INDICATIONS AND IMPORTANT SAFETY INFORMATION for the WHITESTAR SIGNATURE® PRO System

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

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.

WARNINGS

1. 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.
2. Do not modify the **WHITESTAR SIGNATURE® PRO** System.
3. 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.
4. When using peristaltic, make sure that the balanced salt solution bottle is at or above the eye level of the patient.
5. The surgical staff must monitor the balanced salt solution bottle height and fluid level at all times. A low bottle or empty bottle affects the fluid balance and the intraocular pressure (IOP) while aspirating. Low bottle height or low or empty bottle fluid level can result in: • Inadvertent chamber shallowing or collapse • Aspiration or abrasion of the iris or other tissue • An ultrasonic wound heating commonly called wound burn (extreme case).
6. DO NOT attempt to use the system if the system fails to perform properly as stated in this manual.
7. 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 • oxidizing agents
8. Make sure that 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.
9. The patient must not come into contact with grounded metal parts or metal parts that have appreciable capacitance to ground. Johnson & Johnson Surgical Vision, Inc. (JJSV) recommends the use of an antistatic mat for this purpose.
10. Use proper handling and disposal methods for biohazards when you dispose of the fluidics pack, Mayo tray drape, and monitor drape.
11. Make sure that the fluidics pack drain bag does not over-fill. The maximum capacity of the bag is 750 cc.
12. Use caution when you extend, retract, or swivel the Mayo tray articulating arm. Stay clear of the hinged hardware.
13. Do not modify the pole height or manually force the pole height because this could cause incorrect indication of bottle height and patient injury.
14. Place monitoring electrodes or other types of equipment as far from those of the **WHITESTAR SIGNATURE® PRO** System as possible. JJSV recommends high current limiting devices for the protection of such systems. Do not use needle monitoring electrodes.

15. 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.
16. The output power selected must be as low as possible for the intended purpose.
17. 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.
18. 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: JJSV recommends that you check the condition of all interconnecting and handpiece cables on a regular basis.
19. 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.
20. Hazardous electrical output. This equipment is for use only by qualified personnel.
21. Disconnect the power before you service the equipment.
22. Remove the power cord from the power outlet when the equipment is not in use.
23. Do not obstruct the power outlet so you can readily remove the power cord.
24. 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.
25. You do not need to use a NEUTRAL ELECTRODE with this HIGH FREQUENCY (HF) SURGICAL EQUIPMENT.
26. Failure of the HIGH FREQUENCY (HF) SURGICAL EQUIPMENT could result in an unintended increase of output power.
27. DO NOT try to replace the batteries for the wireless remote control, the Advanced Control Pedal. Call your JJSV technical service representative to replace the batteries.
28. DO NOT try to replace the wireless remote control batteries. Call your JJSV technical service representative to replace the batteries.
29. Sterility assurance is the responsibility of the user. You must sterilize all non-sterile accessories prior to use.
30. 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.
31. Do not have the handpiece tip in the eye of the patient when you prime and tune the handpiece.
32. Do not use non-JJSV approved products with the **WHITESTAR SIGNATURE® PRO** System, as this can affect overall system performance. JJSV cannot be responsible for system surgical performance if you use these products in surgery.
33. 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.
34. **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.
35. Portable and mobile RF communications equipment can affect **WHITESTAR SIGNATURE® PRO** System.
36. The use of accessories, transducers and cables other than those specified by JJSV, may result in increased EMISSIONS or decreased IMMUNITY of the **WHITESTAR SIGNATURE® PRO** System.
37. 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.

38. Do not replace the Advanced Linear Pedal (ALP) battery when the pedal is attached to a power source.
39. 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.
40. **WHITESTAR SIGNATURE® PRO** System may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
41. 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.

1. Do not use extension cords with your system.
2. Do not overload your electrical receptacle (outlet).
3. 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 JJSV customer service to order a new cord.
4. 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.
5. Do not try to move the system cart on deep pile carpets or over objects on the floor such as cables and power cords.
6. Take care not to trip over power and foot pedal cords.
7. Do not try to lift the system console.
8. Do not place the instrument on uneven or sloped surfaces.
9. 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 JJSV.
10. Do not operate the system in a condensing environment. Take care to protect the instrument from fluid sprays or fluid buildup.
11. To protect the patient from contaminated fluids or handpieces, use only: • sterile tubing packs • sterile irrigation fluid • sterile handpieces
12. Wrap the excess power cord neatly around the cord wrap on the back of the console.
13. Use caution when you use handpieces with sharp edges or pointed tips.
14. Always replace the tubing pack and the balanced salt solution bottle between cases.

CAUTIONS

1. Never attempt to straighten a bent needle. This might produce a broken tip when you apply ultrasound.
2. 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.
3. If you do not hear a tone when you press the foot pedal and volume adjustment is unsuccessful, the mode is not functioning properly.

WARNINGS FOR CASA:

1. System passwords are set only by JJSV Service personnel. Be sure to keep system passwords in a secure location.
2. 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.
3. The CASA application will display a notification when the total storage capacity of the iPad device is less than 2 GB.
4. 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.
5. Care must be taken when removing data from the iPad device. If the data is removed without having exported it in an email, there will be no way to import the data back into the iPad device.

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