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OPHTHALMOLOGISTS

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Ophthalmic Services Guidance

# Ophthalmic Instrument Decontamination

October 2016

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18 Stephenson Way, London, NW1 2HD T. 020 7935 0702

[contact@rcophth.ac.uk](mailto:contact@rcophth.ac.uk) [rcophth.ac.uk](http://rcophth.ac.uk) @RCOphth

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# 1 General principles and definitions

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Decontamination is the term used to describe a combination of processes, including cleaning, disinfection and/or sterilization, used to make a re-usable item safe for further use. The effective decontamination of re-usable surgical instruments and clinical devices used in direct contact with tissues is essential in minimising the risk of transferring microorganisms or other contaminants which might lead to infection or other harmful response.

Medical Devices are all the products, except drugs, used in health care for diagnosis, prevention, monitoring or treatment. The list is enormous, ranging from tonometers and slit lamps, through surgical instruments to hospital beds and MRI scanners. This document will concentrate on products which are particularly important to, or specific for, ophthalmology.

## Choosing a method of decontamination

A multitude of different processes are available for decontamination. Choice of the appropriate procedure for a given situation or device needs to take into account factors such as:

- The processes available locally
- Nature and level of risk of harm to patients
- Nature and level of risk of harm to staff using method
- Manufacturer's instructions for decontamination.
- Heat, pressure, moisture and chemical tolerance of the object
- Reliability of method
- Cost effectiveness and practicality of method

Ideally a risk assessment is carried out as part of the device purchasing process to determine decontamination process required.

*Table 1 Rough guide to determining risk and methods*

Risk	Use	Method
High	In close contact with broken skin or broken mucous membrane  Introduce into sterile body areas	Cleaning followed by sterilisation OR Single use device, where available and practical
Medium	In contact with mucous membranes, contaminated with highly virulent or readily transmissible organisms, before use on immunocompromised patients	Cleaning followed by sterilization or disinfection  NB: Where sterilization will damage equipment, cleaning followed by high level disinfection is an alternative
Low	In contact with healthy skin not in contact with patient	Cleaning

## Procedures in place in units

Ophthalmic service decontamination programmes will require providers to be compliant with relevant national guidance and regulation and in particular should ensure:

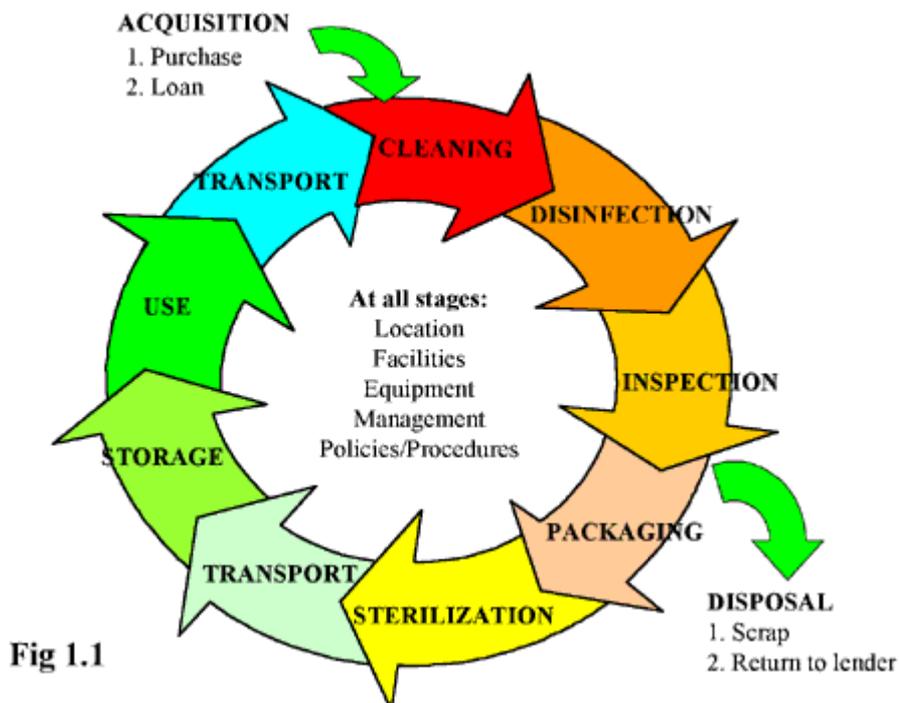
- The decontamination of reusable medical devices takes place in the appropriate facilities
- Appropriate procedures are followed for the acquisition and maintenance of decontamination equipment and for managing equipment in general
- Staff are trained in decontamination processes and hold appropriate competencies for their role
- A monitoring system is in place to ensure that decontamination processes are fit for purpose and meet the required standard
- Appropriate infection control processes and staffing are in place
- Appropriate theatre facilities in particular the ability to separate clean from dirty instruments

## Decontamination methods

The reusable medical device life cycle comprises the following processes: acquisition, disposal, cleaning, disinfection, inspection, packaging, sterilisation, transportation, and storage, and use.

