IMPORTANT

The Biovision SurgAssist™ Insufflator/Electrosurgical Generator has been designed to facilitate non and minimally invasive diagnostic and therapeutic procedures. It should be used only for those procedures and only by personnel who are trained to perform them.

This manual describes the recommended procedures for preparing and operating the SurgAssist™. It does not describe how any medical procedure is to be performed on a patient with this instrument.

Read all instructions in this manual carefully before using the SurgAssist™ on patients.

Carefully follow all safety instructions to prevent fire, electrical shock, damage to this device, and injury to user and patient.

To maintain this device in optimal condition, follow all recommendations in this manual for its handling, cleaning, and storage.

This equipment is strictly for veterinary use.
1. Introduction
Thank you for your purchase of the SurgAssist™ Combination Insufflator and Electrosurgical Generator (IEG) from Biovision Veterinary Endoscopy, LLC.

1.1 The SurgAssist™ Insufflator and Electrosurgical Generator

The SurgAssist™ system integrates two essential surgical and diagnostic needs into a single compact & portable package:

*Insufflation System*

The SurgAssist™ Insufflator is specifically designed to fulfill all requirements for laparoscopic CO₂ insufflation. It offers all essential functions needed for minimally invasive surgical procedures, along with Biovision Veterinary Endoscopy’s signature “ease of use.”

*Electrosurgical Generator*

The SurgAssist™ Electrosurgical Generator is specifically designed for cutting and coagulating using high-frequency RF currents. It offers all essential functions for everyday clinical practice. Both monopolar and bipolar outputs are available to suit various therapeutic situations.
1.2 Regulatory Compliance Info, Disclaimers, etc.

This device has been tested and found to comply with the limits for a class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interferences in a residential installation.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio or television reception. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause interference to radio and television reception, which can be determined by turning the equipment on and off, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that which the receiver is connected.

This apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus as set out in the radio interference regulations of Industry Canada.
1.3 Warranty Information

The Biovision Veterinary Endoscopy SurgAssist™ Insufflator and Electrosurgical Generator (IEG2000), when delivered to you in new condition in the original container, is warranted to be free from defects in material or workmanship for one year from the date of shipment to you by the distributor, upon proof of date. Within this time period, parts that are returned, freight prepaid, to Biovision Veterinary Endoscopy, LLC (“Biovision”) and are determined by Biovision to be defective will be repaired or replaced by Biovision without charge for parts, labor, or return ground shipping costs. Biovision will make every effort to accomplish this repair or replacement within a reasonable time. After the warranty period, you must pay all charges for repair and replacement. This warranty does not cover light bulbs or other consumable items.

The above actions by Biovision shall constitute your exclusive remedy and Biovision's sole obligation under this warranty. Biovision shall not be responsi-ble for warranty claims made after the warranty period. To obtain warranty repair service, you must contact Biovision to obtain a Return Material Authorization (“RMA”) number, then return the product, freight prepaid, to Biovision or to a service facility authorized by Biovision. The RMA number and a complete explanation of the problem must be includ-ed with the product being returned to Biovision for warranty service. The product to be repaired must be returned in its original box and packaging, or a similar box and packaging affording an equivalent degree of protection. Upon completion of repairs, Biovision will return the product to you, freight prepaid.

The warranty period for replacement parts shall begin upon ship-ment of same, but shall in no event exceed the warranty period of the defective part. Biovision shall have no liability or obligation for a product that has been subjected to any of the fol-lowing: improper use, abuse, negligent care or handling, accident, faulty installation, improper cleaning, improper maintenance, lightning or other indications of excess voltage. This warranty is also void if the product has been repaired or modified without prior written authorization from Biovision, if the end-user has failed to follow the instructions or heed the warnings or specifications in the Operation and Care Manual, or if the product’s serial number has been altered or removed.
EXCEPT FOR THE FOREGOING WARRANTIES, BIOVISION HEREBY DISCLAIMS AND EXCLUDES ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY AND/OR ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. BIOVISION HEREBY DISCLAIMS ANY REPRESENTATIONS OR WARRANTY THAT THIS PRODUCT OR ANY OF ITS PARTS IS COMPATIBLE WITH NON-BIOVISION PRODUCTS OTHER THAN VIDEO EQUIPMENT ATTACHED TO ITS VIDEO OUTPUTS, AS DESCRIBED IN THE OPERATOR’S MANUAL. THE LIABILITY OF BIOVISION, IF ANY, AND PURCHASER’S SOLE AND EXCLUSIVE REMEDY FOR DAMAGES FOR ANY CLAIM OF ANY KIND WHATSOEVER, REGARDLESS OF THE LEGAL THEORY, SHALL NOT BE GREATER IN AMOUNT THAN THE PURCHASE PRICE OF THE PRODUCT SOLD BY BIOVISION THAT CAUSED ANY ALLEGED DAMAGE. IN NO EVENT SHALL BIOVISION BE LIABLE TO PURCHASER FOR ANY SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OF ANY KIND.
1.4 How to Use This Manual
The intention of the document is to convey the proper and prescribed operation and care of the SurgAssist™ IEG2000 Insufflator/Electrosurgical Generator

