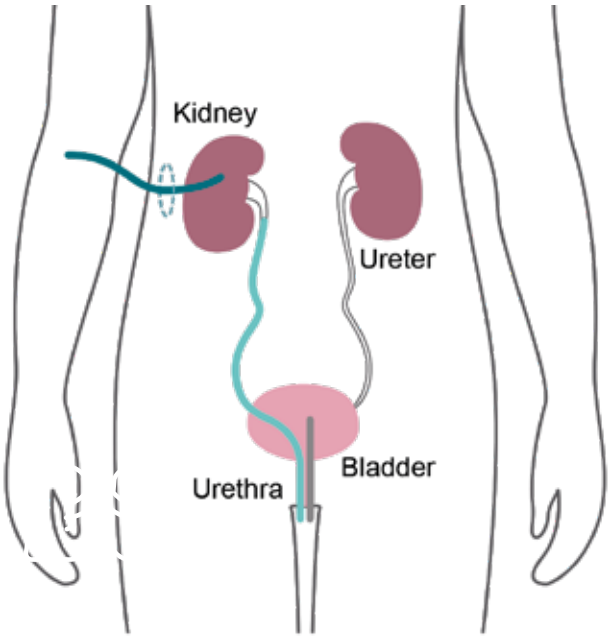
UROLOGY

is the medical specialty that is concerned with the function and disorders of the urinary or urogenital system

The urethra, bladder, ureter and kidneys, as well as the prostate gland in men



Nephroscopes, cystoscopes and **ureteroscopes** are key devices in urology that allow the physician to visualize and treat the area of interest.



These specialized endoscopes can be flexible or rigid, with surgeons deciding between the two depending on the exact procedure they are performing. **This factsheet will focus on flexible devices.**

Nephroscopes

Inserted into the kidney through a small abdominal incision (percutaneous nephrolithotomy ([PCNL]), and as such used critically

Used to remove stones from the chambers of the kidney

Ureteroscopes

Inserted through the bladder and into the ureter

Often used critially as substitutes for nephroscopes for PCNL[1]

Cystoscopes

Inserted into the bladder, via the urethra

Commonly used for removing bladder stones, or for treating bladder cancer

Often used critically instead of nephroscopes for PCNL[2]

Device Reprocessing

Urological endoscopes are reprocessed according to the Spaulding Classification

Semi-critical devices require a minimum of high-level disinfection (HLD)

Critical devices must be reprocessed by sterilization

This is problematic in urology since it is difficult for sterilization managers to know what procedure each urological device will be used for next, and therefore reliably determine the required level of reprocessing. This can lead to endoscopes that have only been reprocessed by HLD being used critically, putting patients at a preventable risk of infection.[3]

OPTIMIZING
PATIENT CARE

More HAIs have been linked to inadequately cleaned or disinfected endoscopes undergoing HLD, such as those used in urology units, than any other medical device.[4]

There have also been reports of flexible cystoscopes knowingly being used when not being reprocessed according to what their next use would require and therefore exposing patients to an unnecessarily high risk of infection.[3]

Case study

A multidrug-resistant NDM-1 Klebsiella outbreak from a contaminated endoscope camera head in the urology unit

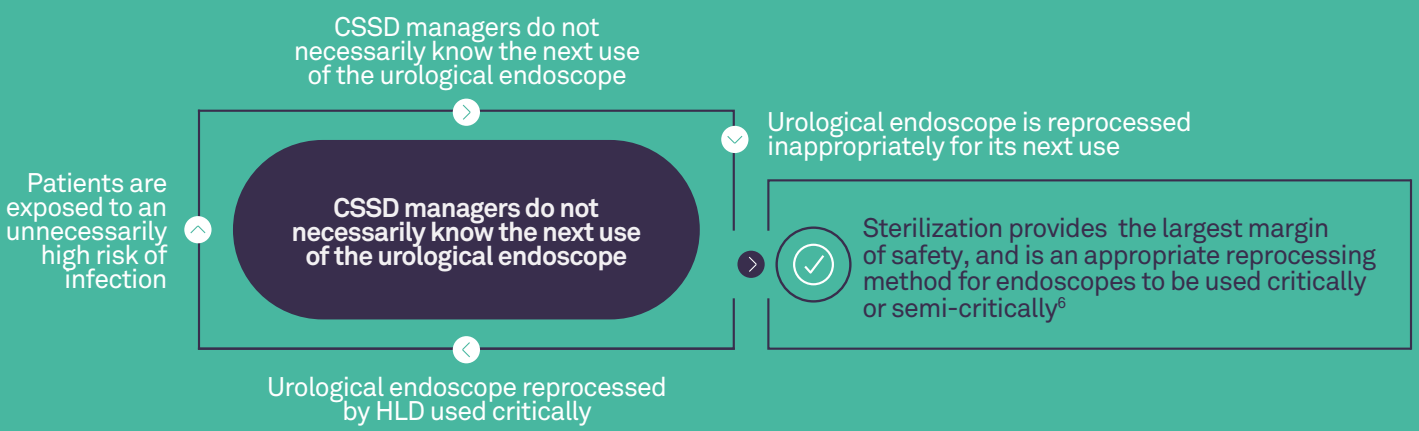
Koo et al. 2012 reported an outbreak of NDM-1 Klebsiella involving 12 patients in 2010. This outbreak was traced back to the video camera head that connected to the eyepiece of a urological endoscope. Even though the camera head did not come into direct contact with the patient (and was therefore considered non-critical), cross-contamination still led to infection; the authors suggested that the entire device be sterilized.[5]

