SPINE®
CONCEPTS

# SPINEX 9000

## USER MANUAL

# SPINEX 9000


Product description 4

Principle of operation 4

Product performance 4

Basic performance of the product 5

Main dtructural components of product 5

Table 1

Tecnical caracteristic

Table 2

Table 3

Table 4

Scople of application 8

contraindications 9

Precautions, warnings and safety instructions 12

Aplication specifications 13

Graphics, symbols, and abbrevations on medical device labels

Cleaning, disinfection and sterilization 14

Installation and use instructions or diagrams 14

Warning

Power on

Use of vaporizarion resection mode

use of ablation and coagulation mode

other usage information

Product Name ArthroBlade®
Model No. 4077-290-090

## Product Description

ArthroBlade® system is a bipolar plasma electrosurgical device (hereinafter referred to as device) deliverying radio-frequency energy to electrodes elements in use of procedures for resection, ablation and coagulation of soft tissue.

## Principle of Operation

Plasma electrosurgical device shall be used with disposable plasma electrosurgical bipolar electrodes under the condition of normal saline (conductive solution).

*There are two operation modes available on the device as follows:*

1. Vaporization resection (ABLATE)

When radio frequency energy is applied, the normal saline (conductive solution) between the active electrode elecment and the passive electrode element is converted into a plasma vapor layer containing charged particles. When high-energy load particles come into contact with soft tissue, they will disintegrate the tissue through molecular dissociation, thereby achieving vaporization resection of soft tissue.

2. Ablation and coagulation (COAG)

When a low voltage is applied between the active electrode element and the passive electrode element of, the electric field is below the threshold required to form a plasma layer. At this time, resistive tissue heating will occur. When in contact with soft tissue or bleeding blood vessels, its high thermal effect causes soft tissue ablation or blood vessel coagulation, thereby achieving ablation and coagulation of soft tissue or bleeding blood vessels.

## Product Performance

1. Radio-frequency output parameters
2. Operating and Modulation frequency: check Table 3
3. Output power and voltage: check Table 3
4. Peak coefficient: check Table 3
5. Footswitch
6. It shall meet the requirements of standard IEC/EN60601-1
7. Basicsafetyandperformance
8. It is according to IEC/EN606011:2012,MOD and IEC/EN60601-2-2: 2017,MOD
9. Electromagneticcompatibility
10. It meets the relevant requirements of IEC/EN60601-1-2:2007,MOD and IEC/EN60601-2-2: 2017,MOD
11. Concentrationinfluence
12. When the saline concentration changes, the device should be able to be normally excited at the maximum output setting and no damage should occur.
13. Temperaturemeasurement
14. When the device is connected to electrosurgical accessory with temperature measurement function, the temperature tolerance shall stay ≤ ±3 °C.
15. Standby noise: <60dB(A)

## Basic Performance of the product

Set the vaporization resection power at 0~380W, ≤ ±20%, and set the ablation coagulation power at 0~45W, ≤ ±20%

## Main Dtructural Components of Product

The device consists of a main unit and the accessories including a power cord, a foot switch, and a flow controller (optional).

1. Main Unit
2. Power cord
3. Foot switch
4. Ablation and coagulation pedal
5. Vaporization and resection pedal
6. Foot switch connection
7. Electrode handle connection
8. Electrode knife rod
9. Suction tube (optional according to electrode type)
10. Flow drip tube (optional according to electrode type)
11. Flow controller (optional)
12. Flow controller cable (optional)