1.5 Manual Conventions

This manual adheres to a set of conventions to help you easily find the information you need and inform you of important information that will help you efficiently and effectively use your equipment.

Sections and sub sections are noted as follows:

1. Section Title

1.1 Subsection title

Special and important information is called out using notes and warnings. Notes usually pertain to a recommended protocol that will help extend the life of your equipment. Warnings pertain to protocols that delineate appropriate actions which maintain a safe and healthy work environment.

Notes and warnings are called out in the following manners:

Note: This is a note.

WARNING: This is a warning.
2. Product Specifications
The following section describes the components and features of the SurgAssist™ system.

2.1 Contents
The following components are included in your SurgAssist™ system:

- SurgAssist™ Insufflator/Electrosurgical Generator
- Medical Grade Power cord
- Hoses
  - 1 CO2 input hose
  - 1 CO2 output, insufflation hose
- Saddle and regulator for “E” tank
- Footswitch
- Patient Grounding Plate

Check to see that you have all of these components before proceeding. If any of these components are missing, contact Biovision immediately using the contact information below.

Biovision Veterinary Endoscopy, LLC
2525 15th St., Ste. 1A
Denver, CO 80211

Phone: 303.225.0960
Fax: 720.259-5235
2.2 Features and Specifications

2.2.1 Features

Front - Insufflator

- Patient Pressure Gauge
- Flow Rate Gauge
- Liters Delivered Gauge (Gas Gauge)
- Auto/Manual flow switch
- Fill Button
- Insufflation On/Off Switch

Front - Electrosurgical Generator

- Bipolar Mode Indicator
- Bipolar Power Level
- Mode Selector
- Monopolar Mode Indicator
- Monopolar Power Level
- Monopolar Output
- Patient Plate Connectors
- Waveform Selector
- System Power Indicator
- Bipolar Output
**Insufflator Item Description**

- **Patient Pressure Gauge**: Pneumoperitoneum in mmHg.
- **Flow Gauge**: Rate of CO2 release to patient.
- **Liters Delivered**: Remaining capacity of internal tank.
- **Auto/Manual Flow Switch**: CO2 flow to patient.
- **Fill Button**: Refills internal tank from “E” tank (applies only to Manual flow).
- **Insufflation On/Off**: Turns insufflation output on or off.
- **Insufflation Output**: Connects to patient via insufflation hose.

**Electrosurgical Generator Item Description**

- **Bipolar Mode Indicator**: Indicates the bipolar mode is selected.
- **Bipolar Power Level**: Controls bipolar output power.
- **Mode Selector**: Selects between Monopolar and Bipolar.
- **Monopolar Mode Ind.**: Indicates the monopolar mode is selected.
- **Monopolar Power Level**: Controls monopolar output power.
- **Monopolar Output**: Connects to monopolar handpiece.
- **Patient Plate Connectors**: Connect to patient plate.
- **Waveform Selector**: Selects Cut, Blend or Coag waveform.
- **System Power Indicator**: Lights when system power is on.
- **Bipolar Output**: Connects to bipolar handpieces.

**Rear Item Description**

- **Footswitch Connector**: Snap connector for footswitch.
- **CO2 Input**: Snap connector for hose from CO2 “E” tank.
- **Patient Pressure Select**: Selects high or low patient pressure.
- **Pressure Level Indicator**: Bypasses over/under pressure indicators.
- **System Power Switch**: Turns the SurgAssist™ unit on and off.
- **System A/C Input**: Connects to wall A/C via medical grade cord.
2.2.2 Technical Specifications

General

Operating conditions: 10º to 40º C
0 to 90% relative humidity, non-condensing.

