

Reusable Loop/Ball Electrode

Electrosurgical Cutting & Coagulation accessories



Intended Use

It is intended to use with standard electrosurgical pencils in gynecological procedures for smooth excision of abnormal or cancerous cervical tissue in a woman's lower genital tract.

Device Description

Premier's Reusable Loop Electrode consists a wire loop, welded to standard 3/32" diameter, 5" long shaft. The wire loop size/shape varies to match clinical procedural requirements. PTFE made insulated shaft layer protects the user and patient while handling an energized device. Device provides compatible friction fitting with standard electrosurgical pencils.

Contraindications

- During Pregnancy.
- Active infection or bleeding diathesis.
- Acute or active inflammation of the cervix, endometrium, fallopian tube, ovary or peritoneum.
- Invasive cancer that is visible on examination.
- Known or suspected cervical changes secondary to DES (diethylstilbestrol) intrauterine exposure.
- In the presence of flammable gases, liquids and/or oxygen enriched environments.
- Noticed visible evidence of damage to shaft insulation or wire loop.
- Re-use of device on different patient without proper sterilization.

PRECAUTIONS

- Do not use if the package is damaged/broken, prior to use.
- Discard the device, if any thinning of the wire loop or shaft and cross-bar insulation cracks/fractures are noticed.
- Device must be cleaned and sterilized, prior to first and subsequent usage.
- Prior to first and subsequent use, examine the device for breaks, cracks and/or malfunction.
- Do not use if the wire is noticeably thinned, prior to use.
- Medical professionals and assistants should always wear eye protection, surgical masks, and other appropriate personal protective equipment (PPE) when performing Loop electrode excision procedure.

- High vacuum evacuation should be used to avoid inhalation of plume and/or particulate matter generated during surgical procedure.
- Do not apply excessive pressure on the operating loop electrodes, as this could generate excessive heat and may cause device to fail.
- Prescription device, Rx only.

WARNINGS

- Adverse effects of loop electrode electrosurgical excision procedure during pregnancy outcome is unknown.

ADVERSE EVENTS

- Electromagnetic interference for Patient with ICD (Implantable Cardioverter Defibrillator) or Pacemakers.
- Permanent scarring and/or cervical incompetence due to the removal of cervical tissue.

Contents:

Loop Electrodes	
1006310	– Loop (1.0cm * 1.0cm)
1006320	– Loop (1.5cm * 1.5cm)
1006325	– Loop (2.0cm * 0.8cm)
1006330	– Loop (2.0cm * 1.2cm)
Ball Electrode	
1006340	– Ball (0.5cm)

Materials:

Component	Material
Electrode wire	ASTM A276 – 302 Stainless Steel
Tubing/Shaft	ASTM A269 – 304 Stainless Steel
Shaft insulating layer	PTFE (Polytetrafluoroethylene)
Ball	ASTM A582 – 303 Stainless Steel

Directions for Use:

- Insert the shaft end of device into standard electro-surgical pencil.
- Ensure the Loop/Ball electrode is fully seated and securely gripped into surgical pencil, prior to use.
- Check for adequate input power supply from the electro-surgical generator.
- Turning the ON-OFF switch to ON position energizes the hand control or foot control pencil.
- Select appropriate mode for Loop/Ball electrode excision procedure.
- Activate the hand control or foot control pencil before making the Loop/Ball electrode in contact with patient.
- Turn ON surgical smoke evacuator to capture and filter the plume generated during procedure.
- Loop/Ball electrode must be moved at constant speed, restricting the device movement may cause excessive heat generation and burn the excised tissue.
- Avoid using Loop/Ball electrode with heavy transverse excision, use of light pressure is recommended.

Cleaning

- Loop/Ball electrodes should be cleaned whenever carbonization (black char) occurs on the wire loop.

Do not use any corrosive cleaning agents or acids.

- Recommended to gently apply fine instrument paste to the wire loop and lightly rub the electrode between pieces of gauze to remove carbonization.

Sterilization:

- Loop/Ball electrodes can be sterilized by autoclave.
- Autoclave process carried out at temperature 273°F (134°C) for 5 minutes, 30 minutes of dry time.
- Dry heat sterilization not recommended.

Storage

- Always store the device in original protective packaging, prior to first usage.
- Device storage and handling temperature should not exceed (37.7° C) 100° F.
- Extra care should be taken while handling and avoid the Loop/Ball electrodes from coming in contact with aggressive and/or caustic solutions.

Shelf Life






- Premier Reusable Loop/Ball Electrodes have indefinite shelf life.

Disposal

- Dispose the device as biohazardous medical waste in accordance to facility or institutional guidelines/procedures.

For Further Information

Please visit premiermedicalco.com

Symbols	Symbol Meaning
	Manufacturer
	Batch number
	Caution: See instructions for use
Rx ONLY	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician
	Non-Sterile
	Fragile, Handle with care



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Made in USA
Rx ONLY

