
gebrauchsanweisung
chirurgische instrumente und container

instructions for use
surgical instruments and containers

nopa[®] instruments



EN

nopa[®] instruments



Sterilization

What is sterilization?

- >> Sterilization is a measure taken with the purpose of making something completely germ-free; according to the DAB (Deutsches Arzneibuch = German pharmacopoeia), sterilization means: "The killing or removal of all viable vegetative and persistent forms of pathogenic and apathogenic microorganisms in substances, preparations or on objects".
- >> To say that an object is germ-free – in other words, sterile – is only possible with a certain probability, however. In DIN EN ISO 17665 sterility is defined by the probability that one in one million products has a germ which is capable of multiplying.

Sterilization - first use

- >> All instruments which are used for the first time, must be thoroughly cleaned, rinsed and sterilized before they are used.

Sterilization - processing

- >> Thorough cleaning and disinfection follow the instructions for use of the cleaning and disinfection solutions.
- >> If possible, disassemble instruments otherwise, clean instruments in their open state.
- >> Clean either manually, with machine or with ultrasound.
- >> Rinse thoroughly under running water.
- >> Dry instruments carefully.
- >> Moving parts, such as scissor blades, must be lubricated.

Sterilization - function check

- >> Check for residues or contamination.
- >> Examine for cracks, breaks or any corrosion.
- >> Check all moving parts and working tips.
- >> When flaws are found, these instruments must be removed from service immediately.

Sterilization methods

1. Physical sterilization methods

Dry heat sterilization

- >> Sterilization temperatures between 160 and 180 degrees C.
- >> Destruction with dry heat by means of protein coagulation as well as by means of oxidation processes.
- >> Microorganisms are more resistant to dry heat than moist heat.

Ionising radiation

- >> Complicated – rarely used Sterilization methods

Steam sterilization

- >> With air-free, saturated pressurized steam $T > 100^{\circ}\text{C}$ $p > 1$ bar
 - >> Flow method
 - >> Gravitation method
 - >> Vacuum method (fractionated vacuum method)

Properties of steam

- >> When steam condenses on the object to be sterilized, energy is released, which causes irreversible damage to the microorganisms.

- >> In order to achieve sterilization, the steam must directly condense on the microorganisms that are meant to destroy.
- >> Sterilization is only possible with air-free steam at a temperature $> 100^{\circ}\text{C}$ as well as a pressure > 1 bar. This implies pressurized steam.
- >> Steam pressure corresponds to a certain temperature. For this reason, if you know the pressure of the steam, you can calculate its temperature, and vice versa.
- >> Sterilization is only possible after 15 min. at 121°C and 2 bar of steam pressure, or after 3 min. at 134°C with 3 bar of steam pressure.

What is meant by the "flow method"?

- >> This is a method displacing air by steam from the sterilization chamber and the object to be sterilized.

What is meant by the "gravitation method"?

- >> Method where the air is displaced downward by the steam, out of the sterilization chamber, via a flow control valve.
- >> The object to be sterilized must be inserted in the device in steam permeable packaging so that the steam can flow through from top to bottom, and the formation of air pockets is avoided.
- >> At temperatures above 100°C , the outlet flow valve begins to close for air. Following this, the equalization time begins in order to equalize the temperature differences between the sterilization chamber and the object to be sterilized. Right now the germ destruction phase begins. The destruction time plus added time for security is finally the sterilization time.

It is absolutely required that containers have perforated bases and lids in order to guarantee that sterilization has effected.

What is meant by the "fractionated vacuum method"?

- >> In the fractionated vacuum method (or pre-vac method), after evacuation, steam is introduced into the sterilization chamber and immediately afterwards, the steam/remaining air mixture is suctioned out again. This process is repeated several times and is also referred to as "pulsing". Remaining air pockets are eliminated by process.
- >> Working temperature 134°C which is maintained at approx. 2.3 bar for 5 minutes.
- >> For this method, containers are required only with filter system in the cover. (Standard)

This process is the internationally recognized to be the standard method!

2. Chemical sterilization methods

Ethylene oxide sterilization

- >> Explosive gas, carcinogenic, mutagenic, is adsorbed by various materials
- >> Application only required if not possible to treat thermally

Formaldehyde gas sterilization

- >> Non-flammable, non-explosive, not necessary to air out.
- >> For thermally labile objects gas sterilization

Plasma sterilization

- >> with hydrogen peroxide

Cold sterilization

- >> placed in spore-killing agents
- >> involves disinfection by dipping

What is meant by "Gas sterilization with ethylene oxide"?

