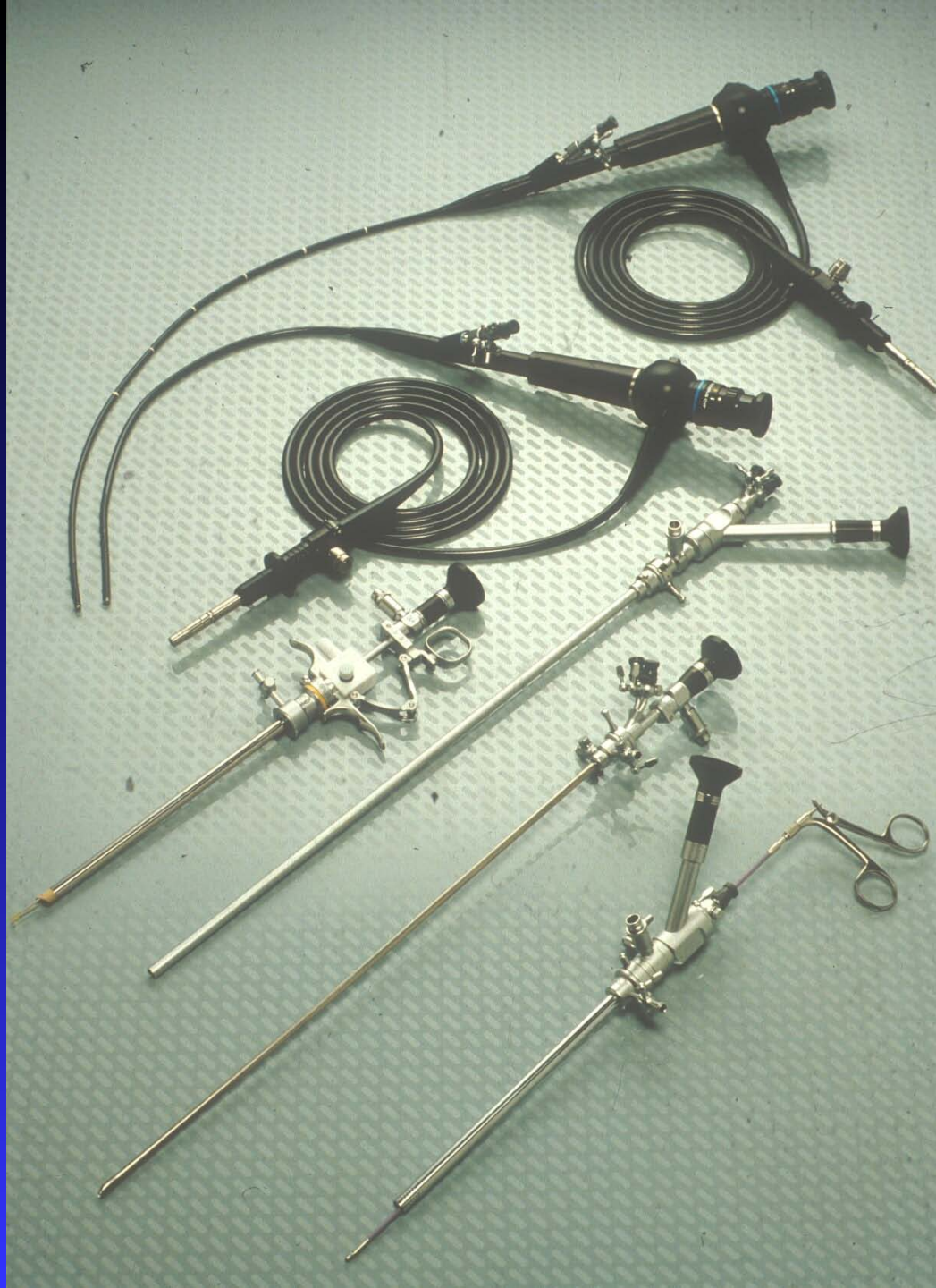


ENDOSCOPE DECONTAMINATION : Where are we now!

