


Instructions for use MUNDITIA SYSTEM CASE

1. Symbols used

Criterion	Description
	CE Marking
	Attention
	Manufacturer









2. Introduction

With the purchase of this WiMedical Tray System you will receive a high-quality product, the proper handling and use of which is described below. In order to minimise risks and unnecessary stress for patients, users and third parties, we ask you to read the instructions for use carefully and to keep them safe.

3. Scope

The Munditia System Case family consists of the Munditia System Case Flex Smart, the Munditia System Case Flex Hybrid, the Munditia System Case Standard and the Munditia System Case Special. The models consist of case and lid. It concerns all models with or without flexible or integrated shaft holders in the base and spring holders in the lid as well as flushing adapter access and caro perforation. The tray sizes range from 5 x 5 x 5 mm to 2000 x 2000 x 2000 mm. The Munditia System Cases allow the safe rinsing and sterilization of standard medical instruments (scissors, clamps, forceps) and textiles.

4. Warnings

The medical devices are supplied non-sterile and must be cleaned, disinfected and sterilized before first use.	
Defective products must not be used and must have gone through the entire reprocessing process before being returned.	
Please observe the additional instructions enclosed with the product!	
Remove all protective covers and films before the first use or preparation.	
The safe combination of the devices must be checked by the user before clinical use.	
Avoid throwing or dropping the products improperly.	
To avoid any contact corrosion, products with damaged surfaces must be sorted out immediately!	
If the products are used in patients with Creutzfeldt-Jakob disease or HIV infection, we disclaim all responsibility for reuse.	

5. Field of application

The Munditia system cases combine proven holding techniques, tested materials and design features to create a reliable reprocessing system. The reusable stainless steel cleaning trays, which offer a wide range of dimensions and features, are suitable for effective packaging, storage and transport of the instruments to be sterilized. The cleaning trays are suitable for fractional vacuum processes. The trays are designed for loading medical devices that are to be reprocessed, cleaned and sterilized. Sterilisation and storage of the inserted medical devices is possible. The tray system can be used in combination with sterile containers, fleece packaging and plastic packaging. For this purpose, the respective documents supplied for the products used must be observed. The use of tray and container systems takes place in the Central Sterile Supply Department (CSSD).

5.1 Purpose

Tray: A product for storing surgical instruments, usually in sets, electrically operated drills, saws and their guides, but also other instruments during sterilization and subsequent storage. The tray system holds the medical devices securely in the receptacles. The spring holder in the lid generates a flexible loading. Coarse contamination is rinsed out by the large check pattern. The complete system is stackable and is available in standard and special sizes. This guarantees a safe combination and loading with standard sterile containers. It is a reusable product.

Instrument holder: An instrument holder is used for safe storage of instruments in a tray or basket. It is a reusable product.

5.2 Contraindications

There are no known contraindications.

6. Preparation

6.1 Recommended sterilization procedure

This procedure is applicable to all tray sizes.

Criterion	Description
Method	3x pre-vacuum steam sterilization
Temperature	134°C (273°F)
Holding time	3 minutes
Drying time	10 minutes
Loading	standard medical instruments (scissors, clamps, forceps) and textiles

7. Handling

7.1 General

The Munditia System Cases are made of stainless steel sheet whose surface is electropolished to protect against corrosion. In addition, they guarantee a short drying phase due to their high thermal conductivity. Aggressive cleaning agents, metal brushes or scouring pads can permanently damage this surface and must therefore not be used.

If this instruction is not followed, the warranty will be invalidated. The tray system may only be handled by instructed or trained personnel to prevent damage to the containers and closures.

7.2 Commissioning of a brand-new tray

1. in the Munditia system Case Flex Smart and Hybrid, when working with the spring and shaft holders, they must be locked in the desired position in the drainage slots in the lid and base. Make sure that the spring holders are fitted in the lid and the shaft holders in the base.
2. before the first use the tray must be cleaned thoroughly.
3. the tray must be prepared with a validated machine cleaning and disinfection program.
4. a neutral cleaning agent (PH value 7) should be used in the machine for this purpose. A mild alkaline cleaner (PH value 10- 11) can also be used.
5. after reprocessing in the washer-disinfector, we recommend sterilisation in a sterile container at 121°C or 134°C
6. we also recommend that the spring holders be manually retightened with each new load

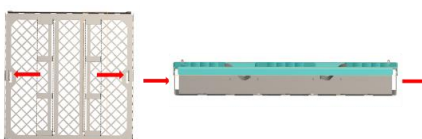


7.3 Preparation for cleaning

1. open the cover
2. remove the contents of the tray
3. cleaning of instruments and medical devices according to their instructions for use
4. check the spring holder for tension, if necessary pull it slightly backwards to tension the medical device (see illustration)



5. check whether the closing mechanism is under tension, adjust it by light thumb pressure from the inside to the outside in the open state without cover, so that the cover only engages by light lateral pressure.



