Somerset Partnership NHS
NHS Foundation Trust

DECONTAMINATION OF NON LUMENED ENDOSCOPIC EQUIPMENT (INCLUDING CYSTOSCOPES AND NASENDOSCOPES)

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Applies to:	Clinical staff undertaking Endoscopy and Nasendoscope interventions

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DOCUMENT CONTROL

Reference	**Version**	**Status**	**Author**
KA/Oct14/DFEEP	3	Final	Head of IPC / Decontamination Lead

Amendments

1.5 – Amended following change of Decontamination responsibilities post move to new Bridgwater Community Hospital location

October 2017; Policy updated to reflect changes in Endoscopy service provision (Bridgwater and Minehead Community Hospitals).

Document objectives: To ensure that the Trust is able to provide assurance of compliance with robust Endoscope/Nasendoscope decontamination methodology, thus ensuring patient safety.		
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CONTRIBUTION LIST Key individuals involved in developing the document

Designation or Group
Infection Prevention and Control Team
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CONTENTS

1. INTRODUCTION

1.1 Flexible endoscopes are complex re-usable instruments that require unique consideration with respect to decontamination and must be decontaminated following every endoscopic procedure.

1.2 Staff responsible for flexible endoscope decontamination must be trained for the role and records of training and competency assessment retained.

1.3 There must be documented safe working practices for decontamination and periodic testing must be carried out as detailed in Choice Framework for local Policy and Procedures 01-06 – Decontamination of Flexible endoscopes: Policy and management (CFPP 01/06) and BSG Guidance for Decontamination of Equipment for Gastrointestinal Endoscopy; The Report of a Working Party of the British Society of Gastroenterology Endoscopy Committee March 2014, Revised November 2016.

1.4 Flexible endoscopes are used within Trust managed Community Hospital sites as follows;

Nasendoscopes; at the following locations;

- Minehead Community Hospital;
- Bridgwater Community Hospital;
- Burnham on Sea Community Hospital;
- West Mendip Community Hospital;
- Chard Community Hospital;
- Shepton Mallet Community Hospital

Cystoscopes; at the following locations;

- Minehead Community Hospital Day Unit;
- Bridgwater Community Hospital Outpatient Department.

2. PURPOSE & SCOPE

2.1 In order to prevent the potential for transmission of infection each endoscope and device must be decontaminated with the same rigour following every endoscopic procedure. The guidance contained within, CFPP 01/06 and manufacturer's instructions should be followed.

2.2 This policy applies to all staff involved in the provision care of to patients undergoing an endoscopic procedure within Trust managed services.

2.3 Non lumened endoscopes are used within Somerset Partnership NHS Trust managed locations, and therefore this Policy **DOES NOT** cover lumened Endoscopy equipment.

3. DUTIES AND RESPONSIBLITIES

3.1 **Director of Infection Prevention and Control -** Executive staff member responsible for Trust Decontamination and ensuring decontamination processes used throughout the Trust are according to national standards. Reports risk to the Board.

3.2 **Trust Decontamination Lead-** Advises Director of Infection Prevention and Control as regards any shortfalls against National and European Directives or Guidance and ensures that effective quality control and monitoring systems are in place for the decontamination of reusable devices.

3.3 **Day Case/Out Patient Department Unit Lead -** Day to day Management of Department and ensuring decontamination of flexible Endoscopes and associated items are maintained to required standards as stated in this policy. This post should also make sure all staff are trained to required standard.

3.4 **Staff involved in endoscope decontamination –** All staff involved in decontamination of flexible endoscopes are responsible for:

- Ensuring they have received training and assessed as competent to carry out the process;
- Ensuring they follow the decontamination process as outlined in this policy

3.5 **Infection Prevention and Control Team -** To support all named parties in this policy as regards infection prevention and control issues and give advice as required

4. DEFINITIONS

4.1 **Decontamination:** A process which removes or destroys contamination so that infectious agents or other contaminants cannot reach a susceptible site in sufficient quantities to initiate infection or any other harmful response.

4.2 **Flexible Endoscope:** A flexible Instrument with a fibreoptic camera which is passed into an area of the body (e.g. the bladder) which allows a greatly magnified image to be projected onto a screen.

4.3 **Nasendoscope:** A flexible endoscope used to explore the nasal passages, larynx, and oropharynx.

4.4 **Cystoscope:** A flexible endoscope used to explore the urinary tract and bladder.

