

# GYNECARE VERSAPOINT

*Bipolar Electrosurgery System*

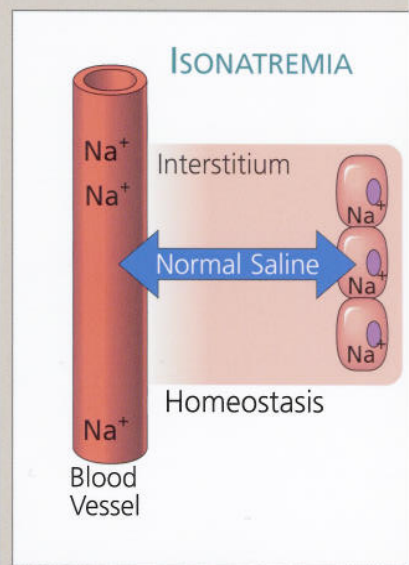


## Advanced technology

for bipolar hysteroscopic  
*electrosurgery in saline*



The GYNECARE VERSAPOINT Bipolar Electrocauterization System enables surgeons to diagnose and treat various benign intrauterine pathology, including myomas, polyps, adhesions and septa, with a single intervention, as well as treat abnormal uterine bleeding by endometrial ablation.



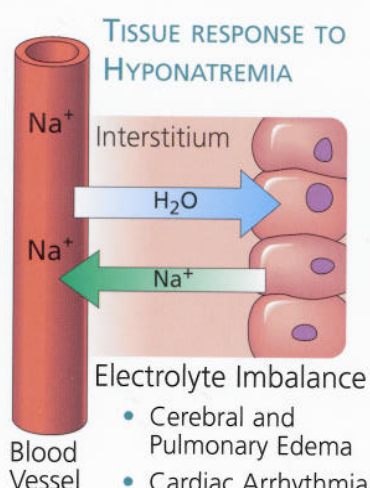
- If fluid intravasation reaches 750 mL, plan for completion of the case, impending excessive intravasation
- If fluid intravasation reaches
  - 1500 mL of a nonelectrolyte solution
  - **2500 mL of normal saline**

REFERENCE: Loffer FD, Bradley LD, Brill AI, Brooks PG, Copper JM. Hysteroscopic fluid monitoring guidelines from the Ad Hoc Committee on Hysteroscopic Fluid Guidelines of the American Association of Gynecologic Laparoscopists. *J Am Assoc Gynecol Laparoscopists*. 2000;7:167-168.



# ELECTROSURGERY

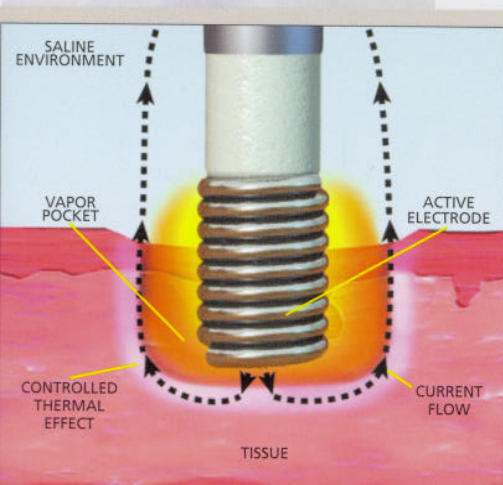
## WHY SALINE IS USED



## REDUCING THE POTENTIAL FOR HYPONATREMIA<sup>1</sup>

Normal electrolyte balance may be disrupted during hysteroscopic surgery when non-isotonic solutions, such as sorbitol, glycine, etc., are used. Intravascular absorption of these solutions may cause hyponatremia. The tissue reaction to hyponatremia can result in cerebral and pulmonary edema cardiac arrhythmia. Normal saline contains physiologic levels of sodium and, therefore, does not disrupt homeostasis.

## HOW THE GYNECARE VERSAPOINT SYSTEM WORKS



## CONTROLLED, PREDICTABLE TISSUE EFFECTS

Energy is delivered from the generator to the tissue through the active electrode. In the vaporization mode, the generator controls the creation of a "vapor pocket," or steam bubble, which upon contact with tissue causes instantaneous cellular rupture characteristic of vaporization. The energy then seeks the path of least resistance—through the saline distention media, to the return electrode and back to the GYNECARE VERSAPOINT Bipolar Generator.

