Viseon, Inc.
MaxView® System – Posterior Set
Safety Information

Indications for Use

The Viseon MaxView System – Posterior Set is indicated to provide minimally invasive access, visualization, illumination, and magnification of the surgical area of the spine.

Contraindications

The Viseon MaxView System – Posterior Set has no known contraindications intrinsic to the device. There are no other known risks associated with the use of the device outside of the standard and expected risks of surgery.

Warnings

	The Tube and Imager are supplied sterile for single-use only and have not been tested to be cleaned or sterilized for multiple uses. If the Tube and Imager are used more than once, the device may not be sterile and could cause a serious infection and may not function as intended. Do not re-sterilize the device.
	Inspect the device package before use. Do not use the device if the sterile packaging has been damaged.
	The Viseon MaxView System – Posterior Set has not been evaluated for compatibility with the use of neurological or spine devices operated in conjunction with the device.
	Only use the Tube and Imager packaged together. Do not interchange the Tube or Imager between different device models as the image quality may be affected. Do not use the Imager with a third-party tubular retractor.
	The use of electrosurgery may cause signal interference with the video image displayed. This effect can be minimized by adhering to the following guidelines: • Avoid overlapping the electrosurgical instrument and/or return electrode cables with the Imager cable. • Avoid overlapping the Imager cable with the articulating arm. • Avoid activating the electrosurgical instrument when in direct contact with the Tube. • Use the lowest power setting necessary and use low voltage electrosurgery modes when possible. Refer to the electrosurgical unit (ESU) instructions for use to determine mode voltages.
	Do not place the Imager in direct contact with patient skin while it is connected to the ICB.
	Avoid shining the LED light source directly in the eyes of user or staff as it could temporarily impair vision and/or cause harm.
	This product is not suitable for use in an oxygen enriched environment or in the presence of flammable anesthetics.

	Do not allow the device to become submerged, partially or wholly, in fluids as doing so may lead to electrical shock.
	The Imager light source can generate significant amounts of heat at the light emitting surfaces and the surrounding enclosure (labeled with the Hot Surface symbol), especially when operated at high Light Intensity settings for prolonged time. Do not place the Imager in direct contact with the patient as doing so can cause burns. Do not touch the light emitting surfaces.

Precautions

	Surgeons should be trained and experienced in performing minimally invasive tubular spine surgery before using this device. Careful pre-operative and operative planning, including training on the use of this device, are important considerations in the successful utilization of the device.
	All components of the device should be thoroughly inspected prior to surgery for possible damage. If you suspect a component to be faulty or damaged, do not use the device.
	Care should be taken when handling the device. It should not be dropped or bent at a sharp angle. Use of excessive force can damage the device leading to malfunction or exposure to electrical hazards.
	Proper, secure component connections must be made to assure proper functioning of the device.
	Avoid spraying, splashing, or dripping fluids directly on the Imager component of the device as doing so may lead to fouling or fogging of the image.
	Refer to the Operator's Manual (VLBL08-002) for instructions on the operation of the Viseon Image Control Box.

Potential Adverse Effects

Risks possibly associated with the use of the Viseon MaxView System – Posterior Set are similar to those associated with any surgery to the planned area of device use. Risks include, but are not limited to the following:

- Bleeding
- Nerve damage
- Damage to the surrounding soft tissue
- Infection
- Paralysis