



Ophthalmic Instrument Decontamination

1 Decontamination

Decontamination is the term used to describe a combination of processes, including cleaning, disinfection and/or sterilization, used to render a re-usable item safe for further use on patients and handling by staff.

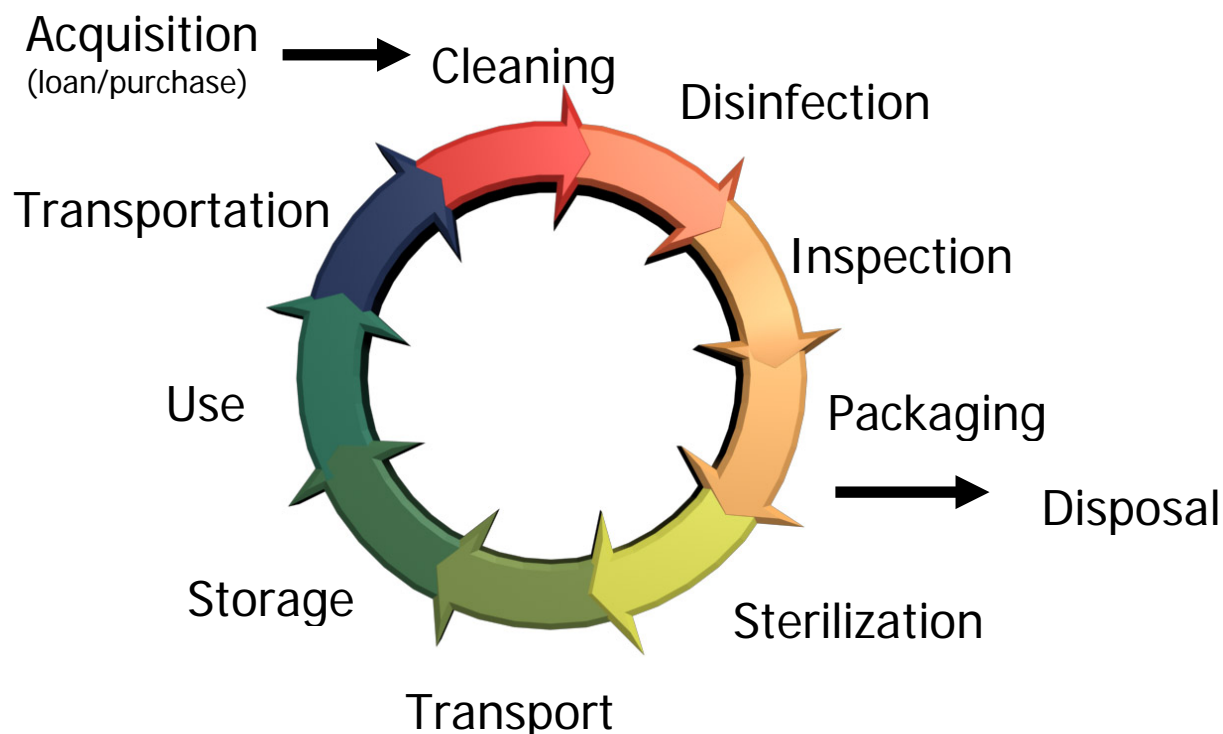
The effective decontamination of re-usable surgical instruments (or other clinical devices used in direct contact with tissues) is essential in minimising the risk of infectious agents.

Ineffective decontamination can result in problems via four main pathways:

- Foreign protein transfer, leading to risk of adverse reaction, or even risk of transmission of prion material.
- Infection, via transfer of microorganisms.
- Particulate material.
- Bacterial endotoxins.

Effective Decontamination:

Life-cycle of re-usable surgical instruments



General Principles - see MRHA [MAC Manual](#)



1.1 Acquisition

Manufacturers of re-usable surgical instruments are required to supply information on the appropriate decontamination process to allow reuse, including cleaning, disinfection and where appropriate the method of sterilization. Theatre staff should ensure that such information is provided and is available for those involved at all stages of the decontamination life-cycle.