<sup>1</sup>Davis JA, Miller CD. Fluid infusion during hysteroscopic surgery. In: Lewis BV, Magos AL, eds. *Endometrial Ablation*. London, UK: Churchill Livingstone; 1993:41-56.

GYNECARE VERSAPOINT 5 FR. BIPOLAR HYSTEROSCOPIC ELECTRODES

GYNECARE VERSAPOINT BIPOLAR RESECTOSCOPIC SYSTEM

GYNECARE VERSAPOINT BIPOLAR GENERATOR

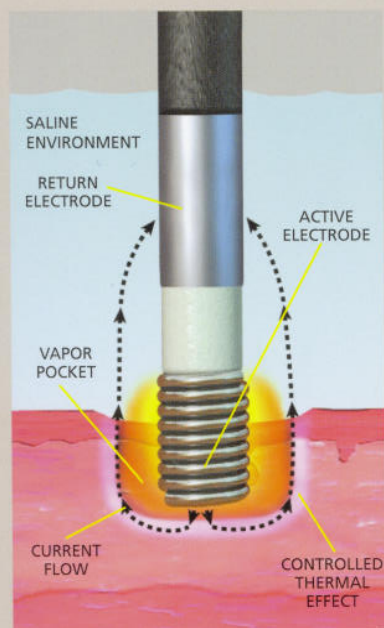
SPECIFICATIONS & ORDER INFORMATION

GYNECARE VERSAPOINT® BIPOLAR ELECTROSURGERY SYSTEM



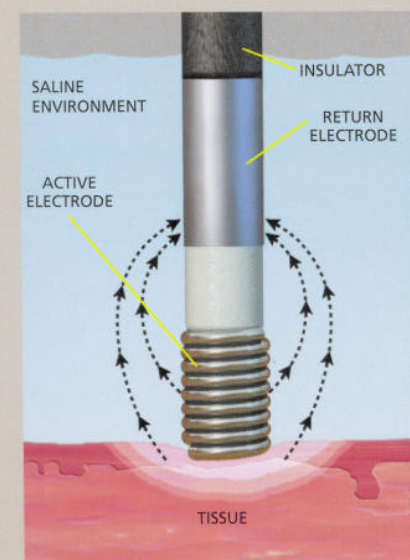
# ELECTRODES

## MECHANISM OF VAPORIZATION



In the vaporization mode, the generator controls the creation of a "vapor pocket," or steam bubble, which upon contact with tissue causes instantaneous cellular rupture characteristic of vaporization.

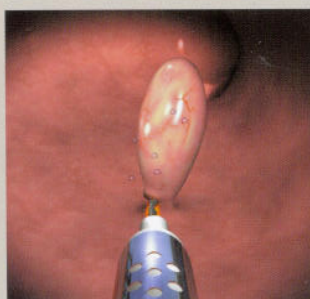
## MECHANISM OF DESICCATION



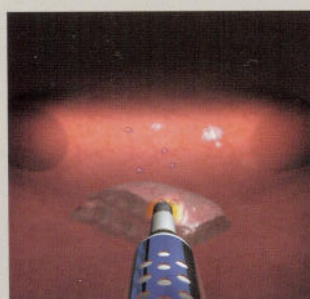
Saline acts as a "safety valve," automatically returning electro-surgical current to prevent over-treatment or carbonization. The bipolar energy flows to tissue, thereby dehydrating cells, causing hemostasis.

## INNOVATIVE ELECTRODES MAXIMIZE TISSUE EFFECTS

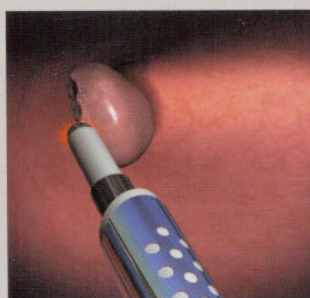
Innovative electrode designs, including Ball, Twizzle and Spring configurations, deliver bipolar energy through 5 Fr. instrument channels to vaporize, cut and desiccate tissue. Each electrode provides a range of tissue effects to give you the surgical technique options you require.



