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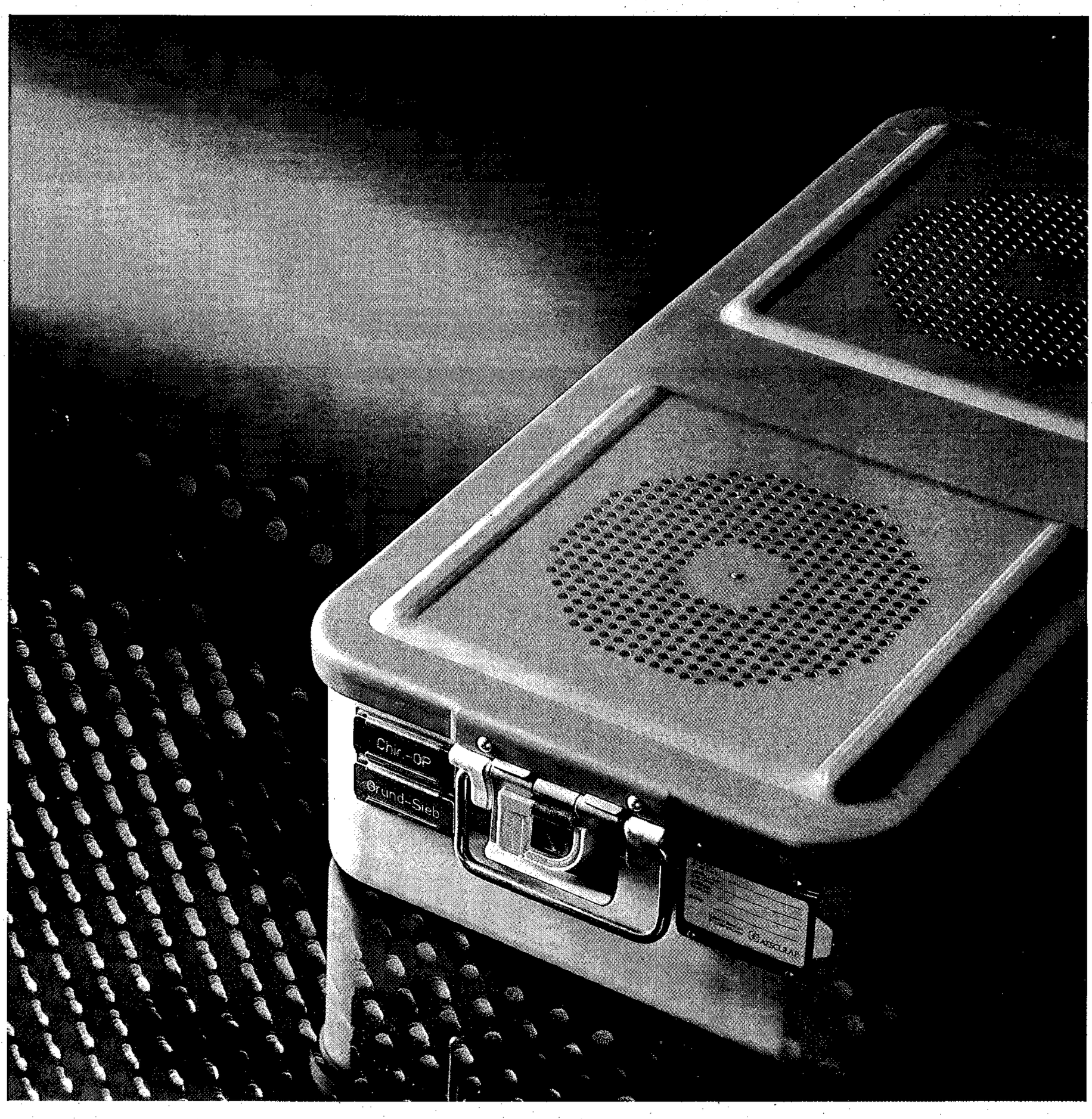

Steril Container System DBP

for supply and return of sterile material

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Sterile material - Supply and return in container system

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Contents

Introduction

The present sterilisation packaging systems are based on the so-called "set concept". Higher hygiene requirements in the sixties and seventies, originating in Scandinavia, Great Britain and the USA, had an effect on sterilisation throughout the world.

The set concept involves the combination of the sterile material into one or more packed units per operation; after the end of the operation, all instruments, textiles, etc. are subjected to cleaning and subsequent sterilisation, regardless of whether or not they have been used.

Up to then it had been usual to store the complete set of instruments for one day of operating in one container. After removal for an operation, the container was closed again and reopened for the next patient in order to remove further unused instruments.

Combining similar activities in the operating theatre, i.e. centralising the supply and return, inevitably resulted in the requirement that instruments and linen be readily available in sufficient quantity and organised systematically according to type of operation, for the day's programme.

The sterile packaging, which includes primarily the container, paper packaging and transparent sterilisation packaging, has to meet very high requirements:

1. The sterile material must be capable of being stored for several weeks without the sterility being adversely affected (see page 20, Table 5).
2. The sterile material must not be contaminated during transport, which in some cases is over long distances.
3. When contaminated material is disposed of, the environment must not be contaminated.

The paper packaging originally envisaged for the set method was soon supplemented by packing in sterile containers. In 1974, AESCULAP was the first German manufacturer to begin production of filter containers for the set system, and thus ensured that the "stable packaging", i.e. the container, displaced "labile packaging", i.e. paper.

Part A

1. Sterilisation methods

Fractional vacuum method

The sterilisation methods can in principle be divided into the following:

- Steam sterilisation
- Gas sterilisation
- Hot air sterilisation

The safest methods is the steam sterilisation method.
Gas sterilisers are used for heat-sensitive materials but are environmentally polluting and are permitted only if appropriate safety measures are taken.
Hot air sterilisers can be used exclusively for heat-resistant materials.

The steam sterilisation methods may in turn be divided into the gravitational method, the prevacuum method, the fractional flow method, the steam injection method and the fractional vacuum method.

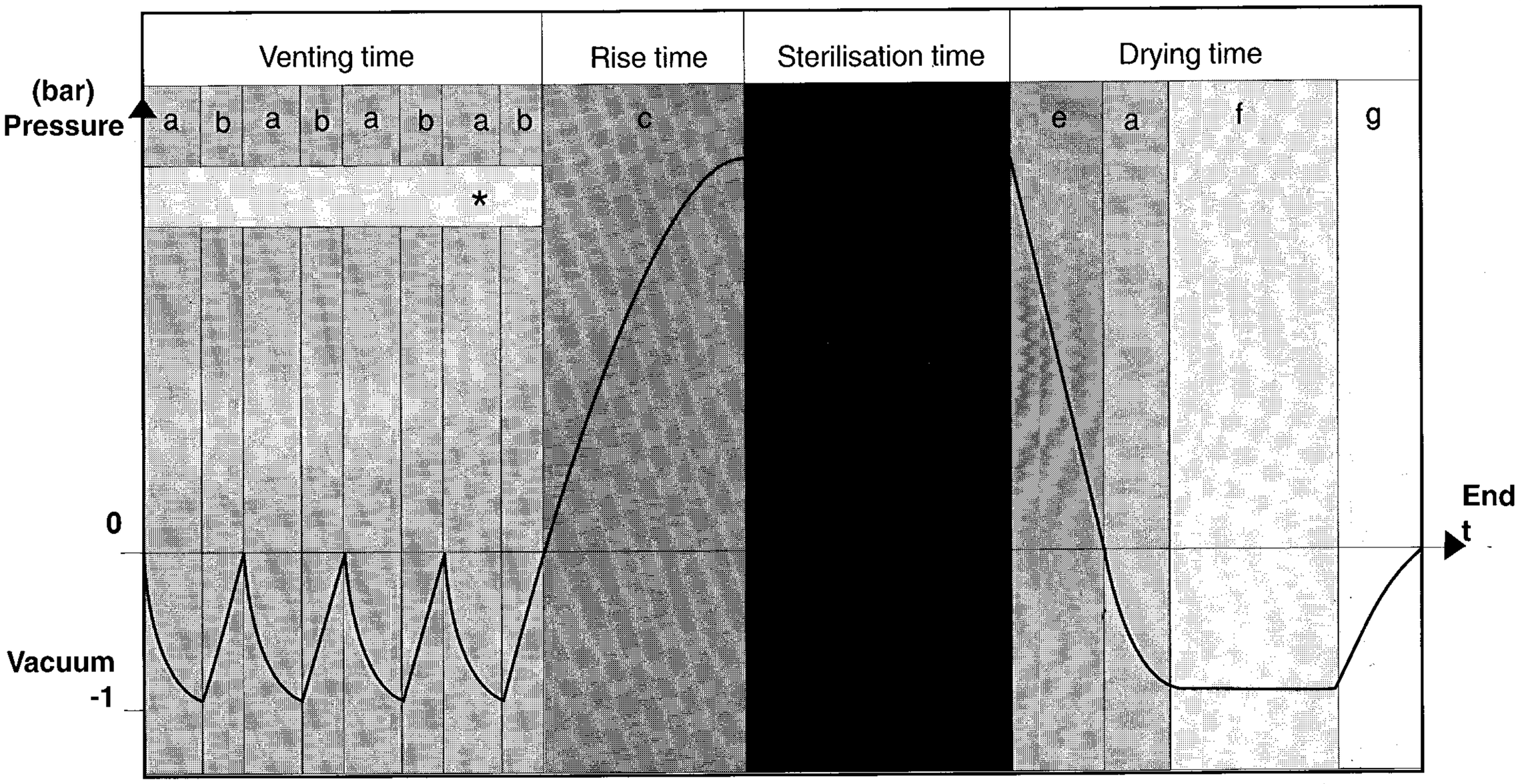
In the gravitational and prevacuum methods, it is essential to ensure that the containers have a perforated cover and base in order to guarantee sterilisation of the container contents.

From the present-day point of view, the fractional vacuum method has become the most widely used method in practice among all steam sterilisation methods.

In the following section, the fractional vacuum method is always assumed when sterilisation methods are referred to.

The fractional vacuum method is characterised by the following operating phases:

Table 1: Operating phases of the fractional vacuum method



a Vacuum generation/evacuation

b Inflow of steam

c Inflow of steam up to sterilisation pressure

Sterilisation (sterilisation time composed of equilibration time, kill time and safety margin)

e Pressure relief

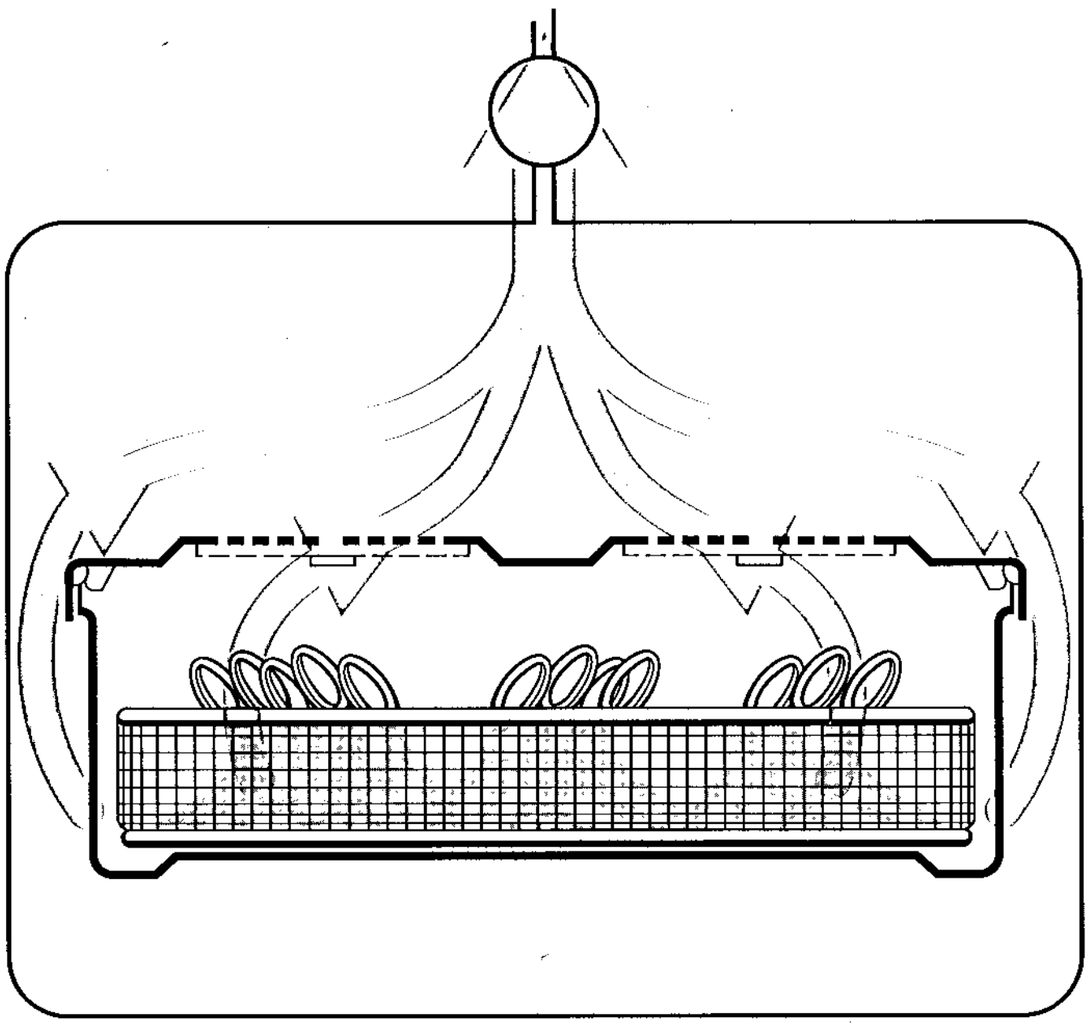
f Post-vacuum phase (drying)

g Aeration of the sterilisation chamber with sterile-filtered air

* Number of required evacuations is determined by the apparatus configuration or by the program chosen.

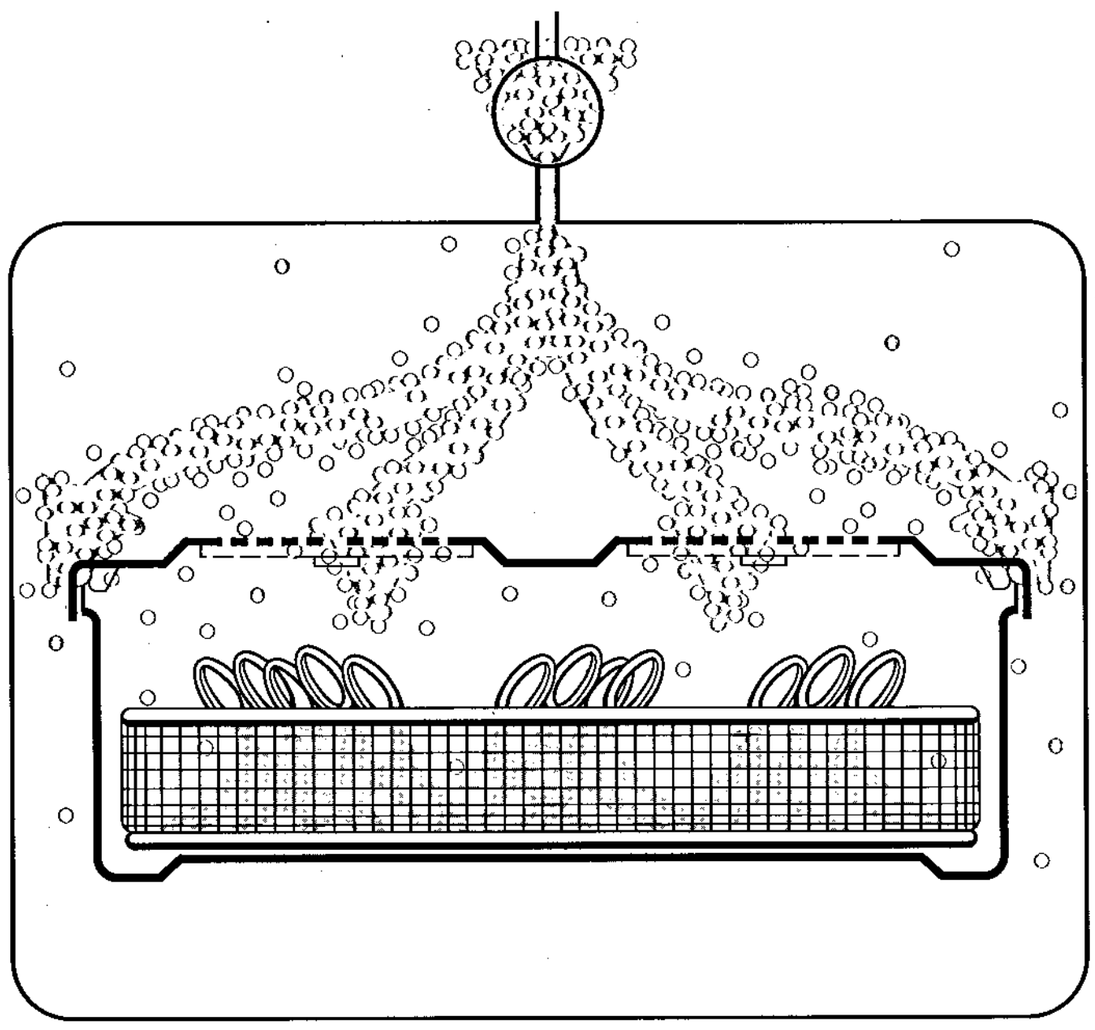
2. Sterilisation procedure

The phases described below correspond to the sterilisation phases from Table 1, page 5.