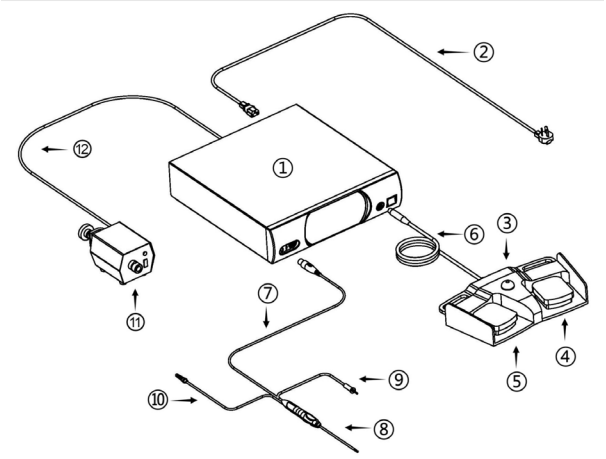



Figure 1

Schematic diagram of the overall device structure

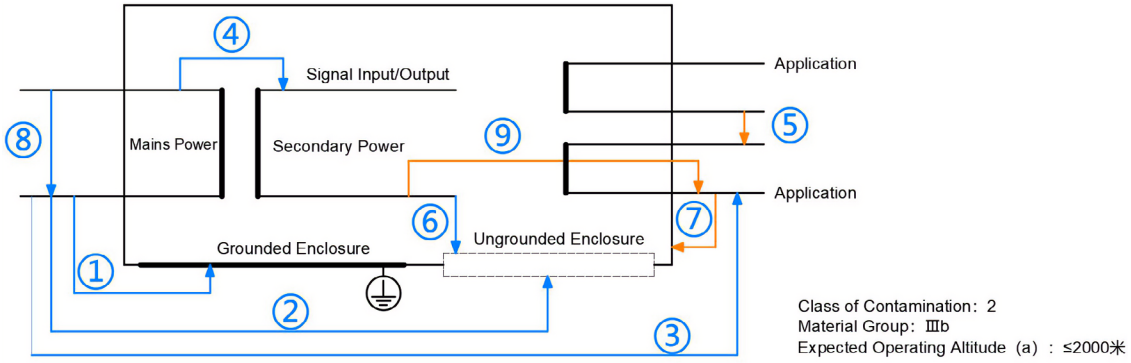
Table 1

Overall structure of the Device

| No. | Part Name | Model/ Specification | Product Description | Remarks |
|---|---|---|---|---|
| 1 | Main Host | 4077-290-090 | Radio Frequency Plasma Generator | |
| 2 | Foot Switch | 4077-290-090-1 | Controls the ablation and coagulation | |
| 3 | Power Cord | 10A AC 250V | Connects the main unit to the power supply | |
| 4 | Flow Controller | L-01 | Controls the flow of saline | Optional |

## Tecnical Characteristics

1. Output main frequency: 100kHz±10%
2. Classification by electric shock protection type: Class I
3. Classification by electric shock protection degree: BF type
4. Classification by protection degree against liquid and particulate matter: Normal standard (the foot switch is water-proof type)
5. Classification by safety level when used in oxygen enriched atmospheres, and oxidizing agents such as nitrous oxide (N2O) atmospheres environment: not applicable
6. Classification by operation mode: non-continuous operation, the longest excitation time is 60S, the shortest non-excitation time is 30S.
7. Can the device protect against defibrillation discharge effects: Yes
8. Does the device have a signal output or input part: No
9. Permanently or non-permanently installed device: Non-permanently installed device
10. Electrical insulation diagram and insulation list:




| Position | Insulation Type | Operating Voltage (AC) | Peak Voltage | Test Voltage |
|---|---|---|---|---|
| ① | 1MOOP | 220V | 312V | 1500V |
| ② | 2MOOP | 220V | 312V | 3000V |
| ③ | 2MOPP | 220V | 312V | 4000V |
| ④ | 2MOOP | 220V+Secondary circuit voltage | 412V | 2560V |
| ⑤ | 2MOPP | Secondary circuit voltage + applied part working voltage | 460V | 4300V |
| ⑥ | 2MOOP | Secondary circuit voltage | 100V | 1500V |
| ⑦ | 1MOPP | 220V | 312V | 1500V |
| ⑧ | 1MOOP | 220V | 312V | 1500V |

11. Radio-frequency isolation method: transformer and capacitor isolation method
12. Neutral electrode monitoring circuit: not applicable
13. Pollution level: 2
14. Overvoltage category: Ⅱ
15. Material group classification: ⅢⅠb
16. Product specifications, models, output parameter table

Table 2
Output Parameter Table

| | 18-core electrode socket | | 27-core electrode socket | |
|---|---|---|---|---|
| | ABLATE | COAG | ABLATE | COAG |
| Operating Frequency (KHz) ≤ ±10% | 100 | 100 | 100 | 100 |
| Modulation Frequency (KHz) ≤ ±10% | / | / | / | / |
| Rated Power (W) ≤ ±20% | 370 | 40 | 380 | 40 |
| Rated Load (Ω) | 200 | 200 | 200 | 200 |
| Max. Output Voltage (AC Vp) ≤ ±10% | 500 | 200 | 500 | 200 |
| Crest Factor ≤ ±0.5 | 1.4 | 1.4 | 1.4 | 1.4 |

Table 3
Power Output settingse

| Display | 18-core electrode socket output power (W) ±20% | | 27-core electrode socket output power (W) ±20% | |
|---|---|---|---|---|
| | ABLATE | COAG | ABLATE | COAG |
| 0 | 0 | 0 | 0 | 0 |
| 1 | 40 | 17 | 40 | 17 |
| 2 | 63 | 40 | 62 | 40 |
| 3 | 93 | / | 92 | / |
| 4 | 127 | / | 126 | / |
| 5 | 168 | / | 166 | / |
| 6 | 214 | / | 212 | / |
| 7 | 241 | / | 239 | / |
| 8 | 268 | / | 265 | / |
| 9 | 378 | / | 329 | / |
| 10 | / | / | 372 | / |

Note: The each output power is measured under rated load.

Table 4
Maximum Output Current

| Output Mode | Maximum Current (mA) | Impedance (Ω) |
|---|---|---|
| ABLATE | 1400 | 225 |
| COAG | 470 | 225 |

17. For the power-impedance characteristic curve, check Impedance Characteristic Curve; for the maximum output voltage, see Maximum Output Voltage and Power Setting Diagram.
18. Physical characteristics: Dimension: 425*400*150mm (L*W*H ±10mm), Weight: 5.8 ±0.5kg
19. Fuse model specification: T4A, AC 250V.
20. The application part of this product: Bipolar plasma electrosurgical electrode.

## Scope of Application

It works under a saline environment used in conjunction with the disposable bipolar plasma electrosurgical electrodes suitable for resection and coagulation of soft tissues procedures.

## Contraindications

It is prohibited in any surgeries without using conducting solutions.