4.5 **Creutzfeldt-Jakob Disease (Cjd) And Variant Creutzfeldt-Jakob Disease (Vcjd) -** Transmissible spongiform encephalopathies (TSEs) are a group of diseases which affect both humans and animals.

4.6 **SSD:** Sterile Services Department; an integrated place in hospitals and other health-care facilities that reprocesses sterilization and other actions on medical devices

5. FLEXIBLE ENDOSCOPY SERVICE

5.1 An Endoscopy (Cystoscopy) service is delivered via Bridgwater and Minehead Community Hospitals.

5.2 The Minehead based service is delivered via the Hospital Day Surgery Unit, and is managed via a locally appointed lead, who has received appropriate training to

manage the decontamination facilities within this location. The Bridgwater Community Hospital based service is delivered via the Outpatient Department. The activity generated within this site is owned by Taunton and Somerset NHS Foundation Trust.

5.3 The Endsocopy activity delivered via Minehead Day Case unit and Bridgwater OPD are owned by Taunton and Somerset NHS Foundation Trust , with Somerset Partnership NHS Foundation Trust managing the premises and providing clinician support.

5.4 The process for decontamination of cystoscopes between patients has been agreed between Taunton and Somerset NHS Foundation Trust and Somerset Clinical Commissioning Group. The agreed process will involve the use of a 'sheathed' cover for the endoscope, with the endoscope being manually decontaminated between patients via the use of the Tristal 3 wipe system. Training for this process is provided via the Sheath product manufacturer. For any system breaches, equipment will be decontaminated via the Taunton and Somerset managed SSD service

5.5 Nasendoscopy is undertaken in a proportion of the community hospital settings (see section 1.4) and manual cleaning is utilised for the decontamination of this equipment, using the Tristal three stage cleaning process. All staff in these locations are required to receive training to ensure full compliance with the decontamination process.

6. DECONTAMINATION PRINCIPLES (see also Appendix 1)

6.1 General Decontamination Principles for Flexible Endoscopes

- Decontamination of endoscopes should begin as soon as possible after use.
- Flexible endoscopes entering sterile body cavities must have undergone a sterilisation process OR be using the single use sheath system.

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- It is important that staff are familiar with the equipment they are responsible for decontaminating, testing and maintaining.
- Standard infection prevention and control precautions apply and appropriate personal protective equipment must be readily available and should be used to protect the healthcare worker, from exposure to biological agents and toxic chemicals.
- All staff responsible for flexible endoscope decontamination must have been trained for the role.
- A record should be kept of all training given and levels of competencies achieved as per the Staff Training Matrix.
- Safe working practices in the decontamination area should be written down and understood by all staff.
- Decontamination of endoscopes/nasendoscopes must be undertaken between patients, at the beginning and end of each list by staff trained for the purpose. The department should be followed. A record should be kept of the serial

number of each endoscope and each re-useable accessory used in each patient. This is important for any future contact tracing when possible endoscopic transmission of disease is being investigated.

- It is essential that all decontamination stages are included after every use of the endoscope and that none are omitted.

- Endoscopy should be avoided wherever possible in patients with suspected or confirmed CJD. A dedicated endoscope should be used and fully cleaned and decontaminated via the Taunton and Somerset NHS Foundation Trust CSSD after use. The scope should then be quarantined and may be reused exclusively on the same individual patient if required. For further details see CJD policy.

7. LOCAL MONITORING (see Appendix 1)

8. TRAINING REQUIREMENTS

8.1 Local Leads will disseminate training as per the requirements of the equipment manufacturer's training and guidance

8.2 Equipment Manufacturer will support locally based training.

8.3 The Trust will work towards all staff being appropriately trained.

9. MONITORING COMPLIANCE AND EFFECTIVENESS

9.1 The policy will be monitored via Trust Theatre and Endoscopy Group which reports to the Infection Prevention and Control Assurance Group. Quarterly Infection Prevention and Control Reports include Endoscopy related information and are submitted to the Trust Clinical Governance Group who report directly to the Trust Board.

9.2 An audit of flexible endoscope decontamination will be carried out annually by the Department Lead to check that all procedures are being followed and the flexible endoscopes are in good state of repair. A report highlighting any non-conformity will be sent to the Theatre and Endoscopy Working Group for further investigation and an action plan developed to rectify any issues. Progress against these action plans will be monitored via the Theatre and Endoscopy Working Group and also the Trust Infection Prevention and Control Assurance Group (IPCAG). Exceptions will be reported via the IPCAG via The Trust Clinical Governance Group.

