Cataract & Refractive Surgery

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EXPLORING THE CATARACT REFRACTIVE SUITE

FEATURING

The CENTURION Vision System

The CENTURION Vision System: The Next Step in Cataract Surgery

BY MIKHAIL BOUKHNY, PhD

LOOKING BACK

For an ophthalmologist today, it is hard to imagine the long struggle Charles Kelman, MD, experienced while investigating a means to remove a cataract through an incision small enough to eliminate the need for hospitalization and general anesthesia, and then to get his idea accepted by his peers.¹ In the 46 years since Kelman introduced phacoemulsification, a continuous and rapid evolution of technology and knowledge has brought about smaller incisions, less trauma, improved lenses, and faster visual rehabilitation. Today, cataract surgery has one of the best surgical risk profiles in all of medicine.²

THE LIMITATIONS OF GRAVITY-BASED FLUIDICS

More than a decade of research has gone into the next revolutionary advancement in phaco systems: creating a highly controlled anterior chamber. In order for a surgeon to safely emulsify the crystalline lens and aspirate it from the eye, the anterior chamber has to remain stable throughout all phases of the procedure. Stability is maintained by ensuring a proper balance of fluid entering

and exiting the eye. Balanced salt solution originates in a bag or bottle, travels through tubing into the handpiece, and finally flows into the anterior chamber of the eye. Fluid leaves the anterior chamber in one of two ways: via aspiration, or via leakage at the incision site. Thus, irrigation flow equals aspiration flow plus incisional leakage.

Historically, inflow fluid pressure has been controlled by gravity—the higher the bottle or bag is above the eye, the greater the input pressure. The limitation to this design comes from the fact that input pressure is set by the fixed bottle height, but pressure delivered to the eye is variable and changes based on flow rate. Pressure in the anterior chamber equals the input pressure minus pressure losses caused by flow restrictions between the irrigation source and the eye. The higher the aspiration flow rate, the higher the demand for irrigation, and therefore the more pressure that is lost as fluid makes its way from the source to the eye. This



Figure 1. The CENTURION Vision System is the first phacoemulsification system to provide an alternative to fixed irrigation sources.

pressure loss becomes more pronounced with smaller incisions, which present higher resistance to irrigation. The pressure in the eye is therefore constantly changing depending on flow rate, which causes fluid to move within the anterior chamber. It is not feasible to raise and lower the bottle or bag fast enough to accommodate for dynamic changes in flow that occur during the procedure.

A NEW ERA OF FLUIDICS

For the first time, the CENTURION Vision System (Alcon Laboratories, Inc.; Figure 1) provides an alternative to fixed irrigation sources. Rather than relying on gravitational pull, the CENTURION Vision System's ACTIVE FLUIDICS Technology places the BSS solution bag into a compartment between two plates. These plates rapidly compress or decompress the bag based on the dynamic changes occurring during the surgery (Figure 2).

The system employs two pressure sensors to monitor fluidic performance (Figure 3). Information from these sensors, together with the pump's speed

and the resistance of the irrigation path, is used to predict the amount of pressure loss that will occur between the source and the eye. The system is then able to compensate for this pressure loss in order to accurately maintain pressure in the eye at the target value selected by the surgeon. Rapid increases or decreases in the amount of compression on the bag dynamically change the input pressure as needed to counteract losses in pressure due to flow, thereby maintaining near-constant target IOP.

The key to accurately maintaining target IOP is the very tightly controlled ACTIVE FLUIDICS Technology with precisely calibrated components such as: a high-torque digital stepper motor, lightweight aluminum compression plates, a low-stretch irrigation bag, and a carefully primed fluidics path with most of the air removed. Furthermore, the surgeon is able to tune the system for his or her particular choice of tip, sleeve, and incision geometry by adjusting an



Figure 2. ACTIVE FLUIDICS Technology tightly controls inflow fluid pressure by placing the BSS solution bag between two compression plates that dynamically respond to the events of surgery.

"Irrigation Factor" parameter from the CENTURION Vision System's screen. An increase in "Irrigation Factor" adjusts for a more restrictive combination, while a decrease in "Irrigation Factor" adjusts for a less restrictive combination.

