

# nopa<sup>®</sup> instruments



 INFORMATION PLUS  
sterilization container

choose your color



Here, it is not only about taste, it is also about separation and organization. Different colored lids help to separate and organize the containers which are used for different purposes. Mostly they hold surgical instrument sets and maintain the sterility of instruments during transportation and storage.



Container bottom

Material: Aluminum  
Types: perforated  
non-perforated



Safety lock

shows that the container  
has not been opened



Safety lid

Material: Aluminum  
protection for the filters in the lid to  
assure a safe transportation and to  
avoid damages



Container lid

Material: Aluminum  
Types: perforated  
non-perforated

Lock

Material: stainless steel  
guarantees a proper closure of the  
container lid



Filter holder

nopa patented filter holder  
with safe and user-friendly  
close/open mechanism



nopa filter

Types:  
single-use (paper)  
multi-use (textile/teflon-PTFE)

features



**nopa closure:**  
ensures a proper  
closure of the container to  
guarantee sterility

**Corner protection:**  
for transport and storage

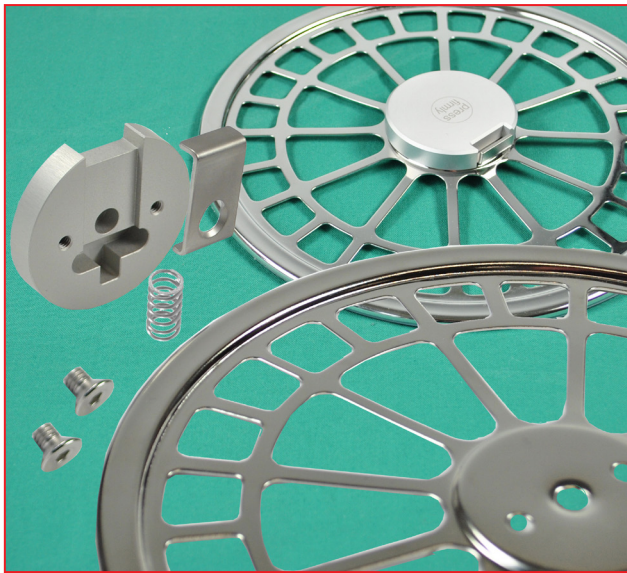
**Handles:**  
ergonomically shaped

**Labels:**  
for proper identification

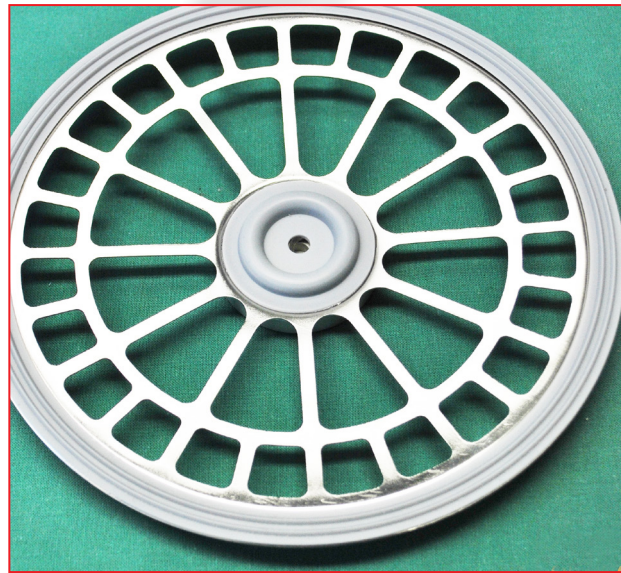
**nopa** instruments constantly improves procedures to establish the highest quality standards. The German proved quality is the main focus in our daily work. A long product life-time is ensured by using high quality materials and a detailed check of functionality.

**All our containers are validated for sterilization and cleaning.**

The certificate for the validation of the **nopa** containers done with „SMP GmbH - Service für Medizinprodukte, Tübingen/Germany“ can be found on [www.nopa.de](http://www.nopa.de).



