Summary Clinical Investigation data

ARTISAN MYOPIA 5/8.5	ARTISAN Myopia 6/8.5	ARTISAN Hyperopia 5/8.5
Model: 206001W	**Model: 204001W**	**Model: 203001W**
Basic UDI-DI: 8717819Artisan206/4A	**Basic UDI-DI: 8717819Artisan204/44**	**Basic UDI-DI: 8717819Artisan203/3Z**

Indications for use:

The ARTISAN phakic intraocular lens (pIOL) is indicated for the correction of myopia or hyperopia, in patients aged 18 and older, when there are no compromising ocular pathology(ies).

Several studies have been conducted with the ARTISAN Myopia pIOLs. The ARTISAN Hyperopia pIOL was parented on ARTISAN Myopia model 206001W. Hence, no additional clinical investigation was performed with the ARTISAN Hyperopia pIOL since its safety and performance was already established through the studies with the ARTISAN Myopia pIOLs described below:

European Multicenter Study with the ARTISAN Myopia pIOL

The ARTISAN Myopia pIOL model 206001W was investigated in a European multicenter clinical investigation. The study was a prospective one with a follow-up of three years. The objective of the study was to determine the safety and performance of the ARTISAN Myopia pIOL. The endpoints were near and distant visual acuity, complications and adverse events, and identifying groups who are at high risk of developing complications. A number of 518 eyes were enrolled; the results after three years are shown below:

Performance results

The efficacy index was 1.03 after three years, and 57.1% of the cases were within ± 0.5 D of the desired refraction, while 78.8% were within ± 1.0 D. The mean uncorrected visual acuity (UCVA) remained stable over the years. A UCVA of 20/40 (Snellen feet) or better was observed in 76.8% of eyes at three years.
During the study, the availability of the dioptric power range changed from whole diopters to 0.5 D increments, which influenced the performance results.

Safety results

A mean best spectacle-corrected visual acuity (BSCVA) of 20/40 (Snellen feet) was achieved for 93.9% of the eyes after three years, and the safety index was 1.31. The most frequently reported complications at three years were glare and halo's, and decentered IOLs (surgical-related). Secondary surgical interventions (SSI) were performed in 22 cases because of:

- IOL repositioning (n=5).
- IOL exchange (n=8).
- IOL removal (n=7).
- Repositioning iris hernia (n=1).
- Correcting astigmatism with photorefractive keratectomy (PRK; n=1).

Endothelial cell counts were performed in a subgroup of 129 eyes at six months, one year, two years, and three years. The largest drop in cell loss was seen at six months (4.8%), after which the endothelial cell loss stabilized to a mean physiological loss of 0.7% per year between two and three years.

The results of this study have been published in J Cataract Refract Surgery, 2000; 26:1163-71 by Budo et al.
It was concluded that the ARTISAN Myopia pIOL is a safe, stable, efficacious, and predictable method to correct myopia and that the surgical technique is simple, effective, safe, and reversible.

United States (US) Food and Drug Administration (FDA) Clinical Trial

The ARTISAN Myopia pIOLs models 206001W and 204001W were investigated in a US FDA multicenter clinical trial. The study was prospective, open-label, non-comparative, with a follow-up of three years. The objective of the study was to assess the safety and efficacy of the ARTISAN Myopia pIOL. The endpoints were:

- visual acuity.
- refractive predictability and stability.
- contrast sensitivity.
- intraocular pressure.
- slit-lamp observations.
- endothelial cell density (ECD).
- complications.
- patient satisfaction.
- adverse events.

A total of 684 adults were enrolled; the results after three years are shown below:

Performance results

The preoperative mean manifest refractive spherical equivalent (MRSE) was -12.3 ± 3.2 D. After three years, 71.7% of eyes were within 0.5 D of target refraction, while 94.7% were within 1.0 D. The preoperative UCVA was 20/400 (Snellen feet) or worse in 92% of eyes. Postoperative at three years, the UCVA was 20/40 (Snellen feet) or better in 84%.

Safety results

The preoperative BCVA was ≥20/40 (Snellen feet) in all eyes. The BCVA was ≥20/40 (Snellen feet) for 99% to 100% from the one-month visit through three years. Complications reported were inflammation, iris pigment precipitates, corneal edema, and oval pupils, occurring in the first months after surgery with a decreased prevalence at each visit. At three years postoperative, the only complication reported was an oval pupil. An SSI was performed in 22 cases because of:

- IOL removal (n=13).
- IOL exchange (n=12).
- IOL repositioning (n=10).
- Retinal repair (n=6).

The mean change in ECD from baseline to three years was -4.76 ± 7.8%, with a 2.21% loss between two and three years. The ECD data is from a subset of patients who used the same Konan specular microscopy for endothelial cell measurements.

The results of this study have been published in Ophthalmology, 2008 Mar; 115(3):464-472.e1 by Stulting et al.
It was concluded that the ARTISAN Myopia pIOL models 206001W and 204001W provide excellent refractive outcomes with few complications.