

The MIVS 27+® Product Portfolio

27+® TOTAL PLUS® Paks



8065752062	27+® 7500 cpm TOTAL PLUS® Pak
8065752059	27+® 7500 cpm Combined Procedure Pak, 0.9 mm
8065751700	27+® 7500 cpm Vitrectomy Probe
8065752173	27+® Infusion Cannula in Priming Tray
8065752125	27+® Advanced Infusion Cannula in Priming Tray
8065751697	27+® EDGEPLUS® Entry System (3 count)
8065751701	27+® Straight Endoilluminator

27+® Laser Probes



8065751709	27+® Flexible Tip Laser Probe (RFID)
8065751708	27+® Flexible Tip Laser Probe (non-RFID)

27+® GRIESHABER® DSP Instruments



8065149529	27+® Soft Tip, 0.8 mm
337.87	27+® Advanced Backflush, DSP – Blunt
337.88	27+® Advanced Backflush, DSP – Soft Tip
711.13	27+® GRIESHABER REVOLUTION® DSP MAXGRIP® Forceps
711.43	27+® GRIESHABER REVOLUTION® DSP End-grasping Forceps
711.44	27+® GRIESHABER REVOLUTION® DSP ILM Forceps
711.53	27+® GRIESHABER REVOLUTION® DSP Straight Scissors
727.13	27+® Advanced DSP Tip, MAXGRIP® Forceps
727.43	27+® Advanced DSP Tip, End-grasping Forceps
727.44	27+® Advanced DSP Tip, ILM Forceps
727.53	27+® Advanced DSP Tip, Straight Scissors
339.31	27+® Diathermy, DSP

IMPORTANT SAFETY INFORMATION

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.

The ULTRAVIT® Vitrectomy Probe is indicated for vitreous cutting and aspiration, membrane cutting and aspiration, dissection of tissue and lens removal. The valved entry system is indicated for scleral incision, canulae for posterior instrument access and venting of valved canulae. The infusion cannula is indicated for posterior segment infusion of liquid or gas.

WARNINGS AND PRECAUTIONS:

- The infusion cannula is contraindicated for use of oil infusion.
- 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: Please refer to the CONSTELLATION® Vision System Operators Manual for a complete listing of indications, warnings and precautions.

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.

The PUREPOINT® Laser is indicated for use in photocoagulation of both anterior and posterior segments of the eye including:

- Retinal photocoagulation, panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroid including: Proliferative and nonproliferative retinopathy (including diabetic); choroidal neovascularization secondary to age-related macular degeneration; retinal tears and detachments; macular edema, retinopathy of prematurity; choroidal neovascularization; leaking microaneurysms.
- Iridotomy/Iridectomy for treatment of chronic/primary open angle glaucoma, acute angle closure glaucoma and refractory glaucoma.
- Trabeculoplasty for treatment of chronic/primary open angle glaucoma and refractory glaucoma.
- And other laser treatments including: internal sclerostomy; lattice degeneration; central and branch retinal vein occlusion; suturelysis; vascular and pigment skin lesions.

The FlexTip® laser probe is intended to be used with ALCON® 532nm laser systems.

CONTRAINDICATIONS:

- Patients with a condition that prevents visualization of target tissue (cloudy cornea, or extreme haze of the aqueous humor of the anterior chamber of vitreous humor) are poor candidates for LIO delivered laser treatments.
- The infusion cannula is contraindicated for use of oil infusion.

COMPLICATIONS: Corneal burns, inflammation, loss of best-corrected visual acuity, loss of visual field and transient elevations in intraocular pressure can occur as a result of ophthalmic laser treatment. Unintentional retinal burns can occur if excessive treatment beam power or duration is used.

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 post operative hypotony.
- Back scattered radiation is of low intensity and is not harmful when viewed through a protective filter. All personnel in the treatment room must wear protective eyewear, OD4 or above at 532nm, when the system is in Standby/Ready mode as well as during treatment. The doctor protection filter is an OD greater than 4 at 532nm.

ATTENTION: Please refer to the CONSTELLATION® Vision System Operators Manual for a complete listing of indications, warnings, and precautions.

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.

*Trademarks are property of their respective owners.

GRIESHABER® DSP INSTRUMENTATION

INDICATIONS FOR USE: GRIESHABER® 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.

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.

ILLUMINATION

CAUTION: This document is not intended to substitute for the necessity of reading and understanding the light source Operator's Manual.