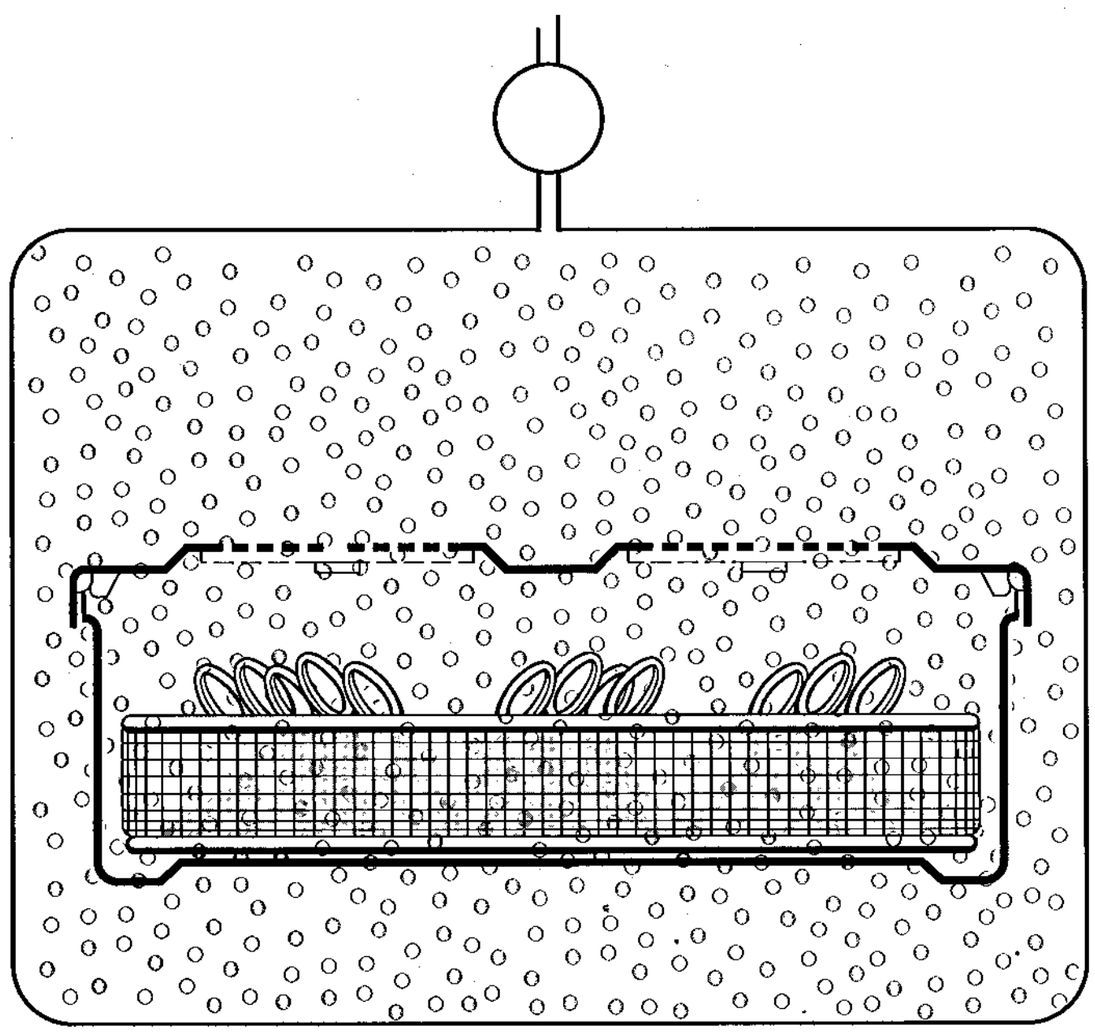
Vacuum generation

The air is removed from the sterilisation chamber and from the sterilisation material by means of a vacuum pump (see page 5, Table 1, phase a).



Inflow of steam

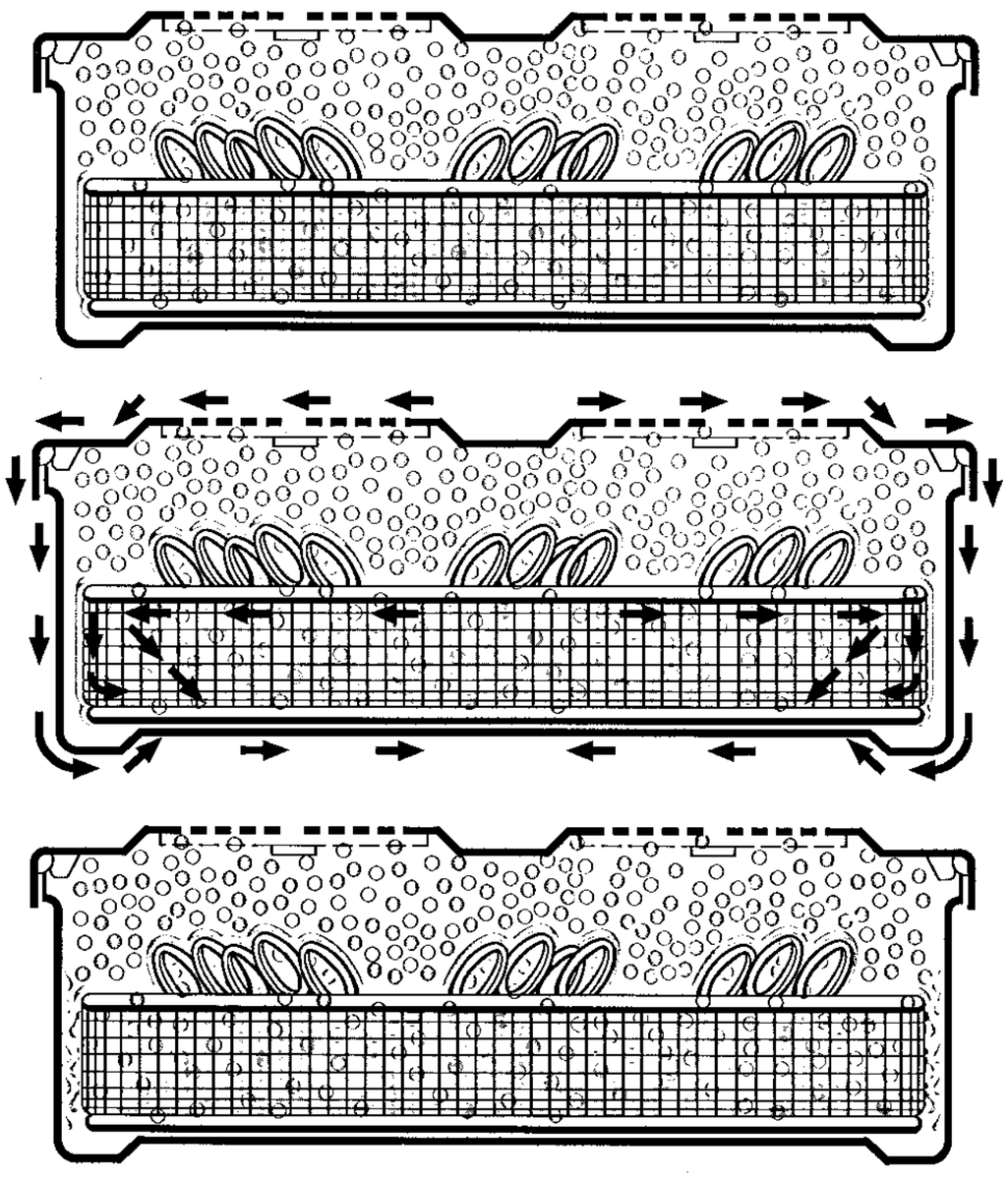
The steriliser chamber is filled with steam which is passed in the opposite direction. Vacuum generation and steam inflow are repeated several times (in a pulsating manner) until the entire air volume has been replaced with steam (see page 5, Table 1, phases a and b).



Inflow of steam up to sterilisation pressure/sterilisation

The steam then flows into the steriliser chamber until the sterilisation pressure has been reached (see page 5, Table 1, phase c).

The sterilisation pressure is maintained over a defined period. This period corresponds to phase d, the actual sterilisation (see page 5, Table 1, phase d).

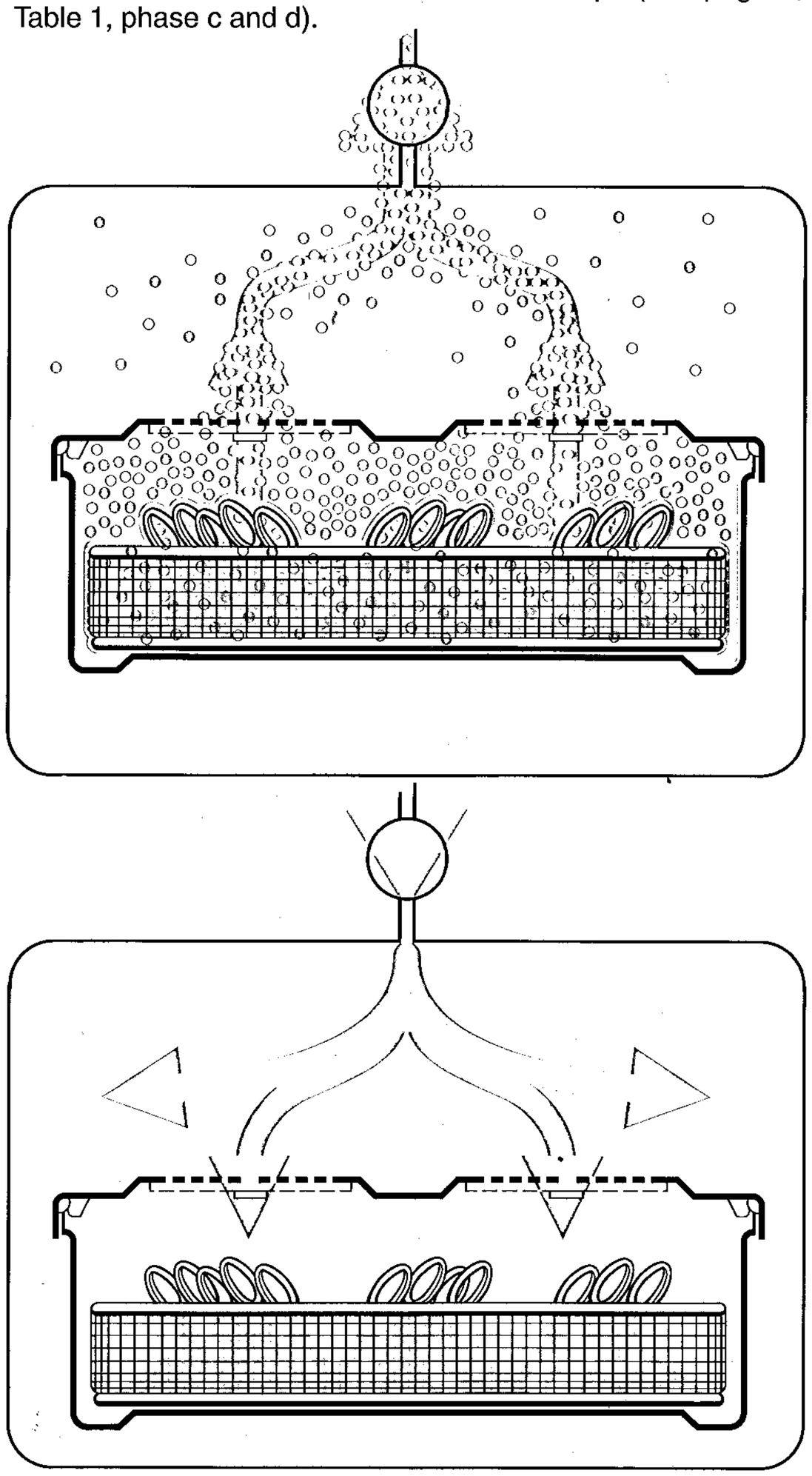


Inflow of steam up to sterilisation pressure/sterilisation (phase development)

Condensation takes place during phases c and d. This means that the steam is converted abruptly into condensation water on all cold surfaces and covers all cold surfaces with a “water skin” (see page 5, Table 1, phases c and d).

The steam has released its heat energy to all cold surfaces on turning from steam into condensation water. The cold surfaces heat up and pass this heat into the interior of the articles (see page 5, Table 1, phase c and d).

The condensation continues after formation of the “water skin” until the material being sterilised has reached the same temperature as the steam. This results in a certain volume of condensate depending on the quantity and weight of the material being sterilised. The condensate formed in addition to the “water skin” then runs off the surfaces in the form of drops (see page 5, Table 1, phase c and d).



Pressure relief/post-vacuum phase (Drying)

After the sterilisation under pressure, pressure relief first takes place, followed directly by a post-vacuum phase. Here, steam is sucked out of the container and the steriliser chamber.

The condensation water attempts to turn into steam again under a vacuum and is removed from the container and the steriliser chamber.

At the end of the post-vacuum phase, the container is freed from the condensate, i.e. dry (see page 5, Table 1, phases e and f).

Aeration of the sterilisation chamber and of the container with sterile-filtered air

To bring the steriliser chamber to atmospheric pressure at the end of the sterilisation, sterile-filtered air is passed into the steriliser chamber and container.

The sterilisation cycle is complete, and the steriliser doors can be opened (see page 5, Table 1, phase g).

3. Detailed description of the steam sterilisation

3.1. Condensation of saturated steam

In order to carry out sterilisation, a certain apparatus is required - the steriliser.

In this steriliser, a water-filled vessel which is connected via a steam pipe to the steriliser chamber is heated until the water begins to evaporate and the required quantity of steam has been formed for the subsequent sterilisation. Alternatively, there is also a central steam supply and the steriliser chamber is fed by an external steam pipe.

Depending on the program, the steam flows into the steriliser chamber at a temperature of 120° to 140°C and condenses instantaneously on all cold surfaces. This means that the steam is converted from a gaseous, high-energy state of aggregation into the liquid, low-energy state of aggregation. In other words, water in the form of condensate is formed from the steam.

During the condensation, the energy originally required to produce the steam for sterilisation from water is released to the material to be sterilised. As a result of the energy transferred, the material to be sterilised heats up until it reaches the steam temperature (sterilisation temperature). It is assumed that this energy transfer and the associated temperature increase, in combination with superatmospheric pressure and moisture, produces the actual sterilisation.

In principle, two different materials are distinguished in the condensation:

- Smooth surfaces (e.g. instruments)
- Textile, porous surfaces (e.g. linen)

3.1.1. Condensation on smooth solid surfaces (e.g. instruments, containers, etc.)

The heat energy does not remain at the surface of the material to be sterilised but is uniformly distributed in the entire material. The temperature of the material being sterilised gradually reaches the temperature of the steam.

As long as there is a temperature difference between steam and the material being sterilised, condensation takes place.

What condensate remains on the cooler surface forms a so-called "water skin". Further condensation results in the formation of drops. These drops run off from the surface when the gravitational forces are greater than the forces produced by friction between condensate and surface.

During the sterilisation process, condensation water forms on trays, instruments and packaging. The wrapping cloth absorbs part of the condensate while the remaining moisture remains suspended from instruments and tray in the form of drops. In the drying phase, this water is then finally evaporated.

3.1.2. Condensation on textile surfaces (e.g. linen)

Owing to its high pressure, the hot steam penetrates the linen layers, condenses in the fabric and releases its heat energy. Due to the hygroscopic, i.e. moisture-absorbing, property of the linen (capillary effect), drop formation is avoided. The condensate largely remains at the site of energy storage and is uniformly distributed over a large area, as in a sponge.

3.1.3. Sites of condensate formation

The following points are possible sites of condensate formation:

- Container walls/paper-cloth packaging
- Material to be sterilised (e.g. instruments, etc.)
- Tray
- Wrapping cloth

3.1.4. Amount of condensate

The amount of condensate depends in the main on the following factors:

- Weight - the heavier a tray, the more condensate is formed.
- Initial temperature - the lower the temperature of the materials to be sterilised, the greater the amount of condensate formed.

3.2. Drying

Drying of the sterile material is dependent on several components. Thermal conductivity and thermal storage capacity are two of the most important ones.

3.2.1. Thermal conductivity

The thermal conductivity of the material plays an important role with regard to drying. It is a measure of the rate at which the heat can be transported in the drying phase to points with particularly high evaporation activity.

The greater the coefficient of thermal conduction and hence the thermal conductivity, the more rapidly does the temperature become the same for the entire container.

As a result of this equilibration, condensate can be evaporated continuously at a point. The container will cool at certain points due to the removal of the required energy of vaporisation, and a temperature gradient will be produced within the container. This gradient is essential for heat conduction since heat always flows only in the direction of a temperature gradient.

In the ideal case, accumulated condensation water can thus gradually turn into steam during the final vacuum phase of the sterilisation cycle.

Drying can be promoted by means of a wrapping cloth.

If the materials recommended for sterilisation containers in DIN 58952 Part 1, stainless steel and aluminium alloy are compared, it is found (see page 9, Table 2) that the coefficient of thermal conduction of aluminium is about 14 times greater, i.e. aluminium conducts heat 14 times faster than stainless steel.

3.2.2. Heat storage capacity

The absorption of heat energy causes the material being sterilised to heat up from ambient temperature to the sterilisation temperature. Condensate is formed in proportion to the total weight of the loaded container.

The condensate formed on the outer walls of the container drips into the sterilisation chamber and is removed there via condensate traps or is extracted in the vacuum phases. However, the associated amount of energy released remains stored in the container and is available in the drying phase for evaporating the condensate in the container.

In addition, heat is transferred to the container bottom via the base inserts in the steriliser.

In theory, more heat energy is therefore available than would be

	Aluminium AL 99,5% Al Mg 0,5	Stainless steel Cr Ni 18/9	Paper	Water	Cotton material
Density (g/cm³)	2,7	7,9	–	1	–
Specific heat (kj/kg · K) Temperature range 20°C . . . 137°C	0,9	0,5	1,2	4,2	1,4
Coefficient of thermal conduction (w/m · K)	2,1	0,15	0,1	0,6	0,06

Table 2: Physical properties of the packaging material which are relevant for subsequent drying

required for evaporation of the condensate in the container; this is why reference is made to the heat storage capacity of containers.

The site of heat storage and the site of the condensate accumulation are frequently not identical. A major part of this heat energy must therefore first be transported by thermal conduction in the direction of the condensate to be evaporated (container bottom). This requires time since, especially in the case of instruments, there are only small contact areas via the instrument tray to the bottom, and the heat transport thus meets resistance.

The longer the drying time the more advantageous is the effectiveness of the residual condensate at the end of the sterilisation.

The amount of stored energy in the sterile material is dependent, among other things, on the weight of the sterile material and on the "specific heat" of the sterile material.

The "specific heat" is the quantity of heat required to heat a certain weight of a material (1 kg) by 1 degree Centigrade.

The greater the weight of the sterile material and the "specific heat", the better are the energy storage properties of the material. However, it should be noted that the weight of the packaging as a sterile material should be kept as low as possible in order to avoid the necessary stress for the personnel.

Accordingly, preference should be given to a material with high specific heat, in order to achieve optimal heat storage and hence drying.

If the materials aluminium and stainless steel are compared, it is found that the specific heat of aluminium is 1.8 times greater. An aluminum body (100 g, 20°C) has accordingly stored 1.8 times more heat energy than a comparable steel body (100 g, 20°C).

Attention must also be paid to the specific density of the material. Aluminium has a lower specific density than steel, i.e. an aluminium body is lighter than a steel body with exactly the same geometries. For containers with identical dimensions, this means that a steel container is about three times heavier than an aluminium container. The advantage of an aluminium container is that it can be designed with thicker walls than a steel container without reaching the high weight of the steel container.

3.2.3. Drying with instrument load

The major part of the condensate is formed during the expulsion of air and collects at the bottom. During sterilisation, saturated steam is present in the steriliser.

In the course of drying, the steam is removed and the pressure in the sterilisation chamber is reduced. With decreasing pressure, the boiling point of the water is reduced from 100°C (at atmospheric pressure of about 1013 mbar) to 36°C (at about 60 mbar). Containers, instruments and condensate have a temperature of more than 46°C and this will cause the condensation of water, present on these surfaces to begin to boil and hence to turn into steam again. This steam is removed from the container by the vacuum applied to the steriliser chamber. In the ideal case, instruments and container bottom are absolutely dry immediately after the end of the sterilisation procedure.

