GIMA

PROFESSIONAL MEDICAL PRODUCTS

PINZE BIPOLARI
BIPOLAR FORCEPS
FORCEPS BIPOLAIRES
BIPOLARE PINZETTEN
PINZAS BIPOLARES
PINÇAS BIPOLARES
ΔΙΠΟΛΙΚΕΣ ΛΑΒΙΔΕΣ

Codice GIMA	REF	Codice GIMA	REF	Codice GIMA	REF
30460	310-120-10 NS	**30623**	110-360-10	**30658**	310-140-20
30461	310-130-10 NS	**30645**	310-560	**30659**	310-190-10
30462	310-140-10 NS	**30646**	310-500	**30660**	310-132-03
30464	310-132-10 NS	**30647**	310-540	**30661**	310-130-03
30465	310-142-10 NS	**30648**	310-590	**30662**	310-140-03
30468	310-170-10 NS	**30650**	310-130-10	**30663**	310-200-10
30469	310-180-10 NS	**30651**	310-140-10	**30664**	310-300-10
30472	310-110-07 NS	**30652**	310-132-10	**30665**	310-110-03
30473	310-112-07 NS	**30653**	310-142-10	**30666**	310-112-03
30474	310-300-10 NS	**30654**	310-170-10	**30667**	310-120-05
30620	110-200-10	**30655**	310-180-10	**30668**	310-122-03
30621	110-220-05	**30656**	310-130-10IR	**30669**	310-100-05
30622	110-230-10	**30657**	310-160-10		

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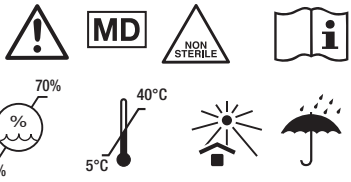

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DESCRIPTION/INTENDED USE:
These devices are reusable and are supplied non-sterile. Process through cleaning and sterilization prior to initial use. These devices are designed to be used as accessories in conjunction with those cables and electrosurgical 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:

ForcepsType	Instrument Connector	ESU Generator Connector
US2 pin	1.8mm Female	4.0mm/Martin/ ERBE
European	Flat Plug	4.0mm/Martin/ ERBE
Aesculap	Flat Pin Plug	4.0mm/Martin/ ERBE

REUSE:
We guarantee our products to withstand a minimum of 20 sterilization cycles when sterilized in accordance with the validated instructions contained herein. Care in use and handling can extend useful life.

Recommended Voltage	Shelf Life	Operation Environment
500Vp	5Years	Temperature: 5°C to 40°C Humidity: 0% to 90% R.H Pressure: 70 kPa to 106 kPa

CONTRAINDICATIONS:
Incident swhich 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 onspots where the patient or user comes into contact with components without insulation.
3. In the presence of flammable gases, liquids, and/or oxygenenriched environments.
4. Electrosurgery is potentially hazardousf or patients with active implants such as pacemakers, AICDs and neuro stimulators.

USEAND SAFETY INSTRUCTIONS:
The non-observance of the presentuse and safetyinstructionsmaylead toinjuries, malfunctions, or other unexpected incidents.
1. Before initial use and any other use, all instruments must be completely cleaned, disinfected, sterilized and their functionality must be examined.
2. It is especially important to check each instrument for visible damage and wear, suchas cracks, breaks or insulation defects before each use.
3. Never use damage instruments.
4. Never use the instrument sin the presence of flammable or explosive substances.
5. The instrument may not be laid down on the patient.
6. Frequently clean the tips from blood and debris.
7. Coagulation should only be performed if the contact surfaces are visible and ensure a good contact to the tissue selected for coagulation.
8. 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:
Thisdevice issuitable foruse forchildrenandadult.

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 medica device conforms to IEC60601-1 forbasic safety & essential requirements.

PRIORTO USE:
Before connecting forceps and cables to an electrosurgical unit, make sure that the unit has been switched off or is in stand by mode. Disregarding these instructions may lead to burns and electrical shock.

DURING USE:
Always use the lowest powersetting available to achieve the desired surgical effect.

