

The Surgical Control of ACTIVE FLUIDICS

Innovative technology impacts surgeons' choice of fluidics dynamics with the CENTURION Vision System.

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One of the defining features of the CENTURION Vision System is the ability of the surgeon to choose a target intraocular pressure (IOP) for the procedure. This ability opens a range of possibilities for surgeons in the way they can conduct their cataract surgery.

ACTIVE FLUIDICS TECHNOLOGY

In the past, most phaco systems relied on gravity fluidics. Thus, the height of the irrigation bottle made sure that the vacuum and aspiration of fluid and lens material from the eye did not cause collapse of the anterior chamber due to postocclusion surge. In in vivo studies, IOP fluctuations have been shown to be responsible for increased turbulence in the anterior chamber. Further, as more fluid has to pass through the eye to maintain the anterior chamber, this can have an adverse effect on the corneal endothelium.

The system of fluidics on the CENTURION Vision System approaches the stability of the anterior chamber in a different manner. Instead of a bag or bottle suspended above the machine to use gravity as just described, there is a compartment into which a bag of BSS (Alcon Laboratories, Inc.) is placed between two paddles. The bag is made of a polymer which, under the pressures to which it is subjected, is almost stretch-free. This means that very small and precise movements of the electronically controlled paddles against the bag are designed to lead to exquisite control of the fluid entering the eye. This control is part of the technology called ACTIVE FLUIDICS, which allows the surgeon to choose a target IOP. To assist in the way the paddles move, the outflow and inflow from the CENTURION Vision System are monitored by pressure sensors on the Fluidics Management System (FMS). To speed the responsiveness and thus rise time, there are two rotary valves. The pump itself now has seven rollers, compared with four on the INFINITI Vision System (Alcon Laboratories, Inc.). These seven rollers act on the entire 360° of the tubing in which

they are in contact, compared with only 180° on the INFINITI Vision System. This again is designed to lead to improved response times. The aspiration tubing has a reduced inner diameter and is very difficult to compress. This is designed to have two effects; firstly, to increase resistance to flow; and second, to prevent any tubing collapse, which can reduce postocclusion surge and thus increase anterior chamber stability.

CUSTOMIZABLE FLUIDICS PARAMETERS

The ACTIVE FLUIDICS Technology is designed to offer adjustments, including the Irrigation Factor (IF).

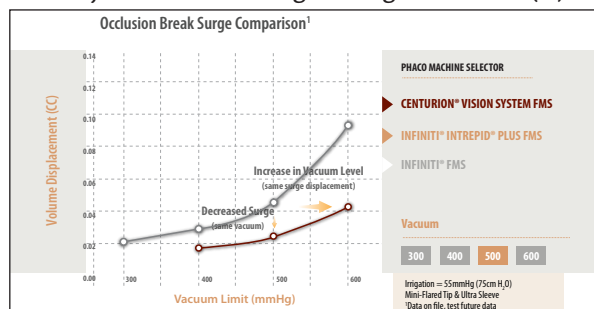


Figure 1. Active Fluidics Technology on the CENTURION Vision System results in much less fluid displacement and an overall more stable anterior chamber than with other phaco systems.

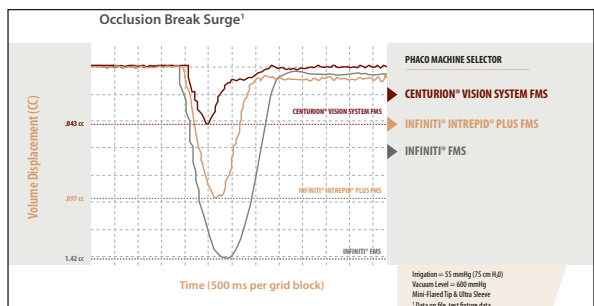


Figure 2. Fluid displacement at variable vacuum limits. The CENTURION Vision System FMS exhibits less fluid displacement compared with the INFINITI INTREPID PLUS FMS and INFINITI FMS.

The IF can be customized once the chosen fluidics parameters have been entered. It takes account of considerations such as the fluidics settings (ie, are they aggressive or more conservative), and also incision size, incision architecture, phaco tip diameter, and sleeve size. Wound leakage through either the main incision or, more commonly, the sideport incision can also be compensated for by adjusting the IF or through a separate leakage compensation setting. The effect is to make the paddles squeeze the BSS bag a little more or less to adjust for dynamic fluidics changes (Figures 1 and 2).

ACTIVE FLUIDICS Technology offers the surgeon a paradigm of choice for the way in which he or she conducts surgery. The selection of a target IOP setting offers a wide range of fluidics options. For example, if the surgeon prefers a harder eye for maneuvers such as chopping, a higher IOP, say of 80 mm Hg, can be selected, which is the equivalent of using a bottle height of 110 cm. ACTIVE FLUIDICS Technology is designed to allow the use of much higher fluidics parameters than on the INFINITI system at this bottle height. Thus, it is possible to use a vacuum setting of the order 750 mm Hg and an aspiration flow rate (AFR) of 60 cc/min and maintain a stable anterior chamber.

For surgeons for whom such high settings and speed of response are uncomfortable and who would like the idea of operating at a lower target IOP, an IOP of 50 mm Hg may work well. This is the equivalent of a

bottle height of 68 cm, somewhat lower than most people might currently use on the INFINITI system. Despite this, it is perfectly possible to operate with a vacuum of 550 mm Hg and AFR of 35 cc/min and maintain a stable chamber.

Finally, a third option is to lower the target IOP to the lowest setting available, of 30 mm Hg, which is the equivalent of a bottle height of 41 cm. I am currently using this with a 2.2-mm incision, an 800- μ m phaco tip, vacuum of 475 mm Hg, and an AFR of 30 cc/min. I feel very comfortable with this, but the eye does feel much softer, and maneuvers need to be adjusted accordingly. Operating near to physiological IOPs may have advantages in challenging cases.

ACTIVE FLUIDICS Technology is a critical advantage to surgeons of various skill levels. They can tailor their settings in the knowledge that ACTIVE FLUIDICS Technology is designed to provide a more stable anterior chamber throughout the operation, and through this, they may feel a greater confidence. ■

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1. Data on file. Alcon Laboratories, Inc., Fort Worth, TX.

CENTURION® Vision System Important Safety 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 and Operator's Manual for a complete listing of indications, warnings, cautions and notes.

INFINITI® Vision System

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

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

The following system modalities additionally support the described indications:

- Ultrasound with UltraChopper® Tip achieves the functionality of cataract separation.
- The INTREPID® AutoSert® IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The INTREPID® AutoSert® IOL Injector Handpiece is indicated for use with 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 INFINITI® 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.

Adjusting aspiration rates or vacuum limits above the preset values, or lowering the IV pole below the preset values, may cause chamber shallowing or collapse which may result in patient injury.

When filling handpiece test chamber, if stream of fluid is weak or absent, good fluidics response will be jeopardized. 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.

AEs/Complications: Use of the INFINITI® Vision System handpieces in the absence of irrigation flow and/or in the presence of reduced or lost aspiration flow can cause excessive heating and potential thermal injury to adjacent eye tissues.

ATTENTION: Refer to the directions for use for a complete listing of indications, warnings and precautions.

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