

Rx Stratified Summary of FDA Results for all Customized LASIK Approved Systems Nearsightedness and Nearsightedness with Astigmatism

Uncorrected Vision \geq 20/16 at 6 Months Post-op per Pre-op Manifest Refractive Spherical Equivalent								n = number of eyes treated	
	-1.00 to -1.99D	-2.00 to -2.99D	-3.00 to -3.99D	-4.00 to -4.99D	-5.00 to -5.99D	-6.00 to -6.99D			
Autonomous LadarVision CustomCornea	NR	NR	NR	NR	NR	NR			
B+L Zyoptix	73.2% n=41	77.9% n=86	70.7% n=82	66.7% n=57	61.5% n=39	66.7% n=27			
VISX CustomVue (3 mo post-op)	NR	NR	NR	NR	NR	NR			
Uncorrected Vision \geq 20/20 at 6 Months Post-op per Pre-op Manifest Refractive Spherical Equivalent								n = number of eyes treated	
	-1.00 to -1.99D	-2.00 to -2.99D	-3.00 to -3.99D	-4.00 to -4.99D	-5.00 to -5.99D	-6.00 to -6.99D			
Autonomous LadarVision CustomCornea	82.6% n=23	75.0% n=40	90.3% n=31	81.5% n=27	69.2% n=13	50.0% n=4			
B+L Zyoptix	97.9% n=41	95.3% n=86	92.7% n=82	91.2% n=57	84.6% n=39	81.5% n=27			
VISX CustomVue (3 mo post-op)	98.1% n=54	89.8% n=59	89.8% n=59	75.6% n=41	70.0% n=20	NR			

	Eyes with $>0.50D$ Astigmatism Pre-Op	Retreatments?	Treatment Zone	Approved Treatment Range
Autonomous LadarVision CustomCornea	287/426 67.4%	*	6.5mm	up to -7.00D sphere; $<0.50D$ cylinder
B+L Zyoptix	223/340 65.6%	None	up to 7mm	up to -7.00D sphere; -3.00D cylinder
VISX CustomVue	141/351 40.2%	12 eyes	6.0mm	up to -6.00D sphere; -3.00D cylinder

* First 40 eyes treated were excluded from the final data after the treatment software was modified

Source Document References: FDA "Summary of Safety and Effectiveness Data"

Autonomous LadarVision CustomCornea	PMA# P970043/S10: Table 6
B+L Zyoptix	PMA# P990027/S6: Table 6
VISX CustomVue	PMA# P930016/S16: Table 6c

All source documents available for public download from the FDA website: www.fda.gov/cdrh/