All devices should be CE marked. Exceptions may occur for specific custom-made instruments, or those undergoing investigation, but should only be used with local authorisation and monitoring agreed by the hospital or trust decontamination lead.

1.1.1 Single-use instruments (SUI) v Re-useable

Single use is an advisable option for certain instruments used in many ophthalmic procedures: instruments that can be difficult or costly to decontaminate safely (e.g. those with a lumen), or those dependent on a cutting edge (e.g. scalpel blades or phako needles). It is also a means by which risk of transmission of CJD/vCJD can be reduced. (see below).

Instruments marked by the manufacturer “for single use only” should never be reused for a number of reasons:

- Inadequate cleaning and decontamination of instrument occurs with reuse. This can be due to instrument construction (e.g. small bore), or surface damage occurring, preventing removal of all debris or organisms.
- Component materials can become damaged or brittle. This leads to the risk of loose fragments entering the eye during surgery.
- Some materials can adsorb or absorb certain chemicals, potentially causing harm.

MHRA Device Bulletin Single-use Medical Devices: Implications and Consequences of Reuse DB2006(04) v2.0 December 2011

<http://www.mhra.gov.uk/home/groups/dts-iac/documents/publication/con2025021.pdf>



1.2 Cleaning

Due to the high volume of operations in ophthalmology, particularly for cataract surgery, there is a need to ensure that sufficient instruments exist to allow for adequate cleaning and re-sterilization of instruments, even if the reprocessing facility is some distance from the ophthalmic unit. (Where there is transition to a centralised unit, it is important that service contracts and provision of sufficient tray sets reflect the expected local demands).

Cleaning is the most important stage in the decontamination process. "[A Guide to the decontamination of reusable surgical instruments – NHS Estates 2003](#)" states that "effective cleaning of surgical instruments is of the utmost importance in reducing the risk of transmission of infectious agents".

Immediately after use, the dirty instruments must be taken via a specially dedicated theatre hatch, separate from the "clean" hatch, to an adjacent area. Separation of clean and contaminated instruments is of paramount importance. Complex instruments such as phaco hand-pieces and Aspiration/Irrigation sets should be disassembled following manufacturers' recommendations. It is usual practice (and probably particularly appropriate for phaco hand-pieces) for ophthalmic theatre staff to begin this process in theatre immediately as these are deemed "difficult to clean" items. Appropriate personal protection should be worn. Any instrument with a lumen should be flushed with pure water. Instruments ready for transfer to the Decontamination facility should be kept moist, as drying could cause any residual debris to harden, making further removal difficult. Liaison between theatre staff and HSDU regarding specialised equipment requirements is advisable, even when the HSDU provider is at a distance.

Manual cleaning of some instruments can be performed using an immersion method with a specifically designed detergent (possibly with enzymes). However, such manual cleaning should normally only take place if the manufacturer has made this a specific requirement. Instruments are dismantled and, whilst immersed, are brushed, irrigated, sprayed and agitated to remove dirt. They are then rinsed and then dried with non-linting cloth or mechanical drying. Instruments that should not be soaked, including those with electronic components (e.g. phaco hand-pieces), can be cleaned using a non-immersion method using detergent-soaked cloth, and then dried as above. The manufacturer guidance should always be followed.

Automated cleaning is possible using either properly validated and maintained washer-disinfectors or ultrasonic cleaners, or possibly a combination of both. Some cleaners also incorporate a disinfection stage. The instruments must be adequately packed so as to prevent damage during the washing cycle.



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It is important that only recommended detergents are used. Ideally, manufacturers should have tested them on ophthalmic instruments as it is preferable to know if such products have toxic effects on the eye and if they can be removed adequately from ophthalmic instruments.

1.3 Disinfection

Disinfection is usually achieved by the use of liquid chemicals or by moist heat. Moist heat is the first choice method except for devices unable to withstand high temperatures.

