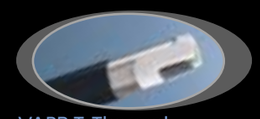
VAPR® Electrode Reference Chart

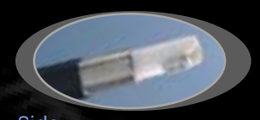
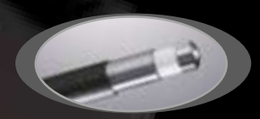
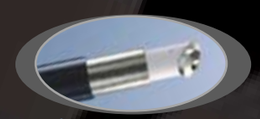
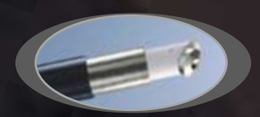
3.5mm Electrodes

	Catalog #		Mode	Default Vap	Default Des	Maximum Vap	Maximum Des	Indications
S	225301	 Side	V2	120	90	180	120	Subacromial Decompression ACL Debridment / Menisectomy Synovectomy / Acromioplasty Bursectomy / Chondroplasty Labral Tear Resection
S	225302	 Angled Side 21˚	V2	120	90	180	120	
S	225303	 End	V2	90	60	130	90	ACL Debridment / Menisectomy Synovectomy / Acromioplasty Bursectomy / Chondroplasty Labral Tear Resection
E	225304	 Angled End 21˚	V2	90	60	130	90	
H	225305	 Hook	BV2	120	90	180	120	Lateral Release Capsular Release
S	225309	 Side Effect (solid tip)	V2	120	90	180	120	Subacromial Decompression ACL Debridment / Menisectomy Synovectomy / Acromioplasty Bursectomy / Chondroplasty Labral Tear Resection
T	225101	 VAPR-T Side	V1	5	20	10	50	
T	225112	 VAPR-T Reverse Angle Side	V1	5-V1	20	10	50	Thermal Modification of Soft Tissue
T	225104	 VAPR-T, Angle End	V1	5-V1	20	10	50	
S	225312	 Flexible Side Effect	V2	120	90	180	120	Subacromial Decompression ACL Debridment / Menisectomy Synovectomy / Acromioplasty Bursectomy / Chondroplasty Labral Tear Resection
E	225314	 Flexible End Effect	V2	90	60	130	90	ACL Debridment / Menisectomy Synovectomy / Acromioplasty Bursectomy / Chondroplasty Labral Tear Resection

3.5mm Electrodes

	Catalog #		Mode	Default Vap	Default Des	Maximum Vap	Maximum Des	Indications
T	225322	 VAPR-T Thermal Flexible Side Effect	V1	5-V1	20	10	50	Thermal Modification of Soft Tissue
T	225324	 VAPR-T Thermal Flexible End Effect	V1	5-V1	20	10	50	
S	225350	 Right Angle with Suction	V2/V3	120 (V2)	90	180 (V3)	120	Subacromial Decompression ACL Debridment / Menisectomy Synovectomy / Acromioplasty Bursectomy / Chondroplasty Labral Tear Resection

2.3mm Electrodes

	Catalog #		Mode	Default Vap	Default Des	Maximum Vap	Maximum Des	Indications
S	225201	 Side	V2	60	45	90	60	
E	225202	 End	V2	90	60	130	90	Plica Removal Acl Debridment / Menisectomy Synovectomy / Acromioplasty Bursectomy / Chondroplasty Labral Tear Resection
W	225203	 Wedge	V2	60	45	90	60	
S	225211	 Side, Short	V2	60	45	90	60	Cartilage Debridment Fracture Debridment Synovectomy / Chrondoplasty Tendon Debridment Thermal Modification
W	225213	 Wedge, Short	?	60	45	90	60	?

VAPR Hardware & Accessories

225001	VAPR Generator
225010	VAPR II Generator Introductory Kit
225011	VAPR II Generator
225002	VAPR Handpiece
225003	VAPR Footswitch
225004	VAPR Sterilization Tray
225005	VAPR Power Cord
225401	2.3 Suction Sheath
225402	3.5 Suction Sheath

Mitek® PRODUCTS

Innovation Defined by Experience

Troubleshooting & Indications

TROUBLESHOOTING GUIDE

Generator Error & Fault Symbols

Most technical problems are indicated by either an ERROR or a FAULT symbol that appears on the Generator display window.

- An ERROR symbol indicates an accessory malfunction or a Generator component failure that requires servicing of the equipment. These symbols include a code number to be used by Mitek technical service to diagnose why the system failed. Displayed as ERROR XXX REF XXX.
- A FAULT symbol indicates a transient non-hazardous event and can be corrected by resetting the system. Displayed as FAULT XXX REF XXX.

