

CENTURION® Vision System Important Product Information

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

As part of a properly maintained surgical environment, it is recommended that a backup IOL injector be made available in the event the AutoSert® IOL Injector Handpiece does not perform as expected.

Indication: The CENTURION® Vision system is indicated for emulsification, separation, irrigation, and aspiration of cataracts, residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intraocular lens injection. The AutoSert® IOL Injector Handpiece is intended to deliver qualified AcrySof® intraocular lenses into the eye following cataract removal.

The AutoSert® IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The AutoSert® IOL Injector Handpiece is indicated for use with the AcrySof® lenses SN6OWF, SN6AD1, SN6AT3 through SN6AT9, as well as approved AcrySof® lenses that are specifically indicated for use with this inserter, as indicated in the approved labeling of those lenses.

Warnings: Appropriate use of CENTURION® Vision System parameters and accessories is important for successful procedures. Use of low vacuum limits, low flow rates, low bottle heights, high power settings, extended power usage, power usage during occlusion conditions (beeping tones), failure to sufficiently aspirate viscoelastic prior to using power, excessively tight incisions, and combinations of the above actions may result in significant temperature increases at incision site and inside the eye, and lead to severe thermal eye tissue damage.

Good clinical practice dictates the testing for adequate irrigation and aspiration flow prior to entering the eye. Ensure that tubings are not occluded or pinched during any phase of operation.

The consumables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of consumables and handpieces other than those manufactured by Alcon may affect system performance and create potential hazards.

AEs/Complications: Inadvertent actuation of Prime or Tune while a handpiece is in the eye can create a hazardous condition that may result in patient injury. During any ultrasonic procedure, metal particles may result from inadvertent touching of the ultrasonic tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasion of the ultrasonic tip.

ATTENTION: Refer to the Directions for Use for the accessories/consumables and Operator's Manual for a complete listing of indications, warnings, cautions and notes.