- >> In opposition to steam sterilization, which is a physical process, gas sterilization with ethylene oxide involves a chemical reaction.
- >> In steam sterilization, the protein structure, of the germs is caused to coagulate by the heat. In the case of gas sterilization, a chemical reaction occurs which changes the protein, so that metabolism is no longer possible. The result is the same in both cases, sterilization, i.e. the germs are no longer able to reproduce themselves.
- >> Sterilization of heat sensitive materials

Ethylene oxide sterilization should only be used when the classical, thermal methods with steam or hot air cannot be applied due to the heat sensitivity of the object to be sterilized!

What is meant by "Gas sterilization with formaldehyde"?

- >> Since gas-flushing with formaldehyde in the conventional sense only leads to disinfection and disinfection, and formaldehyde gas itself is ineffective for sterilization, special process control and instrumental preconditions are required.
- >> The chemical component of the NTDF (Niedertemperatur Dampf mit Formaldehyd = low-temperature steam with formaldehyde) sterilization only works in combination with sufficient moisture. The moisture must be applied to the microorganisms, especially the spores, in combination with heat, so that they are stimulated for metabolizing and thus for cell division and reproduction.

This is only effective when the formaldehyde and steam have come into good contact with every point, and when the previously present air has been removed.

Sterilization with formaldehyde should only be used on materials which cannot be sterilized with steam or hot air. The decisive criterion here is just the temperature resistance / temperature sensitivity of the materials to be sterilized.

What is meant by "plasma sterilization"?

- >> In plasma sterilization, the microorganisms are destroyed by free radicals.
- >> Free radicals are electrically charged particles (atoms, molecules and electrons), which damage the outer walls of the microorganisms by their electric charge and high speed to such a degree, so that the microorganism dies.
- >> The plasma state is reached at very high temperatures (sun) or at low pressure in the presence of an electromagnetic field (lightning).
- >> Plasma can be generated by various gaseous / vaporous materials (air, hydrogen peroxide, neon).
- >> The chamber temperature reaches approx. 45°C. In addition,

a negative pressure of approx. 0.4 mbar is created.

- >> 1.8 ml hydrogen peroxide at a concentration of 58% is required, as well as a high frequency of 13.56 MHz.

The plasma method sterilizes medical instruments and materials quickly, at low temperature, under dry conditions and without toxic residues.

Important

Before **initial use**, before all further **use** and before being sent to the manufacturer for **repair**, the instruments must be prepared according to our care and cleaning instructions.

Caution

The instruments may only be used for their intended purpose in the surgical specialities by educated and qualified personal. The surgeon, the buyer or user shall be responsible for the proper selection of the instruments for each application, for obtaining the appropriate training, knowledge and experience as well as for their operative use. **nopa** instruments Medizintechnik GmbH as manufacturer and seller cannot accept any liability for immediate or consequential damages caused by inappropriate application and use or by inappropriate sterilization and maintenance of the instruments. If instruments are repaired by any companies or persons not authorized by **nopa** instruments Medizintechnik GmbH to do so, all warranties are becoming null and void. Carefully examine each surgical instrument for breaks, cracks, deformations and malfunctions before use. It is especially essential to check areas such as blades, points, locks, ratchet and snaps as well as movables parts. Instruments that are worn out, corroded, deformed, porous or damaged in any other way must be sorted out.

Storage

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

Used materials

- >> Stainless steel as per DIN EN ISO 7153-1
- >> Pure titanium as per DIN ISO 5832-2
- >> Titanium alloys as per DIN ISO 5832-3
- >> Light metal (Aluminium)

Steel instruments

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

Titanium instruments

Instruments made from pure titanium or titanium alloy can be handled and treated like steel instruments and no special precautions have to be taken. Some titanium instruments are completely or partially anodized in blue color for identification purpose.

Aluminium instruments

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

taken by the manufacturer with regards to the selection of the proper materials and its careful processing, the user has to ensure continuous and proper care of the surgical instruments as well as proper preparation, cleaning and sterilization.

We recommend the following methods and procedures for the preparation of our reusable surgical instruments:**Manual cleaning**

The instruments must be disinfected and cleaned according to our reprocessing brochure, immediately after use. Contaminations on the instrument must not get dry or encrusted, as this could cause difficulties in cleaning and disinfecting.