6. check the tray for damage, loose or missing parts, repair them if necessary
7. fix all medical devices in the tray by closing the lid
8. pack the tray in your usual packaging
9. sterilisation process according to the instructions of the packaging manufacturer

7.4 Cleaning and disinfection

Note: Improper cleaning and disinfection can lead to corrosion and load breakage. Therefore, the instructions of the manufacturers of the cleaning and disinfecting agents must be followed. The cleaning agents must be free of sodium, alkali and carbonate, of neutral pH (7) and mild. Only fully demineralised water (quality according to EN 285 Appendix B) is recommended for the preparation of the trays.

1. the tray must be cleaned and disinfected before use
2. trays used for disposal must be cleaned and disinfected after each use

7.4.1 Manual cleaning

1. only use mild, neutral cleaning agents that are expressly approved by the manufacturer for cleaning stainless steel trays. Use a sponge and water.
2. after cleaning, a careful rinsing and manual drying is necessary.
3. do not use metal brushes or abrasive cleaners.

7.4.2 Machine-based cleaning

Machine cleaning of the trays is recommended. When machine cleaning is used, it is essential to follow the specifications of the washing machine and the instructions of the manufacturer. Only use neutral cleaning agents or neutral detergents and disinfectants for cleaning. Do not use detergents containing sodium bicarbonate or caustic soda.

Only use neutral cleaning agents that are expressly approved by the manufacturer for cleaning stainless steel and aluminium trays. The exact dosage is also given in the manufacturer's instructions. No additional use of acidic neutralizers.

For final rinsing, fully demineralised water must be used, as the salts from the water lead to staining in the subsequent sterilisation process. The cleaning system must be designed for cleaning trays and screen baskets. This applies in particular to safe placement in the washing baskets and the arrangement of the spray nozzles or arms.

Dirt that cannot be removed in the usual cleaning process, regardless of the method used (adhesive labels, indicator strips, inscriptions), can be removed with anodising cleaner. After this special treatment the trays are to be cleaned as usual.

7.4.3 Recommended cleaning procedure

We recommend the following cleaning procedure, which was carried out by WiMedical in a suitable washer-disinfector.

- 1 minute pre-wash with cold water
- 3 minutes cleaning with cleaning solution at 45 °C
- Neutralization with demineralized water

7.5 Review

The trays must be checked for proper functioning before each use. Repair or replace loose parts e.g. rivets at silicone corners if necessary. Damage to the closures, spring holders and shaft holders as well as bent and dented parts mean that the trays must be repaired or replaced and may no longer be used. Do not use damaged trays.

8. Loading

The total weight of the loading of the trays including sterile containers should not exceed the recommended quantities, otherwise no satisfactory sterilization can be guaranteed. The recommended loading quantity in kilograms can be found in the instructions for use of your sterile container.

9. Placement in sterilizer

The trays are designed in such a way that they can be integrated into all standard sterile containers. The containers are designed so that they can be used in any commercially available large sterilizer for sterilization with moist heat. Please note that heavy containers are positioned at the bottom of the sterilization chamber. Due to their design, the containers can be stacked on top of each other during sterilization without slipping. Stacking is only recommended for sterilization cycles that work with high vacuum. The stacking height should not exceed 40 to 46 cm to achieve effective air removal and steam penetration. Follow the sterilizer manufacturer's instructions.

10. Flow control

Operate the loaded sterilizer according to the sterilizer manufacturer's instructions for the selected sterilization cycle (in terms of temperature and sterilization time). After sterilization, leave the sterilizer door open for about 15 cm for about 15 minutes to aid drying (see sterilizer manufacturer's recommendations). In order to minimize condensation in the container, the container should be left on the container trolley until the container has cooled down enough to be handled well.

11. Storage

Under normal clinical conditions, sterile goods remain sterile (in unopened sterile containers and undamaged sterile filters) for between a few weeks and 6 months. Usually the storage time depends on the storage conditions and has to be determined by the responsible hygienist. In case of particularly high asepsis requirements, it is recommended to use shorter storage periods or additional packaging. Recommended storage conditions:

- Temperature: 15 - 26°C
- Air humidity: 30 - 50
- Air pressure: normal atmospheric pressure

- Various container loads, storage times and storage conditions are subject to the specification of the responsible hygiene specialist.

12. Maintenance and repair

Maintenance and repair of the trays may only be carried out by qualified persons.

13. Materials

The trays and sieve baskets are made of stainless instrument steel.

- Housing: Material 1.4301
- Shaft holder: Material 1.4301
- Spring holder: Material 1.4310
- Plastic: Silicone Shore 60/80FDA-CFR 21 Part.177.2600
- Surface: electropolished

14. Warranty

The trays are made of high quality materials and have undergone a quality control before delivery. Should any errors nevertheless occur, please contact the above address. The warranty does not apply to repairs carried out by companies that are not authorised by WiMedical.

- WiMedical gives a 12 months warranty on housings, shaft mounts, spring mounts and plastic corners.
- Gross misconduct and willful destruction are not covered by the warranty.

WiMedical accepts no liability if it can be proved that this instruction has been violated.

15. Returns

All returns must be machine-processed and sterilized without residue. No unsterilized products and unclean products will be accepted.

16. Service and manufacturer address



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