Instructions of use for SAMMEX Alu-Containers

Description
SAMMEX Alu Containers are reusable, metal, sterilization containers. They are used for holding operating room instruments and/or textiles during vacuum-steam sterilization procedures and for maintaining sterility during storage and transport under proper hospital conditions.
The containers are intended for use by specialist trained professionals and their assistants working in the fields of hospital hygiene and sterilization technology. This user manual describes important instructions on the proper use and care of SAMMEX Alu containers, and – without claiming to be comprehensive – outlines a number of possible hazards that could result from failure to observe the instructions.

Filter- System
SAMMEX Alu Containers are available with a closed (unperforated) base and perforated filter lid (can be covered by a unperforated lid) or with perforated bottom and lid.They are intended to be used with single use (disposable) filters or reusable textile filters with known serviceable life. Both types of filters cannot be combined, because different types of filter holding device must be used for paper and textile filters.
In case of use of filters which are not supplied from SAMMEX, the user must validate the permeability and barrier properties himself.

For technical reasons relating to design, SteriSet containers are suitable for use only in steam sterilizers using fractionated prevacuum or fractionated circulation processes. Steam sterilizers using a vacuum process, built, installed and operated inaccordance with DIN 58946 („large sterilisers“) or EN 285 are suitable. Note: Table 1 from the hitherto valid German standard DIN 58953/9 „Suitability of sterilizing containers for the various sterilizing procedures“ as well as DIN 58946 „Large sterilizers“ contain further information on applicable combinations of sterilizing containers, load types and sterilizing procedures.
CAUTION: If SAMMEX Alu Containers are used in sterilizers which do not conform to EN285 or DIN 58946 or are not operated in accordance with EN285 or DIN 58946, then it is absolutely essential that the sterilization procedure is validated in accordance with the latest technical standards (e.g. EN 554), as it may otherwise not be possible to guarantee the attainment of sterility.
CAUTION: Hot-air sterilization, gravity or circulation procedures and also formaldehyde or ethylene oxide sterilization or other substitute procedures for the sterilization of thermolabile products such as plasma Sterilization or peroxide sterilization may not be used.
With loads comprising solely instruments (i.e. containing no porous items such as textile packs, etc.), then (simple) prevacuum or injection procedures may also be suitable. If it is intended to use such a procedure, then for safety reasons it is nevertheless recommended that the procedure be validated.

Maintenance
During storage, sterilization containers are better than disposable soft packages at protecting sterile goods from recontamination caused by, for example, mechanical load / damage. Like all reusable equipment, however, the SAMMEX Alu Containers although robust also needs to be treated with care in order to ensure that its protective qualities are preserved. The relevant personnel (including delivery and collection services) must therefore be familiar with the correct handling practices.
CAUTION: Careless handling or the use of inappropriate chemicals can cause damage, thereby putting at risk the ability to attain and preserve sterility. SAMMEX Alu Containers therefore require regular visual and, if necessary, functional checks.
• Undamaged shape: The seating of the seals on the upper rim of the container base tray and on the inner lid must be free of dents and visible deformations. Neither the lid nor the tray may show noticeable buckling or holes.
• The seal in the inner lid must be completely inserted and undamaged.
• Handles, closure clasps and similar fittings must not be loose (no „wobble“).
• Filters or valves: may not show visible malformations. They are to be subjected to visual and mechanical inspections as shown in the pictures: filters must fully cover the visible perforations, valves must be blank and free to move when inspected mechanically. After any accident (such as being dropped on the ground), it is essential
that the sterile container undergoes a thorough check.
• According to EN 868-8 all sealings must be replaced after 100 sterilizing cycles or all 6 months. Damaged or deformed sealings must be replaced earlier. If the closing pressure of the lid is becoming low, a replacement of the sealing usually solves the problem.

Sealing
It is recommended and required (e.g. DIN 58953/9) that containers are sealed in such a way as to prevent inadvertent opening of containers and to ensure that it is evident whether or not a container has been opened. SAMMEX Alu Containers can be protected by disposable plastic seals which, once attached, can be opened only by breaking.

Sterilisation
SAMMEX Alu Containers can also be sterilised whilst stacked.
Stack height: < = 60 cm.
To prevent accidents or mechanical damage,do not handle stacked containers jerkily. To prevent condensation collecting on one side (and thus causing drying problems), the containers should be placed horizontally in the sterilizer.

