Instructions for use
stoma p.i.c.®-container & permanent filter

Article attribution: 6700.04 – 6700.13, 6621.40, 6708.00

General information
Read the instructions for use carefully prior to use. The attending doctor, buyer, or user is responsible for selecting the products for the intended application and/or operational use. The attending doctor and all persons involved in the handling of the product are responsible, within their field of activity, for having corresponding product knowledge based on the current state of technology. This enables the correct handling of the products and prevents health or safety risks for the patient, user, or third parties.

Intended use
Indication
stoma® p.i.c.®-containers are intended to be loaded with medical devices for sterilization. The sterilization and storage of the encased products are enabled and insured until the next use. The container systems are optimally suitable for steam sterilization (fractionated vacuum process).

A permanent filter serves as germ barrier for the steam sterilization of instruments and is a reusable product that can be correctly inserted into sterile containers.

Contraindication
- Improper use can lead to damages to the container and the permanent filter.
- The use of aggressive detergents can lead to discolorations/staining and even damages to the container and the permanent filter.

⚠ **Do not use for any other than the above-mentioned sterilization methods!**

⚠ **The processing of medical devices must be complied with the national regulations and standards.**
In case of patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or any kind of variations of this disease, the currently relevant national regulations must be applied concerning the processing.

Recommendations and warnings to be respected

⚠ **If these warnings are not respected, this can lead to an increased safety risk.**
- Only to be used for the intended purpose indicated.
- All instructions described here must be absolutely followed.
- Use only by specialized personnel!
In case of misuse, all liability is excluded.

Used material
stoma® p.i.c.®-container: aluminum alloy | DIN EN ISO 868-8
Permanent filter: PTFE (teflon)

The stoma® p.i.c.®-containers are made of aluminum alloy with an anodized oxide surface which prevents corrosion. Abrasive cleaners, metal brushes or abrasive cleaning pads can cause permanent damage to the container surface and therefore must not be used. Warranty exclusions will be the result in case these instructions are not followed.

Use/handling
Sterilization containers must be used only by qualified or trained and experienced personnel, in order to prevent damage to the containers, closing devices, gaskets and sterile filters. Colored identification tags provide information about the content and location for their use. The closing device can be provided with a security seal, which has to be broken when opening. Only an intact security seal ensures that the sterilization container has not been opened without permission.

Permanent filters must be used only by qualified or trained and experienced personnel. Taking the correct size attribution into account, permanent filters can be inserted into the containers provided for that. The permanent filter is to be checked before each and every sterilization cycle for damage. Permanent filters must have the correct measurements to cover the perforation completely in the container lid.
After the permanent filter is inserted into the filter holder, the filter holder must be depressed so that it can be heard that it clicks into place. Number of sterilization cycles in case of an intact filter: 1200

No adhesives may be applied to the permanent filters (e.g. to document cycles), since adhesives destroy the germ barrier. Only in case of gross contamination, the filter can be removed and then carefully cleaned manually.

An independent and accredited testing laboratory carried out tests and examinations as to the suitability of the permanent filters. The results are as follows:
The used Stoma-PTFE permanent filters are suitable to prevent bacterial growth according to the requirements of DIN 58953 Part 6, Chapter 2.14.

⚠ **To guarantee flawless functioning of the permanent filters, please pay attention to the following information:**
- Respect the specifications for loading the used containers.
- Never puncture the sterile filters.
- Prevent the penetration of bacteria through:
  - the spilling of dirt, cleaning or disinfection solutions
  - Penetration of contaminated external condensate (for example through the space between the stack of hot containers)
  - Rubbing of dust and dirt in the filter by wiping the containers
  - Long term storage

Use in combination with other products
Security seals are attached to the closures outside by guiding the seal through the opening of the spring lock system and joining the seal. The seal will break by opening/flipping the latches.

The supplied indicator of indicator labels changes its color during steam sterilization at 134° C.

Paper filters are intended for one use only. Paper filters are produced according to ISO 11607-1. The paper filters must have the correct measurements to cover the perforation completely in the container lid.

Warranty services can only be provided in case of the exclusive use of original Stoma products or, if applicable, fitting Ermis products. (see point „General Information“).

