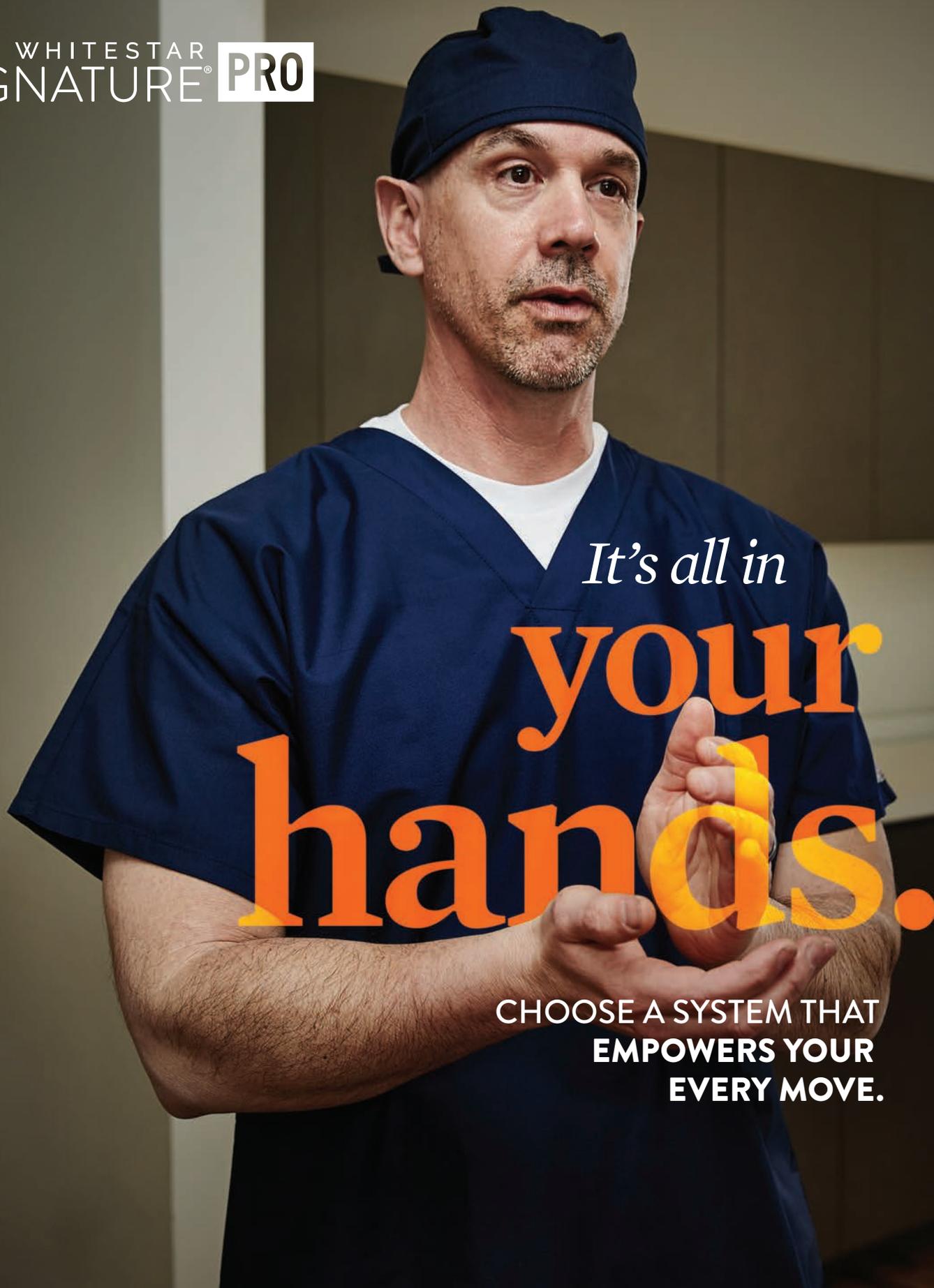


WHITESTAR  
SIGNATURE® PRO



*It's all in*  
**your  
hands.**

**CHOOSE A SYSTEM THAT  
EMPOWERS YOUR  
EVERY MOVE.**

## TECHNIQUE IS MORE THAN THE MOTIONS.

Purposefully engineered for exceptional versatility and high-quality performance, the **WHITESTAR SIGNATURE® PRO** Phacoemulsification System gives you the clinical flexibility, confidence and control to free your focus for what matters most in each procedure.



