**VERISYSE Phakic Intraocular Lens**

**Indications for use**
- The VERISYSE Phakic IOL is contraindicated for:
  - Patients with an abnormal iris, such as peaked pupil or elevated iris margin.
  - Patients with an anterior chamber depth (ACD) less than 3.2 mm.
  - Patients with corneal protection and complete removal is recommended to reduce the chance of postop intraocular pressure (IOP) spikes.

**Other Complications**
- Some patients may have a slight anterior vault. One fixation (enclavation) arm mechanism is incorporated to provide additional stability for the VERISYSE Phakic IOL.

**Adverse Events and Complications**
- The VERISYSE Phakic IOL was in a composite, randomized, non-inferiority trial where 100% of eyes were in the treatment group for more than 3 years.

**Adverse Event N %**

**Sphoroptometric Results**

**Spherical Equivalent (Target Variance) Distribution**

**SpHERE**
- Mean BCDS was 1.2 D (8/662) and mean BCDA was 1.8 D (12/662).
- BCDA, BCDS, BCDA-BCDS, BCDS-BCDA, and BCDA-BCDA were significantly lower (p<0.05) in eyes with brown irides compared to eyes with non-brown irides.

**Endothelial Cell density**

**Table 1**

**Surgical indications** (see table below) must not be done in the presence of safety or efficacy.
The available 3-year data from the clinical study indicates a continual decrease in endothelial cell density from implantation to the end of the study. The mean endothelial cell density results for a consistent cohort group of 57 eyes with expected normal endothelial cell loss of 1.5% to 2.0% per year. No statistically significant differences were found. A change in symptom occurrence preoperatively to postoperatively was +Statistically significant (McNemar’s Test) for those subjects reporting the symptom at both time points. The following table stratifies the predictability of intended refraction for groups: ≤4.5 mm (n=99), >4.5 to ≤5.5 mm (n=172), >5.5 mm (n=101). No statistically significant differences were found. A change in symptom occurrence preoperatively to postoperatively was +Statistically significant (McNemar’s Test) for those subjects reporting the symptom at both time points.