Disinfection aims to reduce the number of viable organisms, but cannot be relied upon to inactivate all organisms, particularly viruses and bacterial spores. The process is more effective if air bubbles are dislodged by agitation.

Manufacturers' guidance must always be provided and followed.

1.4 Inspection

Inspection of devices should be performed by staff members in the decontamination facility other than those responsible for cleaning them. For fine ophthalmic instruments, it is useful for magnification to be used, using a loupe system or microscope. Instruments that are damaged can be identified, as can those that have been inadequately cleaned. Damaged instruments are removed for repair or disposal after decontaminated in accordance with, [MHRA DB2006\(05\)](#) and inadequately cleaned items are returned to the decontamination cycle for further cleaning.

The final visual inspection should be made by the operating surgeon before using any instrument.

1.5 Packaging

The packaging of instruments will depend on its size, planned use, and chosen sterilization method. Some instruments will form part of a multiple package and be packed in suitable trays. Others will be individually packed in sealed peel-apart pouches.

All instruments should be traceable. The use of coloured adhesive marking tapes is not recommended and should be discouraged, as this leads to inadequate decontamination and gradual break-down of the applied material. Ideally, all instruments should be etched with a unique identifying code. Retrograde marking using etching is unlikely to be feasible for all existing instruments, apart from high-value items (such as phaco hand-pieces), so at least all trays should be coded in such a way that they, and their contents, are traceable.



1.6 Sterilization

The preferred method for instruments in the clinical setting is the use of saturated steam under pressure, at the highest temperature compatible with the instruments being processed.

Solid items can be sterilized in Bowl and Instrument Sterilizers that do not have an active air-removal stage. Non-solid items, including those with lumen, or wrapped goods, require sterilization in Porous-Load Sterilizers (Autoclaves), and are not suitable for sterilization in non-vacuum sterilizers.

The use of stand-alone bench-top units in the operating theatre or clinic is discouraged as their maintenance and validation can be difficult. Health care organisations, and indeed individual professionals, could be held liable if guidance is not followed.

1.7 Transport

Transportation of instruments between clinical areas and decontamination facilities will rise as the latter are increasingly centralised. It is essential that transit containers fully protect their contents and individuals handling them. They must be secure, tamper-proof, waterproof, and clearly labelled.

In order to avoid damage, clean instruments must be packed by speciality-trained personnel in trays designed for eye instruments.

1.8 Storage

Ideally, once ready for use, these trays should then be stored in the Eye Theatre (or clinic) suite. The storage area should be safe, dry, above floor level and away from sunlight and water. It is vital that packs are handled carefully in order to prevent damage and loss of sterility.

1.9 Use

Before use, packages should be checked to ensure that:

- The package is intact
- The sterilization indicator confirms sterilization
- Expiry date has not passed

Theatre or clinic staff must notify the decontamination unit staff about any concerns regarding problems with instrument or device availability, or the instruments themselves.



2 CJD

2.1 “High Risk” or “Low Risk” Surgical Procedures

Ophthalmic procedures regarded as high-risk are given in “Transmissible spongiform encephalopathy agents: safe working and the prevention of infection”, Annex L “[Managing CJD/vCJD Risk in Ophthalmology](#)” Appendix 1.

“High Risk” category includes ophthalmic procedures on the Posterior eye, specifically the posterior hyaloid face, retina, retinal pigment epithelium, choroid, subretinal fluid and optic nerve. Procedures on cranial nerves are also “high risk”.

Appendix 2 covers all anterior segment surgery (including corneal surgery and complicated cataract surgery) which is now considered “low risk” for infectivity.

“High risk” procedures are also listed as HES codes in [NICE interventional procedure guidance 196](#) Appendix C:

- C01 Excision of eye
- C79 Operations on vitreous body
- C81 Photocoagulation of retina for detachment (only when the retina is handled directly)
- C82 Destruction of lesion of retina
- C84 Other operations on retina

The inclusion of C79 Operations on vitreous body here refers to posterior approach surgery.