## Precautions, warnings and safety instructions

1. Patients should not touch grounded or metal objects with considerable capacitance to the ground (such as: operating table brackets, etc.). It is recommended to use antistatic partitions. Skin-to-skin contact (such as between the patient's limbs) should be prevented, such as inserting dry gauze.
2. When using this device with physiological monitoring device on the same patient at the same time, any monitoring electrode should be kept as far away from the electrosurgical electrode as possible, and needle-shaped monitoring electrodes should not be used. In all cases, a monitoring system with a high-frequency current limiting device should be used.
3. When placing patient leads, prevent them from contacting the patient or other leads. Electrosurgical electrodes that are not in use temporarily should be stored in a place isolated from the patient.
4. For electrosurgical procedures where high-frequency current may flow through a small cross-sectional area of the human body, it is best to use bipolar technology to prevent unexpected tissue damage.
5. For the expected effect, choose the lowest possible output power. Some devices or accessories may present unacceptable risks at low power settings. For example, when using argon beam coagulation, if the high-frequency power is insufficient to produce a rapidly closed scab on the target tissue, the risk of gas embolism may occur.
6. For the device that operates correctly under normal operating settings, when the output is reduced or interrupted, it may indicate that the neutral electrode is not applied correctly or the connector is in poor contact. Therefore, before selecting a higher output power, check the application of the neutral electrode and its connector, such as stopping the machine to check: a. placement of the electrode plate, b. surface of the electrode, c. electrode cables, d. the insulation, e. contact with the grounding conductor, f. the plugs.
7. If electrosurgery is performed in the chest or head area, avoid the use of flammable anesthetics and oxidizing gases, such as nitrous oxide (N2O) and oxygen, unless these gases are removed before surgery.If possible, non-flammable agents should be used for cleaning and disinfection. It is advisable to use flammable agents for cleaning and disinfection or as solvents for adhesives, but these agents should be evaporated before high-frequency surgery. There is a risk of accumulation of flammable agents in the patient’s body or recesses such as the umbilicus and cavities (such as the vagina). Before using high-frequency electrosurgical device, any accumulated liquid should be wiped clean. (Also) pay attention to the risk of ignition of internal gases. Certain materials such as cotton, wool and gauze, when filled with oxygen, can be ignited by sparks generated during normal use of high-frequency electrosurgical device.
8. For patients with electrically conductive implants, there is a possible danger due to the concentration or redirection of high-frequency current. If in doubt, contact the doctor in the relevant department and take effective preventive measures.
9. Warning The interference generated by high-frequency electrosurgical device during operation may have an adverse effect on the operation of other electronic device. For patients with pacemakers or other active implants, there may be danger because it may interfere with the operation of active implants or damage active implants. If in doubt, contact the doctor in the relevant department and take reliable preventive measures.
10. High-frequency current may interfere with the operation of pacemakers. It should be noted that the current loop must not pass through active implant products worn by patients such as pacemakers.
11. Maximum output voltage of plasma electrosurgical device: 500V. The rated accessory voltage of auxiliary device and electrosurgical accessories should be ≥ the maximum output voltage set by the high-frequency mode.
12. Warning Failure of plasma electrosurgical device may cause unexpected increase in output power.
13. Warning Neuromuscular stimulation may cause risks, especially modes that can cause arcs between electrosurgical electrodes and tissues.

14. Radio-frequency electrosurgical device that can be excited by switch detectors that are not continuously activated, warnings or precautions about risks: This product should use matching high-frequency accessories that meet the requirements, otherwise it will cause the risk of unexpected activation of high-frequency electrosurgical device.
15. For Radio-frequency electrosurgical device, the cable length of accessorie of each connector type should not exceed 3 meters.
16. Prevent the Radio-frequency output setting from causing the maximum output voltage to exceed the rated accessory voltage.
17. It is recommended that the operator regularly check the accessories, especially: the electrode cable and accessories used in Radio-frequency energy endoscopic treatment device should be checked for possibledamage (for example: when magnified); the panel socket should also be checked, and loose panel plugs, damaged electrode cables, etc. may cause poor contact or instrument failure and thus cause hazards such as accidental burns to the operator or patient.
18. For auxiliary device and electrosurgical accessories, including their parts provided separately, the rated accessory voltage is: 500V. Warning Only for Radio-frequency electrosurgical mode output settings, the peak output voltage generated is not higher than the rated accessory voltage.
19. The electrode blade and handle should be checked before use: the handle and the electrode blade should be well electrically connected and matched. Poor electrical contact or poor matching will cause the electrode improper working , fail to meet the intended use, and may even delay the patient's surgery. New electrosurgical electrodes must be replaced in time.
20. Environmental protection: It is recommended that this product be used in conjunction with plasma electrosurgical electrodes. During normal use, smoke may be generated near the electrosurgical electrodes. Operators should use smoke extraction devices appropriately. Recommendations for the correct disposal of waste, residues, etc., as well as device and accessories at the end of their expected service life: They should be disposed of in strict accordance with relevant laws and regulations stipulated by the state and local governments. Products that need to be disposed of should be placed in the waste storage area specified by the user unit and transported and destroyed by professionals to solve the problem of medical waste pollution from the source.
21. **Warning** This product is prohibited from use in an oxygen-rich environment.
22. **Warning** In order to avoid the risk of electric shock, this device must be connected to a power supply network with protective grounding.
23. **Warning** This product may cause significant risks due to mutual interference during special diagnosis or treatment.
24. Safety instructions: There may be potential electromagnetic interference or other interference between this product and other devices. It is recommended to use anti-interference device or take anti-interference measures.
25. The materials of the product that come into contact with the patient and the operator: the chassis material is aluminum, the head material is ABS (fireproof grade: V0), and the mask material is PVC. There are no materials or components that may pose unacceptable risks to the patient and the operator. Under the conditions of the intended use, expected service life, transportation and storage of the product, the mechanical properties of the product will not be reduced to cause unacceptable risks.
26. This product is reusable. The transportation and storage conditions of the responsible party should comply with the provisions of Product Maintenance and Care Methods, Special Storage, Transportation Conditions, Methods.
27. The device and accessories are non-sterile products and should be cleaned, disinfected and sterilized before each use. If the accessories used are disposable sterile products, the packaging should be checked for damage before use. If damaged, it is prohibited to use it, and repeated sterilization is strictly prohibited.
28. **Warning** Modification of this device is not allowed.

