



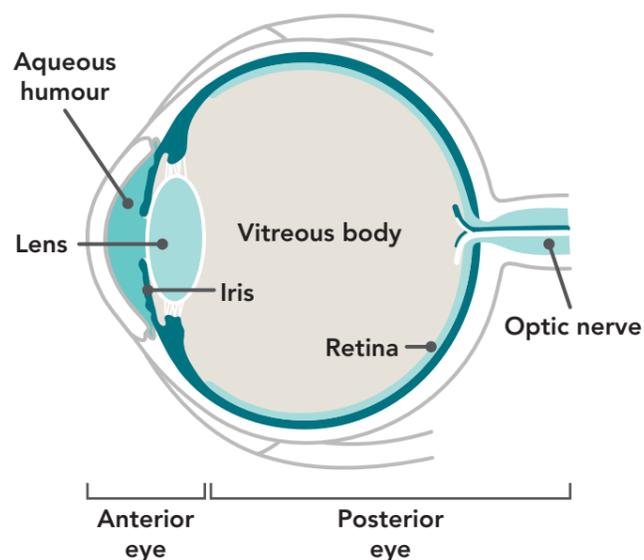
REPROCESSING OF OPHTHALMIC DEVICES



Is It Time For A Change?

- The eye is considered a high-risk tissue; reprocessing guidelines advise that all ophthalmic devices are classified as critical and must be sterilized.
- Most ophthalmic devices are steam sterilized; many are delicate and have a shorter usable lifespan when frequently exposed to high temperature and moisture.
- Sterilizing ophthalmic devices with STERRAD® can not only offer a more convenient reprocessing method but also lead to other financial benefits through better device maintenance.

Ophthalmology is the branch of medicine that is concerned with the medical and surgical management of conditions of the eye. Ophthalmic procedures, such as cataract surgery, are the most common operations performed in the UK every year.¹



Glaucoma

Can be treated by eye drops in the mildest cases, but surgical procedures to improve drainage of fluid, or to remove fluid-producing cells can be needed.

Retinal detachment

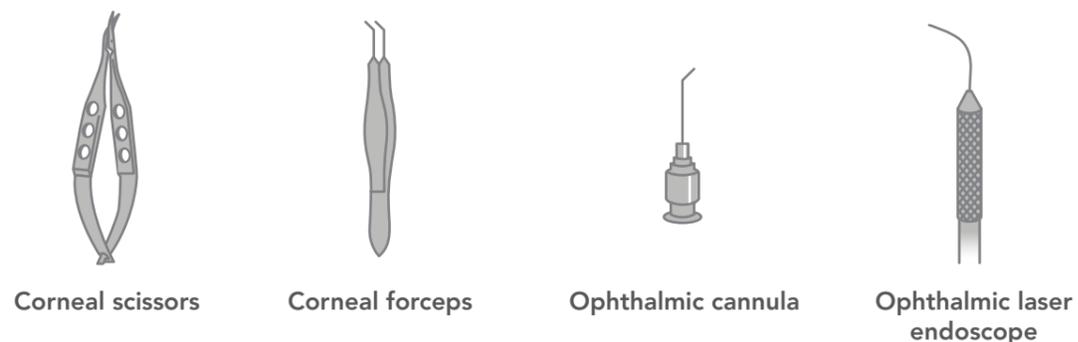
Retinal detachment can be treated by replacing the fluid in the eye with a bubble of liquid or gas that holds the retina in place.

Cataracts

Cataracts are usually treated by surgically removing the lens and implanting a synthetic replacement.

The majority of devices used are simple but delicate steel instruments (eg. forceps, spring scissors, cannulae). However, recent advances in endoscopy have led to the development of novel, more complex devices, such as the ophthalmic laser endoscope.

A selection of ophthalmic surgical devices are shown below:



Device Reprocessing

Ophthalmic procedures are considered high risk for infection. All equipment is considered critical, as per the Spaulding classification,² and must be sterilized.

Eye surgeries are often short procedures, and therefore rapid reprocessing of devices is required to meet the demanding daily case volume.

As the majority of instruments are of a simple steel construction, the most common method of sterilization used for ophthalmic devices is steam sterilization.

Challenges with High Temperature Steam Sterilization

The high temperatures and longer turnaround times of steam sterilization lead to challenges when used for reprocessing ophthalmic surgical equipment:



The need for rapid reprocessing means that immediate use steam sterilization (IUSS or 'flash' sterilization) is sometimes used for reprocessing devices that are needed immediately. However, routine IUSS is not recommended by ophthalmic societies, and sterility assurance of this method is hard to determine.^{3,4}



Improper maintenance of the autoclave steam generator can lead to impurities deposited on equipment, which in turn can lead to toxic anterior segment syndrome (TASS), an acute inflammation of the anterior eye.⁵



Some instruments used by ophthalmic surgeons, such as laser endoscopes, are heavily damaged by exposure to high temperatures and so cannot be steam sterilized.

