



Zuno Smart Sterilization Container

Instructions for Use



Manufacturer

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1. Purpose of Instructions for Use

This user manual provides instructions on the proper use, cleaning, reprocessing, and care of the Zuno Smart Sterilization Container.

Instructions for use and parameters stated in this document are based on validation studies conducted by Zuno Medical. Each facility should ensure their processing system provides similar results.

2. Indications for Use

The Zuno Medical Smart Sterilization Container is a reusable sterilization container intended to be used to enclose another medical device that is to be sterilized by a healthcare provider with pre-vacuum, steam sterilization cycles, to maintain sterility after removal from the sterilizer until used, and to monitor and inform users of the status of the container's sterile barrier integrity.

The Zuno Medical Smart Sterilization Container has been validated to allow for the sterilization of its contents in pre-vacuum steam sterilizers with the following parameters: 132°C sterilization temperature, 4-minute sterilization, 5-minute or greater dry time.

Do not use with instruments containing lumens with an inner diameter smaller than 1.2mm and an overall length longer than 500mm. Do not exceed a total container weight of 25lbs.

3. Device Description

o Overview

The Zuno Medical Smart Sterilization Container consists of an unperforated base with attached handles, an unperforated lid with integrated electromechanical valves, and a control module mounted on the lid to provide an interface with the system, to monitor the environment within the container, and to control the operation of the valves.

Articulating handles, attached to either end of the container base, allow for easy, stable handling and transport of the container. The handles swing down when not in use to decrease the width profile of the container.

Hinged latches affixed to the lid of the container swing down to secure the lid onto the base. A gasket fixed to the lid creates a microbial/sterile barrier when the lid is latched to the base.

Two (2) valves are integrated into the lid of the container. Each valve assembly contains a valve cap which can move between an OPEN (up) and CLOSED (down) position by the user. If lifted to its extent, the valve cap latches to the valve frame, holding the valve in the OPEN position. The valve cap can be manually released from the latch by applying a downward force to the valve cap.

Each of the valve assemblies has an integrated silicone gasket similar to the lid gasket and provides a microbial/sterile barrier when the valves are closed, and the container is sealed.

The control module continuously monitors environmental conditions within the steam sterilizer along with the position of the valves during the sterilization cycle. At the end of a sterilization cycle, the control module closes the valves, establishing a sterile barrier between the internal volume of the container and external environment. Low pressure within the internal volume secures the valve in the CLOSED position and maintains the integrity of sterile barrier until the time of use.

The top surface of the control module features buttons and indicators.

The READY button is pressed by the user prior to loading the container into the autoclave. Activation of the READY button triggers the system to confirm the valves are in the OPEN position. If a valve is CLOSED, an indicator pointing to the closed valve flashes red. If both valves are closed, both indicators flash red. If all valves are open, the READY indicator flashes signifying that the container is ready for sterilization and the control module is monitoring the environment to determine the start of a sterilization cycle.

The STATUS button can be pressed by the user at any time following the completion of a sterilization cycle until it is opened. Activation of the STATUS button triggers the system to confirm that the sterile barrier has not been compromised since it was last sterilized.

If the sterile barrier is intact following a sterilization cycle, the GOOD status indicator (i.e. checkmark) periodically flashes GREEN for a short time following the sterilization cycle and will momentarily flash anytime the STATUS button is pressed.

If the sterile barrier has been compromised, the BAD status indicator (i.e. X-mark) periodically flashes RED for a short time following a sterilization cycle and will momentarily flash anytime the STATUS button is pressed.

- o **Full-Size Sterilization Container**

The Zuno Medical Smart Sterilization Container is designed to be compatible with common device manufacturer or hospital-owned instrumentation, trays, and caddies.

- Overall external dimensions are 24.2" Length x 12.0" Width x 5.8" Height.
- Maximum internal container dimensions are 22.0" Length x 10.75" Width x 3.75" Height.