The following points are to be observed:

- >> Solutions used for the mechanical cleaning must be prepared strictly following the instructions given by the manufacturer.
- >> For the cleaning of cannulas, dead-end holes and cavities a suitable brush must be used so any area can be reached.
- >> Remove blood and all contaminations with a soft brush and a mild neutral or alkline (except for aluminium!) detergent. Never use metal brushes or metal sponges for cleaning.
- >> To ensure proper function of the instrument, make sure that all movable parts are thoroughly cleaned.
- >> Clean instruments with hinges and box-locks in open as well as in closed position.
- >> Detach instruments for cleaning of slots, gaps, ratchets, box-locks, cannulations and dead-end holes.
- >> Surgical instruments should be placed in proper carriers, such as perforated trays, wire baskets etc.

Ultrasonic treatment

For ultrasonic treatment instruments should be placed in open condition on proper perforated trays or wire baskets. Please ensure to avoid any "wave shadows" or covering surfaces caused by wire baskets or perforated trays or by large or bulky instruments.

Warm water without any additives does not have a satisfactory cleaning result and therefore a suitable cleaning agent should be added. Follow strictly the instructions given by the manufacturers regarding concentration and the temperature of the detergents in the ultrasonic basin. A too dirty solution in the ultrasonic basin decreases the cleaning effect. Therefore, the solution should be renewed at intervals according to the instruction given by the manufacturer. Ultrasonic wave times must be used according to the instructions given by manufacturer of the cleaning agent.

After ultrasonic treatment all instruments must be rinsed and checked for loose parts (e.g. screws etc.). For rinsing fully demineralized or distilled water must be used to avoid water spots.

Chemical disinfection

- >> The temperature of soaking solutions used for chemical disinfection must be used according to the instructions given by the manufacturer.
- >> Thinnings have to be made using fully demineralized or distilled pure water only. Detergent or cleaning agent must not be added. Follow precisely the instructions given by the manufacturer of the solution regarding dosage and induction time.
- >> The disinfection solutions must be refreshed daily. Reusing

them can cause an increase of the dosage through evaporation (-> corrosion risk) or a too high contamination level (-> corrosion risk and reduced efficiency).

- >> After chemical disinfection all instruments must be rinsed with pure flowing water. To avoid water spots only fully demineralized or distilled water must be used.
- >> Dry surgical instruments immediately after each cleaning, disinfection and rinsing cycle.

Machine cleaning and disinfecting

- >> Machine cleaning and disinfection is always a preferable method compared to manual cleaning since machine procedures can be standardized.
- >> Follow the operating and loading instructions provided by the manufacturer of the washing machine. Use only the detergents and cleaning agents recommended by the manufacturer for the specific purpose.
- >> Hinged and box-lock instruments must be loaded and cleaned in open condition. Place instruments into the machine in a way that allows the water to flow out of cannulations, dead-end holes and cavities.
- >> Take instruments apart as much as possible for cleaning.
- >> Machine cleaning and disinfection is only suitable for instruments with long or thin cannulations if the hot disinfection solution can actually flow through them.
- >> When removing instruments from the washing machine, pay special attention to the proper cleaning of slots, gaps, ratchets, box-locks, cannulations and dead-end holes. Check for any visible remaining contaminations. If necessary clean manually and/or repeat cycle.

Steam sterilization / Autoclaving

- >> Sterilize all instruments before use.
- >> Recommended sterilization method steam sterilization with fractionated vacuum according to DIN EN ISO 17664.
- >> Recommended temperature 273°F (134°C)
- >> Recommended pressure 3 bar .
- >> Leave on time > 5 min.
- >> When using autoclaves for sterilization of surgical instruments, it has to be strictly ensured that the steam used is absolutely free of foreign substances such as corrosive particles or dirt to avoid subsequent corrosion or dirt (scum) deposit.
- >> Please observe strictly the instructions for use given by the manufacturers of autoclaves.
- >> Do not use any damaged instruments.

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

- >> DIN EN ISO 17664 sterilization of medical devices - information to be provided by the manufacturer for the processing of resterilizable devices
- >> EN 285 sterilization - steam-sterilizers - large sterilizers
- >> EN 554 sterilization of medical devices - validation and routine control of sterilization by moist heat
- >> DIN EN 556-2 sterilization of medical devices - requirements for medical devices to be designated "sterile" - part 1: Requirements for terminally sterilized medical devices
- >> DIN 58946-7 sterilization; steam-sterilizers; architectural

claims for large sterilizers.

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

Limit of the preparation of instruments

Repeat instrument preparation has no significant influence on the lifetime of the surgical instruments. The lifetime of the instrument is usually determined by wear and tear or mutual damage during use.

