



ENGLISH

PADGETT BIPOLAR FORCEPS IMPORTANT INFORMATION - PLEASE READ BEFORE USE!

CAUTION

Please read all information contained in this insert. The use of an instrument for a task other than that for which it is intended, as well as improper, ineffective and insufficient maintenance can greatly reduce the life of an instrument and will invalidate the instrument's warranty. Incorrect handling and care as well as misuse can lead to premature wear or can cause hazards to patients and users.

HOW SUPPLIED

PADGETT BIPOLAR FORCEPS are supplied non-sterile and must be cleaned and sterilized prior to use according to hospital protocol and the procedures outlined in this document. Failure to follow these procedures will invalidate the instrument's warranty and can cause the instrument to fail.

DESCRIPTION

Bipolar Forceps are intended for use in general surgical procedures. The device is connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator unit and activated by a footswitch. The use of an instrument for a task other than for which it is intended, as well as improper, ineffective, and insufficient maintenance can greatly reduce the life of an instrument and will invalidate the instrument's warranty.

INDICATIONS FOR USE

Bipolar Forceps are designed to grasp, manipulate and coagulate selected tissue. It is to be connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Bipolar Forceps must only be used with bipolar coagulation current. The Bipolar Forceps has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

The maximum output of the generator shall not exceed 750 V_p.

Note: Electrosurgical instruments should be used only by individuals who are trained and licensed to use such devices. Examples of such training and experience include: Training through qualified residency program, surgical skills workshops, training programs offered by equipment manufacturers or preceptorship/surgical assistant training.

ADVERSE EVENTS

Adverse events reported while using bipolar electrosurgical devices include: Inadvertent activation with resultant tissue damage at the wrong site and/or equipment damage. Fires involving surgical drapes and other combustible materials have been reported. Alternate current pathways resulting in burns where the patient or physician or assistant is in contact with exposed metal. Explosions

caused by electrosurgical sparking in a flammable gas environment (i.e., explosive anesthetic gases). Organ perforation. Sudden massive hemorrhage.

CAUTIONS & WARNINGS

Special safety precautions should be observed when using electrosurgical instruments. Electrosurgical instruments can pose a significant shock, burn or explosion hazard if used improperly, incorrectly or carelessly. Avoid touching or grounding electrosurgical instruments to non-insulated instruments, scopes, trocar sleeves, etc. All persons using such devices should be knowledgeable in the use and handling of laparoscopic instruments, coagulation equipment, their accessories and other related equipment.

Test all instruments, accessories and equipment prior to each use. Written Standard Operating Procedures for the cleaning, sterilization, storage, inspection and maintenance of the instruments, accessories and equipment are recommended. Do not use in presence of flammable liquids or anesthetics. Electrosurgical generators used with these devices are designed to cause destruction of tissue and are inherently dangerous if operated improperly. Follow all safety precautions and instructions supplied by the manufacturer of the electrosurgical generator. The electrode tip must always be in full view before activating power. Apply power only when electrode tip is in full contact with the tissue selected for coagulation. Electrode tip must not come in contact with other metal instruments during use. Failure to observe these cautions and contraindications may result in injury, malfunction or other unanticipated occurrences or events for the operator, staff and/or the patient.

INITIAL USE OF NEW INSTRUMENTS

Every instrument must be cleaned and sterilized before it is used for the first time. The instrument was developed for sterilization by autoclave and has shown good results using this method.

INSPECTION AND FUNCTIONAL CHECK

It is very important to examine carefully each surgical instrument for breaks, cracks or malfunctions before use. It is especially essential to check areas such as blades, points, ends, stops and snaps as well as all movable parts. **Do not use damaged instruments.** Never attempt to make repairs yourself. Any repairs made by the customer may void the warranty. Service and repairs should be referred to trained qualified persons only. Refer questions about repair to the manufacturer or the biomedical engineering department or return to Miltex for repair.

