Vesta RF Cannula

INSTRUCTIONS FOR USE

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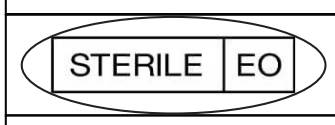
EXPLANATION OF SYMBOLS:

RxOnly	**Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician.		Do not use if package is damaged.
	Sterilized using ethylene oxide	LOT	Lot Number
	Do not re-use		Manufacturer
	Caution: Consult Instructions for Use		Use-By Date
	Keep away from sunlight	QTY	Quantity
REF	Reference Number		Caution
MD	Medical Device		

INDICATIONS FOR USE:

The Vesta RF Cannula, in combination with an RF generator and probe, are intended for use in radiofrequency (RF) heat lesion procedures for relief of pain.

DESCRIPTION:

The Vesta RF Cannula consists of an insulated cannula with an active tip at the distal end. The Vesta RF Cannula device is designed for use with compatible RF generators with rated voltage less than or equal to 280V. The Vesta RF Cannula device is sterilized and intended for single use only.

FEATURES:

1. The Vesta RF Cannula has a rigid cannula with a tip that can be used for insertion into target tissues and is capable of placement via radiography and traditional motor/sensory stimulation protocols.

LESION FORMATION:

The Vesta RF Cannula consists of an insulated cannula with an active tip for use in RF heat lesion procedures for the relief of pain. The active tip transfers RF energy to the target tissue. During the ablation procedure, the RF heat lesion propagates from the active surface of the cannula as dictated by current density distribution.

CUSTOMER SERVICE AND PRODUCT RETURN INFORMATION:
If you have any questions about or problems with the Vesta Cannula contact our technical support personnel.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WARNINGS:

1. Do not use if damage to the device or insulation is noted as tissue damage or electrical leakage could occur which could lead to patient or user injury.
2. Do not use if the package has been opened or damaged.
3. Always fully insert the probe into the cannula. Failure to comply will prevent proper placement of the tip of the probe and may result in patient injury.
4. Always ensure that the correct RF probe and generator are used with the device. The Vesta RF Cannula is rated for use in high frequency lesions up to 280 volts and may only be used with compatible Pain Management Generators with a maximum voltage rating less than or equal to 280 volts. See equipment list below for compatible generators.
5. Do not attach anything (i.e., hemostats, clamps, etc) to the device. This may damage the device or its insulation which could lead to patient or user injury.
6. Do not bend or kink the cannula. This may cause damage to the product and result in reduced functionality or tissue damage during insertion or removal.
7. Do not modify the Vesta RF Cannula. Any modification may compromise the safety and efficiency of the device.
8. Take care when handling as needles can cause injury.
9. Patients with vascular deficiency are at increased risk of thermal injury from dispersive cannula.
10. Patients with frail skin are at increased risk of skin damage from the adhesive on the dispersive pads.
11. Refer to warnings in RF Generator Manual.
12. Federal Law (USA) restricts this device to sale by or on the order of a physician.
13. The entire area of the neutral cannula (grounding pad) should be reliably attached to a suitably prepared and appropriate area of the patient's body during heat ablation for pain management.
14. During the procedure, the patient should not come in contact with metal objects which are earthed or which have an appreciable capacitance to earth (i.e. operating table supports, etc.).
15. The patient leads should be positioned in such a way that contact with the patient or other leads is avoided. Unused active cannula should be temporarily stored in a location that is isolated from the patient.
16. Apparent low output or failure of the Radiofrequency surgical equipment to function correctly at the normal operating settings may indicate faulty application of the neutral cannula (grounding pad) or poor contact with its connections. In this case, the application of the neutral cannula (grounding pad) and its connections should be checked before selecting a higher output power.
17. Failure of the Radiofrequency surgical equipment could result in an unintended increase of output power.
18. Neuromuscular stimulation modes have a risk of producing electrical arcs between RF Cannula and tissue.
19. The Vesta RF Cannula is not for use in the central nervous system.