Maintenance of instruments

Maintenance of surgical instruments means lubrication with physiologically safe instrument oil (acc. to DAB 8 or Ph.Eur. or Usp) or cleaning milk (emulsion of hydrocarbons in water) particularly of the joints. Make it basic rule to thoroughly lubricate surgical instruments prior to checking for function. All movable parts (joints) and cutting blades of scissors have to be lubricated. This avoids metal abrasion when checking for function. Lubricants used must guarantee, that even after frequently repeated use a "sticking" of joints through a multiplying effect is avoided.

Certificate

SMP GmbH Testing, Validation, Research

hereby certifies the

validation of sterilization containers

of the company

nopa instruments Medizintechnik GmbH
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78532 Tuttlingen
Germany

*Tested and validated with original
nopa instruments filters and
original nopa instruments components!*

The SMP investigation, with the project no. 04906021707, was carried out with the nopa container KYE 200/91. The dimensions of this are 580 x 280 mm, it is 260 mm high, has a closed bottom and a perforated filter cover. Thus, the tested container has the most demanding ratio between filter opening and interior volume and represents the "worst case". In this investigation, it was verified that the nopa containers fulfil the requirements of the following standards with regard to the sterilization success, i.e. the achieved sterility, after going through a standard-compliant sterilization process:

DIN ISO 14937
DIN EN 868



Tübingen, Germany; Oct. 21; 2006

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Surgeon	Dr. Gerhard Bueß / University of Tübingen
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Physicist	Dr. Rudolf Reichl
Managing director	Klaus Roth
Physicist, private lecturer	Dr. Ludger Schnieder
Physician	Dr. Marc O. Schurr

The increased demand for the validation and testing of cleaning processes for surgical instruments was what initiated the founding of SMP GmbH. Based on the skilled expertise of the company founders in the area of surgical instruments and hygiene, as well as their experience in many different joint research projects, SMP GmbH offers services which allow medical companies to make substantiated statements about their products in the area of reprocessing and hygiene.



STERILISATION STERILIZATION ESTERILIZACION STERILISATION STERILIZZAZIONE

- 1 Safety lid
- 2 Bottom
- 3 Safety lid lock
- 4 Safety lid latch
- 5 Inner lid
- 6 Inner lid lock
- 7 Label holder
- 8 Label
- 9 Handle
- 10 Filter tightener
- 11 Filter tightener lock
- 12 Filter



Please read the instructions for use carefully prior to operating the device. This will help you to avoid the damages that will stem from improper assembly or improper use, and which, therefore, will invalidate the warranty.

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1. Safe use

Before using the product, please make sure that all functions are working properly.

Use the product according to the instruction for use and follow safety and maintenance instructions.

- >> Never use faulty and damaged sterile containers. Should there be any damaged part, replace it by the original part. Never use different products with **nopa** products.
- >> Improperly repaired containers will affect sufficient sterile use. Check the container well before every use.
- >> Filters, filter holders and silicone gaskets are to be checked before every use.
- >> Make sure that the container and its accessories are used by qualified and experienced personnel.
- >> Make the manual available to personnel and keep it in an easy-to-reach place.
- >> Sterilize the unclean materials, to be sterilized, in compliance with their general instructions and under the aseptic principles.

2. Product description

2.1. Intended use

The container system of **nopa** is designed for sterilization and storage of tools and textiles.

Sterilization is performed via vapor sterilization methods, according to ANSI/AAMI ST46-1993.

Sterile materials are stored in container after having been sterilized and they are kept in a container until use.

Note:

If you intend to use any other vapor sterilization application for your container system, please contact your **nopa** agent.

2.2. Sterilization methods

nopa container system conforms to the standards of DIN EN 868-1, DIN EN 58953-9 and ISO 11607.

3. General information for use

Initial use

- >> Prior to first sterilization, clean the new container manually or with a machine.
- >> After cleaning, use an appropriate filter. (we recommend to use only original **nopa** filter)
- >> The filter system, which impedes germs from entering, is added to every sterile container system of **nopa**, except implant and telescope models.

4. Working with container for sterilization

4.1. Installation of the system

Removing inner/external lid

If the external lid (safety lid) (1) was used, it can be removed for cleaning the container and if it is in an unclean state, the external lid can be separated from the inner lid.

When it is required to remove external and inner lid of fix container please do it like this:

- >> Dismantle the combined external lid (1) and internal lid (5) from bottom (2).
- >> Remove the external lid (1) by loosening the latch of lid (4).

