# SINGLE USE OPTICS IN OPHTHALMOLOGY


## ABSTRACT

This paper addresses the functional and cost advantages of single use ophthalmic lenses for both clinic and surgical functions. These lenses are the first in the category to provide a solution to Joint Commission infection control standards while decreasing the need for reusable medical equipment. The paper provides a cost-benefit analysis based on the VA hospital model. Discussion over the benefits of single use optics as well as the risks associated with reusable lenses is included.



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Dr. Culham was the Head of Optometry at Moorfields Eye Hospital, London UK, and directed all operations for the largest ophthalmic clinical support unit in Europe. Her responsibilities included the management of 7 community clinics as well as the core department.

Concurrently, Dr. Culham held an academic position at the Institute of Ophthalmology, London, undertaking novel research, obtaining grants and supervising several PhD students. Her work has resulted in more than 30 publications in peer reviewed journals.

Dr. Culham was the co-founder and clinical lead of Sensor Medical Technology, the company responsible for the development and launch of sterile, single use lenses for the clinic and the operating room. Sensor Medical was acquired by Katena in January 2016.

Katena offers single use lenses in individual sterile pouches for a wide range of ophthalmic procedures. Ninety percent of all diagnostic and therapeutic procedures undertaken in the clinic and NICU can be carried out with disposable optics costing between $10 and $12 a lens. Similarly, in the operating room, key optics for glaucoma and vitreoretinal surgeries are available for $12-$28 per lens.

***The Benefits of <u>Single Use</u> Optics***

Disposable optics offer numerous advantages and address the needs and concerns of hospital management, doctors and patients. Single use products support the essential requirement of infection control and assist those hospitals wishing to decrease their reusable medical equipment (RME) and meet Joint Commission standards in a simple and cost efficient manner.

Hospital management will recognize the value of patient and staff safety, patient throughput efficiencies and cost benefits. The exceptional optics, new for every procedure, will assist doctors in providing first class medical care. These aspects combine to provide the best experience for patients.

***The Issues and Risks of <u>Reusable</u> Lenses***

Reusable lenses have several disadvantages, including the time consuming and expensive reprocessing costs required to address the potential for disease transmission.

Ophthalmic facilities are environments with notable potential for spread of infections between patients. Pathogens are regularly introduced by patients with ocular and systemic infections. Hence, it is important that ophthalmic lenses are disinfected or sterilized between patients.

Epidemic keratoconjunctivitis (EKC) has been linked to ophthalmology clinics in several states [Adenovirus-Associated Epidemic Keratoconjunctivitis Outbreaks — Four States, 2008–2010, Morbidity and Mortality Weekly Report, CDC, August 16, 2013 / 62(32);637-641]. The CDC's recommended measures for infection control include the careful disinfection of ophthalmic instruments or use of disposable equipment.

In the operating room, problems can occur when reusable equipment is employed, such as the recent closure of the OR for 2 days at Washington Regional Medical Center in Arkansas. [www.outpatientsurgery.net/surgical-facility-administration/infection-control/rare-brain-disease-detected-in-patient--03-17-16]. After a preliminary diagnosis of Creutzfeldt-Jakob disease was made in one of its patients, the OR closed due to the hospital's caution and a desire to ensure the safety of patients and staff. The closure of the OR may have been shortened or avoided if single use products had been used.

Other concerns for the OR can arise around surgical instruments and sterilization, as demonstrated by the adverse event reported to the FDA by a doctor where a reusable iprism gonioprism used for glaucoma surgery was linked to a patient's subsequent endophthalmitis [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=3748361]. This situation could have been avoided with single use optics.

***The Issues and Risks of Disinfection and Sterilization***

Reusable ophthalmic lenses that contact the eye must have a housing that can withstand the high temperatures of autoclaving or harsh process of chemical disinfection. Due to the materials used and existing cleaning regimes, reusable lenses are costly to purchase and reprocess. Further, the disinfection or sterilization of lenses is not a straightforward endeavor.

It can be tedious for the doctor or support staff to work through the various regimes for the different lens types. For chemical disinfection, the compound and concentration have to be considered as well as exposure times. Purchasing and storing chemicals, as well as routinely replacing chemicals used in the process involves time, effort and cost. There is also the risk of chemicals not being removed completely from the lens before use on the next patient. The smallest crack in the lens housing may harbor chemicals that can subsequently come into contact with the patient's cornea.

Some institutions use STERRAD sterilization equipment, but a recent FDA adverse event confirms the lens manufacturer's statements that some systems are incompatible with the lenses and the result is damaged products which are costly to replace. [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=1520779]

Autoclaving is ubiquitous across most hospitals, and while relatively straightforward there is still the need for staff training since only some devices should be autoclaved. For lenses such as the 28D or 20D binocular indirect lenses used during retinal examination and therapy, water marks from the autoclave processing can notably decrease function when good performance is crucial. Further, lenses that are autoclaved typically do not have antireflection coating thereby providing inferior imaging.

Ethylene Oxide (ETO) is used in VA hospitals around the country to sterilize surgical and clinical lenses. The safety profile of ETO is of concern since it is considered to be a carcinogenic, has mutagenic properties and is a known neurotoxic substance. In order to protect staff, expensive containment provisions need to be made, including emergency plans and air quality testing.

