genii®
generating ingenuity

ArC Smart™ Probe

Argon coagulation probe for flexible endoscopy

SYMBOLS

The meaning(s) of the symbols shown on the package and/or this device are as follows:

REF

R_x ONLY

Read Instructions Before Use

Do Not Reuse; Single Use Only

Do Not Resterilize

STERILE EO — Sterile, ETO

Do Not Use Beyond Expiration Date

Do Not Use if Packaging is Damaged or Opened

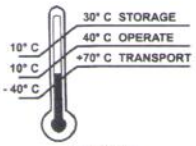
Manufacturer

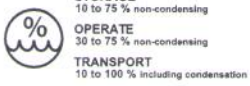
LOT — Lot Number

Date of Manufacture

Type CF Equipment

Not Made With Natural Rubber Latex





SIGNAL WORDS

WARNINGS:

INDICATES A POTENTIALLY HAZARDOUS SITUATION WHICH, IF NOT AVOIDED, COULD RESULT IN DEATH OR SERIOUS INJURY.

CAUTIONS:

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

This device is rated at 5400Vpeak

SAFETY

Indications For Use

The ArC Smart™ Probe is indicated for argon enhanced coagulation of tissue.

Operating Principal

99.99% argon gas is advanced through a tube. Concurrently, RF energy is delivered by wire to an electrode at the distal tip of the tube. Gas passing over the electrode is ionized. The ionized gas forms a noncontact pathway for the delivery of energy to the tissue surface to create therapeutic coagulation.

WARNINGS:

THE USE OF FLAMMABLE ANESTHETICS OR OXIDIZING GASES SHOULD BE AVOIDED WHEN USING THIS DEVICE.

BEFORE USING ANY ELECTROSURGERY, BE SURE THAT THERE ARE NO ENDOGENOUS EXPLOSIVE GASES PRESENT IN THE LUMEN OF THE SUBJECT ORGANS.

BE AWARE OF THE DANGER OF FIRE IN THE TRACHEOBRONCHIAL SYSTEM. THE ARGON COAGULATION PLASMA BEAM MAY CAUSE HIGHLY FLAMMABLE, COMBUSTIBLE MATERIALS TO BURN. EXAMPLES OF COMBUSTIBLE MATERIALS ARE PLASTIC INSULATION AT THE DISTAL END OF THE BRONCHOSCOPE AND A TRACHEAL TUBE. HOWEVER, IGNITION CAN ONLY OCCUR IF THERE IS ALSO A FIRE-SUPPORTING GAS SUCH AS OXYGEN PRESENT. THIS PARTICULARLY APPLIES TO BRONCHOSCOPIC TREATMENTS IN THE PRESENCE OF HIGHLY CONCENTRATED OR PURE OXYGEN. FOR THIS REASON IT IS ESSENTIAL TO FOLLOW THESE RULES:

- BEFORE AND DURING THE PROBE ACTIVATION, NEVER INTRODUCE OXYGEN TO THE TRACHEO BRONCHIAL SYSTEM. THIS ALSO APPLIES TO OTHER COMBUSTIBLE OR FIRE-SUPPORTING GASES OR LIQUIDS.
- IF ARGON COAGULATION THERAPY IS TO BE APPLIED FOR MORE THAN A FEW SECONDS, APPLY THE OXYGEN AND ACTIVATE THE PROBE ALTERNATELY.

THIS DEVICE IS INTENDED FOR SINGLE USE ONLY. THE PRODUCT AND THE PACKAGING HAVE NOT BEEN DESIGNED OR TESTED FOR REUSE. ATTEMPTS TO CLEAN AND RE-STERILIZE THIS DEVICE AND SUBSEQUENTLY REUSE MAY ADVERSELY AFFECT THE CLINICAL PERFORMANCE, SAFETY AND/OR STERILITY OF THE DEVICE.

THESE INSTRUCTIONS FOR USE ARE NOT A SUBSTITUTE FOR THE OPERATING INSTRUCTIONS/USER MANUAL OF THE ARGON EQUIPPED ELECTROSURGERY GENERATOR BEING USED WITH THIS PROBE. USERS MUST ALSO READ AND UNDERSTAND THE OPERATING INSTRUCTIONS PROVIDED WITH THE ARGON EQUIPPED ELECTROSURGERY GENERATOR TO BE USED.

FOR PATIENTS WITH PACEMAKERS OR OTHER ACTIVE IMPLANTS, A POTENTIAL HAZARD EXISTS DUE TO INTERFERENCE WITH OR DAMAGE TO THE ACTIVE IMPLANT. FOLLOW FACILITY GUIDELINES FOR PATIENTS WITH IMPLANTED DEVICES AND CONSULT WITH CARDIOLOGY AND/OR THE MANUFACTURER OF THE IMPLANTED DEVICE BEFORE USING THIS DEVICE ON THE PATIENT.

NEVER ACTIVATE THE ARGON PROBE WHEN THE OPEN TIP IS IN DIRECT CONTACT WITH THE TISSUE AS THIS MAY CAUSE A MILD EMPHYSEMA OR EMBOLISM AND MAY INCREASE THE RISK OF PERFORATION.

THE DISTAL END OF THE PROBE MUST ALWAYS BE WITHIN THE FIELD OF VIEW OF THE ENDOSCOPE BEFORE AND DURING ACTIVATION. NEVER ACTIVATE THE PROBE WITHOUT FIRST VISUALIZING THE TARGET TISSUE.