4.2. Cleaning and disinfection of the sterile container

Cleaning and disinfecting manually:

- >> Select pH 7 level disinfectors and detergents as well as chemical solution which are required for cleaning the sterile container.
- >> Use soft and fibreless cloth while cleaning the surface of container with pH neutral cleaning solutions.
- >> Remove the residues, left on the surface, with a soft plastic brush. Never use hard wire brush and harsh detergent.
- >> Finally, rinse it with clean and pure water.



Cleaning agents with high pH level, like acetone, may damage to the plastic parts. Therefore, use only pH neutral cleaning agents for cleaning the plastic parts.

Machine cleaning and disinfection

The container can be mechanically cleaned in an appropriate shelf under the cleaning instructions of your manufacturer. Rinse well with pure water after completing the cleaning process.



Colored aluminium lids should be cleaned with pH neutral cleaning agents and as much pure water as possible.

Filter change

According to the type of filter used in the container, change the filter under the following instructions:

- >> Disposable filters: Change before every sterilization
- >> Textile filters: Change every 50 sterilization processes
- >> Dismantle the universal filter tightener by continuously pressing (12) buttons.
- >> Insert a new filter (12) and assemble the filter tightener again. Press the cap on universal filter tightener downwards (11) until you hear a click.



Inspect the parts of the sterile container visually and detect if there are damaged parts. Replace the damaged and non-functioning parts with new spare parts immediately. (Do only use original **nopa** parts)

4.3. Safe use

Sterile container is filled according to DIN EN 868-8 and DIN 58953-9 standards. Accordingly, the recommended capacities for use are as follows:

- >> Standard container: 10 kg
- >> 3/4 container: 7 kg
- >> Half container: 5 kg
- >> While placing the tools in the wire basket lay the empty parts (with conical shape) down; these parts should be placed upside down and slightly slanting.
- >> In the doublepacking of sterile materials, wire baskets are separately packed in compliance with DIN 58953-9 standard.
- >> While connecting the inner lid lock (6) to the container bottom (2), the lock bolt should be visible.

If the lock does not function the container is defective and you need to contact your technical service.

Tissues

- >> Pack tissue pieces in a manner to let them wrap around the container vertically.
- >> Fill the container up to a certain degree that lets a hand between the tools.

Placement of label

- >> While filling the sterile container, register sterilization date, sterilization number, expiry date, name and signature data on the label (8).
- >> Push the label into its place in a way to fill up the label space (7) located in the sides of the lock lid.

Filling the sterilizer

- >> Place heavy containers at the bottom of sterilizer.
- >> When stacking the containers, they must not exceed a height of maximum 60 cm.
- >> Do not block air passages of any container type with material like aluminium foil.
- >> Carry the sterile container by the handles to prevent them from falling over.
- >> Follow the instructions of the sterilizer manufacturer.
- >> Proceed the vapor sterilization according to DIN EN ISO 17665-1:2006-11 / ISO 13683 regulations.

Unloading the sterilizer

- >> You have to be careful against burn risk as the containers will be hot right after sterilization.
- >> Always carry sterile containers by grasping their handles and wear gloves.
- >> Do not leave containers, which are still hot immediately after sterilization, in a draughty place or on cold ground. This may cause physical deformation since no homogeneous cooling is provided.
- >> Storage of sterile containers is based on DIN 58953-9 standards.

Supply and control of sterile materials

Sterile materials are required to be sterile in the containers, where they are kept until their re-use after having been sterilized. Likewise, there is a contamination risk, if the materials, to be kept in the container, have not been physically clean before sterilization.

In order to avoid such problems:

- >> Make sure the sterilization process has been performed free of error prior to the storage of sterile materials.
- >> Make sure the indicator gauge color has changed and indicator seal is undamaged before opening the sterilized container.
- >> Make sure that all container parts, especially lid locks, work perfectly.

Storing the sterile containers

- >> Storage is limited to maximum 6 months according to DIN 58953-9.
- >> Keep sterile containers in clean, dry and secure places.
- >> Sterile containers can be stored one by one or by being stacked with a maximum height of 60 cm.

5. Maintenance

According to DIN EN 868-8 standards sterilization process can be performed for minimum 500 cycles. This period has been determined according to the durability of containers lids' gasket, except in case a damage is visible. In this case you need to replace the damaged part or contact **nopa** technical service. Probable damages of lid gaskets can be prevented by ordering seals or adhesive.

