TECNIS Multifocal 1-Piece Intracorneal Lens (IL), Models ZKB00 (+2.75 D) and ZLB00 (+3.25 D)

1. DESCRIPTION

The TECNIS Multifocal 1-Piece Intracorneal Lens (IL) is a one-piece, soft foldable intraocular lens that is implanted in the posterior capsule and may have beneficial effects on the corneal surface and anterior chamber dynamics. The lens is composed of silicone and is designed to provide multifocal vision.

2. MATERIAL

The TECNIS Multifocal 1-Piece IL is made of soft foldable acrylic with a covalently bound UV absorber for ocular protection. The lens package includes instructions for use, patient information, and directions for proper lens care.

3. HAPTIC THICKNESS

The haptic thickness is 0.46 mm, which allows for easy insertion and removal during the implantation process.

4. PRIOR TO IMPLANTING, EXAMINE THE LENS PACKAGE FOR PROPER LENS MODEL, DIOPTRIC POWER, AND OPTICAL QUALITY.

5. THE SUPERPOSITION OF FOCUSED AND UNFOCUSED IMAGES. THESE MAY INCLUDE A POTENTIAL EDGE GLARE EFFECTS.

6. THE INITIAL CLINICAL STUDY OF THE TECNIS MULTIFOCAL SILICONE IL, MODEL ZM900 WAS A MULTICENTER STUDY CONDUCTED TO EVALUATE THE SAFETY AND EFFICACY OF THE LENS.

7. DISTRIBUTIONS OF NEAR VISUAL ACUITY RESULTS AT 6 MONTHS FOR ALL THREE LENS GROUPS ARE PRESENTED IN TABLES 26.

8. THE M.EAN AGE FOR MULTIFOCAL SUBJECTS WAS 65.9 YEARS (RANGING TO 77.9 YEARS) AND 60.8% FEMALEs IN THE MULTIFOCAL LENS GROUP AND 65.9% IN THE MONOFOCAL CONTROL GROUP (TECNIS 1-Piece, MODEL ZCB00).

9. ADDITIONALLY, 99.3% (143/144) OF THE ZKB00 BEST-CASE FIRST EYES AND 100% (149/149) OF THE ZLB00 BEST-CASE FIRST EYES ACHIEVED 20/25 OR BETTER BINOcular DISTANCE VISUAL ACUITY RESULTS AT 6 MONTHS FOR ALL THREE LENS GROUPS.

10. THE INCIDENCE OF CUMULATIVE ADVERSE EVENTS FOR THE TECNIS ZM900 MULTIFOCAL FIRST EYES WAS 33.6% (146/436) AND 2200/2200 FOR THE MONOFOCAL CONTROL GROUP.

11. NEAR VISUAL ACUITY RESULTS AT 6 MONTHS FOR ALL THREE LENS GROUPS ARE PRESENTED IN TABLES 26.

12. THE MEAN MONOCULAR DISTANCE CORRECTED NEAR VISUAL ACUITY RESULTS AT 6 MONTHS FOR ALL THREE LENS GROUPS ARE PRESENTED IN TABLES 26.

13. THE MEAN MONOCULAR DISTANCE CORRECTED NEAR VISUAL ACUITY RESULTS AT 6 MONTHS FOR ALL THREE LENS GROUPS ARE PRESENTED IN TABLES 26.

14. THE PERCENTAGE OF SUBJECTS AT 6 MONTHS WAS 82.7% (150/179) FOR THE ZKB00 MULTIFOCAL LENS, 86.8% (149/170) FOR THE ZLB00 MULTIFOCAL LENS, AND 85.2% (173/203) FOR THE MONOFOCAL CONTROL GROUP.

15. THE MEAN MONOCULAR DISTANCE CORRECTED NEAR VISUAL ACUITY RESULTS AT 6 MONTHS FOR ALL THREE LENS GROUPS ARE PRESENTED IN TABLES 26.

