The European Clinical Investigation of the ARTISAN® Myopia Lens began in September 1991. A total of nine investigational sites have participated in the study, completing the protocol enrollment of 600 study subjects in 1997. All subjects have been monitored for a minimum of three years to determine the safety and efficacy of the Artisan® PIOL. A final report of the European Clinical Investigation was published in 2000.* The results of the 518 eyes that met with the inclusion criteria are presented here.

Study Group
Netherlands: Prof. Dr. Worst, Dr. Luyten; Belgium: Dr. Budo, Dr. Tassignon, Dr. Termote; France: Dr. Hessloehl; Slovakia: Dr. Izak; Spain: Dr. Menezo; Turkey: Dr. Sener.

Study Inclusion Criteria
- Stable myopia between -5.0 D and -20.0 D
- Anterior chamber depth ≥ 3.0 mm from epithelium
- Preoperative endothelial cell count ≥ 2000 cells / mm²
- Preoperative intraocular pressure ≤ 21 mmHg
- Fixed Pupil Size < 4.5 mm


### DEMOGRAPHICS

<table>
<thead>
<tr>
<th>Eyes (N)</th>
<th>518</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age @ OP</td>
<td>36.4 (range 18 to 65)</td>
</tr>
<tr>
<td>Gender</td>
<td>59.5 % female, 40.5 % male</td>
</tr>
<tr>
<td>ACD</td>
<td>3.38 mm ± 0.71</td>
</tr>
<tr>
<td>Spherical equivalent</td>
<td>-12.95 D ± 4.35 (range -5.0 to -20.0)</td>
</tr>
<tr>
<td>Cylinder</td>
<td>1.23 D ± 1.13 (range 0 to 6.0)</td>
</tr>
</tbody>
</table>

### FIGURES

#### Distribution of lens power

- Implanted power:
  - N: 518
  - Mean: -12.7 D
  - Std: 3.19

#### Efficacy after 3 years

- Efficacy Index:
  - 6 months: 105%
  - 1 year: 106%
  - 2 years: 105%
  - 3 years: 103%

- Deviation from target:
  - ≤ 0.5 D: 76.8%
  - 0.5 to 1.0 D: 28.8%
  - 1.0 or better: 4.4%

- Correlation: visual acuity (Snellen decimals)

#### Intended vs achieved after 3 years

- Deviation from target:
  - ≤ 0.5 D: 52.1%
  - ≤ 1.0 D: 78.8%
Persistant complications after 3 years:

- Glare: 4.8%
- Halo’s: 8.8%
- Age related cataract formation: 2.4%
- Corneal Oedema: 0.8%
- Iris Atrophy: 0.4%
- Other: 4.0%

Cumulative complications during study:

- IOL removal*: 2.8% (n=7)
- Lens replacement: 3.2% (n=8)
- Lens repositioning: 2.0% (n=5)
- Repositioning Iris Hernia: 0.4% (n=1)
- Correcting Astigmatism with PRK: 0.4% (n=1)
- Pupillary Block: 0.8% (n=2)
- Retinal Detachment: 0.8% (n=2)
- Hyphema: 1.6% (n=4)
- IOL not well centered at surgery: 8.8% (n=22)

* Wide Pupil Diameter (1)
** Critical Endothelial Cell Count (1)
Trauma (punch on the eye), leading to a loosening of the claws (2)
Posterior Capsule Opacification followed by cataract formation (3)