4. Cleaning

- o **General Precautions regarding Cleaning**

1. Reprocessing of the container has been validated using pH-neutral enzymatic detergents. Use of highly acidic or highly alkaline detergents for cleaning may damage the container finish.
2. Do not use abrasive cleaners, abrasive cleaning pads or metal brushes to assist cleaning, as they may damage the container finish.
3. Do not use substances containing halogen or chloride. Use of these substances can promote corrosion.
4. Thorough rinsing with fresh water is required to remove all cleaning agent residues.
5. Container components must be thoroughly dried and stored in a dry environment after cleaning.
6. Containers should be cleaned as soon as is reasonably practical after use. Excess gross soil should be removed from the container as soon as possible.

- o **Automated Cleaning Method**

1. Separate lid from base.
2. Remove all instruments and/or instrument caddies from the container.
3. Rinse visible debris from Container Lid and Base.
4. Place separated Lid and Base on washer rack to secure parts and to avoid excess movement during cleaning.
5. Follow recommended dosage of the detergent.

*Caution: do not use alkaline detergents, acid neutralizers or scratch pads. Caustic detergents will oxidize the anodized aluminum surface of the container and cause discoloration and corrosion.

- o **Manual Cleaning Method**

1. Separate lid from base.
2. Remove all instruments and/or instrument caddies from the container.
3. Rinse visible debris and fluids from all container components. Use a soft sponge or soft bristle brush (e.g. nylon) moistened with warm tap water.
4. Prepare a pH-neutral, enzymatic detergent per the manufacturer's instructions using warm tap water.

5. Completely immerse and soak the container components in the detergent solution for a minimum of five (5) minutes
6. While container is immersed, scrub the components with a soft sponge or brush.
 - o Focusing on areas with any visible debris.
 - o Thoroughly scrub both latches and handles. Actuate the latches and the handles while scrubbing.
 - o Scrub the bottom surface of the valve caps and rim of the valve openings from the bottom surface of the lid. Actuate the valve caps as necessary to access the entire circumference of the rim.
7. Rinse the container components by immersing in fresh critical water for a minimum of one (1) minute to remove all traces of cleaning detergent.
8. Dry lid and base with a clean, lint-free cloth or air dry.
9. Repeat the cleaning process if a visually clean endpoint has not been achieved.
10. Place lid and base into dry storage location. Bases can nest vertically. Do not place the lid and base on surfaces where they can become damaged or tip. Do not place other items on top of lid.

5. Container Inspection, Preparation, and Instrument Sterilization

o Inspection of the Container Prior to Use

Perform the following inspections prior to use. If any inspections do not pass, do not use the container. Select new container components and repeat inspections. Contact Zuno Medical for inspection, repair, and/or replacement by a service representative. See Figure 1 for reference.

1. Manually move each of the valves between the OPEN and CLOSED position. They should move freely and be able to latch in the OPEN position.
2. Confirm that the valve gaskets are pliable, securely fastened to the valve caps and free from breaks or cuts.

Note: The valve gaskets are best inspected by looking at the bottom/internal face of the container lid.

3. Confirm that the lid gasket is pliable, securely fastened to the lid and free from breaks or cuts.
4. Visually inspect the container to ensure that:
 - o The aluminum lid and base are free from cracks and pitting,
 - o Components are free from dents, damage, or misalignment that prevents the lid from adequately mating with the base,
 - o Confirm that the rim of the container base is not dented or chipped.
5. Confirm that latches swing freely when not latched to the base.
6. Confirm that handles swing freely.

o Inspection of the Control Module Prior to Use

1. Manually CLOSE the container valves and press the READY button to confirm that the valve indicator arrows flash RED.
2. Press the STATUS button and confirm that X-MARK flashes RED.

Note: If both valves are in the open position and the READY button is pressed, the control module will begin to monitor the environment for the start of a sterilization cycle. If this situation occurs, both valves may be manually closed to cancel the operation.