① Assembling of filter holder



② Gluing of inner and outer ring onto the filter holder

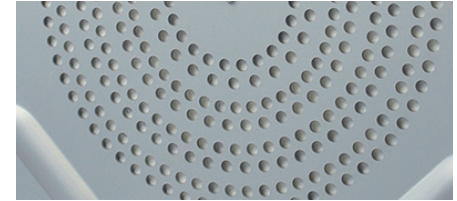


③ Accurate gluing of the silicone seal into the container lid

why nopa containers?

>> easy check:

The outside of our lids is designed to see immediately if the container is equipped with a filter. A clear view of the filter area is guaranteed.



>> easy cleaning:

Our lids and the perforated area for the filter holder are easy to clean. Residues can be detected immediately because there are no hidden areas. Rounded corners make the containers easy and quick to clean, inside and outside.



>> dryness check:

After manually or mechanical cleaning of the lid, it is easy to check whether the **filter area** is dry before inserting of a new filter.



>> long-term functionality:

The long-standing, unchanged shape of our filter holder with its proven spokes-based design provides the necessary contact pressure. Our patent proprietary closure system is optimized for cleanliness and hygiene. A fixed holding pin ensures long-term functionality.



## why nopa containers?

### >> high quality seals

All seals are glued in at our nopa instruments headquarter in Tuttlingen, Germany. It is very unlikely that the seal will be separated from the lid while use, manual or mechanical cleaning, thanks to the adhesive bond. This avoids that the lid will be placed on the base without seal.



### >> safety first

**Corner protection:**  
*for transport and storage*



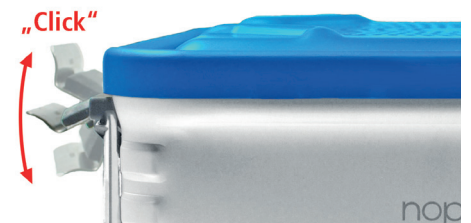
### Handles:

Long and robust handles ensure an user-friendly carrying and safe transport of heavy loaded containers. The length of our handles facilitates a safe handover to the sterile operation room.



### Advanced closure system:

Guarantees improved handling, closure-check with a „click“.



safety instructions /  
functional test

To guarantee sterility it is important to check the containers visually for damage after every disinfection. Make sure you use the latest version of the instruction for use, to check the function of the container and to ensure safety by following the instructions at every time.



- >> check if the filter holder works properly
  - release the filter holder pressing the unlock mechanism
  - push down the filter holder firmly till a „click“ sound appears

Notice:  
make sure that the filter holder is firmly fixed without rotating



- >> check the outside and inside of the container for damages
- >> lid and bottom should not show any dents and bends



- >> the closing mechanism has to be fully intact
- >> make sure the closing and opening of the lid is smooth
- >> lubricate the locking mechanism from time to time
- >> double check if the adjustment of the lid and bottom part works smoothly
- >> „click“ sound should appear



- >> check the lid's sealing for damages
- >> no cracks, wear corrosion or loose parts should be visible
- >> sealing has to be fixed to the lid



- >> check if the handles are intact and not damaged for safe carrying of the containers

**NOTICE:**

- >> only use undamaged sterile nopa containers
- >> replace damaged parts immediately
- >> in case of insecurity, please contact your dealer



## general information

Before using the container, please read the instructions carefully. This will prevent damage caused by incorrect assembly or use, which is not covered by the warranty.

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### 1. Safe use

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

Use the product in accordance with the instructions for use and observe the safety and maintenance instructions.

- Never use faulty or damaged containers. Replace damaged parts with original spare parts. Never use third-party products together with **nopa** products.
- Incorrectly repaired containers do not guarantee sufficient sterility of the contents. Carefully inspect the container before each use.
- The container and its accessories should only be used by qualified and experienced personnel.
- Filters, filter holders and silicone gaskets must be checked for damage and a proper fit before each use.
- Keep the instructions for use in an easily accessible place where they are available to the relevant personnel.
- When handling the sterile items, observe their general instructions for use as well as the aseptic principles.