The three processes included in decontamination are:

1. Cleaning
2. Disinfection
3. Sterilisation.



## 2 Good practice for ophthalmic theatre instruments

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### Acquisition and disposal

Manufacturers of re-usable surgical instruments must 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 (Conformité Européenne) marked which confirms that they comply with the essential requirements of the relevant European health, safety and environmental protection legislation (product directives) and are fit for the intended use.



Exceptions may occur for specific custom-made instruments, those undergoing investigation, or for exceptional circumstance humanitarian grounds, but this must involve consultation with the MHRA, local authorisation from managers, infection control and device leads, monitoring, patient counselling and consent and, where relevant, ethics approval.

### Single use instruments

Single use is a useful option for certain ophthalmic instruments such as: instruments that are difficult or costly to decontaminate safely (e.g. those with a lumen), or those dependent on a cutting edge (e.g. scalpel blades). It is also a means by which risk of transmission of CJD/vCJD (Creutzfeldt-Jakob Disease and variant CJD) can be reduced (see below). However, staff need to be satisfied that the single use device quality is sufficient for purpose and weigh up the risks of potentially different quality vs the benefits and convenience of disposability.

Single use devices carry the single use logo



and should never be reused for a number of reasons:

- Inadequate cleaning and decontamination of instrument may occur with reuse due to instrument construction (e.g. small bore), or surface damage, preventing removal of all debris or organisms.
- Component materials may become damaged or brittle leading to the risk of loose fragments entering the eye during surgery.
- Some materials can adsorb or absorb certain chemicals, potentially causing harm
- Legally, if a single-use item is reused this may negate the manufacturer's warranty, cause liability to the unit or hospital and the employee under criminal and civil law if damage or injury is caused.

## **Disposal**

Single use instruments are isolated after use and disposed of in accordance with manufacturer's guidance and national healthcare requirements, usually as clinical waste.

Advice can be sought from the manufacturer or MHRA regarding details of environmental disposal, recycling or structural requirements. Any item that stores patient identifiable information, should have this securely erased when the device is prepared for disposal.

See CJD section for relevant disposal.

## **Tracking**

Reusable surgical devices must be decontaminated with a system that gives total traceability through all the decontamination processes so that the links to patients and clinical staff are identifiable. Ideally a computerised tracking system is used.

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.

## **Cleaning**

Cleaning is the most important stage in the decontamination process. Cleaning is a process which removes dust, dirt, excretions, secretions, organic matter and all contamination including harmful and undesirable substances as well as a large proportion of micro-organisms which may be present.

Micro-organisms cannot multiply on a clean dry surface and the majority rapidly die. Cleaning must always be thoroughly performed before disinfection or sterilisation is attempted, to remove organic matter that may compromise the further processes.

Manual cleaning of instruments should only be used when mechanical/automated methods are inappropriate or not available. Mechanical/automated cleaning is the most effective and reproducible method and minimises the risk of staff exposure to pathogens including prions.

Reprocessing of surgical instruments should ideally be done in central processing units (often known as hospital sterilisation and decontamination unit [HSDU] or central sterile services department [CSSD]) rather than in the local clinical environment. Due to the high volume of operations in ophthalmology, particularly cataract surgery, there is a need to ensure that sufficient instruments and sets exist to allow for demand and for adequate decontamination even if the reprocessing facility is some distance from the ophthalmic unit.

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 common 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 water. Instruments ready for transfer to the Sterile Services Department (SSD) should be kept moist, as drying could cause any residual debris to harden, making further removal difficult. Liaison between theatre staff and SSD regarding specialised equipment requirements is advisable.

## **Disinfection**

Disinfection is a process that removes or destroys potentially harmful microorganisms (apart from spores) to a level non-harmful to health. Manufacturers' guidance must always be followed.

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. Chemical disinfectants may not be effective when they are used on dirty instruments/equipment (due to inability to make contact with micro-organisms or the surface to be decontaminated), if the solution is not freshly made or it is at the incorrect temperature. All disinfectants must be stored, reconstituted and used in accordance with health and safety regulations.

## **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 should be removed for repair or disposal after being decontaminated 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.

## **Packaging**

The packaging of an instrument 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.

## **Sterilisation**

Sterilisation is a process that removes or destroys all micro-organisms and spores. The preferred method for instruments is autoclaving which achieves sterilisation by applying steam under pressure at the highest temperature compatible with the instruments being processed.

