**INSTRUCTIONS FOR USE INCLUDE INFORMATION FOR THE VIVEVE® 2.0 SYSTEM AND TREATMENT TIPS**

**Viveve® 2.0 Treatment Tips**
Instructions for Use

**Symbols/Abbreviations**

| | | | |
|---|---|---|---|
|  | Single Use only |  | Do not re-sterilize |
|  | Follow Instructions for Use |  | Do not use if packaging is damaged |
|  | Reference Number |  | Lot number |
|  | Sterilization by Ethylene Oxide |  | Legal Manufacturer |
|  | Use by |  | Date of Manufacture |
|  | Keep Dry |  | Prescription Only |
|  | Separate Collection |  | No Latex |
|  | Contact Quality Monitoring | | |

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**CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.**
The Viveve 2.0 System Technical User's Manual (TUM) is supplied as a separate document. The (TUM) contains detailed information describing the system components, console set up, and guide to operation, maintenance, trouble shooting, and specifications. Please read the TUM prior to operation of the Viveve 2.0 system (the system).

**Description**
The Viveve 2.0 treatment tips contained in this package are a sterile single use component designed to deliver radiofrequency (RF) energy from the Viveve 2.0 system. The treatment tips can only be used in conjunction with the dedicated Viveve 2.0 system.

The following Instructions for Use (IFU) describe the use of the Viveve 2.0 System. Review instructions in the Viveve 2.0 TUM carefully on how to set up the system, including the warnings and precautions. Read all manuals and instructions completely before using the system or performing any procedures.

**Indications for Use**

The Viveve 2.0 System is indicated for use in the United States for General Surgical procedures for electrocoagulation and hemostasis.

**Contraindications**

The Viveve 2.0 system is contraindicated for use in patients with either an Implantable Pacemaker or an Automatic Implantable Cardioverter/Defibrillator (AICD), or any other implantable electrical device, as they may be adversely affected by radiofrequency (RF) fields or electrical current.

**WARNING: The Viveve System is not indicated for, nor has FDA cleared the system, for vaginal rejuvenation.**

**Potential Treatment Risks/Discomforts**

The following potential risks or discomforts the patient may be experienced during or following treatment:

- Pain or discomfort during procedure related to warmth/heat and/or cold in the designated treated area
- Transient inflammation and/or swelling in the designated treated area
- Transient discharge from treated tissue
- Transient erythema/redness in the designated treated area
- Transient allergic reaction or hypersensitivity in the designated treated area to any component of the device
- Excessive skin tightening
- Damage to organs
- Altered sensation that may be focal or transient, manifested as numbness or tingling in the designated treated area.
- Burning of the Vaginal Mucosa
- Cramping
- Vaginal Spotting
- Change in Vaginal Sensation

Additional spontaneously reported events that are not necessarily related to the treatment include:

- Shock, nausea, giddiness, metallic taste in mouth

**Storage Conditions**

Store in a cool, dry place.

**Warnings**

- Use Viveve 2.0 authorized parts and accessories only.
  - The Viveve 2.0 treatment tip is intended for use only with the dedicated Viveve 2.0 System console.
  - **ONLY** Viveve coupling fluid must be used for each treatment. Failure to use the Viveve coupling fluid could result in patient injury. Do **NOT** use any other gels or lubricants in the treatment area.
  - Ensure the entire area of the return pad is in direct contact with the tissue. Failure to use the Viveve return pad could result in injury and/or patient burns
- Only properly trained personnel should use the system.
- Position the system cable and cords to avoid contact with the patient or other leads. Do not wrap cords around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient and/or system operator.
- Examine all connections to the console and all accessories before using. Improper connection may result in arcs, sparks, accessory malfunction, or unintended surgical effects.
- Do not re-use the treatment tip. It is a single-patient-use item and is not intended for multiple patients. Reuse of the treatment tip can lead to failure and patient injury.
- 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 the treatment tip electrodes and flammable materials and substances, including some forms of anesthetic or skin preparation agents, flammable materials and substances produced by natural processes within body cavities, and flammable materials and substances such as surgical drapes or other materials present in the operative field.

**Treatment Precautions**

- The treatment tip must be in full contact with tissue or skin for safe operation.

- Inspect cables and cords for breaks, cracks, nicks, or other damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or system operator.
- If a treatment tip and/or hand piece appears damaged, do not use.
- If the packaging appears damaged or the sterile barrier is compromised, do not use the treatment tip. Infection may result if the sterile barrier is breached and the tip is contaminated.