- Twizzle Electrode for vaporization and needle-like cutting



- Spring Electrode for rapid tissue vaporization and desiccation



- Ball Electrode for precise tissue vaporization and desiccation

GYNECARE VERSAPPOINT 5 FR. BIPOLAR HYSTEROSCOPIC ELECTRODES

GYNECARE VERSAPPOINT BIPOLAR RESECTOSCOPIC SYSTEM

GYNECARE VERSAPPOINT BIPOLAR GENERATOR

SPECIFICATIONS & ORDER INFORMATION

GYNECARE VERSAPPOINT® BIPOLAR ELECTROSURGERY SYSTEM



# BIPOLAR RESECTOSCOPIC SYSTEM

The GYNECARE VERSAPOINT Bipolar Resectoscopic System consists of two bipolar resectoscopic electrodes and a dedicated resectoscope. This innovative instrumentation operates in normal saline solution distention medium for use in the treatment of benign uterine pathologies, such as submucosal fibroids and polyps, as well as the treatment of abnormal uterine bleeding by endometrial ablation.

## Features:

### Bipolar Loop Resecting Electrode

Loop configuration for tissue resecting and cutting

### Bipolar 0° Vaporizing Electrode

Instantaneous tissue vaporization eliminates resection chips

Color-coded and keyed connectors expedite selection and automatically preset specific generator settings

Quick disconnect and connect locking system for fast hysteroscope changes

Accessible and visible outflow and inflow valve levers

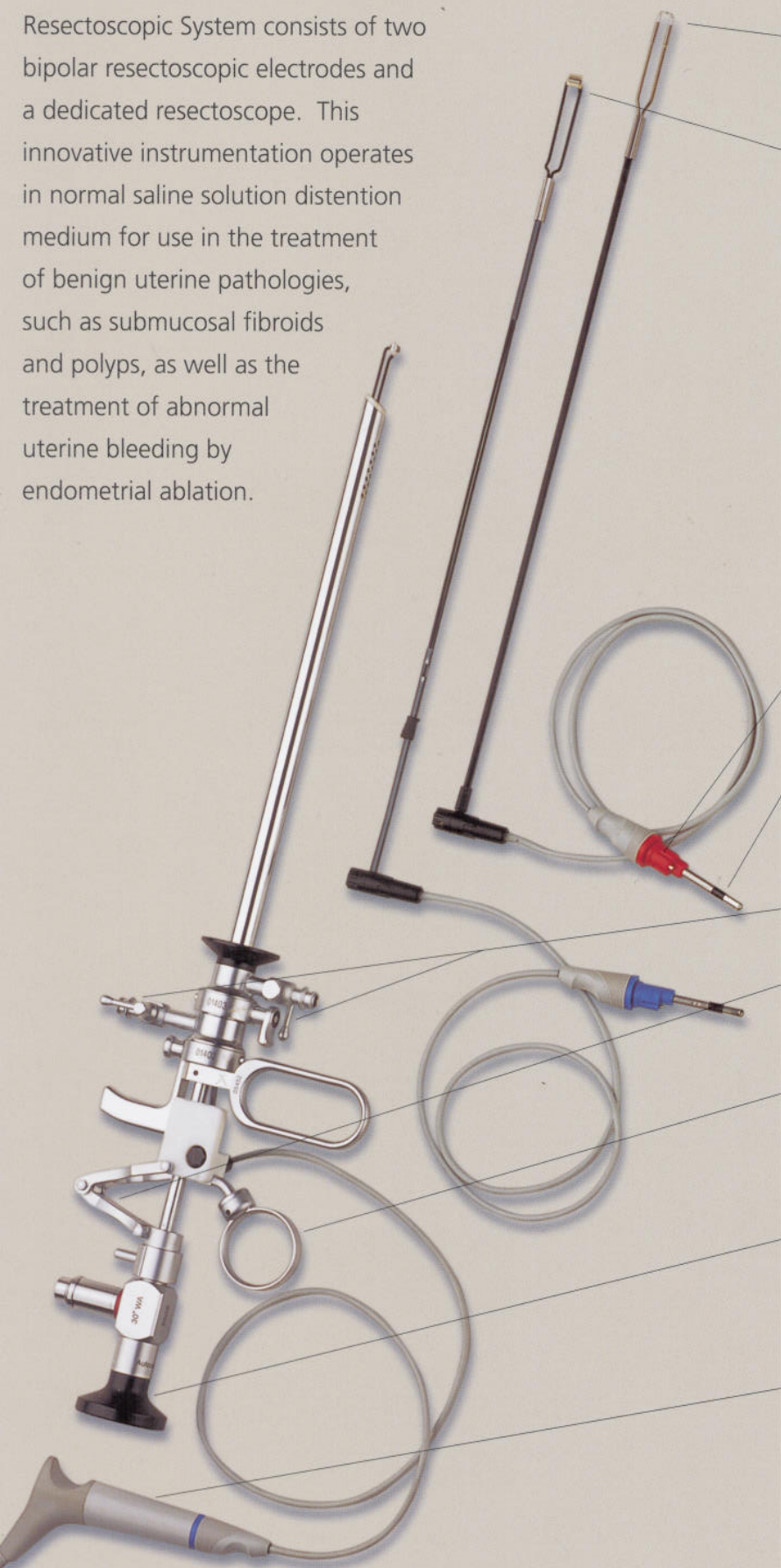
Smooth lever-spring mechanism ensures positive electrode control

