8. Rotation of TECNIS Symfony® Toric IOLs away from their intended axis can reduce their
insertion success rate.  The TECNIS Symfony® Extended Range of Vision IOLs are designed to be positioned in the
appropriate axis.  If the axis is misaligned, this can result in reduced visual acuity.  The Model Series ZXT IOLs are intended for
patients who have undergone cataract surgery and require correction of residual refractive astigmatism.

4. Prior clinical studies of the multifocal parent of the TECNIS Symfony® IOLs, the TECNIS® Extended Range of Vision IOLs,

5. Two prior clinical studies of the multifocal parent of the TECNIS Symfony® IOLs, the TECNIS® Extended Range of Vision IOLs,

6. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
with lower astigmatism.

7. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
with lower astigmatism.

8. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
with lower astigmatism.

9. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
with lower astigmatism.

10. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
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11. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
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12. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
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13. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
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15. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
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16. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
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17. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
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18. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
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19. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
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20. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
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21. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
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22. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
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23. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
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24. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
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25. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
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26. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
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27. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
with lower astigmatism.

28. The best corrected distance visual acuity results for Symfony-implanted subjects would have greater "tolerance to refractive error." This was evaluated
with lower astigmatism.
ZCT150 Model

All

ZCB00

ZCB00

Would Want to Have Lens(es) Removed and Replaced due to Visual Symptoms

Preop Kcyl); Percent cylinder reduction (ANSI formula) adjusted for eyes (3) with small denominators and axis), estimated SIA and incision axis.

Keratometric

Preoperative

29

≥1.50

First Eyes Randomized Control Arm ZCT150 and ZCB00

22

20.00

91

22

19.43

n

0.36

0.42

0.49

P-

293 ± 33 320 ± 32 27 8.4% 5.70 6.23

Pedestrian 387 ± 109 495 ± 96 108 21.7% 4.80 6.14

Secondary Surgical Intervention 6 3.4

Cumulative Adverse Event

b

Retinal detachment 0 0.0 0.3

p=0.4059 compared to cumulative ISO SPE rate of 0.8%

Mean Visibility Distance

Mean Visibility Distance

No trouble at all

Severe trouble

A little trouble

No trouble at all

Severe trouble

A little trouble

Subsequent to endophthalmitis and hypopyon

Excludes subjects with macular degeneration at any time during the study.

Table 32

Overall = 4.2%

Severe = 3.6%

Note: Includes any findings reported with a statistically significant (p < 0.05) difference in

6.9 %

Overall = 4.2%

%7.1 %7.1 %0.6 %9.3 eralg yaD

b Some subjects reported more than one visual disturbance. Reports of severe halos, night glare or starbursts were noted for

Note: Includes any findings reported with an incidence of 3% or higher at 6 months.