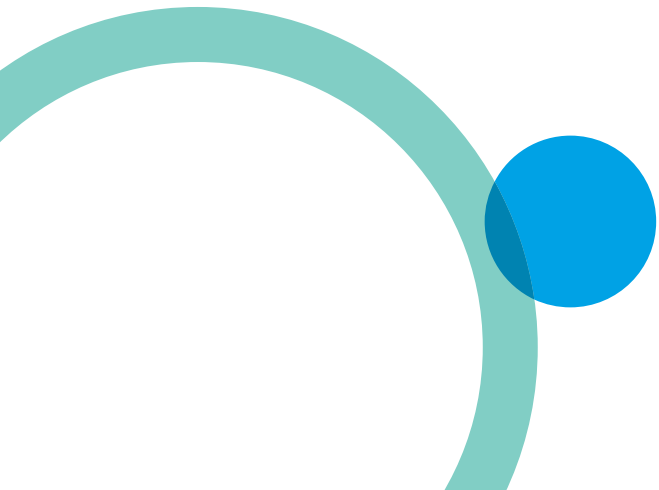
NHS National Services Scotland

Decontamination of medical devices (surgical instruments)

Guidance for service users - GUID 5017

Supplement to SHTM 01- 01
Decontamination of medical devices in a Central Decontamination Unit



September 2018

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1. Introduction

1.1 A government funded project (reference PID 2.17) was approved by the Scottish Antimicrobial Resistance and Healthcare Associated Infection (SARHAI) group. The aim of the project was to revise the guidance for decontamination equipment and processes for the production of sterile medical devices in a Central Decontamination Unit (CDU).

Note: In the context of this guidance document the term "medical device" is taken to be a surgical instrument unless indicated otherwise.

The guidance was to be known as Scottish Health Technical Memorandum (SHTM) 01-01 series. Part A of the series would cover management of medical devices. A detailed brief identified an element in the decontamination process to be "device preparation in the clinical environment". The expert working group developing the guidance considered that it would be more beneficial if this element was covered in a separate guidance document targeted at theatre personnel. This would be a significantly smaller document to consider and be more user friendly. This Service users guidance document would be prepared in parallel with the SHTM 01-01 series and be a supplement of SHTM 01-01. Part A would include a section on the work of Infection Prevention Control Teams (IPCTs).

1.2 This guidance GUID 5017 covers treatment of medical devices at theatre after patient use, including complex and lumen medical devices and for patients at increased risk of Creutzfeldt-Jakob Disease (CJD). New requirements were set by the Advisory Committee on Dangerous Pathogens (ACDP) on Transmissible Spongiform Encephalopathy (TSE) in their guidance of 2015 and 2016. Annex C (section C4) of their 2015 guidance indicated that if devices cannot be returned from Service Users to their Central Decontamination Unit in a timely manner, the devices should be kept moist using appropriate methods. This method(s) was required to be approved and verified by the CDU management. Refer to Section 3 in this guidance GUID 5017 for the definition and methods to establish moist conditions.

1.3 This guidance compliments theatre guidance previously published in December 2014 namely GUID 5010 which covered management of medical devices during transportation, storage and after clinical use'. http://www.hfs.scot.nhs.uk/publications-/guidance-publications/?keywords=&section=4&category=&month=&year=&show=10

1.4 For loan devices, refer to guidance on loan medical devices contained in section 5 of Theatre/Clinic roles and responsibilities of "National Decontamination Guidance on Loan Medical Devices (Reusable): Roles & Responsibilities" GUID 5002 published 2015. http://www.hfs.scot.nhs.uk/publications-/guidance-publications/?keywords=&section=4&category=&month=&year=&show=10

Scope

1.5 The content of GUID 5017 includes:

- Acquisition of medical devices;
- Treatment of medical devices (including complex and lumen) at theatre after patient use;

- Treatment of medical devices after use on patients at increased risk of vCJD;
- Quarantine of medical devices.

Note: In this guidance the manufacturers' instructions will be known as Instructions For Use (IFU).

2. Acquisition of medical devices

2.1 Prior to the acquisition of reusable medical devices, check the medical device manufacturer's Instructions for Use (IFU) to ensure they are compatible with the process and equipment in local settings. The preferred method of processing medical devices is the use of a validated washer disinfector and porous load sterilizer in a Central Decontamination Unit (CDU) setting.