If condensate collects on the container bottom, it will be difficult to convert this water completely into steam. The steam originally condenses at a point other than the bottom and has released its energy, for example, to an instrument. The energy is now present in this instrument, which has only indirect contact with the condensation water present on the container bottom.

Large resistances to heat transfer result in a time lag in the energy transfer. The energy transfer takes place from the instrument to the tray or the support and from there to the container bottom. The time lag prevents the energy of the instrument from being used in the autoclave itself for evaporation of the condensation water on the container bottom.

In the case of overloaded trays, the ideal conditions often do not exist, i.e. after sterilisation there is a danger of a certain residual moisture. After sterilisation is complete, this residual moisture can be evaporated by the stored heat energy of the sterile material. A precondition for subsequent drying is the possibility of gas exchange, which is easily ensured by the sterile filter in the case of filter containers. In filter containers, the residual moisture is finally eliminated.

It is advisable additionally to wrap an instrument tray in a cloth before placing it in a container. In this way, the condensate dripping downwards is absorbed by the absorptive action of the cloth and is distributed. The cloth is in direct contact at several points with hot instruments, trays, container walls, etc., and can dry at these specific points. The moisture which still exists in moist but already cooled container regions is attracted by the capillary action of the cloth to dry but still hot areas.

According to DIN 58953, a wrapping cloth as inner packing together with a container as outer packing forms a dual packaging and is regarded as being sterile for 6 weeks in unprotected storage and for 6 months in protected storage (see Table 5, page 20).

3.2.4. Drying with linen load

In contrast to the instrument load, in the case of the linen load the condensate can be absorbed by the linen at the site of formation by hygroscopic condensation and is distributed over a large area. In the drying phase of the sterilisation process, intensive evaporation of the moisture from the linen occurs since the temperature of the linen in this phase is well above the evaporation temperature of the water. This reduction in the evaporation temperature is achieved by applying a post-vacuum during the drying phase.

Drying is decisively influenced by the following material-specific parameters (see Sections 3.2.1. and 3.2.2.):

- Thermal conductivity
- Heat storage capacity

4. Tests on residual moisture

The test series described below are concerned with the residual moisture content for different sterile packagings after sterilisation. Test series: A. Stihler. The following were used as packaging material:

1. Aluminium container with filter system
2. Stainless steel container with filter system
3. Disposable paper sterilisation packaging

The trays in the packagings were stainless steel wire mesh sterilising trays according to DIN 58952 Part 3.

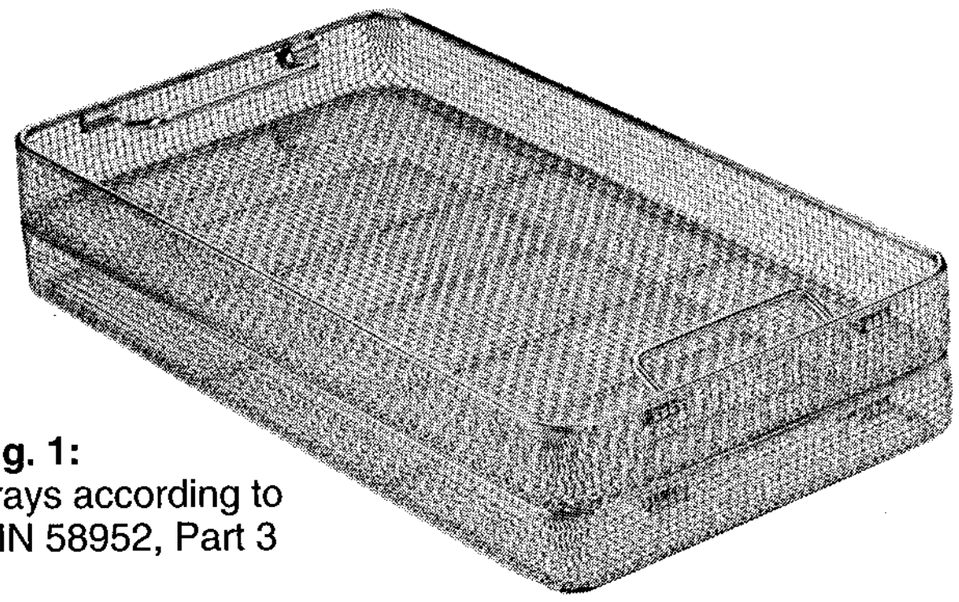


Fig. 1:
Trays according to DIN 58952, Part 3

Each tray was first wrapped in a cloth (inner packaging) and then provided with an outer packaging (container or paper).

Two parallel test series, each with the three different packaging materials (aluminium container, steel container, dual paper pakkaging), were carried out.

The first test series consisted of the corresponding packaging materials with an instrument load. The load rate, consisting of tray weight, instrument weight and wrapping cloth weight, was varied. In the second test series, linen in different packaging materials was tested, the load weights being varied.

4.1. Test procedure

The packed material to be sterilized is weighed directly before sterilisation. After the sterilisation process, a weight comparison is made. The result is entered in prepared record sheets. The weight difference found is due to the residual moisture.

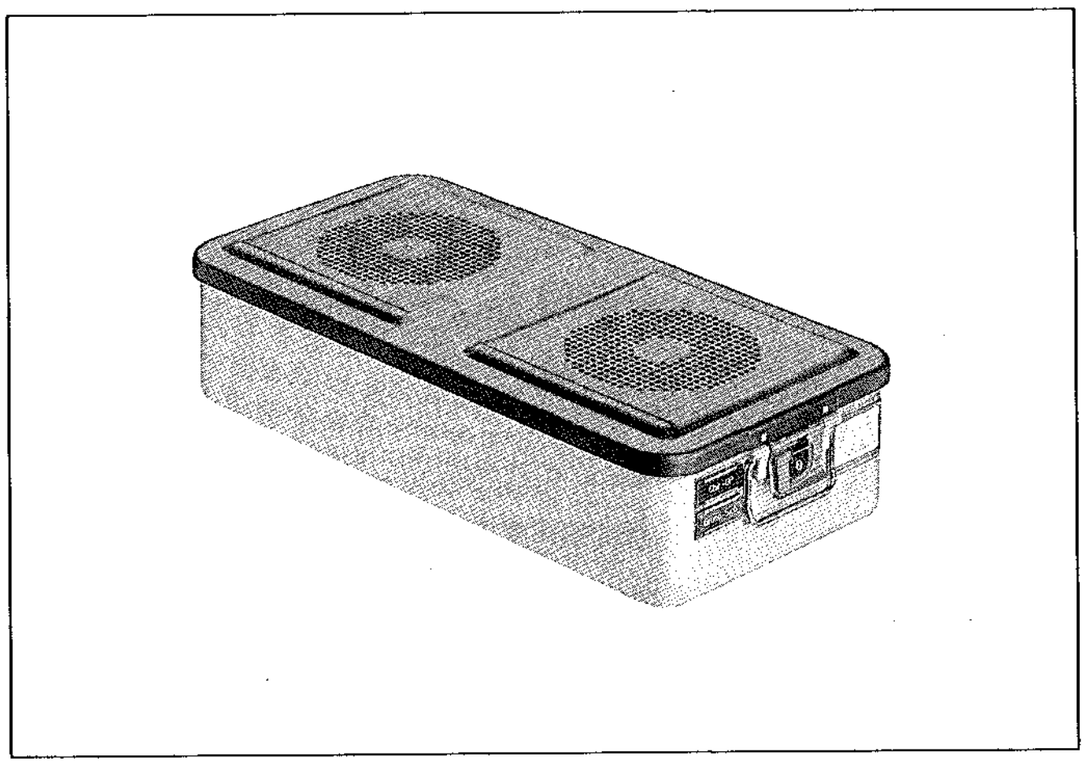


Fig. 2: Instrument container with closed bottom and filter in the lid.

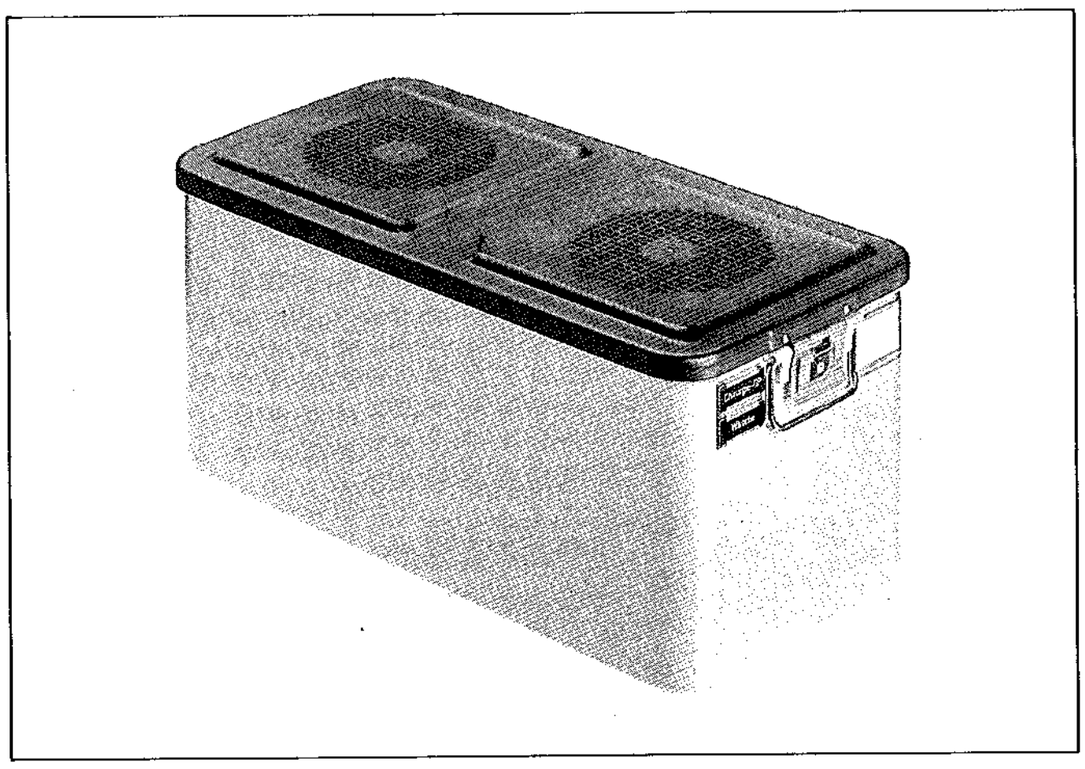


Fig. 3: Linen container with closed bottom and filter in the lid.

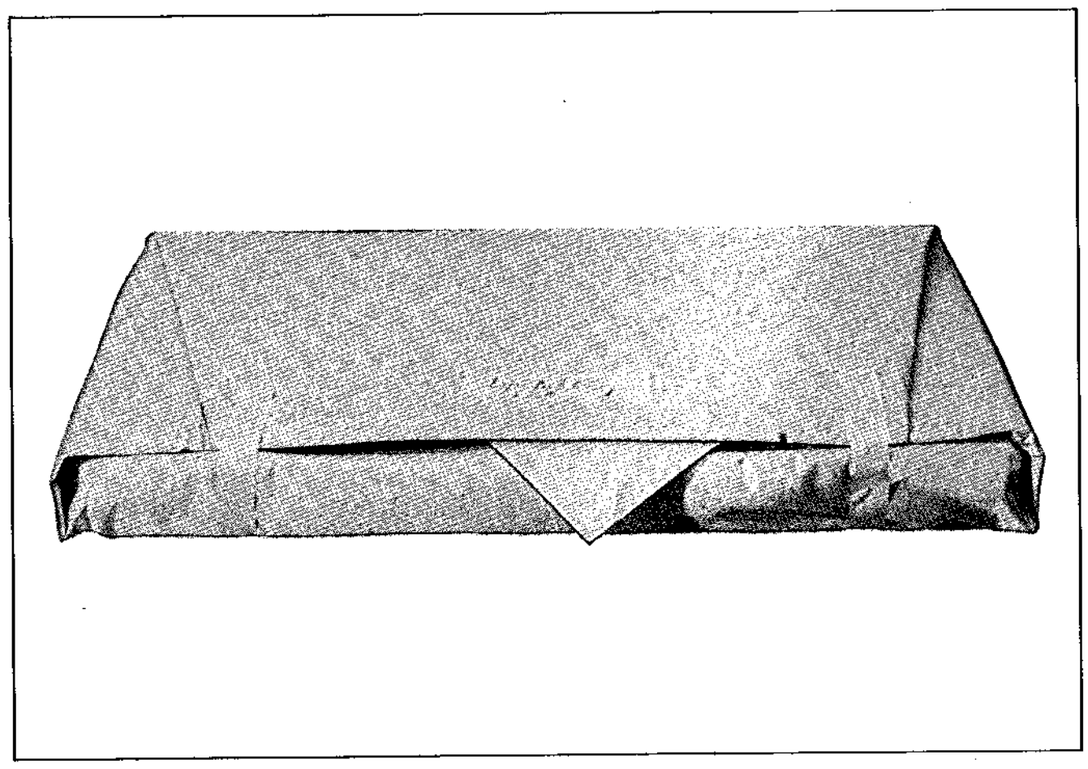
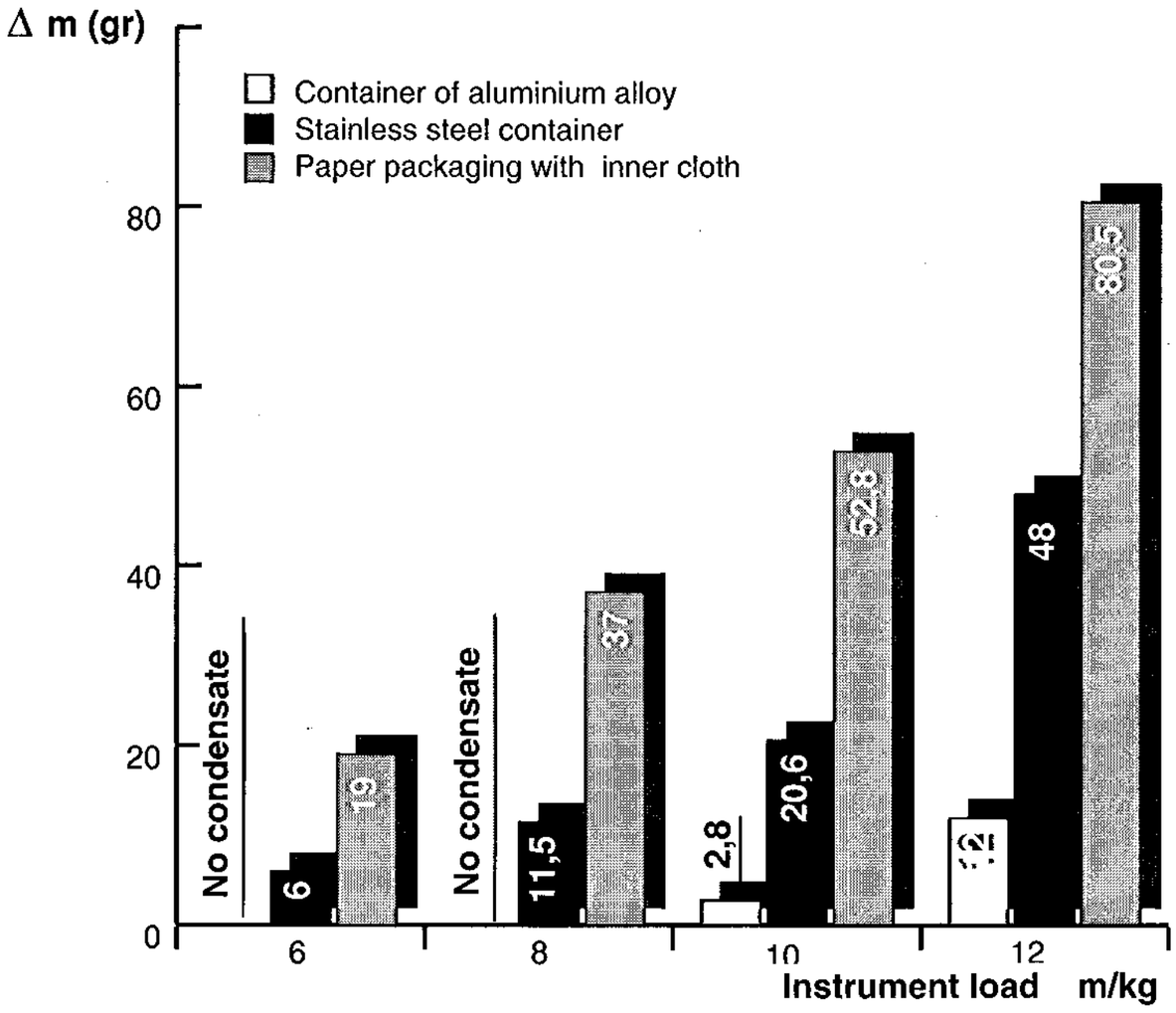


Fig. 4: Disposable sterilising packaging in sterilisation paper based on the envelope method.

4.2. Test results for instrument load

Table 3: Residual condensate as a function of the instrument load weight for various packaging methods (mean value)



4.2.1. Instrument container of aluminium alloy

In this container, good subsequent drying results were obtained up to a load weight of 10.0 kg. The wrapping cloth was completely dry with the loads of 6.0 kg and 8.0 kg and was slightly damp in the upper corners only with a load of 10 kg or higher.

4.2.2. Stainless steel instrument container

In contrast to the aluminium containers, the steel container had adhering residual condensate. A substantial increase in weight of the empty steel container was measured.

The bottom of the steel container was covered on the outside with drops over a large area while the inside of the bottom had a film of moisture. The base area and the upper corners were moist in all tests. At the maximum load of 12.5 kg, the wrapping cloth was wet.

4.2.3. Disposable sterilising packaging

The largest weight increases in absolute terms were measured for this type of packaging. The residual condensate was distributed evenly in the wrapping cloth, as described under Part A, Section 3.1.2. Up to a load of 10 kg, the corners of the wrapping cloth were moist, in some cases over a large area. At the maximum load of 12.5 kg, the instruments were partially covered with a moisture film and the bottom region of the paper packaging was moist.

