Instructions For Use
CAT1785 VivAer® Stylus
Model: FG1787

Max Voltage: 70.7 V_{rms}

English (US)

Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. Failure to do so may result in patient complications. Aerin Medical relies on the physician to determine, assess and communicate to each patient all foreseeable risks of the procedure. Resale of this device is prohibited by law.

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Rx ONLY

Caution: Federal law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The VivAer® Stylus is a disposable handheld device capable of delivering bipolar radiofrequency energy to tissue.

The VivAer® Stylus consists of a handle, shaft and treatment tip (see Figure 1). An array of bipolar electrodes is positioned on a non-conductive tip (see Figure 2) which is attached to a handle via a non-conductive shaft. A temperature sensor is located on the tip (see Figure 2) to monitor tissue temperature. The Stylus is attached to a temperature-controlled radiofrequency generator via a flexible cable.

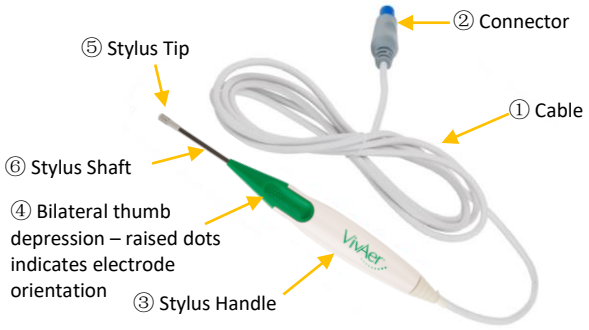

Figure 1: VivAer® Stylus

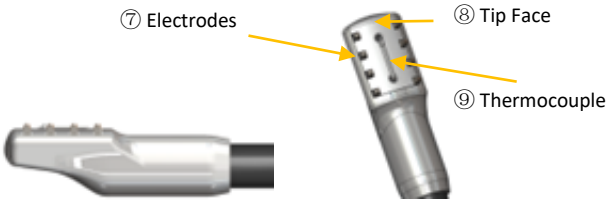

Figure 2: VivAer® Stylus Tip

The VivAer® Stylus improves nasal breathing by modifying the tissues of the nasal airway using low doses of radiofrequency energy. The low-power radiofrequency energy generates heat within the tissue and creates a coagulation lesion. As the lesion heals, the tissue retracts and stiffens, thereby decreasing nasal airway obstruction and improving airflow.

The VivAer® Stylus tip is temporarily inserted into the nose to access the treatment area. The procedure requires local anesthesia only.

The Stylus is supplied sterile and for single use only. It is terminally sterilized by ethylene oxide.

ADDITIONAL EQUIPMENT NEEDED

The VivAer® Stylus has been designed to be used with an Aerin Console (see Figure 3).

The Aerin Console consists of the following:

- One (1) Aerin Console Unit
- One (1) Power Cord
- One (1) Foot Switch

Refer to the instructions for use (IFU) for the Aerin Console for set-up and operating instructions.

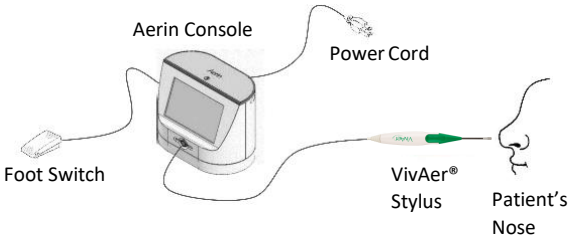

Figure 3: Aerin Console with VivAer® Stylus

INDICATIONS FOR USE

The VivAer® Stylus is indicated for use in otorhinolaryngology (ENT) surgery for the coagulation of soft tissue in the nasal airway, to treat nasal airway obstruction by shrinking submucosal tissue, including cartilage in the internal nasal valve area.

INTENDED USER

The intended users of the VivAer® Stylus are physicians including otolaryngologists, maxillofacial surgeons and other physicians specialized in nasal procedures.

CONTRAINDICATIONS

- Patients who have had nasal surgery within the last 3 months.
- Patients with extreme nasal pathology or a history of extreme nasal injuries.
- Patients with medical conditions that may impair normal healing processes or be exacerbated by the stress of surgery.

WARNINGS

The VivAer® Stylus is for single use only. **Do not resterilize, autoclave, or reuse**. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device malfunction, failure or patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

DO NOT USE in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.

DO NOT USE in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N_2O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.

DO NOT place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.

When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

DO NOT allow fluid to contact the VivAer® Stylus cable connector.

INSPECT instruments and cables for damage prior to each use. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator.

DO NOT activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling.

The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.

Connect adaptors and accessories to the electrosurgical unit only when the unit is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.

Treatment reduces the mucous cells and glands, therefore, excessive treatment of the nasal mucosal tissue should be avoided as over use may lead to crusting or dryness of nose.

No modification of the VivAer® Stylus is allowed.

PRECAUTIONS

When using the VivAer® Stylus in Aerin Console custom treatment mode, set the power, temperature, and treatment duration as low as possible to achieve the desired effect.