TO AVOID RISK OF ELECTRIC SHOCK, THIS DEVICE MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH.

WHEN IN USE, THE TEMPERATURE OF THE PROBE CAN EXCEED 41° C. THERE IS A POTENTIAL FOR UNINTENDED SURGICAL SITE BURNS DUE TO DIRECT CONTACT WITH THE PROBE.

AFTER USE, THIS PRODUCT MAY BE A POTENTIAL BIOHAZARD. HANDLE AND DISPOSE OF IN ACCORDANCE WITH ACCEPTED MEDICAL PRACTICE AND APPLICABLE LOCAL, STATE AND FEDERAL LAWS AND REGULATIONS.

CAUTIONS:

Argon coagulation therapy should be used only by endoscopists experienced in argon coagulation techniques and safety.

Be sure to use care when using argon coagulation therapy near metal devices such as stents or clips.

To reduce the potential of gas emphysema or embolism, use the minimum argon gas flow rate that will support the arc beam and achieve the appropriate clinical effect.

Do not touch the probe tip, or touch it to tissue immediately after it has been activated as the tip may be hot.

Do not activate probe until it is at least 4mm forward from the tip of the endoscope and clearly visible.

Do not exceed the maximum electrical capacity for the ArC Smart Probe.

The use of high frequency electrosurgical units, with or without argon capability, may cause interference with other devices and video endoscopic equipment.

Do not insert or retract the probe in a duodenoscope with the elevator in the up position.

Electrosurgical accessories constitute a potential electrical hazard to the patient or operator.

Be sure that the proper path from the patient return electrode to the electrosurgery unit is maintained throughout the procedure.

Be sure to use proper accessory passing technique, and short forward strokes, to avoid kinking while introducing the probe into the endoscope accessory channel.

PRE-CAUTIONS:

Inspect all devices prior to use.

Do not use this device if there is detectable handling or shipping damage.

Do not use any sterile device beyond its expiration date.

Never modify the probe tip in anyway. Doing so will void all warranties and may be unsafe.

Use this probe only with properly equipped argon capable electrosurgical generators that meet or exceed all appropriate IEC 60601-1 Standards.

Ex Vivo Argon Coagulation Zone Width Measurement in Two Tissue Types (Average Measures at Two Watt Settings)

	Bovine Liver	Porcine Kidney
45 watts	5.56 mm	4.88 mm
60 watts	5.99 mm	5.73 mm

Probe Configurations:

Reference Number	Outer Diameter	Length	Min. Scope Channel	Max Watts
G11-400-01	2.3mm	220cm	2.7mm	90 Watts
G11-400-02	2.3mm	320cm	2.7mm	90 Watts
G11-400-03	3.2mm	220cm	3.6mm	90 Watts

The chart above shows the suggested Genii gi4000 wattage maximum for each probe size. Follow all appropriate instructions for use provided with the gi4000. Use the minimum wattage and flow rate for the desired tissue effect and the maintenance of an argon coagulation plasma beam sufficient to apply non-contact therapy. The physician is responsible for choosing the appropriate settings to treat a patient. This determination is based upon the physician's preference and technique as well as the patients size, condition, age, etc. and the desired outcome of the planned treatment.

INSTRUCTIONS FOR USE

Before you begin:

1. Be sure to check the compatibility of the endoscope channel with the package label for the ArC Smart™ Probe.
2. Inspect the package for damage that may have occurred during transit or handling. If damaged, do not use.
3. Use aseptic or appropriate clean techniques when removing the device from the package and inspecting for damage.
4. Inspect the ArC Smart™ Probe, including the tip, and do not use if cracked, sharp or damaged in any way.

Connection to the Genii gi4000 using the Genii single use ArConnect®:

1. Inspect the ArConnect® for damage.
2. Inspect the ArC Smart™ Probe for damage.
3. First remove the ArConnect® from the package and insert the distal connector into the gi4000 per the generator Operation and Maintenance Manual and the instructions for use provided with the ArConnect®. Ensure a complete connection.
4. Remove the ArC Smart™ Probe and connect the distal connector of the probe to the proximal end of the ArConnect®. Ensure a complete connection.
5. Be sure that the patient is properly connected to a return electrode (grounding pad).
6. Activate the purge button on the gi4000 to fill the connected devices with argon gas.

Insertion into the endoscope:

1. Insert the ArC Smart™ Probe into the endoscope instrument channel using short strokes until the distal tip appears in the field of view. A minimum distance of 4mm protruding from the endoscope is recommended.

The device is ready for activation.

After use:

Discard both the ArConnect® and the ArC Smart™ probe using proper disposal technique.

WARNING:

THIS PRODUCT MAY BE A POTENTIAL BIOHAZARD. HANDLE AND DISPOSE OF IN ACCORDANCE WITH ACCEPTED MEDICAL PRACTICE AND APPLICABLE LOCAL, STATE AND FEDERAL LAWS AND REGULATIONS.

Environmental Conditions:

Operating Environmental Conditions	Storage Environmental Conditions	Transport Environmental Conditions
Ambient Temp: +10°C to +40°C	Ambient Temp: +10°C to +30°C	Ambient Temp: -40°C to +70°C
Relative Humidity: 30% to 75%, non-condensing	Relative Humidity: 10% to 75%, non-condensing	Relative Humidity: 10% to 100%, including condensation
Atmospheric Pressure: 70kPa to 106kPa	Atmospheric Pressure: 50kPa to 106kPa	Atmospheric Pressure: 50kPa to 106kPa