

## User manual

### Surgical tools are reusable

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#### **GOLD TIER MIC (Medical Instrument Company)**

**Address: Nawaz Sayal Street Haji Pura, Fateh Garh Road, Sialkot-Pakistan**

**Products: Surgical, Dental, Veterinary Instruments**

#### **Uses:**

Die GOLD TIER MIC (Medical Instrument Company) manufactures equipment as standard tools for use in general surgical operations. However, the attending physician is responsible for the selection of instruments and has been appropriately trained and fully informed and experienced in the use of instruments suitable for surgery.



#### **WARNING**

- All surgical instruments are sold non-sterile.
- All surgical instruments must be cleaned, disinfected, and sterilized before and after use.
- Do not use strong acid or alkaline cleaning solutions

#### **Handling restrictions:**

- Regular reprocessing (ultrasonic, manual cleaning, disinfection) will have little impact on tools.
- Check products carefully before each use to make sure they are working properly.
- Product lifespan is often determined by wear and tear or damage during surgical use.
- Signs of damage and wear on the product may include corrosion (rust, pitting), discoloration, severe scratches, flaking, wear, and cracking. Do not use products that are out of function, products with unrecognizable labels, missing or erased (worn), or seriously damaged products.
- Do not use damaged tools. They should be disposed of according to the usual hospital guidelines.

#### **TUTORIAL**

##### Place of use

- Remove dirt with disposable cloth / paper towels.
- All tools must be washed with high-pressure water tap.

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It is recommended that contaminated tools be transported in a clean, sealed container. Product should be prepared no more than 2 hours after use.

#### **Prepare for decontamination:**

Wear personal protective equipment (waterproof gloves, protective gown, mask or goggles and also follow the cleaning or disinfectant manufacturer's instructions).

#### **Pre-cleaning:**

Equipment: Personal protective equipment (as listed above), chilled water ( $20 \pm 2$  ° C) of least potable quality (according to RKI guidelines), high pressure water gun.

1) Flush the product with a high-pressure water gun for at least 1 minute, paying attention to important areas

#### **Cleaning: manual**

- Before cleaning manually and then manually disinfecting: Perform a pre-cleaning (see Pre-cleaning section).
- Equipment: Cleaning solution: multi-stage enzyme cleaner (example: Sekusept® MultiEnzyme from ECOLAB ([www.ecolab.com](http://www.ecolab.com))), plastic brush (example: Interlock # 09095, # 09084, # 09050, # 09068) Sanitary Solution, tap water ( $20 \pm 2$  ° C) of least potable quality (according to RKI guidelines).

The cleaning solution should be prepared according to the manufacturer's instructions (eg, Sekusept® MultiEnzyme 2% solution).

- ✓ Dip the product in the cleaning solution.
- ✓ The soaking time must be in accordance with the manufacturer's instructions (at least 15 minutes for the 2% Secusept® MultiEnzyme solution).
- ✓ During soaking, the product is still soaked in solution; At the same time, the outer surfaces and the recesses are brushed clean with a cleaning brush (example: # 09084) to remove dirt from the surface.
- ✓ Clean the inner surface, working parts and blind holes of surgical tools with cleaning brush (example: # 09095, # 09050 and # 09068) at least 15 times to remove surface dirt face.
- ✓ During soaking, the product is still soaked in solution; At the same time, narrow cavities in surgical instruments and all other hard-to-reach areas inside the product are cleaned with a soft brush at least 15 times to remove visible dirt.

Pay attention to important and difficult to reach areas where the effectiveness of the cleaning cannot be checked with the naked eye.

- ✓ Remove the product from the cleaning solution.
- ✓ Rinse product with running water for 1 minute, rinse all surfaces for at least 10 seconds.
- ✓ Check cleanliness; If you do not be found, the step on must be repeat.

