CHASE MEDICAL

EN **INSTRUMENT PROTECTION SYSTEMS** INSTRUCTIONS FOR USE

For the full instructions for use visit:

www.instrusafe.com/ifus

EN Request a printed instructions for use manual at no cost that arrives within 7 days of request confirmation.

summitmedicalusa.com/contact/

If you have any questions, please contact our customer service representatives at **1.888.229.2875**.

EN

The instructions provided within have been validated by the device manufacturer as being capable of reprocessing reusable medical devices.

Individual sterilizers, instrument cleanliness, specific loading of instrument trays, types and geometry of instruments, sterilization containers, filters, and wrappings vary at each location.

READ THIS SECTION BEFORE PLACING PRODUCT INTO SERVICE

INTENDED USE/INDICATIONS FOR USE SUMMARY

The Instrument Protection Systems cassettes/trays are intended to contain and protect reusable medical devices during transport, sterilization, and storage. Instrument Protection System cassettes/trays are used to organize and protect other medical devices that are sterilized by a healthcare provider. Instrument Protection System cassettes/trays are intended to allow sterilization of the enclosed medical devices during these sterilization cycles:

- Pre-Vacuum Steam (ISO 17665-1 and EN 285)
- Ethylene Oxide (ISO 11135)
- Validated Low Temperature Sterilization, (ISO 14937) i.e.
  - STERRAD® 100S Standard (short)
  - STERRAD® 100NX® Express, Standard, and Flex
  - STERRAD® NX® Standard
  - STERIS® AMSCO® V-PRO 1®, V-PRO 1 Plus, V-PRO maX and V-PRO maX 2
  - Sterizone® VP4

The Instrument Protection System cassettes/trays are not intended on their own to maintain sterility. The Instrument Protection System cassettes/trays are intended to be used in conjunction with a legally marketed wrap, Aesculap® rigid containers, or Genesis™ rigid containers.

InstruSafe Sterilization Containers have been validated for use with Instrument Protection System cassettes/trays, (pre-vacuum, 270° F (132°C), 4-minute steam sterilization cycle only) under 510(k) K180528. Refer to the InstruSafe® Sterilization Container instructions for use for further information.

A full list of device models is provided in Appendix A, which can be viewed at www.instrusafe.com/ifus.

DEVICE DESCRIPTION

Summit Medical InstruSafe Instrument Protection Systems are cassettes/trays used to enclose and hold surgical instruments and instrument accessories in an organized manner during the sterilization process and subsequent storage and transportation. The cassettes/trays do not have direct patient contact. The cassettes/trays by themselves do not maintain sterility. The cassettes/trays are different sizes of the same basic configuration: a rectangular base with latchable cover. The cassettes/trays have perforations to allow sterilant penetration.
The cassettes/trays contain silicone inserts in the base and/or cover to hold, organize, and protect the surgical instruments within the cassette/tray during the sterilization process and subsequent storage and transportation.

INTENDED USER

The Instrument Protection Systems are intended to be used by healthcare professionals in the operating room and sterile processing department for transportation, sterilization, and storage of medical devices.

LIMITATION ON PROCESSING

1. The end of useful life on the Instrument Protection System is a minimum of 25 sterilization cycles. Inspect the tray before use for wear and damage caused by use. Discontinue use if visible signs of wear are present, including corrosion, mechanical failures, cracking, peeling, flaking, broken welds, damaged feet, damaged latches, damaged Hold-Its®/Hold-Downs, discoloration, etc.
2. See **Table 2** for sterilization methods and configurations.
3. **DO NOT OVERLOAD** Systems or components.
4. **DO NOT OVERLOAD** individual Hold-Its slots. Load only one instrument per Hold-Its slot.
5. For rigid container users, **DO NOT WRAP** Systems or components and place inside of container for sterilization.
6. Inside of sterilizers, **DO NOT STACK** individually wrapped or containerized Systems or components. Separate wrapped or containerized Systems or components from each other or any other items on separate shelves of the sterilizer to allow for maximum sterilant flow.
7. The use of non absorbent tray liners (e.g. silicone fingered organizing mat) can cause condensate to pool. If visible moisture is present, re-sterilize with a longer dry time.
8. The total weight of the container system (e.g. container, tray, and instrument load) must not exceed 25 pounds (11.34 kg).
9. Instruments (e.g. endoscopes and instruments with lumens or channels) should be prepared and sterilized according to the instrument manufacturer's instructions.
10. It is the responsibility of the processor to maintain specific validations for the terminal sterilization process being applied to the configurations of instruments and containers being presented to the sterilization process.
11. Consult sterilizer manufacturer's instructions for use for additional limitations (e.g. dimensional or weight constraints).