## 2. Product description

### 2.1 Intended use

The container system from nopa is designed for the purpose of sterilizing and storing instruments and textiles. Sterilization is performed by means of the steam sterilization method in accordance with ANSI/AAM/ISO 11134-1993. After sterilization, the sterilized materials are stored in the container until their next use.

**Note:** If you intend to use a different steam sterilization method for your container system, please contact your nopa representative.

### 2.2 Sterilization methods

The container systems from nopa comply with the following standards: DIN EN 868-1, DIN EN 58953-9 and ISO 11607.

## 3. General information for use

### First use

- Before first use, the container must be cleaned manually or by machine.
- After cleaning, suitable filters must be used. (we always recommend the use of original nopa filters)
- The filter system, which prevents the entry of germs, is enclosed with every nopa container, with the exception of the models designed for implants and endoscopes.

## 4. Working with sterilization containers

### 4.1 Structure of the system

Remove the inner/outer lid

If the outer lid (safety cover) has been used, it must be removed to clean the container. To remove the outer and inner lid from the assembled container, follow these steps:

- Remove the combined outer and inner lid from the base.
- Release the lid lock and remove the outer lid.

### 4.2 Cleaning and disinfecting the container

**We recommend the following validated procedure for re-use of our sterilization containers.** This applies to all container parts made of anodised aluminium and any accessories that are suitable for re-use.

### Preparation for disinfection and cleaning

The containers should be disinfected and cleaned as soon as possible after use. Containers must be disassembled for cleaning. The contaminants should not be allowed to dry, as this will further complicate the disinfection and cleaning process. Cleaning: machine cleaning is recommended.

### Preparation at the place of use:

Remove visible contamination with a soft brush and damp cloth. Do not allow contaminants such as blood to dry. Remove contaminants immediately or at the latest after one hour. In the case of heavy soiling of cavities, gaps or slits (e.g. handles and hinges), they must be flushed out and washed around with a pressurised water spray gun.

**Manual pre-cleaning:**

Flush the disassembled container under cold, running mains drinking water (< 40°C) until all visible contaminants have been removed. Stubborn dirt should be removed with a soft brush (not a wire brush) and with a lint-free, water-soaked cloth. Cavities, gaps and slots (on the handle and hinge) must be flushed intensively (> 10 sec.) with cold mains water (drinking water quality, < 40°C) using a pressurised water spray gun (or similar).

**Machine cleaning:**

For the cleaning/disinfection of the containers a mechanical procedure (washer-disinfector) should be used. Manual procedures are not recommended due to their significantly reduced effectiveness.

Place the disassembled container in a sieve tray on the instrument trolley.

**Washer-disinfector program parameters:**

- 1 minute pre-cleaning with cold mains drinking water, < 40°C
- Drain
- 3 minutes rinsing with cold mains water (< 40°C)
- Drain
- 5 minutes cleaning with an enzymatic cleaner consisting of 0.2 – 1% neodisher® MediZym in mains water at 40 – 50°C
- Drain
- 3 minutes rinsing with mains water (< 40 °C)
- Drain
- 2 minutes rinsing with demineralised, cold water (< 30°C)
- Drain

Any special instructions provided by the manufacturer of the washer-disinfector must be followed.

**Automatic disinfection:**

Automatic thermal disinfection in a washer-disinfector, taking into consideration the A0-value 3000: 5 minutes at 93°C ± 2°C with demineralised water.

**Automatic drying:**

Automatic drying as per the automatic drying process of the washer-disinfector for at least 30 minutes (appliance setting > 100°C). If necessary, perform subsequent manual drying with a lint-free cloth and blow out the lumens using sterile, oil-free compressed air.

## Validated procedures:

### Manual pre-cleaning and machine operation

Equipment: Basin, soft brush, lint-free cloths, pressurised water spray gun  
Water temperature: < 40°C  
Cleaning agent: neodisher<sup>®</sup> MediZym 0.2%, 5 min.  
cleaning at 45°C  
Washer-disinfector type: Miele G 7835 CD

### Filter change

Depending on the type of filter used in the container, the filter change should be performed as follows:

- Disposable filter: change before each sterilization.
- Textile filter: change after every 50 sterilizations.
- Remove the universal filter holder by pressing the button.
- Insert a new filter and install the filter holder. Press the filter holder onto the pin until it clicks into place.