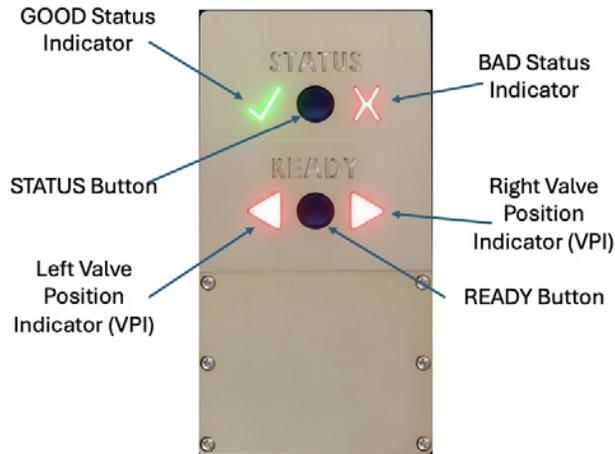


Figure 1

o Preparation and Assembly of the Zuno Medical Container

1. Sort and assemble clean instruments into instrument tray(s), caddy(ies) or basket(s), according to established facility procedures and/or instrument manufacturers' instructions for use.
2. Place instrument tray(s), caddy(ies) or basket(s) into the Zuno Medical sterilization container base.
 - o Instruments should not be placed directly within the container base without the use of a basket, tray, or caddy.
 - o Unwrapped caddies or trays provided by device or instrument manufactures may be placed directly in the Zuno Medical Container.
 - o Multiple caddies or trays may be stacked within the Zuno Medical Container if there is no contact between the contents of the container and the internal surface of the Zuno Medical Container lid when latched onto the base.
3. Do not exceed the maximum load of 25 lbs (container + contents).
4. Place Zuno Medical Container lid onto base and close both lid latches.
 - o Ensure there is no interference between the internal surface of the Zuno Container lid and the container contents and that the lid is latched tightly onto the base.
 - o Ensure there is no interference between the valve caps and the container contents. This may be confirmed by closing the valves and visually confirming that each of the valve cap rests snugly against top surface of the container lid.
 - o Interference can be avoided by ensuring the container contents sit at least ½ inch below the rim of the container base. A tool, such as the Zuno Medical Limbo Stick, may be used to assist in confirming that there is no interference.
5. Position the valve(s) in the OPEN position.
 - o If the valve(s) do not latch in the OPEN position, the container lid may require service. Do not use this container lid. Select a new lid and repeat container preparation. Contact Zuno Medical for inspection, repair, and/or replacement by a service representative.
6. Press the READY button on the control module. Confirm the READY indicator flashes BLUE rapidly for a brief period and periodically, thereafter.

- o If one or more valves is not in the OPEN position, the READY indicator will not flash, and the valve indicator ARROW pointing to the closed valve(s) will flash RED. Re-position the valve(s) to the OPEN position and press the READY button again.
 - o If the control module gives any response not explicitly detailed here or if there is no response, the container lid may require service. Do not use this container lid. Select a new lid and repeat container preparation. Contact Zuno Medical for inspection, repair, and/or replacement by a service representative.
7. Transport the prepared container to the autoclave. The container cannot be placed on its side during the sterilization cycle.
 - o Dropping the container or a harsh bump may unintentionally close one or more valve(s).
 - o If one (1) valve unintentionally closes, the READY indicator will stop flashing periodically and the valve indicator ARROW pointing to the closed valve will begin to flash RED. Re-position the valve to the OPEN position and the valve indicator will stop flashing and the READY indicator will resume flashing signifying that the container is ready for sterilization.
 - o If both valves unintentionally close, the operation will be cancelled. Both valves must be re-opened and the READY button pressed again.
 8. Prior to final insertion into the autoclave, visually confirm that the READY indicator continues to periodically flash BLUE.
 - o If the container is stored without starting a sterilization cycle for more than 60 minutes after pressing the READY button, the system may turn OFF and the READY button must be pressed again.
 - o If the READY indicator is not flashing, open the valve(s) and press the READY button again.
 - o If the container is not going to be immediately sterilized, close all valves to cancel the operation.

o Sterilization

WARNING: Container should only be sterilized in a horizontal position.

The Zuno Medical Smart Sterilization Container has only been validated with the container sitting horizontal within the autoclave. Do not run a sterilization cycle with the container sitting on its side.