Maintain safe handling techniques when electrodes are in use due to electrical field and potentially hot electrodes.

Do not touch the tip of the VivAer® Stylus when operating the Aerin Console. Superficial skin burns could occur.

Simultaneous use of irrigation while activating the VivAer® Stylus may alter the path of the electrical energy away from the target tissue.

When high frequency surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, monitoring electrodes should be placed as far as possible from the surgical electrodes. Position the cable to avoid contact with the patient or other leads, where possible.

Inspect all components prior to use for any obvious signs of damage that may have occurred during transit and/or storage.

Do not use the VivAer® Stylus if the device is damaged or the unit package is opened or damaged.

The VivAer® Stylus uses RF energy for its internal function. Nearby electronic equipment may be affected.

If the user of the VivAer® Stylus requires continued operation during power mains interruptions, it is recommended that the Aerin Console to which the stylus is connected be powered from an uninterruptible power supply or a battery.

Build-up of eschar may reduce the stylus's effectiveness. Do not initiate treatment while cleaning. Injury to user may result.

This device has not been evaluated in the pediatric population.

NOTE: Insert the Stylus into the Console with the insertion key facing up. Do NOT twist the Stylus handle into the connector to avoid damage to the device.

ADVERSE EFFECTS

Common adverse effects related to the use of radiofrequency energy on tissue in the nasal airway include mild bleeding, mucosal necrosis, sensory changes at treatment site, inflammation/generalized redness, temporary swelling/edema, blanching (generalized whiteness), temporary numbness/tingling, bruising including around the orbital area (black eyes), temporary soreness/pain, and disruption of mucosal flow/crusting. Less common adverse effects include infection, severe bleeding, scar formation with increased obstruction, and external deformity.

OPERATING INFORMATION

Set-up Instructions:

1. Set-up the Aerin Console per the instructions in the Aerin Console IFU and plug the Aerin Console's power cord into an appropriate power outlet.
2. Turn on the Aerin Console and inspect the system for any error message or alarm.
3. Inspect the Foot Switch connection and ensure proper connection.
4. Prepare the patient using standard techniques for bipolar electro-surgery including cleaning the treatment site and administering anesthesia as appropriate.
5. Insulate the patient's entire body, including extremities, against contact with grounded metal parts.
6. Following the Check-Out Procedures listed below, remove the Stylus from its package and hand off to the sterile field using sterile technique as applicable.
7. Pass the connector end of the cable out of the sterile field and connect the stylus to the Stylus connector located at the front panel of the Aerin Console.
   NOTE: Insert the Stylus into the Console with the insertion key facing up. Do NOT twist the Stylus handle into the connector to avoid damage to the device.
8. The Aerin Console will detect the Stylus Model and will automatically apply the recommended default treatment settings (Temperature: 60°C, Power: 4 watts, Duration: 18 seconds and Cooling Time: 12 seconds).
9. To set the custom treatment settings for the Stylus on the Aerin Console, refer to the "Custom Treatment Instruction" under "Operating Instructions" in the Aerin Console IFU. The recommended treatment time is 12 to 18 seconds.

Check-out Procedures:

10. Inspect the Stylus package prior to opening. Do not use if the unit package is opened or damaged.
11. Use sterile technique to carefully remove the Stylus from the packaging. Inspect the Stylus to ensure that the device has no visible signs of damage.

Cleaning Instructions:

12. VivAer® Stylus: No cleaning is necessary prior to first use. Inspect the electrodes between treatments for eschar or material build-up; if necessary, gently wipe the tip with sterile gauze.
    CAUTION: Build-up of eschar may reduce the Stylus's effectiveness. Do not initiate treatment while cleaning. Injury to user may result.
13. Aerin Console: Refer to the instructions in the Aerin Console IFU.

Operating Instructions:

14. Apply conductive media (e.g., saline gel) to the Stylus tip, then insert the tip into the nose. Do not activate the Stylus during insertion.
15. Position the electrode-containing portion of the tip of the Stylus against the target tissue of the nasal airway and exert gentle pressure. The orientation of the electrodes may be verified by the raised dots on one side of the Bilateral Thumb Depression on the Stylus handle. Refer to Figure 1.
16. When treating the upper lateral cartilage (ULC) of the nasal valve area, be sure to only treat the nasal scroll area (the junction area between the caudal border of the ULC and the lower lateral cartilage).
17. Continuously press the Foot Switch or the On-Screen Start Button to start the treatment, releasing the Foot Switch/Start Button will pause the treatment, the treatment will completely stop if the Foot Switch/Start Button is not pressed within 2 seconds.
18. Apply consistent pressure with the Stylus against the tissue for the entire duration of the treatment.
19. The total treatment duration countdown timer (including the cooling time) will be displayed inside the treatment circle together with a visual indicator of the overall treatment progress.
20. Remove the Stylus tip from the treatment area. Inspect the electrodes for eschar or material build-up; if necessary, gently wipe the tip with sterile gauze.
    CAUTION: Build-up of eschar may reduce the Stylus's effectiveness. Do not initiate treatment while cleaning. Injury to user may result.
21. Repeat steps 14 through 20 to treat additional target tissue locations within the same nostril and/or the contralateral nostril as necessary.
22. Tissue blanching will be observed in the "footprint" of the tip face. Adjacent lesions may be made by aligning the tip face with the edge of the blanching. **DO NOT overlap treatments.** Do not apply energy for more than 18 seconds at each treatment site.
    WARNING: Treatment reduces the mucous cells and glands, therefore, excessive treatment of the nasal mucosal tissue should be avoided as over use may lead to crusting or dryness of nose.