**Christina Bradley
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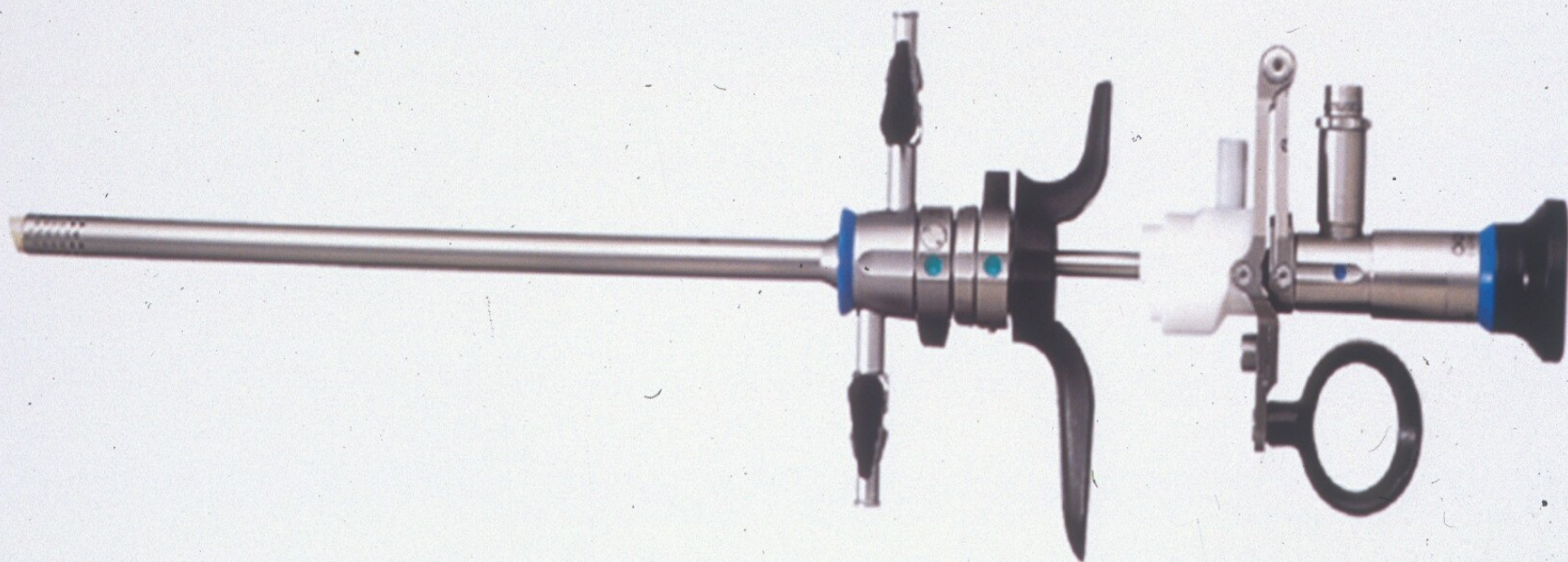


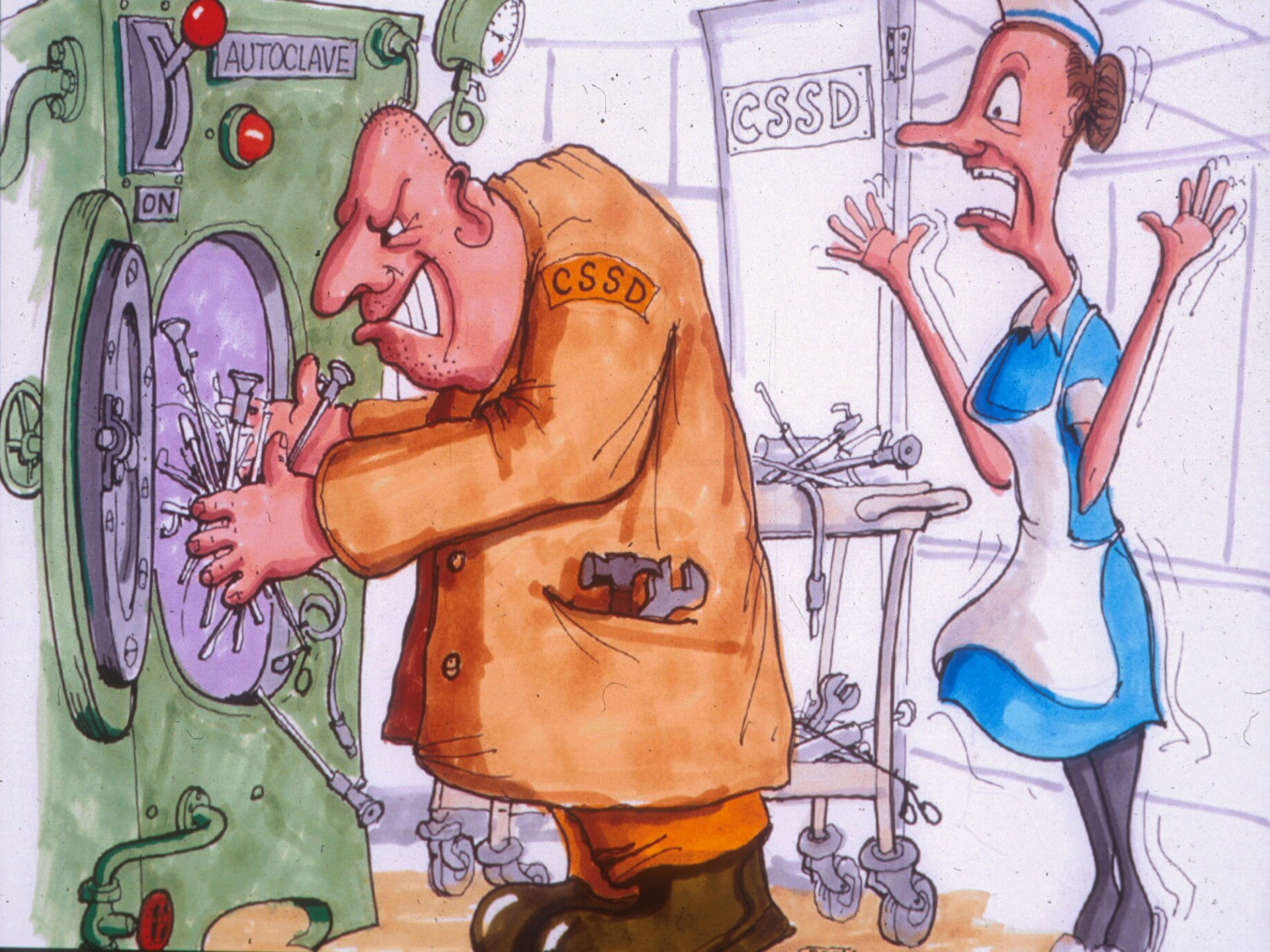
CHOICE OF DECONTAMINATION METHOD

Depends on

- Patient susceptibility to infection
- Tolerance of item to heat, chemicals, pressure, moisture etc
- Nature of the contamination/micro-organisms present
- Time available for processing
- Risks to processing staff
- Cost of processing
- Availability of processing equipment

HEAT IS PREFERRED





SSD PROCESSING

- Established process validation for disinfection and sterilization
- Thermal washer disinfectors available with lumen irrigation
- Porous load (vacuum) steam sterilizers available for packaged lumened devices
- Tracking systems in place
- Turnaround times may be increased
- Services may not be available locally
- Staff training in instrument construction



DECONTAMINATION OF FLEXIBLE ENDOSCOPES

- Processed at point of use
- Meticulous cleaning
- Proper immersion in disinfectant
- Thorough rinsing after disinfection

ENDOSCOPE TASK FORCE (October 2005)

- Following an incident of failure to decontaminate adequately a flexible GI endoscope in May 2004 - MDA 2004/28 was issued (23rd June 2004)
- Action – to carry out an immediate assessment of endoscope decontamination

ENDOSCOPE TASK FORCE

(October 2005)

- 21 incidents reported
 - ◆ Incompatibilities between endoscope and processor
 - ◆ Staff unfamiliar with the decontamination of particular endoscopes
 - ◆ Poor communication between endoscope and processor manufacturers
- Endoscope decontamination : Top 10 tips issued