Swivel thumb-ring permits multi-directional use for greater electrode control and maneuverability

Hysteroscope with a small 4 mm bore size is available in two different options:

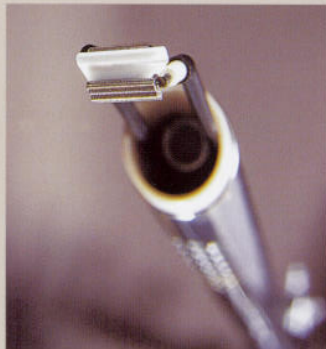
- 30°—WA (Wide Angle)
- 12°

Ergonomic, reusable handpiece quickly accepts all configurations of GYNECARE VERSAPOINT Bipolar Hysteroscopic and Resectoscopic Electrodes





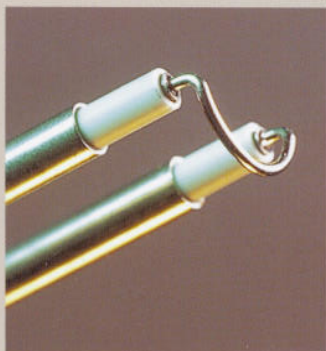
## GYNECARE VERSAPOINT Bipolar 0° Vaporizing Electrode



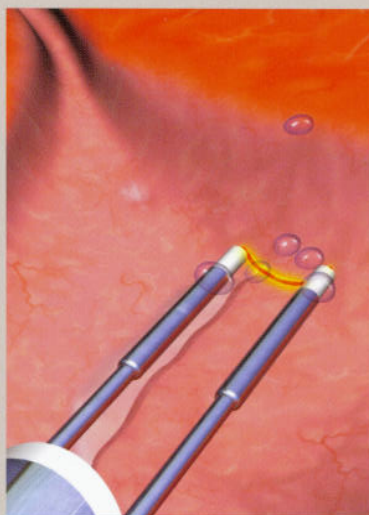
Uniquely designed active electrode configuration provides instantaneous tissue vaporization and desiccation.



## GYNECARE VERSAPOINT Bipolar Loop Resecting Electrode



The Bipolar Loop Resecting Electrode is ideally designed for resecting benign pathologies or treating abnormal uterine bleeding by endometrial ablation.



## GYNECARE VERSAPOINT 5 Fr. Bipolar Electrodes



Hysteroscopic Bridge allows use of GYNECARE VERSAPOINT 5 Fr. Bipolar Electrodes.



• Ball



• Twizzle



• Spring

GYNECARE VERSAPOINT® BIPOLAR ELECTROSURGERY SYSTEM  
SPECIFICATIONS & ORDER INFORMATION  
GYNECARE VERSAPOINT BIPOLAR RESECTOSCOPIC SYSTEM



# BIPOLAR GENERATOR

The GYNECARE VERSAPOINT Bipolar System represents a significant advance in bipolar electrosurgical technology to perform rapid and controlled tissue effects such as vaporization, desiccation and cutting.



GYNECARE VERSAPOINT technology brings a level of performance that combines the most desirable elements from the two conventional output modalities of bipolar and monopolar electrosurgery in specific system configurations for advanced bipolar hysteroscopic surgery. The GYNECARE VERSAPOINT Bipolar System provides a form of electrosurgery specifically developed for endoscopic applications in **saline**.

It appears and performs like a monopolar device, provides laser-like tissue vaporization, yet retains all of the inherent safety features of bipolar electrosurgery.

