

31 January 2022

Flexible Cystoscopes Information & Statistics

- 1. How many urology units currently perform flexible cystoscopies in your Trust for investigatory purposes?**

2

- 2. How many patients are seen in urology in your Trust per week/month/year for investigatory flexible cystoscopies?**

See Question 5

- 3. Is an initial investigation the only reason for cystoscopies with flexible cystoscopes or they can be used for other reasons too? (e.g. laser, taking biopsies).**

No, they can be used for biopsies, sometimes they can also be used for stent removal post ureteroscopy, laser ablation, injection of Botox and during a PCNL procedure.

- 4. How many flexible, and how many rigid cystoscopes are currently in use across the Trust?**

Currently, the Day Procedure Unit in Belfast City Hospital have 32 flexible cystoscopes and 51 rigid cystoscopes.

Tower Theatres Belfast City Hospital have 66 Rigid cystoscopies, 3 paediatric rigid cystoscopes and 19 flexible cystoscopies, 11 Resectosopes.

RVH L3 Theatres has 4 rigid cystoscopies and 2 Resectosopes.

- 5. How many flexible and how many rigid cystoscopies are performed – on average – per week/month/year across the Trust?**

3,395 completed since 1/1/21 to date, they cannot be separated.

31 January 2022

6. Which cystoscope models do you use and how many are there of them currently in practice?

- Olympus flexible video scope model CYF-VH (7)
- Olympus flexible video scope model CYF-V2 (16)
- Storz flexible cystoscope model 11272C1 (27)

- Storz rigid 30 degree 27005BA (67)
- Storz rigid 70 degree 27005CA (29)
- Storz rigid 0 degree 27005AA (24)

- Olympus 30deg Bipolar Resectoscope, WA2T430A x (13)
- 5deg Paediatric wolf telescope (1)
- 25deg Paediatric wolf telescope (1)
- 30deg paediatric wolf telescope (1)
- 30deg telescope long (2)

7. What cleaning/sterilisation process for flexible cystoscopes is currently in place?

**Belfast Health & Social Care Trust (BHSCT)
Cleaning/sterilisation process for flexible cystoscopies**

Flexible Cystoscopes are reprocessed within the BHSCT Endoscope Decontamination Unit (EDU) and are decontaminated in accordance with the manufacturer's instructions and following Health Technical Memorandum (HTM) 01-06 standard. Local Standard Operating Procedures are in place for all stages of the decontamination process and including, the packaging and sterilisation (if required), of the Cystoscopes.

The decontamination service in the Belfast Trust currently reprocess Karl Storz and Olympus cystoscopes. There are 78 cystoscopes in circulation in total. 16 of these scopes require a sterile status and are sterilised by Ethylene Oxide Gas. The other 62 scopes require a high level disinfection status and are then packaged using the SureStore vacuum pack system, which will maintain the high level disinfection status for 21 days.

The Decontamination process commences in the theatre areas, where the Nursing staff perform a bedside flush of the Cystoscope immediately after use and prior to the transfer to the EDU site for full decontamination and reprocessing.

31 January 2022

In the EDU, each stage of the decontamination process will be recorded through the electronic traceability system. The traceability system also records the patient details, date and time stamps and the decontamination operator's details.

Leak Test:

The first stage of the decontamination process in EDU begins with the trained technicians inspecting the cystoscopes for damage and then to proceed to perform a leak test. Leak testing is a vital processing step to detect if there has been fluid invasion of the flexible endoscope. If a leak is not detected, fluid invasion of an endoscope can damage the endoscope and increase repair costs. If an endoscope fails the leak test, it will be manually decontaminated and sent for repair.

Manual wash process:

This process is performed in a sink filled with water at a temperature of less than 30°C. Compatible Enzymatic detergent is then dosed into the sink using a validated automated detergent pump. This detergent is also used to flush the endoscope channels. The endoscope exterior surfaces are then cleaned using a disposable cloth, underneath the water line until visibly clean of all debris. The cystoscope internal channels will be brushed with a compatible single use brush. This process will also occur underneath the water line for a minimum of three times and until the scope is visibly clean of all debris. The cleaning brush is never retracted back through the endoscope.

The endoscope is then transferred to a rinse sink filled with clean tap water. The endoscope will be placed in the sink to remove all detergent and all channels will be flushed to remove excess chemical.

Automated Wash Process:

Following successful completion of the leak test and manual wash process, the endoscope is processed through a validated Endoscope Washer-Disinfector (EWD). The process chemicals consist of a detergent in combination with peracetic acid (PAA). There are seven stages of the automated EWD wash cycle;

1. Leak test
2. Pre-rinse stage
3. Wash stage
4. Disinfection
5. Final rinse 1.
6. Final rinse 2.
7. Dry

Each wash cycle will be verified and confirmed as either a pass or fail by the EWD, which is also monitored by an Independent Monitoring System (IMS) to verify the cycles. Any failed cycles will result in the cystoscopes being fully reprocessed again.

31 January 2022

Packaging and Product Release:

Once the Wash cycle has been verified by the decontamination technician as successful, the Cystoscope will be transferred to the cleanroom for inspection, packaging and if required sterilisation, prior to product release and return to the Endoscopy department.

Cystoscopes that are that require terminal sterilisation will be placed in a validated drying cabinet for a minimum of three hours and a maximum of three days to ensure the endoscope is appropriately dried before packaging and sterilisation. The drying is monitored using the traceability system and the drying cabinet counter. Upon release from the drying cabinet, the cystoscope will be placed in its dedicated basket and wrapped in an approved tray wrap using an aseptic and critical fold wrapping technique. A traceability label and a chemical indicator will be placed on the outside of the pack. The prepared cystoscope will be sent to an external Ethylene Oxide sterilisation provider. The chemical indicators on the package will change colour upon exposure to EO gas Sterilisation. Cystoscopes that have undergone a sterilisation process will have a shelf-life of twelve months from date of sterilisation.

Cystoscopes that are not sterilised are packaged using the SureStore vacuum packaging system and will have a shelf life of the cystoscope to 21 days.

Periodic Testing of Decontamination Equipment:

All decontamination equipment including; Endoscope Washer-Disinfectors, SureStore Packaging system and drying cabinets are tested and checked daily by decontamination operators. The equipment will also undergo periodic maintenance, testing and validation which is performed by service contractors and trained estates personnel. The periodic testing is performed on weekly, quarterly and annual basis. This equipment is maintained to the HTM 01-06 standard.

Protective sheaths

- 1. Do you currently use a protective sheath on your cystoscopes? If yes, for which cystoscope model?**

No the Day Procedure unit in BCH do not use sheaths on cystoscopes

- 2. If the answer for the question above is no, are you considering using protective sheaths for flexible cystoscopes in the future?**

Not Currently

Single use cystoscopes:

- 1. Have you ever used a single-use cystoscope in your practice, or are you considering to? Please provide details on model and reason.**

Yes we do