As ultrasonic energy breaks up the lens, particulate matter of various sizes is attracted to the phaco tip. Some particles may be easily aspirated, while other, larger particles may temporarily block the aspiration tip. When these momentary occlusions resolve, a "surge" in aspiration—a rapid exit of fluid from the anterior chamber called occlusion break surge or postocclusion surge-may result, causing the anterior chamber to shallow. The CENTURION Vision System greatly reduces occlusion break surge relative to previous systems through the careful design of aspiration pathways. The pathways are designed to minimize compliance and maximize resistance to outflow from the anterior chamber during an occlusion break. This resistance to outflow significantly reduces the fluid volume removed from the anterior chamber following an occlusion break, resulting in dramatically less shallowing. The surgeon is therefore able to work more comfortably, even at higher vacuums or lower pressures than with previous systems.

IMPROVED CHAMBER STABILITY

The anterior chamber is a small space, which must remain sufficiently inflated and stable so that the surgeon may work effectively. However, individual surgeons' preferences can fall over a range of degrees of chamber pressurization. ACTIVE FLUIDICS Technology provides a finely controlled environment with automated adjustment for changes in



Figure 3. A highly sensitive Fluidics Management System (FMS) monitors inflow and outflow pressure and triggers the necessary compensation.

flow as well as greatly decreased postocclusion surge. This technology reduces the range of IOP variability during the cataract removal procedure, allowing surgeons to identify their preferred working IOP and have confidence that the CENTURION Vision System will maintain their selection. Surgeons may elect to utilize higher or lower parameter settings for vacuum, aspiration, and IOP than typically possible with gravity-based fluidics, depending on their individual preferences and technique.

With the ACTIVE FLUIDICS Technology of the CENTURION Vision System, surgeons benefit from improved chamber stability during the entire cataract removal process, a reduced likelihood of engaging the posterior capsule due to fluidic variability, a more consistent range of IOP during the procedure, and the ability to employ higher or lower fluidic parameters to increase the efficiency and rate of cataract removal.

For the first time, a phacoemulsification system can intelligently detect and dynamically compensate for the everchanging conditions during the cataract lens removal procedure. Surgeons can now focus more on the cataract removal procedure and less on managing the phaco system. ■

1. Kelman, CD. History of Phacoemulsification. In: Kwitko ML, Kelman CD, eds. *The History of the Modern Cataract Surgery*. The Hague, Netherlands: Kugler Publications; 1998: 123–130.

2. American Academy of Ophthalmology (2006). Cataract in the Adult Eye. Preferred Practice Pattern. San Francisco: American Academy of Ophthalmology. Available online: http://www.aao.org/ppp.

Phaco Without Gravity-Based Fluidics

My experience using a high-parameter microincisional technique with ACTIVE FLUIDICS Technology. BY RICHARD J. MACKOOL, MD

here are three primary aspects to the phacoemulsification procedure: fluidics, incision size, and ultrasonics. The new CENTURION Vision System (Alcon Laboratories, Inc.) offers improvements in each of these areas using state-of-the-art technology. This article describes my experience with this new system using a high-parameter, microincisional technique.

IMPROVED FLUIDICS WITH THE CENTURION VISION SYSTEM

Fluidics is the single most important feature of any phaco system, because this determines the safety of the procedure. Although there is no "correct" IOP for performing phacoemulsification, my surgical preference is to work at a higher pressure; i.e., one that is always greater than 50 mm Hg. I personally find that with a softer eye, it is easier to induce unwanted corneal folds that can inhibit visualization at lower pressures, and I prefer very rapid removal of the nuclear segments. Previously, the infusion bottle had to be very high in order use suitably aggressive fluidics for this emulsification style. The CENTURION Vision System is the first system to allow the surgeon to use high vacuum settings and higher flow rates, without compromising IOP. With a fixed infusion capacity, there is much greater fluctuation in intraocular volume due to varying flow rates and vacuum levels throughout the procedure. The unique capability of ACTIVE FLUIDICS Technology is that the phaco system is able to provide different infusion rates in sync with the changing outflow rate and vacuum pressure. This has never been possible with standard gravity infusion or pressurized infusion systems.

When anterior chamber volume is not consistent, the surgeon must struggle to avoid traumatizing the cornea, iris, and lens capsule. Consider the difference between driving a car in a straight line or around sharp corners. Whenever a potential hazard arrives, the driver has to slow down. Similarly, the surgeon uses low aspiration and vacuum levels to avoid surge. Good fluidics enable the use of the widest range of parameters and permit inflow and outflow to be more unidirectional and less turbulent. Turbulence causes particles to disperse, whereas good fluidics draw the nuclear segments to the tip, so that the phaco tip can remain in the safe central region of the chamber.

