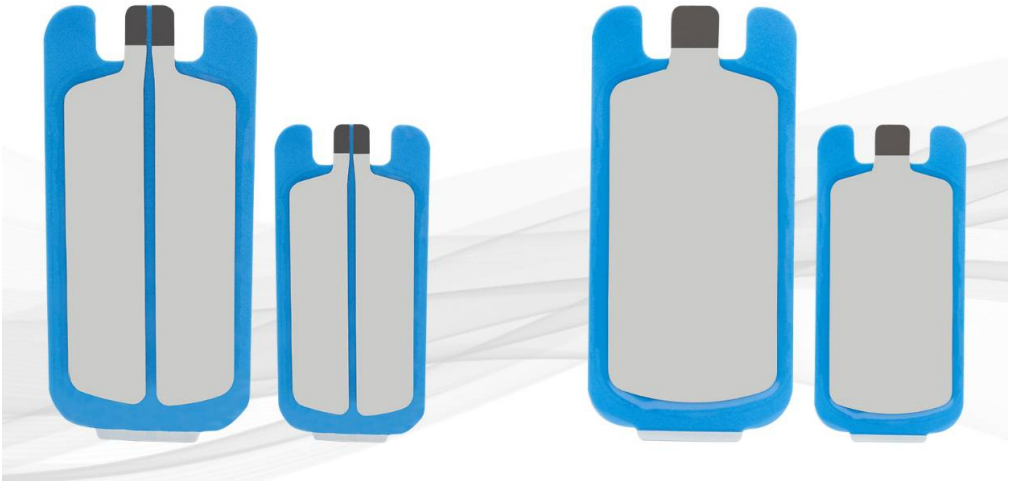
TECHNICAL DATA SHEET

Disposable Electrosurgical Grounding Pad



Product description

CE 0477

Product characteristics

- This product does not contain natural latex, phthalates or compounds of animal or biologic origin.
- This product is in compliance with RoHS standard.
- Bipolar plates are compatible with electrosurgical generators provided with REM monitoring.
- Weight limitations for the patient established according to plate model are the following:

Reference #	Model	Patient	Weight limit
5047	Monopolar	Adult	≥15 kg
5048	Bipolar	Adult	≥15 kg
5053	Monopolar	Paediatrics	5 - 15 kg
5054	Bipolar	Paediatrics	5 - 15 kg

Technical specifications

Materials

- Backing material: Waterproof flexible white PE foam, closed cell, with biocompatible acrylic adhesive.
- Conductive area: Aluminum / PET film with acrylic based hydrogel, biocompatible.
- Release liner: PET.
- Pouch: PET , aluminum , PE film.
- Box: Carton.

Main dimensional properties

Contact area:	Width (mm)		High/ Length (mm)		Total (cm^2)	Conductive surface Monopolar pad (cm^2)	Conductive surface dual pad (cm^2)
	Monopolar	Bipolar	Monopolar	Bipolar			
Adult	100	100	200	200	197	128	121.5
Paediatrics	90	90	150	150	132	77	73
Neonatal	74	74	90	90	63.5	32.5	30

- Hydrogel thickness: 0,69mm gel + aluminum support

Electrical properties (ANSI/AAMI EC12)

- Electrical features of the plate:

Temperature increase (IEC 60601-2-2, cl. 201.15.101.5)	Adult	Paediatrics	Specification
	< 6 ºC	< 6 ºC	< 6 ºC
Contact impedance (IEC 60601-2-2, cl. 201.15.101.6)	< 50 Ω	< 50 Ω	< 50 Ω

- **Electrical features of the cable:**
  - High frequency leakage current (IEC 60601-2-2, cl. 201.8.8.3.102): **OK.**
  - High frequency dielectric strength (IEC 60601-2-2, cl. 201.8.8.3.103): **OK.**
  - Mains frequency dielectric strength (IEC 60601-2-2, cl. 201.8.8.3.104): **OK.**
  - Conclusion: Requirements established by electrical safety standards EN IEC 60601-2-2:2018 and ANSI/AAMI HF-18.

- **Electromagnetic compatibility:**

The product is classified as group 1, class A product according to EN 55011/CISPR 11. This means that this product does not generate and/or use intentionally radio-frequency energy, in the form of electromagnetic radiation, inductive and/or capacitive coupling, for any purpose and that it is suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes. There may be potential difficulties in ensuring electromagnetic compatibility in environments other than hospital or industrial, due to conducted as well as radiated disturbances.

Biocompatibility

- ISO 10993-5: No cytotoxic.
- ISO 10993-10: No sensitizing.
- ISO 10993-10: Negative intracutaneous irritation test.

Conclusion: The product is biocompatible.

Sterilization and expiry date

- Non-sterile product.
- Shelf life: 2 years upon the manufacturing date.

Storage and maintenance

- Keep protected from direct sunlight. keep in a dry place.
- Temperature limitation: 5-40 ºC.
- Single use product.

Packaging

Ref #	Packaging
5047	Unitary pouch in 50 units box.
5048	Unitary pouch in 50 units box.
5053	Unitary pouch in 50 units box.
5054	Unitary pouch in 50 units box.

Instructions for use

- Do not open the package until the plate is ready to be used, to avoid the gel drying out.
- Select a well vascularised area near the incision.
- Do not place on bony protrusions, metallic prosthesis, tattoos or scars.
- Avoid if possible, the areas with a lot of fat under the skin.
- Shave if necessary.
- Clean and dry the application area.
- In the case of the elderly, smooth out the skin beforehand.
- Apply the adhesive face of the plate smoothing and pressing lightly.
- Once the intervention is finished, remove the plate gently.

Regulatory information

- D.G.Dena guarantees that this product is in conformity with **Regulation (EU) 2017/745** and that it has been manufactured following the directives of the Quality Assurance System certified as **ISO 13485**.

- This product is classified as:
  - **Class IIb** product according to Annex VIII of **Regulation (EU) 2017/745**., rule 9.
  - GMDN code: 58494 – Electrosurgical return electrode, single-use, non-sterile.