

VAPR® II



VAPR® II
GENERATOR &
TC ELECTRODE


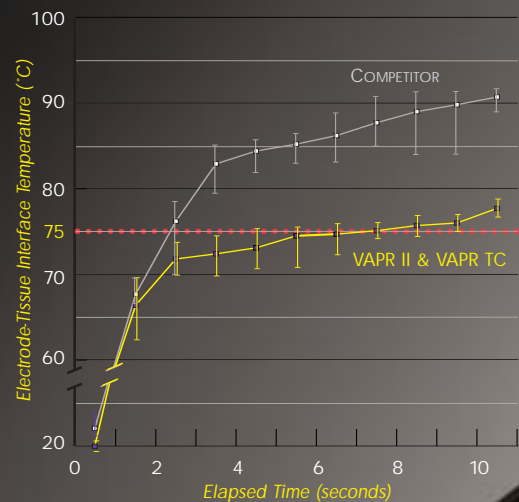


VAPR® II

Mitek
VAPR® II

Only the Mitek VAPR® II Generator and TC Temperature Control Electrode can offer you the assurance of safe, reliable soft-tissue modification with the most accurate temperature measurement in the industry. Set temperature is achieved rapidly – within four seconds – and is constantly monitored via sensors in the electrode tip.

THE TEMPERATURE IN THIS EXAMPLE WAS SET FOR 75°C



The VAPR II RF System quickly achieves set temperature and maintains the accuracy of the setting throughout the RF application.

VAPR TC (Temperature Control) Electrode

2.3mm End-effect
Cat. No. 225252

UNSURPASSED ACCURACY IN THERMAL SOFT-TISSUE MODIFICATION

The Mitek VAPR II Generator and Temperature Control (TC) Electrode system offer unsurpassed accuracy, safety and reliability for arthroscopic thermal modification. Microprocessor controlled technology and an accurate thermistor in the tip ensure precision performance.

TEMPERATURE CONTROL TO CRITICAL RANGE

- System operates within 5°C of set temperature without undesirable spiking; easily maintains optimal reading of 65°C within range
- Fully programmable unit offers surgeon-controlled temperature adjustment for thermal modification of both capsular tissue and articular cartilage
- Advanced software and thermistor-based design offer best accuracy/temperature measurement available for arthroscopy
- Superior temperature control maximizes surgical outcome

SAFE, WORRY-FREE BIPOLAR RF OPERATION

The VAPR® II System features bipolar RF (radiofrequency) energy for rapid tissue modification and maximum safety. Bipolar energy has been shown to be safer than monopolar energy as it limits potential damage to alternate sites by containing the energy around the tip. It does not require a grounding pad. The system itself is less complicated and easier to use than monopolar units.

The specially designed Mitek TC Electrode constantly monitors temperature with sensors in the electrode tip. The microprocessor-controlled generator tightly controls temperature within a preset range for maximum accuracy and optimal surgical results.

mitek[®]
PRODUCTS
ETHICON
a Johnson & Johnson company

Innovation Defined by Experience

VAPR® II RF SYSTEM

2.3MM END-EFFECT TC ELECTRODE & GENERATOR



Please read all information carefully, in particular the User Manual that is provided with the Mitek VAPR or VAPR II Generator prior to use. The components of the Mitek VAPR & VAPR II System are designed for use together as a System. Failure to follow instructions may lead to improper functioning of the device and cause electrical or thermal injury.

SYSTEM DESCRIPTION

The Mitek VAPR and VAPR II RF Systems are designed for arthroscopic surgical procedures. Each system consists of a high frequency RF Generator, a reusable Handpiece with Connector Cable, disposable Electrodes and a Footswitch. The components are designed and intended to be operated as a single unit. Use only Mitek VAPR Electrodes and accessories with either Mitek VAPR System.

DEVICE DESCRIPTION

The VAPR TC (Temperature Control) Electrode is a soft-tissue desiccation device intended for use with the VAPR or VAPR II Systems. Utilization with a VAPR II system allows the tip temperature of the electrode to be indicated on the generator display.

INDICATIONS

The Mitek VAPR II RF System, when used with a VAPR TC Electrode, is intended for coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow, and wrist.

CONTRAINDICATIONS

The Mitek VAPR II RF System is contraindicated in any non-arthroscopic surgical procedure and in any arthroscopic procedure where saline or Ringer's Lactate is not used as an irrigant. Use of the system is also contraindicated in patients with heart pacemakers or other electronic device implants, or for patients for whom arthroscopic procedures are contraindicated for any reason.

HOW SUPPLIED

The VAPR TC Temperature Control Electrode is provided sterile unless the package is opened or damaged. It is intended to be disposed of after a single use.