INDICATIONS AND USAGE: Fiber Optic Instruments with ENGAUGE® Radio Frequency Identification Device (RFID) for use with the CONSTELLATION® System. These instruments can be used on the ACCURUS® System or ACCURUS® High Brightness Illuminator (HBI) using the RFID Adapter Model Number 8065751140.

WARNINGS AND PRECAUTIONS:

- Minimize the light intensity and duration of exposure to the retina to reduce risk of retinal photic injury.
- Avoid operation of a fiber in air on consoles capable of illumination levels and settings higher than 10 lumens. This may result in fiber probe deformation and/or high surface temperatures that may cause patient injury.

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

1. Avery R. Single surgeon experience with an enhanced 25+ vitrectomy probe/entry system. ASRS Poster, 2009.
 2. Data on File: DHF 430 Verification Report 2,080.8 Revision 02.
 3. Dugel P, Abulon D, Dimalanta R. Tissue Attraction Laboratory Comparison of 7500 CPM Dual-Pneumatic Vitrectomy Probes. ARVO Poster 2014.



a Novartis company



See where smaller can take you

Discover greater access to the smallest of spaces with the MIVS 27+® portfolio. (compared with larger gauge instruments)

WITH ULTRAVIT 7500



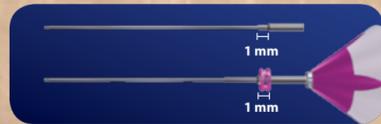
a Novartis company



Go to Smaller Gauge of 27+® With Confidence

The MIVS 27+® portfolio from Alcon delivers unmatched advantages for improved small-gauge performance compared with larger gauge instruments:

- Improved access to small tissue planes³
- Multifunctional tool efficiency with 7500 cpm ULTRAVIT® 27+® dual pneumatic probe³
- Stiffness experience similar to 25+® instrumentation. This was demonstrated in separate laboratory measurements of the stiffness of 25-gauge, 25+® and 27+®^{1,2}