Shelf conditions: -10º to 50º C
0 to 90% relative humidity, non-condensing

Dimensions: 15”W x 12”L x 6”H

Weight: 22 lbs (9.43 kg)

Electrosurgical Generator

Main voltage 115/230 VAC 50/60 Hz nom.
Input Connection IEC filtered and fused.
Classification I
Type CF (IEC60601-1)

HF Output

Waveform: Sinusoid
Operating Frequency 1.7 MHz
Stability +/- 0.2 MHz

<table>
<thead>
<tr>
<th>Cut (W max)</th>
<th>Blend (W max)</th>
<th>Coagulation (W max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monopolar</td>
<td>100</td>
<td>90</td>
</tr>
<tr>
<td>Bipolar</td>
<td>70</td>
<td>63</td>
</tr>
</tbody>
</table>

Maximum open-circuit voltage

Monopolar mode 2000Vp-p
Bipolar mode 600Vp-p

Insufflator

Insufflation medium Medical CO2
Max. gas supply pressure 3000psi (into tank regulator)
Regulated supply pressure 50psi (into insufflator unit)
Nominal output pressure High 12mmHg; Low 7mmHg
Maximum output pressure High 15mmHg; Low 8mmHg
Overpressure indicator ~20mmHg
Underpressure indicator ~5mmHg
Maximum gas flow ~5 l/min
Output connection Male barb for 1/8” ID hose
It is important that you read, understand, and comply with all of the following safety precautions.

Failure to follow these precautions could result in injury to the patient or user, or damage to the SurgAssist™ unit.

2.3.1 General Safety Information

Keep the SurgAssist™ unit on a flat, level, and secure surface.

Be sure to leave sufficient clearance for ventilation by not placing any other equipment or objects on, in front of, or near the vents on either side of the SurgAssist™ unit.

Do not set the SurgAssist™ on another soft or otherwise smothering surface such as clothing, fabric or towels. This will interfere with the unit’s ability to cool itself.

Do not allow liquids on the SurgAssist™ unit.

Only use medical-grade power cords and power outlets with the SurgAssist™ unit.

Be sure to sterilize the hoses and all parts of the SurgAssist™ unit that come in contact with patients using the sterilization procedures described in this manual.

Always disconnect the SurgAssist™ unit from its power source when performing maintenance (e.g. cleaning, replacing fuses, etc.).
2.3.2 Insufflator Safety Information

**WARNING:** The CO₂ gas in an “E” tank is under extremely high pressure. Follow all prescribed procedures for handling high pressure CO₂ tanks. These can be obtained by your gas vendor.

*Note:* Use caution when disconnecting the CO₂ supply hose from the rear of the SurgAssist™ unit. The pressure in the use may cause the hose to eject from the SurgAssist™ connector with unexpected force.

When the procedure is finished, close the top valve on the “E” tank to prevent leaking of the gas.

*Note:* If taking the SurgAssist™ unit on an airplane, be sure to empty the internal tank by leaving the Power switch ON.

2.3.3 Electrosurgical Generator Safety Information

When performing monopolar electrosurgery, be sure to place a grounding plate on or under the patient before starting any procedure. Failure to do this can cause excessive burning of patient tissue.

**WARNING:** The grounding plate cannot come in contact with the operating table or any other metal object. If the grounding plate does contact any metal, it can seriously injure or electrocute the patient.

Always ensure that all connections to the electrosurgical generator are secure and free from debris and any standing or condensing moisture.

3. Setup and Basic Usage
The following section describes how to set up and use the SurgAssist™ system for most basic surgical procedures.

3.1 System Setup
Start by placing the SurgAssist™ unit on a flat, level, and secure surface.

Be sure to leave sufficient clearance (at least 4 inches) for ventilation by not placing any other equipment or objects on, in front of, or near the vents on the SurgAssist™ unit. Do not set on any soft or conforming material such as towels or drapes that
will block ventilation to the bottom of the unit. Ensure the footswitch is connected to the rear of the unit. The “L” shaped connector will point out, away from the label on the rear of the unit.

Connect the medical-grade power cord for the SurgAssist™ unit to an outlet that has also been approved for medical use.

Turn on the SurgAssist™ unit by turning the Power switch on the rear of the SurgAssist™ unit to “On.” The power light under the waveform selector on the front of the generator should be illuminated at this point.

3.1.1 Insufflator Setup Information

Assemble the regulator and CO2 supply hose. One end of the supply hose has a quick connector (white tip and O-ring). The other end has a large nut for connecting to the regulator. Thread this nut connector onto the regulator being careful not to cross-thread the nut. Cross-threading can produce a CO2 gas leak. Snug the connection with two wrenches. Do not over tighten.