4.3. Test results for linen load

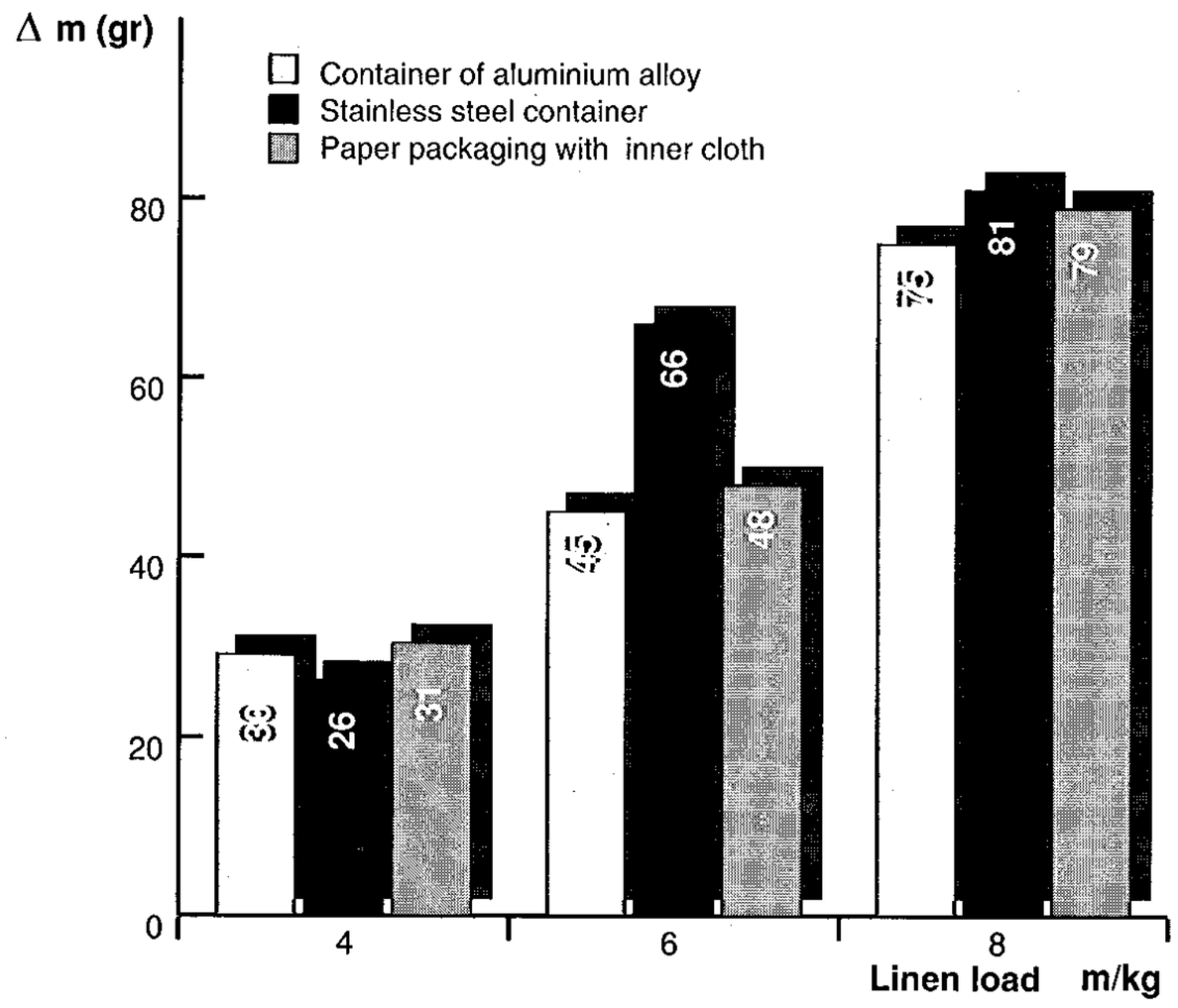
4.3.1. All types of packaging

The test results have shown that the weight increase was below the limit of the weight increase prescribed in the standard DIN 58946 Part 2, i.e. 1.2% of the net load weight, in all packaging materials.

Regardless of the load weight, drying of the packaging materials was very good without exception. The linen itself was found to be dry throughout on subjective assessment.

In the case of the linen load, the container material is not of such decisive importance as for the instrument load, since the condensate is evenly distributed in the material.

Table 4: Residual condensate as a function of the linen load weight for various types of packaging (mean value)



4.4. Summary

The test results show that the container material is of decisive importance in the drying of instrument trays with the same load weight.

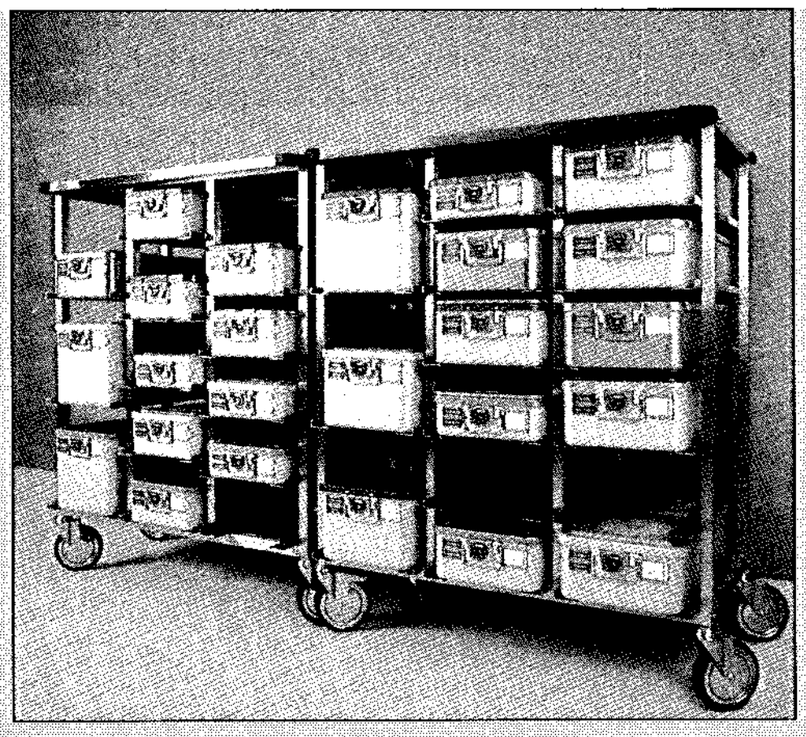
Drying in the instrument containers made of alloy was substantially better then in the stainless steel instrument containers. This is due entirely to the different material properties. Paper packaging gave the poorest results with respect to drying, since a great deal of condensate had been absorbed by the packaging material.

As is evident from the values contained in Table 2, page 9, the specific heat of aluminium is 1.8 times greater than that of stainless steel and the thermal conductivity 14 times greater. The low heat capacity and poor thermal conduction of the stainless steel container is responsible for the fact that good drying cannot be achieved particularly in the bottom region highly contaminated by condensate.

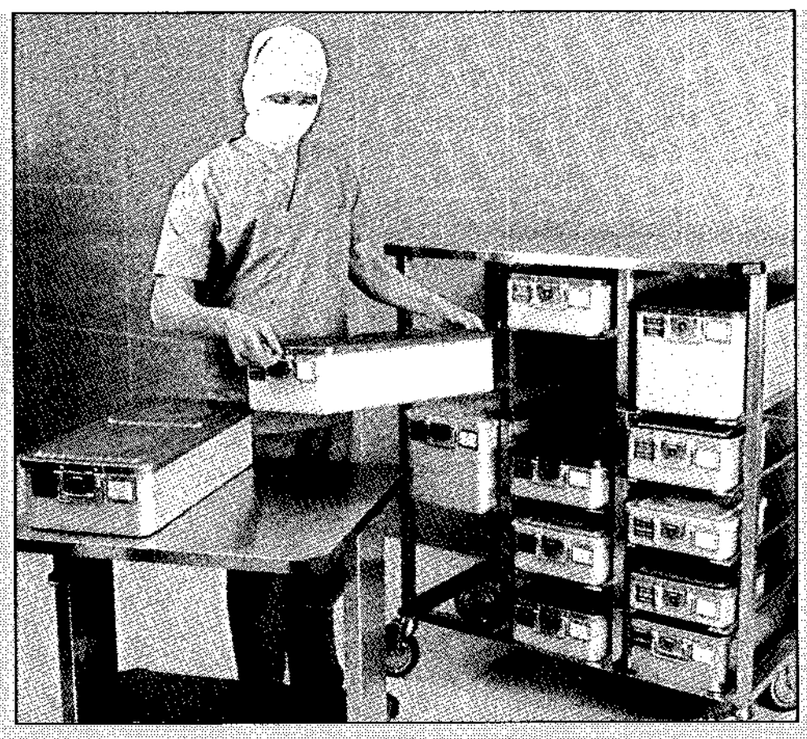
In the case of the linen loads, the results were similar for all packaging types. This indicates that the packaging material is not very important in the case of linen loads.

Part B

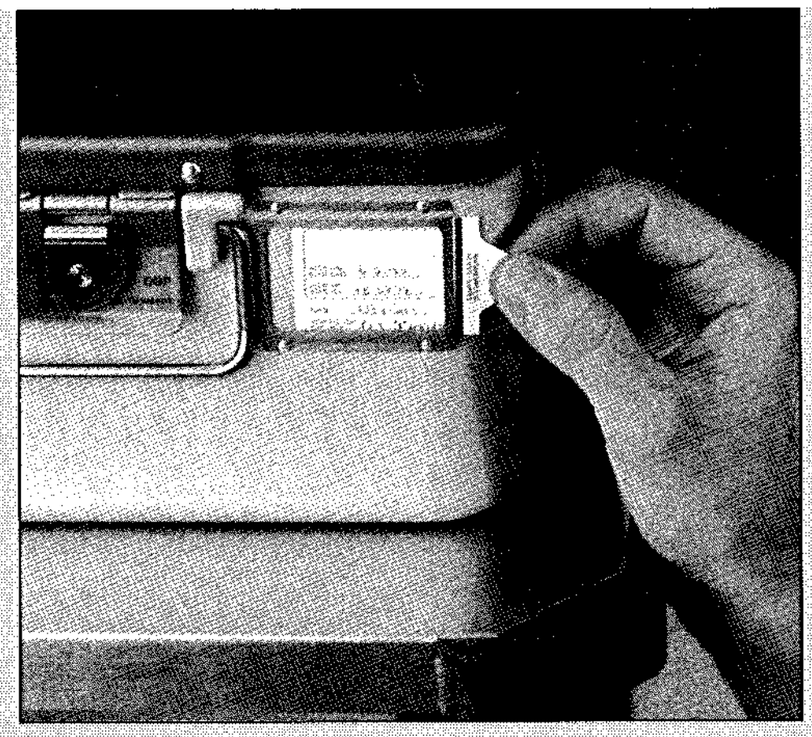
1. Supply of sterile material based on the set system.



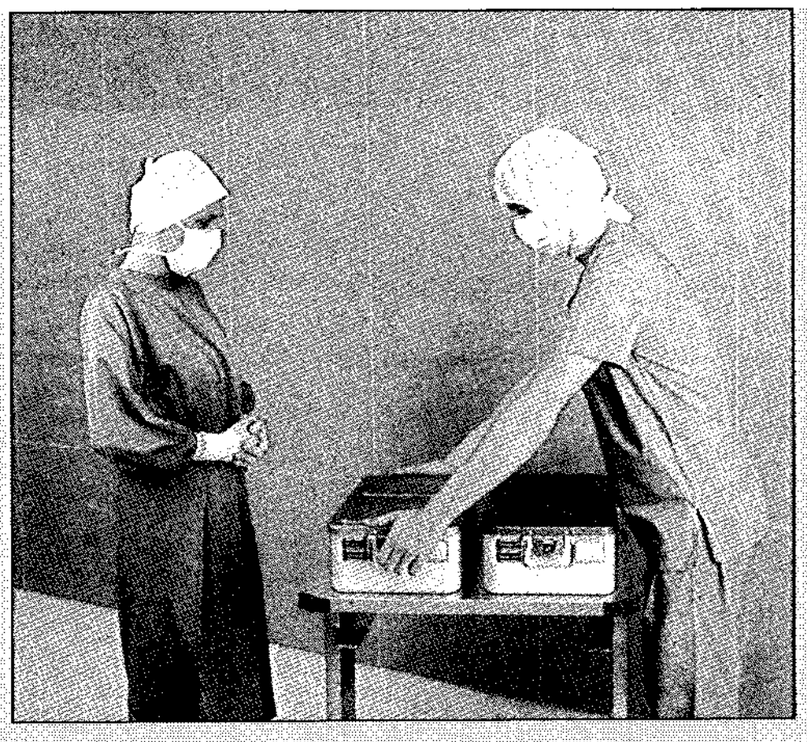
1.1. Sterile storage of the tray and linen containers in the preoperative area on rack trolleys or on stationary storage shelves.



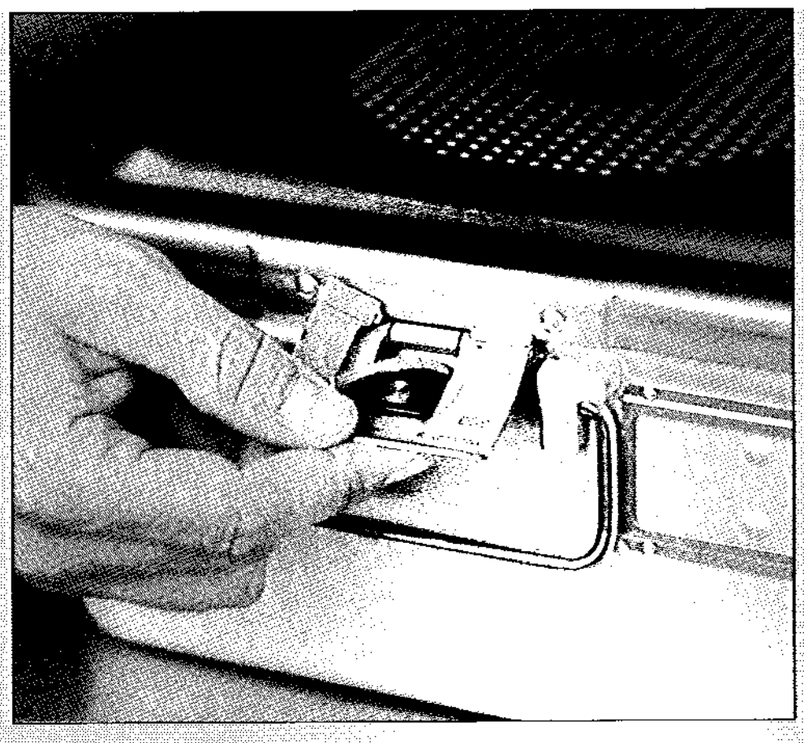
1.2. The complete set is assembled for an operation. It may consist of, for example, basic instrument tray, additional tray, and linen and swab containers.



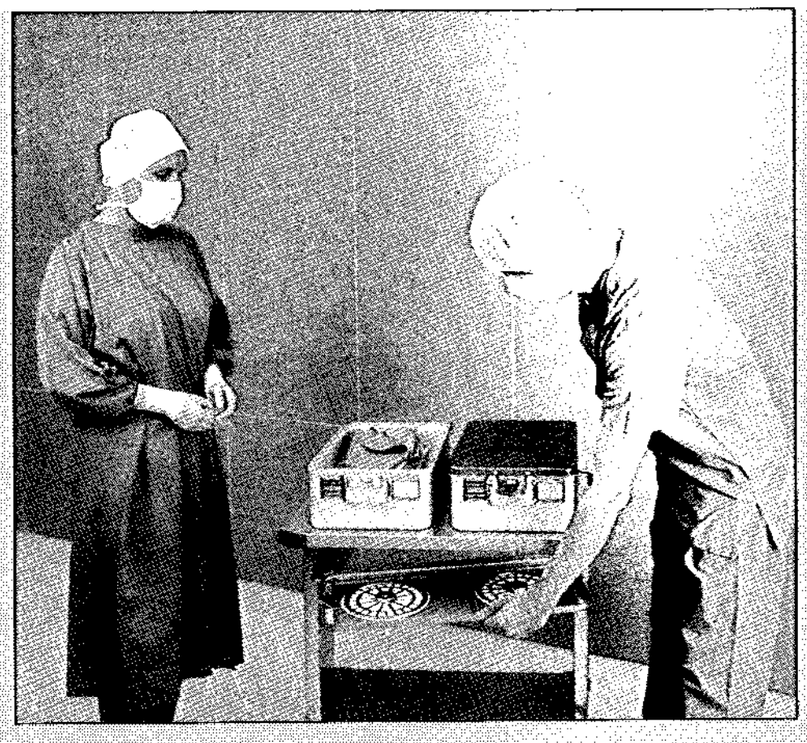
1.3. The assistant removes the indicator plate and sticks it in the patient's record for documentation purposes.



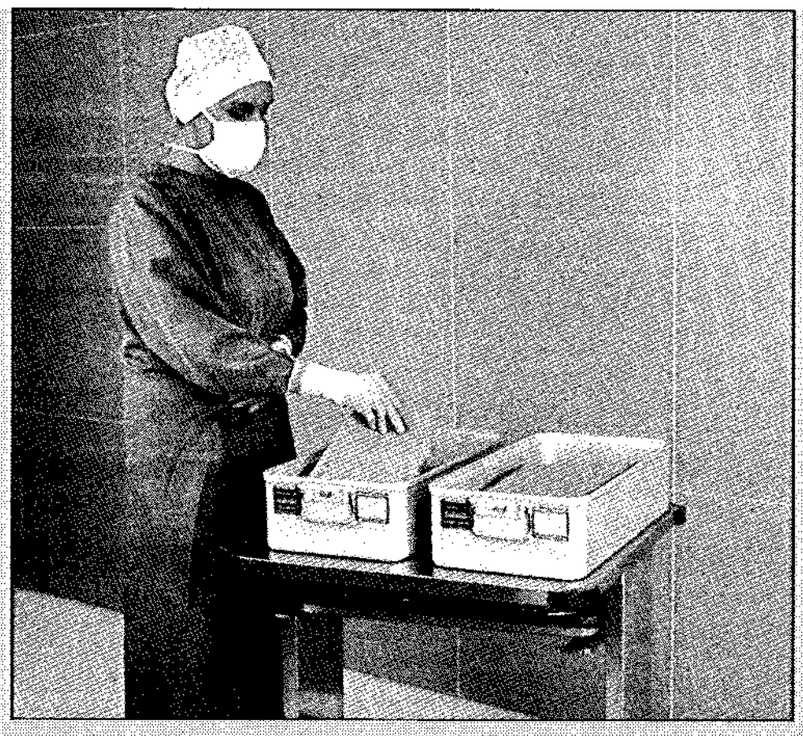
1.4. The assistant arranges the container on the sterile materials table in such a way that the basic tray is closest to the scrub nurse.



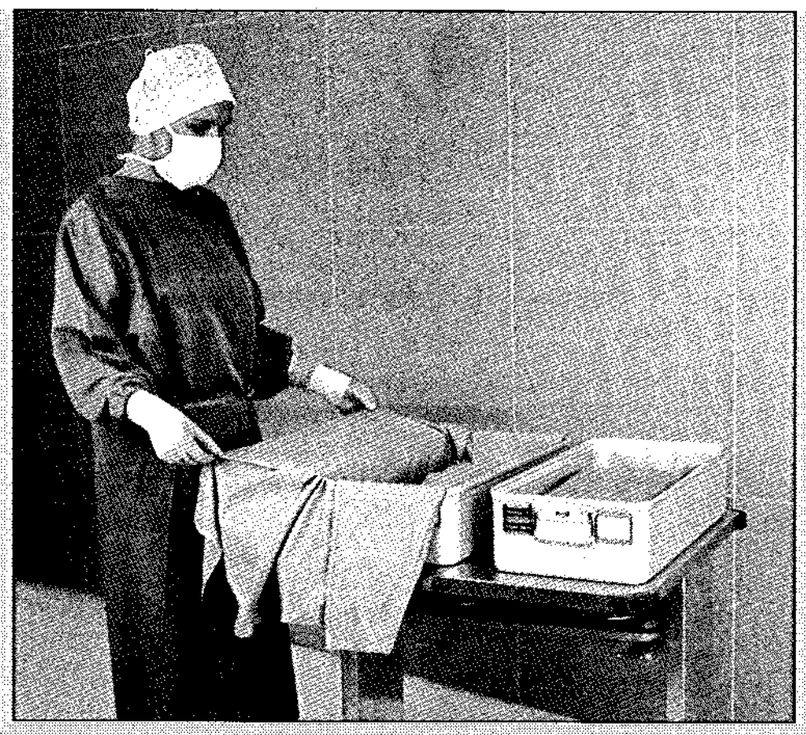
1.5. The assistant opens the basic tray container and thus destroys the lead seal.