## Features:

User adjustable audio signals and graphic alerts assist the operator through the proper use of the generator



Mode Selection



Fault Indicator

External case design eliminates cooling vents to reduce danger of liquid and debris ingress and allows for easier cleaning of unit

Easy to read 16 digit alpha-numeric display is visible at a distance or in dim lighting

Integrated membrane display and control panel for easy use and cleaning

## Bipolar Electrosurgical Technology

**Dedicated Bipolar Generator**  
No stray current through the patient's body

**Reusable Handpiece**  
Cost effective

**Disposable Electrode**  
Expedites *in situ* changes, prevents cross contamination

**Rapid Set-up Electronic "Smart Electrodes"**  
Automatically adjust power to default settings

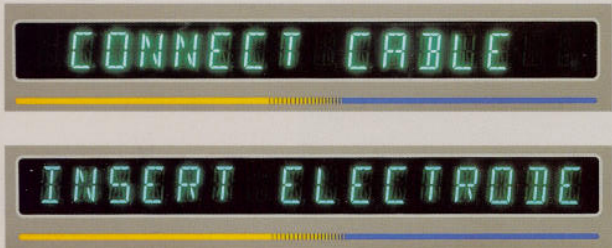
**Electroluminescent Display**  
Clear and easy to read

**Six Modes of Operation for Maximum Versatility**  
Vapor Cut 1, 2, 3;  
Blend 1, 2; Desiccate

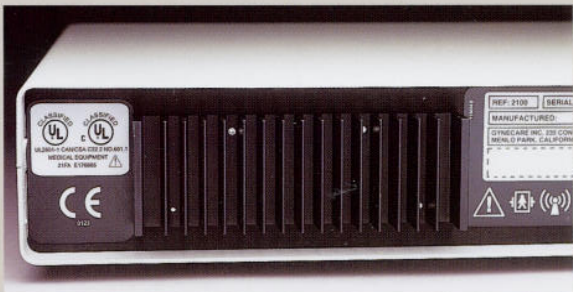


An audible signal will sound whenever electrosurgical energy is being output. Diagnostic circuits within the GYNECARE VERSAPOINT Bipolar Generator continuously monitor system performance such that any detected faults are indicated on the user display in conjunction with illumination of the front panel warning symbol.

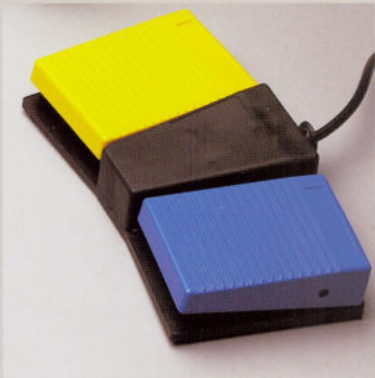
Menu-driven programming provides an easy-to-read electroluminescent display for quick-reference prompts.



Electrodes are color-coded for quick identification and "keyed" to automatically cue the computerized generator to select the ideal power output setting required. This proprietary feature facilitates rapid set-up and quick, easy electrode exchanges.



The back of the GYNECARE VERSAPOINT Bipolar Generator reveals a solid-state heat sink that provides continuous cooling of the unit.



Two-pedal foot switch with stable, non-slip feet.

GYNECARE VERSAPOINT BIPOLAR GENERATOR  
SPECIFICATIONS & ORDER INFORMATION



# SPECIFICATIONS AND ORDER INFORMATION

*Features:*

GYNECARE VERSAPOINT  
Bipolar Generator

Electroluminescent Display

Connector Cable/Handpiece

Hysteroscopic Bipolar  
5 Fr. Electrodes  
(Ball, Twizzle, Spring)

Two-Pedal Foot Switch

GYNECARE VERSAPOINT  
Hysteroscopic Bridge

GYNECARE VERSAPOINT  
Bipolar Resectoscopic System

Hysteroscope is available in  
two different options:  
• 4 mm 30°  
• 4 mm 12°

Resectoscopic Electrode  
Vaporizing Tip

Resectoscopic Electrode  
Bipolar Loop Tip



## Specifications

### GYNECARE VERSAPOINT 5 Fr. BIPOLAR HYSTEROSCOPIC ELECTRODES

<b>Diameter:</b>	5 Fr. (1.6 mm)		
<b>Working Length:</b>	360 mm		
<b>Configurations:</b>	<b>Dimensions:</b>	<b>Color Codes:</b>	<b>Electrode Power Output Default Settings:</b>
• Ball	1.0 mm Diameter (spherical)	Yellow	VC1 50 DES 24
• Twizzle	0.6 mm Diameter x 3.0 mm long	Red	VC1 100 DES 50
• Spring	1.2 mm Diameter x 1.6 mm long	Blue	VC1 130 DES 60

