INSTRUSAFE

STERILIZATION CONTAINER SYSTEMS

INSTRUCTIONS FOR USE

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INTRODUCTION

InstruSafe® Sterilization Containers are reusable rigid containers used for the packaging, transportation, and storage of instruments prior to, during, and after sterilization. They consist of various sizes of bottoms and lids.

The InstruSafe Sterilization Container is manufactured using aluminum alloy, stainless steel and silicone. The aluminum surfaces are protected by a layer of anodized aluminum oxide to prevent corrosion.

The purpose of this document is to provide a description of the container components, detailed instructions on how to use, decontaminate, clean, and process InstruSafe Sterilization Containers.

INDICATIONS FOR USE

The InstruSafe Sterilization Container is a reusable sterilization container system intended to be used to enclose medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and also maintain sterility for 365 days. It includes accessories such as trays, baskets, filters, data cards, and tamper proof locks.

The InstruSafe Sterilization Container consists of a validated product line with various models. All models are available with perforated lids and either perforated or solid bottoms. Models are intended to be used with single use paper filters.

The container is a reusable device designed to be used with the following sterilization cycle parameters:

Pre-Vacuum Steam Sterilization Cycle:
Temperature: 132°C (270°F)
Exposure Time: 4 minutes
Minimum Drying Time: 30 minutes

Maximum Loading Weight

Model Number	Description	Maximum Container Load Weight (lbs)	Load Description
CS-1001	One Half (½) Perforated Container Lid	Not Applicable	Metal (stainless steel) surgical instruments like forceps, scissors, clamps, etc. including lumened/cannulated instruments.
CS-1002, CS-1003, CS-1012, CS-1013	One Half (½) Container Bottom	18 lbs	
CS-2001	Three-Quarter (¾) Perforated Container Lid	Not applicable	
CS-2002, CS-2003, CS-2012, CS-2013	Three-Quarter (¾) Container Bottom	25 lbs	
CS-3001	Full (1/1) Perforated Container Lid	Not Applicable	
CS-3002, CS-3003, CS-3004, CS-3005, CS-3012, CS-3013, CS-3014, CS-3015	Full (1/1) Container Bottom	25 lbs	
CS-5001	Extra Large (XL) Perforated Container Lid	Not Applicable	
CS-5002	Extra Large (XL) Container Bottom	25 lbs	

DEVICE DESCRIPTION

Parts of a Sterilization Container

Bottom

Bottoms are made of either perforated or non-perforated aluminum. The handles are made of aluminum, stainless steel, and silicone.

Perforated
Container Bottom

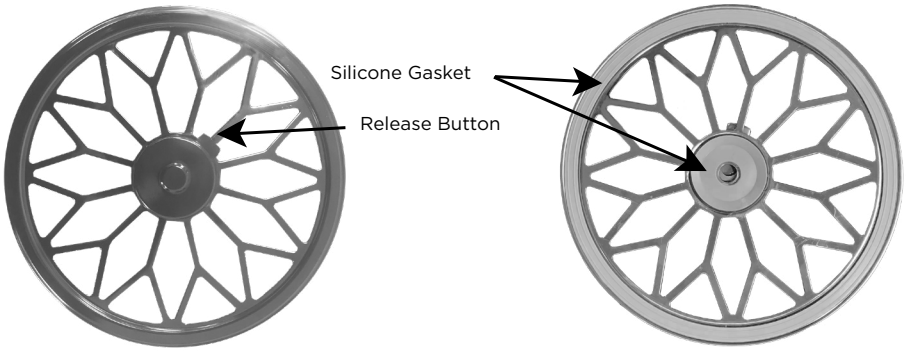
Non-Perforated
Container Bottom

Lid
Lids are perforated and made of aluminum with stainless steel latches and a silicone seal.

Outside
Container Lid

Inside
Container Lid

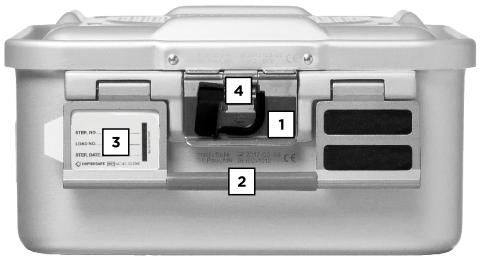
Filter Retention Plate
Filter retention Plates are made of stainless steel and a silicone gasket.



