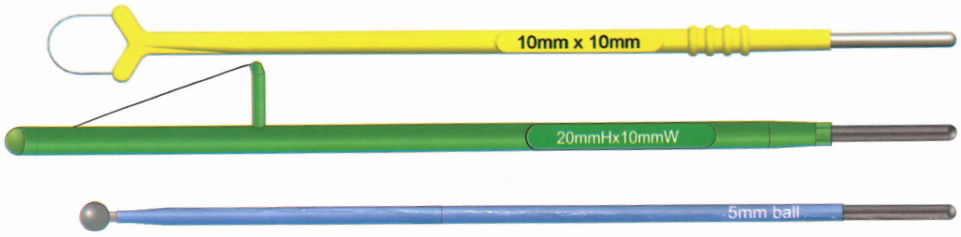
# LEEP Electrode - Single Use
# Instructions for Use

MD-IFU-LEEP.17A




## Description/Intended Use:

The intended use of LEEP electrodes is excision of the transformation zone of the human uterine cervix in the treatment of CIN lesions. Genital warts, cysts, vulva and for other gynecological tissue biopsies.
Maximum voltage not to exceed 5.5 KV peak.
Medstar LEEP electrodes have a 3/32in. (2.36mm) diameter shaft and are designed to fit Medstar and most other electrosurgical pencils and accessories. However, prior to use, it is important to check the electrode connection to the accessory you are using to assure proper fit and compatibility.

## Contraindications:

Do not use monopolar electrosurgery on small appendages, as in circumcision or finger surgery.
These devices should never be used when:

- There is visible evidence of damage to the exterior of the device such as cracked or damaged plastic.
- These devices fail the inspection described herein.
- In the presence of flammable gases, flammable prep solutions or drapes, oxidizing gases such as Nitrous Oxide (N2O) or in oxygen-enriched environments.
- Do not use LEEP electrodes for the treatment of structures such as the bowel, cornea, anda omentum.
- Do not allow the electrode to touch or conduct (arc) electrosurgical current to a vaginal speculae.

Electrosurgery is potentially hazardous for patients with pacemakers, AICDs, neurostimulators or other active implants. High frequency energy may damage or adversely affect active implants. Ventricular fibrillation may occur.

## Warning:

- Keep active accessory away from the patient when not in use. An Accessory Holster may be used to hold active accessories safely.
- Do not use in the presence of combustible or explosive materials!
- Do not reuse because the ability to effectively clean and re-sterilize this single patient use device has not been established and subsequent re-use may adversely affect the performance, safety, and/or sterility of the device.

## Caution:

- The use-by-date is indicated on the packaging. Do not use this product if the use-by-date has been exceeded!
- Improper electrode installation may result in injury to the patient or operating room personnel by arcing at the pencil/electrode connection.
- Do not activate the electrosurgical generator until the loop is at the target tissue. Premature activation of the electrosurgical generator may result in a patient injury.
- Use lowest possible power setting on the associated electrosurgical unit capable of achieving desired surgical effect. • Activation time should be as short as possible.
- Never allow the associated accessories connected to these devices to be in contact with skin of the patient or operator except during intended activations.
- Do not permit the cables connected to the associated electrosurgical accessories to be parallel and in close proximity to the leads of other electrical devices.
- Always place unused associated electrosurgical accessories in a safe insulated location such as a holster when not in use.
- Inspect and test each device before each use.
- After use, this product may be a potential biohazard. Handle and dispose of as required by hospital policy and applicable law.

## Inspection

These devices should be inspected before each use. Visually examine the devices for obvious physical damage including:

- Cracked, broken or otherwise distorted plastic parts.
- Broken or significantly bent connector contacts.
- Damage including cuts, punctures , nicks, abrasions, unusual lumps, significant discoloration.
- Verify that the electrode is fully and securely seated in the handpiece before use.

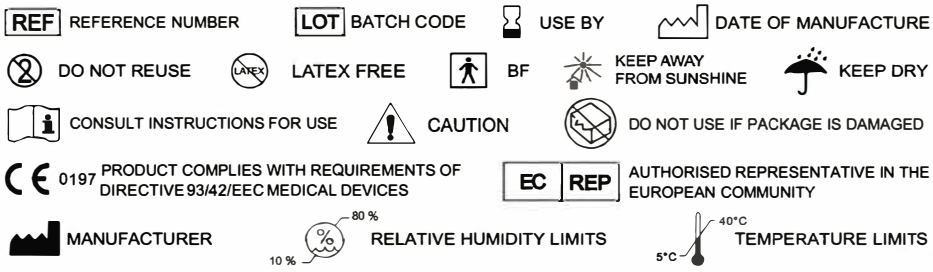
## Instructions for Use:

• Loop Electrodes – The loop electrodes are designed only for cutting, and may be damaged if used for coagulation.
Loop Electrodes are supplied with round shape and square shape.
The electrosurgical generator should be set for low crest factor, i.e. "Pure" cutting power of 20 to 35 Watts.
Activate cut mode prior to bringing the loop in contact with the tissue.
Keep the generator activated and the loop moving continuously until the excision is complete and the loop is withdrawn fully from the tissue.

• Ball Electrodes – The ball electrodes are intended only for coagulation of the excisional bed.
Ball Electrodes are supplied with 3mm/4mm/5mm diameter,also available with non-stick teflon coating.
Located bleeders may be coagulated using direct contact with the ball and a coagulation power of 25 to 45 watts.
Diffuse capillary bleeding and sealing of the excisional margin is best performed using non-contact fulguration.
Fulguration depends on a spray of sparks crossing a small air gap between the electrode and tissue.
Generation of adequately high voltage to cause sparks to jump this gap may require coagulation power settings from 35 to 60 watts.

• Conization Electrode - The conization electrodes are designed only for cutting, and may be damaged if used for coagulation.
If the diameter of a lesion exceeds the width of the largest loop or triangle electrode, the lesion may be removed by multiple passes in separate pieces. The central part of the lesion is removed first, followed by the peripheral parts.If the lesion has extensive endocervical involvement, triangle electrodes can remove a cone-shaped specimen with a depth of 1.3-2.0 cm. If an even deeper removal of the endocervix is warranted, a smaller round loop can excise the endocervix on top of the initial "cone."
In most cases excision with a triangle loop guarantees endocervical lesion removal and usually guarantees excision of the lesion and the transformation zone. Using a triangle loop as the preferred initial loop is recommended in most cases.
The electrosurgical generator should be set for low crest factor, i.e. "Pure" cutting power of 20 to 35 Watts.
Activate cut mode prior to bringing the electrode in contact with the tissue.
Keep the generator activated and the electrode rotating continuously until the excision is complete and the cone-shaped exceed tissue is removable.

## Symbols used on labeling:





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