16. THE PERCENTAGE OF SUBJECTS AT 6 MONTHS WAS 82.7% (150/179) FOR THE ZKB00 MULTIFOCAL LENS, 86.8% (149/170) FOR THE ZLB00 MULTIFOCAL LENS, AND 85.2% (173/203) FOR THE MONOFOCAL CONTROL GROUP.

17. THE MEAN MONOCULAR DISTANCE CORRECTED NEAR VISUAL ACUITY RESULTS AT 6 MONTHS FOR ALL THREE LENS GROUPS ARE PRESENTED IN TABLES 26.

18. THE PERCENTAGE OF SUBJECTS AT 6 MONTHS WAS 82.7% (150/179) FOR THE ZKB00 MULTIFOCAL LENS, 86.8% (149/170) FOR THE ZLB00 MULTIFOCAL LENS, AND 85.2% (173/203) FOR THE MONOFOCAL CONTROL GROUP.

19. THE MEAN MONOCULAR DISTANCE CORRECTED NEAR VISUAL ACUITY RESULTS AT 6 MONTHS FOR ALL THREE LENS GROUPS ARE PRESENTED IN TABLES 26.

20. THE PERCENTAGE OF SUBJECTS AT 6 MONTHS WAS 82.7% (150/179) FOR THE ZKB00 MULTIFOCAL LENS, 86.8% (149/170) FOR THE ZLB00 MULTIFOCAL LENS, AND 85.2% (173/203) FOR THE MONOFOCAL CONTROL GROUP.


22. THE PERCENTAGE OF SUBJECTS AT 6 MONTHS WAS 82.7% (150/179) FOR THE ZKB00 MULTIFOCAL LENS, 86.8% (149/170) FOR THE ZLB00 MULTIFOCAL LENS, AND 85.2% (173/203) FOR THE MONOFOCAL CONTROL GROUP.

23. THE MEAN MONOCULAR DISTANCE CORRECTED NEAR VISUAL ACUITY RESULTS AT 6 MONTHS FOR ALL THREE LENS GROUPS ARE PRESENTED IN TABLES 26.

24. THE PERCENTAGE OF SUBJECTS AT 6 MONTHS WAS 82.7% (150/179) FOR THE ZKB00 MULTIFOCAL LENS, 86.8% (149/170) FOR THE ZLB00 MULTIFOCAL LENS, AND 85.2% (173/203) FOR THE MONOFOCAL CONTROL GROUP.

25. THE MEAN MONOCULAR DISTANCE CORRECTED NEAR VISUAL ACUITY RESULTS AT 6 MONTHS FOR ALL THREE LENS GROUPS ARE PRESENTED IN TABLES 26.

26. THE PERCENTAGE OF SUBJECTS AT 6 MONTHS WAS 82.7% (150/179) FOR THE ZKB00 MULTIFOCAL LENS, 86.8% (149/170) FOR THE ZLB00 MULTIFOCAL LENS, AND 85.2% (173/203) FOR THE MONOFOCAL CONTROL GROUP.
Note: The figures above describe the optical performance of the TECNIS® ZM 900 and ZLB00, in the ACE* eyes at 50 cycle/mm measured in white light as the focus is gradually shifted from 0.75 diopters (D) to 4.00 D. The focus is then fixed at the respective distance for 4 seconds and then shifted to the next focus setting. The focus is then fixed at the respective distance for 4 seconds. The MTF was measured at 0.75 D, 1.50 D, 2.00 D, 2.25 D, and 4.00 D of defocus.

The figures above also show the frequency of ocular symptoms and adverse events reported by subjects at 4-6 months post-surgery. The frequency of symptoms is reported on a scale of 1-5, with 1 being no difficulty and 5 being worst. The frequency of adverse events is reported as the percentage of subjects experiencing the event, with a significance level of p<0.0001.

The figures above also show the frequency of symptoms and adverse events reported by subjects at 1 year post-surgery. The frequency of symptoms is reported on a scale of 1-5, with 1 being no difficulty and 5 being worst. The frequency of adverse events is reported as the percentage of subjects experiencing the event, with a significance level of p<0.0001.