HLD

- If performed properly, eliminates all micro-organisms except large numbers of bacterial spores
- Labor-intensive and steps can be easily neglected
- Does not provide the margin of safety required to protect patients from infection risk

STERILIZATION

- Adequately reprocess devices whether they are used critically or semi-critically
- May lead to reduced labor requirements
- Provides the largest margin of safety, which may lead to reduced patient infections
- No repeat reprocessing required with sealed, sterilized instruments



STERILIZATION

There has recently been a shift in the recommendations of many significant clinical organizations and societies towards the use of sterilization as the standard for endoscope reprocessing.

As of March 2015, the US FDA updated their guidelines to advise that even devices that are used semi-critically should be sterilized if possible.

COUNTRY	GUIDELINE RECOMMENDATION
US (FDA)[6]	Endoscopes used in sterile body cavities, and all endoscope biopsy accessories, should be sterilized. Devices used semi-critically should also be sterilized unless the device design prevents this.
UK[7,8]	Endoscopes used for invasive procedures, such as cystoscopes, should be sterilized by steam or gas plasma. Sterilization is preferred where practicable for endoscopes used semi-critically.
Australia[9]	Sterilization of semi-critical flexible endoscopes is preferred.
Japan[10]	Sterilization of urological endoscopes is preferred. For flexible endoscopes, strictly monitored HLD is currently permitted.

STERRAD™ offers a low-temperature sterilization method that helps protect heat- and moisture-sensitive components of endoscopes, whilst offering further benefits to patients, surgeons and sterilizer operators.

	Improve patient and staff safety	Efficiency and ease of use	Reduced financial burden
Increases the margin of safety	✓	✓	
Sterile devices are ready for use when needed		✓	
Short cycle time increases device availability without needing larger inventories			✓
Avoid pathogen recontamination (no water source or aeration needed)	✓		
Non-toxic residues	✓	✓	
Increases compliance		✓	
Reduces workload on staff		✓	✓
No need for repeat reprocessing when devices are not used		✓	✓
Relieve HAI-associated costs and patient burden	✓	✓	✓

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1. Spencer W. Low temperature sterilisation process. The Clinical Services Journal 2014:1–4; 2. Chou DS, McDougall EM, Ed. Nakada SY, et al. Endoscopic Imaging and Instrumentation. Advanced Endourology 2006;1:3–18; 3. The Dirt on Flexible Endoscope Reprocessing. Pa Patient Saf Advis 2010;7:135–140; 4. Rutala WA, Weber DJ. New developments in reprocessing semicritical items. Am J Infect Control 2013;41:S60–6; 5. Koo VS, O'Neill P, Elves A. Multidrug-resistant NDM-1 Klebsiella outbreak and infection control in endoscopic urology. BJU Int 2012;110:E922–6; 6. U.S. Food and Drug Administration. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. 2015; 7. Swift, AC. ENT UK Guidance on the Decontamination and Sterilization of Rigid and Flexible Endoscopes. 2010; 8. Medical Devices Agency Guidelines Sterilisation of Endoscopes. 2002; 9. CHRSP (Queensland). Disinfection & Sterilization Infection Control Guidelines. 2008; 10. Hamasuna R, Takahashi S, Yamamoto S, et al. Guideline for the prevention of health care-associated infection in urological practice in Japan. Int J Urol 2011;18:495–502.

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