Appendix 4

Infection Prevention & Control Quick Reference Guide

Tracking & Traceability

Quick Reference Guide Version 1

To be used in conjunction with the

Decontamination of medical devices policy

- SBUHB Decontamination of Medical devices policy (when complete)
- Manufactures guidance for the device being used
- Local standard operating procedures for the device being used
- Useful Contact Numbers

Department of Infection Prevention & Control

Responsible Author: *Operational decontamination lead*

Approved by:*:*

Issue Date:

Review Date:

The Health Board is required to operate a tracking and traceability system to allow re-usable medical devices such as surgical instruments, endoscopes (and their accessories) and intra-cavity probes, to be tracked through each stage of the decontamination process. This ensures the processes have been carried out effectively. In addition to tracking progress through the decontamination cycle, it is also necessary to identify the patients that come in contact with these invasive and semi-invasive devices along with the accessories used during their procedure.

The following guidance is prepared for Endoscope and Intra-cavity probes only.

The flow chart incorporated in this quick reference guide covers the traceability requirement only and should **NOT** be used as a guide for the setup, use or decontamination of Endoscopes or Intra-cavity probes. Manufacturers, National and local guidelines should be followed at all times.

Traceability systems should record each process of the decontamination cycle to ensure that only devices that have been reprocessed correctly and within the documented timescales, can be safely used on a patient. The system should ensure that Endoscopes and Intra-cavity probes are effectively and accurately traced through bedside clean, manual wash, automated process, storage, dispatch to the user and finally patient use.

Traceability records should include the following-

- Serial numbers for endoscope/ probe and accessories.
- Manual wash record, to include visual inspection, manual leak test and cleaning of channels (where applicable)
- Batch numbers from any accessories used during the procedure- bedside detergent pots, brushes etc.
- The AER / UV system/ Trophon used
- The cycle number
- The result – Pass or fail
- The record from the storage cabinet (where applicable)
- All data entries dated and timed
- Patient identification- Printed labels should be used to eradicate transcription errors.
- Staff performing each step of the decontamination process.

To ensure robust tracking and traceability systems are place, the departments are required to undertake a six monthly tracking and traceability audit (Please see appendix 1). A copy of these audits must be sent to SBU.Decontamination@wales.nhs.uk

Within Swansea Bay University Health Board, there are both manual and electronic traceability systems in place. The flowchart below has been designed to ensure a consistent process is followed when using a manual traceability system.

Flow Chart for Manual track & trace system

Check device has the adequate documentation from the previous use to ensure it has been decontaminated and stored correctly. If the endoscope has been >3hrs since decontamination/ removal from storage cabinet, it **MUST** be reprocessed prior to use.

Endoscopes

Disposable accessories such as biopsy valve lot numbers are placed on traceability checklist.

Bedside clean- Must be performed immediately after use as per guidelines. Detergent pot batch label to be attached to traceability/ cleaning checklist.

Manual clean- Visual inspection of scope, leak test and cleaning of valves (Brushing & flushing), along with Lot numbers of brushes to be documented on relevant documentation for the area.

Automated process (AER/ UV system) - 1x Printout to be kept with the endoscope and placed in the next patients notes, 1x printout to be attached to the cleaning/ traceability sheet.

Storage - If the scope has been stored in the ESC, the printout should go with the scope and AER/ UV printout, to the patient. If the endoscope has been >3hrs since decontamination/ removal from storage cabinet, it MUST be reprocessed prior to use.

Intra-cavity probes

Tristel trio

Trophon

Pre clean wipe lot number to be documented in Traceability book.

Patient identification label, device & serial number, time and date of decontamination to be added to the traceability book

Affix sporicidal traceability label to traceability book, ensuring activator Lot. No has been clearly recorded.

Confirm rinse wipe has been used and record Lot. No on traceability book

1x Trophon printout to be attached to patients' notes/ referral form & scanned into radis. 1x printout to be placed into traceability book

Member of staff completing decontamination process MUST sign traceability book.

Patient identification label, device & serial number, time and date of decontamination, should **ALL** be recorded in the traceability book/ cleaning record in all circumstances.