### GYNECARE VERSAPOINT BIPOLAR RESECTOSCOPIC SYSTEM

#### Hysteroscope

- 30° WA 4.0 mm rod lens STORZ mount<sup>†</sup>
- 12° STD 4.0 mm rod lens STORZ mount

<sup>†</sup>Recommended

<b>Outer Sheath Diameter:</b>	27 Fr. (9 mm)
<b>Inner Sheath Diameter:</b>	24 Fr. (8 mm)
<b>Working Length:</b>	200 mm
<b>Working Element:</b>	Passive
<b>Hysteroscopic Bridge:</b>	5 Fr Working Channel

#### Resectoscopic Electrodes

<b>Dimensions:</b>	<b>Width</b>	<b>Diameter</b>
0° Vaporizing	4.0 mm	
Bipolar Loop Resecting	4.0 mm	2.5 mm
<b>Color Codes:</b>		
0° Vaporizing	Blue	
Bipolar Loop Resecting	Red	
<b>Electrode Power Output Default Settings:</b>		
0° Vaporizing	VC1 170 DES 80	
Bipolar Loop Resecting	VC1 170 DES 80	

### GYNECARE VERSAPOINT BIPOLAR GENERATOR

<b>Output Power Range:</b>	5-200 watts
<b>Output Frequency Range:</b>	340-450 kHz
<b>Input Power Requirements:</b>	115 Volts RMS or 240 Volts RMS, 50/60 Hz

## Order Information

PRODUCT CODE	DESCRIPTION
<b>GYNECARE VERSAPOINT 5 Fr. Bipolar Hysteroscopic Electrodes</b>	
00466	Ball Tip Electrode – 5 pk
00467	Twizzle Tip Electrode – 5 pk
00468	Spring Tip Electrode – 5 pk
<b>GYNECARE VERSAPOINT Bipolar Resectoscopic System</b>	
01950	Bipolar Electrode, Resectoscopic – Vaporizing Tip (0°) – 5 pk
01985	Bipolar Electrode, Resectoscopic – Angled-Loop Tip – 5 pk
01931	Resectoscope Working Element – Passive
01932	Resectoscope Inner Sheath – 24 Fr.
01933	Resectoscope Outer Sheath (Standard) – 27 Fr.
01939	Resectoscope Outer Sheath (Rotatable) – 27 Fr.
01934	Resectoscope Obturator – Standard
01735	Hysteroscopic Bridge (Obturator – Visual) – 5 Fr.
01938	Hysteroscope 4.0 mm 12°
01936	Hysteroscope 4.0 mm 30°
<b>GYNECARE VERSAPOINT Bipolar Generator</b>	
00482	GYNECARE VERSAPOINT Bipolar Generator
00481	Foot Switch
00480	Connector Cable (Handpiece)
04995	Universal Power Cord

For additional product information, contact your Gynecare sales representative, or to place an order, call 1-800-255-2500.

Visit our web site at [www.gynecare.com](http://www.gynecare.com) for more information about other Gynecare innovations in women's health care.



# GYNECARE VERSAPOINT\* Bipolar Electrosurgery System

(Summary of Package Insert)

## INDICATIONS

The GYNECARE VERSAPOINT Bipolar Resectoscope is used to permit direct viewing and access to the uterine cavity for the purposes of performing hysteroscopic surgical procedures. The indications for use include:

- Removal of submucous fibroids
- Removal of polyps
- Transection of intrauterine adhesions
- Transection of intrauterine septa
- Endometrial Ablation

The GYNECARE VERSAPOINT Bipolar Electrodes are indicated for use in tissue cutting, removal, and desiccation as required or encountered in gynecologic hysteroscopic electrosurgical procedures for the treatment of intrauterine myomas, polyps, adhesions, and septa and benign conditions requiring endometrial ablation.

## CONTRAINDICATIONS

The GYNECARE VERSAPOINT Bipolar System is contraindicated for non-hysteroscopic surgical procedures. The GYNECARE VERSAPOINT Bipolar System is contraindicated where hysteroscopic procedures are contraindicated. This includes, but is not limited to the following:

- pregnancy
- invasive carcinoma of the cervix
- cervical stenosis
- cervical or vaginal infection
- inability to adequately distend the intrauterine cavity
- uterine bleeding or menses
- recent uterine perforation
- intolerance to anesthesia
- medical contraindications

