Clinical Study of the ARTISAN Aphakia Lens for the Correction of Aphakia in Children

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 2 Years to 21 Years old
This study is also accepting healthy volunteers

Inclusion Criteria:

- 2 to 21 years of age
- Have a visually significant cataract or need IOL replacement surgery
- Compromised capsular bag prohibiting implantation of standard posterior IOL
- Subject or parent/guardian must be able to comply with visit schedule and study requirements
- Subject's legal representative must be able to sign the Informed Consent

Exclusion Criteria:

- Under 2 years of age
- Unable to meet Postoperative evaluation requirements
- No useful vision or vision potential in fellow eye
- Mentally retarded patients
- History of corneal disease
- Abnormality of the iris or ocular structure
- ACD less than 3.2 mm
- Uncontrolled glaucoma
- IOP > 25 mmHg
- Chronic or recurrent uveitis
- Preexisting macular pathology that may complicate the ability to assess the benefit of this lens
- Retinal detachment or family history
- Retinal disease that may limit visual potential
- Optic nerve disease that may limit visual potential
- Diabetes mellitus
- Pregnant, lactating or plan to become pregnant

Conditions & Interventions

Interventions:
Device: Artisan Aphakia Intraocular Lens
Conditions:
Aphakia
Keywords:
aphakia, secondary intraocular lens, congenital cataract, marfan syndrome, pediatric cataract, ectopia lentis, subluxated lens

More Information

Description: In this study, subjects who had a cataract removed but due to their eye structure, are not able to have a traditional intraocular lens (IOL) implanted, receive a special type of lens called the ARTISAN IOL. The objective of this study is to determine the effectiveness of the ARTISAN IOL and to precisely define the associated risks and, if possible, identify particular groups of patients who may be at high risk of developing complications resulting from the surgical procedure of implanting the lens.
Contact(s): Ann Holleschau - holle004@umn.edu
Principal Investigator: Jill Anderson
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