### OUTSTANDING PERFORMANCE

- Proactive IOP management with automatic occlusion sensing
- On-demand fluidics with peristaltic, venturi or combination pump capabilities
- Ultrasound efficiency from the **ELLIPS® FX** Handpiece



### SURGICAL SUITE OPTIMIZATION

- State-of-the-art analytics for empowered surgical suite management
- Versatile, surgeon-driven experience

#### INDICATIONS

The **WHITESTAR SIGNATURE® PRO** System is a modular ophthalmic microsurgical system that facilitates anterior segment (cataract) surgery. The modular design allows the users to configure the system to meet their surgical requirements. *See Important Safety Information continued on page 8.*

*The way you work*

# matters.

Every surgeon is  
**different.**

**Phaco Your Way.**

Ready-made to respond to adverse pressure changes during surgery, the **WHITESTAR SIGNATURE® PRO** System is a stable and efficient solution whether you use peristaltic, venturi or a bit of both.

“With the **WHITESTAR SIGNATURE® PRO** System, I get the dual-pump technology advantage, the advantage of changing my fluidics to meet the patient’s needs, and the knowledge that I can take on events inside an eye with the security that I’m dealing with a technology that’s giving me an advantage, which translates to real clinical results.”

**ERIC D. DONNENFELD, MD**  
Long Island, New York



**TAKE COMFORT IN STABILITY**

With automatic occlusion sensing, the **WHITESTAR SIGNATURE® PRO** System proactively adjusts to maintain intraocular pressure (IOP), freeing you to concentrate on the details of each procedure.

**PROTECTS THE PATIENT’S EYE BY WORKING BEHIND THE SCENES TO MAINTAIN IOP THROUGHOUT THE PROCEDURE:**

- Continuously monitors vacuum levels
- Anticipates pressure changes
- Fast, proactive response to occlusion breaks



**HAVE IT YOUR WAY**

Choose the flow that fits each step, case, preference and patient. With on-demand fluidics, you have freedom of choice throughout the procedure — whatever your technique may be.

- Peristaltic for holdability and intraoperative control
- Venturi for followability and improved efficiency<sup>2</sup>
- Switch between pumps as you choose, at the press of the footpedal



**FOSTER EFFICIENCY THROUGH CONTROL**

Work the way you want. The **ELLIPS® FX** Handpiece smoothly and efficiently cuts while protecting the eye and giving you total control.

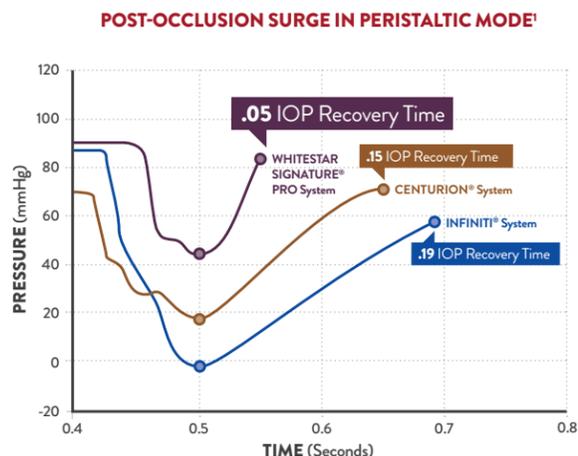
- Continuous, elliptical ultrasound for both power and followability
- Reduced heat generated at the incision<sup>3</sup>
- Less corneal edema<sup>4</sup>
- Lower endothelial cell loss<sup>4</sup>