FAULT SYMBOL	REF	DESCRIPTION	CORRECTIVE ACTION
100	10	Software failure	Press Mode Button Twice
100	12	Memory failure	
100	14	Generator unable to develop sufficient power	
300	10	Internal overheating	
300	12	Input voltage from outlet is low	
300	13	Input voltage from outlet is high	
300	14	Contact may have been made with other equipment during activation such as the scope or other instrumentation	
400	10	Blue Footswitch pedal depressed	
400	11	Yellow Footswitch petal depressed	
400	14	Electrode not identified by Generator	
400		Front panel buttons inadvertently depressed during initalization switch fault.	
	15	yellow UP button	
	16	yellow DOWN button	
	17	blue UP button	
	18	blue DOWN button	
	19	MODE button	
400	20	During activation irregular conditions were detected from footswitch	

INDICATIONS

The Mitek VAPR Electrosurgical System, when used with a VAPR Electrode or VAPR FLEX Electrode, is intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels, and coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, ankle, elbow and wrist.

The Mitek VAPR Electrosurgical System, when used with a VAPR T Thermal 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 System is contraindicated in any non-arthroscopic surgical procedure and in procedures where saline or Ringer's lactate is not used as an irrigant. The System is also not appropriate for patients for whom an arthroscopic procedure is contraindicated for any reason. Use of the System is also contraindicated in patients with heart pacemakers or other electronic device implants.

WARNINGS

- Do not touch the Electrode tip when power is being applied.
- Do not insert or withdraw the Electrode while power is being applied.
- Inadvertent activation or movement of the Electrode outside the field of vision may result in patient injury.
- Avoid unnecessary and prolonged activation between tissue applications as unintended injury may result.
- Avoid bubble accumulation in the joint space during use. The accumulation of bubbles around the working tip of the Electrode will diminish performance and may produce overheating sufficient to damage adjacent structures.
- Do not reuse any accessories labeled as SINGLE USE.
- Using arthroscopic guidance, ensure that the Electrode tip is completely surrounded by conductive irrigant solution during use.
- When bending the FLEX Electrode, do not exceed a 45° angle with the plane of the shaft.
- Do not change the FLEX Electrode shape at the same point on the shaft more than three times. More than three angle modifications can result in electrode fracture.
- Use of instruments other than fingers to bend the electrodes can cause damage to the FLEX Electrode.
- Avoid touching the ceramic and coil tip of the Electrode with your fingers or any instruments.
- Attempts to bend non-FLEX 3.5 mm Electrodes can result in electrode fracture.

CAUTIONS

- Use only conductive irrigant solution (e.g., saline or Ringer's lactate). Do not use nonconductive irrigants (e.g., sterile water, air, gas, glycine, etc).
- Ensure that the Electrode is fully seated in the Handpiece prior to use.
- Avoid fluid contact with the proximal end of the Electrode/Handpiece interface.
- Place accessories in a clean, dry, nonconductive and highly visible area away from the patient when not in use. Inadvertent contact with the patient may result in burns. Contact with drapes or other flammable materials may cause fire.
- Do not wrap the Handpiece cable around metal objects. Doing so may induce currents that could lead to shock, fires, or injury to the patient or surgical personnel.
- During arthroscopic procedures, be alert to these potential hazards:
  - As with all electrosurgical devices, do not use in the presence of flammable anesthetics or oxidizing gases, such as nitrous oxide or oxygen. An electrosurgical device has the potential for providing a source for ignition. Endogenous gases which accumulate in body cavities can also be a source of ignition.
  - The Electrode tip may remain hot enough to cause burns after the electrosurgical current is deactivated.
- Do not activate the Electrode while in contact with metal objects and instruments, as unintended tissue injury may occur.
- Carefully insert and withdraw Electrodes to avoid possible damage to the devices and/or injury to the patient or surgical personnel.
- The patient should not be allowed to come in contact with grounded metal objects.
- 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 on equipment design, but also on factors under the control of the user (Refer to User Manual).

Temperature Control Electrode (VAPR TC Electrode)

2.3mm End-Effect

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 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 Electrosurgical Systems are designed for arthroscopic surgical procedures. Each system consists of a high frequency electrosurgical 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 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 FOR USE

The Mitek VAPR Electrosurgical 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 Electrosurgical System is contraindicated in any non-arthroscopic surgical procedure and in any arthroscopic procedures 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 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. Switch on the Mitek VAPR or VAPR II Generator. 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 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 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 Desication 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 8º Celsius, then a distinct alarm will sound.

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 sterilisation.

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 is 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

1. 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).
2. As with all electrosurgical devices, do not use in the presence of flammable anaesthetics, oxidising gases or other flammable substances, as an electrosurgical device has the potential for providing a source of ignition.
3. 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.
4. 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.
5. 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.
6. Do not activate the Electrode while it is in contact with metal objects or instruments as unintended injury to the patient may occur.
7. Carefully insert and withdraw Electrodes to avoid possible damage to the device and/or injury to the patient or surgical personnel.

IMPORTANT

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

Storage

- Store below 25ºC (77ºF) 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
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For more information, call your Mitek representative at 1–800–382–4682 or visit us at www.mitek.com.
Mitek Products, Division of ETHICON, Inc., 60 Glacier Drive, Westwood, Massachusetts 02090

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