INSTRUCTIONS FOR USE

Before Surgery

1. Connect footswitch to the VAPR or VAPR II Generator and switch it on. Follow the instructions in the User Manual so that the generator displays the symbol "CONNECT CABLE".
2. Connect a sterile Handpiece to the Generator. Follow the instructions in the User Manual so that the Generator displays the symbol "INSERT ELECTRODE".
3. Connect a new Mitek VAPR TC (Temperature Control) Electrode to the Handpiece. Check that the Handpiece and Electrode are properly aligned before pushing together and tightening the screw lock.
4. For optimal performance, safety and convenience, the VAPR TC Temperature Control Electrode automatically presets the generator to default output. If alternate power levels are desired with the VAPR unit, adjust the VAPR Generator to the desired settings using the BLUE and YELLOW arrows on the front of the VAPR Generator. Use the lowest possible power to achieve the desired end-effect. When the VAPR TC Electrode is used with the VAPR II system, vaporization is disabled, and the display replaced by either the set temperature (SET) or the tip temperature (TIP). If an alternate power level is desired with the VAPR II Generator, adjust it using the BLUE arrows on the front of the generator. Adjust the Set Temperature using the YELLOW arrows on the front of the VAPR II Generator. The default settings are as follows:

VAPR TC Electrode		
Electrode Geometry		
2.3mm End-Effect		
VAPR System	VAPR	VAPR II
Default mode	V1	None
Default Vaporization Power (W)	5	None
Default Desiccation Power (W)	20	20
Maximum Vaporization Power (W)	10	None
Maximum Desiccation Power (W)	50	50
Default Set Temp (°C)	None	65

CAUTION

If the VAPR Generator display does not match the default setting as specified above, consult the User Manual for further instructions.

During Surgery

1. Insert the electrode into a fluid filled joint space through a prepared entry point. Ensure that the electrode is surrounded by conductive irrigant solution when in use.
2. Use the lowest power setting to achieve the desired clinical effect.
3. Use the blue foot pedal to activate the electrode. When used with a VAPR II system, the Set Temperature (SET) will be replaced by the Tip Temperature (TIP), and the desiccation power value will flash.
4. If the power level is inappropriately low, the tip temperature (TIP) may not approach the set temperature (SET).
5. As a safety feature, if the tip temperature (TIP) exceeds the set temperature (SET) for more than one second or by 8°C, then a distinct alarm will sound, and the power output will automatically be reduced until the temperature returns to the set temperature.

After Surgery

1. Remove the electrode from the joint space.
2. Disassemble the VAPR TC Electrode and VAPR Handpiece. Disconnect the Handpiece from the Generator by pulling on the plug body. DO NOT pull on the cable as it may cause damage to the device.
3. Dispose of the single use components of the System, and prepare the reusable accessories for cleaning and sterilization.

WARNINGS

1. The operator should be experienced in arthroscopic surgical techniques.
2. Please refer to the user manual for step by step instructions regarding the assembly and initial system check of the Mitek VAPR or VAPR II System.
3. Ensure that fluid inflow and outflow are adequate, and the electrode is only activated when surrounded by conductive irrigant solution (e.g. saline or Ringer's Lactate).
4. Do not touch the electrode tip when power is being applied.
5. Do not withdraw or insert the electrode when power is being applied.
6. Activation of the electrode outside the field of vision may result in patient injury.
7. Avoid unnecessary and prolonged activation of the electrode between tissue applications as unintended injury may result.
8. Do not reuse any accessories labeled as 'Single Use'.
9. Avoid touching the distal tip of the instrument (insulator and metal active component) with fingers or instruments.

CAUTIONS

Prior to initial use, ensure that all package inserts including warnings, cautions and Instructions for Use are read and understood. Safe and effective electrosurgery is dependent not only upon equipment design but also on factors under the control of the user (refer to the User Manual).

1. As with all electrosurgical devices, do not use in the presence of flammable anesthetics, oxidizing gases or other flammable substances, as an electrosurgical device has the potential for providing a source of ignition.
2. Place accessories in a clean, dry, non-conductive and highly visible area (away from the patient) when not in use. The Electrode tip may remain hot sometime after it has ceased to be activated.
3. Inadvertent contact with the patient when the VAPR System is activated may result in burns. The patient should not be allowed to come in contact with grounded metal objects.
4. Do not wrap the Handpiece cable around metal objects, as this may induce currents that could lead to electric shocks, fires or injury to the patient and/or surgical personnel.
5. Do not activate the electrode while it is in contact with metal objects or instruments as unintended injury to the patient may occur.
6. Carefully insert and withdraw Electrodes to avoid possible damage to the device and/or injury to the patient or surgical personnel.

IMPORTANT

This is designed to provide instructions for use of VAPR TC Electrode. It is not intended as a reference to electrosurgical technique.

STORAGE

Store below 25°C (77°F) away from moisture and direct heat. Do not use after "USE BY" date.

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

Mitek
PRODUCTS

ETHICON
a Johnson & Johnson company

For more information, call your Mitek representative at 1-800-382-4682 or visit us at www.vapr.com. Mitek Products, Division of ETHICON, Inc., 60 Glacier Drive, Westwood, Massachusetts 02090

Mitek and VAPR are trademarks of ETHICON, Inc., a Johnson & Johnson company, or its Mitek Products Division. Patents pending. © Mitek Products, a Division of ETHICON, Inc., 2000. All rights reserved. Printed in the USA. P/N 900558 Rev. A 11/00.