N.B. Anterior vitrectomy is considered “low risk” and warrants no specific variation from normal practice in instrumentation, or in decontamination of instruments and equipment.

As single-use instrumentation has improved and is more readily available, disposable equipment can be considered for “High Risk” procedures. It is no longer a requirement that such procedures are undertaken with disposable instruments. The costs involved may preclude this approach, as recognised by NICE. Referring to high-risk surgical procedures, including eye surgery, [NICE interventional procedure guidance 196](#) (para 1.4) states: “the evidence on cost effectiveness related to the possible transmission of CJD does not support a change to single-use instruments based on current costs”.

If SUIs are used, it is essential that they are of consistent and suitable quality.

If re-usable instruments are used, they must not migrate between sets, and should be fully traceable. There should be a separate pool of instruments for patients born after 1 January 1997.



2.2 The Patient with, or “at increased risk” of, CJD or vCJD

2.2.1 Identification of the patient with, or “at increased risk” of CJD or vCJD

“Transmissible spongiform encephalopathy agents: safe working and the prevention of infection”, [Annex J](#) advises that **ALL** patients undergoing **ANY** surgical procedure should be asked:

“Have you ever been notified that you are at increased risk of CJD or vCJD for public health purposes?”

The patient’s response should be recorded in the notes. A positive response requires further questioning and consultation with local infection control team.

For patients undergoing High Risk (posterior segment) surgery, in addition to checking patient records and observing any clinic signs of CJD/vCJD, a series of questions should be asked, as outlined in Table J1 of Annex J above. These questions relate to family history, growth hormone treatment, previous neurosurgery and exposure to multiple blood transfusions.

(N.B. Annex J is continually under review, and changes may occur with any new evidence).

2.2.2 Low risk surgery in a patient with, or “at increased risk” of CJD/vCJD

For routine Anterior Segment surgery and other “Low Risk” ophthalmic procedures, no change to routine instrumentation or decontamination is required. Avoiding instrument migration between trays and instrument sets remains good practice. Anterior Segment surgery that becomes complicated, involving instrument contact with optic nerve or retina, should then be considered “High Risk”. (see para L39-44 of [Annex L](#) “Transmissible spongiform encephalopathy agents: safe working and the prevention of infection”).

2.2.3 High risk surgery in a patient with, or “at increased risk” of CJD/vCJD

For “High Risk” ophthalmic surgery (Posterior Segment), if a patient is suspected to be suffering from any form of CJD, a further opinion may be considered. If surgery is deemed urgent, then consideration should be given to the operation being carried out entirely with single-use instruments. If this is not possible, at the end of the procedure then quarantining instruments should be considered ([see Annex E](#) of “Transmissible spongiform encephalopathy agents: safe working and the prevention of infection”).

Single-Use Instrument (SUI) use as an option to reduce risk of CJD/vCJD transmission in ophthalmic surgery is also covered in more detail in Appendix 4 of Annex L “[Managing CJD/vCJD Risk in Ophthalmology](#)” from the ACDP TSE Risk Management Subgroup. SUIs should be of equivalent standard to re-usable instruments.



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After washing, instruments (single-use or re-usable) should be placed on a disposable instrument tray and allowed to air-dry. They should then be placed in an impervious rigid plastic container with a close-fitting lid. The lid should be sealed with heavy-duty tape (e.g. autoclave tape) and labelled with the patient's identification details (i.e. name, date of birth and hospital number). The label should also state the surgical procedure in which the instruments were used and the name of the responsible person (e.g. theatre superintendent). The original instrument tray should be disposed of by incineration.

The sealed box can be stored indefinitely in a suitable designated place until the outcomes of any further investigations are known. If the patient is confirmed as suffering from CJD or vCJD, the box and its contents should be incinerated without any further examination. The instruments could alternatively be donated to the DH sponsored research store organized by the Health Protection Agency. (This is in order to retain for decontamination experiments).