10. REFERENCES, ACKNOWLEDGEMENTS AND ASSOCIATED DOCUMENTS

- Department of Health publications (England only): Choice Framework for local Policy and Procedures 01-06 – Decontamination of flexible endoscopes: Operational management manual 13536:1.0.

- Musgrove Park Hospital, Taunton and Somerset NHS Foundation Trust Decontamination of Flexible Endoscope Equipment Policy;
- The Health and Safety at Work Act and associated Regulations;
- The Control of Substances Hazardous to Health Regulations;
- EU Council Directive 93/42 EEC concerning Medical Devices;
- EU Council Directive 99/44 EEC concerning product liability;
- Health Technical Memorandum 01-01 Decontamination of reusable medical devices;
- Health Technical Memorandum 03-01: Specialised ventilation for - healthcare premise (Sections A&B);
- BSG Guidance for Decontamination of Equipment for Gastrointestinal Endoscopy; the Report of a Working Party of the British Society of Gastroenterology Endoscopy Committee March 2014, Revised November 2016.

Cross reference to other procedural documents

- Cleaning of equipment and decontamination policy (to be read in conjunction with the medical devices policy);
- Creutzfeldt-Jakob disease (CJD) policy;
- Hand Hygiene Policy;
- Infection Control Surveillance Policy;
- Infection control: standard infection control precautions policy (incorporating blood and body fluid spillage) Policy;
- Learning Development and Mandatory Training Policy;
- Risk Management Policy and Procedure;
- Staff Mandatory Training Matrix (Training Needs Analysis);
- Untoward Event Reporting Policy and procedure;

All current policies and procedures are accessible in the policy section of the public website (on the home page, click on 'Policies and Procedures'). Trust Guidance is accessible to staff on the Trust Intranet.

APPENDIX 1

STANDARD OPERATING PROCEDURE

General Decontamination Principles for Endoscopes and Nasendoscopes

A scientifically validated product must be used when manual decontamination is being undertaken. The approved product is the Tristel Sporicidal Wipes System which incorporates;-

- Pre-clean wipe;
- Sporicidal wipe;
- Rinse wipe.

Do NOT use if the wipe sachet or foam bottle has been damaged.

1) Use Tristel pre-clean wipe to decontaminate the instrument, open sachet to activate foam of the enzymatic, proceed to wipe over instrument including cord for 20 seconds.

2) Second step in decontamination process is to put on clean gloves and apron. Using Tristel Sporicidal Wipe sachet pump 4 measures of “activator foam” onto sporicidal wipe, scrunch to mix active ingredients, wait 15 seconds, wipe the surface of the instrument ensuring all areas have come in contact with the solution, all areas of the surface must come into contact with the wipe at least once. Wait 30 seconds.

3) Third step open Tristel Rinse Wipe sachet and wipe over instrument, place the cleaned instrument onto a clean paper towel. The Rinse wipe is utilised to remove and neutralise chemical residues from the surface.

4) Dispose of paper roll into clinical waste bag.

5) Remove and dispose of gloves into clinical waste bag.

6) Wash and dry hands.

7) Complete audit book (for traceability), remove both labels from the book of the sporicidal wipe, place one label in the patients chart and one label in the audit book.

8) Repeat above process between each patient and at the end of the clinic decontaminated equipment should be returned to storage area.

Precautions and Considerations

The cleaning and disinfection of Nasendoscopes requires a high-level disinfection process. Cleaning of Nasendoscopes is to be performed between each patient examination

MONITORING (AUDIT/TRACEABILITY TRAIL)

Tristal 3 Stage Decontamination Process

- Maintain log book. Entry required for each patient;
- At the completion of each list, all patient's records must be completed;
- When the log book is completed, sign off on front cover and archive;
- The scope is to be checked post each clinical intervention for any evidence of breach;
- In the event of identifying a breach, the scope will be cleaned as per the TrIstal Three stage decontamination process and sent to Taunton and Somerset NHS Foundation Trust , to undergo an automated sterilisation process. A report will be submitted via the DATIX Incident reporting system, detailing actions taken.

WEEKLY TESTS

Flexible Endoscopes: For each endoscope prior to use;

- Check the integrity of the insertion tube and the distal end
- Check the entire endoscope as described in the manufacturer's instructions.

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