POINT OF USE TREATMENT (IN THE OPERATING ROOM):
1. Disconnect cable from forceps.
2. Clean Device as soon as possible after use.
3. Remove excess solids using disposable lint free wipes, enzymatic foam or per hospital procedure. Soiled devices should be separated from unsoileddevices. Soiled devices should be covered with a lint free towel dampened with tap, sterile or critical water to prevent blood

and/or debris from drying. Encrusted soil can increase the time and effort required to complete processing.
4. If there commendations in the steps above are not possible, the device may be placed in container and immersed in tap, sterile or critical waterand covered for transport to the processing area.
5. Do not use aggressive/abrasive cleaners.
6. Follow the cleaning and sterilization instructions below.

CLEANING (AFTER PROCEDURE):

Cleaning should be performed as soon as possible after use, preferably withinone hour of use. The devicehas been designed for thorough cleaning andsafe sterilization, without disassembly. It is the responsibility of the end usertoensure that the cleaning is performed using appropriate equipment, materialsand personnel to achieve the desired result.

The user must ensure that cleaning and sterilization are conducted in accordance with the appropriate guidelines, standards, or National Health Authority requirements. Hospital grade low foaming neutral pH to mildly alkaline enzymatic detergents, hospital grade low foaming neutral pH-detergents (pH 7-9) or hospital grade low foaming mildly alkaline detergents with a pH of ≤ 11 (prepared according to manufacturer's instructions) should be used. "Detergent(s)" will be used generically throughout the rest of theseinstructions.

Ensure that detergentmanufacturer instructions are followed for concentration,temperature and water quality throughout the cleaning process. When usingmildly alkaline detergents, critical watershouldbeusedthroughout thecleaningprocess.

Further information regarding the use of specific cleaning agents, ultrasonicwashers, washer-disinfector, packaging materials or sterilizers duringvalidation studies are available on request. The following detergents wereused during validation process.

- Manual Pre-Cleaning with neodisher® MediZym Enzymatic Detergent -5 mL/L at 40°C
- Manual Cleaning with neodisher® MediZym Enzymatic Detergent -5mL/L at 40°C
- Manual Disinfection with Johnson & Johnson CIDEXOPA
- Automated WD Cleaning & Disinfection with neodisher® Medi Clean forte– 2 mL/L at 55°C

The chemical quality of the water used during processing can impact device safety. Facilities should use the recommended water quality requirements for device processing in accordance with local guidance (such as AAMI TIR 34, Water for the reprocessing of medical devices), detergent manufacturers and these instructions for use. Critical water is recommended for thermal disinfection and final rinsing of devices. For the purpose of these instructions for use, critical water is defined as a treatment process that may include deionization (DI), reverse osmosis (RO) or distillation.

PRE-CLEANING: MANUALLY

Equipment: Enzymatic cleaner, cleaning brush, tap water/flowing water (20±2°C), tank/basin, ultrasonic bath.
1. Rinse the medical device completely under cold running tap water (atleast drinking water quality) for minimum of 1 minute.
2. The cleaner is prepared in accordance to manufacturer's instructionsfor the detergent and filled in the ultrasonic bath.
3. Soak the medical device completely in the ultrasonic bath.
4. Brush the hard-to-reach areas of submerged instrument with soft brush for 1 minute(min.). Pay attention to the critical hard toreach areas where it is not possible to assess the cleaning efficacy.
5. Make sure that all surfaces are completely moistened with cleaning solution.
6. Start the Ultrasonic for at least 10 minutes (temperature max. 40°C, ultrasonic frequency 35kHz.
7. Remove the medical device from the ultrasonic bath and rinse undercold running tap water for 1 minute (min.).

CLEANING: MANUALLY

Equipment: Enzymatic Cleaner, tap water/flowing water (20± 2°C), tank/basin, demineralized water (20± 2°C).
1. The cleaner is prepared in accordance with themanufacture's instruction.
2. Soak the medical device completely in the cleaning solution.
3. Move the movable parts of the medical device 3 times in the cleaning solution.
4. Make sure that all surfaces are completely moistened with cleaningsolution.
5. Exposuretime (10 minutes) or as manufacturer's instructions.
6. Remove the medical device from the cleaning solution.
7. Rinse the medical device completely under demineralized water for minimum of 1 minute. To remove the cleaning solution completely. Check for cleanliness, if dirtis visible, repeat

the steps above.

DISINFECTION: MANUALLY

Equipment: Non-protein-fixing VAH-listed instrument disinfectant,
cleaning brush, demineralized water (20± 2°C), disinfection tank, lint free gauze and/or medical quality compressed air.