Guidance from ACDP TSE Risk Management Subgroup ([Part 4 of 'Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection'](#)) is that *'for all patients with, or "at increased risk" of, CJD or vCJD, single-use should be used where possible, and subsequently destroyed by incineration or sent to the instrument store'*. It is possible for instruments to be segregated and processed using standard decontamination process, for use again on the same patient.

If an alternative diagnosis is confirmed, the instruments may be removed from the box by the responsible person (or a named deputy) and any re-usable instruments reprocessed according to best practice and returned to use. Additional decontamination procedures are not required.

Records must be kept of all decisions, and the Sterile Service Department (SSD) must be informed about the decision before the instruments are sent for routine reprocessing

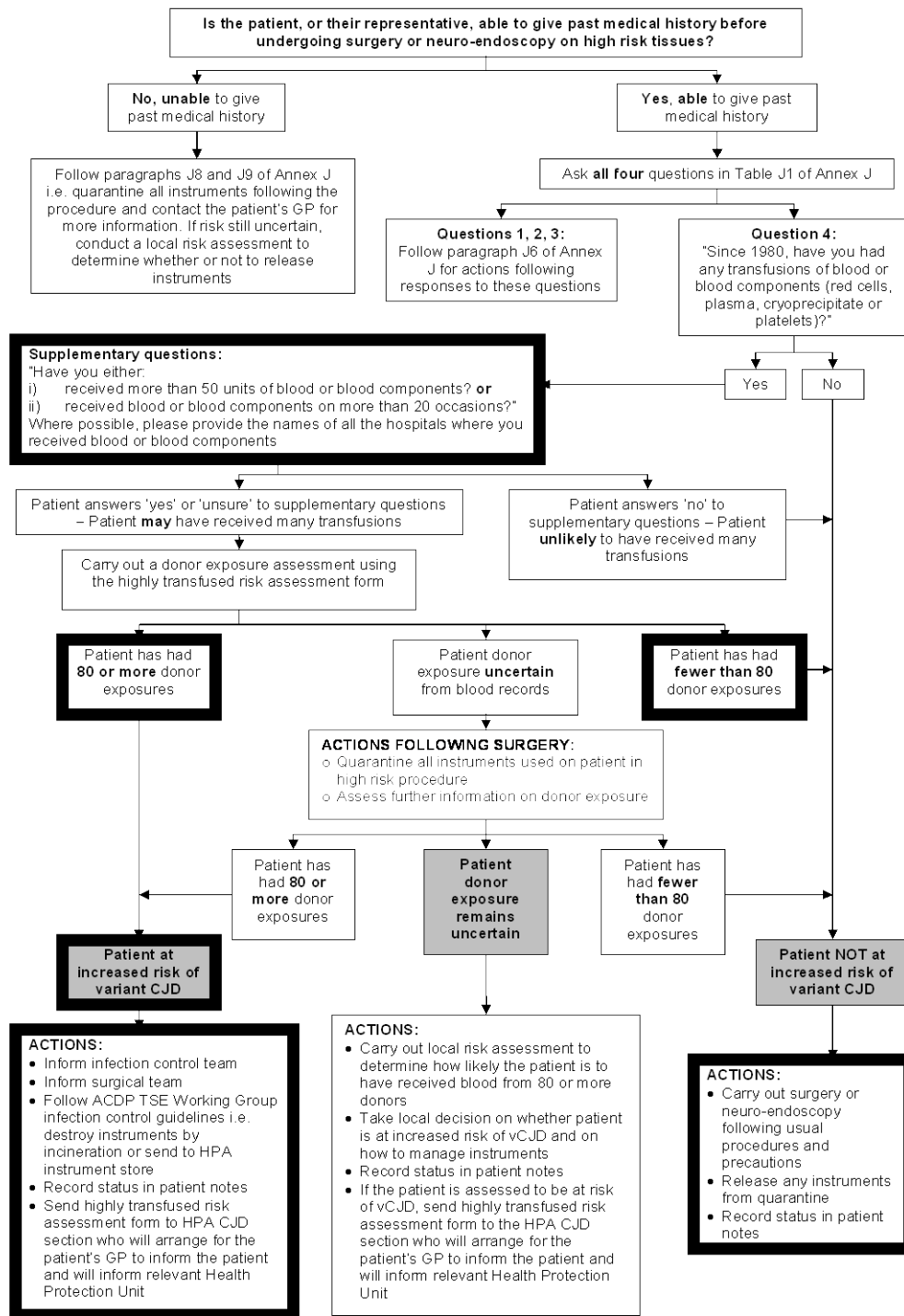
In summary: for any High Risk surgery performed on patients with, or "at risk" of CJD/vCJD, the instruments should be either single-use (and destroyed post-operatively), or re-usable, in which case they should be destroyed or kept for re-use solely on the individual patient.