WARNING: Do not stack containers in the autoclave during a sterilization cycle.

The Zuno Medical Smart Sterilization Container has not been validated with multiple containers stacked directly on top of each other during a sterilization cycle.

1. Initiate a sterilization cycle per the autoclave manufacturer’s instructions and facility procedures.
 - o Zuno Medical Smart Sterilization Containers are validated to allow for the sterilization of its contents with pre-vacuum steam sterilization cycles using the parameters defined in Table 1.

Sterilization Exposure Temperature	Sterilization Exposure Time	Dry Time
132° - 135°C (270° - 275°F)	4 minutes	5 minutes minimum

Table 1: Validated sterilization parameters.

WARNING: Do not include other sterilization containers or sterile barrier systems in a sterilization cycle with Zuno Medical Smart Sterilization Containers when using an abbreviated dry time, unless those systems have documented validation demonstrating suitability for those parameters.

The Zuno Medical Smart Sterilization Container has been validated to maintain sterility following sterilization cycles with dry times as short as 5 minutes until the container is opened or other event compromises the sterile barrier.

6. Post Sterilization Processing

o Sterile barrier verification

1. Remove the container from the autoclave within 20 minutes of the completion of an autoclave cycle and allow to cool on a cooling rack or equivalent storage rack per facility protocol.

o NOTE:

The Zuno Medical Smart Sterilization Container does not contain any porous sterile barriers and can be handled immediately following a sterilization cycle without risk of compromising the sterile barrier.

CAUTION: The sterilization container will be hot immediately following a sterilization cycle and may cause burns if contacted with bare skin. Use protective equipment and proper techniques for handling hot containers.

- #### o NOTE:
- The Control Module status indicator will flash the CHECK-MARK or X-MARK indicating the status of the sterile barrier for several minutes following the sterilization cycle. This notification provides an immediate indication of the status after a cycle. The indication is a convenience and should not replace the sterile barrier status check in the following steps.

2. When the container has cooled sufficiently for manual handling without the use of protective equipment, SPD staff should perform the following steps to confirm the sterile barrier is intact prior to placing the container into sterile storage.

- o Press the STATUS button and confirm the STATUS indicator's CHECK-MARK flashes GREEN, and
- o Confirm the container is sealed tightly by attempting to lift one of the valves with a single finger using the technique illustrated in Figure 2.

Technique for Confirming Sterile Barrier



Figure 2

- o If one of the following occurs, the sterile barrier is assumed to be compromised and the instruments must be re-processed:
 - STATUS indicator X-MARK flashes RED.
 - The X-MARK and CHECK-MARK flash simultaneously or neither status indicator is displayed after pressing the Status button. Contact Zuno Medical for inspection, repair, and/or replacement by a service representative.
 - One or more valves is OPEN.
 - Either of the valves can be lifted with one finger

Note: If any of the above conditions persist, the sterilization container may require servicing. Remove instruments from the container and reprocess them. Set the container aside and contact Zuno Medical for inspection, repair, and/or replacement by a service representative.

3. Transport the Zuno Medical Smart Sterilization Container to the storage location. Containers should be transported, handled, and stored in a manner that reduces potential for contamination (see AAMI ST79).
4. Zuno Medical Smart Sterilization Containers are stackable when stored. Follow the shelf manufacturer's weight and height limit recommendations when stacking the containers during sterile storage. Containers should be stored in a manner that reduces the potential for contamination (see AAMI ST79).
5. Instruments processed and stored in a Zuno Medical Smart Sterilization Container are considered sterile until an event occurs that prevents the STATUS indicator's CHECK-MARK from flashing GREEN when the STATUS button is pressed, or the valves are easily opened by lifting one of the valve tabs with one finger.

NOTE: The Zuno Medical Smart Sterilization Container has no porous barriers and no pathway between the exterior and interior volume once sealed. There is no pathway for microorganisms to wick into the container and contaminate the contents if residual moisture accumulates within the interior or on the exterior of the container due to abbreviated dry times, poor steam quality, environmental conditions, and/or heavy or dense loads. Zuno Medical conducted bacterial ingress studies and validated that the container maintains a secure sterile barrier in the presence of moisture (Data on file at Zuno Medical).

