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with low illumination and low contrast as you see during the day; these situations may include, but are not limited to, nighttime; fog; dimly lit rooms. It is possible that you may not be able to drive at night. You should take precautions in situations where you may be at risk, because of your possible decreased visual acuity in the above situations. It is also possible that your eyes will become more tired than usual toward the end of the day."

Based on your patient questionnaires, you may be able to reassess this caution and provide to your patients some idea of the percentage of patients experiencing moderate to significant difficulty in seeing well in low light level situations. At PMA time, patient questionnaires can be reviewed by you and the agency for appropriate PMA labeling regarding the caution for low light level situations. In addition if you wish, you may conduct a substudy for contrast sensitivity and use this data as additional information for your PMA patient labeling or to reassess your IDE caution.

2. Because of concern about the non-spherical and multifocal properties of your ablations, please add the following to your patient questionnaire:
 - a. a question regarding the patient's pre- and post-op ability to see well in low light level situations, such as in the dark, in dimly lit rooms or auditoriums, while driving at night, etc.; and,
 - b. a question regarding how tired the patient's eyes become in the evening.
3. In addition to the times already specified in your protocol, your patient questionnaire should be administered at the one week, one month and six month visits.
4. Additional information is required regarding your PMMA ablations:
 - a. Your PMMA ablations appear to be wider at the bottom than the algorithm predicts; for instance, most of the ablations are 2. FDA wide at the bottom, rather than 2.0 mm. Please explain what causes difference in width. 0 0017
 - b. Your PMMA ablations also appear to have a "hump" in the bottom of each ablation of about 10% to 20% of the maximum depth. Please explain what causes these "humps".