**For systems compliant with Contact Quality Monitoring functionality**

- Contact Quality Monitoring (CQM), is integrated into the Viveve 2.0 System as a safety circuit which checks the contact of the Neutral Electrode (Return Pad) with the patient's skin. CQM regulations were developed to prevent patient burns due to inadequate contact of the return electrode across all commercialized radio frequency, and this circuit is now included as a featured functionality in systems manufactured after March 2020. Pad site burns can be due to the decreased contact area at the return electrode site. The Viveve 2.0 System actively monitors this contact as well as the amount of impedance at the patient/pad interface because there is a direct relationship between this impedance and the contact area. If the Viveve 2.0 System detects a dangerously high level of impedance at the patient/pad interface, it will deactivate the generator before an injury can occur. The Viveve 2.0 System fulfills the requirements of the relevant standard, IEC 60601-2-2, whereas the patient's skin must not be heated by more than 6$^{o}$C to be safe for the patient. The Viveve 2.0 System has been validated to ensure compliance with this standard and be safe for use on any patient.

### Viveve 2.0 System and Accessories

| Viveve 2.0 System | Viveve 2.0 System Accessories |
|---|---|
| **Model 1413466-01**<br>• Viveve 2.0 Console, Catalog Number VIVGE02<br>• Viveve 2.0 Handpiece, Catalog Number VIVHP03<br>• Viveve 2.0 Footswitch, Catalog Number VIVFS02<br>• Viveve 2.0 Return Cable, Catalog Number VIVRC02<br>• Viveve 2.0 Treatment Tips:<br>- 5 cm Treatment Tip, Catalog Number VIVTT08 (case of 6)<br>- 8 cm Treatment Tip, Catalog Number VIVTT09 (case of 6) | • Viveve Return Pad, Catalog Number VIVRP01<br>• Viveve Cryogen Canister:<br>• Viveve Cryogen Canister, Catalog Number VIVCC02<br>• Viveve Coupling Fluid, Catalog Number VIVCF01<br>• Viveve 2.0 power cords:<br>- United States, Canada, Mexico, Latin America, Thailand Catalog Number VIVPC01<br>- European Union, Ukraine, Russia, Catalog Number VIVPC02<br>- Chile, Italy, Catalog Number VIVPC03<br>- Australia, New Zealand, Catalog Number VIVPC04<br>- UK, Ireland, Singapore, Hong Kong, Philippines, Malaysia, UAE, Dubai, Lebanon, Catalog Number VIVPC05<br>- Japan, Catalog Number VIVPC06<br>- Brazil, Catalog Number VIVPC07<br>- China, Catalog Number VIVPC08<br>- Argentina, Catalog Number VIVPC09<br>- Korea, Catalog Number VIVPC10<br>- India, Catalog Number VIVPC11<br>- Denmark, Greenland, Catalog Number VIVPC12<br>- Taiwan, Catalog Number VIVPC13 |

**Procedural Instructions**

1. Clean and prepare the treatment area and the surrounding surface with a non-alcohol based cleaner. Remove any jewelry worn near to the treatment area (e.g., piercings, etc.).
2. Confirm that the Viveve 2.0 System, console with cooling module, hand piece, and footswitch is set up properly as described in the Technical User's Manual (TUM).
3. Apply the Viveve return pad electrode onto a clean dry area of the skin that is appropriate for grounding of the current relative to the tissue being treated (e.g., upper outer thigh for treatment in pelvic floor area). Ensure the entire area of the return pad is in contact with the skin.

4. Ensure that the treatment tip is fully connected with the handpiece before using.
5. Coupling fluid is applied to the treatment area and on the treatment tip regularly throughout the treatment to ensure good electrical contact with the treatment surface. Failure to have good electrical contact could affect the treatment outcome.
6. While ensuring that the treatment tip is in good contact with the treatment surface and confirming that the flashing blue light on the handpiece is illuminated, apply the RF energy to the target area by depressing the footswitch.
    a. The energy setting is 180 J.
    b. The energy density is 90 J/cm$^2$.
    c. Each energy application will treat a 1 cm x 2 cm area.
7. Repeat until treatment is complete.
    a. A total of five (5) passes are made in the treatment area.
    b. To ensure complete coverage, overlap the energy application by 50% or 0.5 cm.
    c. Apply additional Viveve coupling fluid during the treatment procedure.
8. After treatment is complete:
    a. The patient and her healthcare professional should have a conversation about when to resume certain activities based on the patient's medical history and tolerability during the procedure.
    b. The Viveve 2.0 treatment tip must be disposed of properly in accordance with the applicable national/local/state environmental laws. Check local regulations for proper disposal of the treatment tip.