**51%** LESS CHANGE IN IOP than the INFINITI® Vision System\*

**74%** FASTER IOP RECOVERY than the INFINITI® Vision System\*\*

**12%** LESS CHANGE IN IOP than the CENTURION® System\*

**67%** FASTER IOP RECOVERY than the CENTURION® System\*\*

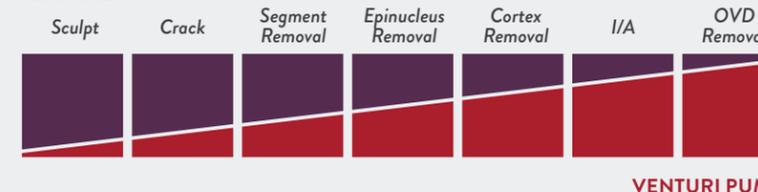


**WHITESTAR SIGNATURE® PRO** System: Aspiration 30 ccm, Vacuum 400 mmHg, Pump Ramp 100%, Bottle Height 90 cm, CASE Vacuum 200 mmHg, OPO73.

**CENTURION®** System: Active FMS, Aspiration 30 ccm, Vacuum 400 mmHg, IOP Target 65 mmHg.

**INFINITI®** System: INTREPID® Plus Fluidics Management System, Aspiration 30 ccm, Vacuum 400 mmHg, Bottle Height 90 cm.

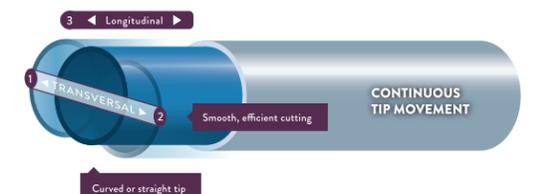
**PERISTALTIC PUMP**



Peristaltic can be optimal for sculpt, crack and segment control while venturi is well suited for I/A.

**WARNINGS**

When using peristaltic, make sure the balanced salt solution bottle is at or above the eye level of the patient. See **Important Safety Information continued on page 8.**



In both blocked and unblocked conditions, elliptical energy management maintains significantly cooler temperatures than the competitor handpiece.<sup>4</sup>

# More

*than just the motions.*

*A system to fit your priorities.*

The **WHITESTAR SIGNATURE® PRO** System complements your process in and out of the OR. With state-of-the-art analytics and a simplified user experience, it delivers performance insights and customizability to empower the way you phaco.

\*Based on publically available sources on the Stellaris® System, INFINITI® System and CENTURION® System in the U.S. as of April 2016.



## ANALYZE TO OPTIMIZE

Empower your surgical suite management with the **Cataract Analysis and Settings Application (CASA)**, the first\* mobile analytics tool for phaco. By providing practice-eye-level data, it empowers you to optimize your surgical suite with every procedure.

- Wirelessly connect to one or multiple systems
- Get a customized, strategic view of your practice
- Access easy-to-interpret performance charts
- Empower surgeons, technicians and administrators

*Available in the Apple App Store*

Johnson & Johnson Vision does not provide or sell iPad devices with the CASA application, phaco systems, LCS platforms or their accessories. CASA is not currently available for Android devices.



Easily access **WHITESTAR SIGNATURE® PRO** System data from iPad devices.



## PERSONALIZE EVERY PROCEDURE

Choose a system that can phaco the way you do. With a customizable, modular design, the **WHITESTAR SIGNATURE® PRO** System offers comfort and control for a versatile, surgeon-driven experience.

- Perform phaco only or use after laser softening and segmentation
- Choose accessories that complement your technique, from remotes to vitrectors
- Work with your preferred phaco tip, straight, curved or bent
- Phaco intuitively with a simplified graphical user interface (GUI)
- Tailor your OR to your unique needs with our wide portfolio of cataract innovations



## PERFORMANCE-SPECIFIC PLAYBACK

With the **High-Definition Surgical Media Center (HD-SMC)**, you can easily capture high-definition videos of your procedures, giving you the ability to learn from each case and inform your technique.



*Let's talk.*

Schedule a demo with your phaco specialist today.