WARNINGS

- For aluminum Systems, use only neutral pH (6.0 – 8.5) detergents to avoid damaging the finish. A detergent with a highly acidic or highly alkaline pH could permanently damage the anodized aluminum finish of the cassette and metal components.
- Do not use if package is damaged or unintentionally opened prior to use.

Note: Clean and inspect cassettes according to the instructions provided prior to placing into service.

UNIVERSAL PRECAUTIONS

- Personnel should wear all personal protective clothing and equipment as required by their employer's/department's operating procedures for the contamination level they will be exposed to.
- Keep dissimilar metals separated during sterilization to prevent corrosion.

POINT OF USE

Remove gross soil with disposable cloth/paper wipe. Contaminated components should be kept moist until qualified cleaning processes can be applied.

CLEANING

Refer to the instrument manufacturer's instructions for use for specific instructions for cleaning the instruments in the cassettes.

Use one of the following validated cleaning options to clean the cassette/tray is recommended.

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

DO NOT use scouring pads or abrasive cleaners. **DO NOT** store cassette in liquid.

1. Manual Gross Decontamination:

A. Materials needed: Neutral pH (6.0 – 8.5) enzymatic detergent, soft bristle brush, and running water.
B. Remove all visible soil and contaminates using a soft bristle brush. The entire cassette 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 instructions on the detergent label.

2. Ultrasonic Clean:

A. Prepare enzyme wash in an ultrasonic cleaning unit.
B. Place a single cassette in the detergent and run for a minimum of ten minutes.
C. Rinse for a minimum of 2 minutes with cold tap water.
D. Visually inspect cassette for contaminates. Repeat the cycle if necessary to remove visible contamination.

3. Automated Washer:

The Instrument Protection Systems have been validated for the automatic wash system cycle listed in **Table 1**.
Qualification of specific parameters will need to be conducted by the processor.

Table 1

CYCLE	WATER TEMPERATURE	CLEANING PROCESS
Pre-Wash 1 & 2	Cold Tap Water	Re-Circulation Time: 2 Minutes
Enzyme Wash	Hot Tap Water	Soaking Time: 4 Minutes
Wash 1	Heated at 150°F (65.5°C)	Re-Circulation Time: 15 Minutes
Rinse 1 & 2	Hot Tap Water	Re-Circulation Time: 5 Minutes

Note: *After completion of an automatic wash cycle, visually inspect the System (cassette and accessories) for any remaining visible soil. All visible soil must be removed by hand cleaning, brushing, ultrasonic, or additional automatic cycles prior to sending to sterilization.*

DISINFECTION

Systems are intended to be terminally sterilized.

MAINTENANCE, INSPECTION, AND TESTING

Systems may be reused until unacceptable deterioration such as corrosion, cracking, rust, peeling, flaking, discoloration, or mechanical failure occurs.

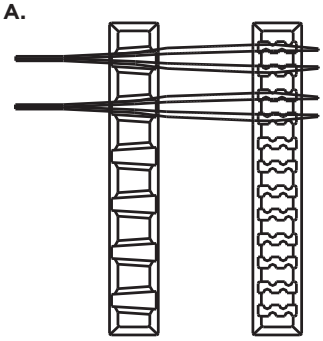
Signs of Mechanical Failure Include:

- Broken or cracked corners or welds
- Broken or non-working latches
- Missing, torn, or cut silicone inserts
- Missing or damaged feet

ASSEMBLY

1. Place the instruments in the predetermined holders or area defined by the locating posts so that all instrument surfaces will be exposed to sterilant. See **Figure A**. Be sure that only one instrument is in each slot. When possible, disassemble or open all parts of the instrumentation per the instrument manufacturer's instructions.
   DO NOT overload holders or exceed weight limits of cassettes. See Appendix A.

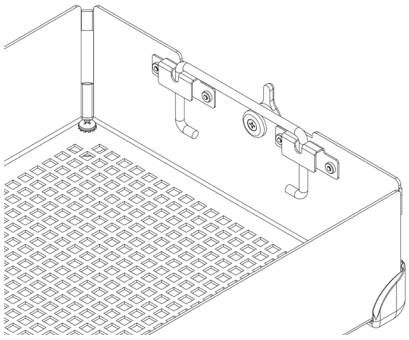
Figure A.