During processing, especially off-site processing, lenses can be lost or damaged. And optical degradation from repeated disinfection or sterilization can impact the imaging and treatment ability of a lens.

Deteriorated optics of a reusable lens

New, sterile optics of a single use lens

***Costs Benefit Analysis: Reusable versus Single Use***

The cost of cleaning and disinfection or sterilization is notable, particularly when cost of personnel, materials and utilities are taken into account. To better define the expenses related to purchasing and maintaining a reusable contact lens throughout its life, a Cost Benefit Analysis (CBA) is presented below. Different clinical environments need varying procedures to fulfill local protocols as well as manufacturers' instructions for use. Some processes are simpler in the clinic procedures, while others require notable staff time, off site transportation of lenses and sterilization instead of disinfection.

The example CBA below is for a typical VA hospital clinic undertaking 240 gonioscopy procedures annually; the cost related to ***reusable*** gonioprisms versus ***single use*** gonioprisms can be determined. In order to allow for a sufficient number of lenses to be available in clinic while some are off-site for reprocessing, a total of 8 lenses is required, with a notable up-front capital cost of $3,560. The clinic calculated that these lenses would last for 4 years before they needed replacement. Once disinfection and transport, including staff time was taken into account, the per procedure cost is $46.25. The same procedure undertaken with a single use gonio lens would cost $10.15.

**240 Gonioscopy Procedures per Year**

| 4 MIRROR GONIO LENS | Reusable<br>8 lenses required | Single Use |
|---|---|---|
| [Price of lenses ($445 each x 8 lenses)]<br>Amortized over 4 years, per procedure | **[$3,560]**<br>**$3.70** | **$10.00** |
| Materials (each time) | **$10.30** | -- |
| Processing (each time)<br>Transportation off-site, disinfection/sterilization, packaging, staff time | **$32.25** | -- |
| Shipping per lens | | **$0.15** |
| Cost per procedure | **$46.25** | **$10.15** |
| For 240 procedures per year | **$11,100** | **$2,436** |

This is specifically for a VA hospital sending lenses off-site for sterilization – these figures were provided by that VA hospital. While not every VA has this method of cleaning and disinfection, generally VA hospitals are striving for the highest standards of patient care and consequently do have local time-consuming and costly protocols. Single use lenses remove the burden of re-processing and release staff for other work.

In summary, Katena's single use optics for ophthalmology can address many of the needs of VA hospitals in a practical, convenient and cost efficient manner. The products currently available are shown below in Appendix 1.

Appendix 1

| STERILE SINGLE USE LENSES (STERILE) | |
|---|---|
| **Product Code** | **Product Description** |
| SMT 001 (K30-1000) | 3 Mirror Lens Sterile |
| SMT 002 (K30-1005) | 4 Mirror Gonioscopy Lens Sterile |
| SMT 029 (K30-1010) | 4 Mirror Gonio Lens with Handle Sterile |
| SMT 003 (K30-1015) | Single Mirror Lens Sterile |
| SMT 035 (K30-1020) | Single Mirror with Handle Sterile |
| SMT 004 (K30-1110) | Fundus Lens Sterile |
| SMT 005 (K30-1320) | Retina 90 Lens Sterile |
| SMT 006 (K30-1315) | Retina 130 Lens Sterile |
| SMT 025 (K30-1310) | Retina 170 Lens Sterile |
| SMT 013 (K30-1300) | Retina 180 Lens Sterile |
| SMT 007 (K30-1120) | Capsulotomy Lens Sterile |
| SMT 008 (K30-1130) | Iridotomy Lens Sterile |

| SINGLE USE BI-ASPHERIC LENSES (STERILE) | |
|---|---|
| **Product Code** | **Product Description** |
| SMT 009 (K30-2400) | 90 D Lens Sterile |
| SMT 019 (K30-2405) | Osher 78 D Lens Sterile |
| SMT 010 (K30-2410) | 60 D Lens Sterile |
| SMT 011 (K30-2415) | 28 D Lens Sterile |
| SMT 012 (K30-2420) | 20 D Lens Sterile |

| SURGICAL LENSES (STERILE) | |
|---|---|
| **Product Code** | **Product Description** |
| SMT 024 (K30-1440) | Plano Lens Sterile |
| SMT 023 (K30-1435) | Magnifier Lens Sterile |
| SMT 022 (K30-1430) | Bi-Concave Lens Sterile |
| SMT 020 (K30-1420) | 20 Degree Prism Lens Sterile |
| SMT 021 (K30-1425) | 30 Degree Prism Lens Sterile |
| SMT 026 (K30-1530) | Suture Ring Sterile |
| SMT 038 (K30-1535) | Suture Ring with Tabs Sterile |
| SMT 027 (K30-1505) | Forceps Sterile |
| SMT 037 (K30-1450) | Surgical Wide Field Lens Sterile |
| SMT 019 (K30-2405) | Osher 78D Lens Sterile |
| SMT 032 (K30-1400) | Surgical Gonio Prism, RH Sterile |
| SMT 033 (K30-1405) | Surgical Gonio Prism, LH Sterile |