28. **Warning** The only interchangeable or removable parts of this device are fuses and power cords. Their replacement should be performed by professional maintenance personnel authorized by the manufacturer, otherwise it may cause hazards.
29. Please carefully read the product instructions of the plasma electrosurgical device and its accessories before installing and usage. The requirements of the product instructions of the plasma electrosurgical device and its accessories must be strictly followed during operation.
30. The operation of this product should be carried out by trained and qualified professional medical personnel. The requirements of the instructions must be strictly followed during operation. Using this product without training may cause serious accidental injuries to patients.
31. Before use, the connections of all accessories of the plasma electrosurgical device should be checked to prevent incompatibility and unsafe operation. Improper connection may cause arcs, sparks, accessory failures or unexpected electrosurgical results.
32. Do not knot the Radio-frequency cable or bundle it with the cables of other medical device. Otherwise, the high-frequency signal and spark discharge interference of the plasma electrosurgical device may cause abnormal functions of other medical device and cause adverse effects on patients.
33. Applicability of accessories: The safety of patients and users depends not only on the plasma electrosurgical device itself, but also on the accessories of the plasma electrosurgical device used. Therefore, it is necessary to use the compatible accessories provided by the same manufacturer or by other supplier with a registration certificate and qualified inspection report.
34. Plasma electrosurgical device is suitable for patients who need soft tissue surgery
35. Excessive noise caused by device failure may cause harm to patients, and the manufacturer should be contacted for repair.
36. If the maximum power of the device exceeds 20% of the set power, the device will alarm automatically when overloaded and stop output.
37. Note: When this product is used for its intended purpose, it may reduce the performance of other electrical device and systems.
38. This product is only for use in medical institutions that meet the product use environment and standard working conditions.
39. Note: Do not use this product under strong electromagnetic conditions, otherwise it may cause the product to fail to maintain the specified electromagnetic compatibility performance, thereby causing certain harm to, patients. When using, try to keep the device away from strong electromagnetic radiation device.
40. When the plasma electrosurgical device is started (output excitation), the exposed limbs of medical staff must not contact with the plates and the body of the electrosurgical patient. For this reason, the relevant medical staff must wear well-insulated medical rubber gloves.
41. When an accident occurs during operation, it should be turned off first, and then relevant professionals should be asked to handle it.
42. The device defibrillation protection recovery time is 2 minutes.
43. Do not use non-conductive media (such as sterile water, air, glycerin, etc.) for this device. Only conductive media such as saline can be used.
44. For other precautions and warnings, please refer to the instructions of other device and accessories used.

Application Specifications

| | | |
|---|---|---|
| Product Name | | Plasma Electrosurgical Units |
| Model No. | | 4077-290-090 |
| Intended medical indications | | One or more diseases being treated. |
| Expected patient population | | Patients who require soft tissue surgery. |
| The intended body part or tissue type to which this device is applied or interacts | | Human tissue |
| Expected User Characteristics | User | Medical staff |
| | Medical and nursing staff | Education: at least 18 years old and a medical or nursing graduate;<br>Knowledge: understanding of medical or nursing related knowledge;<br>Language: language specified in the plasma electrosurgical device sales plan;<br>Experience: at least 18 years old and a medical or nursing graduate, who can fully understand the instructions after training;<br>Allowable impairment: slight reading vision or vision corrected to log MAR 0,2; ability to control the device with one arm/one hand; average degree of short-term memory impairment related to aging; 40% impairment resulting in only 60% of normal hearing at 500Hz-2kHz. |
| | Patient | Any |
| | Place of Use | Hospital |
| Intended conditions of use | Environmental conditions | Indoor use;<br>Altitude: below 2,000 meters;<br>Transportation and storage: temperature -40℃~+70℃,<br>Relative humidity: 10%~85%, air pressure 500hpa~1060hpa;<br>Operation: temperature 10℃~40℃, relative humidity 30% ~ 75%, air pressure 700hpa~1060hpa;<br>Power supply: AC220V±10%, 50Hz±1Hz;<br>Input power: 1000VA;<br>It cannot be used in a strong electromagnetic environment, which may cause the product to fail to maintain the specified electromagnetic compatibility performance, thereby causing certain harm to the patient. When using, try to keep the device away from strong electromagnetic radiation device;<br>Ambient illumination range: 100 lx to 1 500 lx;<br>Observation distance: 40cm to 120cm;<br>Observation angle: perpendicular to the product marking surface ±30°;<br>Frequency of use: can be used multiple times a day;<br>Mobility: portable medical device. |

