



Product

BLAYCO®

Sterile electrosurgical pencil

References

MB-100: Hand control electrosurgical pencil with 70mm blade electrode with cable 3m length.
MB-100/5: Hand control electrosurgical pencil with 70mm blade electrode with cable 5m length.
MB-300: Hand control electrosurgical pencil with 70mm insulated blade electrode with cable 3m length.
MB-400: Rocker switch electrosurgical pencil with 70mm insulated blade electrode with cable 3m length.
MB-500: Rocker switch electrosurgical pencil with 70mm blade electrode with cable 3m length.

CE
0197

Date

April 2022

Specification N.

ETP/026/17

TECHNICAL SPECIFICATIONS

Materials

- Handle cover: ABS.
- Electrode connector: Copper.
- Printed circuit: PCB.
- Activation switches CUT & COAG :
 - Buttons:(MB-100, MB-100/5, MB-300): ABS.
 - Rocker switch (MB-400, MB-500): ABS.
- Connector mould: ABS.
- Connector pins: Brass.
- Cable: Copper coating with PVC.
- Blade electrode 70mm:
 - Electrode body: 304 stainless steel
 - Plastic insertion: ABS
 - Insulation tube (MB-300, MB-400): PTFE
 - Tip protector: PE
- Sterile pouch:
 - Cellulose, medical grade.
 - Film PET/Polyethylene.

Main dimensional properties

- Banana plugs: 3 x Ø4.0 mm ±0.2 mm.
- Wire length:
 - MB-100: 300 ±15 cm.
 - MB-100/5: 500 ±15 cm.
- Total electrode length: 70 ±1 mm.
- Diameter of the electrode: 2.36 ±0.03 mm.
- Electrode insert: hexagonal.





Other properties

Electrical assays EN 60601-2-2

- (High-frequency voltage rating of 5kV peak)
- Cable leakage current.
- Cable dielectric withstand, high frequency (6 kV peak).
- Cable dielectric withstand, mains frequency (6 kV peak, 60 Hz).
- Cable strain relief.
- Handpiece dielectric withstand, high frequency (6 kV peak).
- Handpiece dielectric withstand, mains frequency (6 kV peak, 60 Hz).
- Handpiece resistance to ingress of liquids.
- Handpiece retention of removable electrode.

Conclusion: electrical requirements are met.

Biocompatibility

- ISO 10993-5: No cytotoxic.
- ISO 10993-10: no sensitizing, negative intracutaneous irritation test.
- ISO 10993-11: no pyrogen presence, negative systemic injection test.
- ISO 10993-4: negative haemolysis test.

Conclusion: product is biocompatible.

Sterilization and expiry date

- Sterility: Ethylene oxide.
- Shelf life: 5 years.

Storage and maintenance

- Keep protected from direct sunlight / the outside.
- Keep in a dry place.
- Temperature limitation: 5-45°C.
- Single use product. No maintenance required.

Packaging

- Cardboard boxes containing 50 units.

PRODUCT CHARACTERISTICS

- Suitable for all models of Blayco Electrosurgical accessories.
- Latex Free.

REGULATORY INFORMATION

TELIC, S.A.U. guarantees that this product is in conformity with **Directive 93/42/EEC** 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** sterile product according to Annex IX of Directive 93/42/EEC, rule 9.
- GMDN code: 61869. Open-surgery electrosurgical handpiece/electrode, monopolar, single-use.
- EMDN code: K0201010501 open electrosurgery handpieces, single-use.