7. Opening a Sterile Container in the Operating Room

WARNING: Sterile containers should only be opened in the clean environment of the Operating Room.

A processed and sterilized container should only be opened within the clean environment of an operating room if the contents of the container are to be used in a surgical procedure requiring sterile instruments. If the sterilization container is opened outside the operating room the contents of the container should be considered unsterile and must be reprocessed.

CAUTION: The sterilization container and its contents will be hot immediately following a sterilization cycle and may cause burns if contacted. The operating room staff should use protective equipment, proper handling techniques and cool the container's contents prior to use.

- o **Sterile Barrier Check and Aseptic Presentation of Sterile Container Contents in the Operating Room**
 1. Facility procedures and AORN guidelines should be followed when using and presenting the Zuno Medical Smart Sterilization Container. The following steps are for aseptic presentation of a processed sterile container.
 2. Non-scrubbed staff – Position container within the OR but outside the sterile field on a separate dry flat surface.
 3. Non-scrubbed staff – Perform the following steps to confirm sterile barrier has not been compromised:

- Press the STATUS button and confirm the STATUS indicator's CHECK-MARK flashes GREEN, and
- Confirm the container is sealed tightly by attempting to lift one of the valves with a single finger using the technique illustrated in Figure 3.

Technique for Confirming Sterile Barrier



Figure 3

- If one of the following occurs, the sterile barrier is assumed to be compromised, and the instruments must be re-processed before use:
 - STATUS indicator X-MARK flashes RED.
 - The X-MARK and CHECK-MARK flash simultaneously or neither status indicator is displayed after pressing the Status button. Contact Zuno Medical for inspection, repair, and/or replacement by a service representative.
 - One or more valves is OPEN.
 - Either of the valves can be lifted with one finger
4. Non-scrubbed Staff:
- Remove tamper evident indicators, if applicable.
 - With gloved hands, manually lift one of the valves using the technique described below, until the container reaches equilibrium. Confirm the container produces the distinctive, audible pressure equalization sound as the valve is opened.

Technique for Opening Valve of Sealed Container



Figure 4

1. Rest palm(s) on the valve cover and tuck fingers under tabs of the valve cap.
2. Lift fingertips and the valve cap while keeping palm(s) pressed against the valve cover.
3. A distinct sound of pressure equalization should be heard.

5. Assume the container's sterile barrier is not intact and instruments must be re-sterilized if:
 - o The valve was not tightly sealed, and very little force was required to open a valve.
 - o The container did not produce the distinctive, audible pressure equalization sound.
 - o If either of these events are observed, the container's sterile barrier is assumed to be compromised, even if the STATUS indicator's CHECK-MARK flashed GREEN immediately prior to opening the valve.
6. Non-scrubbed staff – Unlatch both lid latches and remove the lid from the container base.
7. Non-scrubbed staff – Inspect external chemical indicators and tamper evident indicators, if applicable.
8. Non-scrubbed staff – Place the lid onto the non-sterile case cart or other rack.
 - o Do not place the lid on a surface where it can be damaged or contaminated by soiled instruments.
 - o Do not place items on top of the lid.
9. Non-scrubbed or scrubbed staff: Confirm internal process indicators indicate successful sterilization, if applicable.
10. Scrubbed staff – Remove the sterile contents from inside the container by grasping both handles on the internal instrument tray, caddy, or basket using appropriate aseptic technique and lifting it out of the container.
11. Non-scrubbed staff – Place container base onto the non-sterile case cart or other rack. Container bases can be nested.
 - o Do not place the base on a surface where it can be damaged or contaminated by soiled instruments.