2.2 Where a washer disinfector or a porous load sterilizer cannot be used, or additional processes such as a manual pre-wash, ultrasonic cleaning or use of an alternative sterilizer are specified in the manufacturers' instructions, these should be discussed prior to the procurement stage with the CDU operational manager. The review would include logistics, equipment and cost implications for reprocessing such medical devices. For complex medical devices that are especially difficult to reliably clean (or sterilize) then consideration should be given to the adoption of single use medical devices.

2.3 Purchase medical devices through the national procurement framework when available.

2.4 European Standard EN ISO 17664:2017 'Information to be provided by the medical device manufacturer for the processing of medical devices' specifies requirements for the information to be provided by the medical device manufacturer, so that the medical device can be processed safely and will continue to meet its performance specification. The requirements are specified for processing that includes the treatment of the medical device at the point of use. Therefore, the decontamination process which includes treatment of medical devices (post patient use) in the clinical area, should be followed in accordance to the medical device manufacturer's IFU.

Publications on single use to consider

Tonsillectomy instruments

2.5 In February 2015 the government published a letter titled "Adenotonsillar surgical procedures: revision of advice on single use vs reusable instruments". This revised advice stated that single use instruments should continue for routine tonsillectomy for adults born before 1997 and that reusable instruments should now be used for routine tonsillectomy for children i.e. those born after 1996.

Implants

2.6 Government letter SEHD/CMO (2006)13 "Migration to single-use pre-sterilised individually wrapped small orthopaedic implants in NHSScotland" instructed that screws, small plates and other orthopaedic implants should be single use.

Government letter HDL (2007)4 January 2007 "Decontamination – Migration to single use pre-sterilised individually wrapped small orthopaedic implants" set compliance deadlines for all orthopaedic units to have changed over to using pre-packed sterile single use implants. Government letter published in 9th April 2009 titled

"Decontamination – Migration to single use pre-sterilised individually wrapped implants – remaining specialities".

Endodontic Instruments

2.7 CMO (2007)05 titled "Important Advice for Dentists on reuse of Endodontic Instruments and Variant Creutzfeldt-Jakob Disease (vCJD)" stated that dentists should ensure that endodontic reamers and files are treated as single use.

Supplementary instruments high risk CJD tissues and rigid neuroendoscopes and their accessories

2.8 The CMO letter of 30 July 2013 titled "Risk of Iatrogenic* Transmission of Variant CJD During Neurosurgery" confirmed that the guidance remained extant. NICE 2007 guidance IP196 stated:

- "supplementary surgical instruments that come into contact with high-risk CJD tissues should either be single use or should remain with the set to which they have been introduced;
- rigid neuroendoscopes should be used whenever possible. They should be of a kind that can be autoclaved and they should be thoroughly cleaned and autoclaved after each use;
- all accessories used through neuroendoscopes should be single use;
- single-use instruments should be manufactured and procured to specifications equivalent to those used for reusable instruments and should be subject to high standards and consistent quality control. Single-use instruments which are not similar in quality to the reusable instruments which they replace have the potential to harm patients and should not be purchased or used."

Footnote *the published letter states 'Latrogenic' as opposed to Iatrogenic

3. Handling/treatment of medical devices at theatre after patient use

Principle

3.1 Gross debris and cements/adhesives should be removed immediately from medical devices by theatre staff after clinical procedure. Retention of this contamination will restrict the efficacy of the cleaning process. Set cement on medical devices is often impossible to remove and the use of wire brushes/scouring pads to remove cement will result in damage to the surface of the medical device and can induce corrosion and should not be used.

3.2 A full reconciliation of the medical devices should be performed.

3.3 At the end of the case, reusable medical device sets within trays and supplementals should be kept moist* for transport to the CDU. Medical devices kept moist during transportation back to CDU after use are easier to clean[1,2&3] which includes the important removal of prion protein from used medical devices.

Note: *'Moist' is considered to be high levels of relative humidity of the air in the pack.

3.4 There is no difference in principle when handling/treatment of medical devices for out of hours. It is especially important that medical device sets are wrapped and contained in a moist environment.

