

Indication for Use

The MAXPLATE of MediMaxTech is a disposable, single use, neutral electrode, which provides a return path for high frequency electrical current to the ESU device.

The ESU grounding plates are compatible with High-frequency electrosurgical generator with Contact Quality Monitoring System (e.g., REM™, ARM™, NESSY™). For ESU grounding plates with solid type, the use of the plates do not allow to activate the contact Quality Monitoring System of electrosurgical generator.

Instructions for use

1. For grounding plate placement, choose a flat muscular or well vascularized convex skin site near the surgical area but not closer than 20cm, on adults preferably the anterior or lateral arm or thigh, on children preferably the trunk section of the body.
2. Avoid skin site with excessive hair, adipose tissue, scar tissue, tissue directly over bone, traumatized area of any kind.
3. Shave the chosen site, thoroughly clean(e.g. cosmetics) and dry it.
4. Check the electrode for defects, such as dried-out gel or insufficient amounts of conduction gel or adhesive.
5. Place the grounding plate in a location where it is no likely to come in contact with fluids.
6. After applying the electrode, run a hand over the grounding plate to confirm uniform placement.
7. Connect securely to the electrosurgical unit.
8. Use this product within 24 hours of contact with the patient. Observe skin status during contact with the patient.
9. After use disconnect the cable from the electrosurgical unit and remove the plate by lifting it at corner.
10. To avoid a surface skin reaction, gently peeling it off.

Cautions

1. Do not use additional gel, do not cut the grounding plate.
2. Do not overlap.
3. Do not reposition the grounding plate.
4. Place ECG electrode as far as possible from the surgical area and grounding plate site.
5. Do not allow the patient's body to touch conductive objects.
6. Spilt type must be used to activate this type of monitoring system.
7. Do only use plate on adult patients weighing 15 kg<, pediatric patients weighing 5 kg to 15 kg, neonatal patients weighing less than 5kg.
8. Correct application and proper site selection can prevent the possible burn.
9. Avoid removing and/or reapplying plates the skin site frequently.
10. Do not use a plate if the gel is dry or dislodged from the aluminum-foil of the plate. Otherwise, burns could result at the skin site.
11. Avoid skin-to-skin contact (for example between the arms and body of the patient).
12. Whenever the ESU fails to produce the desired effect, make sure that the plate is in full contact on the skin site before turning up power.
13. Observe the safety instructions provided in the instructions for use of the diathermy device.
14. Do not reuse the grounding plate.
- ※ Reuse may cause a risk of cross-contamination, electrical burn. And the electrodes may not be firmly attached from skin to the patient's skin.
15. The transparent plastic liner has to be disposed to trash can immediately after the separation of the electrodes in order to prevent any possible slippery damage.
16. The electrode has to be disposed to trash can immediately after usage.
17. Do not use the device on different targeted patients.

Warning

Not following these instructions may lead to skin burns during use.

* User and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.