NOTE: The Zuno Medical Smart Sterilization Container has no porous barriers and no pathway between the exterior and interior volume once sealed. There is no pathway for microorganisms to wick into the container and contaminate the contents if residual moisture accumulates within the interior or on the exterior of the container due to abbreviated dry times, poor steam quality, environmental conditions, and/or heavy or dense loads. Zuno Medical conducted bacterial ingress studies and validated that the container maintains a secure sterile barrier in the presence of moisture (Data on file at Zuno Medical).

o Post-surgery transportation to decontamination

Facilities should follow AAMI ST79 guidelines and facility policies and procedures for handling and transporting contaminated instruments and their containers.

Do not place soiled instruments into the container base or stack soiled instruments on top of the lid.

Facility policy and procedure should be used to determine if a container has become soiled during use. Soiled containers must be cleaned as described in Section 4.

- **Internal Process Indicators:**

Zuno Medical Smart Sterilization Containers are compatible with internal process indicators.

Follow facility policy and relevant technical guidance recommendations for use of internal process indicators.

- **External Process Indicators and Tamper-Evident Indicators:**

Zuno Medical Smart Sterilization Containers are compatible with external process indicators.

Follow facility policy and relevant technical guidance recommendations for use of external process indicators. Do not place indicators near the valve openings or on top of the valves. If the indicators are placed in the valve opening, they can obstruct the valves and prevent the device from creating an effective sterile barrier.

Zuno Medical Smart Sterilization Containers are compatible with various tamper-evident indicators; however, Zuno Medical Smart Sterilization Containers feature multiple tamper-evident indications that are designed into the container. These features are detailed in the Tamper-Evident Seal section of this IFU. Follow facility policy and relevant technical guidance recommendations for use of external process indicators.

8. Validation

Sterilization parameters stated in this document are based on validation studies conducted by Zuno Medical. The Zuno Smart Sterilization Container has been validated to allow the sterilization of instruments using a challenge device (lumen with a diameter of 1.2mm by 500mm long) and a maximum load weight of 25 lbs per AAMI and AORN guidance. Each facility should ensure their processing system provides similar results.

The Zuno Smart Sterilization Container has been validated to meet the performance metrics presented in this IFU. The container has been validated to show that it is able to establish a sterile barrier during a pre-vacuum, steam sterilization cycle using sterilization parameters prescribed in this IFU, to maintain the integrity of the sterile barrier until the container is opened or other event compromises the sterile barrier, and to accurately inform the user of the integrity of the sterile barrier.

Facilities are required to verify that the performance described in this IFU can be achieved for their application in their facility.

Zuno Smart Sterilization Containers have NOT been validated for use with other sterilization modalities, such as gravity, immediate-use steam, formaldehyde, ethylene oxide, plasma, or peroxide sterilization. It is NOT recommended to use these alternative sterilization modalities with Zuno Smart Sterilization Containers.

- **Service Life**

The Zuno Smart Sterilization Container is designed for repeated-use and its durability has been verified through testing with no loss of function that adversely affects the container's performance. The container's service life is defined by the container's ability to meet the inspection criteria detailed in the Inspection Prior to Use section. If a container does not meet the inspection criteria, the container may require service. Contact Zuno Medical for inspection, repair, and/or replacement by a service representative.

9. Maintenance & Care

Zuno Smart Sterilization Container durability has been tested and verified; however, maintenance and care must be practiced when handling and storing the container to ensure the performance qualities of the container are preserved and unintentional wear or damage is not introduced to the container.

- Only use Zuno Smart Sterilization Containers per the instructions contained in this IFU. Take care not to damage the container when handling or storing.
- Relevant personnel and staff must be trained and familiar with the correct handling and storage practices.

- Ensure the IFU is easily accessible for all relevant personnel and staff. IFU can be found at www.zunomedical.com/IFU/.
- Observe current, relevant technical standards.
- Follow general guidelines and hygiene principles on handling contaminated products, products awaiting sterilization, and products that have been sterilized.
- Before using the sterilization container or after any accident (or observed damage to the container), perform thorough visual and functional inspection per the Inspection Prior to Use section of this IFU.
- Never use a damaged or defective sterilization container.

10. Service and Repair

Zuno service representatives are trained to repair containers to the original dimensions and specifications that were used in validation testing and replace damaged or worn components such as gaskets, valves, handles and latches with in-specification Zuno components. Contact a Zuno service representative for assistance with servicing and repairs.

