CONSTELLATION® Vision System

Indications for Use: The CONSTELLATION® Vision System is an ophthalmic microsurgical system that is indicated for both anterior segment (i.e., phacoemulsification and removal of cataracts) and posterior segment (i.e., vitreoretinal) ophthalmic surgery.

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

Warnings and Precautions:
- The disposables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of disposables and handpieces other than those manufactured by Alcon may affect system performance and create potential hazards.
- Attach only ALCON® supplied consumables to console and cassette luer fittings. Do not connect consumables to the patient's intravenous connections.
- Mismatch of consumable components and use of settings not specifically adjusted for a particular combination of consumable components may create a patient hazard.
- Vitreous traction has been known to create retinal tears and retinal detachments.
- The closed loop system of the CONSTELLATION® Vision System that adjusts IOP cannot replace the standard of care in judging IOP intraoperatively. If the surgeon believes that the IOP is not responding to the system settings and is dangerously high or low, this may represent a system failure. Note: To ensure proper IOP Compensation calibration, place infusion tubing and infusion cannula on a sterile draped tray at mid-cassette level during the priming cycle.
- Leaking sclerotomy may lead to postoperative hypotony.

Important Safety Information: Warnings and Cautions: A complete listing is available in the CONSTELLATION® Vision System Operators Manual. To obtain a copy, please contact Alcon Customer Service.

ATTENTION: Reference the Directions for Use for a complete listing of indications, warnings, and precautions.

GRIESEHABER® DSP Instrumentation

Indications for Use: GRIESEHABER® DSP instruments are a line of single-use vitreoretinal micro-instruments which are used in ophthalmic surgery, for cases either in the anterior or the posterior segment.

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

Warnings and Precautions:
- Verify correct tip attachment, function and tip actuation before placing it into the eye for surgery.
- For light fiber instruments: Minimize light intensity and duration of exposure to the retina to reduce risk of retinal photic injury. The light fiber instruments are designed for use with an ALCON® illumination source.
• Potential risk from reuse or reprocessing include reduced cutting or grasping performance and foreign particle introduction into the eye.

**ATTENTION:** Reference the Directions for Use for a complete listing of indications, warnings, and precautions.

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**Micro-Incisional Vitrectomy System (MIVS)**

**Indications for Use:** The CONSTELLATION® Vision System is an ophthalmic microsurgical system that is indicated for both anterior segment (i.e., phacoemulsification and removal of cataracts) and posterior segment (i.e., vitreoretinal) ophthalmic surgery.

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

**Warnings and Precautions:**
- Attach only ALCON® supplied products to console and cassette luer fittings. Improper usage or assembly could result in a potentially hazardous condition for the patient. Mismatch of surgical components and use of settings not specifically adjusted for a particular combination of surgical components may affect system performance and create a patient hazard. Do not connect surgical components to the patient's intravenous connections.
- Each surgical equipment/component combination may require specific surgical setting adjustments. Ensure that appropriate system settings are used with each product combination. Prior to initial use, contact your Alcon sales representative for in-service information.
- Care should be taken when inserting sharp instruments through the valve of the Valved Trocar Cannula. Cutting instrument such as vitreous cutters should not be actuated during insertion or removal to avoid cutting the valve membrane. Use the Valved Cannula Vent to vent fluids or gases as needed during injection of viscous oils or heavy liquids.
- Visually confirm that adequate air and liquid infusion flow occurs prior to attachment of infusion cannula to the eye.
- Ensure proper placement of trocar cannulas to prevent sub-retinal infusion.
- Leaking sclerotomies may lead to post operative hypotony.
- Vitreous traction has been known to create retinal tears and retinal detachments.
- Minimize light intensity and duration of exposure to the retina to reduce the risk of retinal photic injury.

**ATTENTION:** Reference the Directions for Use labeling for a complete listing of indications, warnings, precautions, complications and adverse events.

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Carl Claes, MD is a paid consultant for Alcon.

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Expanding the Scope of MIVS

Substantial improvements in technology have increased the capabilities of surgeons and the indications for small-incision surgery.

By Carl Claes, MD

The advances in vitreoretinal surgery that our profession has experienced in recent years can justifiably be called revolutionary. With the advent of microincision vitreoretinal surgery (MIVS), small, self-sealing incisions now allow for fast and uneventful patient recovery, with less inflammation and induced astigmatism to complicate the postoperative period.

Equally impressive is the pace of innovation. Since its introduction in 2002, MIVS has progressed from infancy to maturity in under a decade. Once considered a somewhat risky alternative to conventional 20-gauge surgery, it is now the standard of care in many surgical practices, including my own.

Historical Perspective

But like any revolution, the transition to MIVS was not without setbacks. Early enthusiasm for 25-gauge surgery was tempered by legitimate concerns about its lack of parity with 20-gauge procedures. Flexure of instruments reduced the precision of tissue manipulation. Slower aspiration flow rates increased case duration and the attendant risks to patient safety that go with it. Hypotony and endophthalmitis risks loomed.