Note: *Instruments (e.g. endoscopes and instruments with lumens or channels) should be prepared and sterilized according to the instrument manufacturer's instructions for use.*

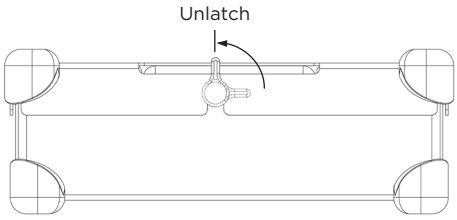
2. Ensure that handles are positioned inside the cassette (retracted position). Shown in **Figure B**.

Figure B.



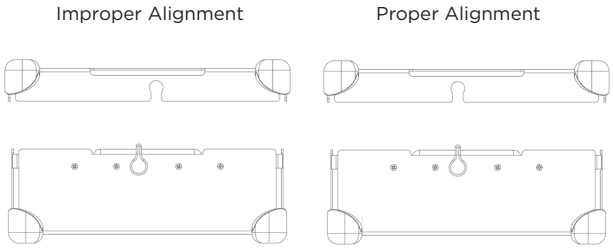
3. Place the cassette cover on the cassette base ensuring that the latches are properly positioned with the latch slot on the cassette cover, then close the latches. See **Figure C**.

Figure C.



Note: *The latches are offset so that the cassette cover always aligns properly with the base. This ensures that the holders are aligned when the cover is secured. See* ***Figure D*** *for proper alignment.*
DO NOT force the cassette cover onto the cassette base as it may damage instruments and the cassette.

Figure D.



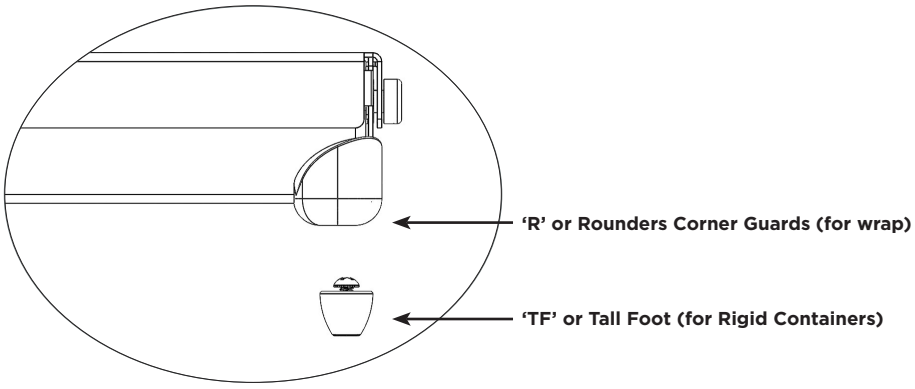
PACKAGING

Systems may be wrapped with a legally marketed wrap or placed in a legally marketed rigid container. Refer to the Indications for Use statements found in the instructions for use.

Using with Wrap:

1. Before wrapping the cassette, ensure it has the proper foot style. R should be used with wrap. See **Figure F**.

Figure F.



2. Wrap the cassette using legally marketed wrap per the wrap manufacturer's instructions.

3. Sterilize the pack using one of the sterilization cycles listed in the instructions for use.

Using with Rigid Container:

Refer to the Indications for Use statements found in the instructions for use.

1. Before placing the cassette in a rigid container ensure it has the proper foot style. TF should be used with a rigid container. See **Figure F**.

2. Place the cassette into the rigid container. Follow the container manufacturer's instructions for sealing the container.
   Note: *Do not wrap the cassettes before placing into the container for sterilization.*

3. Sterilize the container and contents using one of the sterilization cycles listed in the instructions for use.

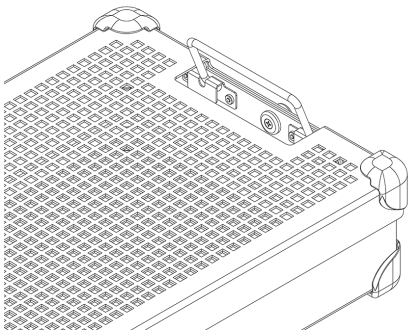
Additional Information:

To remove the cassette from a rigid container aseptically, follow container manufacturer's instructions for use.