Top Ten Tips Endoscope Decontamination

- 1 Compatibility**
Ensure compatibility with the existing hospital decontamination processes, including compatibility with the washer disinfectant, when purchasing.
- 2 Instructions**
Ensure that all equipment is operated and controlled in accordance with the manufacturers' instructions.
- 3 Identification**
Identify all endoscopes and washer disinfectors used in the hospital to ensure they are being maintained and that the correct decontamination process is being used.
- 4 Channel connection**
Check the number of channels in each endoscope and ensure that they can all be connected to the washer disinfectant using the correct connectors/connection sets provided by the manufacturer.
- 5 Manual cleaning**
Ensure endoscopes and accessories are manually cleaned prior to processing in a washer disinfectant including the flushing of all channels even if they have not been used during the procedure.
- 6 Chemical compatibility**
Use only chemicals compatible with the endoscope and their accessories and at the correct concentration as recommended by the manufacturer throughout the decontamination process.
- 7 Process validation**
Use only validated processes following guidance in NHS Estates HTM 2030 Washer Disinfectors, MHRA Device Bulletin DB2002(05) and MAC Manual on Decontamination.
- 8 Preventative maintenance**
Have a regular planned preventative maintenance in place with records kept on each washer disinfectant.
- 9 Staff training**
Ensure all staff, including new staff, involved in the decontamination process are fully trained and that this training is kept up to date as appropriate*.
- 10 Incident reporting**
Report any equipment problems relating to endoscope, endoscope washer disinfectant or associated chemicals to the MHRA via our website www.mhra.gov.uk or e-mail: aic@mhra.gsi.gov.uk or telephone 020 7084 3080. Report identified problems with any decontamination process to the local consultant in communicable disease control (CCDC) at your local health protection unit.

Products claiming to remove/inactivate prion protein from contaminated medical devices: It is important that until the efficacy of these products and technologies is established fully against human prions, that clinicians ensure the current ACDP-TSE Guidelines remain extant. (The reference for the Guidelines is: ACDP - TSE Agents: Safe working and the prevention of infection; available on the Department of Health website www.dh.gov.uk)

Comprehensive advice and guidance can be found in MHRA Device Bulletin DB2002(05) 'Decontamination of Endoscopes', available from www.mhra.gov.uk

*An e-learning course on decontamination is available from the National Decontamination Training Programme (<http://decontaminationtraining.mhra.gov.uk>) which includes a module on endoscopy. In addition, endoscope manufacturers run courses in endoscope decontamination.

Note: The importance of decontamination needs to be clearly understood at all levels throughout the organisation. There could be legal implications if failures in this process are identified.

MANUAL CLEANING

- **At point of use**

- ◆ Air/water channel
- ◆ External surfaces
- ◆ Suction channel

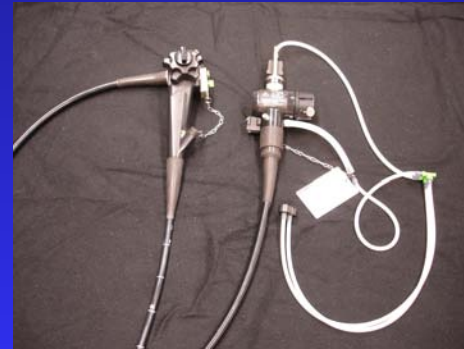


- **At the sink in dedicated decontamination room**

- ◆ Brushing



Flushing

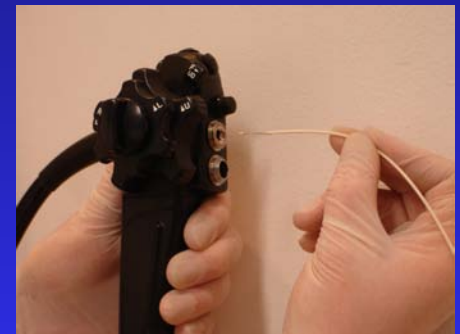


MANUAL CLEANING

- Single use brushes must be used for cleaning at all times
- Staff must ensure meticulous adherence to manufacturers instructions for cleaning

Important to ensure

- Access to all channels whether they have been used or not e.g. forceps raiser channel, auxiliary water channel
- Irrigation of all channels that cannot be brushed



WASHER DISINFECTORS

Should :-

- Be validated in accordance with HTM 2030
- Have regular PPM
- Records of all maintenance and testing should be kept

DECONTAMINATION EQUIPMENT

OPERATIONAL MANAGEMENT

PERSONNEL INVOLVED

HTM 2030

- Management
- User – nominated person
- Authorised person
- Test person
- Maintenance person
- Infection Control
- Microbiologist
- Operator