Graphics, symbols, and abbreviations on medical device labels

| No. | Graphics/ Symbols | Definitions | No. | Graphics/ Symbols | Definitions |
|---|---|---|---|---|---|
| 1 |  | Alternating current (AC) | 12 |  | Warning |
| 2 |  | Potential equalization | 13 |  | Ablation of coagulation |
| 3 |  | Disconnect the power | 14 |  | Vaporization resection |
| 4 |  | Switch on (power) | 15 |  | Buzzer |
| 5 |  | Defibrillator-proof BF type Applied parts | 16 |  | WARNING: Non-ionizing radiation |
| 6 |  | Electrode connection | 17 |  | Fragile items, please handle with care |
| 7 |  | Protective ground (earth) | 18 |  | Free of rain |
| 8 |  | Food Switch | 19 |  | Free of sun exposure |
| 9 | IPX8 | IPX8 Waterproof parts | 20 |  | This side Up |
| 11 |  | Pulse peak | 21 | SPINE CONCEPTS | Trade Mark |
| 12 |  | Follow the operating instructions | / | / | / |

## Cleaning, disinfection and sterilization

The power cord and plasma electrosurgical electrodes of this device are fumigated or soaked with disinfectant, or disposable plasma electrosurgical electrodes provided or recommended by the manufacturer are used.

The parts of plasma electrosurgical electrodes that come into contact with patients can be cleaned with mild detergents, and disinfected and sterilized according to the instructions for use of the accessories. After cleaning and before disinfection, check the electrical properties of the cable.

Special attention: It is strictly forbidden to disinfect with flammable and explosive liquids such as alcohol.

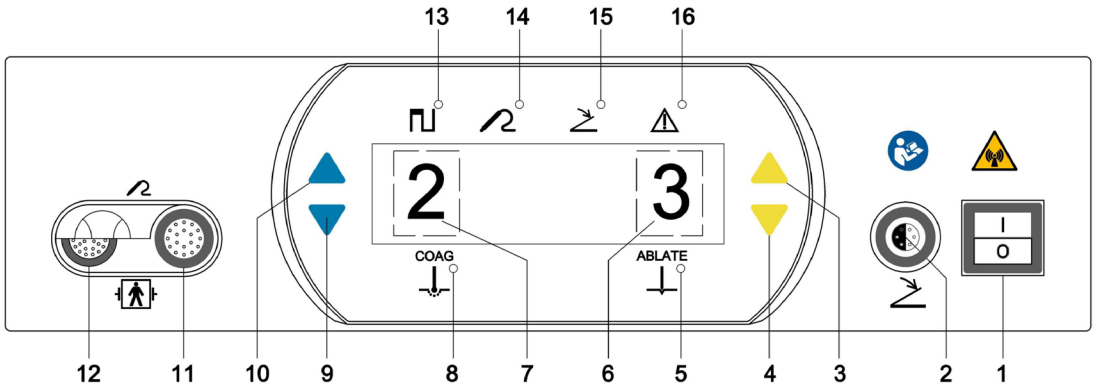
## Installation and use instructions or diagrams

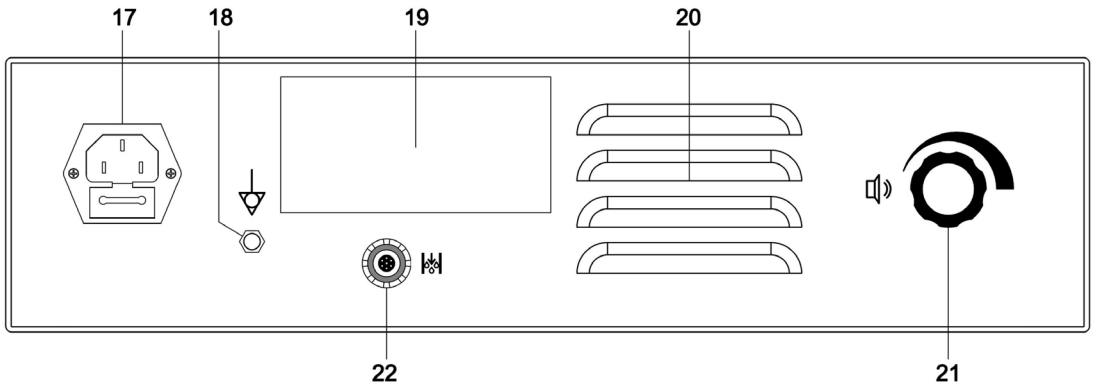
I. Preparation of the device before installation or use: before using this device, it is best to preheat it to make the high-frequency output power more stable.

**Warning** The product function can be activated by the plasma electrosurgical electrode in a saline environment.

The working part of the electrode glows orange and is accompanied by a "hissing" sound, indicating that high-frequency energy is being transmitted. Do not touch the skin or tissue during the test.

II. Installation and use instructions or diagrams of various specifications and models of the ArthroBlade® series plasma electrosurgical device:




1. Power switch
2. Foot switch socket
3. Vaporization resection setting up key
4. Vaporization resection setting down key
5. Vaporization resection indicator
6. Vaporization resection setting display bar
7. Ablation and coagulation setting display bar
8. Ablation and coagulation indicator
9. Ablation and coagulation setting down key
10. Ablation and coagulation setting up key
11. 18 coreElectrode socket

12. 27 coreElectrode socket
13. Pulse peak indicator
14. Electrode connection indicator
15. Foot switch connection indicator
16. device fault indicator
17. Power socket
18. Equipotential
19. device nameplate
20. Fan outlet
21. Volume adjustment knob
22. Fow controller connection socket

### 1. Power on

On the back panel of the plasma electrosurgical device, use the power cord to connect the power socket (Figure 17) and the grounded 220V main power supply, and turn it on by power switch on the front panel (Figure 1). The display on the front panel will have obvious instructions and the screen will light up.