Connect the regulator to the external “E” CO2 tank. Examine the valve at the top of the “E” tank. The square area on the valve should have two opposing smooth sides and one side with three holes and one side with a divot. Hold the regulator so that the pressure gauge is up and slide the saddle over the valve lining up the saddle’s “T” knob with the divot and the two pins on the opposite side fit into the bottom two holes. Push the saddle into the side with three holes and tighten the “T” knob into the divot. The “T” knob may need further tightening if CO2 leaks when the “E” tank valve is opened.

Connect the quick connect end of the supply hose to the CO2 input on the back of the SurgAssist™ (see page 15). The tab on this outlet will pop up in order to lock the hose in place. (If you encounter difficulty connecting the hose to the unit, check that the latch tab is “set”, by pushing it toward the connector body until a click is heard.)

To allow CO2 to flow to the SurgAssist™, use a tank wrench (can be supplied by your gas vendor) to open the valve stem on the top of the tank. This is a standard system: counterclockwise
to open and clockwise to close.

Select the desired operating pressure with the Patient Pressure Select switch (see page 15). Select either low or high, pressure setting. The preset pressures are nominally 7mmHg (low) and 12 mmHg (high) respectively.

Connect the female end of the 1/8” ID hose to the “Output” male barb on the front of the Insufflator (See page 14).

Note: The under pressure indicator at 5 mmHg and the over pressure indicator at 20mmHg may be bypassed according to doctor preference. To bypass, turn the Pressure Level Indicator switch on the back of the SurgAssist™ unit to Off (See page 15).

To disconnect the regulator/hose, pull up the tab on top of the outlet. This will cause the hose to (gently) “pop out.”

3.1.2 Electrosurgical Generator Setup Information

Attach the connector of the Foot Switch to the “Foot Switch” outlet on the back of the Generator.

Note: The waveform selector selects an energy waveform for a particular task. Cut to separate tissue and coag to cauterize tissue. Blend is a combination of cut and coag and perform both functions simultaneously.

For Monopolar Electrosurgery:

Begin by placing a ground plate on or under the patient. Failure to do this can cause excessive burning of patient tissue.

Attach the two electrical connectors of the ground plate to the two black (lower) “Monopolar Output” outlets on the front of the generator (See page 14).

Attach the power end of the monopolar surgical instrument to the green (upper) “Monopolar Output” outlet on the front of the Generator (See page 14).

Turn the mode selector switch to the left for Monopolar Electrosurgery.

Adjust the Monopolar Power Level knob to the desired level.
Energy is applied to the handunit when stepping down on the footswitch. Should one or both connections to the grounding plate become disconnected, an audible indicator will sound, and no electrical current will flow to the handpiece.

Energy is applied to the handunit when stepping down on the footswitch.

*For Bipolar Electrosurgery:* Attach the two electrical connectors of the bipolar surgical instrument to the “Bipolar Output” (blue) outlets on front of the generator (See page 14).

Turn the Selector switch to the right for Bipolar Electrosurgery.

Adjust the Bipolar Power Level knob to the desired level.

Energy is applied to the hand unit when stepping down on the footswitch.

### 3.2 Basic Usage
The following section describes basic usage of the SurgAssist™ Unit.

#### 3.2.1 Qualified Training
Only personnel qualified to perform a specific procedure, diagnostic or therapeutic, should perform the procedures. Biovision always advocates the application of qualified training before attempting any procedure. Qualified training and Continuing Education is available through Biovision and many other channels. If you purchased this unit as a part of a Biovision EndoDiagnostic and Surgical Suite, training is included in the price of the suite. If you do not feel comfortable with a procedure, please seek additional training.

#### 3.2.2 General Proper Usage
The SurgAssist™ system is designed to support minimally invasive and some general surgical procedures. Usage is suggested when either abdominal distention for surgery or electrocautery is desired.
3.2.3 Insufflator Usage

(for Manual Flow only)

Before performing insufflation, first fill the SurgAssist™ unit’s internal CO2 tank. Do this by pressing the yellow “Fill” button until the “Liters Delivered” gauge reads 0. This means that none of the CO2 in the internal tank has been used yet for insufflation.

(for Auto Fill)
The “Fill” button is not necessary, CO2 is automatically delivered from the external E-tank via the internal CO2 tank to the patient.

Before selecting the “Auto Fill” or “Manual Fill” mode, first choose the desired patient pressure for insufflation by selecting “High” or “Low” using the patient pressure select switch (See page 15). The selected patient pressure (in mm Hg) will appear on the “patient pressure gauge” on the front right side of the insufflator panel.

To begin insufflation, turn the “On/Off” switch (on the front of the Insufflator panel) to “On.” CO2 will begin flowing into the patient at the rate shown on the “Flow Rate” gauge.