PAIRING MICROINCISIONS WITH HIGH FLUIDIC FLOW

The second most important aspect of phaco surgery is incision size. Precise incisions are a benefit of femtosecond laser surgery. While precise is good, small and precise is better. An incision size greater than 2.4 mm can increase surgically induced astigmatism. A smaller incision requires phaco needles and infusion sleeves that correspond in size, smaller sleeves have historically inhibited the infusion of fluid, and this limits the fluidic parameters to a much lower level. The CENTURION Vision System eliminates this problem. The machine functions to maintain the preset IOP, essentially forcing infusion fluid through the smaller sleeve. The ability to use a very small sleeve/microincision and still operate with a relatively high IOP and stable chamber is a tremendous benefit of superb fluidics.

A BALANCED TIP TO REDUCE ULTRASOUND

The third aspect of phacoemulsification is the efficiency of ultrasonic energy. Advanced ultrasonics work with the fluidics to reduce chatter and attract particles toward the tip. All of this contributes to a quicker and slicker operation. Ultrasonic energy needs to be greatest at the tip, but it is detrimental in the shaft. The shaft passes through the incision, so increased



Figure 4. The Balanced Tip of the CENTURION Vision System.

energy at this location results in greater potential to raise the temperature within the incision. If this increases to a certain level, incision burn can result. Any time more energy can be created at the tip without increasing energy along the shaft, it is desirable. The new Balanced Tip (Alcon Laboratories, Inc.; Figure 4), available with the CENTURION System, is similar to the 45° Mini Flare tip (Alcon Laboratories, Inc.) with one significant exception: it has a precisely calculated curvature along the shaft that maximizes transmission of ultrasonic energy to the tip, thereby minimizing the energy that is at the incision site.¹ I have found the Balanced Tip to be truly exceptional for dense nuclei.

A WINNING COMBINATION

I have been performing phacoemulsification since 1973, and have completed over 50,000 procedures on patients

"I have found the Balanced Tip to be truly exceptional for dense nuclei."

—Richard J. Mackool, MD

ranging in age from 2 days to 107 years. I started with the original Cavitron handpiece and I have used everything in between. I have used Venturi pumps, multiple peristaltic pumps, linear and torsional ultrasound, and a host of other options both in clinical practice and laboratory settings. The combination of ACTIVE FLUIDICS Technology and the Balanced Tip have made the CENTURION Vision System the most advanced phacoemulsification system that I have ever used. ■

1. Data on file, Alcon Laboratories, Inc.

Controlled Phaco Fluidics Reduces Surgical Variables

Greater fluidics is designed to increase comfort for patients and reduce stress on surgeons.

BY RICHARD L. LINDSTROM, MD

he key to success with phacoemulsification is to emulsify and remove the nucleus without damaging any of the surrounding structures. A more efficient procedure in the hands of a confident surgeon means that less fluid passes through the eye, less ultrasonic energy or other trauma is inflicted on the surrounding tissues, and fewer free radicals are released.

SAFETY IS THE PRIMARY CONCERN DURING PHACOEMULSIFICATION

The amount of fluid present in the eye during phacoemulsification is approximately 0.50 cc at any given time. This minimal amount makes it necessary to tightly control the environment. Avoiding postocclusion surge, which can rapidly drain the anterior chamber and leave the surrounding structures subject to damage, is always of primary concern during the procedure. If a surgeon is worried a surge may occur, he or she will work less confidently. The surgeon may use lower vacuum and flow rates just to ensure that an occlusion break does not result in damage to the cornea or iris or in a posterior capsular break. If you have a fluidics system that is designed to minimize risks, the surgeon becomes more confident and does not have to lower vacuum and flow rates to remove larger particles (Figure 5).

THE VERSATILITY OF ACTIVE FLUIDICS TECHNOLOGY

Some surgeons like to operate with very low vacuum settings. In extremely high-risk patients, such as those who have previously undergone vitrectomy, a slower, lowpressure approach is preferable. Other surgeons like to be in and out of the eye in the shortest time possible, or some may rely upon a chopping technique that benefits from a high-vacuum, high-flow approach. My personal technique is somewhere in the middle. In the majority of my surgeries, I use a moderate vacuum level with the vacuum not exceeding 500 mm Hg and the IOP set to 60 mm Hg. ACTIVE FLUIDICS Technology on the CENTURION Vision System is phenomenal, because it can accommodate all of these styles. Rather than BSS solution entering the eye at a consistent rate depending on the gravitational force placed upon it, the pressure, outflow, and pump volume are closely monitored, and the inflow fluid is adjusted as necessary.

