

Table 1.1.G-2: Adverse Events Summary Table

ADVERSE EVENT	1 Month n/N (%) N=153	1 Month n/N (%) N=156	6 Months n/N (%) N = 80	12 Months n/N (%) N=7
Corneal infiltrate or ulcer	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Any corneal epithelial defect involving the keratectomy site at ≥ 1 mo.	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Corneal edema at 1 month or later (specify flap or bed)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Epithelium in the interface	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Lost, misplaced, or misaligned flap	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Melting of the flap	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Uncontrolled IOP with increase of >5 mm Hg above baseline and any reading >35 mm Hg	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Last onset of haze beyond 6 months with loss of 2 lines (10 letters) or more BSCVA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Decrease in BSCVA of > 10 letters not due to irregular astigmatism	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Retinal detachment	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Retinal vascular accidents	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TOTAL	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

N = number of eyes completing the postoperative visit