HTM 01-01 Part A

- Executive Manager
- Decontamination Lead
- Designated Person
- Senior Operational Manager
- User
- Authorising Engineer AE(D)
- Authorised Person AP(D)
- Competent Person CP(D)
- DIPC
- ICD
- Microbiologist
- User

ENDOSCOPE WASHER DISINFECTORS : PROBLEMS

- Disinfectant concentration
- Verification of all channel irrigation
- Machine contamination
- Water quality
- Maintenance
- Validation

DISINFECTANTS AND ENDOSCOPE WASHER DISINFECTOR

Ensure disinfectant

- has broad spectrum of microbicidal activity
- is compatible with instruments and processing equipment
- is used at effective concentration
- is in contact with all surfaces

SOURCES OF RINSE WATER CONTAMINATION

- Incoming water
- Water treatment system
- Endoscope washer disinfectors

MACHINE CONTAMINATION

Due to:-

- Inadequate cleaning, disinfection and maintenance of machine
- Static water remaining in tanks and pipework
- Poor quality water supply
- Biofilm within the machine

WATER TREATMENT METHODS

- Filtration – 0.22 μ m
- Reverse Osmosis
- Addition of biocides
- Ultraviolet light
- Combination of methods

PERIODIC TESTS – ENDOSCOPE WD

- Quarterly tests plus
- Water system - chemical purity, bacterial endotoxins, TVC, environmental mycobacteria
- Drainage - blocked drain protection, free draining, pipework residual volume
- Venting system - load contamination
- Doors and door interlocks
- Fault interlock
- Chemical vapour discharge test
- Chemical additive dosing test - reproducibility, low level detection
- Load carriers
- WD Self disinfection test
- Final rinse decontamination test
- Channel patency test
- Disinfectant concentration test
- Cleansing efficacy test - test soil, reference load
- Thermometric testing of chamber wall and load carrier (if applicable)
- Microbiological test of disinfectant efficacy
- Load dryness test
- Test for air quality
- Sound level

VALIDATION OF DECONTAMINATION

Numerous important tests are described in HTM 2030 but at the minimum, the user must ensure that

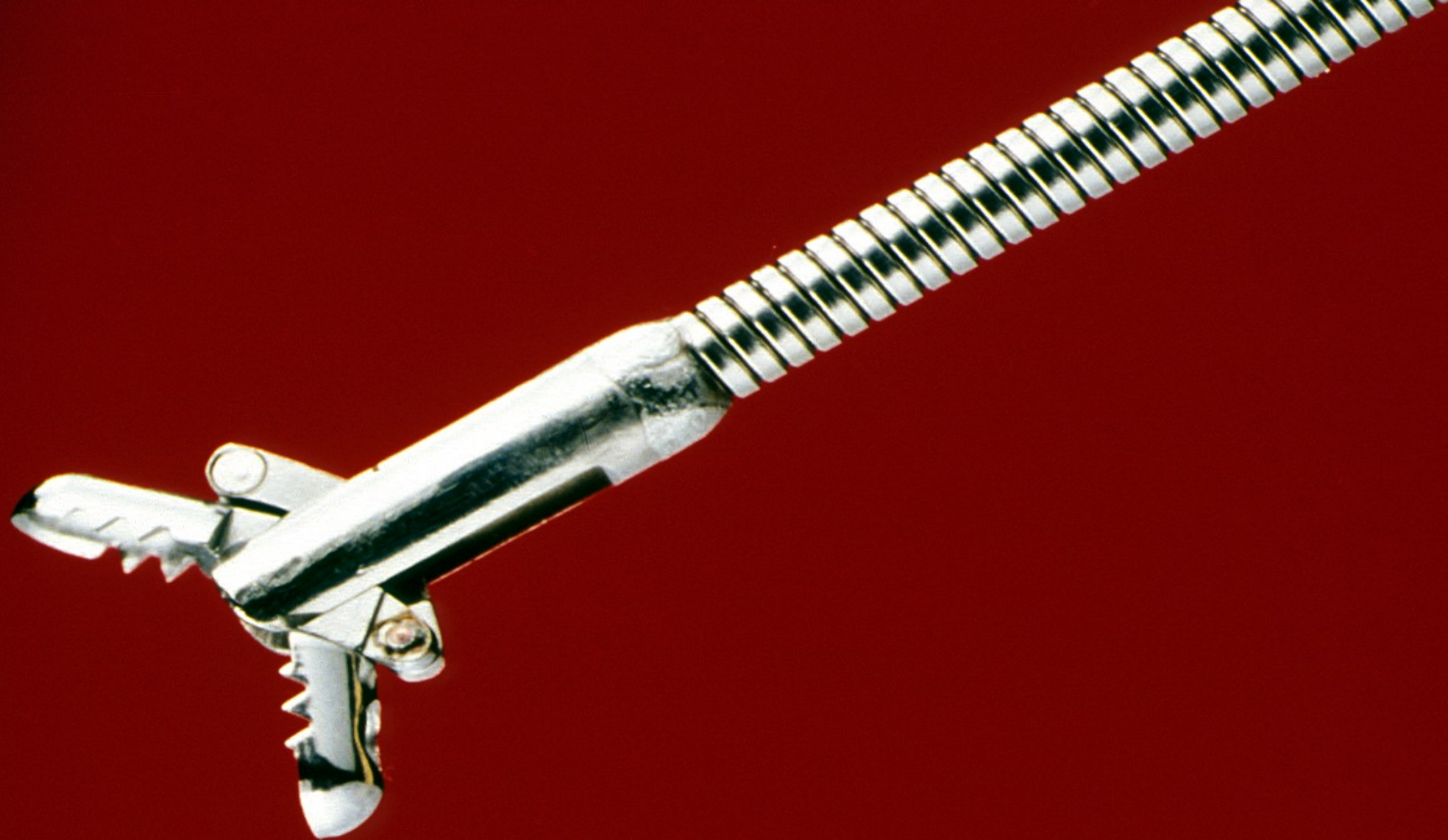
- All channel irrigation occurs
- Disinfectant is within minimum effective concentration
- Quality of water is adequate

