GIMA

PROFESSIONAL MEDICAL PRODUCTS

SPECULUM CUSCO ISOLATO – MEDIO
S.S. CUSCO SPECULUM – MEDIUM INSULATED
SPÉCULUM DE CUSCO ISOLÉ – MOYEN
ESPECULO DE CUSCO AISLADO – MEDIANO
ESPÉCULO DE CUSCO ISOLADO – MÉDIO
ISOLIERTES CUSCO-SPEKULUM – MITTEL
ΜΟΝΩΜΕΝΟΣ ΚΑΛΩΔΙΟΔΡΟΜΟΣ CUSCO – ΜΕΣΑΙΟ
SPECULUM IZOLAT DE CUSCO – MEDIU

- Manuale d'uso e manutenzione
- Use and maintenance book
- Instructions de foncionnement et entretien
- Manual de uso y mantenimiento
- Manual de uso e manutenção
- Betriebs und wartungs anweisungen
- Εγχειριδιο χρησης και συντηρησης
- Manual de utilizare și întreținere

GIMA 29763

CE

Tecno Instruments (Pvt) Ltd.
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Sialkot, 51340 - Pakistan
Made in Pakistan

REF **130-109**

EC REP
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ENGLISH

DESCRIPTION/INTENDED USE:

These devices are reusable and are supplied non-sterile. Process through cleaning and sterilization prior to initial use.

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.

Shelf Life	Operation Environment
5 Years	Temperature: 5°C to 40°C Humidity: 30% to 70% 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. 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, such as cracks, breaks or insulation defects before each use.
3. Never use damage instruments.
4. Never use the instruments in the presence of flammable or explosive substances.
5. The instrument may not be laid down on the patient.
6. 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 medica device conforms to IEC 60601-1 for basic safety & essential requirements.

POINT OF USE TREATMENT (IN THE OPERATING ROOM):

1. Clean Device as soon as possible after use.
2. Remove excess solids using disposable lint free wipes, enzymatic foam or per hospital procedure. Soiled devices should be separated from unsoiled devices. 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.
3. If the recommendations in the steps above are not possible, the device may be placed in container and immersed in tap, sterile or critical water and covered for transport to the processing area.
4. Do not use aggressive/abrasive cleaners.
5. Follow the cleaning and sterilization instructions below.

CLEANING (AFTER PROCEDURE):

Cleaning should be performed as soon as possible after use, preferably within one hour of use. The device has been designed for thorough cleaning and safe sterilization, without disassembly. It is the responsibility of the end user to ensure that the cleaning is performed using appropriate equipment, materials and 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 these instructions.
Ensure that detergent manufacturer instructions are followed for concentration, temperature and water quality throughout the cleaning process. When using mildly alkaline detergents, critical water should be used throughout the cleaning process.

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

- Manual Pre-Cleaning with neodisher® MediZym Enzymatic Detergent - 5 mL/L at 40°C
- Manual Cleaning with neodisher® MediZym Enzymatic Detergent - 5 mL/L at 40°C
- Manual Disinfection with Johnson & Johnson CIDEX OPA
- Automated WD Cleaning & Disinfection with neodisher® MediClean 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 (at least drinking water quality) for minimum of 1 minute.
2. The cleaner is prepared in accordance to manufacturer's instructions for 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 to reach 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 under cold 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 the manufacture'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 cleaning solution.
5. Exposure time (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 dirt is 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 dirt is still visible, clean the medical device manually. Afterwards 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 sterilizer according to DIN EN 285 or DIN EN 13060 with type 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	Method	Cycle Time (minimum time at temperature)	Temperature Set Point	Minimum Drying Time
Pre- vacuum	Wrapped	3 minutes	134°C (273°F)	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. These devices must be stored in a clean, cool and dry area.
2. Protect from mechanical damage & direct sun light. Handle with extreme care.

WARRANTY:

1. These products are guaranteed against material and workmanship. 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.

ADVERSE EVENT:

Report to the manufacturer / authorized representative and the competent authority of the member state in which user and/or patient is established; about any serious incident that has occurred in relation to the device(s).

SYMBOLS:

	Keep away from sunlight		Keep in a cool, dry place	MD	Medical Device
	Caution: read instructions (warnings) carefully	CE	Medical Device compliant with Regulation (EU) 2017/745	REF	Product code
	Manufacturer		Consult instructions for use	LOT	Lot number
	Non-sterile	UDI	Unique device identifier		Imported by
	Date of manufacture		Expiration date	EC REP	Authorized representative in the European community
	Not made with natural rubber latex		Temperature limit		Humidity limit

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.