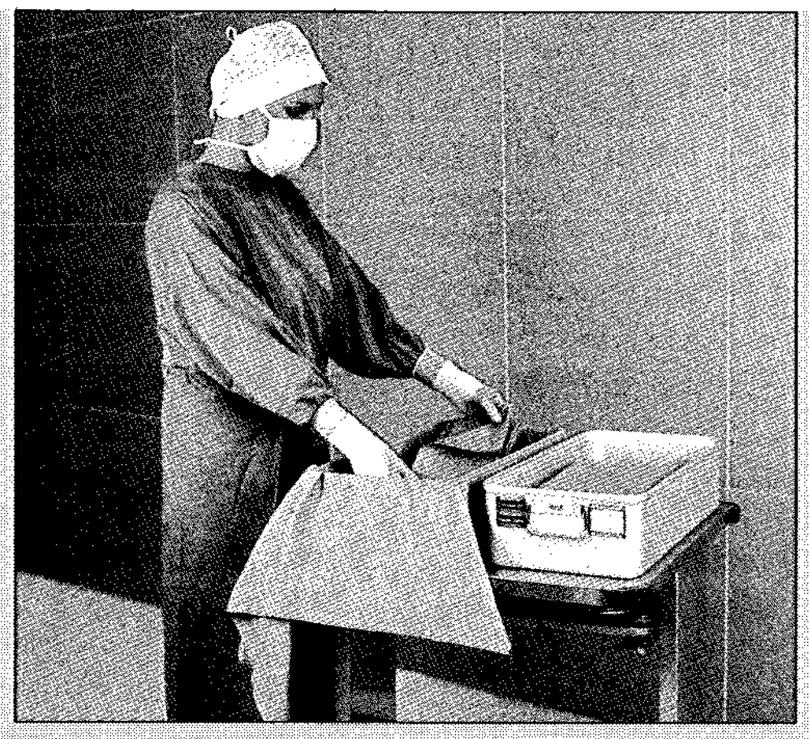
1.6. The assistant lifts the lid by the lid handles integrated in the lock, folds the handles into the lid and places the lid on the rails under the sterile materials table.



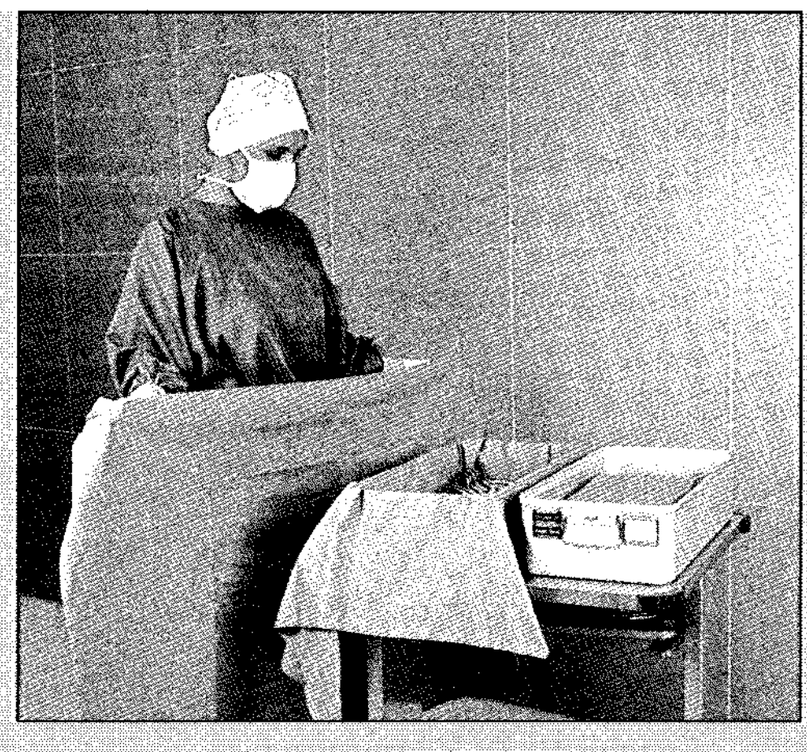
1.7. The scrub nurse unfolds the tray wrapping cloth of the basic tray container ...



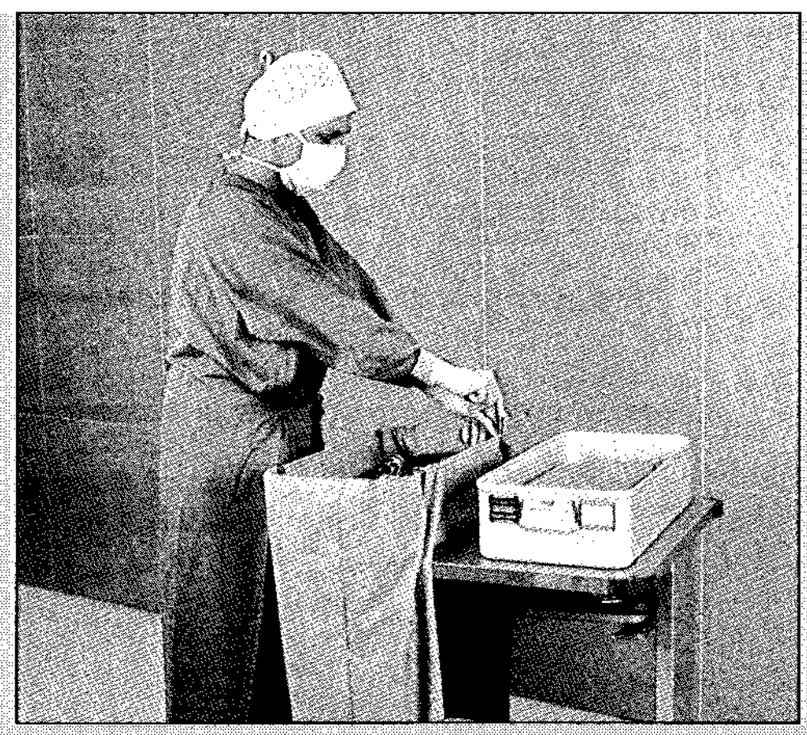
1.8. ... and covers the outer walls of the container with it in a sterile manner.



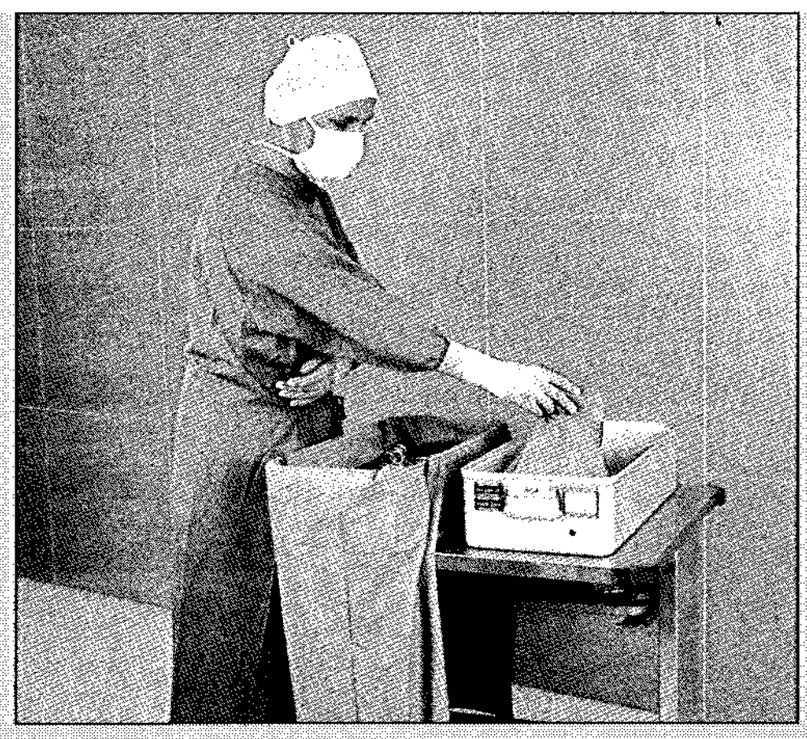
1.9. She then takes an additional tablecloth from the container ...



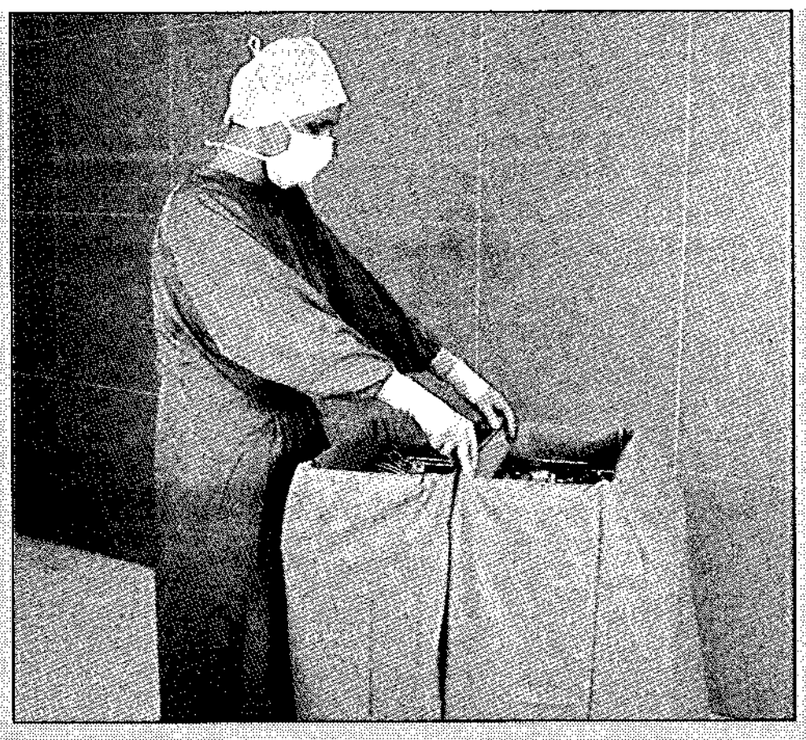
1.10. unfolds it ...



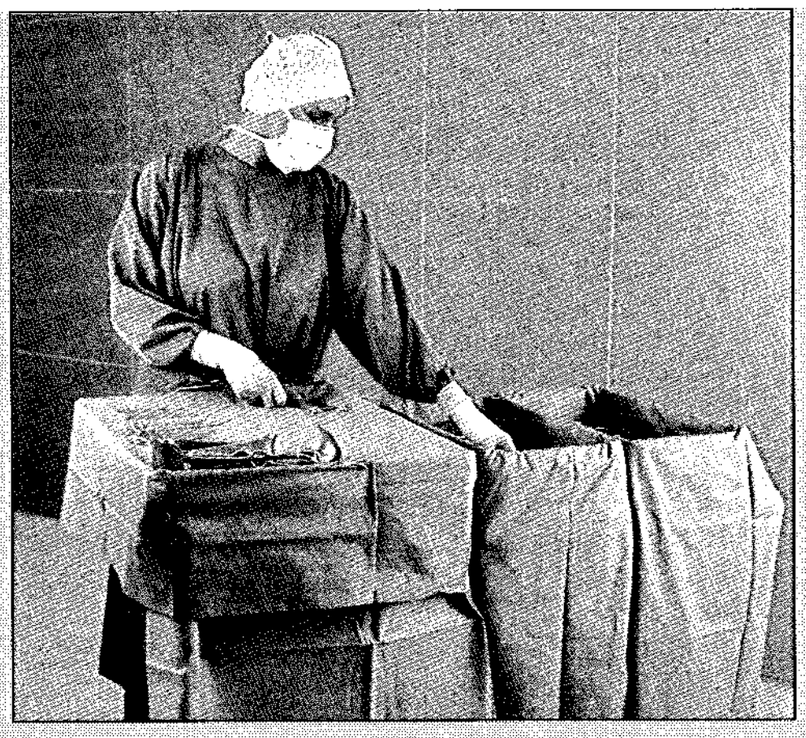
1.11. ... and fastens it with fixing clips to the container edge for safe sterile covering.



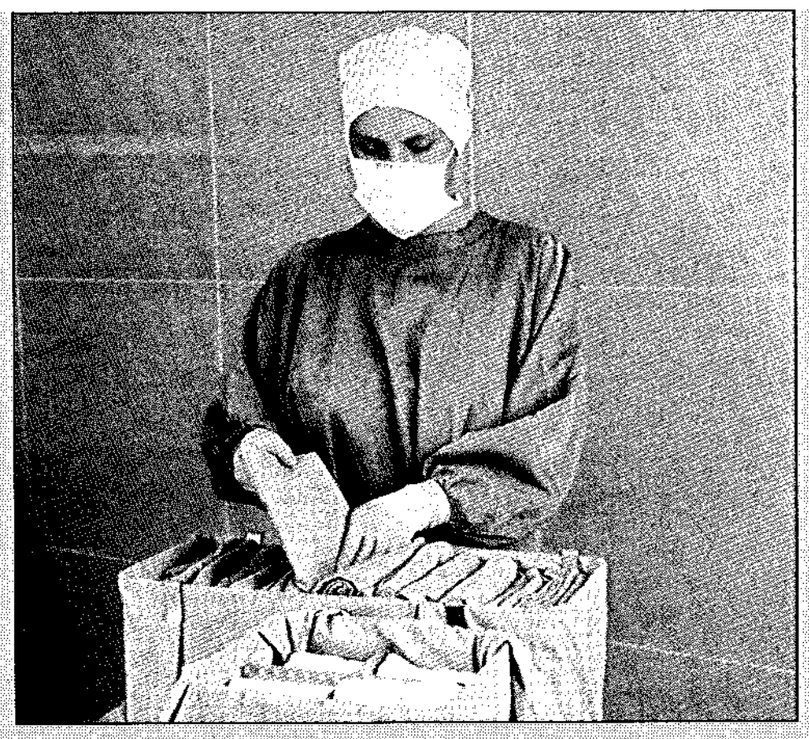
1.12. The same procedure is then carried out for the additional tray.



1.13. The basic and additional trays are pushed together.



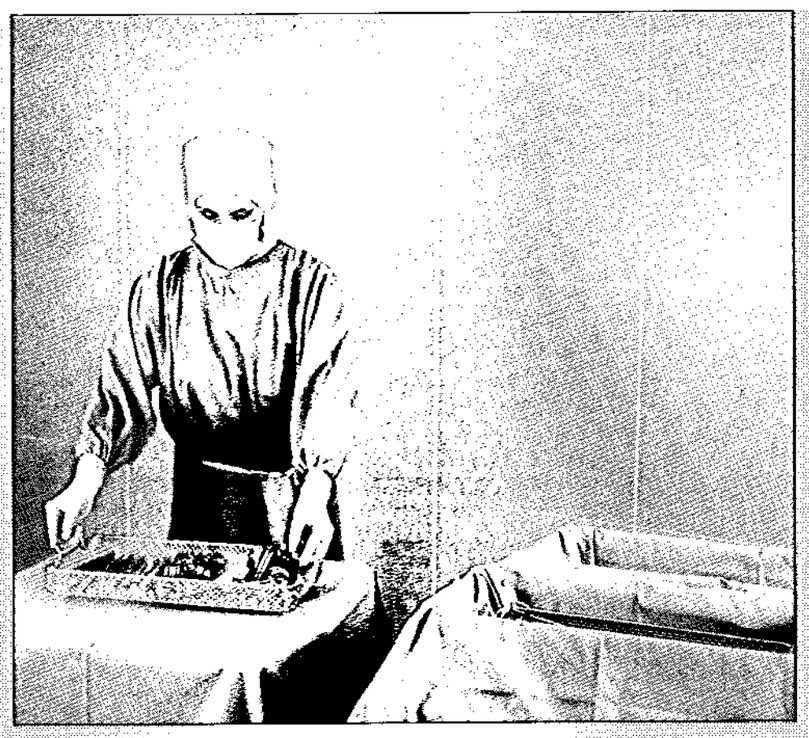
1.14. The instruments are placed on the passing table.



1.15. The linen is laid out according to the same principle as the instruments.

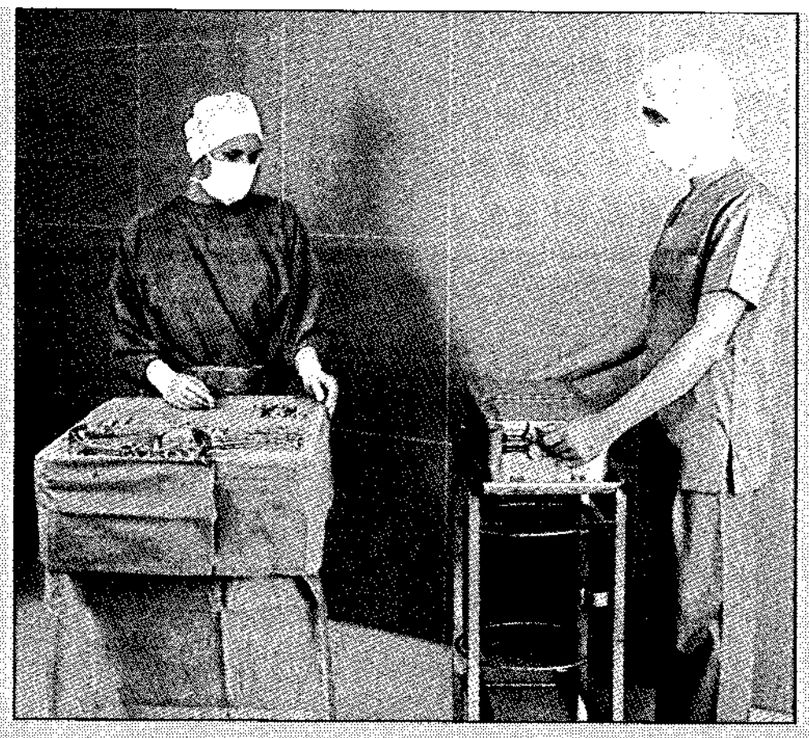
2. Alternative possibility for sterile arrangement of basic and additional tray outside the container.