### 2. Use of vaporization resection mode

Insert the sterilized plasma electrosurgical electrode and foot switch plug into the corresponding electrode socket (Figure 11 or Figure 12) and foot switch socket (Figure 2) respectively, and the electrode connection indicator (Figure 14) and foot switch connection indicator (Figure 15) will light up. Adjust the vaporization resection setting up key (Figure 3) and the vaporization resection setting down key (Figure 4) to the expected electrosurgical setting. Step on the yellow pedal of the foot switch to activate the device, and the plasma electrosurgical electrode can be used for the intended purpose.

### 3. Use of ablation and coagulation mode

Insert the sterilized plasma electrosurgical electrode and foot switch plug into the corresponding electrode socket (Figure 11 or Figure 12) and foot switch socket (Figure 2) respectively. The electrode connection indicator (Figure 14) and foot switch connection indicator (Figure 15) light up. Adjust the ablation and coagulation setting up key (Figure 10) and the ablation and coagulation setting down key (Figure 9) to the setting required for the expected surgery. Step on the blue pedal of the foot switch to activate the device, and the plasma electrosurgical electrode can be used for the intended purpose.

## III. Other Usage Information

Note: The foot switch is placed in front of the surgeon's feet. From the operator's perspective, the yellow pedal on the left controls the vaporization resection function, and the blue pedal on the right controls the ablation and coagulation function. When the yellow or blue pedal is pressed, the plasma electrosurgical device will be in the working state of vaporization resection or ablation and coagulation.

Note: The foot switch control and the reusable plasma electrosurgical electrode hand control switch can be used in the same electrosurgical process, but not at the same time

1. Vaporization resection setting value conversion button

Press the vaporization resection set value conversion button, the vaporization resection display bar number increases by 1, reaches the maximum set point, continue to press the button, the system will cycle back to set point 1.

2. Timer Icon

A plasma surgery electrode that limits the high frequency energy transmission time to a predetermined value is connected to the plasma surgery device.

3. Temperature monitor display


A plasma electrosurgical electrode with temperature monitoring function has been connected to the plasma electrosurgical device. If the measured temperature of the electrosurgical area exceeds the alarm set point, the auditory and visual alarms are activated.

## 4. Use of the flow controller

4.1. The flow controller and the host are connected with a connecting wire. Please note that the arrow is aligned with the groove. After connecting, turn on the power switch of the device.
4.2. Turn on the switch on the flow controller, the green indicator light turns on, and the mechanism of the flow limiting valve pops open, leaving a gap for the infusion tube to be stuck.
4.3. Insert the infusion tube into the flow limiting valve, press the switch on the panel again, and the infusion tube is stuck.
4.4. During the operation, the flow controller and the main units are interacted to control the opening and closing of the infusion tube through the foot switch.

## IV. Shutdown

1. After the operation, turn off the power switch and unplug the power plug.
2. Clean the used device and accessories according to regulations.

## Product maintenance and care methods, special storage, transportation conditions and methods

1. Environmental conditions:
   1.1. The ambient temperature for product transportation and storage: -40℃～55℃, relative humidity is 10%～100%, and air pressure is 500hpa～1060hpa;
   1.2. During transportation, the product should take measures such as anti-fouling, moisture-proof, fire-proof, rain-proof, sun-proof, and anti-extrusion. The product should be stored in a clean room without corrosive gas, cool, dry and well-ventilated.
2. Maintenance and care methods for device, accessories and components:
   2.1. Main Unit: the main unit itself does not require special maintenance, except for regular cleaning of the chassis and front panel, which can be done with gauze dipped in alcohol. Regular inspection of electrical performance by the manufacturer or authorized agency (once a year) can increase the service life of plasma electrosurgical device.

2.2. Foot switch: It can be cleaned in the same way as the generator, for example, the cable can be checked for damage with a multimeter.
2.3. Flow controller: It can be cleaned in the same way as the generator.

1. Note: If the humidity is too high or it comes into contact with corrosive liquid, the main unit jack may rust and should be replaced regularly. When replacing accessories, use products provided or recommended by the manufacturer.
2. When maintaining the plasma electrosurgical device, it is strictly forbidden to disassemble, replace components or clean when power on, If you have any questions about the device, please contact the manufacturer for service.
5. The only interchangeable or removable parts of this device are fuses and power cords. Their replacement should be performed by professional maintenance personnel authorized by the manufacturer. The model of the replacement fuse is T4A, 250VAC, and the model of the power cord is AC250V 10A.
6. If the following adverse conditions occur, you must contact the after-sales service center for repair:
   6.1. The up and down key switches of the adjustment controller are broken, which will cause the power setting to be unable to adjust.
   6.2. If the screen displays a broken code or is not bright, the device will cause a display error.