Methods to achieve

3.5 Local theatre procedure should be developed to include the removal of gross debris, adhesive and cement at the end of the procedure.

3.6 At the end of the clinical procedure a final wipe down of used medical devices using sterile gauze and water should be completed as per the IFU where applicable.

3.7 A full medical device count should be performed as per an accountable items local policy and a tray checklist completed.

3.8 Medical device sets can be kept 'moist' during transportation by, for example, use of absorbent pads and several millilitres of purified water (usually sterile water is readily available in theatre settings). Note the following:

- saline should not be used as a substitute for the purified water;
- spray gels sold for the intended purpose of keeping the surgical instruments moist may also be used. Their effectiveness and any possible adverse effects should be considered;
- trays should be covered and sealed in a clear plastic bag;
- the tray list, where used, can be protected from moisture by enclosing it in a separate bag and enclosed in the tray plastic bag;
- the tray list must be faced upward so it can be read.

3.9 The creation of ‘moist’ conditions inside a pack should neither increase the weight of the pack significantly nor produce “free” liquid in the pack that could move about.

3.10 Prior to adopting or changing the method, consult with your CDU management. A trial may need to be conducted to assess the effectiveness of the method and determine possible adverse effects.

4. Additional treatment required for complex and lumen medical devices

Principle

4.1 The construction of many medical devices are complex meaning they have multiple joints, hidden surfaces, hollows and lumens. These elements inhibit access by cleaning water jets and chemicals in the CDU washer disinfector and may present challenges to the sterilization process. In addition, these areas are difficult to inspect during reprocessing to ensure all debris has been removed. Some items such as suction tips and tubing can be sourced as single use and this should be considered the preferred option for this family of medical devices. Other difficult to clean medical devices should be assessed at the procurement stage to ascertain the balance between clinical functionality, cost and cross-infection risk.

4.2 Where possible and balancing costs with efficacy and risks, for those medical devices deemed to be difficult to clean, the preferred option would be to source single use.

Methods to achieve

4.3 Local theatre procedure should be developed to include the removal of gross debris, adhesive and cement at the end of the procedure.

4.4 At the end of the procedure a final wipe down using sterile gauze and water should also be completed **but** with additional precautions that complex medical devices are identified and manipulated to expose hidden surfaces and joints for wiping using gauze and sterile water.

4.5 In some cases, the working parts of a medical device can be manipulated submerged in a bowl (for example, stainless steel bowls are frequently available in a theatre setting) of sterile water to encourage dislodging of debris from inaccessible areas.

4.6 In addition, some medical devices with lumens can be attached to the theatre suction system and flushed through with sterile water or irrigated with sterile water and syringe. Care should be taken to avoid the generation of aerosols.

4.7 Medical device sets can be kept ‘moist’ during transportation by, for example, use of absorbent pads and addition of several mls of purified water (usually sterile water is readily available in theatre settings). Trays should then be covered with a clear plastic bag. The tray list can be protected from moisture by enclosing in a separate bag and enclosed in the tray plastic bag. The tray list must be faced upward so it can be read.

Explanatory notes

4.8 Costing of single use versus reusable difficult to clean medical devices should take into account the extra staff time required to clean and inspect such devices to provide a similar degree of assurance of cleanliness compared to less difficult to clean medical devices.

4.9 Identification of difficult to clean medical devices by theatre personnel and extra cleaning processes should be part of documented training policies and procedures.

5. Handling/treatment of medical devices at theatre after use for patients at increased risk of CJD

5.1 There is no evidence that normal social or routine clinical contact with a Creutzfeldt Jakob Disease (CJD) patient presents a risk to healthcare workers, relatives or others (Source 4.23 Hospital care of CJD patients ACDP TSE guide part 4*). Body secretions, body fluids (including saliva, blood, cerebrospinal fluid and excreta) are all low risk for CJD. It is therefore likely that the majority of procedures performed will be low risk.

5.2 Blood and body fluid samples from patients with, or "at increased risk" of, CJD should be treated as potentially infectious for blood-borne viruses and handled with standard infection prevention and control precautions as for any other patient (Source 4.24 Sample-taking and other invasive medical procedures to 4.26 ACDP TSE guide part 4).