**WHITESTAR SIGNATURE® PRO**

## IMPORTANT SAFETY INFORMATION FOR THE WHITESTAR SIGNATURE® PRO SYSTEM

Rx Only

**WARNINGS:** All personnel who might operate this equipment must read and understand the instructions in this manual before they use the system. Failure to do so might result in the improper operation of the system. Only a trained, licensed physician can use this device. Do not modify the WHITESTAR SIGNATURE® PRO System. The system comes equipped with a 3-prong power plug, which you must plug into an outlet with a ground receptacle. If the plug does not fit the outlet, contact an electrician. DO NOT modify or remove the ground pin. DO NOT attempt to use the system if the system fails to perform properly as stated in this manual. DO NOT use the system in the presence of any of the following as a fire can result: flammable anesthetics, other flammable gases, flammable fluids, flammable objects and oxidizing agents. Make sure the patient does not have a cardiac pacemaker as this unit might interfere with any cardiac pacemaker; therefore obtain qualified advice prior to such use. The patient must not come into contact with grounded metal parts or metal parts that have appreciable capacitance to ground. AMO recommends the use of an antistatic mat for this purpose. Use proper handling and disposal methods for biohazards when you dispose of the fluidics pack, Mayo tray drape, and monitor drape. Make sure that the fluidics pack drain bag does not over-fill. The maximum capacity of the bag is 750 cc. Use caution when you extend, retract, or swivel the Mayo tray articulating arm. Stay clear of the hinged hardware. Do not modify the pole height or manually force the pole height because this could cause incorrect indication of bottle height and patient injury. Place monitoring electrodes or other types of equipment as far from those of the WHITESTAR SIGNATURE® PRO System as possible. AMO recommends high current limiting devices for the protection of such systems. Do not use needle-monitoring electrodes. Keep the diathermy cord away from the patient and other handpieces or leads (for example, monitoring electrodes). Keep unused ACTIVE ELECTRODES away from the patient. The output power selected must be as low as possible for the intended purpose. This unit complies with all Electromagnetic Interference (EMI) standards and requirements. It is possible that interference provided by the operation of the HIGH FREQUENCY (HF) SURGICAL EQUIPMENT can adversely influence the operation of other electronic equipment. Do not have skin-to-skin contact on the patient. For example, between the arms and the torso. Insert dry gauze to avoid contact, as appropriate. Note: The unit does not contain any neutral electrode. Note: The diathermy output is bipolar. Note: AMO recommends that you check the condition of all interconnecting and handpiece cables on a regular basis. Risk of burns and fire. Do not use the system near conductive materials such as metal bed parts, inner spring mattresses, or similar items. Replace electrode cables on evidence of deterioration. Hazardous electrical output. This equipment is for use only by qualified personnel. Disconnect the power before you service the equipment. Remove the power cord from the power outlet when the equipment is not in use. Do not obstruct the power outlet so you can readily remove the power cord. Not recommended for use in condensing environments. If exposed to a condensing environment, allow the system to equilibrate to typical operating room conditions prior to use. You do not need to use a NEUTRAL ELECTRODE with this HIGH FREQUENCY (HF) SURGICAL EQUIPMENT. Failure of the HIGH FREQUENCY (HF) SURGICAL EQUIPMENT could result in an unintended increase of output power. DO NOT try to replace the batteries for the wireless remote control, the Advanced Control Pedal. Call your AMO technical service representative to replace the batteries. DO NOT try to replace the wireless remote control batteries. Call your AMO technical service representative to replace the batteries. Sterility assurance is the responsibility of the user. You must sterilize all non-sterile accessories prior to use. Prior to using any invasive portions of the handpiece assembly, examine under the microscope for any obvious damage, oxidation, or the presence of foreign material. You must note any questionable characteristics; use a backup handpiece for surgery. Use of contaminated or damaged system accessories can cause patient injury. Do not have the handpiece tip in the eye of the patient when you prime and tune the handpiece. Do not use non-AMO approved products with the WHITESTAR SIGNATURE® PRO System, as this can affect overall system performance. AMO cannot be responsible for system surgical performance if you use these products in surgery. This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the WHITESTAR SIGNATURE® PRO System or shielding the location. WHITESTAR SIGNATURE® PRO System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. Portable and mobile RF communications equipment can affect WHITESTAR SIGNATURE® PRO System. The use of accessories, transducers and cables other than those specified by AMO, may result in increased EMISSIONS or decreased IMMUNITY of the WHITESTAR SIGNATURE® PRO System. The WHITESTAR SIGNATURE® PRO System should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the WHITESTAR SIGNATURE® PRO System should be observed to verify normal operation in the configuration in which it will be used. Do not replace the Advanced Linear Pedal (ALP) battery when the pedal is attached to a power source. This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the WHITESTAR SIGNATURE® PRO System or shielding the location. WHITESTAR SIGNATURE® PRO System may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements. If you do not properly prime the I/A tubing, errors can occur. **SAFETY PRECAUTIONS:** Read the following safety precautions and warnings carefully before you use the system in surgery. Do not use extension cords with your system. Do not overload your electrical receptacle (outlet). If there is damage to the cord or the plug, do not use the instrument. A damaged cable can cause an electric shock to the user or a fire hazard to the system. Call AMO customer service to order a new cord. The instrument has ventilation openings at the rear of the console to allow ambient air intake and the release of heat generated during operation. Do not block the openings; as heat build-up can cause system failures, which can result in a fire hazard. Do not try to move the system cart on deep pile carpets or over objects on the floor such as cables and power cords. Take care not to trip over power and foot pedal cords. Do not try to lift the system console. Do not place the instrument on uneven or sloped surfaces. Only use disposables, accessories, or other surgical instruments designed for this system. For optimum performance of the system and safety, use only parts recommended by AMO. Do not operate the system in a condensing environment. Take care to protect the instrument from fluid sprays or fluid buildup. To protect the patient from contaminated fluids or handpieces, use only sterile tubing packs, sterile irrigation fluid, and sterile handpieces. Wrap the excess power cord neatly around the cord wrap on the back of the console. Use caution when you use handpieces with sharp edges or pointed tips. Always replace the tubing pack and the balanced salt solution bottle between cases. **CAUTIONS:** Never attempt to straighten a bent needle. This might produce a broken tip when you apply ultrasound. Do not activate the phaco handpiece and vitrectomy cutter with the tip in the air. Exposure of the tip to air drastically reduces the useful life of the handpiece. If you introduce power to the phaco handpiece or vitrectomy cutter, the tip must be in a test chamber filled with balanced salt solution, in a container of balanced salt solution, or in the patient's eye. If you do not hear a tone when you press the foot pedal and volume adjustment is unsuccessful, the mode is not functioning properly. **ATTENTION:** Reference the Directions for Use for a complete listing of indications, warnings, and precautions.

