



# GIMA

PROFESSIONAL MEDICAL PRODUCTS

## **ELETTRODI (MONOUSO)** **ELECTRODES (SINGLE USE)**

**REF 30370 - 30371 - 30372 - 30373 - 30374 - 30375 - 30677 - 30679**



Tecno Instruments Pvt. Ltd.  
316C Small Industrial Estate  
Sialkot, 51340 - Pakistan  
Made in Pakistan



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Importiert von/ Importado por/ Importado por/  
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**Description/Intended Use:**

These devices are single use and supplied sterile. These devices are designed to be used as accessories in conjunction with those cables and electrosurgical units with which they are known to be compatible. Their use enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit and accessory cables to the operative site for the desired surgical effect.

**Compatibility:**

Electrode Type	Instrument Connector	ESU Generator Connector
Blade/Ball/Needle/Loop/Conization	2.4mm	N/A
Blade/Ball/Plat/Needle/Loop	4.0mm	N/A

**Recommendations:**

Recommended Voltage	Shelf Life	Operation Environment
1500 Vp	5 Years	Temperature: 5°C to 40°C Humidity: 0% to 90% R.H Pressure: 70 kPa to 106 kPa

**Contraindications:**

Incidents which have been reported in connection with the use of bipolar systems:

1. Unintended activation with resulting tissue injury on the wrong spot and/or damage to the equipment.
2. Alternating current paths leading to burns on spots where the patient or user comes into contact with components without insulation.
3. In the presence of flammable gases, liquids, and/or oxygen enriched environments.
4. Electrosurgery is potentially hazardous for patients with active implants such as pacemakers, AICDs and neuro stimulators.

**Use and Safety Instructions:**

The non-observance of the present use and safety instructions may lead to injuries, malfunctions, or other unexpected incidents.

1. It is especially important to check each instrument for visible damage and wear, such as cracks, breaks or insulation defects before each use.
2. Never use damage instruments.
3. Never use the instruments in the presence of flammable or explosive substances.
4. The instrument may not be laid down on the patient.
5. Frequently clean the tips from blood and debris.
6. Coagulation should only be performed if the contact surfaces are visible and ensure a good contact to the tissue selected for coagulation.
7. Do not touch any other metallic instruments, trocar sleeves, optics or the likes during use.

**Side Effects:**

There are no side effects, associated with the use of device if use by professional person.

**Users:**

This device only be used by persons who are specially trained doctors.

**Patient population:**

This device is suitable for use for children and adult.

**Performance Claims:**

- These medical devices are made of biocompatible material which conforms to ENS ISO 10993-1 standard.
- These medical device conforms to IEC 60601-2-2 standard for electrical safety.
- These medical device conforms to IEC 60601-1 for basic safety & essential requirements.

#### Prior to Use:

Before connecting electrode with electrodes handle, make sure that the unit has been switched off or is in standby mode. Disregarding these instructions may lead to burns and electrical shock.
















#### During Use:

Always use the lowest power setting available to achieve the desired surgical effect.

#### Storage & Handling:

1. These medical devices must be stored in a clean, cool and dry area.
2. Protect from mechanical damage & direct sun light. Handle with extreme care.

#### Symbols:

	Caution: read instructions (warnings) carefully		Keep away from sunlight
	Keep in a cool, dry place		Date of manufacture
	Manufacturer		Product code
	Lot number		Authorized representative in the European community
	Medical Device complies with Directive 93/42/EEC		Disposable device, do not re-use
	Temperature limit		Expiration date
	Sterilized using ethylene oxide		Consult instructions for use
	Authorized Representative in the UK		

#### GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.