

First IC-8® Small Aperture IOL Implanted in the United States

IRVINE, Calif. – (December 18, 2018) – AcuFocus, Inc., a privately held ophthalmic medical device company, announced today that the first US patient has been implanted with the **IC-8** small aperture intraocular lens (IOL) as part of its pivotal study of the **IC-8** lens in cataract patients. The company recently announced approval for an Investigational Device Exemption (IDE) from the U.S. Food and Drug Administration to conduct the study.

The **IC-8** IOL is a clear monofocal lens with an embedded mini-ring or pinhole in the center. This novel lens is designed to increase a patient’s natural range of vision by extending the focus of light rays that enter the eye and restricting peripheral defocused light rays.

“The **IC-8** is truly a unique IOL, and I am honored to be the first surgeon in the United States to implant the lens as part of the IDE clinical trial,” said Satish Modi, MD, Seeta Eye Centers, New York. “Cataract surgery and intraocular lens technology are a core part of our practice. Over the years, we have seen and participated in significant developments in this field and have been fortunate enough to provide these solutions to our patients.”

This prospective, multicenter, parallel-group study will enroll approximately 475 patients with bilateral cataracts. Participants in the **IC-8** lens test group will receive a standard monofocal IOL in their first eye and if visual requirements are met, the **IC-8** IOL in their second eye. Participants in the control group will receive bilateral monofocal IOLs. Participants will be followed for 12 months and evaluated for improvement in their vision at all distances. More information about the study can be found at www.IC8lensclinicalstudy.com.

“The IDE study design is unique. The **IC-8** lens test group must meet an initial set of enrollment criteria, and a secondary set of enrollment criteria based on the results of the first eye,” said Dr. Kevin Waltz, co-medical monitor for the **IC-8** lens clinical trial. “To have the first **IC-8** IOL implant placed so quickly after IDE approval is impressive.”

ABOUT ACUFOCUS

AcuFocus, Inc., is a privately held ophthalmic medical device company that develops and markets breakthrough technologies for the improvement of vision. The **IC-8** IOL received CE mark in 2014 and is available in select markets across Europe and Asia.

Founded in 2001, AcuFocus is based in Irvine, Calif. For additional information about the **IC-8** intraocular lens, visit www.acufocus.com.

Caution: Investigational Device. Limited by Federal (or United States) law to investigational use.