**Note:** During insufflation, be sure to pay close attention to the “Patient Pressure” gauge in order to avoid too much pressure inside the patient cavity.

Insufflation occurs automatically until 15 (high) or 8 (low) mmHg of pressure is reached (this reading may vary slightly with altitude). The application of additional/external pressure on the abdomen (e.g. by creating another incision, inserting another instrument, etc.) will cause patient pressure to spike upwards, and the “Pressure Indicators” may sound.

3.2.4 Electrosurgical Generator Usage

For Monopolar Surgery:
Ensure the you have followed the “For Monopolar Surgery” directions in section 3.2.1.
Start your procedure at a low power setting and increase the power until the desired cutting/hemostasis is accomplished. Trying different energy waveform setting may also help accomplish desirable results.

For Bipolar Electrosurgery:
Ensure the you have followed the “For Bipolar Surgery” directions in section 3.2.1.

Again, start with a low power setting and adjust the power and energy waveform knobs to produce the desired results.

Note: In most cases, it is best to leave this knob on the “Blend” setting. This provides the proper wavelength for either cutting or coagulating without having to manually switch between the two modes.

4. SurgAssist™ Accessories
The following section describes how to set up and use the various accessories available for SurgAssist™ system.

4.1 Monopolar Electrosurgery Accessories
The SurgAssist™ monopolar generator is compatible with most monopolar hand instruments. Hand pieces with a 4mm “banana” connector are designated as footswitch operated, and are usually compatible. This unit is incompatible with Valley Lab monopolar handpieces.

4.2 Bipolar Electrosurgery Accessories
The SurgAssist™ bipolar generator is compatible with most bipolar hand instruments that terminate in dual 4mm “banana” connectors. This unit is incompatible with LigaSure™ handpieces.

5. Cleaning and Maintenance
The following section described the proper method(s) for cleaning and maintaining your SurgAssist™ system.

Note: Never immerse or soak any part of the SurgAssist™ unit in any liquid, as this can cause significant damage not covered by the warranty.

5.1 General Cleaning of SurgAssist™ Unit
Use a lightly damp cloth. Wipe down the entire SurgAssist™ unit with it.

Allow the unit to dry before using it again.

Any blood on the SurgAssist™ unit can be removed using cotton or gauze soaked in alcohol.

5.2 Sterilization
Sterilize electrosurgical handpieces according to manufacturer’s instructions.

The patient plate does not normally need to be sterilized. Should you need to sterilize your patient plate, please contact Biovision for the best sterilization procedure.

The supplied insufflation hose (SurgAssist™ to patient) is sterilizable by Ethylene Oxide. Ensure that the sterilized pack containing the hose is sufficiently ventilated to prevent any residual ethylene oxide contact with you, your staff or your patient.

5.3 Fuse Replacement

1. Use a flat screwdriver in the slot at the top of the fuse cover.

2. Swing cover down to reveal fuse holder. Cover will not detach.
3. Use screwdriver to gently pry the fuse holder out of the unit.

4. Replace the fuses and observe the correct replacement orientation.

Replace with 3.15A, 250V Type F fuses only.

5. Re-insert the fuse holder.
6. Close the fuse cover.

7. Ensure that “115” is showing through the window.

Note: If 230 VAC is required, then follow the above procedure, but be sure to turn the fuse holder upside-down before re-inserting it. Ensure that “230” is showing through the window.
6. Troubleshooting

Scenario:

A. No insufflation

No Flow, No Patient Pressure  
Turn insufflation on.

Flow, No Patient Pressure  
Leak: check gas egress.

No Flow, Patient Pressure  
Closed valve: turn on valves and stopcocks.

Should these measures fail, call Biovision Veterinary Endoscopy for further technical support.

B. Cannot fill internal tank

1. Check Supply Hose, check for proper connection.

2. Turn on “E” Tank valve using tank wrench

3. Replace “E” Tank

Should these measures fail, call BioVision Technologies for further technical support.

C. Pressure indicators not heard

1. Turn on unit. System power must be on for the indicators to operate.

2. Turn on indicators on the rear panel of the unit.

Should these measures fail, call Biovision Veterinary Endoscopy for further technical support.
D. No electrocautery/cutting

1. Turn on unit using the power switch on the rear of the unit.

2. Select proper mode

3. Turn up proper power level

4. Change energy waveform

5. Check electrical connectors

6. Replace handpiece

Should these measures fail, call Biovision Veterinary Endoscopy for further technical support.

Biovision Customer Care
Phone: 303.225.0960
Email: info@biovisionvet.com

Please copy your serial number here for future reference: