English

**KK-02.1** 06.2026 / Rev:01

# Instructions for Use

Sterilization Container Systems - Low Temperature Sterilization

(STERRAD/Steris V-PRO Sterilization)

BAHADIR TIBBİ ALETLER AŞ

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References

DIN 58952-2,3
EN ISO 15883
ISO 22441
ISO 14937
ISO 11607-1
ISO/TC 198
ANSI/AAMI
ST77:2013

**EN** Sterilization Container Systems

### Symbol Explanations

| | | | |
|---|---|---|---|
| Read instructions before use! | | Manufacturer | |
| Warning! | | Production Date: Located on the package. | |
| Non-Sterile | | Serial Number: Located on both the product and the package. | SN |
| CE marking according to Regulation (EU) 2017/745 | | Lot/Batch Number: Located on both the product and the package. | LOT |
| Store in a dry place | | Catalog Number: Located on both the product and the package. | REF |
| Protect from sunlight | | | |

## 1. GENERAL SAFETY WARNINGS

- Read, the instructions for use before each use.
- Keep this instructions for use throughout the product use.

- Products are **NON-STERILE!** It must be cleaned and sterilized before use according to the instructions below.

- In order to prevent damage to the containers during usage it is important that the containers be handled by fully trained and qualified personnel in all areas of sterilization containers, hospital hygiene and sterilization technology.
- Do not use other than intended use!
- Before each use, products should be checked/inspected. (See **8.1 Inspection & Check**)
- In cases with infectious disease risk, the legislation determined by the relevant authority.

## 2. INTENDED USE AND INDICATIONS

Bahadir Sterilization Containers are reusable, metal, sterilization containers. They are designed for holding operating room instruments and/or textiles during low temperature hydrogen peroxide sterilization procedures and for maintaining sterility during storage and transport under proper hospital conditions. This container system is compatible for use with the following low temperature sterilizers and the cycles identified below:

*STERIS V-PRO maX/maX2 - Lumen, Non-Lumen and Flexible Cycles
*STERIS V-PRO s2/60 - Lumen, Non-Lumen and Flexible Cycles
*STERRAD 100NX - Duo, Express, Standard and Flex Cycles
*STERRAD NX - Standard and Advanced Cycles

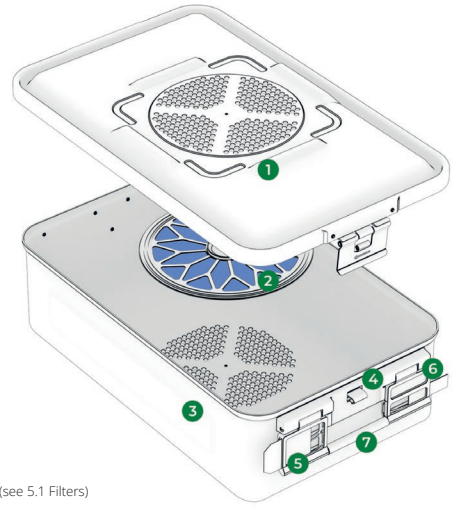
## 3. CONTRAINDICATIONS

- All other applications are contraindicated except for the Hydrogen Peroxide sterilization.

## 4. TECHNICAL DESCRIPTIONS

- Bahadır Container Systems are manufactured from anodized aluminum alloy and surgical stainless steel according to DIN 58952-2, and DIN 58952-3 standards.
- Bahadır Sterilization Container Systems consist of containers, filters, wire/sheet metal trays, and accessories. Accessories are a component of the container and are not used externally.
- Bahadır Container Systems has different model and size variants. Perforated versions and different filter options are available depending on the sterilization method and preferences.

### 4.1 Structure



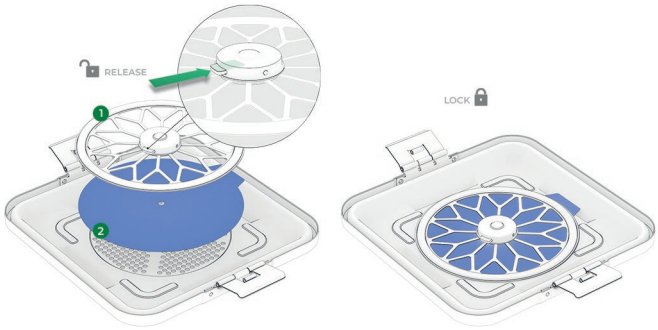

(1) Lid
(2) Filter/Filter Retainer*
(3) Container (Bottom)
(4) Front Panel
(5) Indicator Slot
(6) Label Slot
(7) Handle

* (see 5.1 Filters)

## 5. USAGE / APPLICATION

- Use The Bahadır Containers, together with the accessories and other components in this catalog (CT20). Please review this catalog for the suitability of the trays to be used in the containers.

### 5.1 Filters



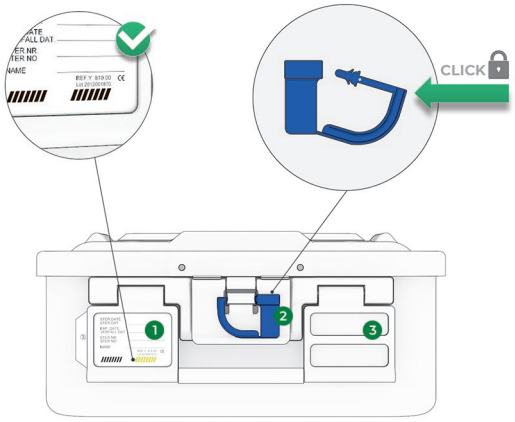

- **(1) Filter Retainer:**
  - Release the filter retainer lock with the help of the button shown on the image. After, place one sheet of filter over each perforated section on the inside of Bahadir Sterilization Containers. (Make sure it covers all the perforation holes properly).
  - Make sure that filters and filter retainers are placed properly. 'Click' sound should be heard while placing filter retainers by pressing on them which indicates locking is realized.
  - Ensure the filter retention plates are seated properly and securely locked tight in position.

- **(2) Polypropylene Filter:** The disposable; single-use filters are fabricated from polypropylene and act as a microbial barrier to maintain sterility of the devices in the containers after sterilization.

Bahadir Sterilization Containers are designed to be used with single-use Polypropylene filters validated for use with the containers (BAHADIR USA item number Y801.01).

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### 5.2 Front Panel




- **(1) Indicator:** VH2O2 indicators are developed to react to all Hydrogen Peroxide critical paratemers of sterilization. The change of color of the indicator ink shall only occur in presente of these conditions, thus providing visual evidence immediately after the sterilization cycle. Check the color change on the indicator after each sterilization process.
  - Select the appropriate indicator card and insert into the holding brackets on the outside of the container.

- **(2) Security Seal:** The security seal ensures the safety of the sterile package against unauthorized opening. It is placed to the locking hinge before sterilization as shown in the image and opened by break off.
  - Insert the security seals.
  - Secure and Lock.

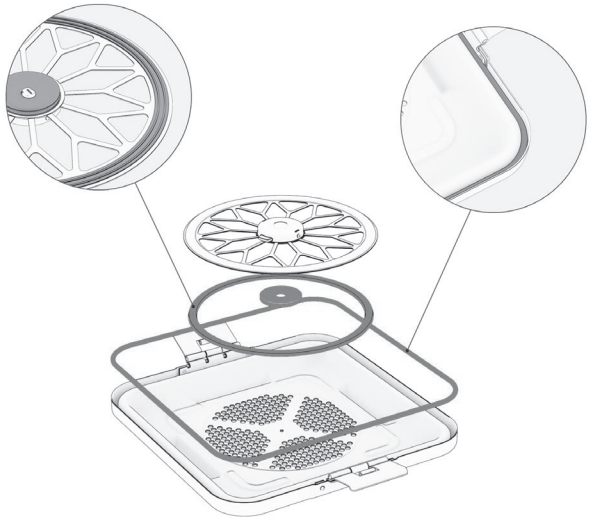
- **(3) Labels:** The labels are used to categorize information of the surgical set, department, etc.

Do not reuse

Do not reuse disposable components such as polypropylene filters, indicators and security seals!

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### 5.2 Silicone Gaskets



- Silicone gaskets are seated on the retaining groove and filter retainer and ensure microbiological sealing.
  - The gaskets should only be replaced by the manufacturer and authorized personnel.

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## ⚠ 6. WARNINGS REGARDING CLEANING, DISINFECTION AND STERILIZATION

- For the cleaning, disinfection and sterilization of products, national and international standards, directives and clinical hygiene instructions must be followed.
- The containers must be properly cleaned and sterilized prior to first use.
- Use cleaning and disinfectant agents according to the manufacturer's instructions.
- For patients with a diagnosis or suspicion of Creutzfeldt-Jakob disease (CJD) or variants, national regulations regarding disinfection and sterilization of products must be followed.
- Handle with validated methods and sterilizers at all times.
- Prefer mechanical cleaning cleaning instead of manual cleaning as it gives more reliable results.
- Handle with care. Do not drop or apply excessive forces to the products during reprocessing.

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### 6.1 Cleaning and Maintenance Products / Tools

warning

Do not use metal brushes or any abrasive cleaning material. Never use bleach or other corrosive chemicals to clean Bahadir Sterilization Containers. Abrasive products may cause chemical and physical corrosions that will void all manufacturer warranties!

warning

The use of chlorine solutions (saline solutions, bleaching agent, ringer solution) causes pitting corrosion or stress corrosion cracking!

- Long-term processes with disinfectants based on alkylamine active ingredient in silicone elastomers (silicone-coated products) may cause hardening.
- Use cleaning agents with approved efficacy (VAH or FDA approval or CE mark)
- Cleaners with a disinfectant effect (manual cleaning) must be in accordance with EN 14885 or equivalent national guidelines.
- Use soft, lint-free cloths, soft bristle brushes and compressed air guns.
- Do not use aldehyde-based cleaning products due to their protein-fixing properties.
- Cleaning solutions should be changed on daily basis. If the solution gets contaminated visibly, it can be changed earlier.

If for more information concerning the inspection and cleaning of closed sterilization containers, please see Section and 7 and Section 8.

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### 6.2 Water Qualifications

- **Drinking (Tap) Water***: Uses for the first wash and intermediate rinse.
  - Drinking water quality according to EC Directive 98/83/EC or AAMI TIR34

- **Softened water***: Water hardening substances (calcium and magnesium cations) are reduced.

- **Demineralised water***: Mineral substances largely removed by reverse osmosis or cation & anion exchangers or electrode ionization or distillation.

  - For H2O2 sterilization and the final rinsing of cleaning processing, limit values for feed Water quality is specified in ISO 22441 and ISO 14937

⚠ Non-conforming water properties causes:

- Scaling and lime deposits,
- Pitting corrosion
- Brown-red deposits
- White-grey, colored surface changes
- Spotting and rusts.

## 7. CLEANING AND DISINFECTION INSTRUCTIONS

### 7.1 Preparation for Cleaning / Pre-cleaning

⚠ warning

**Do not exceed** 25 °C for pre-cleaning temperature!

- Remove the lid from the container and separate all detachable components such as filter/filter retainer, basket, indicator and labels.
- Rinse all parts under cold tap water to remove coarse contaminations and visible soils.

### 7.2 Manual Cleaning / Disinfection

⚠ warning

**Do not exceed** the maximum permitted cleaning temperature of 45 °C. Otherwise, protein denaturation may occur.

⚠ warning

Use a non-protein fixing cleaning solution that **does not contain alcohol, aldehyde, phenol and QUAT** with a disinfection effect according to the manufacturer's instructions.

| | Process Step | Water Quality | Heat | Time |
|---|---|---|---|---|
| 1 | Cleaning/disinfecting[1] | Drinking Water* | Room Temp. | 2 min |
| 2 | First Rinsing | Drinking Water* | 1 – 16° C | 1 min |
| 3 | Disinfecting[1] | Drinking Water* | Room Temp. | 10 min |
| 4 | Final Rinsing | Demineralized Water* | Room Temp. | 2 min |
| 5 | Drying | - | Room Temp. | - |

**1.** Pour a 25 ml dose the enzymatic enzymatic / neutral pH detergent solution in 5 liters of water (%0,5 dilution). Immerse the container completely in the solution and shake it gently to avoid air bubbles. Actuate all hinges and movable parts to ensure contact of the solution with all surfaces. Using a soft-bristled brush, remove all visible soil and debris while soaking the container.

**2.** Remove the containers from the solution and rinse under cold tap water for a minimum of 1 minute. Actuate all hinges and moveable parts while rinsing. Thoroughly and aggressively flush hard to clean areas.

**3.** Pour a 125 ml disinfectant solution dose in 5 liters of water (%2,5 dilution). Immerse fully in the disinfectant solution and allow container to soak for a minimum of 10 minutes. Actuate all hinges and movable parts to ensure contact of the solution with all surfaces. Using a soft-bristled brush, remove all visible soil and debris while soaking the container. Particular attention should be given to hinges, joints, and hard to clean areas.

**4.** Rinse with running demineralized water for at least 2 minutes.

**5.** Dry the products with a clean, lint-free cloth or compressed air.

[1] Anios - Aniosyme DD1 Solution was used to verify cleaning.

- Check for cleanliness visually at the end of the cleaning process especially the hinges, joints, etc. and hard to clean areas. Repeat the cleaning process if necessary.
- Apply maintenance procedures (see **7.4 Maintenance & Care**)
- Control visually and functioning of the containers according to the " **8.1 Inspection & Check**" part of this document.

### 7.3 Mechanical Cleaning and Disinfecting

⚠ warning

Use low alkaline cleaning agents (8.0-10.5 pH). Do not use high alkaline value (>11.0 pH) cleaning agents.

⚠ warning

Follow the washer-disinfector manufacturer's instructions. Use a washer-disinfector validated according to EN ISO 15883.

- Make sure no residues from the Pre-cleaning process remain on the lid or bottom. If debris remains, repeat rinsing.
- Place the containers to the washer-difinfector in an open position and separated from their components.
- Arrange the position of the containers in the washer-disinfector to prevent mechanical damage through contact.
- Avoid overloading to make sure the surface of the containers effectively gets in contact with cleaning solution.
- With regard to the process chemicals used, consider the manufacturer's instructions concerning dosing, concentration, temperature, and exposure time.
  To prevent corrosion, unload the washer-disinfector immediately when the process steps done.
- Demineralized water is recommended for the final rinse and steam generation to avoid discoloration or damage resulting from minerals found in utility water

| | Process Steps | Water Quality | Heat | Time |
|---|---|---|---|---|
| 1 | Pre-wash | Softened water* | <25 °C | 2 min |
| 2 | Cleaning | Demineralized Water* | 45 – 55 °C | 5 min |
| 3 | First rinse / Neutralization | Demineralized Water* | >10 °C | 2 min |
| 4 | Intermediate rinse | Demineralized Water* | >10 °C | 2 min |
| 5 | Thermal disinfection / Final rinse | Demineralized Water* | 90 °C | 5 min |
| 6 | Drying | - | - | *** |

- Check for cleanliness visually at the end of the cleaning process especially the hinges, joints, etc. and hard to clean areas. Repeat the cleaning process if necessary.
- Apply maintenance procedures (see **7.4 Maintenance & Care**)
- Control visually and functioning of the containers according to the "**Inspection & Check**" part of this document.

* See **"Water Qualifications"** section of this document for water properties.

** If a high alkaline cleaning solution to be used, neutralization may be required.

*** Drying times vary depending on the loading capacity and must be observed according to the manufacturer's instructions.

Mechanical cleaning of the containers is preferred to manual cleaning provided that the washing machine is designed for cleaning sterilization containers. This applies in particular to ensure secure placement in the washing baskets and arrangement of the spray jets and arms. Washer must also have a special washing program for aluminum containers.

### 7.4 Maintenance & Care

⚠ warning

Ensure to apply care product (lubricant) to metal sliding surfaces, moving parts, joints prior to **"Inspection & Check"**.

⚠ warning

Raw materials used in care products must comply with pharmacopeias such as USP/NF, Ph. Eur, and national and international cosmetics regulations. **Do not use** silicone oil-based products!

- Ensure that the products are cleaned effectively before maintenance. Visually and physically inspect the products for blood and protein soils.

Care products must be:

- Paraffin/white oil based,
- Biocompatible,

- Allow the products to cool down to room temperature.
- Apply the care product directly to joints, hinges and friction surfaces.
- Actuate moving mechanisms a few times to spread the care product evenly.
- Wipe the excessive care product with a lint-free cloth.

⚠ warning

Failure to apply sufficient care products to moving parts causes friction-related damage and corrosion!

## 8. PRE-ASSEMBLY INSPECTION AND PREPARATION

- Select surgical instrument set for sterilization.
- Be sure all the components are completely dry.
- Select appropriate size baskets and containers.

**8.1 Inspection & Check**

Verify the following:

- Bahadir Sterilization Containers must be checked visually before each usage. Inspect the container bottoms, container lids and the surfaces where seals sit must be free of dents, visible deformations and anything else that might appear out of the ordinary.
- Users are responsible for pre-inspection prior to assembly for use of containment devices to verify that the gaskets in the lid and filter retention plates are in good working order, the plates properly seal over the vented area of the container lid and base, and that no rust or corrosion are present on any surfaces.
- Furthermore, the gasket should be intact and the edge of the container base nest properly within the container lid. Dents and deformations can affect the seal of the container compromising the integrity of the containment device.

warning

Do not use spray oil or solvents on the lid seals. The seal in the inner lid must be completely inserted and undamaged. If there is any kind of damage detected, lids should not be used

warning

If any of the above controls are not confirmed, **do not use** the product, contact with Bahadir Medical Devices (manufacturer). Damaged products **must only** be repaired by the manufacturer.

### Filter Assembly

(see **5.1 Filters**)

- Filters and filter retainers must show no visual deformations. These parts must be checked visually and for their functionality before usage!

### Instrument and Container Assembly

- Place thoroughly cleaned and dried instruments into the instrument basket(s) according to established hospital procedures. Complex instruments, such as air-powered instruments have to be prepared and sterilized according to the instrument manufacturer's instructions. Small baskets, trays and other types of accessories, especially with covers and lids, should only be used with the sterilization container which has been specifically designed for that purpose. Place instrument basket(s) into the prepared container bottom. Place assembled lid onto the container bottom, aligning handles on bottom with latches on lid. Simultaneously close both locking latches on the lid.

- Leave one inch of free space between the instruments and the inside of the container lid for effective processing!

### Processing Assembly

(see **5.2 Front Panel**)

- Bahadir Sterilization Containers are protected by disposable plastic security seals which once attached can be opened only by breaking which prevents inadvertent opening of the containers, and ensures that it is evident whether or not the sterility of the contents has been compromised. Use of internal and external indicators should be in accordance with in-house protocol that is determined by the user.

## 9. STERILIZATION INSTRUCTIONS

**Sterilization Method**

- The sterilizer must comply with ISO 22441 and ISO 14937 standard.

**Placing & Loading**

warning

The loading instructions of the sterilizer manufacturer should be observed!

- Bahadir Sterilization Containers should be placed horizontally in the sterilizer for effective sterilization and drying.
- Stacking NOT permitted in the chamber during the sterilization
- In order to avoid post-sterilization against accidents Containers need to remain on the container cart, in draft free area until cool enough to handle!

### 9.1 Sterilization Cycle Parameters and Configurations

| Cycle | Container Size & Total Loading (lbs) | Compatible Lumens |
|---|---|---|
| STERIS VPRO maX/maX2 Lumen Cycle | 1/1 Full Size (19.65 lbs) | ≥0.77mm x ≤527mm (single, dual or triple channel)<br>≥0.8mm x ≤542mm (single, dual or triple channel)<br>≥0.48mm x ≤100mm (single, dual or triple channel)<br>≥1.3mm x ≤73mm (dead end lumen)<br>≥3mm x ≤298mm (rigid non-metallic lumen)<br>≥4mm x ≤424mm (rigid non-metallic lumen) |
| | 3/4 Mid Size (19.65 lbs) | ≥0.77mm x ≤527mm (single, dual or triple channel)<br>≥0.8mm x ≤542mm (single, dual or triple channel)<br>≥0.48mm x ≤100mm (single, dual or triple channel)<br>≥1.3mm x ≤73mm (dead end lumen)<br>≥3mm x ≤298mm (rigid non-metallic lumen)<br>≥4mm x ≤424mm (rigid non-metallic lumen) |
| | 1/2 Half Size (15 lbs) | ≥0.77mm x ≤527mm (single, dual or triple channel)<br>≥0.8mm x ≤542mm (single, dual or triple channel)<br>≥0.48mm x ≤100mm (single, dual or triple channel)<br>≥1.3mm x ≤73mm (dead end lumen)<br>≥3mm x ≤298mm (rigid non-metallic lumen)<br>≥4mm x ≤424mm (rigid non-metallic lumen) |
| STERIS VPRO maX/maX2 Flexible Cycle | 1/1 Full Size (21lbs) | (2) flexible endoscopes with light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain Single or Dual channel lumens ≥1mm x ≤1050mm<br>or<br>(1) flexible endoscope with light cord (if not integral to endoscope), endoscope accessories, mat and additional instruments. The flexible endoscope may contain Single or dual channel lumens that are ≥1mm x ≤1050mm. Additional single, dual or triple channel<br>stainless steel lumen device that is ≥0.48mm x ≤100mm OR non-lumen device |
| | 3/4 Mid Size (21 lbs) | (2) flexible endoscopes with light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain Single or Dual channel lumens ≥1mm x ≤1050mm<br>Or<br>(1) flexible endoscope with light cord (if not integral to endoscope), endoscope accessories, mat and additional instruments. The flexible endoscope may contain Single or dual channel lumens that are ≥1mm x ≤1050mm. Additional single, dual or triple channel stainless steel lumen device that is ≥0.48mm x ≤100mm OR non-lumen device |
| | 1/2 Half Size (21 lbs) | (2) flexible endoscopes with light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain Single or Dual channel lumens ≥1mm x ≤1050mm<br>Or<br>(1) flexible endoscope with light cord (if not integral to endoscope), endoscope accessories, mat and additional instruments. The flexible endoscope may contain Single or dual channel lumens that are ≥1mm x ≤1050mm. Additional single, dual or triple channel stainless steel lumen device that is ≥0.48mm x ≤100mm OR non-lumen device |
| STERIS VPRO maX/maX2 Non-Lumen Cycle | 1/1 Full Size (26 lbs) | -Non lumened instruments |
| | 3/4 Mid Size (26 lbs) | -Non lumened instruments |
| | 1/2 Half Size (19 lbs) | -Non lumened instruments |
| STERIS VPRO S2/60 Lumen Cycle | 1/1 Full Size (11 lbs) | ≥0.77mm x ≤410mm (single or dual channel)<br>≥1.8mm x ≤542mm (single or dual channel)<br>≥1.2mm x ≤275mm (triple channel)<br>≥1.8mm x ≤310mm (triple channel)<br>≥2.8mm x ≤317mm (triple channel) |
| | 3/4 Mid Size (11 lbs) | ≥0.77mm x ≤410mm (single or dual channel)<br>≥1.8mm x ≤542mm (single or dual channel)<br>≥1.2mm x ≤275mm (triple channel)<br>≥1.8mm x ≤310mm (triple channel)<br>≥2.8mm x ≤317mm (triple channel) |
| | 1/2 Half Size (11 lbs) | ≥0.77mm x ≤410mm (single or dual channel)<br>≥1.8mm x ≤542mm (single or dual channel)<br>≥1.2mm x ≤275mm (triple channel)<br>≥1.8mm x ≤310mm (triple channel)<br>≥2.8mm x ≤317mm (triple channel) |
| STERIS VPRO S2/60 Flexible Cycle | 1/1 Full Size (11 lbs) | -Non-lumened instruments and instruments with diffusion restricted spaces (such as the hinged portion of forceps and scissors)<br>-(1) surgical flexible endoscope or bronchoscope with light cord (if not integral to the endoscope). The flexible endoscope may be single or dual lumen device with lumens that are ≥1mm x ≤990mm |
| | 3/4 Mid Size (11 lbs) | -Non-lumened instruments and instruments with diffusion restricted spaces (such as the hinged portion of forceps and scissors)<br>-(1) surgical flexible endoscope or bronchoscope with light cord (if not integral to the endoscope). The flexible endoscope may be single or dual lumen device with lumens that are ≥1mm x ≤990mm |
| | 1/2 Half Size (11 lbs) | -Non-lumened instruments and instruments with diffusion restricted spaces (such as the hinged portion of forceps and scissors)<br>-(1) surgical flexible endoscope or bronchoscope with light cord (if not integral to the endoscope). The flexible endoscope may be single or dual lumen device with lumens that are ≥1mm x ≤990mm |

| Cycle | Container Size & Total Loading (lbs) | Compatible Lumens |
|---|---|---|
| STERIS VPRO s2/60 Non-Lumen Cycle | 1/1 Full Size (19 lbs) | -Non lumened instruments |
| | 3/4 Mid Size (19 lbs) | -Non lumened instruments |
| | 1/2 Half Size (12.5 lbs) | -Non lumened instruments |
| STERRAD NX Standard Cycle | 1/1 Full Size (10.7 lbs) | (5) SS lumens 1mm I.D. x 150mm L<br>(5) SS lumens 2mm I.D. x 400mm L |
| | 3/4 Mid Size (10.7 lbs) | (10) SS lumens 1mm I.D. x 150mm L |
| | 1/2 Half Size (10.7 lbs) | (10) SS lumens 1mm I.D. x 150mm L |
| STERRAD NX Advanced Cycle | 1/1 Full Size (10.7 lbs) | (10) SS lumens 2mm I.D. x 500mm L |
| | 3/4 Mid Size (13.85 lbs) | (6) SS lumens 1mm I.D. x 350mm L |
| | 1/2 Half Size (10.7 lbs) | (10) SS lumens 1mm I.D. x 200mm L |
| STERRAD 100NX Standard Cycle | 1/1 Full Size (21.4 lbs) | (5) SS lumens 1mm I.D. x 500mm L |
| | 3/4 Mid Size (13.85 lbs) | (5) SS lumens 1mm I.D. x 350mm L |
| | 1/2 Half Size (13.85 lbs) | (5) SS lumens 0.7mm I.D. x 200mm L |
| STERRAD 100NX Express Cycle | 1/1 Full Size (21.4 lbs) | -Non lumened instruments |
| | 3/4 Mid Size (13.85 lbs) | -Non lumened instruments |
| | 1/2 Half Size (13.85 lbs) | -Non lumened instruments |
| STERRAD 100NX Duo Cycle | 1/1 Full Size (13.2 lbs) | (1)PTFE tubing 1.5 mm I.D. x 850mm L |
| | 3/4 Mid Size (7.2 lbs) | (1)PTFE tubing 1.5 mm I.D. x 850mm L |
| | 1/2 Half Size (7.2 lbs) | (1)PTFE tubing 1.5 mm I.D. x 850mm L |
| STERRAD 100NX Flexible Cycle | 1/1 Full Size (12.59 lbs) | (1) Scope lumen 1mm I.D. x 850mm L |
| | 3/4 Mid Size (13.85 lbs) | (1) Scope lumen 1mm I.D. x 850mm L |
| | 1/2 Half Size (13.85 lbs) | (1)PTFE tubing 1mm I.D. x 850mm L |

| Cycle | Baskets including holding pins, holding clamps, silicone holders, partition sheets, tamper evident locks | Silicone Mats |
|---|---|---|
| Steris VPRO 60/s2 Lumen, Non-Lumen, Flex | YES | YES |
| Steris VPRO maX/maX2 Lumen, Non-Lumen, Flex | YES | YES |
| STERRAD NX – Standard | YES | NO |
| STERRAD NX – Advanced | YES | NO |
| STERRAD 100NX – Standard | YES | NO |
| STERRAD 100NX – Duo | YES | NO |
| STERRAD 100NX – Flex | YES | NO |
| STERRAD 100NX - Express | YES | YES |

**Storage**

- Containers **must not be stored** together with chemicals!
- Sterile, packaged products should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.
- The containers maintain their sterility for 12 months under appropriate storage conditions. Tested in accordance with EN ISO 11607-1.
- Please refer to DIN 58953-8 (Logistics of sterile medical devices) for the storage period of medical devices in sterilization containers. The storage time usually depends on the storage conditions and must be determined by the responsible hygiene specialists.

Storage conditions:

- Temperature: 15-26°C
- Humidity: 30 – 50%
- Air pressure: 500-1060 hPa

**Shelf Life**

- In protected storage (temperature, humidity, air filtration etc. controlled hospital storage room conditions) containers can store sterilized medical devices for up to 12 months, provided the integrity of the container is not compromised (Tamper-evident security seal (Y819.00) remains intact). Facilities should follow industry guidelines and establish processes and procedures related to shelf-life and storage.
  **Note:** Bahadir Sterilization Containers can be stacked during storage, one on top of another. Be sure that heavier container is placed at the bottom.
- 100 cycles are considered a minimum as a service life for containers and silicone seals can be used throughout the service life.
- Products that cannot pass functional and visual inspections should not be used.

warning

Products **must be sterilized** before being sent to the manufacturer or the manufacturer's technical service.

warning

In case of any serious incident related to the device, Bahadır Tıbbi Aletler AŞ (manufacturer) or local authorities should be reported.

## 9. TECHNICAL SERVICE

**9.1- Warranty & Repair**

- The containers are covered by a 2-year warranty.
- Users must not attempt any unauthorized service interventions; maintenance and repair are the responsibility of the manufacturer.
- The user is solely responsible for any adverse events resulting from the use of products after the warranty period has expired.

## Manufacturer Contact Information

**BAHADIR TIBBİ ALET CİHAZ VE İNŞAAT MAKİNA SANAYİ VE TİCARET ANONİM ŞİRKETİ**

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## Notified Body Contact Information

**KIWA BELGELENDİRME HİZMETLERİ AŞ**

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