⚠ **Combine only original Stoma component parts such as lids, bottoms, filters, gaskets and filter holders with each other in order to avoid putting at risk the leak tightness and germ barrier.**
All filters or joints from other manufacturers (excluding the above-mentioned manufacturer) must be accepted by Stoma before they can be used, otherwise Stoma does not assume any warranty.

Implementing of a new/unused container
- The container must be thoroughly cleaned before it is used for the first time.
- The container must be pre-processed in a validated cleaning/washing machine and disinfection process.
- A neutral cleaning agent (pH value 7) should be used for this purpose in the machine.
- Once the pre-processing in the cleaning and disinfection device is completed the products must be steam sterilized at 134° C in a fractionated steam sterilization process.
- Furthermore, all movable parts on the container must be treated regularly with approved instrument maintenance oil.
- A suitable new filter will have to be inserted after the cleaning process (see „Changing of filter”).

Preparation for cleaning
1. Separate the container bottom and lid
2. Remove the contents of the container (tray, instruments, etc.)
3. When using a disposable filter:
   a. Remove the filter holders from the inside of the lid and if applicable from the bottom part (in the case of containers with perforated bottom)
   b. Dispose the disposable filter.
4. When using a permanent filter:
   a. Machine cleaning can be done without removing the filter, but the filter, if necessary, can also be cleaned separately in the cleaning and disinfection device.
   b. Manual cleaning is only done in case of severe contamination of the filter. The filter is removed from the container and cleaned carefully with an appropriate detergent with tested effectiveness (e. g. VAH or FDA approval/CE-labeling).
5. Remove the disposable seals and indicator labels.

⚠ **All paper filters are disposable filters and must be replaced after each use of the container.**

Cleaning and disinfection

⚠ **Improper washing and disinfection may lead to corrosion and stress fractures. For that reason, the specifications of the washing/ disinfection product manufacturer must be considered. The cleaning agent must be free of sodium, alkaline and carbonate and it must have a neutral pH value and/or approved for the treatment of anodized aluminum by the chemical's manufacturer.**

Only demineralized water (quality according to EN 285 Enclosure B) is recommended for the preparation of the containers.
- The container must be washed and disinfected before the first use.
- Containers used for disposal must be cleaned and disinfected after every use.

Manual cleaning/disinfection
- Mild, neutral cleaning agents should be used for the stoma® p.i.c.®-containers and lids which are specifically approved also for the treatment of aluminum containers by the manufacturer. A soft sponge should be used.
- After washing, a thoroughly rinsing with suitable low-salt water (such as demineralized water) and sufficient drying is necessary.

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(translation: 03.07.2018 [en])

- Do not use any metal brushes or abrasive cleanser.
- Finally, disinfection is to accomplish according to the respective hygiene requirements.
- Manual cleaning of the permanent filter is only done in case of a severe contamination of the filter. The filter is removed from the container and carefully cleaned with an appropriate detergent with tested effectiveness (e. g. VAH or FDA approval / CE labeling).

Mechanical cleaning
Contaminations that cannot be removed in the usual cleaning procedure, irrespective of the method (sticking labels, indicator strips, markings), can be removed with Eloxal detergent. After this special treatment, the containers must be cleaned as usual.

- Neutral or other suitable cleaning and disinfection solutions are to be used which are explicitly approved for the treatment of aluminum products. If necessary, the products must be checked for the suitability for the relevant procedure.
- Only use neutral cleaning agent for the stoma p.i.c.®-containers, which are specifically approved for the washing of aluminum containers by the manufacturer. For the proper dosing please refer also to the manufacturer's specifications. These products are also suitable for cleaning surgical instruments by optimizing the program.
- If using neutralization agent the products must be checked for the suitability for aluminum.
- Low-salt water should necessarily be used for the final rinsing.
- The cleaning devices and inserts must be suitable for the processing of containers and lids. This applies particularly for the correct positioning in the loading inserts to allow adequate and unobstructed rinsing of media flow and the drying of all containers and lids.
- Containers and lids may not be cleaned and disinfected in a closed/assembled state.
- Attention must be paid when loading the machine to ensure a sufficient media flow during the process.
- The container bottom must be placed into the washing machine with the opening downward in order to prevent the accumulation of water and to ensure that the used media flows off adequately.
- The container lid must be washed with the inside facing downward and the latches/closures folded outward.
- The containers and their accessories, without any visible residues, will be removed from the media after completing the mechanical cleaning and disinfection process.
- Should there be still any residues detected then the position of the containers and accessories in the device should be rechecked and possibly changed.
- Machine cleaning of the permanent filter can be done without removing the filter, but the filter, if necessary, can also be washed separately in the cleaning and disinfection device.