Monitoring of the Device:

23. During treatment, the Aerin Console should be monitored for any error message or alarm. Discontinue treatment if an error message or alarm occurs.

Description of Maintenance:

24. The Stylus is for single use only. No maintenance is required.
25. Aerin Console: Refer to the instructions in the Aerin Console IFU.

Storage Instructions:

26. The Stylus(s) should be stored in their packaging. Do not stack heavy objects on the shipping boxes and/or sterile packaging.
27. Aerin Console: Refer to the instructions in the Aerin Console IFU.

Safe Disposal of the Device:

28. The Stylus should be disposed of in accordance with applicable local and national legislation procedures and requirements.

TROUBLESHOOTING INFORMATION

If the Stylus malfunctions for any reason, discontinue use and obtain a new Stylus to complete the procedure. If the Aerin Console malfunctions, refer to its Instructions for Use.

RECOMMENDED STORAGE AND USAGE CONDITIONS

Parameters	Storage	Usage
Temperature	5°C to 40°C	20°C to 28°C
Relative Humidity	20% to 85% at 30°C	30% to 75% at 30°C
Pressure	50kPa to 106kPa	70kPa to 106kPa

ELECTROMAGNETIC COMPATIBILITY

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS		
The VivAer® Stylus is intended for use in the electromagnetic environment specified below. The user of the VivAer® Stylus should assure that it is used in such an environment.		
Emission Test	**Compliance Level**	**Electromagnetic Environment Guidance**
RF emissions CISPR 11	Group 1	The VivAer® Stylus uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The VivAer® Stylus is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker emissions IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
The VivAer® Stylus is intended for use in the electromagnetic environment specified below. The user of the VivAer® Stylus should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	UT = 0%, 0.5 cycle (0, 45, 90, 135, 180, 225, 270 and 315°) UT = 40%; 10 cycle UT = 70%; 25 cycles UT = 0%; 250 cycle	< UT = 0%, 0.5 cycle (0, 45, 90, 135, 180, 225, 270 and 315°) UT = 40%; 10 cycle UT = 70%; 25 cycles UT = 0%; 250 cycle	Mains power quality should be that of a typical domestic, commercial or hospital environment. If the user of the VivAer® Stylus requires continued operation during power mains interruptions, it is recommended that the VivAer® Stylus be powered from an uninterruptible power supply or a battery.
(50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms & 6 Vrms 150 kHz to 80 MHz	3 Vrms & 6 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the VivAer® Stylus, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz Spot frequencies 385 MHz – 5.750 GHz Pulse Modulation	3 V/m 80 MHz to 2.7 GHz Spot frequencies 385 MHz – 5.750 GHz Pulse Modulation	

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
The VivAer® Stylus is intended for use in the electromagnetic environment specified below. The user of the VivAer® Stylus should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 *U*T is the a.c. mains voltage prior to application of the test level. NOTE 2 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VivAer® Stylus is used exceeds the applicable RF compliance level above, the VivAer® Stylus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the VivAer® Stylus. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE VIVAER® STYLUS

The VivAer® Stylus is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the VivAer® Stylus can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VivAer® Stylus as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Conforms to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-6:2010/AMD2:2020 for use in conjunction with IEC 62366-1:2015, IEC 62366-1:2015/AMD1:2020, IEC 60601-2-2:2017, and IEC 60601-2-2:2017/AMD1:2023 for use in conjunction with IEC 60601-1:2005.

CALIFORNIA PROPOSITION 65 WARNING

WARNING: This product contains a chemical known to the State of California to cause cancer.

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

DEFINITIONS OF SYMBOLS USED

	Sterilized using ethylene oxide, single sterile barrier system
	Batch code
	Do not re-use
	Caution
	Manufacturer
	Country and date of manufacture
	Use-by date
	Model number
	Catalogue number
	Quantity
	Consult instructions for use
	Do not resterilize
	Do not use if package is damaged
	Type BF applied part
	Temperature Limit
	Humidity Limitation
Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician.
	Number of treatment cycles the Stylus is programmed to deliver.

LIMITED WARRANTY

The VivAer® Stylus is designed for single patient use and warranted against manufacturing defects at the time of delivery. If this happen, contact your Aerin Medical's sales representative.