2.1. The scrub nurse removes the basic and additional trays from the opened container.

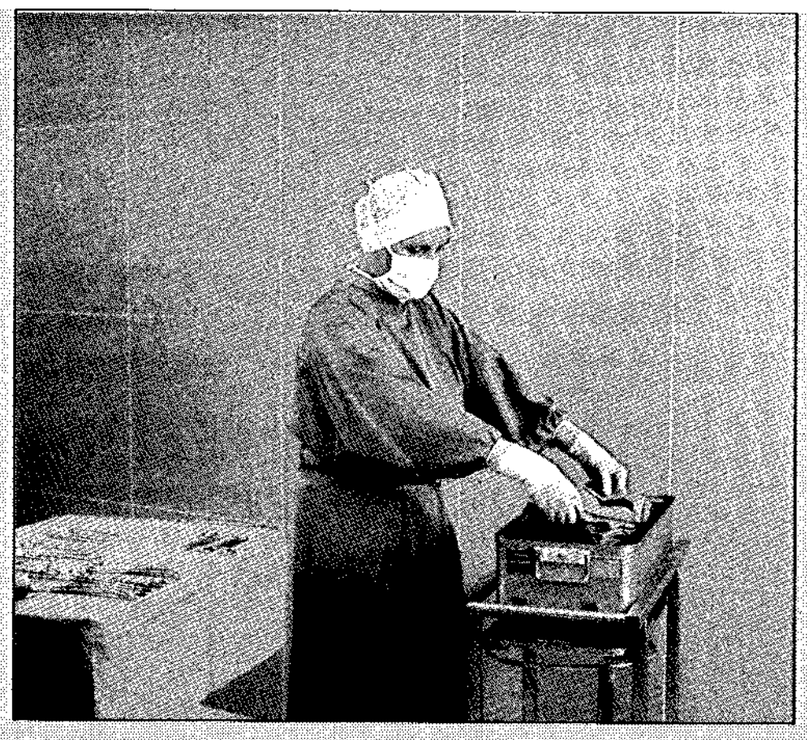


2.2. After the trays have been laid out, the instruments are placed on the passing table.

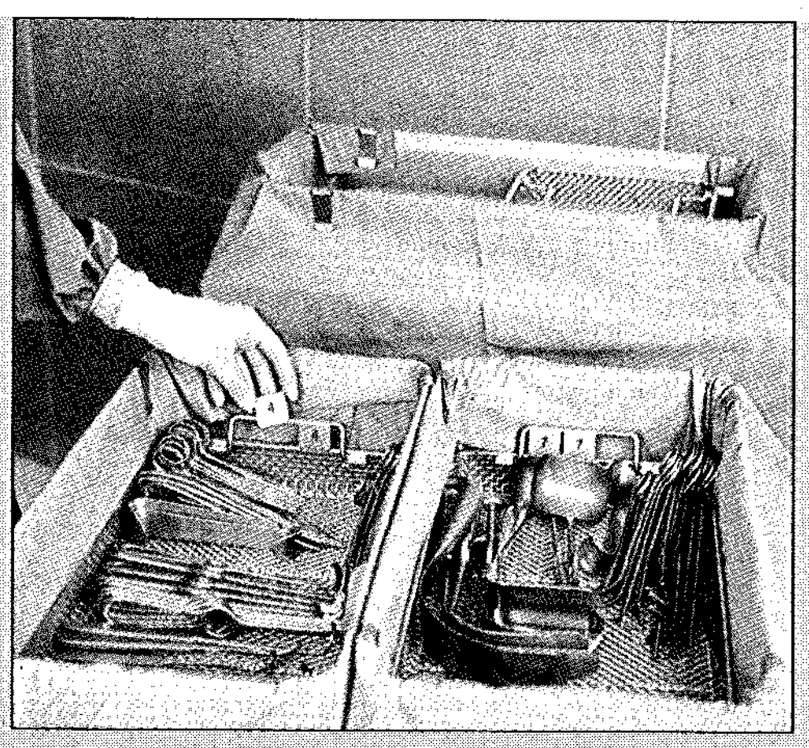
3. Tray-related return and preparation in the operating theatre.



3.1. The assistant opens the removal container, ...

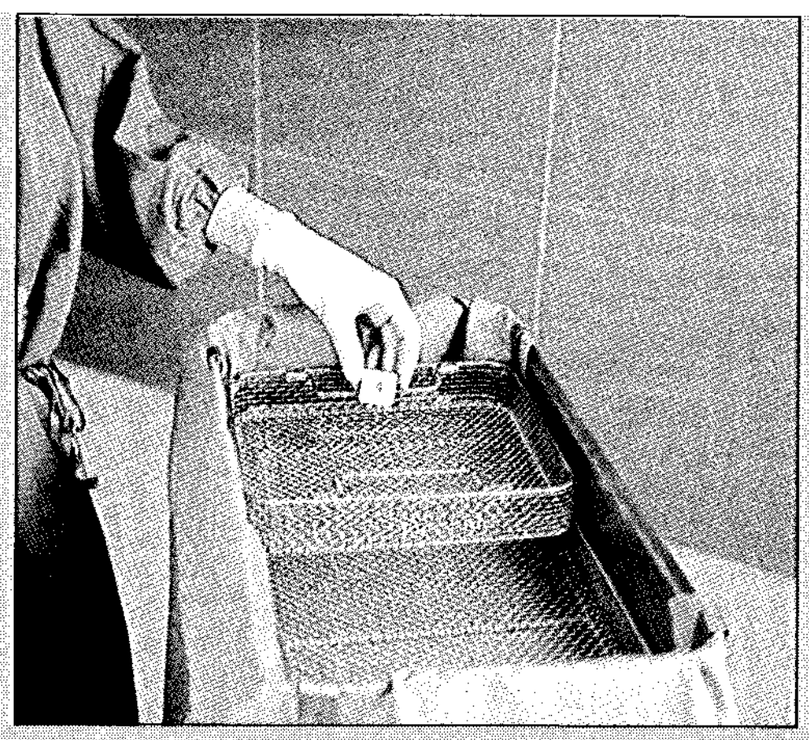


3.2. ... so that the scrub nurse can cover the removal container with a sterile cloth.

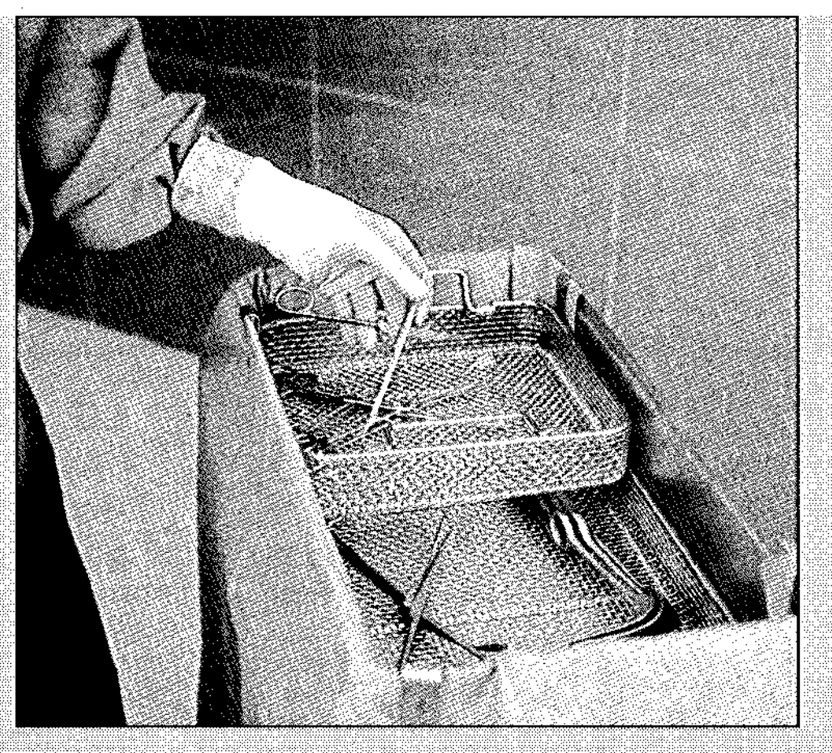


3.3. The instrument trays each contain two identical numbers to permit tray-related return.

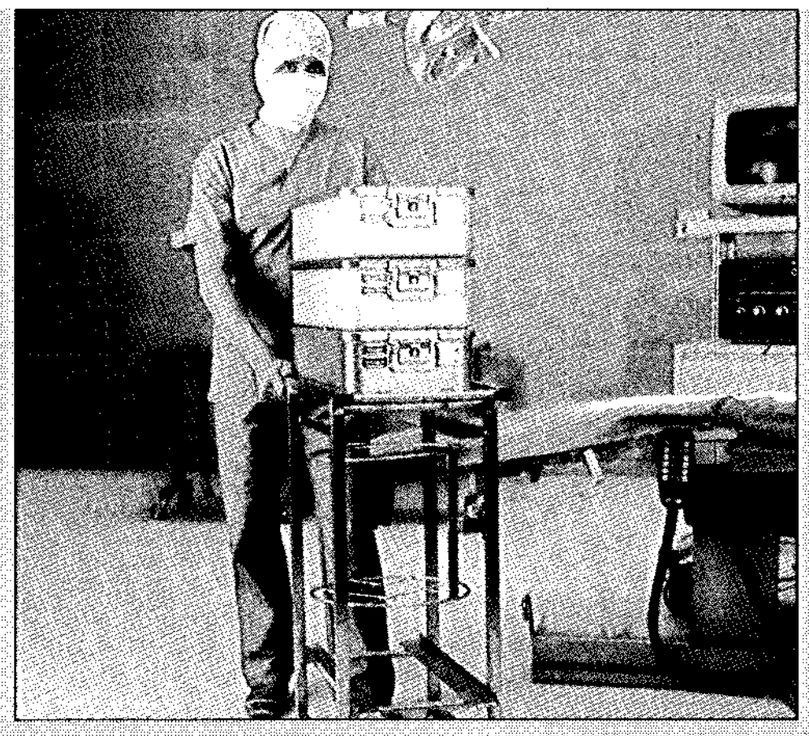
3.4. One of the two numbers from each instrument tray ...



3.5. ... is fastened to a tray of the removal container.

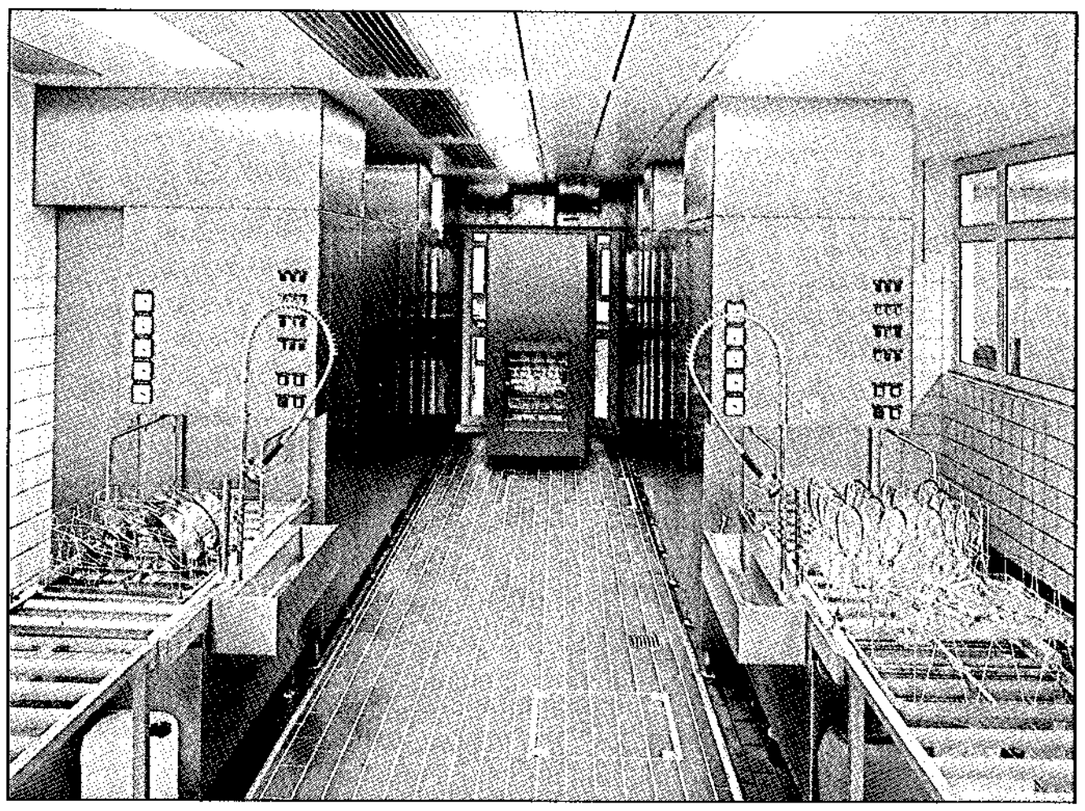


3.6. Tray-related return can be carried out by separating the basic and additional instruments when they are discarded. The addition of disinfectant solution during return permits wet return. Wet return is advisable when the instruments used cannot be processed in the short term and operation residues can therefore form a crust. Experience has shown that instruments kept moist can be cleaned more easily and reliably both by machine and manually. Wet return in disinfectant solution is used in particular for return of instruments from septic operations.

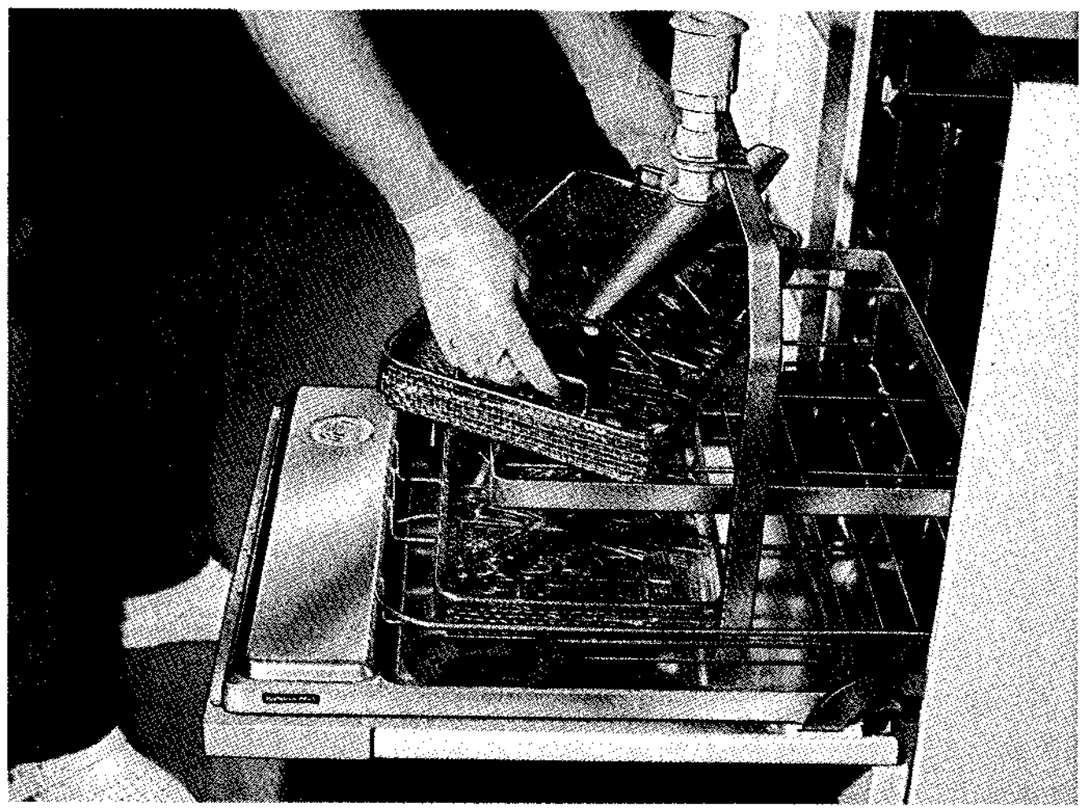


3.7. The used instruments are transported back to the central sterilisation unit in closed removal containers without danger of contamination. The unused instruments of the basic and additional tray are present in the upper two containers.

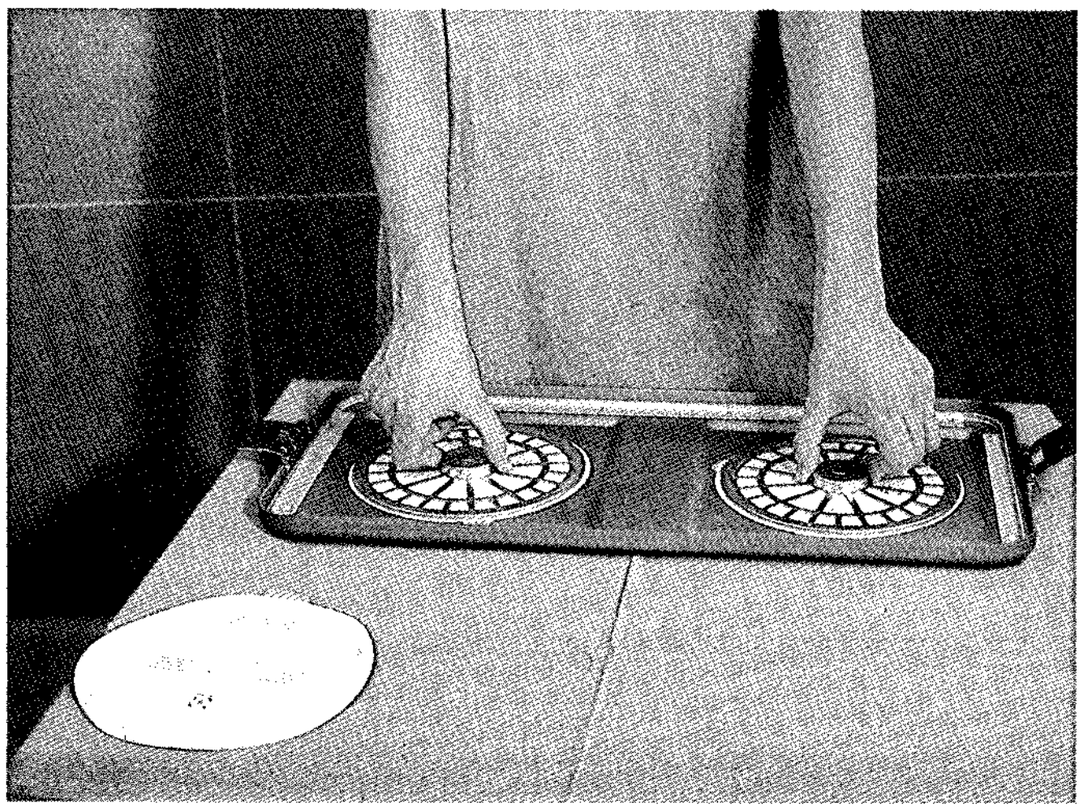
4. Tray-related return and preparation in the central sterilisation units.