## Fault analysis and troubleshooting

| Fault | Symptom | Fault Analysis and Troubleshooting |
|---|---|---|
| Unable to be powered on | No display on the panel | 1. Is the power supply voltage 220V±22V?<br>2. Is the power cord broken?<br>3. Is the fuse blown? |
| No output | The electrode tip is immersed in saline and no energy output after a period of normal startup. | 1. Carefully check whether the metal part of the blade is in contact with the test tissue or the wall of the saline bottle at the same time;<br>2. Check whether the blade, handle connection, and foot pedal connectors are correctly connected to the host;<br>3. When it is confirmed that there is no problem with the accessories (replace other handle connections, electrodes and other accessories and test again), it can be determined that the host has a low power output fault, and you should contact our after-sales service in time. |

## Fault Code definition

| Fault Code | Definition | Remarks |
|---|---|---|
| E1 | Press both ABLATE/COAG buttons simultaneously | ABLATE and COAG are simultaneously activated |
| E2 | Electrodes disconnected when device activated | Electrode error |
| E3 | The usage limit time has expired | Electrode error |
| E4 | Electrode short circuit | Electrode short circuit |
| E5 | Reused electrode detected | Electrode error |
| E6 | Thermocouple Open Circuit | Thermocouple open circuit |
| E7 | Reused electrode detected | Electrode error |
| E8 | When the device is on, reusable electrodes are connected | Electrode error |
| F1 | The integrity of the stored procedure is compromised | Hardware failure |
| / | Chip memory failure | The screen cannot display information |
| F3 | System control failure | Hardware failure |
| F4 | Internal power failure | Hardware failure |
| F5 | Internal electronic component failure | Hardware failure |
| F6 | Footswich, fingerswitch or front panel switch pressed during power on | Switch stuck |
| F7 | Over temperature of internal electronics | Internal over-temperature |

## Company Statement

1. The manufacturer can only be responsible for the safety, reliability and characteristics of the plasma electrosurgical device and accessories under the following circumstances:
   1.1. Repairs, modifications and internal adjustments shall be carried out by personnel authorized and approved by the manufacturer.
   1.2. The electrical installation of the device used indoors shall comply with national standards. The use of the device (including accessories) should be combined with the manufacturer's recommended instructions.
2. The manufacturer may provide circuit diagrams, component lists, legends, correction details, or other information that helps maintenance personnel repair device parts that can be repaired by maintenance personnel designated by the manufacturer upon request.

## Description of Electromagnetic Compatibility

Information about EMC Compliance IEC/EN60601-1-2:2007,MOD

Warning

1. This device may affect other medical electrical device. Purchasers or users must install and use it according to the information about EMC Compliance IEC/EN60601-1-2:2007,MOD provided in the instruction manual.
2. Portable and mobile radio frequency communication device may affect the use of medical electrical device.
3. Except for the cables sold by our company as spare parts for internal components, the use of accessories and cables other than those specified may lead to an increase in the emission of plasma electrosurgical device or a decrease in immunity. The device produced by our company may use bipolar electrosurgical electrodes with cables, and the cable length should not exceed 3m. If these devices are used, they should comply with the requirements of IEC/EN60601-1-2:2007,MOD.
4. The device should not be used close to or stacked with other device. If it must be used close to or stacked, it should be observed and verified that it can operate normally under the configuration it is used in.
5. The device generates the radio frequency energy, it is recommended that other device shall be kept as far away as possible;
6. Each transmission frequency of the plasma electrosurgical device: 100kHz, modulation type: amplitude modulation, frequency characteristics: self-excited oscillation.
7. Requirements for cables and other accessories. The device contains foot switches and flow controllers which are in according to requirements of IEC/EN60601-1-2:2007,MOD. The length of cable cord on foot switches and flow controllers shall be less than 3meters.
8. Basic performance of the product: Set the vaporization resection power to 0~380W (≤±20%), and set the ablation coagulation power to 0~45W (≤±20%).
9. The device should be kept away from other devices or avoided being used simultaneously with other devices, and refer to the Precautions, Warnings and Safety Instructions in the user manual of this product to resolve the harmful electromagnetic effects on other devices caused by the use of this device or system.
10. For the guidelines and the company's statement, please refer to EMC Table 1-Table 4:

EMC Table 1 Guidelines and our company's declaration - Electromagnetic emissions

Plasma electrosurgical device is intended to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in this electromagnetic environment.

| Emission Testing | Compliance | Electromagnetic environment - Guidance |
|---|---|---|
| RF Transmission IEC/ EN55022 | 1 Group | Plasma electrosurgical device must emit electromagnetic energy to perform its intended function. Nearby electronic device may be affected, Group 2 device. According to IEC/EN60601-1-2:2007,MOD: Plasma electrosurgical device is powered on but the output is not excited, which meets the Group 1 limit requirements. |
| RF Transmission IEC/ EN55022 | Class A | The plasma electrosurgical device is suitable for use in all establishments other than domestic and not directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes! |
| Harmonic emission EN 61000-3-2:2009 | Not applicable | |
| Voltage fluctuation/ flicker emission IEC/ EN 61000-3-3 | Not applicable | |

EMC Table 2 Guidance and our company's declaration - Electromagnetic immunity

The plasma electrosurgical device is intended to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in this electromagnetic environment.