Top View
Filter Retention Plate

Bottom View
Filter Retention Plate

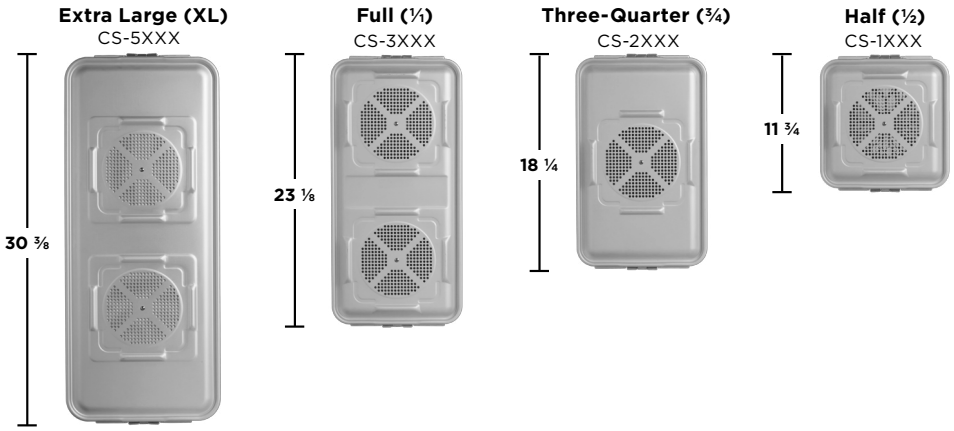
Container
1. Latch
2. Handle
3. Data Card in Holding Bracket
4. Tamper Proof Lock in Locking Channel



Sterilization Container Accessories
The following accessories are used with the container and were included in the testing performed to support substantial equivalence.

Description
InstruSafe Instrument Protection Trays in pre-vacuum steam sterilization.
InstruSafe Baskets in pre-vacuum steam sterilization.
Single use paper filters with process indicator for steam and without process indicator for steam.
Data cards with process indicator for steam.
Polypropylene tamper proof locks with process indicator for steam.

Sterilization Container Length Variations
The containers are available in different models such as full size (1/1), three-quarter size (3/4), half size (1/2) and extra large (XL).
**Reference of all available sizes on page 11.*



CLEANING AND DECONTAMINATION

Follow facility's policies, procedures, and AAMI ST79 recommended guidelines for the transportation of soiled instruments and containers. Always wear appropriate personal protective equipment (PPE) per the healthcare facility's policy and procedures when transporting and cleaning the InstruSafe Sterilization Container System.

DO NOT USE abrasive cleaners, metal brushes or abrasive cleaning pads. Use of abrasive products can cause permanent damage to container surfaces. DO NOT store Container in liquid. Use of abrasive cleaners, pads, storage in liquid, or use of liquid outside the designated range will result in warranty exclusion.

Water Quality
Water quality is an important consideration in all stages of medical device reprocessing and can contribute to providing effective reprocessing and should be monitored by the facility. AAMI TIR34:2014 outlines the different types of water and the specific use of each.

Detergent
Use only neutral (6.0 – 8.5) pH solutions free of sodium carbonate to avoid damaging finish of aluminum container.

Note: *Improper cleaning and disinfection can lead to corrosion and stress cracks. (Therefore, follow the detergent manufacturer's recommendations.)* Refer to AAMI TIR34 for guidance on water used for reprocessing medical devices.

Note: *Clean and inspect the container and lid per the provided instructions prior to placing into service and before each use.*

Preparation for Cleaning
1. Separate the lid and bottom of the container.
2. Remove any devices (trays, baskets, or instruments) from the container.
3. Remove all filter retention plates inside the lid and bottom (in case of perforated bottom containers).
    A. To remove the filter retention plate(s) push inward on the button on the center section of the filter retention plate.
    B. With the button fully depressed the filter retention plate will pop off the post.
4. Discard the disposable filter(s).

Note: *Single-use paper filters should be disposed of after each processing cycle.*

Use only the following validated cleaning options listed below to clean container. Refer to instrument manufacture's instruction for use for cleaning the instrument.