#### **Disinfection: manual**

- ✓ Equipment: peroxide-based disinfectant (e.g. Sekusept® aktiv from ECOLAB ([www.ecolab.com](http://www.ecolab.com))), disinfectant container, tap water ( $20 \pm 2$  ° C) of least quality (according to RKI guideline), ultrasound (35 kHz), deionized water (according to KRINKO / BfArM recommendation, free of pathogenic microorganisms), lint-free cloth or pneumatic gun for medical purposes (according to Pharmacy Europe), one 20 ml sterile syringe (example: BB Braun # 4606205V)
- ✓ Duplicate solutions (eg Sekusept® aktiv 2%) solution should be prepared under ultrasound according to the manufacturer's instructions.
- ✓ Completely immerse the product in duplicate solution.

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- ✓ Soak time should be in accordance with the manufacturer's instructions (at least 10 minutes for 2% Se-kusept® active solution).
- ✓ Fill the 20 ml syringe with disinfectant and wash the closed holes and blind holes on the surgical instrument and all other hard to reach areas of the product at least 5 times during the soaking period.
- ✓ Pay attention to important and inaccessible areas where the effectiveness of the cleaning cannot be checked visually.
- ✓ After 5 minutes soaking, start cleaning with 5 minutes ultrasonic waves.
- ✓ Turn off ultrasonic cleaning.
- ✓ Remove the product from the disinfectant solution.
- ✓ Rinse the product with running water for at least 1 minute.
- ✓ Repeat the washing process with deionized water.
- ✓ Wipe the product with a lint-free disposable cloth either manually or dry with compressed air.

#### Cleaning and disinfection: automatic

• If there is visible residue in crevices, crevices, coupling surfaces, seams and other hard-to-reach areas: Perform pre-cleaning (see Pre-cleaning section) and continue cleaning handmade.

• **Equipment:** heat sterilization system (washing machine / disinfection system) according to DIN EN ISO 15883-1 / -2 with heat program (temperature 90-93 ° C), cleaning agent mild alkaline (eg Sekumatic® MultiClean 200 ml), lint-free cloth or pneumatic pistol for medical purposes (according to the European Pharmacopeia).

- ✓ Place all parts of the product in a cleaning sieve / trolley suitable for heat disinfection (washer / disinfection system) or connect surgical instruments to a light with a sieve wash unit / suitable cleaning cart.
- ✓ Close equipment and start a heat program; The program parameters are listed in the table.
- ✓ Remove the product at the end of the program.
- ✓ Check that the product is completely dry. If necessary, wipe the product with a cloth or lint-free one-time user manual or air dry.

| Process step        | Water              | Amount                                 | Time   | Temperature                            |
|---------------------|--------------------|--|--|--|
| Wash first          | Cold               |  | 5 minutes  |  |
| Instrument cleaning |                    | Follow the manufacturer's instructions |  | Follow the manufacturer's instructions |
| Clean               | Disinfectant water |  | 10 minutes   | 55 ° C                                 |
| Wash                | Disinfectant water |  | 2 minutes  |  |
| Antiseptic          | Disinfectant water |  | Temperature > value > 3000<br>Eg: minutes, 90° C ) |  |
| drying              |                    |  | 15 minutes   | Up to 120° C                           |

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Lubricate tool moving parts with silicone-free tool oils suitable for steam disinfection.

#### **Packaging:**

Packaged in a sterile barrier system according to DIN EN ISO 11607 or DIN 58953 (two-layer coated sterile paper used for confirmation)

#### **Antiseptic:**

**Equipment:** sterilization equipment according to DIN EN 13060 and / or DIN EN 285.

- Pre-vacuum, 134 ° C and sterilization time at least 3 minutes (can hold longer and temperature up to 141 ° C).

- Sterilize the product in the detachable state, if possible

- 1) Place the wrapped product into the sterilization chamber.

- 2) Run the program.

- 3) Remove the product after finishing the program and allow to cool.

- 4) Check that the packaging is tightly closed and dry.

#### **Storage:**

The storage time and shelf life are determined by the user.

- Tools must be stored in a dry, clean, moisture-free environment, and away from direct sunlight.

- Do not store in places where chemicals release caustic vapors or where temperature or humidity changes lead to the formation of condensate on the device.

#### **More information:**

Only validated procedures can be used to reprocess medical devices.

#### **Symbols used:**



Manufacturer



Order number



Lot number



Careful



Not sterile



Follow the instructions



Protect from moisture



Protect from light exposure



CE marking according to Directive 93/42 / EEC