

Table 4-1: NEM-27-002 Adverse Events Summary for All Eyes Treated

N	Intraop		1 Month		2 Months		6 Months		9 Months		12 Month		18 Months		24 Months	
	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%
<b>ADVERSE EVENTS</b>																
Corneal epithelial defects	0	0.0	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal epithelial defect involving keratometry spot at 1 month or later			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Epithelium to interface			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Leak, unexplained, or unexplained/low	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Mixing of the fluid			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Thrombosed IOP with increase of > 5 mm Hg above baseline or any reading above 15 mm Hg			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Leak noted at time beyond 3 mos. With loss of 2.5 or more BCVA							0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Decrease in BCVA > 2 or 10 letters due to irregular epithelial growth over by 4mm or less from interface at 6 months or later							0	0.0	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	0	0.0	0	0.0	0	0.0	0	0.0
Retinal vascular occlusion	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
<b>COMPLICATIONS</b>																
Visual edema between 1 week and 1 month after procedure			0	0.0												
Peripheral corneal defect at 1 month or later			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Epithelium to interface			0	0.0	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Excessive epithelial growth at 1 month or later			0	0.0	0	0.0	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	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	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	0	0.0	0	0.0
Flare out of the eye and stage as initially indicated or more than one clipped microcyst	5	0.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Central island			0	0.0	5	0.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Pretectal vitreous detachment			1	0.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Ghost images			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Scattered microcysts			0	0.0	0	0.0	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0
Foreign body under flap			0	0.0	0	0.0	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0
Hypotonia			1	0.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Interface haze			0	0.0	2	0.2	2	0.2	0	0.0	0	0.0	0	0.0	0	0.0
SPE (location not specified)			7	0.7	1	0.1	2	0.2	0	0.0	2	0.2	0	0.0	0	0.0
SPE (inferior)			0	0.0	1	0.1	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0
SPE (superior)			1	0.1	0	0.0	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0