Manual Gross Decontamination Followed by Ultrasonic Cleaning
1. Manual Gross Decontamination
    A. Materials needed: Neutral pH (6.0-8.5) enzymatic detergent, soft bristle brush, running water.
    B. Remove all visible soil and contaminates using a soft bristle brush. The entire container should be immersed while cleaning to aid in the removal of contaminates and to reduce splashing of detergent on personnel for a minimum of 2 minutes.
    C. Rinse thoroughly for a minimum of 1 minute with clean water to remove all detergent. See rinsing instruction on the detergent label.

2. Ultrasonic Cleaning

A. Prepare enzyme wash in an ultrasonic cleaning unit. Place a single container in the detergent and run for a minimum of ten minutes. Rinse for a minimum of 2 minutes with cold tap water.

B. Visually inspect container for contaminates.

C. Repeat the cycle, if necessary, to remove visible contamination.

D. Dry with a lint-free cloth and/or compressed air.

Mechanical Cleaning

1. Automated (Mechanical) Cleaning:

A. The container lid, bottom, and filter retention plates must remain separated from each other while being cleaned.

B. Place the container bottom upside down in the washer/disinfector to avoid the collection of water.

C. Place the inside of the container lid face down in the bottom of the machine with the latching mechanism folded into the inner part of the lid.

D. Place filter retention plates in the washer/disinfector.

E. Based on validation studies, the following cleaning parameters for use with equipment that has been qualified for automated cleaning are recommended:

Cycle	Water Temperature	Cleaning Process
Pre-Wash 1 & 2	Cold Tap Water	Recirculation Time: 2 Minutes
Enzyme Wash	Hot Tap Water	Soaking Time: 4 Minutes
Wash 1	Heated at 65.5˚C	Recirculation Time: 15 Minutes
Rinse 1 & 2	Hot Tap Water	Recirculation Time: 5 Minutes

F. After the automated cleaning cycle is completed, dry with a lint-free cloth and/or compressed air.

After Drying

1. Replace the filter retention plates(s).

A. To replace filter retention plate(s) press down evenly on the center of the filter retention plate and listen for an audible snap confirming it is locked in place.

INSPECTION PRIOR TO USE

InstruSafe Sterilization Containers must be inspected every time before use, including prior to first use, to ensure proper functionality. If the user detects any visible signs of wear, the containers must be removed from service.

Examples of Wear Include:

1. Misalignment of the container lid and bottom
2. Loose filter retention plate(s) or loose filter retention plate pin(s)
3. Filter retention plate silicone gasket(s) should be free of cracks or damage. To inspect, place filter retention plate on a flat surface and check for continuous contact between the gasket and the surface.
4. Dents
5. Cracks
6. Peeling
7. Flaking
8. Burrs or sharp edges
9. Loose or missing rivets
10. Loose handles
11. Bent parts
12. Lid seal damage
    A. Worn seal
    B. Cut/creased seal
    C. Loose/stretched seal
    D. Hardened/degraded seal
    E. Discoloration

PREPARATION AND ASSEMBLY

WARNING DO NOT load the container in a manner where instruments are positioned in a way that can poke, tear, or damage the filter(s) either in the top or bottom of the container. A punctured filter will compromise the sterile barrier.

WARNING Only original InstruSafe components such as lids, bottoms, and filter retention plates should be used together so the container functionality is not compromised.

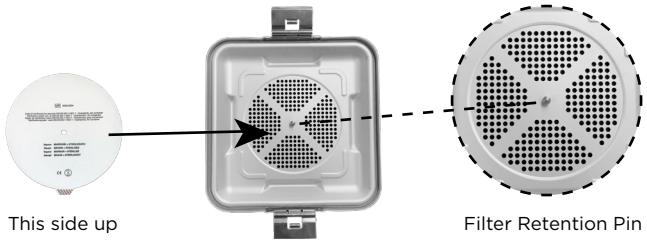
For more details on InstruSafe Protection Trays visit the InstruSafe website, www.instrusafe.com.

Confirm container components are dry.

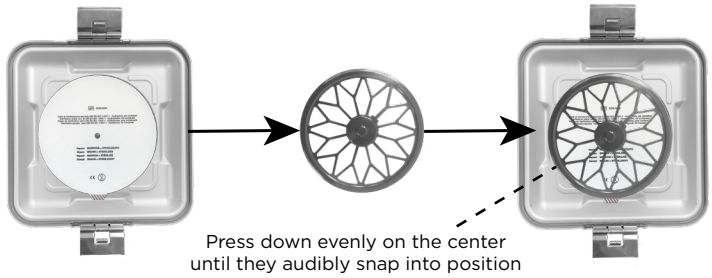
Internal Process Indicators: Refer to AAMI ST79 and the facility's operating procedures for use of indicators.