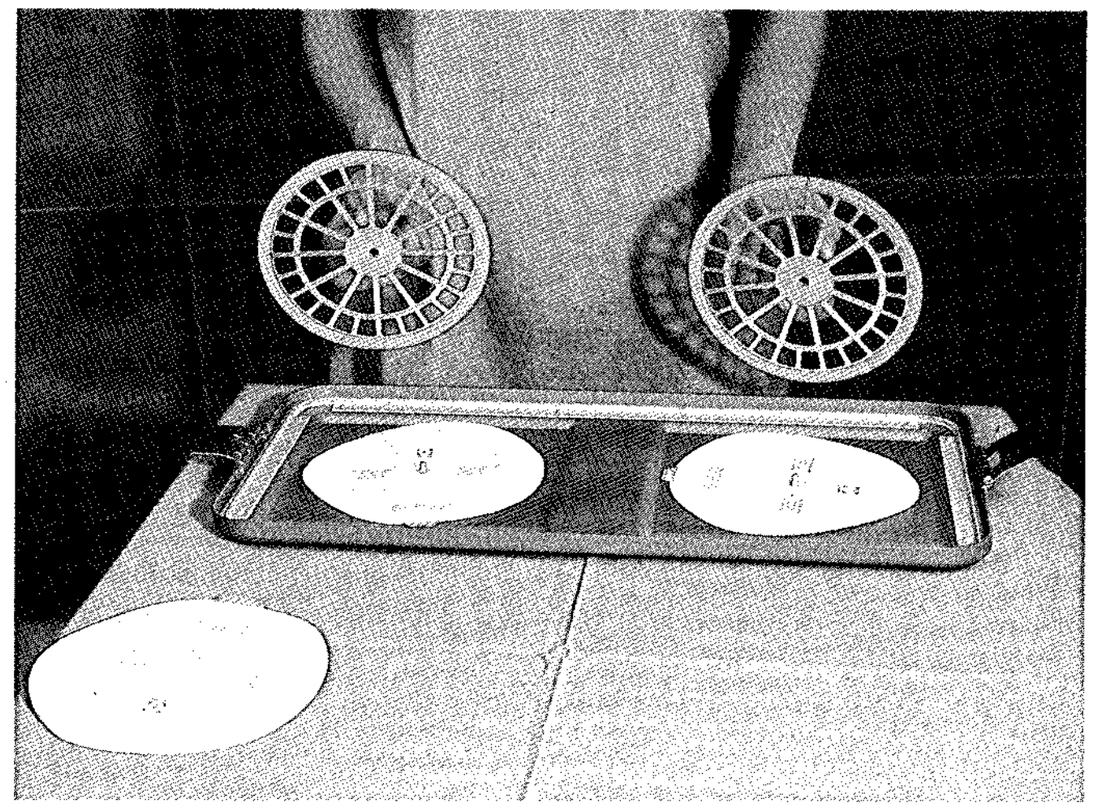
4.1. Instrument cleaning can be carried out according to the existing facilities: by ultrasonics, thermal disinfection, mechanically or preferably by a combined method.



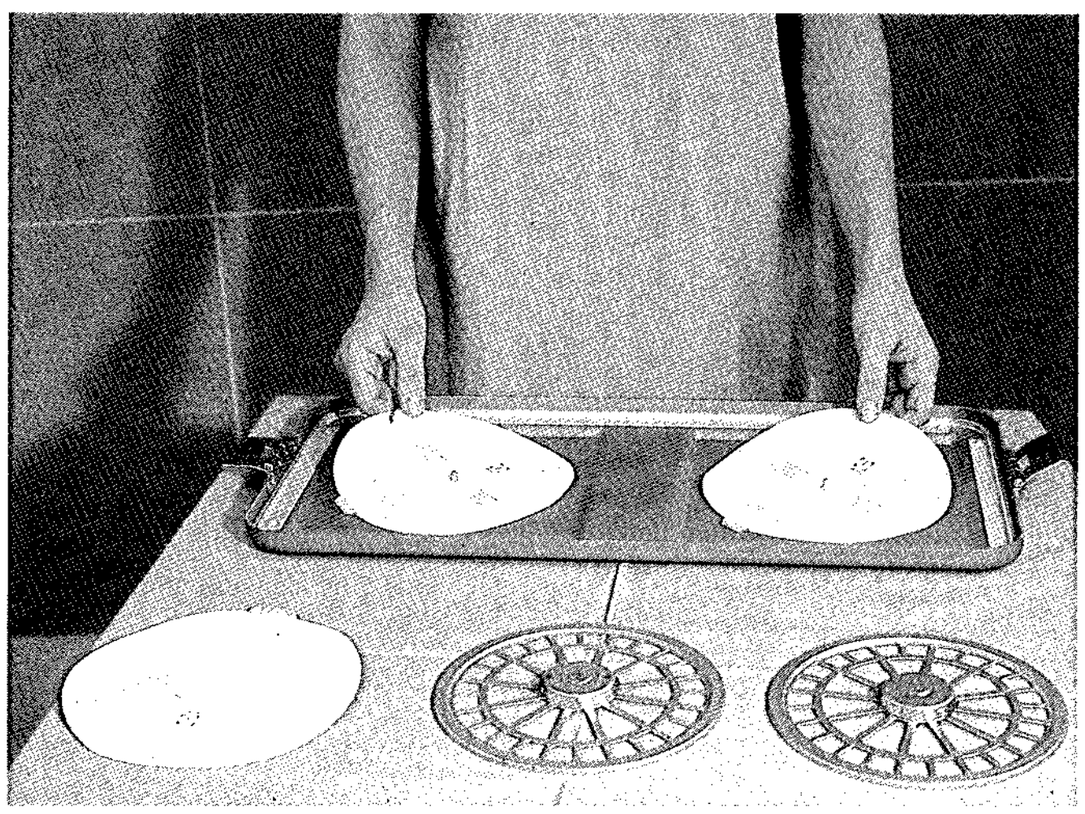
4.2. The AESCULAP container trays conform in their dimensions to the DIN standard and are therefore suitable for both washing machines and washing lines.



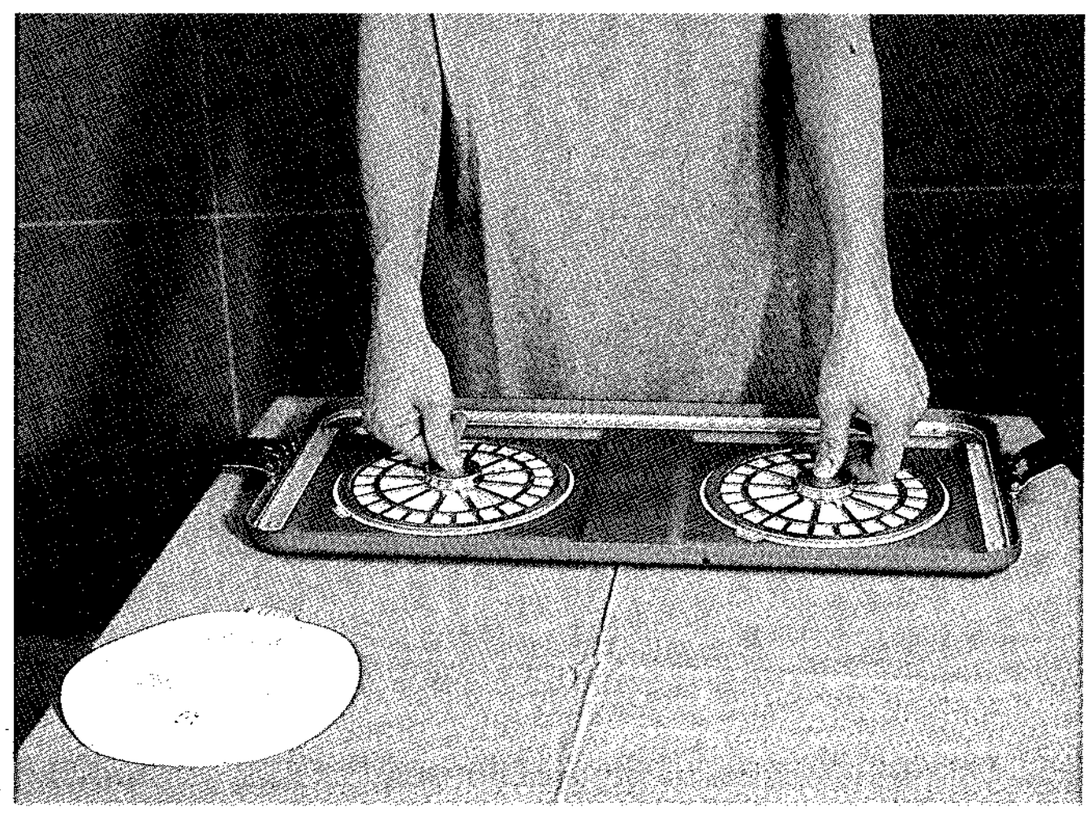
4.3. For changing the filters, the filter holders can be removed by pressing buttons on both sides ...



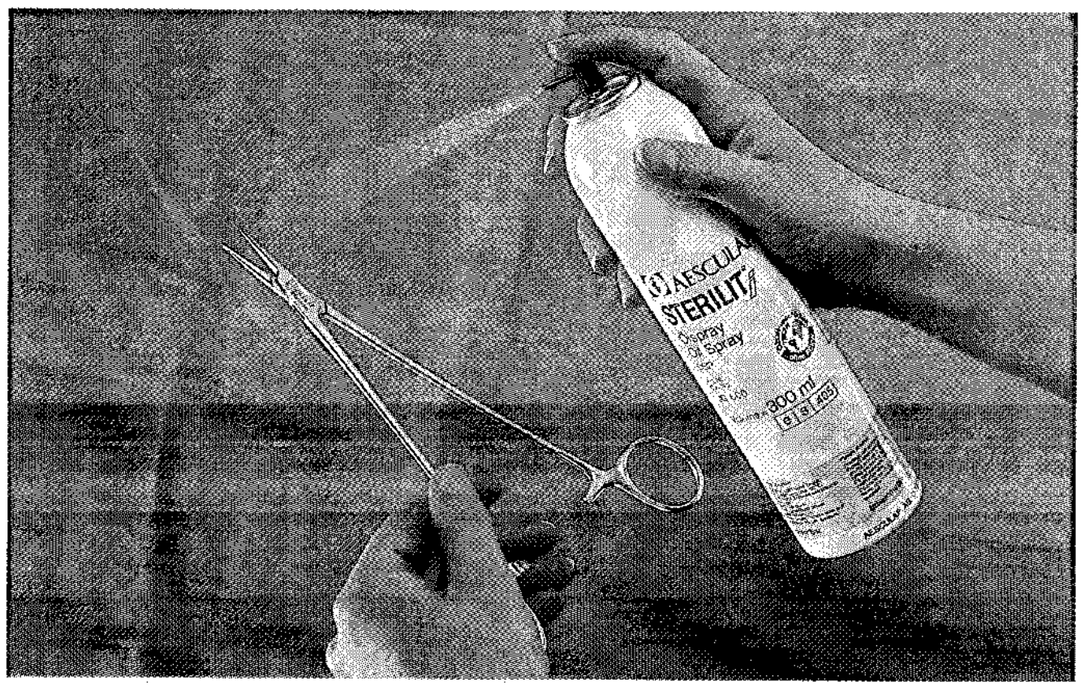
4.4. ... and can then be lifted off.



4.5. The filter papers are replaced ...



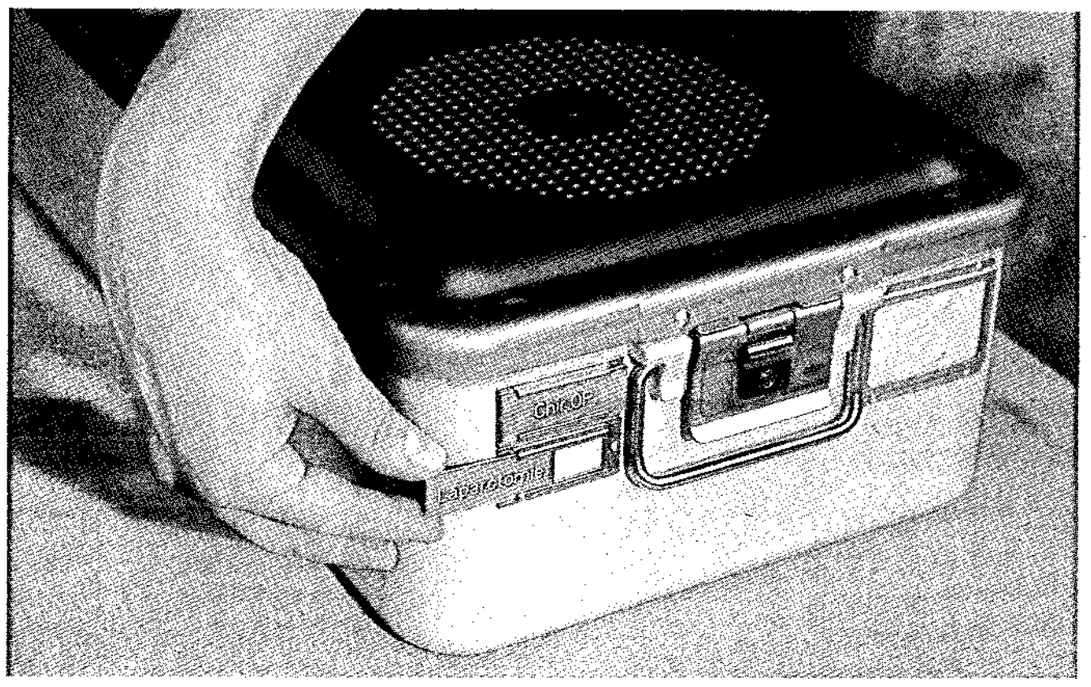
4.6. ... and the filter holders are brought to their original position by means of a pushbutton mechanism.



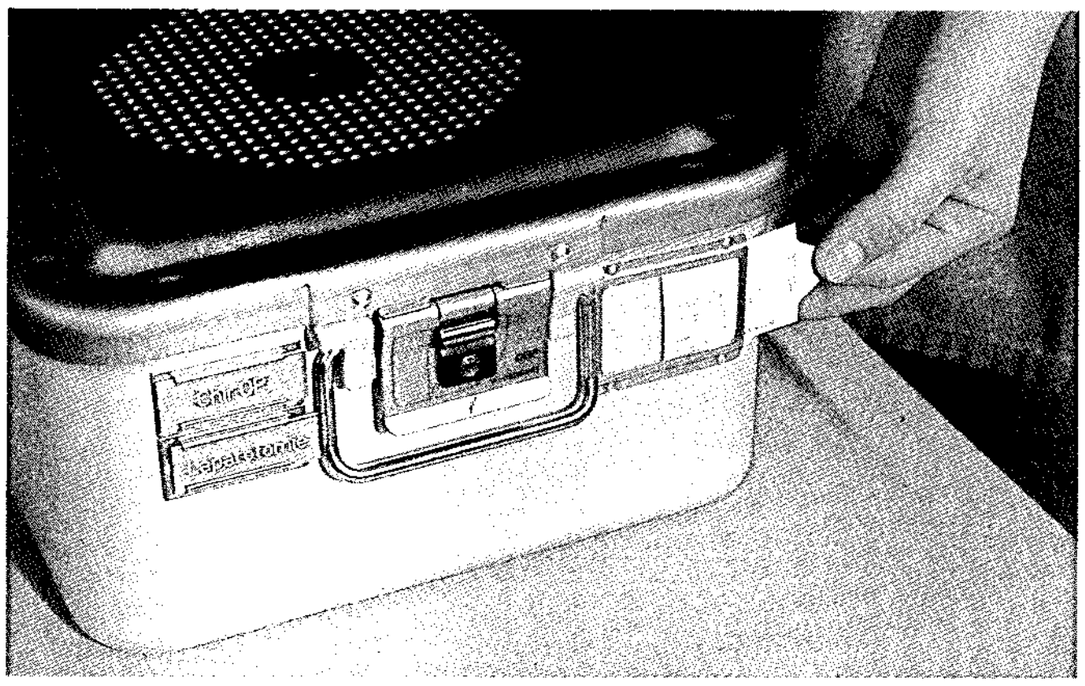
4.7. After thorough cleaning by a washing line or a washing machine, the instruments are oiled in the joint with a special oil to reduce friction and arranged in the tray in accordance with the packing list.

4.8. The tray containing the instruments is placed in the container and covered with the wrapping cloth.

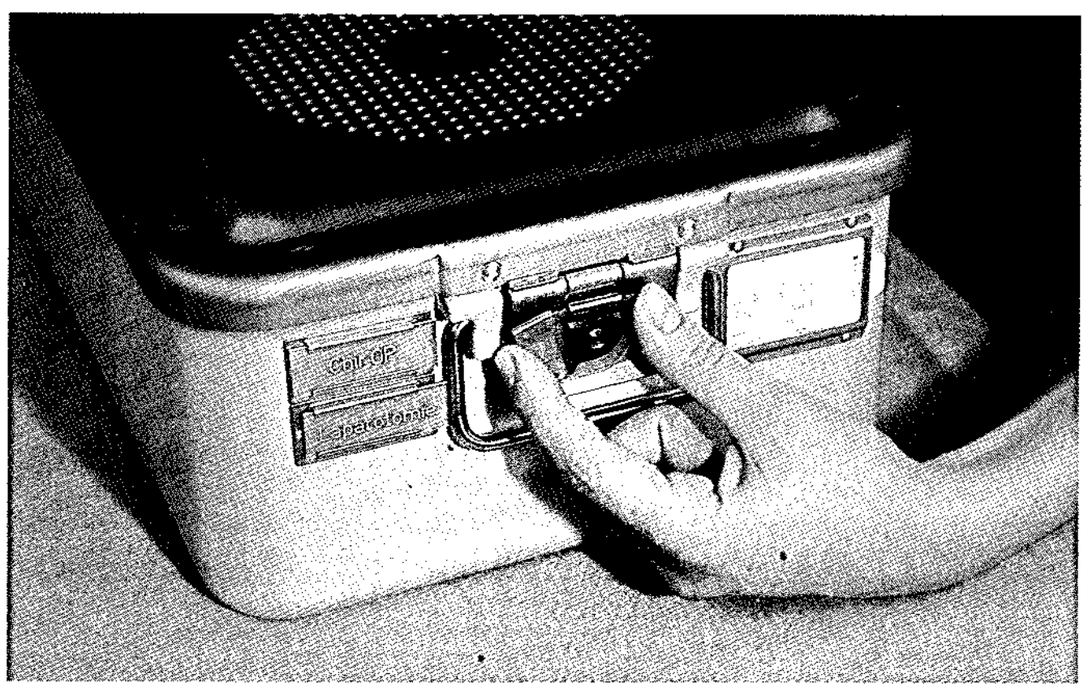
4.9. The lid provided with new filters is placed on top and lokked. Paper filters must be replaced after a single sterilisation, and textile filters after about 50 sterilisations or after about two to three months.