Internal Packing
We recommend using SAMMEX Alu Containers with simple internal packaging (e.g. cloth wraps or drip sheets). These assist the final drying stage, allow a longer storage period according to DIN 58953/9, and make possible aseptic presentation of the sterile goods. The size of the cloth wraps should be calculated so that when they are unfolded all the external walls of the container can be covered. As an alternative to reusable cloths, easily wrapable (non-woven) disposable materials can also be used. Because non-woven materials have a higher flow resistance than cloths, we recommend that in such cases the perforated tray be placed in the arch and fixed with adhesive tape before the load is placed into the container. The package cannot then open during sterilization and block the inlets and outlets of the container (the resulting raised flow pressure could damage the container). Because of the problem associated with folding, the use of sterilization paper is not recommended. In order to prevent colours leaching and thereby staining the containers, non-coloured materials (or in the case of green or blue cloths, previously

washed sheets) should be used.
CAUTION: Never sterilize the container Wrapped in additional packaging. Apart From the risk of lack of sterility, the increased flow resistance could impair the sterilization effect (non-sterility) or even destroy the container.

Sterilisation operational limits
In order to ensure that the lid can close properly, sterilization containers must not be filled above the level of the lower ridge of the edge indentation on the container tray. The lid must lie flat on the lower section without being forced and so that it does not wobble even when the clasps are open. It must also be possible to close the clasps without additional pressure on the lid.
CAUTION: improperly-sealed lids can jeopardise sterility.
• In the case of instrument sterilization, the load weight (including perforated tray) should not exceed 10 kg, as residual moisture may otherwise remain even despite the use of materials to assist drying.
• With cloth loads (or similar), the load weight should not exceed 6.5 - 7 kg.
• When using internal packaging (nonwoven or cloth), care should be taken that the correct closing of the lid is not impeded, for example, by a protruding corner of the packaging.
CAUTION: For example, there is a risk of non-sterility if protruding cloth corners prevent the container from closing correctly.
• In order to prevent damage to the parts of the container or its load, we recommend that the container be transported with its lid closed whenever possible.
CAUTION: If the sterilization procedure causes sterilization containers to become deformed in any way, then there is no guarantee of sterility. In such cases, the entire batch must not be used, and an investigation started to determine the cause (analysis of the sterilization record; examination of the sterilizer as well as the other sterile packs; investigation into the cause involving functional tests on the damaged sterilizing container).

Data cards / indicators
We recommend the use of documentation cards with chemical process indicators in the outer holding frame of the container (see also DIN 58953/9). These cards help substantiate that the containers were treated correctly, and facilitate performance documentation.

CAUTION: If procedure indicators are not used, then other organisational Measures should ensure that no unsterilized – and thus non-sterile - containers are inadvertently released.
The additional use of chemical sterilization indicators inside the containers is not absolutely necessary. Such indicators are basically able to prove that a sterilization procedure has been performed, but are just as unable as an external card to indicate whether the contents of the container actually attained sterility (they indicate only that the contents at the location of indicator are sterile). If they are used, we recommend that they are placed in the middle of the load as this is usually the most critical point.
The use of, for example, a single chemical indicator in a specific „worst case“ test receptacle is considered to be a sensible alternative to batch documentation obtained by placing chemical indicators in every single sterile pack. If such a „worst case pack“ signals „sterile“, then there is a much smaller probability of the procedure having failed (for example as a result of spontaneous changes such as insufficient air circulation caused by faulty door seals) than if indicators are place in a normal container.
NOTE: The batch documentation does not replace the regular checking and documentation of the sterilizers (ventilation tests; sterilization tests with chemical and biological indicators; vacuum-leak tests,
etc.).

After Sterilisation
To safeguard against accidents (burns, dropping, etc.), containers that are still hot should never be handled with bare hands. The containers should not be cooled to room temperature too rapidly (e.g. do not place on cold surfaces or expose to a cold draught), as excessively rapid external cooling can lead to recondensation of the water vapour inside the container with an unwanted accumulation of condensate.

Storage / Transportation
Sterility can be maintained inside proper packaging during clean hospital storage for a practically unlimited period. Depending upon storage duration and conditions, however, external contamination occurs, and this represents a potential risk during subsequent use, transport and aseptic presentation. According to DIN 58953/9 this risk factor can be reduced by the following measures:

• The use of internal packaging
• Storage under (dust)-protected conditions
• Limitation of the storage period
The recommendations of DIN 58953 part 9 (May 1987) are therefore.
• Containers with internal packaging, protected storage up to: 6 months
• Containers with internal packaging, unprotected storage up to: 6 weeks
• Containers without internal packaging, protected storage up to: 6 weeks
• Containers without internal packaging, unprotected storage: „use as soon as possible“
Other important points are:
• Dry storage under controlled conditions (low air-contamination, constant humidity, etc.)
• Handling as vibration-free as possible
• Packaging mechanically undamaged
If these points are followed, then the risk of recontamination will be essentially restricted to the effects of external contamination accumulated during storage. Unlike other types of packaging, the protective cover concept of the SAMMEX Alu Containers is a simple method of eliminating this potential risk (e.g. by swab disinfection of the protective lid). We nevertheless recommend following DIN 58953/9 „Operation procedures for sterilization containers“.
SPECIAL CASES: When storing or transporting sterile containers under nonstandard conditions (e.g. house-external transport; strong vibration, high humidity, or rapid pressure changes due to transportation in aeroplanes or trucks), then internal packaging and transport packaging to protect against dust contamination should be used to reduce the associated risks.

Aseptic presentation
If containers are to be opened after a long period of storage or after storage under non-ideal conditions, then we recommend wiping the unperforated cover with a disinfectant before handling in order to minimise the risk of contamination by airborne particles.

Cleaning and disinfection
In the operating room SAMMEX Alu Containers are normally protected from contamination, as they are covered with sheets or are removed from the room before the operation starts. They must, however, be routinely cleaned.
Experience has shown that optically „clean“ containers are not microbiologically burdened (bioburden) to such an extent that this can influence the effectiveness of sterilization.
However, if this cannot be excluded (inspection by hygiene control personnel, for example by surface contact), there is a theoretical risk of crossinfection. In this case the containers should be disinfected before next use, even when technically „clean“.

Compatibility with materials
Container bases , inner lids and outer lids are made of anodized aluminium.
When selecting cleaning and disinfection agents and methods, particular attention must be paid to tolerance by aluminium as well as the following points:
• Do not use lathering cleaning substances (powder) or abrasive metal brushes or similar.
• Thorough rinsing must remove all cleaning agent residues.
• The individual parts must be thoroughly dried and stored in a dry place following cleaning/disinfection,
• The selected cleaning agents must be appropriate for the quality of the available water:
For THERMAL cleaning and disinfection we recommend:
a. in case of fully desalinated water: cleaning with i.e. the pH-neutral enzymatic cleaner NEODISHER MEDIZYM at app. 45°C and subsequent thermodisinfection during final rinsing by use of fully desalinated water.
b. in case of only softened water: cleaning by use of mild alkaline, non-chlorous substances (such as NEODISHER FA / liquid or NEODISHER MA / powder) during simultaneous thermodisinfection.
For CHEMICAL cleaning and disinfection we recommend:
a. in case of fully desalinated water: pHneutral or weak acidic substances – such as e.g. NEODISHER Dekonta - a combined cleaning & disinfection product, OR cleaning with NEODISHER MEDIZYM at app. 45°C and subsequent disinfection with NEODISHER Septo DN.
b. in case of only softened water: use of mild alkaline, active-chlorousubstances such as NEODISHER ALKA 300 or NEODISCHER FI (both combined cleaning & disinfection products)
CAUTION: The above recommendations are not mandatory. Adherence to the recommendations is no guarantee that the material can tolerate the cleaning agent.
In case of doubt ask the manufacturer of the cleaning agent whether the agent is tolerated by aluminium under the selected conditions of use.
As there are generally no chemically-resistant anodised colours, we recommend that coloured anodised aluminium sections be cleaned preferably manually and without using chemicals.

Machine cleaning
Internal and external lids should be separated and placed diagonally in the washing tray. The lower section should be inverted and face downwards.

Disinfectants
Disinfectants should be checked not just for chemical tolerance to aluminium (see above) but also for effectiveness. We therefore recommend selecting a disinfectant with proven material tolerance from List VII issued by the „Deutsche Gesellschaft für Hygiene und Mikrobiologie“ /
DGHM (= German Society for Hygiene and Microbiology)..
CAUTION: When such substances are applied manually, the instructions for use should be followed exactly to ensure that inadequate effect and damage to the material are avoided. Specific attention should be paid to ensuring that the substances selected are tolerated by the materials, as well as to the mixing ratio, exposure time and effect of mixing various different cleaning agents.

Literature/Standards
• „Instrumenten-Aufbereitung richtig gemacht“, edited by „Arbeitskreis Instrumenten- Aufbereitung“, 6.Edition.
• DIN 169 paperback „Sterilisation und Desinfektion“
• DIN 263 paperback „Sterilisation von Medizinprodukten“
• DIN 58946 „Sterilisation, Autoclaven“
• DIN 58953 „Sterilisation“
• EN 868
The DIN Standards are available at BEUTH Verlag Berlin.
For further information about cleaning and sterilization visit: www.a-k-i.org