The balanced dual-segment peristaltic pump on the CENTURION Vision System is incredibly responsive. Throughout the procedure, there are a variety of things that must be evacuated from the eye, including dense cataract pieces, a heavy nucleus, cortex, fluid, and viscoelastic. The amount of vacuum that is needed at any given moment varies, as does the amount of ultrasonic power. I

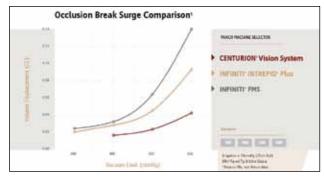


Figure 5. ACTIVE FLUIDICS Technology on the CENTURION Vision System demonstrates greatly reduced occlusion break surge compared to other phaco systems.

prefer a machine that is rapidly responsive—by the second to exactly control the combination of fluid inflow, aspiration, and power that is required. ACTIVE FLUIDICS Technology removes fluid inflow from the surgeon's list of things to monitor and worry about. The pump on the CENTURION Vision System allows me to increase and decrease power instantaneously to reflect the material being aspirated from the eye.

Some surgeons prefer a slower response time; a little lag on the pedal to create a slight delay in rise and ramp time. If the anterior chamber fills too quickly, it may cause the patient to feel pressure, and some surgeons try to avoid this. The CENTURION Vision System is designed so that the surgeon can customize the rise and ramp times according to his or her own personal surgical style. "ACTIVE FLUIDICS Technology removes fluid inflow from the surgeon's list of things to monitor and worry about." —Richard L. Lindstrom, MD

CONTROLLED FLUIDICS = REDUCED STRESS FOR SURGEONS

When I started performing cataract surgery 35 years ago, it was a more challenging experience for the surgeon and for the patient. Postocclusion surge and shallowing chambers were common, and surgeons had to learn to adapt. Sequential surgeries took their toll. With the CENTURION Vision System, the surgeon has the benefit of working with a system that is designed to provide the efficient removal of the cataract, it is also quiet, ergonomically comfortable, and pleasant to use. After an entire day in surgery, this makes a large difference in the surgeon's stress level.

The patient benefits from a system that can accommodate special needs and does not induce unduly high IOP. The outcomes will speak for themselves. Phacoemulsification is really all about controlled fluidics. Currently, the CENTURION Vision System is the only phacoemulsification system on the market with ACTIVE FLUIDICS Technology.

A Phaco System That Adapts to the Surgeon

The CENTURION Vision System gives surgeons more control over the surgical parameters and the patient's position.

BY RICHARD PACKARD, MD, FRCS, FRCOPHTH

deally, the fluidics on any phacoemulsification system should be designed to maintain a constant intraocular pressure (IOP). Gravity-based fluidics require the surgeon to overcompensate for possible postocclusion surge by placing the bottle higher than necessary, which creates an IOP of sufficient magnitude to overcome any fluctuations. The alternative is to force the surgeon to operate at lower vacuum and aspiration flow rate levels to build in a safety factor. The CENTURION Vision System (Alcon Laboratories, Inc.) approaches fluidics from a different standpoint. By measuring volume and pressure within the system and adjusting the fluid inflow dynamically, maintenance of the anterior chamber at the surgeon's chosen IOP level can be achieved.

AN ALTERNATIVE TO GRAVITY-BASED FLUIDICS SYSTEMS

Rather than using gravity, the CENTURION Vision System places the irrigation fluid in a bag between two plates that compress or decompress it instantaneously, depending on the fluid inflow needs within the chamber. The Fluidics Management System (FMS) monitors pressure on the irrigation path, and as soon as it detects lower pressure, it compresses the BSS solution bag in a very precise

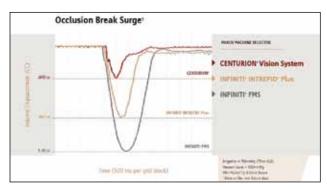


Figure 6. ACTIVE FLUIDICS Technology on the CENTURION Vision System results in much less fluid displacement and an overall more stable anterior chamber than with other phaco systems.

manner to compensate for this pressure loss. When the aspiration flow rate increases, the FMS detects the decreased pressure very quickly. The speed with which the FMS detects even very small changes in pressure is the key to its success. Thus it controls fluid inflow to compensate for the pressure change even before the surgeon detects a shift in chamber volume.