Principle

5.3 Patients at increased risk of CJD are defined as shown in Table 1 (From the ACDP TSE section 4 Table 4a Categorisation of patients by risk published 2015).

For all patients with, or "at increased risk" of, CJD, the following precautions should be taken for surgical procedures:

- use Standard Infection Control Precautions and standard theatre procedure for all patients;
- single-use disposable medical devices and equipment should be used where possible (providing the standard of clinical care is not compromised), and subsequently destroyed by incineration;
- effective tracking of medical devices should be in place, so that they can be related to use on a particular patient and if safe and practical quarantined for re-use exclusively on the same patient pending diagnosis. This is based on the premise that these medical devices can be robustly traced through the decontamination process and returned to appropriate clinical area for designated patient use (adapted from Source 4.46 Surgical procedures and instrument management in ACDP TSE guide part 4 published 2015).

Footnote * Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection: Part 4 Infection prevention and control of CJD and variant CJD in healthcare and community settings published 2015

Category	Patient groups
Symptomatic patients	Patients who fulfill the diagnostic criteria for definite, probable or possible CJD (see Annex B ACDP/TSE 2015 for diagnostic criteria). Patients with neurological disease of unknown aetiology, who do not fit the criteria for possible CJD, but where the diagnosis of CJD is being actively considered.
Patients "at increased risk" from genetic forms of CJD	Individuals who have been shown by specific genetic testing to be at significant risk of developing CJD. Individuals who have a blood relative known to have a genetic mutation indicative of genetic CJD; Individuals who have or have had two or more blood relatives affected by CJD or other prion disease
Patients identified as "at increased risk" of vCJD through receipt of blood from a donor who later developed vCJD	Individuals who have received labile blood components (whole blood, red cells, white cells or platelets) from a donor who later went on to develop vCJD.
Patients identified as "at increased risk" of CJD through iatrogenic exposures	Recipients of hormone derived from human pituitary glands, e.g. growth hormone, gonadotrophin, are "at increased risk" of transmission of sporadic CJD. In the UK the use of human- derived gonadotrophin was discontinued in 1973, and use of cadaver-derived human growth hormone was banned in 1985. However, use of human-derived products may have continued in other countries after these dates. Individuals who underwent intradural brain or intradural spinal surgery before August 1992 who received (or might have received) a graft of human-derived dura mater are "at increased risk" of transmission of sporadic CJD (unless evidence can be provided that human-derived dura mater was not used). Individuals who have had surgery using medical devices that had been used on someone who went on to develop CJD, or was "at increased risk" of CJD; • Individuals who have received an organ or tissue from a donor infected with CJD or "at increased risk" of CJD; • Individuals who have been identified as having received blood or blood components from 300 or more donors since January 1990; • Individuals who have given blood to someone who went on to develop vCJD; • Individuals who have received blood from someone who has also given blood to a patient who went on to develop vCJD; Individuals who have been treated with certain implicated UK sourced plasma products between 1990 and 2001.

Table 1: Patient groups defined by category

Methods to achieve

5.4 Where single-use medical devices are not available, the handling of reusable medical devices depends on:

- how likely the patient is to be carrying the infectious agent (the patient's risk status);
- whether the patient has, or is "at increased risk" of, CJD; and
- how likely it is that infection could be transmitted by the procedure being carried out i.e. whether there is contact with tissues of high or medium infectivity.

5.5 In brief, for a patient with any form of CJD with a status of definite/probable, possible or at-risk and where medical devices have been in contact with high and/or medium risk tissue (see Tables 4c Handling of instruments – patients with, or "at increased risk" of, CJD (other than vCJD) and 4d Handling of instruments – patients with, or "at increased risk" of vCJD Section 4 ACDP TSE 2015 for details) the medical devices should either be single use, destroyed or if safe and practical quarantined for re-use exclusively on the same patient pending diagnosis. The latter option is based on the premise that such medical devices can be robustly traced through the decontamination process and returned to appropriate clinical area for designated patient use.

5.6 This process of selecting single use or reusable applies to medical devices that that have been used for procedures involving tissues designated as high or medium infectivity, on patients either;

- with, or at increased risk of, CJD/vCJD, for reuse exclusively on the same patient; or
- with a possible CJD/vCJD diagnosis, pending a confirmed diagnosis.