WATER TESTING

- Who will carry out the testing?
- How are the samples transported to the laboratory?
- Who receives the results?
- Are the results presented in an understandable format
- Who will take action dependant on the results?
- What action will be taken in the event of contamination being detected?

STAFF TRAINING

- At induction and regular updates
- Anatomy/construction of endoscopes
- Use of washer disinfectors
- Traceability systems
- Importance of record keeping



Single-use Medical Devices

MHRA

How do I know if a device is for single-use?

It will have this symbol on the packaging or the device:



What does single-use mean?

Do not reuse. A single-use device is used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.

Is single-patient use the same as single-use?

No. Single-patient use means the medical device may be used for more than one episode of use on one patient only; the device may undergo some form of reprocessing between each use.

Why shouldn't they be reused?

The MHRA is aware of serious incidents relating to reuse of single-use devices.

Reuse can be unsafe because of risk of:

- **cross-infection** – inability to clean and decontaminate due to design.
- **endotoxin reaction** – excessive bacterial breakdown products, which cannot be adequately removed by cleaning.
- **patient injury** – device failure from reprocessing or reuse because of fatigue, material alteration and embrittlement.
- **chemical burns or sensitisation** – residues from chemical decontamination agents on materials that can absorb/adsorb chemicals.

Also, if you reuse a single-use device you may be legally liable for the safe performance of the device.

Can I sterilise a single-use device?

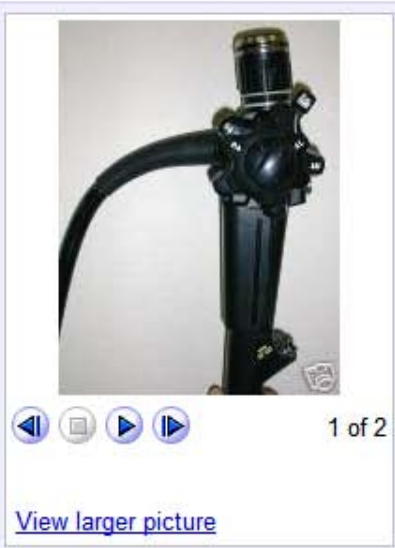
A few single-use devices are marketed as non-sterile. These may require processing, in line with the manufacturer's instructions, to make them sterile and ready for use. You must not resterilise them.



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Olympus GIF-Q40 Fiber Gastroscope/endoscope **L@@K** Item number: 220149982872
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