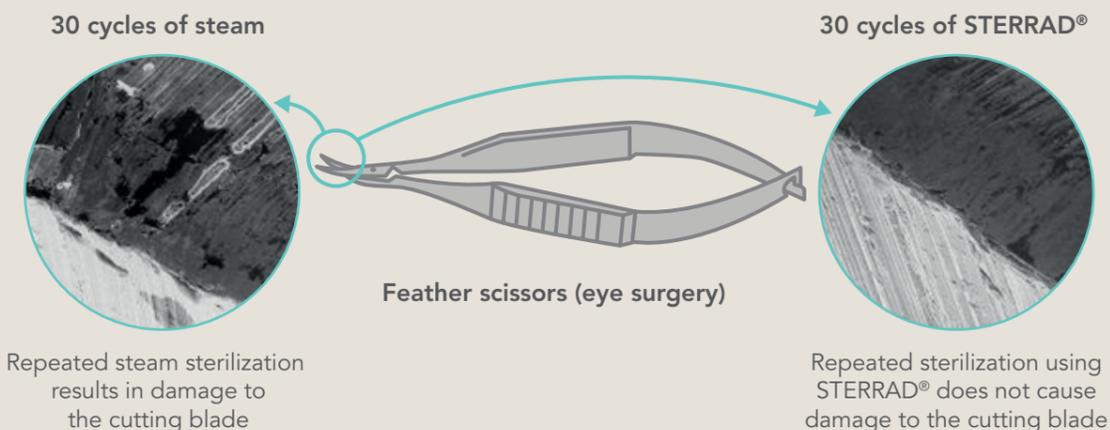


The harsh process of steam sterilization can damage delicate steel surgical equipment, particularly the fine tips and cutting blades of microsurgical devices used in ophthalmic procedures. There are a number of consequences of this that may impact patient care:⁶

- Reduced longevity of delicate surgical instruments leading to higher costs through additional repairs and earlier replacements
- Devices that wear faster may show reduced performance until they can be repaired or replaced
- Discovery of damaged equipment during surgery can lead to disruptions in the operating theatre

Case study: Surgical equipment steam sterilized by autoclaving showed greater damage per cycle compared to STERRAD[®]

A side-by-side comparison of delicate microsurgical scissors sterilized by steam and by low-temperature hydrogen peroxide gas plasma using STERRAD[®] showed that, after 30 reprocessing cycles, the autoclaved scissors demonstrated a noticeable drag in cutting whereas there was no loss of functionality caused by STERRAD[®] reprocessing. This was confirmed using high magnification imaging of the cutting edge.



Repeated steam sterilization results in damage to the cutting blade

Repeated sterilization using STERRAD[®] does not cause damage to the cutting blade

Benefits of STERRAD® for Low Temperature Sterilization

Given these challenges, there is a need for low temperature sterilization methods that are able to meet the short turnaround times required to reprocess ophthalmic devices, whilst also improving the longevity of these devices and enhancing patient safety.

Two of the main methods for low temperature sterilization are hydrogen peroxide gas plasma (STERRAD®) and ethylene oxide (EtO). The use of EtO, however, has significant limitations:



EtO is extremely toxic and flammable. It is a workplace hazard due to being classified as a human carcinogen, and may pose fire and explosion risks⁷



Toxic residues left after EtO sterilization may also lead to TASS⁸

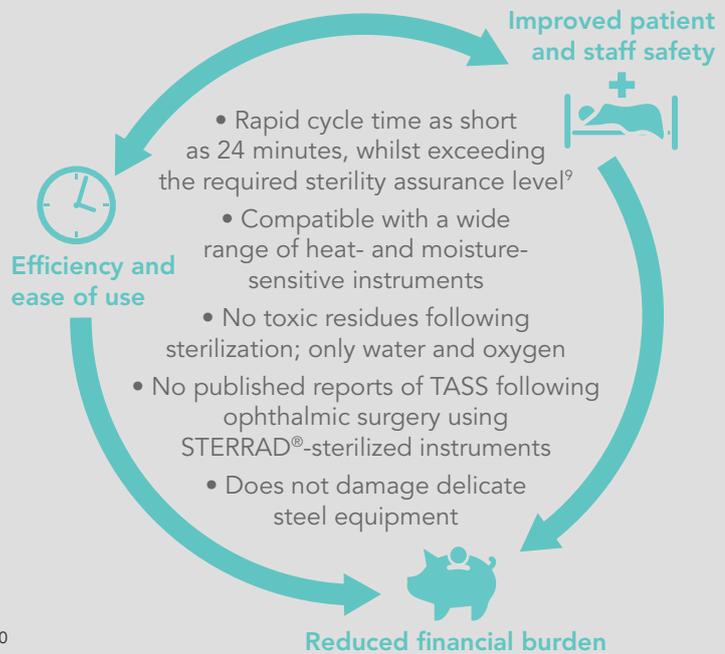


A very long cycle time means that EtO sterilization is particularly unsuitable to meet the rapid turnaround time demands in ophthalmic surgery⁷

Why Choose STERRAD®?

STERRAD® Systems sterilize ophthalmic devices safely and effectively, without the instrument damage associated with high temperature steam sterilization.

Reprocessing instruments using low-temperature hydrogen peroxide gas plasma with STERRAD® also avoids the safety and time issues of EtO sterilization, optimizing device reprocessing and the delivery of patient care. Using STERRAD® can also lead to substantial cost savings, such as EUR 8,800 per unit on water and energy compared to steam sterilization, and up to USD 9,000 on water compared to EtO sterilization.^{9, 10}



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