The figures above also show the frequency of symptoms and adverse events reported by subjects at 2 years post-surgery. The frequency of symptoms is reported on a scale of 1-5, with 1 being no difficulty and 5 being worst. The frequency of adverse events is reported as the percentage of subjects experiencing the event, with a significance level of p<0.0001.

The figures above also show the frequency of symptoms and adverse events reported by subjects at 3 years post-surgery. The frequency of symptoms is reported on a scale of 1-5, with 1 being no difficulty and 5 being worst. The frequency of adverse events is reported as the percentage of subjects experiencing the event, with a significance level of p<0.0001.

The figures above also show the frequency of symptoms and adverse events reported by subjects at 4 years post-surgery. The frequency of symptoms is reported on a scale of 1-5, with 1 being no difficulty and 5 being worst. The frequency of adverse events is reported as the percentage of subjects experiencing the event, with a significance level of p<0.0001.

The figures above also show the frequency of symptoms and adverse events reported by subjects at 5 years post-surgery. The frequency of symptoms is reported on a scale of 1-5, with 1 being no difficulty and 5 being worst. The frequency of adverse events is reported as the percentage of subjects experiencing the event, with a significance level of p<0.0001.

The figures above also show the frequency of symptoms and adverse events reported by subjects at 6 years post-surgery. The frequency of symptoms is reported on a scale of 1-5, with 1 being no difficulty and 5 being worst. The frequency of adverse events is reported as the percentage of subjects experiencing the event, with a significance level of p<0.0001.

The figures above also show the frequency of symptoms and adverse events reported by subjects at 7 years post-surgery. The frequency of symptoms is reported on a scale of 1-5, with 1 being no difficulty and 5 being worst. The frequency of adverse events is reported as the percentage of subjects experiencing the event, with a significance level of p<0.0001.

The figures above also show the frequency of symptoms and adverse events reported by subjects at 8 years post-surgery. The frequency of symptoms is reported on a scale of 1-5, with 1 being no difficulty and 5 being worst. The frequency of adverse events is reported as the percentage of subjects experiencing the event, with a significance level of p<0.0001.

The figures above also show the frequency of symptoms and adverse events reported by subjects at 9 years post-surgery. The frequency of symptoms is reported on a scale of 1-5, with 1 being no difficulty and 5 being worst. The frequency of adverse events is reported as the percentage of subjects experiencing the event, with a significance level of p<0.0001.

The figures above also show the frequency of symptoms and adverse events reported by subjects at 10 years post-surgery. The frequency of symptoms is reported on a scale of 1-5, with 1 being no difficulty and 5 being worst. The frequency of adverse events is reported as the percentage of subjects experiencing the event, with a significance level of p<0.0001.

The figures above also show the frequency of symptoms and adverse events reported by subjects at 11 years post-surgery. The frequency of symptoms is reported on a scale of 1-5, with 1 being no difficulty and 5 being worst. The frequency of adverse events is reported as the percentage of subjects experiencing the event, with a significance level of p<0.0001.

The figures above also show the frequency of symptoms and adverse events reported by subjects at 12 years post-surgery. The frequency of symptoms is reported on a scale of 1-5, with 1 being no difficulty and 5 being worst. The frequency of adverse events is reported as the percentage of subjects experiencing the event, with a significance level of p<0.0001.

The figures above also show the frequency of symptoms and adverse events reported by subjects at 13 years post-surgery. The frequency of symptoms is reported on a scale of 1-5, with 1 being no difficulty and 5 being worst. The frequency of adverse events is reported as the percentage of subjects experiencing the event, with a significance level of p<0.0001.

The figures above also show the frequency of symptoms and adverse events reported by subjects at 14 years post-surgery. The frequency of symptoms is reported on a scale of 1-5, with 1 being no difficulty and 5 being worst. The frequency of adverse events is reported as the percentage of subjects experiencing the event, with a significance level of p<0.0001.