

Pre-gelled electrosurgical plates

BLAYCO

> Product description

Electrosurgical plates are used as closing element in the circuit constituted together with the active electrode and the electrosurgical unit in electrosurgical interventions. The electrode provides a large contact surface with the patient, compared with the active electrode, that allows reducing the current flow density and minimize the risk of electrosurgical effects or burnings.



CE
2797

> 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.
- Dual plates are compatible with electrosurgical generators provided with REM monitoring.

Weight limitations for the patient established according to plate model are the following:

- Adult ≥ 15 kg
- Paediatrics 5- 15 kg
- Neonatal < 5kg
- Universal ≥ 5 kg

- See annex of the present specification for further details about cables and their compatibilities.

Compatible models for high energies up to 1100mA: 2125

Models compatible with conventional procedure: 2225, 2425, 2500, 2510, 2600, 2700, 2900

> Technical specifications

> Materials

- Backing material: Waterproof flexible white PE foam, closed cell, with biocompatible acrylic adhesive.
- Conductive area: Aluminium / PET film with acrylic based hydrogel, biocompatible.

- Release liner: PET.
- Cable (references –C/XX y –C/XX/5):
 - Staples: Plated brass.
 - Wire: Copper (10 x 0.14mm) coated with non-toxic PVC.
 - Inner terminal: Nickel-plated brass.
 - Plug: Non-toxic PVC.
 - Pin (cable 4212): Polycarbonate.
- Pouch: PET / aluminium / PE film.
- Service Box: Carton.

➤ Main dimensional properties

Contact area:	Width (mm)		High/ Length (mm)		Total (cm ²)	Conductive surface unipolar plate (cm ²)	Conductive surface dual plate (cm ²)
	Unipolar	Dual	Unipolar	Dual			
Adult	105	105	217	217	217	136	128
Adult oblong	-	177	-	125	221	-	128
Paediatrics	105	105	150	150	145	83	73
Neonatal	74	74	160	160	83	32	31
Universal	-	163.5	-	117	168	-	105

- Hydrogel thickness: 0,69mm gel + aluminium support
- Cable length:
 - REF-C/XX: 280cm – 320cm
 - REF-C/XX/5: 490cm – 510cm
- Plug: See drawing in annex.

➤ Electrical properties (ANSI/AAMI EC12)

- Electrical features of the plate:

	Adult	Paediatrics	Neonatal	Universal	Specification
Temperature increase (IEC 60601-2-2, cl. 201.15.101.5)	< 4 °K	< 6 °K	< 6 °K	< 6 °K	< 6 °K
Contact impedance (IEC 60601-2-2, cl. 201.15.101.6)	< 3 Ω	< 5 Ω	< 10 Ω	< 3 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: 3 years upon the manufacturing date.

Storage and maintenance

- Keep protected from direct sunlight / the outside.
- Keep in a dry place.
- Temperature limitation: 5-40°C.
- Single use product. No maintenance required.

Packaging

#	Ref	Packaging
TPXXX	REF	Unitary pouch in 100 units service box.
TPXXX	REF-5	Pouch containing 5 units, in 100 units service box.
TPXXX	REF-C/XX	Unitary pouch in 50 units service box.
TPXXX	REF-C/XX/5	Unitary pouch in 50 units service box.

> Instructions for use

- Do not open the envelope 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.

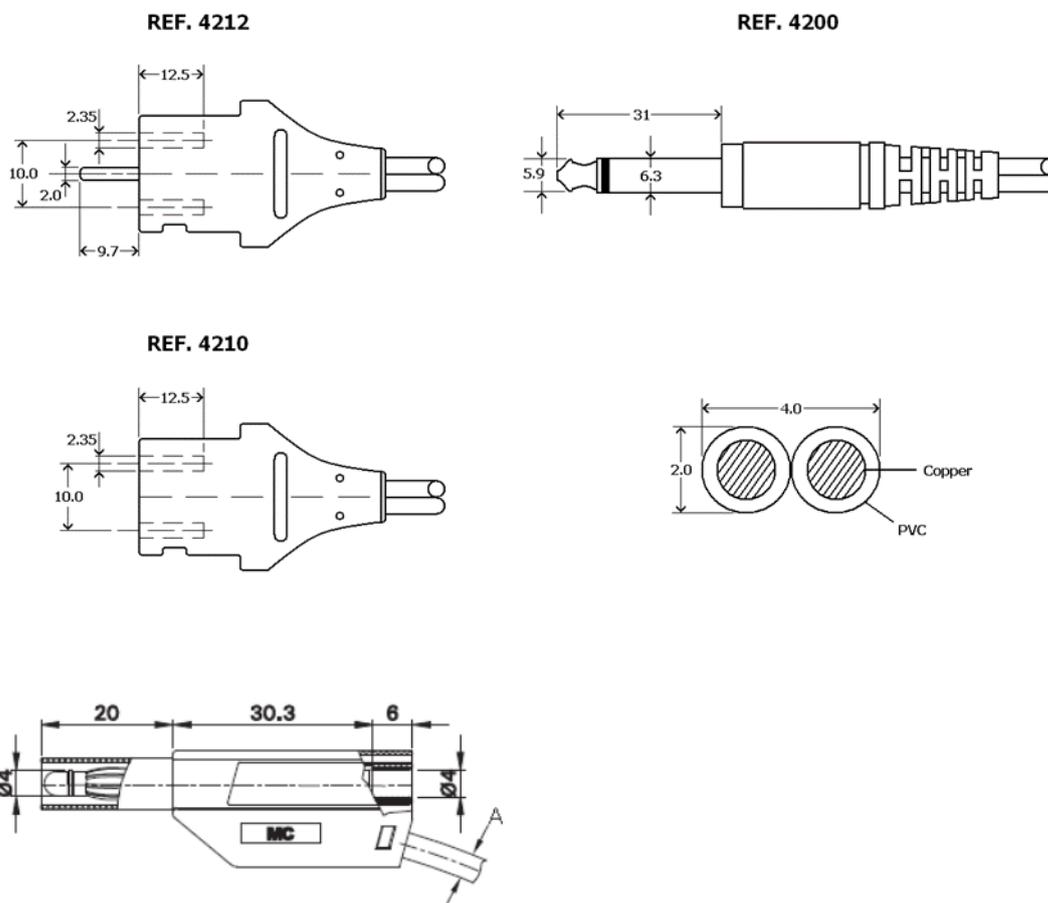
Date: January 2023

Nº Specification: ETP/002/12

> Regulatory information

- TELIC, S.A.U. 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.
 - EMDN code: K020102 (Electrosurgery pads (neutral electrodes) and cables, single-us)

> Annex - Plugs



> Compatibility

Plate with cable	Connector	Description	Unipolar	Dual
REF-C/00 et REF-C/00/5	4200	ERBE type connector	X	X
REF-C/10 et REF-C/10/5	4210	VALLEYLAB type connector	X	
REF-C/12 et REF-C/12/5	4212	VALLEYLAB type connector		X
REF-C/21 et REF-C/21/5	4221	AMICA type connector	X	