Autoclaving should be performed in a fully regulated manner and controlled environment and is best undertaken in a SSD by fully trained staff. The use of stand-alone bench-top units in the operating theatre or clinic is discouraged as their maintenance and validation can be difficult.

## **Transport**

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.

## **Storage**

Ideally, once ready for use, the instrument trays should then be stored in the eye theatre or clinic area. 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.

## 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.

## 3 Good practice for devices and equipment in outpatient clinics

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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 pachymeters 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.

The greatest risk for transmission of infection is likely to be poor hand hygiene in the clinic environment. 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) 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.

For low risk equipment such as slit lamps, laser machines, pin hole occluders etc. detergent wipe or liquid soap cleaning can be used at intervals (e.g. daily) and when visibly soiled, and alcohol can provide disinfection between patients, especially on areas of close contact such as head rests and chin rests. This needs to air dry or be dried with a tissue or non shedding clean cloth.

For reusable devices which contact the cornea, or mucous membrane of the eye consider the use of non contact or disposable devices, or the use of disposable covers, where possible and where it does not impact on the quality of care.

The College supports the following actions for reusable devices contacting the cornea:

- Refer to manufacturer's instructions for each specific instrument or device
- Ensure involvement of local infection control team and risk assess procedures
- Check the device for damage before use
- Do not allow device to dry after use
- Clean with detergent, liquid soap or neutral detergent wipes for at least 20 seconds
- Rinse with sterile water or saline
- Dry with clean non-linting tissue
- If used on infected patient it must be disinfected or sterilised

## **Surgical instruments in clinic**

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 CJD and other prion diseases**

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*See references especially Annex L, J and E in references for full details.*

### **Background and transmission in ophthalmic healthcare**

Creutzfeldt-Jakob Disease (CJD) is a fatal human form of transmissible spongiform encephalopathy (TSE) associated with a build up of prion proteins in brain tissue. In humans, the disease can be familial (autosomal dominant) or sporadic (usually in older patients). Variant CJD (vCJD), thought to be related to ingestion of contaminated beef, usually occurs in younger patients. All are rare. Because the disease can be very slowly progressive and can have a prolonged preclinical phase, there is a concern about potential transmission in patients without any symptoms or signs of the disease.

Latrogenic transmission has occurred via blood transfusion, human derived growth hormone, dura mater transplantation and contaminated neurosurgical needles or instruments. Worldwide, there is one definite reported case from corneal transplantation and a handful of possible but unproven cases, and no reported cases of transmission from any other ophthalmic intervention. There is definite evidence of prion protein in the retina and optic nerve tissues of affected patients. NICE has concluded, from current evidence, that the routine use of disposable instruments for any sort of ophthalmic surgery is not a cost effective use of resources.

There are no known cases of transmission resulting from diagnostic examination or contact lens wear.

### **Minimising the risk of CJD transmission in ophthalmic surgery**

The decision to take specific extra action to prevent onwards CJD transmission via contaminated reusable instruments from a patient having ophthalmic surgery depends on whether the operation is considered high or low risk, and whether the patient has an increased risk of having CJD. Please see Annex J and Annex L and consult local infection control teams for full details of how to assess risk and which particular operation codes are mentioned.

#### ***1. Identify whether the planned procedure is high or low risk for prion transmission***

*Posterior segment and some orbital procedures are considered high risk:*

- Orbital operations in which instruments may come into contact with retina or optic nerve e.g. evisceration, and orbital implant
- Operations on the optic nerve e.g. excision optic nerve lesion, decompression of optic nerve
- Scleral buckling (due to likelihood of drainage of subretinal fluid)

- Operations on vitreous body ONLY if they come into contact with the posterior hyaloid face e.g. vitrectomy and membrane peel. Anterior approach vitrectomy and intravitreal injections are low risk.
- Operations on the retina and retinal pigment epithelium (RPE)
- Operations involving the choroid and subretinal fluid.

*Anterior segment operations are considered low risk:*

- Orbital operations which will not come into contact with the retina or optic nerve e.g. removal of orbital lesion
- Eyebrow and eyelid operations
- Lacrimal operations
- Eye muscle operations
- Conjunctiva and corneal operations
- Scleral and iris operations
- Operations on the lens and anterior chamber including complicated cataract surgery and anterior vitrectomy

## **2. Identify whether the patient has CJD or is at higher risk of having CJD**

There must be a policy in place to identify preoperatively, surgical patients who have CJD or are a higher risk of having it. Medical records and referral information should be checked for any record of CJD status. All patients undergoing elective or emergency surgery must be asked **“Have you ever been notified that you are at increased risk of CJD or vCJD for public health purposes?”**

For low risk procedures, if the above are negative, no further extra actions are required. If there is a positive response or concern from the referral information, the local infection control team should be consulted.