Recommended cleaning procedure
We recommend the following validated cleaning procedure:

- 1 minute pre-cleaning with cold (<40°C) water
- 3 minutes cleaning with Mediclean 0,5 % (Dr. Weigert) at 45 °C
- Neutralization with demineralized water

Inspection, maintenance and testing
The sterilization containers rnust be inspected for their functionality before each use. Damages on the closures, gaskets, filter holders and filters as well as bent or dented parts indicate for the need of repair of the sterilization containers and may not be used. Do not use defective sterilization containers.

- The durability of the gasket is up to 500 sterilization cycles. After that, the gaskets will have to be checked out.
- All movable parts on the container must be treated with approved instrument maintenance oil.
- If there are any damages detected on the gaskets, then they have to be replaced immediately.
- The gaskets should not be treated with spray, oil or solvents. It is enough for cleaning and maintenance to wipe occasionally with a moist cloth.
- If there are any damages detected on the sterilization containers then they have to be inspected, repaired or replaced if necessary.
- The sterilization containers may be maintained and repaired only by qualified persons. Do not try to repair yourself the gaskets or attachments in order not to compromise the safe use of the container.
- The sterilization containers may be returned for maintenance or repair to Stoma.
- Spare parts such as filter holders, disposable paper filters, PTFE permanent filters, colored marking labels and plastic security seals can be obtained at Stoma.

Changing of filter
After changing the filter, the filter holder has to be placed by pressing into its correct position with an audible snap. Stoma lids may only be used with Stoma filter holders.

- Disposable paper filters must be reinserted before every re-sterilization.
- PTFE filters have been tested for usage duration of 1200 cycles and must be replaced afterwards.

Recommended sterilization process
stoma p.i.c.®-containers have been validated with the following sterilization parameters:

Method:	3 x pre-vacuum steam sterilization
Temperature:	134 °C (273 °F)
Holding time:	5 minutes
Drying time:	10 minutes
Loading:	Standard medical instruments (scissors, clamps, forceps) and textiles

⚠ **Use with gas sterilization is not appropriate because it is done with formaldehyde or ethylene oxide.**
The stoma p.i.c.®-containers are not prepared for that.

Loading of the container
The total weight of the load of a container should not exceed the following loading size. Otherwise a satisfying sterilization result cannot be ensured.

Model	Ref.no.	dimensions in mm	max. recommended loading in kg	
			instruments	textiles
dental container	6700.04	ca. 310x190x40	0,6	0,5
	6700.06 resp. 6622.00	ca. 310x190x65	0,9	0,7
	6700.10 resp. 6623.00	ca. 310x190x100	1,4	1,0
	6700.13 resp. 6624.00	ca. 310x190x130	1,8	1,4

In case of loading with textiles, please pay attention that the pieces of laundry or folded textiles are in vertical position. It should still be easily possible to slide an open hand between the pieces of laundry by a fully loaded container.

⚠ **The sterilization of various container loadings and the configurations must be determined by the responsible personnel. Endoscopes, instruments with lumina, compressed air or mains-powered units and instruments with cannulas must be prepared for the sterilization according to the specifications of the manufacturer. Small baskets, trays or other accessories, especially the ones with lids or flaps, should only be used together with sterilization container systems, if these were specifically designed and tested for this purpose.**

⚠ **Using water resistant inserts (such as plastic/silicone inserts) may cause remaining condensate inside of the container. Instead please use moisture-absorbing mats. Check the integrity of the inserted filter and the proper sealing of the filter holder. Always use the locking mechanism to attach the container lid to the bottom before placing the container into the sterilizer. Otherwise, the container content becomes unsterile as soon the sterilizer door is opened.**

Position in sterilizer
The stoma p.i.c.®-containers are designed so that they can be used in any commercially available large sterilizer for the sterilization with moist heat. Keep in mind that heavy containers are to be positioned at the bottom of the sterilization chamber. The containers can be stacked easily and safely on top of each other due to their design, without slipping during the sterilization procedure. Stacking is only recommended for sterilization cycles operating with a fractionated vacuum system. The maximum stacking height should not exceed 46 cm in order to ensure an effective air removal and steam penetration. The instructions of the manufacturer of the sterilizer must be followed.