**Perform a visual inspection of all parts and record any damaged parts. Immediately replace any damaged or malfunctioning parts with new replacement parts.**

## 4.3 Safe use

### Filling the container

Sterilization containers are filled in accordance with the DIN EN 686-8 and DIN 58953-9 standards. Accordingly, the recommended utilisation capacities are as follows:

- 1/1 standard container: 10 kg
- 3/4 container: 7 kg
- 1/2 container: 5 kg
- When placing the items to be sterilised in the wire basket, please make sure that the empty parts (with conical shape) are placed at the bottom. These parts should be placed upside down and slightly tilted.
- For double packs of sterilised items, the wire baskets are packed individually in accordance with DIN 58953-9.
- When connecting the inner lid locks to the container bottom, the locking pin should be visible.

**If the lock does not work, the container may be broken and you should contact your distributor.**

### Cloths

- Place the cloths in the container so that they can be aligned vertically.
- When filling the container, leave enough space between the sterile items.

### **Placement of the label**

- When filling the container, please note the sterilization date, sterilization number, expiry date, name and signature on the label.
- Position the label so that it fills the brackets on the sides of the lid lock.

### **Filling the sterilizers**

- Place heavy containers on the bottom of the steriliser.
- Stacked containers must not exceed a maximum stacking height of 60 cm.
- The air outlet must not be blocked by materials such as aluminium foil. This applies to all container types.
- Stacked containers should not tip over. Therefore, hold them by the handles.
- Observe the instructions for use provided by the sterilizer manufacturer.
- Carry out the steam sterilization in accordance with the DIN EN ISO 17665-1:2006-11 / ISO 13683 regulations.

### **Unloading the sterilizer**

- Caution: risk of burns, as the containers are hot immediately after sterilization.
- Always hold containers by the handles and wear gloves.
- Immediately after the sterilization process, do not place containers that are still hot in a draughty area or on a cold surface. This may cause the containers to deform due to uneven cooling.
- The storage of sterile containers is based on the DIN 58953-9 standards.

### **Delivery and control of sterile materials**

Sterile materials must be sufficiently sterilized inside the container in which they are stored until reuse after sterilization. Equally, there is a risk of contamination if materials stored in the container have not been sterilized in a clean condition.

### **To avoid such problems, please note the following:**

- Make sure that the sterilization process was performed properly before storing the sterilized material.
- Make sure that the colour of the indicator has changed and the seal of the indicator is undamaged before opening the sterilized container.
- Make sure that all parts of the container, especially the lid locks, work perfectly.

### **Storage of sterile containers**

- The storage period is a maximum of 6 months in accordance with DIN 58953-9.
- Store sterile containers in a clean, dry and secure place.
- Sterile containers can be stored next to each other or on top of each other with a maximum stacking height of 60 cm.

## 5. Maintenance

In accordance with the DIN EN 868-8 standards, at least 500 sterilizations can be carried out. This number of sterilizations was determined by the operating life of the seal in the container lid. However, if damage is evident earlier, replace the damaged part or contact your nopa distributor.

## 6. Technical support

For customer service, maintenance or repairs, please contact your nopa representative. Any modification or adjustment of the containers and/or their accessories will invalidate any warranty claims asserted against our company.

## Contact us

nopa instruments

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## 7. Specifications

See container models and specifications.

## 8. Applied standards

The following standards were applied with regard to sterilization 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

Extract from DIN 58953-9 (translation of the original German text)

Storage times for sterile goods, deliveries of sterile goods.

Appropriate storage times are determined by the Hygiene Control Committee. This time does not significantly depend on packaging, storage and transportation. It is therefore not possible to specify appropriate universal storage times. These must be checked by the user or the clinic management.

Packaging of the sterile goods	Packaging type	Storage times
Sterile container in accordance with DIN EN 868-1 or DIN EN 868-8 Standards	Single or double packaging of the sterile goods	6 months
<p><b>Note:</b> To ensure sterile use, the storage time of the sterile goods should not exceed the time stated on the container. Certain storage conditions, even in ideal areas that are kept dry, dust-free and at a normal temperature, may increase the risk of contamination. Depending on the storage conditions, it may also be possible to store the sterile items for a longer period.</p> <p>The use of an inner sleeve for double-packaged items represents a higher degree of aseptic protection and is therefore recommended.</p>		

*We expressly point out that the products shown/mentioned may only be used and operated by trained specialist personnel with the appropriate qualifications, and for the proper, intended and prescribed purpose as specified in the operating instructions. Improper and/or non-prescribed use of the products may lead to serious and undesirable consequences as well as complications.*

## accessories

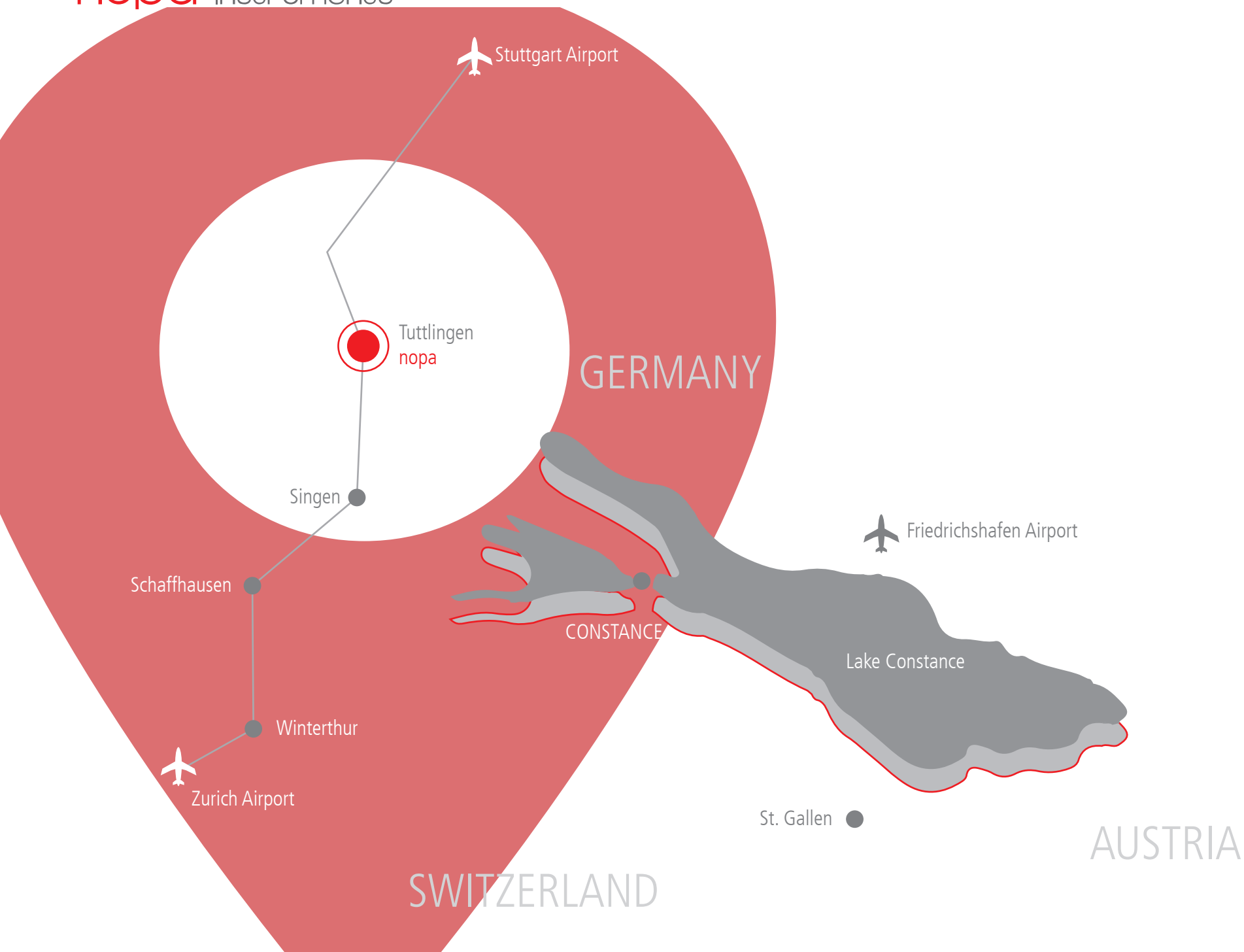
A list of container accessories to be found in the latest version of the **nopa** container catalogue. Please contact the **nopa** instruments sales-team.