(Source: 4.50 Quarantining of surgical instruments Annex E of ACDP TSE 2016 guidance provides guidance on the procedures that should be followed when quarantining medical devices is considered).

6. Quarantining medical devices

6.1 The ACDP/TSE 2016 Annex E guidance provides advice on quarantining medical devices. Local risk assessments may result in the disposal of medical devices that fall into this category. This decision will be influenced by the cost and availability of the medical device set(s) in question, availability of secure quarantining locations, nature of the medical device/set track and trace processes and the duration of storage prior to reprocessing whilst awaiting decisions.

Methods to achieve

The method for quarantining medical devices is shown, see Figure 1.

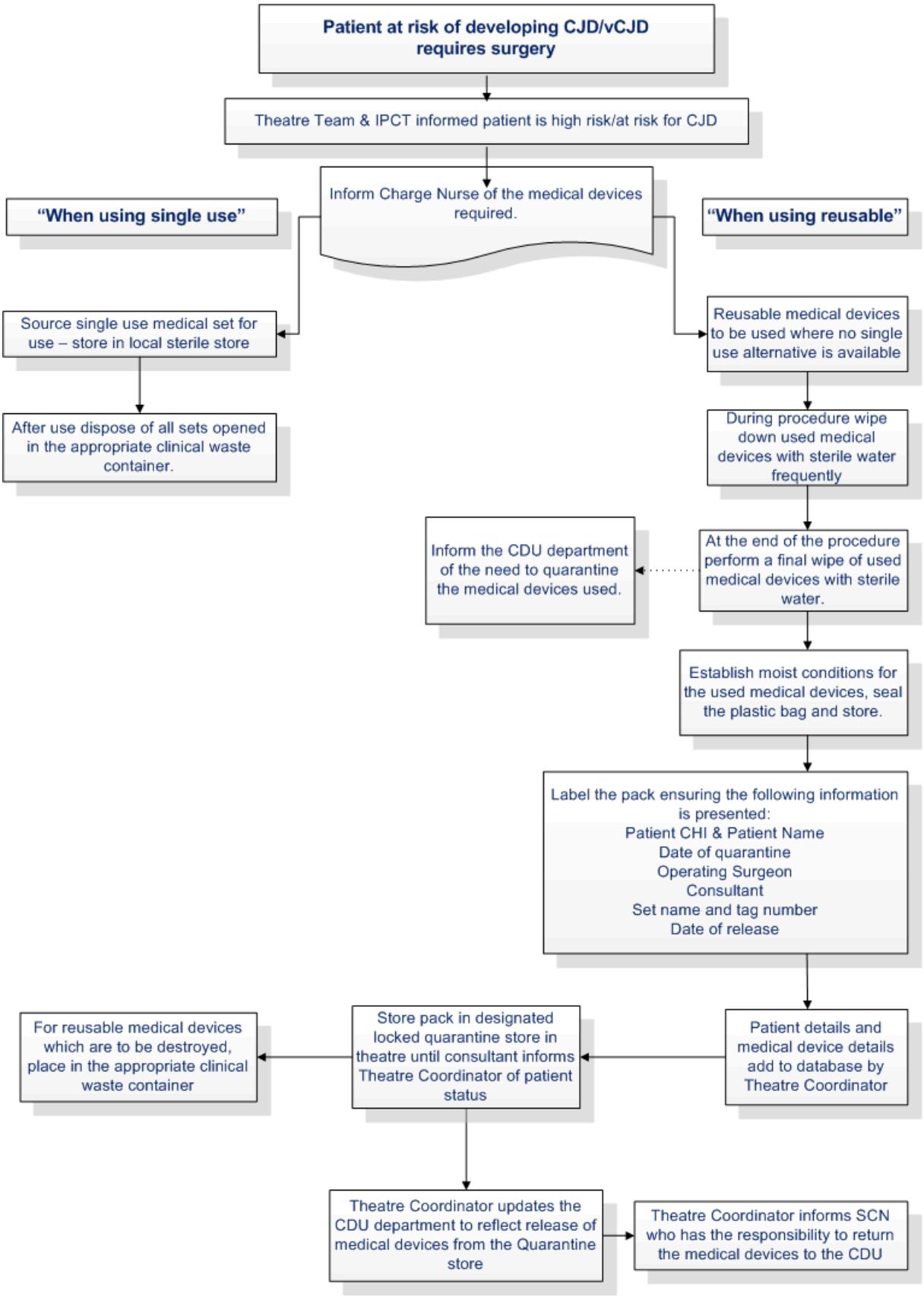

Figure 1: Process for quarantining medical devices

7. Definitions

Single-use device means a device that is intended to be used on one individual during a single procedure.

