Approved by Alpha IRB November 12, 2018

IC-8® Lens Clinical Study Frequently Asked Questions

Before you decide if the **IC-8** lens clinical study is right for you, it is important to make sure your questions are answered. Below are answers to the most common questions we hear. We encourage you to discuss any additional questions you may have with your doctor.

Q: ***What is an investigational device?***
A: An investigational device is one that is used in a clinical research study and is being studied for safety and effectiveness. The device has not been approved for commercial use by the United States Food and Drug Administration (FDA).

Q: ***Has the IC-8 lens been approved in other countries?***
A: Yes. The **IC-8** lens has a CE Mark, which makes it available for commercial use in countries in Europe. It is also available in Asia Pacific, Latin America and the Middle East.

Q: ***Do I have to pay for anything or will my insurance be billed?***
A: You or your insurance company will be responsible for all usual and customary fees related to your cataract surgeries, including but not limited to regular copays for office visits. However, patients who participate in the clinical study and comply with study commitments will be compensated.

Q: ***How many times will I have to visit the eye clinic?***
A: You will be asked to return to the doctor's office for approximately eight follow-up visits over a period of one year. During these visits, the doctor will perform a thorough assessment of your eye health. You may also be asked to attend additional annual follow-up visits for up to three years.

Q: ***How long will the appointments last?***
A: The research study visits vary in length depending on the type of visit. You can expect the visit before your surgery to last between two to three hours. Other visits range from one to two hours.

Q: ***Why is the IC-8 lens implanted in one eye?***
A: Your eyes work together to help you see at all distances. The **IC-8** lens is intended to be implanted in one eye, and work with a monofocal lens in the other eye. The clinical study will determine if the **IC-8** lens in one eye, when paired with a monofocal lens in the other eye, will provide near, intermediate and far vision.

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

Q: ***How can I participate?***
A: There are two ways you may be able to participate in the clinical study:

1. **Test Group (IC-8 Lens Group)** will have a standard monofocal lens implanted in the first eye. If visual requirements are met after the first lens is implanted, the **IC-8** lens will be implanted into the other eye. The **IC-8** lens is an investigational device and is being studied to determine if vision at all distances is clearer than with a standard monofocal lens in both eyes.
2. **Control Group (Monofocal Lens Group)** will have a standard FDA approved monofocal lens implanted in the first eye. If visual requirements are met, a standard monofocal lens will be implanted in the other eye. A standard monofocal lens is designed to provide far vision, but not near or intermediate vision.

Q: ***Does my current eye doctor or primary care doctor have to give me permission?***
A: It is a good idea to notify your doctor(s) about your participation.

Q: ***Will I have to discontinue any of my current medication?***
A: Please do not discontinue any of your current medications until you have been instructed to do so by the doctor during an office visit. The Research Study Coordinator can give you more information about your medications.

Q: ***Are there any side effects, risks, or complications with the procedure or device?***
A: The Research Study coordinator or doctor will discuss all potential side effects, risks and complications prior to confirming your participation in the clinical study.

Q: ***How quickly will I heal after surgery?***
A: Everyone heals at a different pace. However, you can help accelerate your recovery by taking eye drops as prescribed and keeping all follow-up appointments**.**