Joint Task Force makes recommendations to industry regarding the elimination of enzymatic detergents for routine cleaning of intraocular surgical instruments

by Nick Mamalis, MD, and David F. Chang, MD

Toxic anterior segment syndrome (TASS) is an acute, sterile postoperative inflammation secondary to intraocular toxic substances introduced during anterior segment surgery. The ASCRS TASS Task Force has analyzed causes of TASS during 2 periods: 2007 through 2009 and 2009 through 2012.1,2 Data from 130 questionnaires and 71 site visits to affected ambulatory surgery centers (ASCs) resulted in 1,454 reported cases of TASS out of approximately 69,000 concomitant cataract surgery cases. One of the most commonly identified risk factors for TASS included inadequate flushing of handpieces, use of enzymatic detergents, and use of ultrasound baths.

Human and animal studies have shown that enzymatic detergents are toxic to the corneal endothelium, and in the clinical analyses, enzymatic residue was implicated as a source of TASS when incompletely rinsed from the ophthalmic instruments prior to sterilization. The enzymatic residues are not deactivated by autoclave sterilization. Furthermore, enzymatic detergents are intended to remove bulk biomaterial from surgical instruments; however, anterior segment ophthalmic instruments acquire little bioburden during surgery and the material they do collect can be completely removed with prompt rinsing and manual cleaning. Therefore, enzymatic detergents (including pH neutral agents) appear to elevate the risk for TASS without providing any offsetting benefit. It was the conclusion of the TASS Task Force that enzymatic detergents should not be used for routine decontamination of anterior segment ophthalmic instruments.

Unfortunately, the manufacturer’s directions for use (DFU) that accompany instruments and ultrasound cleaning baths often call for the use of enzymatic detergents. Hospitals and ASCs are required by CMS to strictly adhere to ophthalmic instrument DFUs during the cleaning process, and surveyors are increasingly citing facilities for failure to use enzymatic detergent if so required. Perhaps as a result of these rulings, the TASS Task Force is seeing an increase in TASS cases associated with enzyme use.

Over the past 2 years, a joint Task Force on ophthalmic instrument cleaning and sterilization (OICS) with representatives from the American Society of Cataract & Refractive Surgery (ASCRS), American Academy of Ophthalmology (AAO), Outpatient Ophthalmic Surgery Society (O OSS), and American Society of Ophthalmic Registered Nurses (ASORN) has focused on regulatory issues relating to the cleaning and sterilization of intraocular surgical instruments. The Task Force is chaired by the 2 authors of this article. Members of the OICS Task Force have had separate meetings with the Centers for Medicare & Medicaid Services (CMS), the FDA, and the Association for the Advancement of Medical Instrumentation.
(AAMI) on the problem of requiring ASCs to use enzymatic detergents to decontaminate intraocular ophthalmic instruments. In December 2015, ASCRS, AAO, and OOSS released a joint advisory statement to their respective memberships warning about the potential for enzymatic detergent residue to cause TASS. A recent study at the Intermountain Ocular Research Center of the University of Utah found that enzyme residues can persist on phacoemulsification tips despite proper rinsing, and other studies have shown that small amounts of enzyme residue can cause TASS.

Because the potential for enzymatic detergent residue on ophthalmic instruments is problematic, the Task Force is working with the ophthalmic instrument industry to eliminate the requirement for routine use of enzymatic detergents for decontamination of intraocular surgical instruments as stated in the DFUs. If intraocular surgical instruments are thoroughly rinsed with sterile distilled or deionized water promptly after each use, then the routine use of enzymatic detergents should not be necessary. While the OICS Task Force recognizes that enzymatic detergent cleaning could be necessary in some instances, our goal is to eliminate the routine requirement in some instrument DFUs for decontamination with enzymatic detergent in every case. The OICS Task Force and the FDA have concluded that the best way to eliminate this risk of TASS would be to have manufacturers validate alternate decontamination methods that do not require enzymatic detergents. Through the OICS Task Force, ASCRS, AAO, OOSS, and ASORN have formally recommended that intraocular instrument manufacturers devise and validate methods to clean and decontaminate instruments without using enzymatic detergents. EW

**References**


Editors’ note: Drs. Mamalis and Chang have no financial interests related to this article.

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**Improve Patient Safety and Eliminate a Risk Factor for TASS**

**Background**

Over the past year, ASCRS, AAO, OOSS, and ASORN have been participating in a task force focusing on the cleaning and sterilization of intraocular surgical instruments. In addition to meeting with CMS, the task force most recently met with both the Association for the Advancement of Medical Instrumentation (AAMI) and the FDA specifically on the issue of the required enzymatic detergent use in the cleaning/sterilization process of intraocular ophthalmic instruments. In December 2015, ASCRS, AAO, and OOSS released a joint advisory document (see page 3 of the January 2016 issue of EyeWorld) warning about the potential for enzymatic detergent to cause toxic anterior segment syndrome (TASS).

Studies have shown that while following the manufacturers’ DFUs, even the slightest enzyme residue can cause TASS. A new study has suggested that enzyme residues may persist despite proper rinsing.

During the FDA meeting, all agreed that the potential for enzymatic detergent residue is problematic.

**Objective**

Elimination of Requirement for Routine Use of Enzymatic Detergent for Decontamination of Intraocular Surgical Instruments, as stated in the Directions for Use (DFUs)

Some intraocular instruments’ DFUs for reprocessing include the requirement to use enzymatic detergent following each use. In many cases, prompt rinsing with sterile water should be adequate if the instruments are not contaminated with a significant bio burden. An earlier survey of ophthalmic ASCs by our task force revealed that more than half of the respondents avoid the use of enzymatic detergent for intraocular instrument decontamination. However, DFUs commonly require routine use of enzymatic detergent and have caused surgeons and surgical centers to be cited by CMS or other regulators because they are not using enzymatic detergent.

We recognize that enzymatic detergent cleaning may be necessary in some instances. However, our goal is to eliminate the requirement in some intraocular surgical instruments’ DFUs that decontamination and reprocessing must include the use of enzymatic detergent in every case.

The FDA has concluded, and we concur, that the best way to effect change would be through manufacturer validation testing of alternate decontamination methods that do not require enzymatic detergent.

**What is Included**

Class 1 and Class 2 surgical devices for intraocular use. Class 1 devices would not require a submission of the DFUs to the FDA, however, Class 2 devices would need FDA review.

**Request**

ASCRS, AAO, OOSS, and ASORN request intraocular instrument manufacturers validate cleaning instructions without enzymatic detergent and update DFUs accordingly.