Single Use Paper Filters

1. Always use a new filter for every use.
2. Use legally marketed single use paper filters only.
3. Use only one filter with each filter retention plate.
4. Check each filter to confirm there are no visible holes in the filter.
5. Install filter over filter retention pin with text and/or process indicator for steam visible from inside the container.



6. After placing the filters over the perforated areas on the inside of the lid and on the bottom of the container, (if applicable) the filter retention plate(s) have to be pressed down evenly on the center until they audibly **SNAP** into position.



Note: *If the filter retention plate is not properly attached to the filter retention pin, the filter retention plate can come loose during processing. A filter retention plate that is not securely attached to the filter retention pin will compromise the sterile barrier.*

7. InstruSafe lids should only be assembled with InstruSafe filter retention plates.

Loading

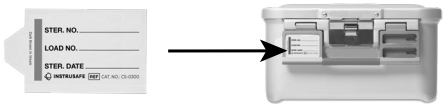
Per AAMI ST79, the overall weight for loaded containers should not exceed 25 pounds. Please reference the Maximum Loading Weight Table on page 3 or Appenix A on page 11.

Always attach the lid to the bottom via the latching mechanism before placing the container in the sterilizer otherwise the content of the container will become unsterile as soon as the sterilizer door is opened.

Note: *The maximum number of lumens/lumen configurations is as follows: 2 lumens with ≥ 1mm I.D. x ≤ 200mm and a second lumen ≥ 5mm I.D. x ≤ 400mm.*

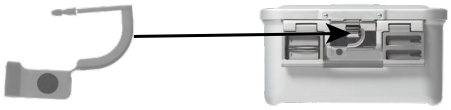
External Process Indicators (data cards) and Tamper Proof Seals (locks)
Per AAMI ST79, external data cards are used to indicate that the container has been exposed to the sterilization process and to distinguish between processed and unprocessed containers. Use of data cards should be in accordance with the facility's operating procedures. The tamper proof seals indicate if the container has been opened.

Data Cards
1. Inspect for damage (no rips).
2. Data cards can be inserted into the holding bracket on the outside of the container. For easy installation and removal of data card, use your thumb to depress the spring while sliding the card.



Data cards will turn brown/dark brown when exposed to a prevacuum steam cycle (270° F, 4 minutes). Data cards are single-use only.

Tamper Proof Locks
1. Inspect for damage (broken).
2. Tamper proof locks are inserted into the locking channel on the latch on each end of the container.



3. Secure and close the tamper proof lock.

If the lock has a chemical indicator, it will turn brown/dark brown when exposed to a prevacuum steam cycle (270° F, 4 minutes). Locks are single-use only.

STERILIZATION

PRECAUTIONS

Store accessories in a controlled room temperature environment in the original packaging.

Never wrap the container in any kind of outer packaging. Never cover the perforated area of the container with any sterilization packaging, as this will block the flow of steam through the perforation. The result of this is vacuum damage due to insufficient pressure venting and the container contents will not be sterilized.

DO NOT use if the indicator dot has changed to brown/dark brown before being processed.

Complex instruments like endoscopes, instruments with a lumen, compressed air-driven instruments, power systems, and instruments with cannulas are to be prepared according to the manufacturer's instructions for reprocessing and to be sterilized accordingly.

InstruSafe Container Systems are **NOT** to be stacked during sterilization.

Follow the time and temperature listed below for the sterilization cycle.
Pre-Vacuum Steam Sterilization Cycle:
Temperature: 132°C (270°F)
Exposure Time: 4 minutes
Minimum Drying Time: 30 minutes

To minimize condensation inside the container, leave the container on a container cart until it is cool enough to handle. Refer to AAMI ST79 for details.

After sterilization, always observe indicators and verify that the container latch remains closed.

Wet filters or visible moisture within a load may compromise the sterile barrier and container contents should not be considered sterile when removed from the sterilizer.

During loading and unloading of the sterilizer and during transport, the sterilization container should always be carried by the handles and never by the lid.

STORAGE

InstruSafe Container Systems can be stacked 3 units high.

All models were tested in sufficient conditions per ANSI/AAMI ST79 and ASHRAE.

All models were tested to allow sterilization of the enclosed device and maintain sterility for 365 days.

