

# INSTRUCTION FOR USE





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Read Instruction for use



Non sterile



Medical device class I



Medical Device



Batch code



Catalogue number



Keep dry



Keep away from sunlight



Read the instruction for use regarding warnings and precautions

Thank you for purchasing.  
Please read carefully the instruction for use.

**First use of new container systems**

Every container system *must* be cleaned and sterilised before it is used.

**Caution**

The container system may only be used for their intended purpose in the surgical specialties by educated and qualified personal. The surgeon shall be responsible for the proper selection of the container system for each application, for obtaining the appropriate training, knowledge and experience, and for their operative use.

**Disposal containers without perforation as well as without filter are not suitable for sterilization of medical devices. Autoclaving in a closed state will damage the container.**

a1 medical GmbH as manufacturer and seller cannot accept any liability for immediate or consequential damages caused by inappropriate application and use or by inappropriate sterilisation and maintenance of the instruments.

If instruments are repaired by any companies or persons not authorized by a1 medical GmbH to do so, all warranties are becoming null and void.

Carefully examine each surgical instrument for breaks, cracks, deformations and malfunctions before use. It is especially essential to check areas such as blades, points, ends, stops and snaps as well as movable parts. Instruments that are worn out, corroded, deformed, porous or damaged in any other way must be sorted out.

**Indication**

The sterilization containers are used for loading medical instruments.

**Contraindication**

No contraindications available.

**Infection risk**

- Prepare before use
- Prepare container before returning to manufacturer

**Risk of injury**

- Use only original accessories or compatible third-party accessories
- Do not use or repair damaged container
- Carefully remove from the packaging
- Do not touch sharp edges

**User**

The attending medical practitioner or instructed persons are exclusively responsible for the use of the product.

**Patient target group**

The user is responsible for the intended patient target group.

**Storage**

Container system should be stored in a clean, dry, moisture free area. Instruments should be stored individually in their shipping carton or in a protective tray with partitions. Protect tips, edges, etc. with tubing, protecting caps, gauze or fabric. Make sure that no chemicals are close to or in the storage area.

**Disposal**

Please ensure safe disposal of the product, its accessories and any consumables used.

**Used materials**

Stainless steel	EN ISO 7153-1
Light metal (Aluminum)	EN 573-3
Teflon Filter	---
Silicone	---

**Steel instruments**

The high-grade steels (rustproof, stainless) that are used for manufacturing surgical instruments and container systems create due to the chemical composition specific passive layers as protective surfaces. Those steels however are only to a certain extent resistant against attacks of chloride ions and aggressive waters! Chloride ions mainly cause pitting but can also cause stress corrosion cracking. The greatest danger is water in which considerable quantities of common salts (sodium chloride) are dissolved.

**Aluminum instruments**

Only non-alkaline, neutral cleaning agents in combination with fully demineralized water must be used. Otherwise damages to the anodized surface are possible. Alkaline cleaning causes marks and color fading on the surface particularly of colored instruments and container systems already after just a few cycles.

**PTFE (Teflon)**

The process of filtering a wide variety of media with PTFE filters has been known for a long time and has now been made usable for use in sterilization containers.

In addition to the endeavours undertaken by the manufacturer with regards to the selection of the proper materials and its careful processing, the user has to ensure continuous and proper care of the container systems as well as proper preparation, cleaning and sterilisation.

**We recommend the following procedures for the reprocessing of our reusable surgical instruments (container system):**

**For this purpose, please follow the reprocessing instructions from the "Instructions for use Surgical Instruments".**

**Note:**

Please check the instruments for visual, functional and corrosion damage before and after each reprocessing and do not use the instruments if any of these damages occur or if you are unsure. Reprocessing procedures have only limited implications to a surgical instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. In case of damage the device should be reprocessed before sending back to the manufacturer for repair. At the end of the product's service life, dispose of the surgical instruments properly or recycle them.

**Reprocessing validation study information:**

The following testing test devices, materials & machines have been used in this validation study:

General:	Description:
Detergent:	Neodisher® MediClean forte; Dr. Weigert, Hamburg (alkaline)
Neutralizer:	Neodisher® Z; Dr. Weigert, Hamburg
Washer / Disinfector::	Miele G 7835 CD
Key hole surgery rack:	MIC-Wagen E 450
Details:	Cleaning Report No. 1807.1185
	Sterilization Report No. 1807.1919
<b>Additional instructions:</b> If the above-described chemicals and machines are not available, the user must validate his own process. The user must ensure that the biocompatibility of the devices could be assured through the selection of appropriate cleaning chemicals and re-processing procedures. The user is responsible for the removal of the cleaning chemicals after the used cleaning process. The complete removal of the cleaning chemicals for the used process must be specified and made valid. When using autoclaves for sterilization of surgical instruments, it has to be strictly ensured that the steam used is absolutely free of foreign substances such as corrosive particles or dirt to avoid subsequent corrosion or dirt (scum) deposit. Please observe strictly the instructions for use given by the manufacturers of autoclaves. Do not use any damaged instruments. It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.	

#### Hints for the sterilization of the instruments with sterilization container systems

- Do not wrap the sterilization container on the outside with paper or textile filters during the sterilization cycle. This would cover the holes, press the filter inside and does not allow for the steam to move in and out properly. Also drying is not possible in proper manner
- A drying cycle time of 20 minutes after autoclave cycles must be observed by all means! It's not allowed to skip this dry time, because it's crucial! After this the sterilization container and the goods should be quite dry inside. This should be tested.  
Remaining humidity in sterilization container and subsequent storage in this way can cause brownish discoloration or rust on instruments
- IMPORTANT! Loading weight of 1/1 sterilization containers shall be not more than 10 kgs! The loading weight of the smaler sterilization containers shall be appropriate less than the 1/1 sterilization containers.
- For Crutchfield-Jacob contaminationed instruments sometimes the holding time at the sterilization cycle will be increase to a higher time of 30 min. This is known to cause problems on many instruments. It's better to use a proper disinfectant before and use common holding time for instruments.
- However, if sterilization cannot be performed safely in the event of suspected or actual contamination of the instruments with the Creutzfeldt-Jakob pathogen, the corresponding instruments must be disposed of properly.

**Equipment and methods used for cleaning, disinfection and sterilization have to be in accordance with the following standards and recommendations:**

EN ISO 17664	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable devices
EN 285	Sterilization – Steam-sterilizers – Large Sterilizers
EN ISO 14937	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process
EN ISO 17665-1	Sterilization of health care products - Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
EN 13060	Small steam sterilizers
EN 556-1	Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices
ISO 15883	Washer-disinfectors
EN ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN 868	Packaging materials for terminally sterilized medical devices
EN ISO 11737-1	Sterilization of medical devices - Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2	Sterilization of medical devices - Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process
DIN 58946-7	Sterilization - Steam sterilizers – Part 7: Edificial preconditions, requirements for the services and the operation of steam sterilizers used in health care facilities

Proper maintenance of instruments, working group instrument preparation <http://www.a-k-i.org/>

### Examination

In principle, the sterilization containers must be checked for proper functioning before each use. Especially if, for example, trays or lids are reordered individually. Since the functionality of the existing product and the new product may no longer be given here.

### Maintenance of instruments

As a matter of principle, container systems must be subjected to sufficient care, namely before the functional test. Care products must guarantee that the parts do not "stick together" due to their cumulative effect, even in continuous use.

### Information

If you require further information or product demonstration / product training, please contact the responsible a1 medical Product Specialist.