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From **Annex J** of “*Transmissible spongiform encephalopathy agents: safe working and the prevention of infection*”:

Management of patients undergoing procedures which may involve contact with high risk tissues





3 Devices used in Clinic

Numerous instruments are used in eye clinics that come into contact with the surface of the eye or the mucous membrane surface of the conjunctiva. Whilst some are available as single-use items, it is necessary to re-use others.

For items such as diagnostic contact lenses, ultrasound probes or pachymetry that cannot be replaced after each use, it is essential that departments have a policy for ensuring the risk of transmission of infection is reduced to the minimum practical level.

3.1 General Principles

The greatest risk for transmission of infection is likely to be poor hand hygiene in the clinic environment. Other infections can be transmitted during ophthalmic examinations, particularly those involving direct contact with mucous membranes and tears. Whereas the transmission of prions is an unlikely and theoretical risk, albeit one that cannot be ignored, many other infections (such as adenovirus outbreaks) pose well-recognised and significant risks. It is possible to disinfect the contaminated surface of an instrument, but without attention to work surface (including slit-lamp) decontamination, hand washing and glove wearing when appropriate, transmission of infections remains a risk.

The APDS TSE Risk Management Subgroup in Appendix 3 of [Managing CJD/vCJD Risk in Ophthalmology](#) has addressed the issue of possible CJD/vCJD in the context of the eye clinic.

A solution containing 10,000 parts per million of available chlorine (sodium hypochlorite) is effective in reducing Transmissible Spongiform Encephalopathies, including vCJD. It is also effective against most organisms likely to be encountered within the environment of the Eye Clinic. [Rutala & Weber](#).

Soaking in 1% hypochlorite solution (e.g. Milton) for 10 minutes between patients as part of a decontamination procedure is therefore recommended as best decontamination practice against the risk of CJD/vCJD. The compatibility of such solutions with various devices has yet to be determined, although it is widely used for tonometer prisms. Clinicians must make their own risk-assessments for their own practice within their own departments, based on the available knowledge, including data from equipment manufacturers. (In considering a balance of risk versus cost-effectiveness, it may be useful to compare the approach taken by NICE on the subject of single-use items in surgical procedures: Referring to surgical procedures, including all eye surgery, NICE interventional procedure guidance 196⁶ para 1.4 states *“the evidence on cost effectiveness related to the possible transmission of CJD does not support a change to single-use instruments based on current costs”*). This will



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undoubtedly apply also to many devices used in an ophthalmic outpatient setting. <http://www.nice.org.uk/guidance/index.jsp?action=download&o=31754>

The use of alcohol wipes alone is insufficient for safe decontamination, and if used before the cleaning stage there is a theoretical risk of binding any prion protein to the instrument surface. 70% alcohol wipes have been shown to be insufficient to inactivate Adenovirus and other viruses.