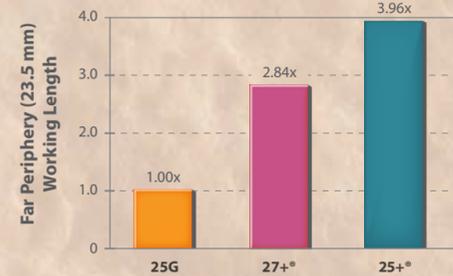


1 mm stepped stiffening sleeve with full 27 mm working length

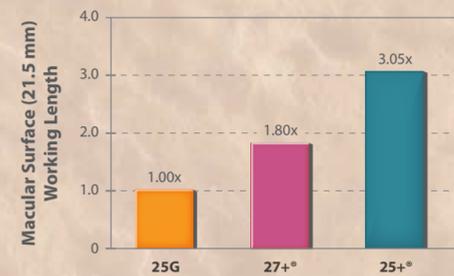


27+® tip size compared to 25+®

27+® Vitrectomy Probe Stiffness^{1,2} – Far Periphery



27+® Vitrectomy Probe Stiffness^{1,2} – Macular Surface

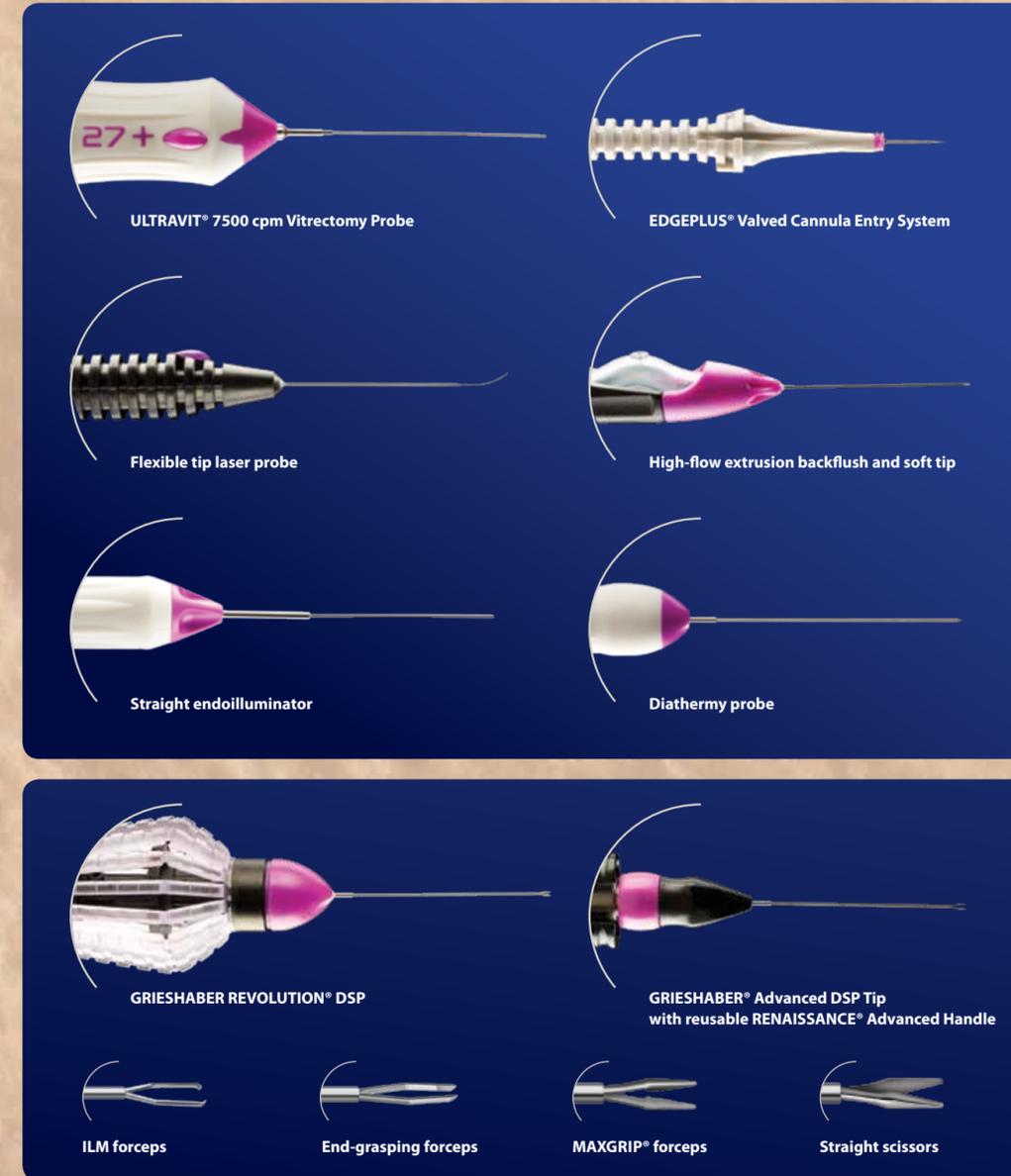


27+® instruments have stiffness that is a marked improvement over 25G probes. This was demonstrated in separate laboratory measurements of the stiffness of 25-gauge, 25+® and 27+®^{1,2}

A Pathway to Go Smaller

Featuring the same consistency and quality you expect from Alcon, the MIVS 27+® family of advanced instrumentation works together seamlessly for a unified 27+® procedure.

WITH
ULTRAVIT®
7500



Multiple 27+® GRIESHABER® instruments deliver precision and control.

*ULTRAVIT® 7500 Vitrectomy Probe

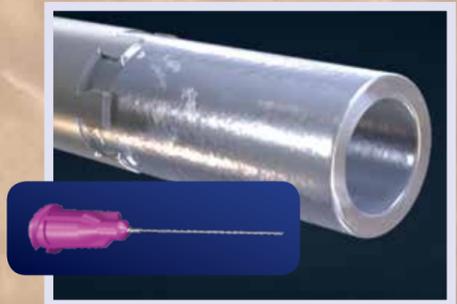
Improved Access and Efficiency Compared with Larger Gauges

With uncompromising accessibility to the smallest of spaces, Alcon's MIVS platform enables a wide range of benefits:

- Greater access to small tissue planes
- Can improve efficiency through fewer instrument exchanges with valved cannulas
- Dual pneumatic 27+® ULTRAVIT® technology provides efficient fluidics for any vitreoretinal pathology
- Smaller instrumentation, such as the 27+® portfolio, may allow for increased utility in difficult pathologies³
- Enhanced fluidic control of the ULTRAVIT® 27+® Dual Pneumatic Probe may be used for dissecting dense, fibrotic membranes or lens material³



27+® instruments offer better access to the retina for improved surgical capabilities, compared with larger gauge instruments³



27+® extrusion accessories feature a high flow design for maximum 27+® aspiration rates.

"With the MIVS 27+® portfolio, I can increase my case efficiency through improved access and dissection precision. Mobile tissue remains stationary, and the probe works as a multifunctional tool, reducing instrument exchanges."

— Pravin Dugel, MD^{*}
Phoenix, Arizona

*Pravin Dugel, MD, is a paid consultant for Alcon.