Although further advancement will undoubtedly continue to refine techniques, I believe we have reached a critical milestone: the newest generation of surgical instrumentation, most notably the EDGEPLUS® and GRIESHABER® DSP product lines (Alcon Laboratories, Fort Worth, Texas), has leveled the playing field between 20-gauge and MIVS options. In fact, we are even finding some opportunities to not merely meet but exceed the outcomes of 20-gauge procedures when using MIVS.

MIVS Moves to the Forefront

Small-gauge surgery was initially performed only under ideal circumstances in cases that offered the greatest chance of success. Indeed, that remains the typical transition path for vitreoretinal surgeons interested in adopting MIVS. It allows one to build a foundation of knowledge on the intraoperative performance of the devices and gradually expand the scope of their use.
What we are finding with the latest wave of product innovation is an ability to use MIVS techniques for an ever-increasing range of cases. My facility sees a significant number of difficult cases, such as patients requiring reoperation and those with comorbid pathologies. I now perform the majority of my cases using either 23- or 25-gauge instrumentation. Here, I will describe recent innovations in product design and surgical technique that have improved the reliability and precision of MIVS.

■ Valved trocar cannulas. Like cataract surgeons, we should strive to work in a closed environment that maintains intraocular pressure (IOP) at a consistent level; otherwise, we will experience complications due to fluid egress. IOP control is demonstrably superior in a case that uses valved cannulas over one without, as it creates a closed globe that avoids risk of leakage. Routine use of valved cannulas eliminates the need for sclerotomy plugs.

I have used valved cannulas for more than 6 years now, and am thoroughly convinced this is the way we in the surgical community simply have to go. Unvalved cannulas, by their very nature, create a great deal of intraoperative leakage and attraction of tissues toward the sclerotomy sites. Substantial variations in IOP can cause serious complications such as choroidal or retinal hemorrhage.

The valved cannula system (Figures 1, 2) in the EDGEPLUS® trocar product line has proven to be very reliable, and from my experience, has been shown not to leak up to a pressure of 120 mm Hg. Thus, the surgeon is able to increase the pressure inside the eye without risk of wound leakage or tissue incarceration into the sclerotomies. Cannula removal is a simple process that sometimes requires slight counterpressure to withdraw the trocar from the scleral tunnel.

Some surgeons prefer an open sclerotomy for silicone oil exchange to avoid IOP spike during this procedure. In such circumstances, a vent (Figure 3) provided with each pack is a useful enhancement and a novel feature of this instrument’s design. For instance, for silicone oil removal, one could use active aspiration in one port and passive evacuation through the open port by making use of the vent.

Although these instruments are compatible with multiple vitrectomy devices, I find their performance is particularly well suited for use in conjunction with the CONSTELLATION® Vision System (Alcon Laboratories, Fort Worth, Texas), which maintains IOP at a constant level through continuous monitoring of infusion rate and intraocular fluid dynamics. Combined use of valved cannulas and the CONSTELLATION® System’s integrated IOP control all but eliminate perioperative pressure changes that might affect outcomes.

■ Trocar design and wound construction. I have been using 25-gauge instrumentation for nearly 10 years. The early trocar designs, made of polyamide, proved difficult to insert and were prone to extrusion; reinserterion was also difficult. Today, stainless steel trocar shafts used in the EDGEPLUS® line maintain rigidity and placement after insertion. For many years, I have used a tangential incision to ensure a good grip of the trocars intrasclerally and also good closure of the tunnel at the time of removal to prevent vitreous incarceration and to create a watertight closure.

With careful attention to wound construction techniques
that ensure self-sealing closure, endophthalmitis risk has been greatly reduced. In my experience, only one endophthalmitis case has occurred in over 3,500 sutureless cases performed — results on par with the very best results to be found in any intraocular surgery.

Unlike many of my colleagues, I am not in favor of conjunctival displacement. I have done several thousand cases without it; excellent scleral tunnel closure is more significant in ensuring good postoperative safety profiles. The rationale for avoiding conjunctival displacement is especially compelling in cases involving silicone oil. In the postoperative period, the oil could leak out of the sclerotomies and enter the sub-Tenon’s and sub-conjunctival spaces; it is very hard, if not impossible, to remove it completely from these anatomical sites. However, if silicone oil leak should occur in a case done without conjunctival displacement, the effusion will continue through the conjunctival wound rather than being trapped subconjunctivally.

Combined cataract/vitrectomy procedures can also be performed with little to no modification of a standard small-incision vitrectomy protocol. After performing conventional phaco and IOL implantation, I perform vitrectomy as usual. Thanks to the very sharp EDGEPLUS® knife, we can almost atraumatically perform the sclerotomies and insert the trocars without disruption to the anterior chamber that might cause dislocation of the IOL.

- **Cutter design and performance.** Instrument predictability and control are essential elements to success with MIVS. Cutter performance was selected as the single most important feature of a vitrectomy platform by 58.5% of respondents to the 2010 Preferences and Trends survey conducted by the American Society of Retina Specialists.