1. With gloved hands, place palms outward and reach through the openings in the cassette cover.

2. Grasp the cassette handles and lift to their raised position. See **Figure G**.

Figure G.



3. Tilt the handles inward, away from the sides of the rigid container, and lift the cassette out of the container being careful to not touch the top or outside of the container.

4. Place cassette on a sterile surface.

STERILIZATION

See **Table 2** for sterilization parameters that have been qualified for the sterilization of Systems.

Table 2.

STERILIZATION METHOD	CYCLE *(times)*
Pre-Vacuum Steam	**Parameter:** Temperature 270°F (132°C) Expose Time 4 minutes Dry Time 30 minutes
Ethylene Oxide (EO)	**Preconditioning:** Temperature 131°F (55°C) Relative humidity 70 ± 15% Precondition time 1 hour **Sterilization:** Exposure time 120 minutes Temperature 131°F (55°C) Aeration time 12 hours
STERRAD 100S	*Standard*
STERRAD 100NX	*Standard, Express, Flex*
STERRAD NX	*Standard*
STERIS AMSCO V-PRO 1	*Standard*
STERIS AMSCO V-PRO 1 PLUS	*Lumen, Non-Lumen*
STERIS AMSCO V-PRO maX	*Lumen, Non-Lumen*
STERIS AMSCO V-PRO maX 2	*Lumen, Non-Lumen*
Sterizone VP4	*Cycle 1*

Summit Medical has validated the following sterilization methods:

- The 4 minute autoclave sterilization cycle in legally marketed wrap, InstruSafe Sterilization Container, Aesculap rigid container, or Genesis rigid container cleared by the FDA. Under K180528, the InstruSafe Sterilization Container was validated for use with the Instrument Protection System cassettes/trays.
- The Ethylene Oxide (EO) sterilization cycle in legally marketed wrap or a Genesis sterile container cleared by the FDA.
- The STERRAD 100S Standard sterilization cycle in legally marketed wrap or an Aesculap rigid container cleared by the FDA.
- The STERRAD 100NX Standard sterilization cycle in legally marketed wrap or an Aesculap rigid container cleared by the FDA.
- The STERRAD 100NX Express sterilization cycle in legally marketed wrap cleared by the FDA.
- The STERRAD 100NX Flex sterilization cycle in legally marketed wrap or an Aesculap rigid container cleared by the FDA.
- The STERRAD NX Standard sterilization cycle in legally marketed wrap or an Aesculap rigid container cleared by the FDA.
- The STERIS AMSCO V-PRO 1, V-PRO 1 PLUS, V-PRO maX and V-PRO maX 2 sterilization cycles in legally marketed wrap or an Aesculap rigid container cleared by the FDA.
- The Sterizone VP4 sterilization cycle in legally marketed wrap or an Aesculap rigid container cleared by the FDA

DO NOT exceed the load capacity of the sterile container as specified by the manufacturer.

Use an FDA cleared accessory to maintain sterility.

Please consult the sterilizer instruction manual to ensure intended loads are compatible with the intended sterilization cycle.

Please consult the container instructions for use to ensure that the intended load is compatible with the FDA cleared loads for the container.

INDICATIONS FOR USE

4 Minute Steam, Wrap & Aesculap® Rigid Container

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a pre-vacuum steam sterilization cycle. The InstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap or Aesculap rigid container. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility.

Autoclave Sterilization Parameter	
Cycle	Pre-Vacuum
Temperature	270°F (132°C)
Exposure Time	4 minutes
Minimum Dry Time	30 minutes
Summit Cassette Model	**Aesculap Container Model**
IN-8823-AE	*JN444
IN-2880	*JK444
IN-6105	*JN742

**Validated by Summit Medical for use in Pre-Vacuum Steam sterilizers ONLY operating at 270°F (132°C) for 4 minutes exposure time. Consult container instructions to ensure that contents do not exceed the sterilization container's intended load claims.*

Lumen Claims for 4 Minute Pre-Vacuum Steam Sterilization Cylcle			
Summit Cassette Model	**Minimum Inside Diameter**	**Maximum Length**	**Number of Lumens**
IN-8823-CF	3mm	400mm	4
IN-8823-CF	3mm	200mm	2
IN-2880	1mm	76mm	2
IN-2880	3mm	177mm	1
IN-6105	5mm	241mm	1
IN-2681	1mm	65mm	1
IN-2681	3mm	200mm	1
IN-7823	1mm	400mm	17

4 Minute Steam, Genesis™ Rigid Container

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a pre-vacuum steam sterilization cycle. The InstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed Genesis rigid containers. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility. A full list of device models is provided in Appendix A.