For high risk procedures, a further set of questions should be asked about family history of CJD, growth hormone treatment, brain or spinal cord surgery, blood transfusions, and there is guidance as to what actions to take depending on the exact answers in Annex J, as well as what to do if the patient cannot provide replies.

## **3. Guidance for use of instruments**

*3a For patients with no extra risk of carrying CJD prion protein:*

Low risk surgery – no extra precautions

High risk surgery - it is recommended that reusable instruments do not migrate between sets and that they should be fully trackable. Supplementary instruments used should be single use or remain with the set long term.

*3b. For patients with extra risk of carrying CJD or who have CJD:*

Low risk surgery – minimise instrument migration and instruments should be trackable. No other precautions required.

High risk surgery

- Consider, in consultation with colleagues and the patient and family whether the procedure is required at all or whether deferral might allow the diagnosis of CJD to be excluded if not certain.

- Perform the procedure with minimum number of staff in theatre and at end of the list
- Use single use instruments if good enough quality and incinerate at end of the procedure
- Reusable instruments can only be reused on the same patient and must follow the strict cleaning and quarantine guidance OR be disposed of by incineration

**In summary:** for any high risk surgery performed on patients with, or “at risk” of, CJD, the instruments should be either single use and destroyed by incineration post-operatively, or reusable, in which case they should be destroyed by incineration or kept strictly quarantined and for reuse solely on that individual patient.

### **Minimising the theoretical risk of prion transmission in the ophthalmic clinic**

There has never been a case of prion transmission via ophthalmic clinic interventions reported. Theoretically risky reusable devices are those where there is contact with the cornea, that is tonometer heads or probes, trial contact lenses, diagnostic and therapeutic contact lenses (e.g. gonioscopy lens, 3 mirror lens, laser capsulotomy lens), A and B scan probes and pachymetry probes, ERG contacts, temporary or trial prosthetic eyes.

#### **1. For patients with known or potential CJD (e.g. dementia of uncertain cause or unexplained neurodegenerative condition)**

Use single use devices or non contact devices where possible. For reusable contact devices, either the device must be under strict quarantine and only reused on that patient or be disposed of. Where this is not possible and it is deemed clinically essential to proceed, obtain the advice of the local infection control team before use of the device.

#### **2. For the majority of patients:**

A balance needs to be reached between routinely performing extensive potentially impractical or expensive decontamination procedures which may well be ignored in busy clinics for what is still a theoretical risk versus not exposing patients unnecessarily and avoidably to a risk of CJD which, although very very low, would be devastating if it occurred. In addition, there is a real and significant risk of transmission of other more common agents, such as adenovirus or bacteria, which does require a consistent, practical and effective decontamination method and which will benefit patients daily. A strategy of risk reduction rather than risk elimination for prion transmission is therefore justified in this situation.

The College encourages the use of non contact or disposable devices where possible and where it does not impact on the quality of care. Where reusable contact devices which touch the cornea are being used, use disposable covers if possible and they should NOT be initially cleaned with alcohol or allowed to dry as this may bind prions to the surface of the device which may not then be removable with further cleaning and also alcohol does not reliably kill relevant adenovirus.

Guidance in Annex L errs on the side of caution and advises the following for devices contacting the cornea:

- Do not allow the device to dry
- Rinse immediately for at least 30 seconds in water for irrigation
- Clean with liquid soap or detergent
- Rinse again with water for 30 seconds
- Immerse in freshly prepared hypochlorite 10,000ppm of chlorine (1%) for at least 10 minutes

- Rinse in 3 changes of sterile water or saline for at least 10 minutes
- Shake, dry with tissue and store dry

However, hypochlorite use has a number of potential disadvantages:

- It is corrosive and can damage instrumentation and is only suitable for PMMA, glass or nonferrous materials. Some devices will not be suitable and manufacturer's instructions will then need to be followed.
- It is irritant to the eye surface and skin
- It can be easily knocked over in clinic
- It needs to be the correct concentration and at least 50ml volume

The College therefore supports the following actions for reusable devices contacting the cornea:

- Refer to manufacturer's instructions for each specific instrument or device
- Ensure involvement of local infection control team and risk assess procedures
- Do not allow device to dry after use
- Clean with detergent, liquid soap or neutral detergent wipes for at least 20 seconds
- Rinse with sterile water or saline
- Dry with clean non-linting tissue
- If used on infected patient it must be disinfected or sterilised

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## Authors

- The Royal College of Ophthalmologists Quality and Safety Group, Chair Mrs Melanie Hingorani FRCOphth.
- Dr Manjusha Narayanan, on behalf of the Microbiology Specialty Advisory Committee, Royal College of Pathologists