The GYNECARE VERSAPOINT Bipolar System is further contraindicated in patients with the following conditions: cervical or uterine malignancy, acute pelvic inflammatory disease, and undressed adnexal pathology. The GYNECARE VERSAPOINT Bipolar System is contraindicated for use in tubal sterilization procedures. Endometrial ablation by electrosurgical means should not be undertaken without adequate training and clinical experience. Additionally, endometrial biopsy should be performed prior to any endometrial ablation procedure. The GYNECARE VERSAPOINT Bipolar Electrodes are contraindicated where hysteroscopic bipolar electrosurgical procedures in normal saline solution are contraindicated. The GYNECARE VERSAPOINT Bipolar Electrodes are contraindicated in any non-hysteroscopic surgical procedure and in procedures where normal saline solution is not used as an irrigation and distention medium. The use of this device is contraindicated in patients with the following conditions: acute cervicitis, pregnancy, cervical or uterine malignancy, acute pelvic inflammatory disease, and undressed adnexal pathology. The GYNECARE VERSAPOINT Bipolar Electrodes are contraindicated for use in tubal sterilization procedures.

Contraindications to Hysteroscopic Myomectomy:

Hysteroscopic myomectomy should not be undertaken without adequate training and clinical experience. The following are clinical conditions that can significantly complicate hysteroscopic myomectomy:

- Severe anemia
- Inability to circumnavigate a myoma due to size (e.g., predominantly intramural myomas with small submucous components)

## WARNINGS

For hysteroscopic procedures, be alert to these potential hazards:

- Failure to follow all applicable instructions may result in serious surgical consequences.
- Before attempting any hysteroscopic procedures, the physician should be trained in the principles of hysteroscopic surgery including patient selection, surgical techniques, current medical literature, management of complications and hazards of hysteroscopy and electrosurgery in that procedure.
- These hazards may include such things as perforation, hemorrhage, fluid overload and gas embolization.
- When hysteroscopic instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in hysteroscopic and electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device and other medical instruments. Ensure that insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid unless specifically designed and labeled to be immersed.
- Refer to the GYNECARE VERSAPOINT Bipolar Electrosurgery System User Manual indications and instructions to ensure all safety precautions.
- Potential complications of Continuous Flow Hysteroscopy using saline as a distention medium include:
  - Hyponatremia
  - Cerebral edema
  - Pulmonary edema
  - Uterine perforation resulting in possible injury to bowel, bladder, major blood vessels, and ureter
  - Hypothermia
- Suspicion of pregnancy should suggest a pregnancy test prior to the performance of hysteroscopy.
- Ultrasonography before hysteroscopy may aid in identifying clinical conditions which could influence decisions regarding patient management.
- Explosion Hazard: The following substances will contribute to increased fire and explosion hazards in the operating room: flammable substances (such as alcohol-based skin prepping agents and tinctures), flammable anesthetics, naturally occurring flammable gases which may accumulate in body cavities such as the bowel, oxygen enriched atmospheres, oxidizing agents such as nitrous oxide ( $N_2O$ ) atmospheres.
- Electric Shock Hazard: Do not connect wet accessories to the generator.
- Fire/Explosion Hazard: Do not place active accessories near or in contact with flammable materials (such as gauze or surgical drapes). Electrosurgical accessories, which are activated or hot from use, can cause a fire.
- The accessory tip may remain hot enough to cause burns after the electrosurgical current is deactivated.
- Inadvertent activation or movement of the electrode outside the field of vision may result in injury to the patient.
- Localized burns to the patient or physician may result from electrosurgical current carried through other instruments and conductive objects. Electrosurgical current may be generated in conductive objects by direct contact with the active electrode or by the active or return electrode being in close proximity to a conductive object.
- The entire bipolar electrode tip assembly must always be kept immersed in the conductive normal saline irrigation solution to ensure proper performance and avoid excessive heating of the electrode.

- Do not activate the generator when the active electrode is not in contact with tissue or excessive heating of the irrigation medium may result and patient injury could occur.