Lumen Claims for 4 Minute Pre-Vacuum Steam Sterilization Cylcle			
Summit Cassette Model	**Minimum Inside Diameter**	**Maximum Length**	**Number of Lumens**
IN-2681	1mm	65mm	1
IN-2681	3mm	200mm	1
IN-6105	5mm	241mm	1
IN-0000	1mm	400mm	5
	3mm	400mm	1
	5mm	400mm	1

INDICATIONS FOR USE (continued)

8 Minute Steam & Ethylene Oxide (EO), Wrap & Genesis™ Rigid Container

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe System cassettes are intended to allow sterilization of the enclosed medical devices during Pre-Vacuum steam or ethylene oxide sterilization cycles. The InstruSafe System cassettes are intended to be used in conjunction with central legally marketed wrap or with a Genesis rigid container. The InstruSafe System cassettes are not intended on the own to maintain sterility.

Sterilization methods and configurations

Steam 8 Minute Preconditioning at 132°C	
140 count woven wrap	10 minute dry time
Non-woven wrap (Kimberly Clark)	50 minute dry time
Genesis Container (reference Table 1 for filter paper to use)	30 minute dry time

Ethylene Oxide (EO)
▪ 1 hour preconditioning at 131°F (55°C) with relative Humidity of 70 ± 15% ▪ 2 hours exposure at 131°F (55°C) ▪ 12 hours aeration

Genesis Container	Genesis Container Filter Paper
CD2-4B	FX3-1: 9x9″
CD2-5B	FX3-1: 9x9″
CD3-4B	FX3-1: 9x9″
CD3-5B	FX3-1: 9x9″
CD3-6B	FX3-1: 9x9″
CD3-7B	FX3-1: 9x9″
CD4-5B	FO3-2: 9x6″
CD5-61B	FO3-2: 9x6″
CD6-6B	FX3-1: 9x9″

See V. Mueller Genesis Sterilizer Container system User's Operating Instructions when using any Genesis Rigid Container.

STERRAD® 100S & STERRAD® 100NX® Standard Cycles, Wrap & Aesculap® Rigid Container

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a Sterrad 100S Standard and Sterrad 100NX Standard sterilization cycles. The InstruSafe Instrument Protection System cassettes are intended to be used in conjunction with legally marketed wrap or Aesculap rigid container. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility. A full list of device models is provided in Appendix A.

The following sterilization trays were validated with the corresponding rigid containers:

STERRAD 100S Standard Cycle	
Summit Cassette Model	**Aesculap Container Model**
IN-8823-AE	*JM444
IN-6105	*JM440

STERRAD 100NX Standard Cycle	
Summit Cassette Model	**Aesculap Container Model**
IN-8823-AE	*JM444
IN-6105	*JM440

**Validated by Summit Medical for use in STERRAD 100S Standard Cycle and STERRAD 100NX Standard Cycle ONLY. Consult container instructions to ensure that contents do not exceed the sterilization container's intended load claims.*

Lumen Claims for STERRAD 100S Standard and STERRAD 100NX Standard Cycles	
4 Stainless steel lumens with 3mm inner diameter x 400mm length	All appropriately sized models are listed in Appendix A with the exception of IN-2681.
2 Stainless steel lumens with 3mm inner diameter x 200mm length	
1 Stainless steel lumens with 3mm inner diameter x 200mm length	IN-2681
1 Stainless steel lumens with 1mm inner diameter x 65mm length	

INDICATIONS FOR USE (continued)

STERRAD® NX® Standard Cycle, Wrap & Aesculap® Rigid Container

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a Sterrad NX Standard Sterilization Cycle. The InstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap or Aesculap rigid container. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility. A full list of device models is provided in Appendix A.

Sterilization Methods and configurations
- Sterrad NX Standard Sterilization Cycle

Lumen Claims for STERRAD NX Standard Sterilization Cycle			
Summit Cassette Model	**Minimum Inside Diameter**	**Maximum Length**	**Number of Lumens**
IN-2681	1mm	65mm	1
IN-2681	3mm	200mm	1
IN-8987-S	1mm	500mm	5
IN-8615	2.3mm	210mm	5
IN-6105	4mm	235mm	1
Note: *The worst case validated load based on vent-to-volume calculation is the IN-2681 tray.*			

STERRAD® 100NX® Express Cycle, Wrap

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a Sterrad® 100NX Express Cycle. The InstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility. The InstruSafe Instrument Protection System has no lumen claims for the Sterrad 100NX Express Cycle.