To assist the ability to alter inflow fluid, the CENTURION Vision System has not only much less compliant tubing but also a smaller bore, which increases resistance, which lessens the effect of occlusion break (Figure 6). It also means that the ability to reach a chosen vacuum will be quicker even without increasing the pump's speed. When this is combined with more effective pump and valve settings due to the increased rollers and a double pump, the stability of the anterior chamber is enhanced. Rather than a pinch valve, the pump is controlled by two rotary valves for irrigation and venting that provides low volume displacement. An innovative 7-roller pump mechanism interfaces with the FMS to produce precise, rapid, and pulsatile-free fluid movement. All of these elements combine to create a much smoother phaco experience.

REDUCED FLUID IN THE EYE

If the surgeon chooses to use a lower IOP setting, the overall amount of fluid that passes through the eye during the procedure should also be reduced. This should help to retain dispersive viscoelastic within the eye to protect the endothelium. Less fluid movement within the anterior chamber should translate into less turbulence. This reduces the opportunities for pieces of nucleus to fly around the anterior chamber causing damage to the endothelium, and may prevent small nuclear chips from getting lodged under the iris. "Phacoemulsification is a balancing act, and a very sensitive and responsive fluidics system helps achieve that delicate equilibrium."

-Richard Packard, MD, FRCS, FRCOphth

MY EXPERIENCE WITH LOW IOP SETTINGS

With the CENTURION Vision System, the chamber remains stable, so I prefer to use a lower IOP setting, which previously would have corresponded to a lower bottle height than I would have used safely. I use 40 to 50 mm Hg as my chosen IOP, and because of the smaller bore, less compliant tubing, I have subsequently increased my vacuum settings on the CENTURION Vision System to 450 mm Hg with an aspiration flow rate of 30 cc/min. As the target IOP is programmed separately from the aspiration flow rate, I can increase the aspiration while still maintaining target chamber pressure. I prefer to use a phaco needle that has a very narrow outer diameter (700 μ m), and I feel very comfortable operating at these levels. More importantly, I feel that removal of nuclear tissue has still been faster than it was previously due to the less compliant tubing and the quicker rise time.

A SYSTEM THAT ADAPTS TO THE SURGEON

The CENTURION Vision System allows the settings to be altered so that it may adapt to different surgical styles. Although on the INFINITI Vision System (Alcon Laboratories, Inc.) it was possible to set the Patient Eye Level, very few surgeons bothered, because the high bottle height overcame any effects due to not doing this accurately. Working at lower IOPs means that variable patient eye level becomes an important feature of the CENTURION Vision System. Although inflow fluidics are not dependent upon gravity, the patient's position needs to be adjusted to the height comfortable for the surgeon to enable ACTIVE FLUIDICS Technology to work most effectively.

I have been performing phacoemulsification since 1979 and have used close to 20 different phaco machines during that time. The CENTURION Vision System presents a completely unique and exciting approach to fluidics that is designed to improve the stability of the anterior chamber, enhancing the surgeon's confidence.

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Mikhail Boukhny, PhD, is heading Cataract Phaco and Microscope Instrumentation at Alcon Laboratories, Inc., and has been leading research and development efforts of the CENTURION Vision System. He has been with Alcon since 1995, and he is also the inventor of the OZil Torsional

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Retractors. Dr. Mackool may be reached at (718) 728-3400, ext 256; mackooleye@aol.com.

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 SN60WF, 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.



Richard L. Lindstrom, MD, is the founder of and an attending surgeon at Minnesota Eye Consultants, PA, in Bloomington. He is a paid consultant to Alcon Laboratories, Inc. Dr. Lindstrom may be reached at (612) 813-3600; rllindstrom@mneye.com.



Richard Packard, MD, FRCS, FRCOphth, practices at the Prince Charles Eye Unit, King Edward VII Hospital, Windsor, England. He is a speaker and paid consultant for Alcon Laboratories, Inc. Dr. Packard may be reached at mail@eyequack.vossnet.co.uk.

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The following system modalities additionally support the described indications:

 Ultrasound with UltraChopper® Tip achieves the functionality of cataract separation.
AquaLase® Liquefracture Device achieves the functionality for removal of residual cortical material and lens epithelial cells.

- 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 SN60WF, 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:

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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 characterized for a participation to the test of the data and a patient in a patient in the patient of thep

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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:

Use of the NeoSoniX[®], 0Zil[®] torsional, U/S, or AquaLase[®] 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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