

REFERENCE 3  
510(K)  
SUMMARY OF SAFETY & EFFICACY

K 974250

FEB 11 1998



**VersaStat™ MULTIPOLAR SCISSORS AND CABLES: INSTRUCTIONS FOR USE**

Please read all information carefully. Failure to properly follow instructions may lead to electrical or thermal injury and result in improper functioning of device.

**Important:** This package insert is designed to provide instructions for use of the VersaStat™ MULTIPOLAR Scissors and Cables. It is not a reference to electrosurgical techniques.

**Indications:**

To coagulate and transect vascular tissue simultaneously, to perform spot coagulation of bleeding vessels; to be used in open surgical procedures.

**Description:**

The VersaStat™ MULTIPOLAR Scissors are non-sterile, reusable surgical devices with an insulated coating to achieve the coagulation function. This device will be available in various sizes and shapes similar to conventional surgical scissors. One shaft incorporates three pole connectors that create the ability of current flow for one or both blades utilizing a monopolar or a bipolar mode. Located on the cables (monopolar and bipolar) is a switch allowing the use of either one blade or both blades as a cautery surface.

The VersaStat™ MULTIPOLAR Scissors are designed for use only with the VersaStat™ MULTIPOLAR Cables, either monopolar or bipolar, when connected to the appropriate electrosurgical generator.

**Directions For Use:**

Read all instructions carefully. Failure to properly follow instructions may lead to electrical or thermal injury and cause improper functioning of the device. These instructions are recommended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

- Verify compatibility of this device and its accessories with other equipment needed to conduct the surgical procedure. The following electrosurgical generators are compatible with the VersaStat™ cable: Valley Lab, Codman, Bircher, Conmed, Wolf, and Erbe.
- To be used in the dissection and transection of vascular tissue with the added feature of simultaneous coagulation of a bleeding vessel via a bipolar or monopolar current.
- Insert the three connector posts on the VersaStat™ MULTIPOLAR Scissors into the connector ports of either the bipolar or the monopolar VersaStat™ Cable. Due to this unique design, a grounding pad is not **NECESSARY**.

**Caution:** If the connection appears loose, inspect the scissor posts for any damage. If posts are damaged, do not use the scissors.

- Connect the VersaStat™ MULTIPOLAR Cable to the appropriate bipolar or monopolar output of the electrosurgical generator. Refer to the electrosurgical generator manual for indications and instructions in making this connection.
- Set the electrosurgical generator to bipolar or monopolar output. Adjust the power as low as possible to achieve adequate hemostasis.
- To coagulate the tissue between the blades of the device, activate the bipolar or monopolar electrosurgical generator by depressing the foot pedal.
- Once coagulation is complete, inspect the surgical area to ensure adequate hemostasis.
- Using the cable switch, select either blade or both for the coagulating function.

**Pretest to verify complete electrical activity:**

1. Soak a 4" x 4" gauze pad with saline.
2. With device slightly open, firmly press the tips of the blades on the gauze pad. Make sure that the electrodes touch the pad.
3. Activate the bipolar mode foot pedal connected to the generator.

*Caution: Do not touch the blades while foot pedal is actuated; it may cause injury*



- 4 Steam generation from the pad or sparking from the blades indicates active power and a complete circuit. The device is ready to be used.
- 5 If there is no steam or sparking: verify power switch is on and in bipolar mode. Ensure generator is functioning properly. Verify proper connections to generator and scissors. Add more saline to pad. Ensure all electrodes are in contact with saline soaked pad. Decrease amount of pad surface contacting two blades. Turn power up in small increments.

**Contraindications:**

The VersaStat™ MULTIPOLAR Scissors are not indicated for contraceptive coagulation of the fallopian tubes, but may be used to achieve hemostasis following transection of the fallopian tubes.

**Warnings and Precautions:**

- ◆ A thorough understanding of the principles and techniques associated with electro-surgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical isolation or grounding is not compromised.
- ◆ The VersaStat™ MULTIPOLAR Scissors are only compatible with the VersaStat™ MULTIPOLAR Cable.
- ◆ These scissors are not intended to be sharpened or repaired in any way. This may damage the electrodes.
- ◆ Do not use abrasive cleaning tools or solutions on this device.
- ◆ Never touch active blades of the scissors while energized. This may result in burns.
- ◆ Do not touch the blades of the VersaStat™ Scissors to any staples or clips.
- ◆ For cutting and coagulation, keep the voltage/power as low as possible to achieve the desired effect. This is needed due to inadvertent burning and increased potential for capacitance coupling at high powers.

**Cleaning and Sterilization Recommendations:**

**VersaStat™ Multipolar Scissors and Reusable Cables:**

- ◆ Immediately after each use soak thoroughly in an enzyme cleaner appropriate for surgical instruments. Mix with warm tap water (100°F - 120°F) for approximately 5 minutes.
- ◆ Clean thoroughly with a soft brush to loosen any coagulum or dried blood. Be careful not to scratch the surface of the scissors. Do not disassemble the scissors.
- ◆ Rinse thoroughly with warm water. Towel dry, treat with instrument lubricant per hospital practice.
- ◆ Steam autoclave sterilization at a minimum temperature of 250° F for 15 minutes in accordance with AAMI/American National Standard ST8-113, Hospital Steam Sterilizers.
- ◆ May be ETO (gas) sterilized in accordance with AAMI Recommended Practice/American National Standard ST41-113. Good Hospital Practice: Ethylene Oxide Sterilization and Sterility Assurance.

**Caution:**

Federal (USA) law restricts this device to sale by or on the order of a physician.

**CE 0120**

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Richard G. Jones  
Vice President of Regulatory Affairs  
420 Delaware Drive  
P.O. Box 7514  
Fort Washington, Pennsylvania 19034

FEB 11 1998

Re: K974250  
Trade Name: Versastat Multipolar Scissors and Cables  
Regulatory Class: II  
Product Code: GEI  
Dated: November 11, 1997  
Received: November 13, 1997

Dear Mr. Jones:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

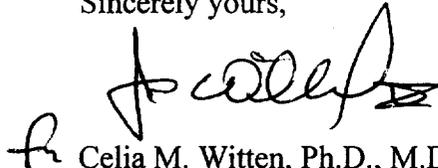
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K974250

Device Name: VersaStat™ Multipolar Scissors and Cables

Indications For Use:

- to coagulate and transect vascular tissue simultaneously;
- to perform spot coagulation of bleeding vessels;
- to be used in open surgical procedures;

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K974250

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use