ONLY Zuno service representatives are authorized to repair and service Zuno Smart Sterilization Containers. Using a non-Zuno service representative will invalidate the service agreement for Zuno Smart Sterilization Containers.

11. Tamper-Proof Sealing

Technical guidance standards recommend and require that sterilization containers are sealed in a way that minimizes inadvertent opening of containers and to ensure that it is evident whether a sterile container has been opened.

Zuno Medical Smart Sterilization Containers are sealed in the autoclave during a sterilization cycle such that when the container is removed from the autoclave, the valves are firmly secured in the CLOSED position by the pressure differential created between the ambient environment and a low-pressure state that exists within the container. The pressure differential increases the manual force required to open the valve and subsequently open the container. The pressure differential also serves as a mechanism to keep the container sealed and sterile barrier intact.

The user can objectively determine whether the sterile barrier remains intact after sterilization by pressing the STATUS button and reading the STATUS indicator. Additionally, the Control Module seals the container at pressure that allows the user to easily discern the integrity of the sterile barrier by the force necessary to open a valve and the distinctive, audible sound created when opening a valve as the container pressure equilibrates with the ambient environment.

Zuno Medical Smart Sterilization Containers are compatible with various disposable tamper-evident indicators. The indicators may be inserted through the metal catch once the latches are closed. Follow facility policy and relevant technical guidance recommendations for use of external process indicators.

12. Contraindications

Zuno Medical Smart Sterilization Containers have NOT been validated for use with other sterilization modalities, such as gravity, immediate-use steam, formaldehyde or ethylene oxide, plasma, or peroxide sterilization cycles. It is NOT recommended to use these alternative sterilization modalities with Zuno Medical Smart Sterilization Containers.

Zuno Medical Smart Sterilization Containers cannot be sterilized in a stacked configuration. Stacking will restrict the flow of sterilant into the container and inhibit adequate sterilization of the contents.

Do not load the Zuno Medical Smart Sterilization Container into the autoclave on its side. The sterilization container should sit horizontally on the shelf or rack within the autoclave.

Zuno Medical Smart Sterilization Containers are not validated for use with cloth wraps, towels, or sterilization paper. It is not recommended to use these textiles with Zuno Smart Sterilization Containers.

13. General Precautions

- Only use Zuno Smart Sterilization Container lid and base with other Zuno Smart Sterilization Container lids and bases of a compatible model and size.
- Use of nonabsorbent tray liners can cause condensate to pool within the container.

14. Electromagnetic Compatibility and Electrical Safety:

The Zuno Medical Smart Sterilization Container meets the requirements per IEC 60601-1-2 regarding electromagnetic compatibility.

The Z2 Zuno Medical Smart Sterilization Container meets all of the requirements of AMMI/ANSI/IEC 60601-1-2:2014 Medical Electric Equipment – General Requirements for Safety and Essential Performance, EN 61000-3-2:2014 Electromagnetic Compatibility – Part 3: Limits – Section 2: Limits for Harmonic Current Emissions, Equipment Input Current ≤ 16 A per phase), EN6100-3-3:2013 (Electromagnetic compatibility – Part 3: Limits – Section 3: Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection).