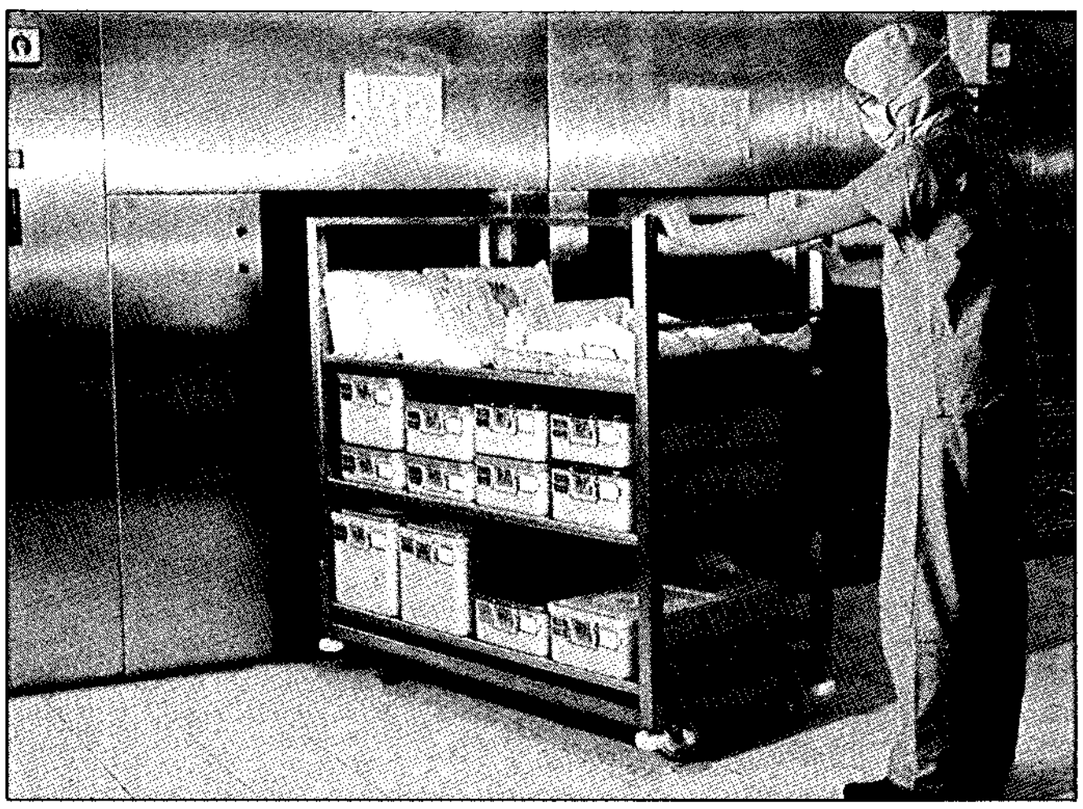
4.10. The inscription labels are inserted, unless this has already been done.



4.11. The indicator carel bearing the date and the signature of the packer is inserted.



4.12. The locks are provided with lead seals to allow unauthorised opening of the sterile containers to be detected.



4.13. The standardised containers on corresponding steriliser trolleys are pushed into the steriliser. AESCULAP containers can be stacked one on top of the other in any number during the sterilisation without impairing the entry of steam. However, it should be noted that no paper packaging must be stacked on containers because this covers the perforated panel of the containers and thus prevents adequate steam exchange.

4.14. After sterilisation is complete, it is possible to provide the perforated cover with a transparent protective cover made of plastic, as a dust cover. Alternatively, a double cover may be used instead of the standard cover. Owing to their distance to the second cover, double covers are generally not regarded as dual packaging since the outer surface of the inner packaging does not remain sterile.

Part C

1. Standards and sizes

The overview below contains a short summary of the DIN standards relevant for sterilisation with sterilising containers. The title of the standards and some brief key aspects are intended to serve as a guide and to make it easier to obtain detailed information. For detailed studies, we recommend DIN Pocket Book 169 "Sterilisation, Desinfektion, Sterilgutversorgung" Beuth Verlag GmbH, ISBN 3-410-12218-4.

DIN Standard	Brief information on content
DIN 58900 Part 1 General principles Terms	Definition of terms: Examples: Killing time ... Sterilisation ... Sterilising unit ... Sterilising time
DIN 58900 Part 2 General principles, requirements	Requirements for the killing time and equilibration time. Requirements for indicators
DIN 58946 Part 2 Steam sterilisers for sterile medical materials	... Chapter 11 Drying "Explanation: Taking into account the prescribed boundary conditions, the net weight increase must not be more than 1.2%." (Linen load)
Large sterilisers Requirements DIN 58946 Part 3 Steam sterilisers for sterile medical materials	- Periodic testing of the steam steriliser - Exceptional testing of the steam steriliser - Carrying out the test - Bowie-Dick test
Large sterilisers Test for efficiency DIN 58946 Part 4 Steam sterilisers for sterile medical materials Bioindicators	Terms, requirements, test
DIN 58946 Part 6 Steam sterilisers Operation of large sterilisers	General principles Obligations of the manufacturer and of the operator Tests at beginning of operation Section 5.2 Loading with material to be sterilised "5.2.1 The loading weight of sterilising trays with instruments should not exceed 8.5 kg per sterilising tray." "5.2.3 The weight of linen pakkages or the loading weight of sterilising containers with linen should not exceed 6 kg per pakkage or sterilising container." Table 1 from DIN Standard: Suitability of the types of packaging for steam sterilisation methods (see Table 5, page 22).

DIN Standard	Brief information on content
DIN 58952 Part 1 Rectangular metal sterilising container	Definition of sterilising container e.g.: - Sterilising container with filter (STB-F) - Sterilising unit (STE) and dimension system - Dimensions - Material
DIN 58952 Part 3 Packaging materials for material to be sterilised Metal sterilising trays	- Terms - Dimensions - Material - Surface
DIN 58953 Part 1 Supply of sterile material Terms	Definition of terms in the area of sterile material division e.g.: "Dual packaging for sterilised material"
DIN 58953 Part 5 Supply of sterile material "Creped and smooth sheets of sterilisation paper for wrapping material to be sterilised" "Requirements, tests"	This standard describes requirements and tests for paper from which filters for the AESCULAP container system are produced.
DIN 58953 Part 9 Applications technology of sterilising containers	1. Applications 2. Purpose 3. Procedure 4. Suitability of sterilising containers 5. Marking "Table 1: Suitability of sterilising containers for various sterilisation methods." 6. Packing of material to be sterilised 6.1 Instruments "Note: For ergonomic reasons and in order to avoid pronounced condensation, the load weight of the sterilising container should not exceed 10 kg." 6.2 Linen 6.3 Rubber goods 7. Sterilisation 8. Cleaning and/or disinfection 9. Maintenance 10. Storage 10.1 Requirements for the storage rooms 10.2 Storage time "Table 2 from DIN standard: Guide values for the storage time of sterile material for use under standard aseptic conditions" (see following Table 5, page 20).

Table 5: Guide values for the storage time of sterilised material for use under standard aseptic conditions1)

Packaging of sterilised material	Type of packaging	Storage time	
		Storage [2] Unprotected	Storage [3] Unprotected
Sterilising container according to DIN 58952 Part 1	Single packaging for sterile material [5]	24 hours [6]	6 weeks
	Dual packaging for sterile material [5]	6 weeks	6 month
	Storage packaging for sterile material [5]	5 years [4]	

[1] For use under conditions under which particularly high requirements for asepsis must be set, it is advisable to use shorter storage times or, through other measures, such as additional packaging, to prevent asepsis from being impaired by microorganisms present on the packaging.

[2] e.g. on shelves

[3] e.g. in cupboards or drawers

[4] Before the storage packaging of the sterilised material is opened, it must be properly freed from dust.

[5] For definition, see DIN 58953 Part 1

[6] Guideline of the Board of Health for the detection, prevention and control of hospital infections.

2. Batch documentation

The hospital authorities and hence the Heads of all departments accept responsibility for proper medical and nursing care when a patient is admitted.

The provision of sterile material is a responsibility of those in charge of operations and/or those in charge of the central sterilisation unit.

If so-called "sterilisation incidents" occur, the legal evaluation is based on the BGA (Federal Board of Health) guidelines and the DIN standards, which serve as a reference for proper handling of sterilised material.

If "prima facie evidence" gives grounds for assuming that contamination might have occurred during the supply of sterile material, the hospital authorities or those responsible for the relevant department must clear themselves and show that no contamination has taken place in their area. This so-called shift in the burden of proof relieves the patient of the obligation to prove that the hospital has made a mistake.

Only complete documentation permits the hospital to prove umabiguously that material for sterilisation was properly sterilised.

s

l is cooled to room temperature, pres-
ur between the interior of the contai-
n owing to climatic fluctuations. Air is
with increasing barometric pressure
is expelled in the opposite case. This
o here as "breathing", takes place du-
e until the material is used.

in the sterilised material store (disin-
anical loads may also cause the con-
scirbed above.

n the outer walls of the container and
r volume is reduced and hence sterile
container. When the pressure is relie-
and the cover return elastically to the
ainer volume increases again. The air
erile filter and is thus free from germs.

ntainers thus protect the sterile mate-
every phase after sterilisation.

An important procedure for documenting the efficiency test of the steriliser is the Bowie-Dick test, which is usually carried out every morning before the beginning of the normal daily programme. Many hospitals additionally place a chemical indicator strip in every pack of material to be sterilised. In some cases, this indicator is attached to the patient's record in the operating theatre.

In addition, a spore test is carried out for every steriliser, according to DIN 58946 Part 6, Section 6.3, on average every 6 months but no later than every 400 batches.

Many sterilisers are now equipped with sterilisation chart recorders with the aid of which the sterilisation time, pressure and temperature can be checked and recorded.

It can be assumed that documentation relating specifically to the patient will become more important in the future and will even be a requirement.

For this purpose, AESCULAP provides an indicator plate which indicates sterilisation by a colour change during the sterilisation and on which the sterilisation date, the steriliser number, the name of the packer and the expiry date can be input. It is often possible to equip the steriliser with a printer which prints the above information on a small sticker. This sticker has a special place on the AESCULAP indicator plate and makes it easier to fill in the data on the plate.

A process indicator which reacts to heat treatment is provided on the back with a covered adhesive layer and allows the plate to be stuck into the patient's record without additional means, for example use of adhesives, is attached to the indicator plate.

Another advisable safety measure is a tamper evident lock which is mounted prior to sterilisation in the container locks and is inevitably destroyed when the container is opened in the operating theatre. If the container is opened beforehand, this can be detected by virtue of the fact that the lead seal has been destroyed, and the instruments are not used in the operating theatre.

With correct use, batch-related patient documentation is possible by means of the indicator plate in conjunction with the chart recorder of the steriliser, i.e. in the event of any right of recourse, it is possible to prove, with reference to the patient's record, that the material used had been subjected to a sterilisation process and the container was not opened between the central sterilisation unit and the operating theatre. From the data on the indicator plate, the central sterilisation unit can check whether the steriliser in which the relevant instruments were sterilised had passed the Bowie-Dick test in the morning, this test indicating correct function of the steriliser on that day.

3.1. Subsequent drying in the steam steriliser

After the end of the sterilisation cycle, a certain time should be allowed to pass before the sterile material is removed from the sterilising chamber. During this time, the sterilised material absorbs additional energy as a result of heat radiation from the steriliser wall. This heat energy is used for further evaporation of condensate, particularly in the case of containers with paper filters.

However, this subsequent drying is not as effective as the vacuum drying which is used at the end of the sterilisation programme.

3.2. Subsequent drying outside the steam steriliser

After removal from the sterilisation chamber, the sterile containers have a residual quantity of heat with the aid of which residual condensate can be evaporated outside the steam steriliser even after sterilisation has ended. During this process, the sterilised material cools from about 80°C to an ambient temperature of about 20°C.

Gases, for example air, occupy a larger volume at higher temperatures than at lower temperatures, i.e. on cooling by 60°C the sterile air volume in the container decreases by up to 20% per sterilising unit. This volume reduction has a suction effect on the surrounding nonsterile air and the pressures are equilibrated again.

Contamination is prevented in the filter container because the nonsterile air can be sucked in again via the sterile filter and is thus germ-free.

3.3. Climatic fluctuation

After the sterilised materia
sure differences may occ
ner and the storage room
sucked into the container
or falling temperature and
process, which we refer t
ring the entire storage tim

3.4. Mechanical loads

During transport or care
fection by wiping), mecha
tainer to "breathe", as des

As a result of pressure or
on the cover, the containe
air is pressed out of the c
ved, the container walls a
rest position and the conta
sucked in enters via the st

The sterile filters of the co
rial from contamination in

3. Container characteristics after sterilisation

When sterilisation is complete, the sterile container is subject to constant gas exchange with the environment for the following reasons:

- Subsequent drying in the steam steriliser
- Cooling process after sterilisation
- Climatic fluctuations during storage
- Mechanical loads during transport and storage

4. Possible sources of error in the case of residual condensate

Source of error	Remedy
- Low initial temperature of the material to be sterilised	- Preheat
- High moisture content (in the case of textiles)	- Use dry linen
- The container load weight has been exceeded	- Instruments + tray: max. 10 kg Linen: max. 6 kg
- Incorrect storage in the container	- Instruments: ● disassembling of detachable instruments - Linen: ● Place in layers vertically ● Do not press - Hollow articles, dishes, plates, etc.: ● Opening obliquely downwards
- No wrapping cloth	- Use wrapping cloth of the right size
- Brown textile filter	- Change filter no later than after 2 or 3 month or 50 sterilisations
- Incorrect positioning in steriliser	- Position heavy containers at bottom
- Immediate removal from the steriliser after the programme cycle	- A longer residence time of the containers in slightly opened autoclave in the case of heavy loads is advisable
- Immediate use of the container after removal from the steriliser	- Allow container to cool to room temperature
- Unfavourable storage of the container in the cooling phase	- Do not store on cold floor or in a draught; as far as possible store in warm, dry rooms
- Unfavourable storage of the container after the cooling phase	- Store in air-conditioned rooms according to DIN 58953 Part 9
- Characteristics of the steriliser do not always conform to DIN 58946 (for example wet steam)	- Ensure that maintenance is carried out regulary (if necessary, increase drying time) - Check steam quality and improve accordingly
- No empty sterilisation or no vacuum test performed before the beginning of the daily programme	- Carry out daily empty sterilisation and vacuum test
- Incorrect steriliser programme chosen	- Select programme according to load
- Autoclave doors kept open for a long time (cooling of the autoclave)	- Rapid unloading/loading procedures

5. Organisational aids/Supports in the tray

For many instruments, careful storage in the tray is absolutely essential.

Sensitive, fine sterile material may be seriously damaged if transported in the tray without organisational aids.

AESCULAP offers a wide range of different storage aids for preserving the optimal quality of instruments over a long period.

The organisational aids range from fixing pins and rails to complete silicone supports for special sets.

The AESCULAP storage elements ensure:

- a clear arrangement
- control
- saving of time
- safety
- protection
- hygiene
- quality.

6. Suitability of the types of packaging for steam sterilisation methods

The suitability of various types of packaging for steam sterilisation methods is shown in Table 6 below (page 23).

7. Information on standards

DIN 58900 Part 1, Sterilisation; General Principles; Definitions

DIN 58900 Part 2, Sterilisation; General Principles; Requirements

DIN 58946 Part 1, Sterilisation; Steam Sterilisers for Medical Materials to be Sterilised; Definitions

DIN 58946 Part 2, Sterilisation; Steam Sterilisers for Medical Materials to be Sterilised; Large Sterilisers; Requirements

DIN 58946 Part 3, Sterilisation; Steam Sterilisers for Medical Materials to be Sterilised; Large Sterilisers; Testing for Efficiency

DIN 58946 Part 6, Sterilisation; Steam Sterilisers Operation of Large Sterilisers

DIN 58952 Part 1, Sterilisation; Packaging Materials for Material to be Sterilised, Rectangular Metal Sterilisation containers

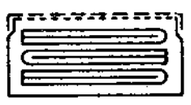
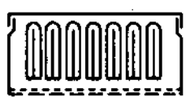
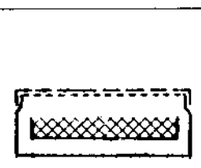
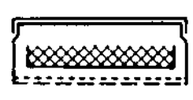
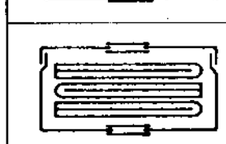
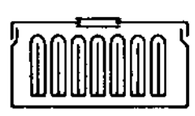
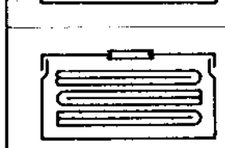
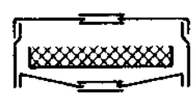
DIN 58952 Part 3, Sterilisation; Packaging Materials for Material to be Sterilised, Metal Sterilising Trays

DIN 58453 Part 1, Sterilisation; Provision of Sterile Material; Definitions

DIN 56953 Part 9, Sterilisation; Provision of Sterile Material; Application Technology of Sterilising Containers

Table 6:

Suitability of the sterilising containers for various steam sterilisation methods[1])
according to DIN 58953 Part 9 (as of May 1987)

Sterilising container	Type of packing: Description	Type of packing: Symbolic representation and packing position	Steam sterilisation method according to DIN 58946 Part 1: Gravitation method	Pre vacuum method	Fractional vacuum method	Fractional flow method	Steam injection method
with filter (StB-F)	Textiles in sterilising container with filter in cover and base, according to DIN 58952 Part 1		+	+	+	+	+
			○	○	+	+	+
	Textiles in sterilising container with filter in cover, base not perforated, according to DIN 58952 Part 1		-	-	+	+	+
			-	-	+	+	○
	Textiles in sterilising container with filter in base, cover not perforated, according to DIN 58952 Part 1		○	+	+	+	+
			-	○	+	+	+
	Instruments on sterilising tray according to DIN 58952 Part 3, in sterilising container with filter in cover and base, according to DIN 58952 Part 1		+[3])	+	+	+	+
	Instruments on sterilising tray according to DIN 58952 Part 3, in sterilising container with filter in cover, base not perforated, according to DIN 58952 Part 1		-	+[2])	+[2])	+[2])	+[2])
	Instruments on sterilising tray according to DIN 58952 Part 3, in sterilising container with filter in base, according to DIN 58952 Part 1		○	+	+	+	+
with valves (StB-V)	Textiles in sterilising container with valves in cover and base, according to DIN 58952 Part 1		-	○	+	+	○
			-	-	+	+	○
	Textiles in sterilising container with valves in cover, no valves in base,		-	-	+	+	-
			-	-	+	+	-
	Instruments on sterilising tray in sterilising container with valve in cover and base		-	+[2])	+[2])	+[2])	+[2])
	Instruments on sterilising tray in sterilising container with valve in cover, base not perforated		-	+[2])	+[2])	+[2])	+[2])

Explanation of symbols: + Can be used - Cannot be used ○ Restrict use

[1]) To avoid loading errors and/or errors in use, Table 1 provides information on the correct or incorrect combination of sterilising containers with standardised steam sterilisation methods.

[2]) Only sterilising containers in which the evaporation or discharge of the condensate is ensured are suitable. See also Section 6.1.

[3]) Sufficient subsequent drying does not take place in the gravitation method without the drying device.