PRECAUTIONS:

1. The safety of electrosurgery will be greatly enhanced by a thorough knowledge of the medical literature on the subject. Study of specific information on the hazards and complications of the procedure in question is especially recommended.
2. The power applied by the Radiofrequency (RF) generator should be kept to the minimum necessary to achieve the desired clinical effect.
3. If removal of the device is difficult, do not exert additional force. Infuse small amounts of saline and gently remove the cannula. The saline will soften coagulated tissues and allow for cannula removal.
4. The Vesta RF Cannula is a single-use device. It should not be cleaned, re-sterilized, or re-used. Reuse can cause patient injury and/or communication of infectious disease(s) from one patient to another.
5. Contamination of the device may lead to injury, illness or death of the patient.
6. Reprocessing may compromise the integrity of the device and/or lead to device failure.
7. The Vesta RF Cannula has NOT been demonstrated compatible with Magnetic Resonance Imaging (MRI). Use of MRI in conjunction with this device may lead to patient or user injury.
8. Never use electrosurgical devices in the presence of flammable liquids, gases or oxidizing agents. The risk of igniting flammable gases or other materials is inherent in electrosurgery and cannot be eliminated by device design. Precautions must be taken to avoid contact of flammable materials and substances with electrosurgical cannula.
9. The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N2O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away.
10. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of Radiofrequency (RF) surgery. There is a risk of pooling of flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be removed before RF surgical equipment is used. Attention should be called to the danger of ignition of endogenous gases. Some materials, for example cotton and gauze, when saturated with oxygen, may be ignited by sparks produced in normal use of the RF surgical equipment.
11. As necessary, clean the needle tip between placements by rinsing the tip in sterile solution and gently wiping the tip to remove excess tissue. Use caution not to use an abrasive substance that may cause damage to the insulation. Accumulation of excess tissue on the tip may make cannula removal difficult.
12. Safe use of the device requires adequate separation between the thermal lesion and adjacent anatomical structures. Skin-to-skin contact (i.e. arms and body of patient, etc.) should be avoided during the procedure. For example, this can be avoided by insertion of dry gauze.

CONTRAINDICATIONS:

- For patients with cardiac pacemakers, a variety of changes can occur during and after the treatment. In sensing mode the pacemaker may interpret the RF signal as a heartbeat and may fail to pace the heart. Contact the pacemaker company to determine if the pacemaker should be converted to a fixed-rate pacing during the radio frequency procedure. Evaluate the patient's pacing system after the procedure.
- Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the radio frequency lesion generator.
- If the patient has a spinal cord stimulator, contact the manufacturer to determine if the stimulator needs to be in the bipolar stimulation mode or in the OFF position. When Radiofrequency (RF) surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, any monitoring cannula should be placed as far as possible from surgical cannula. In all cases, monitoring systems incorporating RF current limiting devices are recommended. Interference produced by the operation of RF surgical equipment may adversely influence the operation of other electronic equipment.
- The Vesta RF Cannula has NOT been demonstrated compatible with Magnetic Resonance Imaging (MRI). Use of MRI in conjunction with this device may lead to patient or user injury.
- The use of general anesthesia is contraindicated. To allow for patient feedback during the procedure, it should be performed under local anesthesia.
- For surgical procedures where the Radiofrequency (RF) current could flow through parts of the body having a relatively small cross sectional area, the use of bipolar techniques may be undesirable in order to avoid unwanted tissue damage.

EQUIPMENT LIST:

RF Lesion procedures should be performed in a specialized clinical setting equipped with a fluoroscopy unit. The equipment required to perform RF procedures are:

- Vesta RF Cannula
- Pain Management Probes
- Pain Management Generator*
- Pain Management Connector Cables
- Pain Management Dispersive Pads

*** NOTE:** The Vesta RF Cannula is rated for use in RF lesions up to 280 volts and may only be used with compatible Pain Management Generators with a maximum voltage rating less than or equal to 280 volts.

INSTRUCTIONS FOR USE:

Pending completion of all patient preparation, the following procedure is the recommended operation for the device.

1. Inspect product packaging. If sterile barrier or device are in any way compromised, do not use.
2. Under sterile procedure, open package by peeling pouch at location indicated on pouch.
3. Remove protective sheath over cannula.
4. Inspect device prior to use including inspecting the insulation at the juncture of the active tip and insulation. DO NOT USE if the device is damaged.
5 Verify that the RF Generator goes through its self-check per the generator's user manual.
6. Insert the device to desired location under radiography. Perform traditional sensory/motor stimulation protocols to ensure safe placement.
7. Insert the RF probe into the connector lumen of the device. If significant resistance or force is required to insert the probe do not force assembly. Use a repeated push and turn process to attempt to align the probe with the probe lumen. Probe should seat fully and bind with the connector.
8. Ensure that the RF probe remains fully seated in the connector.
9. When ready to apply therapeutic RF energy, verify that the RF generator is running a program appropriate to achieve the desired clinical effect.
10. Start RF power via prescribed therapy.
11. Upon completion of therapy, remove the cannula from the tissue by pulling on the Main Body of the device.
12. Reinsert cannula as needed to achieve desired clinical result.
13. Dispose of device per hospital or clinic protocol for "sharps" and/or "biohazards."