  I have been using the new series of 25+™ instruments from Alcon and have been pleasantly surprised to find them quite agile for many complex surgical maneuvers such as membrane peeling using the cutter rather than a forceps, avoiding the use of scissors as frequently as in the past. The high cut rate (up to 5000 cpm), strong aspiration and excellent IOP control of the CONSTELLATION® system allows us to shave the vitreous base, with negligible traction to the surrounding tissues and retina.

  In the 25+™ vitrectomy probe designs, the tip has been redesigned to place the port closer to the distal end of the probe (Figure 5), allowing vitreous shaving closer to the retina. The port size has also been enlarged to increase aspiration rate, and the shaft has been stiffened to reduce flexure and improve control. These enhancements increase efficiency and safety, especially in diabetic proliferative vitreoretinopathy.

  Contrary to the conventional wisdom that small-gauge instruments lengthen procedure time, I find that I am often able to use this technology to save time compared to older techniques. That, to me, is a compelling argument to make the switch to MIVS. Many cases that previously would have required bimanual surgery, with a spatula in one hand and a forceps in the other, can now be done with a single instrument for shaving of epiretinal membranes.

**Handheld Instrument Options and Preferences**

A very important aspect of bringing MIVS to our more complicated cases is the availability of a wider array of specialized tools. A battery of new instruments — some recently introduced, others forthcoming in 2011 — will continue to augment the capabilities of retinal surgeons who have adopted small-gauge surgery.

In addition to scissors and forceps, for which we already have numerous options, specialized pics and spatulas are being embraced. A new illuminated pic allows bimanual dissection in those cases where a cutter is not advisable or when it is too dangerous to remove the membrane.

I have also found great utility in a new GRIESHABER®

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Figure 5. In the 25+™ vitrectomy probe (right), the port is closer to the distal end of the probe. The port size also has been enlarged.

Figure 6. The GRIESHABER® Backflush accessory attaches to the tubing system, allowing active aspiration to create greater shearing forces.

Routine use of valved cannulas eliminates the need for sclerotomy plugs. I have used valved cannulas for more than 6 years now, and am thoroughly convinced this is the way we in the surgical community simply have to go.
Backflush accessory (Figure 6) that attaches to the tubing system, allowing active aspiration to create the greater shearing forces needed for vitreous detachment or to elevate a membrane prior to peeling so that it becomes more accessible for manipulation.

These are but a few of the new specialized devices that are giving surgeons greater sophistication. The GRIESHABER® DSP product line (Figure 7) offers a wide array of instrument options to suit each surgeon’s preferences. My first-line choice is most often the RENAISSANCE® handle (Figure 7c), which I find very controllable and handy.

I like to use disposable tips (Figure 7d) on handheld instruments because it gives me assurance that the instrument quality and precision is 100% for each case. Disposable instruments offer surgeons peace of mind in knowing that their instruments are always safe and sterile. Results can be more predictable as well, since every patient receives the same protocol. In essence, it takes surgical device variability out of the equation.

Although I do maintain a selection of reusable instruments, I favor disposables because I find their quality and readiness for use to be far superior to reusables. This is particularly useful in multi-surgeon practices in which individual surgeons have different gauge and device preferences.

Eliminating the need to resterilize an instrument avoids both delay (an important consideration for a busy surgical practice) and any concerns about cross-contamination or inadequate sterilization. Maintaining an inventory of disposable instruments may at first appear to require a higher level of investment in your practice. However, if one considers the costs of cleaning, sterilizing and repairing reusable instruments, plus always having a backup at the ready in case of emergency as well as the more intangible costs of time lost addressing these tasks, one will likely find that the differences are negligible.

For most conventional cases, such as internal limiting membrane (ILM) peeling in a macular pucker/hole, I favor the GRIESHABER® ILM Forceps (Figure 7b) because of its excellent gripping platform and ability to maintain control of the membrane very well. In cases of more advanced proliferative vitreoretinopathy with strong, fibrotic membranes that are more adherent to the retina, my favor goes to the MAXGrip™ Forceps (Figure 7a), which also provides excellent grip and prevents slippage of the membrane out of the teeth of the instrument.

The Future is Now

I firmly believe that the future is smaller and smaller gauge surgeries. The obvious patient benefits are motivating surgeons and industry to find solutions to even the most challenging cases, without compromising on the quality of the surgical outcome or adding to the duration of the procedure.

The future of vitreoretinal surgery is actually the very near future, because much of what we need is available already. The biggest step forward during my surgical career has been the widespread use of small-gauge instruments, now being used in conjunction with equipment that allows a closed perioperative system: valved cannulas and vitrectomy systems that include precise IOP control that is highly responsive to intraoperative changes. Greater control allows a safer surgical environment, reduces iatrogenic damage and improves outcomes.

Any surgery is an invasive process, and our goal is to conduct our intervention with little to no clinically relevant disruption to the eye.

Retinal surgery is no longer the traumatic event it once was for most patients. For the majority of our surgical cases, the future is brighter than ever.

Dr. Claes practices at Sint-Augustinus Hospital in Antwerp, Belgium. He is a consultant to Alcon.