

G. SUMMARY OF COMPLICATIONS AND ADVERSE EVENTS:

Complications and adverse events that occurred in the study are summarized in the tables below for the pre-IDE and IDE subjects combined. The only reported complications were related to the microkeratome and creation of the corneal flap during the LASIK procedure.

Table 1.1.G-1: Complications Summary Table

COMPLICATION	Intra-operative n/N (%) N = 844	1 Month n/N (%) N = 579	3 Months n/N (%) N = 451	6 Months n/N (%) N = 253	12 Months n/N (%) N = 89
Corneal edema between 1 week and 1 month after the procedure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Peripheral corneal epithelial defect at 1 month or later	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Epithelium in interstice	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Foreign body sensation at 1 month or later	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pain at 1 month or later	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ghost double images in the operative eye	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Flap is not of the size and shape as initially intended or microkeratome stopped in mid-cut.	5 (2.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TOTAL	5 (2.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

N = number of eyes completing the postoperative visit

Table 1.1.G-2: MICROKERATOME RELATED COMPLICATIONS SUMMARY TABLE

COMPLICATION	Intraoperative n/N (%) N = 875	Comment
Incomplete traverse of keratome	2 (0.2%)	Resulted in induced astigmatism (n=1); no effect on visual outcome (n=1).
Flap is not of the size and shape as initially intended	3 (0.3%)	Irregular keratectomy with thin central flap and case aborted (n=1).
Torn flap	12 (1.4%)	Torn flap resulted in wrinkling/ghosting (n=1), holes (n=1), decreased BCVA (n = 5), overcorrection or undercorrection (n=5).