DESCRIPTION	Compliance
Conducted RF Emissions, 150 kHz – 30 MHz.	N/A: Device is battery powered.
Radiated RF Emissions, 30 MHz – 1000 MHz.	The device operates below the minimum allowable limit of 50.50 dB μ V/m for a Class A device per IEC 60601-1-2: 2014.
Current Harmonics Emissions.	N/A: Device is battery powered.
Limitation of Voltage Fluctuations and Flicker.	N/A: Device is battery powered.
Direct ESD, Air Discharge, ± 2.0 kV, ± 4.0 kV, ± 6.0 kV, ± 8.0 kV, ± 10.0 kV, ± 12.0 kV and ± 15.0 kV (Insulated surfaces).	Complies with the relevant requirements of IEC 60601-1-2: 2014.
Direct ESD, Contact Discharge, ± 2.0 kV, ± 4.0 kV, ± 6.0 kV and ± 8.0 kV (conductive surfaces).	Complies with the relevant requirements of IEC 60601-1-2: 2014.
Indirect ESD, ± 2.0 kV, ± 4.0 kV, ± 6.0 kV and ± 8.0 kV (horizontal and vertical coupling planes).	Complies with the relevant requirements of IEC 60601-1-2: 2014.
Radiated, Radio-Frequency, Electromagnetic Field Immunity, 80 MHz to 2700 MHz, 3 V/m with an amplitude modulated 1 kHz sine wave at 80%.	Complies with the relevant requirements of IEC 60601-1-2: 2014.
Radiated, Radio-Frequency, Electromagnetic Field Immunity, 385 MHz to 5785 MHz, 28 V/m and 9 V/m with a pulse modulated 18 Hz or 217 Hz square wave at 50%.	Complies with the relevant requirements of IEC 60601-1-2: 2014.
Electrical Fast Transient / Burst Immunity ± 1.0 kV and ± 2.0 kV on AC power lines at 100kHz ± 1.0 kV and ± 2.0 kV on DC power lines at 100kHz. ± 0.5 kV and ± 1.0 kV on signal lines.	N/A: Device is battery powered and does not have I/O ports.
Surge Immunity, AC & DC Inputs ± 0.5 kV and ± 1.0 kV on differential mode, and ± 0.5 kV, ± 1.0 kV and ± 2.0 kV on common mode. ± 1.0 kV and ± 2.0 kV on outdoor signal lines.	N/A: Device is battery powered and does not have I/O ports.
Immunity to Conducted Disturbances, Induced by Radio-Frequency Fields, 0.150 - 80 MHz, 3 Vrms with an amplitude modulated 1 kHz sine wave at 80% on power lines. 6V/m in ISM Bands	N/A: Device is battery powered and does not have I/O ports.
Power Frequency Magnetic Field Immunity, 30 A/m, 50 Hz.	Complies with the relevant requirements of IEC 60601-1-2: 2014.

Voltage Dips, Short Interruptions and Voltage Variations Immunity, 0 % reduction for 0.5 cycle, 0% reduction for 1 cycle, 70 % reduction for 25/30 cycles, and >0% reduction for 250/300 cycles.	N/A: Device is battery powered.
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The Z2 Zuno Medical Smart Sterilization Container meets all the requirements of AMMI/ANSI/IEC 60601-1:2005 Medical Electric Equipment – General Requirements for Basic Safety and Essential Performance.

DESCRIPTION	Compliance
Touch current (Clause 8.7.3)	The device operates below the maximum allowable limit of 100 μ A of IEC 60601-1:2005.
Mechanical strength (Clause 15.3)	Complies with the relevant requirements of IEC 60601-1:2005.
Excessive Temperatures (Clause 11.1)	N/A
Fire Prevention (Clause 11.2)	Complies with the relevant requirements of IEC 60601-1:2005.
Constructional Requirements for Fire Enclosures (Clause 11.3)	Complies with the relevant requirements of IEC 60601-1:2005.
Intended use with flammable anesthetics (Clause 11.4)	Complies with the relevant requirements of IEC 60601-1:2005.
Intended use with flammable agents (Clause 11.5)	Complies with the relevant requirements of IEC 60601-1:2005.
Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization, and compatibility with substances (Clause 11.6)	Complies with the relevant requirements of IEC 60601-1:2005.
Biocompatibility (Clause 11.7)	Complies with the relevant requirements of IEC 60601-1:2005.
Interruption of the power supply (Clause 11.8)	Complies with the relevant requirements of IEC 60601-1:2005.
Dielectric strength (Clause 8.8.3)	N/A
Serviceability (Clause 15.2)	N/A: The device has no user-serviceable parts.
Device Component and General Assembly Safety (Clause 15.4)	The Zuno Medical Smart Sterilization Container complies with the Device Component and General Assembly Safety requirements per IEC 60601-1:2005.