3.2 Tonometry

Single-use disposable tonometer heads or tonometer shields are an option for use with patients known to have, or under suspicion of having, CJD. This could include neurological diseases such as dementia of unknown aetiology. These devices should be available in all departments, and single-use options used whenever possible for these “potential risk” cases.

It is unnecessary to use disposable tonometry for all routine cases. There is no evidence that using single-use devices for all routine is cost-effective in reducing infection risk. It is acceptable to use reusable tonometer prisms provided that they are decontaminated correctly between patients. Cellular and proteinaceous debris can be present on tonometers after use, although the cornea is now regarded as low risk for prion infectivity. After each use, and before being allowed to dry, re-usable prisms should ideally be rinsed in water, washed with soap/detergent and rinsed again, then immersed in 1% sodium hypochlorite solution for at least 10 minutes; after which they should be rinsed (using sterile water) and dried.

Tonometer prisms can become damaged with time. Regular inspection at the slit-lamp is recommended, with replacement of any prism with significant damage. [Neubauer S et al](#)

3.3 Diagnostic Contact Lenses

These lenses should be decontaminated as for tonometer prisms. They should also be checked on a regular basis for evidence of damage; cracks could not only abrade the cornea but could also harbour debris or hold disinfectant, both possibly leading to further ocular irritation.

3.4 Contact Lenses

The vast majority of contact lenses are for single patient use only. There are some exceptions, such as Trial Contact Lenses or Special Complex Diagnostic Contact Lenses, which may need to be re-used. The College of Optometrist recommend in their document [A03 Infection Control](#) para A3.57 that in these circumstances:

- a) The lenses should be used solely within the clinician’s premises and under the control of the clinician at all times;



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- b) The clinician should ensure that decontamination is carried out to the highest possible standards;
- c) The clinician should keep full records to show the usage of each lens;
- d) The clinician should inform the patient of all the relevant risks and benefits associated with contact lens fitting.

Guidance in the British Standards Draft for Development: "Ophthalmic optics - Contact lenses - Hygienic management of multipatient use trial contact lenses" BSi DD ISO/TS 19979:2004 includes a decontamination method that has been superseded by that suggested by ACDP TSE Risk Management Subgroup, which is in line with current College of Optometrist advice.

3.5 Surgical instruments

Where possible, any instrument used in the clinic should be processed for decontamination just as for use in theatres, except for single-use instruments, which should be disposed of after use. In the event of any instrument that has touched the eye or adnexae, where that instrument needs to be re-used in the clinic setting for any reason, the general principles above should apply.



4 Summary for Clinic Devices Decontamination:

The guidance given in Annex L is a distillation of the views of a multidisciplinary expert advisory group to address the issue of prion transmission. The guidance presented in this document reflects a pragmatic approach to decontamination of most instruments used in an ophthalmic clinic and should enable ophthalmic units to minimise infection risk to patients, staff and to equipment in a cost-effective and practical way. In offering a slightly simplified recommended regime, it is expected that compliance with the recommendations should be both readily achievable and can be easily audited on a regular basis in any department.

This guidance, like the guidance in Annex L, remains advisory. Should individual units have particular concerns regarding any recommended measures, they are strongly advised to seek the advice of their Infection Control Advisors and draw up a written local policy that is both practical and likely to be effective.

- **Good Hand Hygiene is essential**
- **Clean device immediately after use, or keep moist until decontaminated**
- **Wash with clean running tap water with soap or detergent (as for hand-washing).**
 - TSE guidance recommends sterile water at every stage of cleaning, but for frequently used items with hard surfaces, such as tonometer prisms, the above is a practical approach in a clinic setting. Concerns regarding water contamination with *Acanthamoeba* exist; general guidance for standard contact lens management is that tap water should be avoided. The above cleaning technique however would reduce the risk of contamination to equal that of a clean hand holding the device in normal use, and following this immediately with disinfection will reduce any risk of contamination to a negligible level.
 - Further guidance on water quality is the responsibility of local infection control and estates.
- **Soak for min. 10 minutes in sodium hypochlorite solution (10,000ppm chlorine)**
 - Ensure staff are familiar with potential hazards of storing, preparing and handling solutions
 - Label solutions and containers clearly
 - Solutions should be fresh
 - Avoid prolonged soaking
 - Check with instrument manufacture for advice if in doubt regarding use of this method
- **Rinse thoroughly with Sterile Water**
- **Dry using paper tissues**
- **Store to prevent contamination prior to next use**