| Immunity test | IEC/EN 60601 test levels | Comply with level | Electromagnetic environment - Guidance |
|---|---|---|---|
| Electrostatic Discharge IEC/EN61000-4-2 | ±6 kV Contact discharge ±8 kV Air discharge | ±6 kV Contact discharge ±8 kV Air discharge | Floors should be wood, concrete or tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical Fast Transient Burst IEC/EN 61000-4-4 | ±2 kV for power cable ±1 kV for input and output cable | ±2 kV for power cable, not applicable | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC/EN61000-4-5 | ±1 kV Line to line ±2 kV cable to ground | ±1 kV Line to line ±2 kV cable to ground | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on the power input line IEC/EN61000-4-11 | < 5% UT for 0.5 cycle (>95% dip in UT) 40% UT for 5 cycle (60% dip in UT) 70% UT for 25 cycle (30% dip in UT) < 5% UT for 5 s (>95% dip in UT) | < 5% UT for 0.5 cycle (>95% dip in UT) 40% UT for 5 cycle (60% dip in UT) 70% UT for 25 cycle (30% dip in UT) < 5% UT for 5 s (>95% dip in UT) | Mains power quality should be that of a typical commercial or hospital environment. If the user of the plasma electrosurgical device requires continued operation during mains power interruptions, it is recommended that the plasma electrosurgical device be powered from an uninterruptible power supply or a battery. |
| Power Frequency Magnetic | 3A/m | 3A/m | If the output power exceeds ±20% of the specified value, it may be necessary to move the plasma electrosurgical device away from the power frequency magnetic field source or install magnetic shielding. The power frequency magnetic field in the intended installation location should be measured to ensure that it is sufficiently low. |

Note: UT refers to the AC mains voltage before the test voltage is applied.

EMC Table 3 Guidance and manufacturer's declaration - Electromagnetic immunity

The device is intended to be used in the electromagnetic environment specified below

| Immunity test | IEC/EN 60601 test levels | Comply with level | Electromagnetic environment - Guidance |
|---|---|---|---|
| Radio Frequency Conduction IEC/EN61000-4-6<br>Radio Frequency Radiation IEC/EN61000-4-3 | 3V (effective value)<br>150 kHz~80 MHz<br>3V/m<br>80 MHz~2.5 GHz | 3 V (effective value)<br>3V/m | Portable and mobile RF communications device should not be used closer to any part of the plasma electrosurgical device, including cables, than the recommended separation distance. This distance should be calculated using the equation appropriate to the frequency of the transmitter. Recommended separation distance<br><br>d =1.2 √P<br>d =1.2 √P 80 MHz~800 MHz<br>d =2.3 √P 800 MHz~2.5 GHz<br><br>Where:<br>P - the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W);<br>d - the recommended isolation distance, in meters (m).<br>The field strength of the fixed RF transmitter is determined by an electromagnetic field survey a and should be lower than the compliance level in each frequency range b. Interference may occur in the vicinity of device marked with the following symbol.<br>  |

Note 1: At 80MHz and 800MHz, the formula for the higher frequency band is used.

Note 2: These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption
and reflection from structures, objects and people.

a The field strengths of fixed transmitters, such as base stations for wireless (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 where the plasma electrosurgical device is located exceeds the
applicable RF compliance level above, the plasma electrosurgical device should be observed to verify normal operation. If
abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the plasma
electrosurgical device.
b Field strengths should be less than 3V/m over the entire frequency range of 150 kHz to 80 MHz.

EMC Table 4 Recommended isolation distances between portable and mobile RF communication device and plasma electrosurgical device

The plasma electrosurgical device is intended for use in an electromagnetic environment in which RF radiated disturbances are controlled. The purchaser or user of the plasma electrosurgical device can prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications device (transmitters) and the plasma electrosurgical device, depending on the maximum output power of the communications device.

Isolation distance corresponding to different transmitter frequencies/m

| The maximum rated output power of the transmitter W | 150 MHz~80 MHz d =1.2√(P) | 80 MHz~800 MHz d =1.2√(P) | 800 MHz~2.5 GHz d =2.3√(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 with a maximum rated output power not listed in the table above, the recommended separation distance \(d_i\) in meters (m), can be determined using the formula in the corresponding transmitter frequency column, where P is the transmitter's maximum rated output power in watts (W) provided by the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the formula for the higher frequency band should be used.

Note 2: These guidelines may not be appropriate in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

| | |
|---|---|
| Product number | See the device nameplate |
| Production date | See the device nameplate |
| Production batch number | See the device nameplate |
| Expiration date | See the device nameplate |

Accessories list

| No. | Item Name | Model No. | Quantity | Remarks |
|---|---|---|---|---|
| 1 | Food Switch | 4077-290-090-1 | 1 | |
| 2 | Power Cord | 10A AC 250V | 1 | |
| 3 | Flow Controller | L-01 | 1 | Optional |
| 4 | User Manual | / | 1 | |

Production License Number
Su Food and Drug Administration Machinery
Production License No. 20100078

Medical Device Registration Certificate Number
National Machinery Registration Approval 20153012254

Manual Version Number A/0

Manual Revision Date 2024.06.10

Impedance Characteristic Curve
Maximum Output Voltage and Power Setting Diagram

# SPINEX 9000

## USER MANUAL

SPINE CONCEPTS®

07/2025 110011 REV.1.0

SPINE CONCEPTS®

251 Little Falls Drive
Wilmington, DE 19808, USA

Phone: (302) 202-9212

Toll free: (888) 368-0323