⚠ **Pay attention to the following during sterilization:**
Never wrap the container in an additional outer packaging. Never cover the perforation fields in the lid and bottom with foil packaging or something similar because this prevents the air and steam flow in the container. As a result, there would be a container deformation caused by vacuum due to insufficient pressure compensation and the sterility of the loading cannot be guaranteed. Always carry the sterile container by the carrying handles and never by the lid during loading and/or unloading the sterilizer as well as during transport.

Sequence control

- Operate the loaded sterilizer for the selected sterilizer cycle according to the specifications of the sterilizer manufacturer (referring to temperature and sterilization time). The validation results are in the process to be considered.
- The container should cool down completely on the sterilization cart to avoid condensation in the container.
- The sterile goods must be evaluated and approved after each sterilization according to internal directives and validation results. This is consequently conducted by employees with special knowledge, qualification level 1.

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Storage of sterile goods
Under normal clinical conditions, sterile materials remain sterile between several weeks and six months (in closed sterile containers and with undamaged sterile filters). The storage time generally depends on the storage conditions and must be determined by the responsible hygiene specialists. In case of extremely high requirements for asepsis or deviations on the specified storage conditions are shorter storage periods or additional packaging to be used.
Recommended storage conditions:
- Temperature: 15-26 °C
- Humidity: 30-50 %
- Air pressure: normal atmospheric pressure

Different container loadings, storage periods and storage conditions are the responsibility of the hygiene specialists. stoma p.i.c.®-containers have been tested for a storage period of 6 months by applying of Bacillus subtilis – spore suspension. Therefore, we stipulate a storage period of 6 weeks on open shelves and 6 months, if stored under protected circumstances (such as in closed cabinets).

Sorting out worn products

Verify the identity, completeness, integrity, and function of the products. Immediately after the detection of damage, the products may not be used any longer!

Delivery state
The product is delivered in a non-sterile state and must be cleaned, disinfected and sterilized prior to its use.

Safekeeping/storage
- Until the first use, it should be stored in the original package at normal room conditions.
- It should not be stored in direct vicinity of any chemicals.

Returns and repairs
The following applies for products already taken out of the original packaging: Returns and complaints are only accepted if the products are declared as "hygienically safe", cleaned, and disinfected, packaged with corresponding proof of decontamination.

Disposal
Defective and obsolete products must be disposed of in accordance with the applicable regulations and national or regional legal provisions.

Liability
The products may only be used according to their intended purpose in the dental area by respectively trained and qualified personnel. Storz am Mark GmbH does not assume any liability for indirect or consequential damages caused by other than intended use, improper use, handling, processing or maintenance and due to failure to observe the instructions for use. The instructions for use were originally prepared in German and translated into the respective national language. The German version takes precedence in case of doubt.

Standards applied
The following standards were considered to ensure the safety of the sterilization containers during manufacturing and handling:

DIN EN 868-2	Packaging for medical devices to be sterilized in the final packaging - Part 2: Sterilization wrap - Requirements and test methods
DIN EN 868-8	Packaging for medical devices to be sterilized in the final packaging - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods
DIN EN ISO 11607-1	Packaging for medical devices to be sterilized in the final packaging - Part 1: Requirements for materials, sterile barrier systems and packaging systems
DIN 58952-2	Sterilization; Packaging for sterile goods, sterilizing baskets made of metal
DIN 58952-3	Sterilization; Packaging for sterile goods, sterilizing trays made of metal
DIN 58953-9	Sterilization - Sterile goods supply - Part 9: Application technology of sterilization containers
DIN EN ISO 14937	Sterilization of health care products - General requirements for the characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
ISO 11134	Sterilization of health care products; Requirements for validation and routine monitoring; Industrial hot steam sterilization
DIN EN ISO 17665-1	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and control of the application of a sterilization process for medical devices
DIN EN 285	Sterilization – Steam sterilizers – Large sterilizers

Graphic symbols
The graphic symbols used for identification correspond to the following significations:

	Read the instructions for use		Manufacturer information
	Note the information insert	REF	Article number
HIBC	Health industry barcode	LOT	Lot number
CE	CE marking		

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