DO NOT use beyond expiration date.

Processed container systems should be stored in a dry, clean, and protected place. Loss of sterility is typically due to external influences, not storage periods. Therefore, a general statement cannot be made regarding appropriate storage periods, reference EN ISO 11607-1, ANSI/AAMI ST79 and DIN 58953-8.

ASEPTIC PRESENTATION

Hospital procedures and AORN guidelines should always be followed when using and presenting InstruSafe Sterilization Containers.

MAINTENANCE

1. Lid seal should not be treated with spray oils or solvents. To clean and maintain, simply wipe off with a damp cloth.
2. If any damage to the container or its components are noticed, the container should be removed from service.
3. For replacement, use the contact information in the attached warranty (See page 10).

VALIDATION

Sterilization containers are classified by the FDA as Class II devices and therefore require validation testing in order to be cleared for marketing and sale. In order to ensure sterile safety, tests were carried out by an independent and accredited test laboratory. The purpose of these trials were to validate a sterilization process for the reusable InstruSafe Sterilization Container for the following pre-vacuum steam sterilization cycle. InstruSafe Sterilization Containers have been tested for:

- Sterilization efficacy
- Dry time
- Reprocessing validation and verification
- Sterility maintenance

CUSTOMER VERIFICATION

Validation and verification are different. InstruSafe Sterilization Containers are validated according to the FDA guidelines. Validation parameters are cleared by the FDA and are the basis for the parameters recommended in this IFU.

The customer is responsible for verifying the performance in their application.

Refer to AAMI ST79 for verification guidance.

Refer to the FDA 510(k) clearance chart on www.instrusafe.com for clearances for InstruSafe Products.

A full list of validations and intended uses can be found at www.instrusafe.com.

REFERENCES

1. AAMI ST79. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities.
2. AAMI TIR34 Water for the reprocessing of medical devices.
3. AAMI ST77 Containment devices for reusable medical device sterilization.
4. AORN Guidance Documents.

WARRANTY

LIMITED WARRANTY FOR SUMMIT MEDICAL INSTRUSAFE STERILIZATION CONTAINERS.

THIS LIMITED WARRANTY AND THE REMEDY PROVIDED HEREIN ARE EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS WARRANTIES AND, UNLESS STATED HEREIN, ANY STATEMENTS OR REPRESENTATIONS MADE BY ANY OTHER PERSON OR FIRM ARE VOID. THE DURATION OF ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE SHALL BE LIMITED TO THE DURATION OF THE EXPRESS LIMITED WARRANTY. NEITHER SUMMIT MEDICAL. NOR ITS AFFILIATES SHALL BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL LOSSES OR DAMAGES RESULTING FROM THE USE OR INABILITY TO USE THE INSTRUSAFE STERILIZATION CONTAINERS, WHETHER RESULTING FROM BREACH OF WARRANTY OR ANY OTHER LEGAL THEORY.

This Limited Warranty gives you specific legal rights and you may also have other rights which vary from state to state. Some states do not allow limitations on how long an implied warranty lasts or do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusions may not apply to you.

What Is Covered. Summit Medical warrants the original purchaser that the InstruSafe Sterilization Container enclosed with this Limited Warranty conforms to the manufacturer's specifications and is free from defects in workmanship and material for a period of 12 months from the date of original purchase. If the original purchaser transfers the InstruSafe Sterilization Container to another party, this Limited Warranty will not be enforceable by the party to whom the product is transferred.

What We Will Do To Correct Problems. Should your InstruSafe Sterilization Container prove defective during this period, you must notify Summit Medical or an authorized distributor or dealer of Summit Medical. You must permit Summit Medical or its representatives to make such investigation, examination and tests as Summit Medical deems appropriate and, if requested to do so, you will return the product to the factory at the address set forth below. Summit Medical's sole obligation under this Limited Warranty is, at its option, to replace the defective product or products without charge for parts or labor. Postage, insurance or shipping costs incurred in presenting your InstruSafe Sterilization Container for warranty service are your responsibility.

What Is Not Covered. This Limited Warranty is contingent upon proper use and maintenance of the product; it does not cover products that have been improperly shipped, that have been misused, abused, neglected, or improperly maintained, cleaned or stored, or that have been serviced other than by Summit Medical or an authorized distributor or dealer of Summit Medical, or that have been modified without the express approval of Summit Medical. Failure to follow the directions in the owner's manual may constitute improper use or maintenance of the product and causes this Limited Warranty not to apply. This Warranty does not extend to normal wear or to replacement items.

