

## Biocompatible and Autoclavable Hydrophilic Coatings for IOL Inserters

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**Statement of Purpose:** The purpose of this study is to append a biocompatible and autoclavable hydrophilic coating onto the surface of an intraocular lens (IOL) inserter. In recent years, the advances of foldable IOL implantation has not only been accepted as a routine for cataract surgery, but its goal has also moved from restoring sight to correcting refractive error and improving the quality of the patient's vision postoperatively, especially for patients with severe near or farsightedness and sometimes in presbyopia sufferers. Developments in IOL inserters have also contributed to improved success in cataract surgery. In general, the trend is moving away from folding and insertion forceps toward cartridge injector systems in order to avoid surface alterations, scratches, glistening or marks, stress fractures, or structural damage on the IOLs. Moreover, the trend of moving towards greater sterility, ease of folding and insertion and implantation through smaller incisions, i.e., 1.8mm as compared to current 2.2-3.0mm incisions [1], has also created the need of an IOL-preload inserter system with a thin, biocompatible and autoclavable hydrophilic coating, especially for hydrophilic IOLs, to avoid the above problems. In addition, current hydrophilic coatings for IOL inserters on the market are (i) physical-cure-based, i.e., cannot be autoclaved and no durability for a long-term shelf-life in wet state and (ii) thick, i.e., the hydrophilic coating can be transferred onto the IOL when the incision becomes smaller. In this study, a novel coating solution, LubriMATRIX™, was used to hydrophilize the surface of generic butterfly-type IOL inserters. The LubriMATRIX-coated IOL inserters were characterized according to their water uptake content and were subjected to (a) 3 different biocompatibility tests and (b) IOL delivery tests before and after autoclave, and (c) short-term shelf life delivery tests.

**Methods:** Generic polypropylene (PP)-based butterfly-type IOL inserters were used as the substrates for coating (Figure 1). Commercial LubriMATRIX™ coating solutions made at AST Products as per a patent-pending method were used for the hydrophilization of the IOL inserters in accordance with an established method [2]. The LubriMATRIX components were grafted onto the surface of the PP-based IOL inserters via an electron-beam-induced graft polymerization method [3] at various irradiation doses ranging from 5 to 200kGy. The LubriMATRIX-coated surfaces were then characterized by water content measurements. Three different biocompatibility tests: (a) L929 MTT cytotoxicity test (ISO 10993-5), (b) hemolysis complete test (ISO 10993-4) and (c) acute systemic injection test (ISO 10993-11) were conducted by outsourcing to Toxikon Corp. IOL delivery tests using the LubriMATRIX-coated IOL inserters were also performed before and after autoclave as well as after a short-term storage in water.

**Results and Discussion:** The stable coating of LubriMATRIX onto the PP-based IOL inserter was confirmed by its weight gained. Figure 2 shows the water content of the LubriMATRIX-coated PP-based IOL inserters at various electron-beam irradiation doses. The water content increased with increasing irradiation dose and peaked at 25kGy.

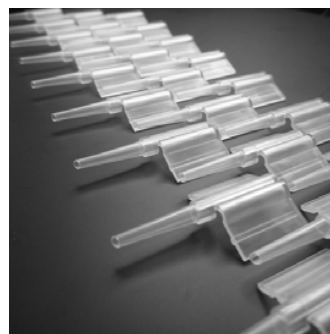


Figure 1. Generic PP-based butterfly-type IOL inserters

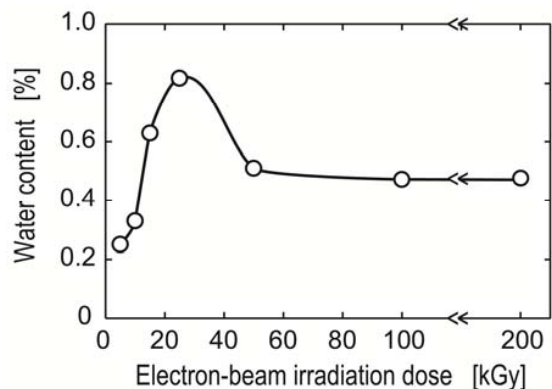


Figure 2. Water content of LubriMATRIX-coated inserters

The LubriMATRIX-coated PP-based IOL inserters passed all 3 biocompatibility tests with non-toxicity, non-hemolytic and negative biological reaction results.

The LubriMATRIX-coated IOL inserters also showed good lubricity during the IOL delivery tests before and after autoclave without any structural damages or coating transfer to the IOLs. After 1-month storage in deionized water, the LubriMATRIX-coated IOL inserters also showed similar good lubricity results.

**Conclusions:** The present study demonstrated that LubriMATRIX is a durable, biocompatible and autoclavable hydrophilic coating for the PP-based IOL inserter. Continuous shelf-life studies up to 2 years of storage in water are in progress.

**References:** [1] Kohnen T. *Ophthalmology*, 112:58-66 (2005). [2] Lee W. U.S. Patent Appl. 61/390,212 (2010). [3] Lee W. *Encyclopedia of Surface and Colloid Sci.* 4780-4795 (2006)