For more information please check: [www.nopa.de](http://www.nopa.de)

9. Troubleshooting		
Error	Reason	Remedy
There are increased levels of condensate in the sterile container.	If the temperature of the sterile items is too low before sterilization, more condensate is formed.	The sterile items should be at a temperature of at least 20°C before sterilization.
	The sterile items were not loaded correctly.	Arrange the items so that they are slightly slanted with the oval areas facing downwards.
		Do not cram in the cloths; instead, stack them in piles.
	No wrapping cloth was used.	Use a suitable wrapping cloth.
	Containers were not placed properly in the sterilizer for sterilization.	Place heavy containers at the bottom and observe the maximum stacking height of 60 cm.
	The sterile container was used immediately after sterilization.	After sterilization, the sterile container must cool to room temperature.
	Incorrect cooling after sterilization.	Do not store sterile containers on cold surfaces or in draughty areas. The cooling process should take place in a climate-controlled area in accordance with DIN 58953-9.
	The sterilizer's specification does not comply with the requirements of the DIN EN 285 standard.	Check the dry vacuum regularly and have the sterilizer serviced in accordance with the relevant standards. When using the steriliser, observe the manufacturer's recommendations. Check the drying and steaming time. Carry out appropriate adjustments or comparisons as necessary.



	Idling and vacuum tests are not performed daily before sterilization.	Carry out idling and vacuum tests before sterilization.
	An unsuitable sterilization program was selected.	Use a sterilization program that is suitable for the respective load.
	The sterile container is too heavy.	Sterile goods and standard container max.: 10 kg
		Sterile goods and half container max.: 5 kg
		Cloths and standard container max.: 8 kg
		Sterile goods and 3/4 container max.: 7 kg
There is moisture in the inner area of the lid.	During sterilization, heavy and/or too many containers were stacked improperly.	Divide the sterilizer with shelves and do not stack them at a height exceeding 60 cm.
The colour of the indicator seal on the label does not change.	Sterilization was not performed properly. The sterilizer may be defective.	Have the steriliser repaired by the manufacturer.
Deformation of the container system.	Holes were blocked during sterilization.	Never block the holes.
Lid lock is defective.	The lid locks were used to carry the sterile containers.	The containers must always be held by the handles.
The textile filter has turned a brownish colour.	The maximum number of 50 cycles has been exceeded.	Replace the filter. Check the steam quality and increase if necessary.
The cover seals have deformed before the expiration date.	Acetone-like, non-pH-neutral detergents were used for manual cleaning.	For manual cleaning, only use pH-neutral-detergents (pH = 7).
There are signs of corrosion on the aluminium lids of the coloured containers.	Hard brushes and hard detergents were used for manual cleaning. However, such signs of corrosion do not impair the container's function.	Use soft plastic brushes and pH-neutral solutions for manual cleaning.
Local deformations on the container's lids or boxes.	After sterilization, the hot container was placed on a cold surface or in a draughty location.	Do not unload the container if the temperature is too high. Extend the drying and cooling phase.





# A INFORMATION PLUS



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traditionally modern

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Herstellung und Verkauf chirurgischer  
und endoskopischer Instrumente.

Manufacture and Sales of Surgical  
and Endoscopic Instruments.