1. Fill the disinfectant tank with disinfectant solution.
2. Immerse the medical device completely in the disinfectant solution.
3. Brush the hard-to-reach areas of submerged medical device with soft brush for 1 minute (min.).
4. Move the moveable parts of medical device 3 times in the disinfectant.
5. Make sure that all surfaces are completely moistened with disinfectant solution.
6. Exposure time (5 minutes) or as per manufacturer's instruction.
7. Place medical devices in a tank of demineralized water for at least 1 minute.
8. Repeat step 7 two times with fresh demineralized water to remove the disinfectant solution completely.
9. Wipe with a lint free gauze and/or dry with medical compressed air.

CLEANING & DISINFECTION: AUTOMATED WD

Prior: Do manual pre cleaning before the automated cleaning and thermal disinfection.
Equipment: Washer disinfector in accordance with EN ISO 15883-1 with thermal program (temperature 90-95° C), mildly alkaline cleaner, lint free gauze and or medical quality compressed air.

1. Place the medical device in a suitable tray or place them on the load carrier that all inner and outer surfaces will be cleaned and disinfected.
2. Close the WD and start the program, the program parameters are shown in the table below.

Program Step	Water	Dosage	Time	Temperature
Pre-Rinse	Cold		5 min	
Dosage Cleaner		According to manufacturer's instructions (0.2% is validated)		According to manufacturer's instructions
Cleaning	Deionized Water		According to manufacturer's instructions (10 min is validated)	According to manufacturer's instructions (55°C is validated)
Rinse	Deionized Water		2 min	
Disinfection	Deionized Water		Ao value ≥ 600 (e.g.1 min, 90°C)	
Drying			15 min	Up to 120°C

3. At the end of the program, remove the medical device.
4. Check for the dryness if it is necessary wipe with lint free gauze and/or dry with medical compressed air.
5. After removal from the WD check the device for cleanliness.If the dirtis still visible, clean the medical device manually. After wards the automated cleaning process must be carried out again.

MAINTENANCE, INSPECTION & TESTING:

1. All medical devices must be visually checked for cleanliness, dryness and damage (e.g., cracks, fractures, corrosion, mobility, pitting etc.) if necessary, using an illuminated magnifier (3-6 Dptr.)
2. Damaged medical devices must be sorted out and not to be used again.
3. These devices do not have an indefinite functional life. All medical devices are subject to a degree of wear and tear as a result of normal use.

STERILIZATION:

Equipment: Steam sterilizeraccording to DIN EN285 or DIN EN 13060 withtype B process. Pre-vacuum process, 134° C and sterilization time at least 3 min (longer holding times are possible).

1. Place the packaged medical device in sterilization chamber.

2. Start the sterilization program.
3. At the end of sterilization program remove the device and let it cool down.
4. Check the package for damage or moisture penetration. Rejected packaging must be considered non-sterile. The product must be repackaged and sterilized.

STERILIZATION IN THE EU/USA AND OTHER COUNTRIES:

Sterilizer Type	Pre-vacuum
Method	Wrapped
Cycle Time (minimum time at temperature)	3 minutes
Temperature Set Point	134°C (273°F)
Minimum Drying Time	15 minutes

5. National Health Authorities in some regulated regions do not accept immediate use sterilization methods, e.g. in the EU. Please review the appropriate guidelines, standards and National Health Authority guidelines when determining acceptable steam sterilization process parameters for use in each respective country.
6. Immediate-use steam sterilization is only intended for individual devices and should only be performed when approved by local policies. Immediate-use steam sterilization of devices is not recommended or supported. It is the sole responsibility of the user to validate immediate-use steam sterilization if performed.
7. Do not handle the device until they are thoroughly cooled.

STORAGE&HANDLING:

1. Bipolar Forceps must be stored in a clean, cool and dry area.
2. Protect from mechanical damage & direct sunlight. Handle with extreme care.

WARRANTY:

1. These products are guaranteed against material and workman ship. The warranty is null and void should damage occur as a result of improper handling use.
2. Care must be taken in the use and reprocessing of these products.

SYMBOLS:

	Caution: read instructions (warnings) carefully
	Keep in a cool, dry place
	Manufacturer
	Product code
	Medical Device complies with Directive 93/42/EEC
	Non-sterile
	Authorized representative in the European community
	Authorized Representative in the UK
	Conservare al riparo dalla luce solare
	Date of manufacture
	Lot number
	Consult instructions for use
	Temperature limit
	Humidity limit
	Medical device
	Use by date
	Product code
	Quantity

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.