CLEANING AND MAINTENANCE

Every surgical instrument should be disinfected and thoroughly cleaned after each use. Proper cleaning, inspection and maintenance will help ensure correct function of the surgical instrument. Clean, inspect and test each instrument carefully. Sterilize all instruments before surgery. A good cleaning and maintenance procedure will extend the useful life of the instrument. Special attention must be paid to slots, stops, ends, hollow tubes and other highly inaccessible areas. Check insulation, cables and connectors for cuts, voids, cracks, tears, abrasions, etc. **Do not use damaged instruments.** Cleaning and rinsing must take place immediately after each use for best effect. Failure to clean promptly may result in adherent particles or dried secretions that may resist

cleaning and complicate or resist future sterilization. Instruments must be completely cleaned and rinsed off of all foreign matter. Use warm water and a commercially available instrument pre-soak or cleaning agent. Enzymatic cleaners must be used to remove protein deposits. Follow the enzymatic cleaner's instructions; rinse thoroughly.

- Do not use corrosive cleaning agents (i.e., bleach). Cleaning solutions and rinses at or near a neutral pH (7.0) are best.
- Do not use abrasive cleaners.
- Only a soft bristle brush should be used.
- Can be disinfected in the washing machine up to 203°F (95°C).
- Rinse thoroughly with distilled water.
- Prepare for storage and/or sterilization.

After cleaning and rinsing, dry instruments completely and carefully with compressed air (including inside channels and highly inaccessible areas). **Note:** After cleaning and before sterilization, treat all instruments with a water soluble lubricant which is considered as being physiologically safe, especially their blades, ends, stops, snaps and all movable parts.

REPAIRS AND MAINTENANCE

Should your instruments require repair or maintenance, contact Miltex for return authorization and address. Instruments returned to Miltex for repair must have a statement testifying that each instrument has been thoroughly cleaned and sterilized. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair. Products repaired by Miltex are guaranteed for 90 days to be free of defects in workmanship and parts when used normally for their intended surgical purpose. Any workmanship or parts proving to be defective will be replaced or repaired, at Miltex's discretion, at no charge to the customer.

STORAGE AND STERILIZATION

Instruments must be stored in a clean, dry, moisture free area.

The instruments should be stored individually in their shipping carton or in a protective tray with partitions. Protect tips with cloth, gauze or tubing if stored in drawers. Instruments and cables are reusable and meet AAMI standards for sterilization. Use steam autoclave sterilization. Thoroughly clean instruments of all debris, tissue and foreign matter prior to sterilization. Follow the sterilizer manufacturer's instructions for operation and loading of steam autoclaves. There must be direct steam exposure to all surfaces of the instruments being sterilized including the internal surface and tubes channels. Allow instrument to air cool to room temperature before use.

STANDARD STERILIZATION METHOD

Use steam autoclave sterilization only.

Bipolar Forceps (Unwrapped):

Sterilization Cycle	Temperature	Exposure Time	Min. Dry Time
Prevacuum, flash	270° F (132° C)	3 minutes	---

Other time and steam temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature. **(Note:** Contact the manufacturer of your steam autoclave to confirm appropriate temperatures and sterilization times.)

Caution: Autoclave temperatures should not exceed 279°F (137°C); handles, insulation or other non-metallic parts may be damaged.

Do not sterilize with hot air.

HANDLING

All surgical instruments must be handled with the greatest care when being transported, cleaned, treated, sterilized and stored. This is especially true for blades, fine points and other sensitive areas. Surgical instruments corrode and their functions are impaired if they come into contact with aggressive materials. The instruments must not be exposed to acids or other aggressive cleaning agents.

PRODUCT INFORMATION DISCLOSURE

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RETURNED GOODS POLICY

Products must be returned in unopened packages with manufacturer's seals intact to be accepted for replacement or credit unless returned due to a complaint of product defect. Determination of a product defect will be made by Miltex. Products will not be accepted for replacement if they have been in the possession of the customer for more than 120 days.

SYMBOLS USED ON LABELING



Manufacturer



Authorized Representative in the European Community



Catalog number



Lot number



See instructions for use



Consult instructions for use



US Federal Law restricts this device to sale by or on the order of a physician only.



Product complies with requirements of directive 93/42/EEC for medical devices



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