Note: Alcohol Swabs

- Alcohol used prior to decontamination risks of fixing any existing prions to the surface.
- 70% alcohol is inadequate to inactivate all virus particles.



5 Bibliography

5.1 Decontamination - General Resources

5.1.1 MHRA <http://www.mhra.gov.uk>

- The MAC Manual “Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Advisory Committee (MAC) to the Department of Health Medical Devices Directorate”.
- **Part 1** (2nd Ed 2002) **PRINCIPLES** of the processes that are available for decontamination.
- **Part 2** (2nd Ed April 2005) **PROTOCOLS** for decontamination using cleaning, disinfection and sterilization processes.
- **Part 3 PROCEDURES**
 - Section 1 (Feb 1999) –General advice regarding European Directives for medical devices
 - Section 2 (Oct 2000) – Provides general procedures for groups of equipment including ophthalmology.

<http://www.mhra.gov.uk/Publications/Safetyguidance/Otherdevicesafetyguidance/CON007438>

- Other Publications available via MHRA Website:
<http://www.mhra.gov.uk/index.htm>
- DB 2006(04) Single-use Medical Devices: Implications and Consequences of Reuse
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5.1.2 Department of Health

- NHS Decontamination Programme : DH – “Managing your organisation”:
<http://www.dh.gov.uk/en/Managingyourorganisation/Leadershipandmanagement/Healthcareenvironment/NHSDecontaminationProgramme/index.htm>
- Guide to the decontamination of reusable surgical instruments (DH 2003)
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4120906

5.1.3 Scotland:

- Health Protection Scotland Decontamination website:
<http://www.hps.scot.nhs.uk/haic/decontamination/index.aspx>
- The Glennie report: <http://www.scotland.gov.uk/Publications/2001/10/10106/File-1>

5.1.4 Wales

- Public Health Wales <http://www.wales.nhs.uk/sitesplus/888/page/43949>



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5.2 CJD Information and Resources:

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- NHS Estates, Health Service Circular HSC 1999/178 “Variant Creutzfeldt-Jakob Disease (vCJD): Minimising the Risk of Transmission”. DH 1999
http://www.dh.gov.uk/en/PublicationsAndStatistics/LettersAndCirculars/HealthServiceCirculars/DH_4004969

5.2.2 Guidance from the ACDP TSE Risk Management Subgroup (formerly TSE Working Group) <http://www.dh.gov.uk/ab/ACDP/TSEguidance/index.htm>

- Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection: **Annex A1**, Distribution of TSE infectivity in human tissues and body fluids
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_132095.pdf
- Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection: **Annex C**, General Principles of decontamination TSE.
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- Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection: **Annex J**, Pre-operative Assessment.
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5.2.3 RCOphth / Dept. Health

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5.2.4 NICE

- NICE interventional procedure guidance 196 Nov. 2006. “Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease (CJD) via interventional procedures”.
<http://www.nice.org.uk/guidance/index.jsp?action=download&o=31754>

5.3 Infection Control - General Principles

- National electronic Library of Infection
http://www.neli.org.uk/IntegratedCRD.nsf/NeLI_Home1?OpenForm
- National Resource for Infection Control (NRIC) decontamination policy
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- Environmental Cleanliness
<http://www.wales.nhs.uk/sites3/page.cfm?orgid=379&pid=38961>
- Hand Hygiene <http://www.wales.nhs.uk/sites3/page.cfm?orgid=379&pid=38962>
- Hand Hygiene Literature Review:
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