6. Technical Service

Please contact **nopa** representatives for service, maintenance or repair matters. Any modification or correction on containers and their accessories shall render the company's warranty invalid.

Contact

nopa instruments
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 78532 Tuttlingen
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For accessories and spare parts

Please refer to accessories and spare parts

7. Specification

Please refer to container models and specifications.

8. Related Standards

The following standards were applied for in relation with sterile containers:

- >> DIN 58953-9
- >> EN 868-1, EN 868-8
- >> EN ANSI/AAMI/ISO 11134-1993
- >> DIN EN ISO 17665-1:2006-11 / ISO 13683
- >> ISO 11607

Quotation from DIN 58953-9 sterile container storing periods, sterile material supply.

Appropriate storing periods are determined by hygiene control committee. This period does not depend on packing, storing and transportation to an important degree. Therefore, reasonable storing periods, which shall be controlled by user or the hospital management, are required as storing periods cannot be generalized.

Recommended storing periods for sterile materials in sterile containers:

<i>Packing of sterile materials</i>	<i>Package type</i>	<i>Storing period</i>
Sterile container in compliance with DIN EN 868-1 or DIN EN 868-8 standards	Single or double packing of sterile materials	6 month
<i>Note:</i> For sufficient sterile use it is required to use sterile materials according to storing periods specified on sterile containers. Storing conditions, even under ideal environments in dry, dust-free and room terms, shall raise the contamination risk. Again depending on storing conditions, it is possible to store for a longer period of time.		
Use of inner wrap in double packed sterile materials is recommended to allow aseptic presentation.		

9. Trouble shooting list

Error	Reason	Solution
	If the heat of the sterile materials is too low prior to sterilization, they will contain more dampness.	The sterile materials should have a temperature of at least 20°C before the sterilization process.
	Sterile materials are not placed in the sterilizer properly.	Lay the sterile materials slightly slanting and upside down their oval parts. Do not jam in to the tissues, place them in horizontal stacks.
	No inner wrap used.	Use a suitable inner wrap.
	Containers were not properly placed in the sterilizer for sterilization.	Put the heavy sterile containers on bottom and maximum height should be 60 cm.
	Sterile Container was put into service right after sterilization.	After sterilization, let sterile containers cool down to room temperature.
	Improper cooling was performed after sterilization.	Do not store sterile containers on cold ground or in drafty places. Cooling process should be performed in air-conditioned rooms according to DIN 58953-9.
	Sterilizer specifications do not meet the requirements of DIN EN 285 standard.	Check the drying vacuum regularly and have the sterilizer maintenance carried out in accordance with standards. Take the recommendations of manufacturer into consideration while using the sterilizer. Check drying time and vapor time. If necessary, make related adjustments and calibrations.
	Empty-cycle and vacuum tests are not run daily prior to sterilization.	Run empty-cycle and vacuum tests before sterilization.
	Inappropriate sterilizer program was selected.	Use a sterilizer program for the load to be sterilized. Use an adequate sterilizer programm
	Sterile container is too heavy.	Tools and standard container max.: 10 kg
		Tools and half container max.: 5 kg
		Tissue and standard container max.: 8 kg
		Tools and 3/4 container max.: 7 kg
There is moist in the inner grove of lid.	During sterilization heavy and excessive number of containers were improperly stacked.	Split sterilizer into shelves and leave max. 60 cm of height for sterilization.
Indicator seal color on label did not change.	Sterilization was performed improperly. Probably sterilizer is defect.	Have sterilizer repaired by the manufacturer company. (or authorized service)
Deformation of container system.	Holes were blocked during sterilization.	Never obstruct the holes.
Lid lock is faulty.	During the carrying of containers lid locks were opened.	Always carry containers by their handles.
Color of tissue filter faded to brown.	More than 50 cycles.	Replace the filters. Check steam quality. Increase it, if necessary.
Lid gasket are deformed before expiration date.	Aceton-like cleaning agents without neutral pH level were used in manual cleaning.	In manual cleaning use cleaning agents with neutral pH level (pH=7).
There is corrosion on the aluminium lids of colored containers.	Hard brush and hard cleaning agents were used in manual cleaning. But such corrosion does not impede their function.	Use soft plastic brush and pH neutral solutions in manual cleaning.
Local deformations are observed on container lids and boxes.	After sterilization, hot container was left on cold ground or in draughty environment.	Leave sterilizer door open after sterilization and wait until sterile containers cool down to room temperature.