

CLAO

Contact Lens Association of Ophthalmologists
An International Educational Association for Refractive Eyecare

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Statement on Contact Lenses as a Medical Device Bruce H. Koffler, MD, President August 23, 2002

"Contact lenses are regulated by the US Food and Drug Administration (FDA) due to the fact that these medical devices, although among the safest medical devices ever invented, still can pose a substantial health risk if not properly fitted, cared for and followed up with professional vision care.

It is important to remember that a contact lens is placed on the eye in direct contact with sensitive ocular tissue and surrounded by the eye tear film. This results in the possibility of a lack of oxygen reaching the highly metabolic cornea, a mechanical impact on the cornea, corneal limbus and/or ocular sclera, and perhaps, of most concern of all, the possibility of a bacterial, viral or fungal infection occurring in the eye.

Although many bacteria may be responsible for infection, the one of most concern is *Pseudomonas*, which if not caught early and treated professionally can result in the loss of an eye. Poor hygiene, dirty hands, improper lens care, overnight wear and sharing of lenses, all lead to an increased risk of infection.

Another infection of great concern is that caused by an amoeba of the genus *Acanthamoeba*, a single celled organism found in tap water, hot tubs and soil. An infection by this organism is difficult to treat, and in some instances results in a corneal transplant.

It absolutely does not matter whether a contact lens is prescribed as plano, (a lens with no refractive power which is fit strictly for cosmetic purposes such as to change eye color or to cover an ocular scar), or prescribed with a specified power for vision correction. The physical and physiological impacts are the same, as is the great concern of the possibility of ocular infection."