### WARNINGS FOR CASA

The connection to a WHITESTAR SIGNATURE® PRO System only provides a means to retrieve files from the system and does not provide the means to send files back to the system. It is important to note there is no patient data on the WHITESTAR SIGNATURE® PRO System, and no patient data is imported to the CASA application.

Johnson & Johnson Vision does not provide or sell iPad devices with the CASA application, phaco systems, LCS platforms or their accessories. CASA is not currently available for Android devices.

1. Data on File. Abbott Medical Optics Inc. 2015.
2. Cahoon JM, et al. Comparison of venturi and peristaltic vacuum in phacoemulsification. *JCRS* 2015; 41:428-432.
3. Floyd M, Valentine J, et al. (2006) Effect of incisional friction and ophthalmic viscosurgical devices on the heat generation of ultrasound during cataract surgery. *JCRS*, 32, 1222-1226.
4. Assil K et al. Transverse vs torsional ultrasound: prospective randomized contralaterally controlled study comparing two phacoemulsification-system handpieces. *Clinical Ophthalmology*. 2015;9 (1405-1411).
5. Schmutz JS, Olson RJ. Thermal comparison of Infiniti OZil and Signature Ellips phacoemulsification systems. *Am J Ophthalmol*. 2010 May; 149:5(762-7).

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