## WARNINGS APPLICABLE TO AIR/GAS EMBOLI HAZARDS

- Gas Bubbles are a normal by-product of electrosurgical procedures performed in liquids. When bubbles occur in the uterus, care should be taken to manage the removal of air/gas bubbles to minimize the inherent risk of emboli. Bubbles produced during tissue vaporization may interrupt surgery by temporarily interfering with vision and may also result in electrode over heating causing damage to the electrode tip. A continuous flow fluid management system is recommended to prevent accumulation of bubbles and continuously remove bubbles from the operative field.
- Surgeons should consider the anticipated length of surgery and size of leiomyomata when selecting patients for procedures.
- Surgeon should consider the selection of electrodes prior to initiating procedures. The electrodes should be matched to the size and type of pathology.
- Operating room personnel must be trained to purge air from fluid lines prior to surgery, avoid entry of air into fluid lines and turn off pumps during bag changes, and to provide constant, careful attention to fluid deficits. Avoid situations where the fluid bag runs dry.
- Basic equipment must be available to fulfill the requirements for monitoring of fluid deficit, assessment and control of intrauterine pressure and anesthesia monitoring. Intrauterine pressure should be maintained as low as possible so as to allow adequate distention and minimize forces potentially driving air and gas into circulation.
- Surgical team must have access to appropriate resuscitative capabilities.
- Patients should be kept flat or in reverse Trendelenberg position.
- If room air or gas embolism is suspected, surgeon should consider interrupting surgery, deflating the uterus and removing sources of fluid and gas until the diagnosis and a management plan are clarified.
- Surgeon should avoid entry of air into uterus by:
  - Carefully purging air from fluid in-flow lines and hysteroscopic devices prior to use.
  - Following cervical dilatation, care should be taken to minimize the exposure of the open cervix to room air.
  - Keeping the cervical os occluded during surgery as much as possible once it is dilated.
  - Using active fluid out-flow to effectively flush the uterus of bubbles and debris.
  - Using a Y-connector on the fluid in-flow line in order to reduce air entrainment during bag changes.
  - Initially selecting the appropriate electrode, to avoid further cervical dilatation and insertion of larger instruments after initiation of the procedure.
  - Minimizing the frequency of removal and reinsertion of hysteroscopic devices.
- Considerations for Anesthesia:
  - Nitrous oxide anesthesia may enlarge the size of air bubbles, and thus should be avoided when possible in operative hysteroscopy.
  - Patients at high risk for room air and gas embolism should be managed using controlled ventilation.
  - For high risk patients undergoing operative hysteroscopy one should consider intra-operative monitoring, such as end-tidal  $CO_2$  monitoring if under general anesthesia, and pre-cordial Doppler monitoring to detect room air and gas emboli early.

## PRECAUTIONS

- Care should be taken to avoid perforation of the uterus. Do not force the electrode into tissue while extending the electrode. Never activate the electrode during extension.
- Do not bury the electrode tip in tissue beyond the junction of the active electrode and the ceramic insulator. Burying of the electrode tip, as described above, may result in product damage during use.
- Do not use the electrode tip to probe or manipulate tissue. Forceful contact between electrode tip and tissue or other instruments may result in damage to the instrument.
- The electrode must be used in a longitudinal (forward/backward) motion. DO NOT use the electrode in a side-to-side "sweeping" motion or electrode damage may ensue.
- If excessive heating or physical forces cause damage to the Electrode tip, foreign body fragments may result, possibly requiring extended surgery for removal.
- Ultrasonography before hysteroscopy may aid in identifying clinical conditions which could alter patient management.
- Intrauterine distention can usually be accomplished with pressures in the range of 35-75 mmHg. Unless systemic blood pressure is excessive, it is seldom necessary to use pressures greater than 75-80mmHg.
- Factors such as uterine pretreatment and mean arterial pressure will have an effect on fluid distention pressure. It is important to use the minimum fluid pressure necessary to achieve adequate distention for good visualization and allow safe surgery.

## ADVERSE EVENTS

- Contact of heated Electrode tip with tissues not intended for electrosurgical treatment may result in tissue injury.
- Extended surgery may be required for removal of foreign body fragments if damage to the electrode tip is caused by excessive heating for physical forces.
- Reported adverse effects include uterine perforation, hemorrhage, fluid overload and gas embolization. Carefully insert and withdraw the bipolar electrode tip assembly from the resectoscope inner sheath to avoid the possibility of damage to the devices and/or injury to the patient.
- Only operate the device in the uterine cavity with continuous flow irrigation to ensure good visualization as well as cooling the accessory tip during use.
- When using a fluid distention medium, strict fluid intake and output monitoring is required. Excessive intravasation of distention fluid can lead to fluid overload.
- Use only normal saline (sodium chloride 0.9% w/v; 150mMol/l) irrigation solution. The performance of the system will be adversely affected by use of any other solution.
- Fluid monitoring is required even when normal saline is used as a hysteroscopic distention and irrigation medium.