If you have questions or claims related to this warranty, contact:
Customer Service Department
Summit Medical
815 Vikings Parkway, Suite 100
St. Paul, MN 55121 | USA
www.instrusafe.com

PHONE: 651.789.3939 | 888.229.2875
FAX: 651.789.3979 | 888.229.1941
EMAIL: customerservice@innoviamedical.com

APPENDIX A

Containers are available with perforated lids and either perforated or solid bottoms. The containers are available in different models such as full size (1/1), three-quarter size (3/4), half size (1/2) and extra large (XL).

Model Number	Description	Standard Dimension Outside With Lid L x W x H in inches	Total Container Loaded Maximum Weight (lbs.)
CS-1001	One Half (½) Perforated Container Lid	11 ¾ L x 11 W x 1 ¼ H	Not Applicable
CS-1002	One Half (½) Solid Container Bottom	11 ¾ L x 11 W x 4 ⅛ H	18 lbs
CS-1003	One Half (½) Solid Container Bottom	11 ¾ L x 11 W x 5 ⅝ H	18 lbs
CS-1012	One Half (½) Perforated Container Bottom	11 ¾ L x 11 W x 4 ⅛ H	18 lbs
CS-1013	One Half (½) Perforated Container Bottom	11 ¾ L x 11 W x 5 ⅝ H	18 lbs
CS-2001	Three Quarter (¾) Perforated Container Lid	18 ¼ L x 11 W x 1 ¼ H	Not Applicable
CS-2002	Three Quarter (¾) Solid Container Bottom	18 ¼ L x 11 W x 4 ⅛ H	25 lbs
CS-2003	Three Quarter (¾) Solid Container Bottom	18 ¼ L x 11 W x 5 ⅝ H	25 lbs
CS-2012	Three Quarter (¾) Perforated Container Bottom	18 ¼ L x 11 W x 4 ⅛ H	25 lbs
CS-2013	Three Quarter (¾) Perforated Container Bottom	18 ¼ L x 11 W x 5 ⅝ H	25 lbs
CS-3001	Full (1/1) Perforated Container Lid	23 ⅛ L x 11 W x 1 ¼ H	Not Applicable
CS-3002	Full (1/1) Solid Container Bottom	23 ⅛ L x 11 W x 4 ⅛ H	25 lbs
CS-3003	Full (1/1) Solid Container Bottom	23 ⅛ L x 11 W x 5 ⅝ H	25 lbs
CS-3004	Full (1/1) Solid Container Bottom	23 ⅛ L x 11 W x 8 ¼ H	25 lbs
CS-3005	Full (1/1) Solid Container Bottom	23 ⅛ L x 11 W x 10 ⅜ H	25 lbs
CS-3012	Full (1/1) Perforated Container Bottom	23 ⅛ L x 11 W x 4 ⅛ H	25 lbs
CS-3013	Full (1/1) Perforated Container Bottom	23 ⅛ L x 11 W x 5 ⅝ H	25 lbs
CS-3014	Full (1/1) Perforated Container Bottom	23 ⅛ L x 11 W x 8 ¼ H	25 lbs
CS-3015	Full (1/1) Perforated Container Bottom	23 ⅛ L x 11 W x 10 ⅜ H	25 lbs
CS-5001	Extra Large (XL) Perforated Container Lid	30 ⅜ L x 12 ⅜ W x 1 ¼ H	Not Applicable
CS-5002	Extra Large (XL) Perforated Container Bottom	30 ⅜ L x 12 ⅜ W x 7 ⅝ H	25 lbs

SYMBOL REFERENCE KEY	
	Consult instructions for use
	Quantity
	Catalogue number
	Lot number
	Country of Manufacture (Made in the US)
	Non-sterile
	Caution
	Medical Device
	Unique Device Identifier
	Do Not Use if Package is Damaged and Consult Instructions for Use
	Manufacturer
Not made with natural rubber latex	

AN INNOVIA MEDICAL COMPANY

Summit Medical LLC
815 Vikings Parkway, Suite 100
St. Paul, MN 55121 | USA

P: 1-888-229-2875 | +1 651-789-3939
F: 1-888-229-1941 | +1 651-789-3979
www.summitmedicalusa.com

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