ISOSafety and Performance Endpoints (SPE) criterion for percent of eyes with best-

-2.75 diopter add in actual lens power and thenear power for Model ZKB00 represents

The TECNIS ® Multifocal 1-Piece intraocular lenses, Models ZKB00 (+2.75 D) and ZLB00 (+3.25 D) was a prospective, multicenter, bilateral, open-label, evaluator-masked,

prior to implanting, examine the lens package for proper lens model, dioptric

Note: The primary analysis group for the primary and secondary study endpoints

123 patients), 56.9% of the patients were female and 43.1% were

placed in the capsular bag.

Defocus curve testing was performed on a subset of approximately 60 subjects from

conditions. On rare occasion these visual effects may be significant enough that

reduction may not be tolerated, such as macular degeneration, retinal pigment

effectiveness in this age group.

However, because this multifocal design

and "Other" (1.4% in the multifocal group and none in the monofocal group).

again, if given the opportunity (1.75 D) was a prospective, multicenter, bilateral, open-label, evaluator-masked,

subjective questionnaire was administered that consisted of sponsor-developed

mean contrast scores for the multifocal group were less than that for the monofocal IOL

At the 6-month study visit, investigators evaluated the ability to visualize the fundus

A subjective questionnaire was administered that consisted of sponsor-developed

were generally within -0.15 log units. The largest median differences were between the

-0.255 for the 12 cpd mesopic without glare and mesopic with glare conditions,

Figure 5 presents the difficulty reported for night vision, glare/flare

DIRECTIONS FOR USE:

The Night Driving Simulator included two driving scenes, a nighttime rural road and a

Tables 32-35 present the proportions of subjects that achieved 20/40 or better

4. The lens may be soaked in sterile balanced salt solution or sterile norma l saline

mean distance visual acuity a t 6 months

Fundus Visualization

Near Visual Acuities

Visual Acuity

Table 46

There was only one persistent event; one first eye unilateral subject was diagnosed

having any difficulties with your eyes or vision as asked at the clinical study exams.

Reading Ability

Tables 32-35 present 4-6 month and one-year results, respectively, for

Near Vision

A subjective questionnaire was administered that consisted of sponsor-developed

Nonetheless, when specifically asked, statistically significant

some statistically significant differences between groups for distorted distance vision

presented the difficulty reported for night vision, glare/flare

-0.255 for the 12 cpd mesopic without glare and mesopic with glare conditions,

Figure 5 presents the difficulty reported for night vision, glare/flare

If given the opportunity (1.75 D) was a prospective, multicenter, bilateral, open-label, evaluator-masked,

Mean contrast scores for the multifocal group were less than that for the monofocal IOL

There was only one persistent event; one first eye unilateral subject was diagnosed

Having any difficulties with your eyes or vision as asked at the clinical study exams.

Reading Ability
Note: Includes reports of symptoms common to multifocal IOLs (halos, night glare, - Intermediate = 11.1%, Severe = 5.4%, Overall = 2.6%).

Photopic Visual Acuity at One Year

Figure 9: Distance and Near Binocular Near Photopic Visual Acuity at One Year

Table 42

Table 40

Table 17

Table 49

Cumulative Adverse Events for TEKNIS ® ZM900 First Eyes

One Year

Monofocal

TECNIS ® ZM900

N=294

4.24

5.70

7.96

0.80

11.5% (34/296) of second eyes at 4-6 months. At one year, reports of severe halos, night glare or starburst were noted for 6.9% (23/331) of first eyes and 6.8% (20/305) of second eyes.

Pedestrian Warning

Fluctuation in acuity

Loss

0.00

0.30

3.6

3.9

4.2

4.3

4.46*

17.8%

11.5%

2007 Sep 10;46(26):6595-605.

Not lens-related

Experienced an event in the first eye during the study. Therefore, the total number of experienced an event in the first eye during the study. Therefore, the total number of