[SOURCE: Regulation (EU) 2017/745 article 2 – (8)]

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.

[SOURCE: Ref Page 14 – MHRA Single-use medical devices: implications and consequences of reuse December 2013]

A full glossary is included within SHTM 01-01 Part A.

References

These references were current at the time this document was produced. Anyone using this document should ensure that they refer to the current versions of any references.

References from section 3.0 of this guidance

[1]**Lipscomb IP, et al.** Effect of drying time, ambient temperature and pre-soaks on prion-infected tissue contamination levels on surgical stainless steel: concerns over prolonged transportation of instruments from theatre to central sterile service departments. *J Hosp Inf* 2007; 65: 72-77.

[2]**Secker TJ, et al.** Adsorption of prion and tissue proteins to surgical stainless steel surfaces and the efficacy of decontamination following dry and wet storage conditions. *J Hosp Inf* 2011; 78: 251-255.

[3]**TJ Secker et al.** Efficacy of humidity retention bags for the reduced adsorption and improved cleaning of tissue proteins including prion-associated amyloid to surgical stainless steel surfaces. Biofouling 31 (6), 535-541. 2015.

Government Publications

SEHD/CMO (2006) 13, “Migration to single-use pre-sterilised individually wrapped small orthopaedic implants in NHSScotland”.

HDL (2007) 4 January 2007 “Decontamination – Migration to single use pre-sterilised individually wrapped small orthopaedic implants”.

CMO (2007) 05 Important advice for dentists on the reuse of endodontic instruments and variant Creutzfeldt-Jakob disease (vCJD).

Government Letter 9 April 2009 titled “Decontamination – Migration to single use pre-sterilised individually wrapped implants – remaining specialities”.

CMO letter of 30 July 2013 to the Chair of the Neurosurgery MSN Office Risk of Latrogenic Transmission of variant CJD during neurosurgery.

SGHD/CMO (2015)2 letter 13th February 2015 Adenotonsillar surgical procedures: revision of advice on single use vs reusable instruments.

HFS publications

GUID 5014 NHSScotland Requirements for compliant Central Decontamination Units, 2016.

GUID 5010 Theatres and CDU Guidance Management of reusable surgical instruments during transportation, storage and after clinical use 2014; Part A – Design advice note for planning, Part B – Operational guidance.

GUID 5008 Guidance for Disposal and Recycling of Medical Devices, 2014.

GUID 5006 NHSScotland Guide to the Carriage of Dangerous Goods Regulations with respect to Used Medical Devices, 2013.

GUID 5002 National Decontamination Guidance on Loan Medical Devices (Reusable): Roles & Responsibilities, 2015.

Scottish Health Technical Memorandum (SHTM) 01-01 Decontamination of medical devices in a Central Decontamination Unit - Part A: Management, 2018.

Standards

EN ISO 1041: 2008+A1: 2013 - Information supplied by the manufacturer of medical devices, CEN.

EN ISO 17664: 2017 Processing of health care products -- Information to be provided by the medical device manufacturer for the processing of medical devices, CEN.

Other Guidance

NICE interventional procedure guidance 196-Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease (CJD) via interventional procedures Feb 2007 http://www.nice.org.uk/

Prevention of CJD and vCJD by Advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathy (ACDP TSE) Subgroup.

TSE agents: safe working and prevention of infection Part 4 Infection prevention and control of CJD and variant CJD in healthcare and community settings Feb 2015.

TSE agents: safe working and prevention of infection: Annex C General principles of decontamination and waste disposal Feb 2015.

TSE agents: safe working and prevention of infection: Annex E Quarantining medical devices August 2016.