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A Novel Low Modulus, High Refractive Index, Non-glistening Crosslinked Polyisobutylene Polymer for Intraocular Lens Applications

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Ophthalmic cataract removal and intraocular lens surgery has always been the vanguard of minimally invasive surgery. The advances in surgery, adjunctive tools and implants continue to provide improved and more consistent clinical outcomes while quickly achieving optimal visual results. The evolution of the intraocular lens (IOL) from rigid PMMA to foldable silicones and today's hydrophobic foldable acrylics have been essential to achieving today's results.

There is now a need for the next generation IOL material for both microincision and advanced accommodating lens applications. The mechanical properties required for insertion through a very small diameter inserter, recover to its desired shape and remain biocompatible and biostable in the eye, free of glistening, whitening and unwanted reactions within the ocular environment, are demanding. A new family of extremely biostable, non-inflammatory and non-embrittling rubbery biomaterials, has been developed to provide this next stage of intraocular lens evolution. Forms of this material have been FDA cleared for use in coronary arteries as a stent coating for over ten years. In all applications, it has demonstrated unsurpassed biocompatibility and chemical stability.

These novel IOL materials are formed from crosslinked polyisobutylene-based thermosets and do not contain any cleavable groups that can dissociate with time and cause adverse reactions in the surrounding tissue or detrimentally affect the clarity of the optic by crazing, hazing or glistening. The ultrapure material is specifically designed for ease of purification and processing. A long-used and proven UV absorber is crosslinked into the matrix and creates a UV cut-off at 400 nm; other tints can also easily be created.

These new xPIB polymers are true rubbery elastomers and return to their original shape after deformation. They have a high index of refraction (1.52-1.54), a relatively high ABBE number (50) a low modulus of elasticity (<1 MPa) and high elongation (>200%), which renders them softer than silicone rubber but with twice the magnification. These elastomeric properties enable single piece IOLs to elongate while being pushed through the bore of a small inserter (1.5 mm diameter) and then recover to their original shape without damage. These mechanical properties also qualify these materials for use as a dual optic or other accommodative lens which changes power in response to forces transmitted from the ciliary muscle. This family of materials can easily be fabricated by molding or machining without the need for post-fabrication solvent extraction or other secondary processing. Their dimensional stability, favorable surface properties and hydrophobicity produce an IOL that can be packaged dry and preloaded in an inserter. The combination of these properties indicates favorable manufacturability and cost of goods. Combined with the advanced performance, this next generation material is well-positioned in today's challenging health care economic climate.