STERRAD® 100NX® Flex Sterilization Cycle, Wrap & Aesculap® Rigid Container

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a Sterrad 100NX Flex Sterilization Cycle. The InstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap or Aesculap rigid container. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility. A full list of device models is provided in Appendix A.

STERRAD 100NX Flex Sterilization Cycle	
Summit Cassette Model	**Aesculap Container Model**
IN-0000	*JM440
IN-6105	*JM440
**Validated by Summit Medical for use in STERRAD 100NX Flex Sterilization Cycle ONLY. Consult container instructions to ensure that contents do not exceed the sterilization container's intended load claims.*	

Lumen Claims for STERRAD 100NX Flex Sterilization Cycle				
Summit Cassette Model	**Minimum Inside Diameter**	**Maximum Length**	**Number of Lumens**	**Wrap/Rigid Container**
IN-0000	1mm	850mm	1	Wrap + Rigid Container
IN-8823	1mm	850mm	1	Wrap + Rigid Container
IN-7344	1mm	850mm	1	Wrap
IN-6105	4mm	235mm	1	Wrap + Rigid Container

The worst case validated load based on vent-to-volume calculation is the IN-0000 tray.

Note: *The IN-0000 tray is for testing purposes only.*

INDICATIONS FOR USE (continued)

AMSCO® V-PRO® Low Temperature Sterilization Cycles, Wrap & Aesculap® Rigid Container

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during Amsco V-PRO Low Temperature Sterilization Cycles. The InstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap or Aesculap rigid container. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility. A full list of device models is provided in Appendix A.

AMSCO V-PRO Low Temperature Sterilization Systems			
Sterilizer	**Standard Cycle**	**Lumen Cycle**	**Non Lumen Cycle**
V-PRO 1	X	N/A	N/A
V-PRO 1 PLUS	N/A	X	X
V-PRO maX	N/A	X	X
V-PRO maX 2	N/A	X	X
Summit Cassette Model		**Aesculap Container Model**	
IN-8823		*JM444	
IN-6105		*JM742	

**Validated by Summit Medical for use in AMSCO V-PRO Low Temperature Sterilization Systems ONLY. When using Aesculap container as sterile barrier, the load (Summit tray and contents), should not exceed the load claims for the container is weight or load type.*

Lumen size of instrumentation validated includes:			
Summit Cassette Model	**Minimum Inside Diameter**	**Maximum Length**	**Number of Lumens**
IN-8823	3mm	400mm	2
IN-6105	3mm	200mm	1
IN-2681	1mm	64mm	1

Note: *The worst case validated load based on vent-to-volume calculation is the IN-2681 tray.*

INDICATIONS FOR USE (continued)

VP4 Sterizone, Wrap & Aesculap® Rigid Container

InstruSafe® Instrument Protection System cassettes (trays) are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during STERIZONE VP4 sterilization Cycle 1. The InstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap or Aesculap rigid container. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility.

Summit Medical has validated the use of the InstruSafe Instrument Protection System cassettes in Cycle 1 of the STERIZONE VP4 sterilizer through demonstrations of sterilization efficacy using representative samples of medical devices including general instruments, rigid and semi-rigid instruments with lumens, and flexible endoscopes. The validation provided information that has been used to establish design limits that are applied across the range of InstruSafe Instrument Protection System cassettes to ensure that all models fall within the validated limits for cassette ventilation, internal shelving, and weight:

- Minimum ventilation-to-volume ratio, general instruments: 0.073
- Minimum ventilation-to-volume ratio, flexible endoscopes: 0.263
- Maximum number of internal shelves: Two (2)
- Maximum cassette weight (including contents): 25 lbs/cassette

Refer to the table below for the validated loads using InstruSafe Instrument Protection System cassettes. Refer to the sterilizer manufacturer's instructions for use to ensure that loads do not exceed the claimed limits for the sterilizer.

Description of InstruSafe Instrument Protect System Loads.

Representative of STERIZONE® VP4 Sterilizer Validation Load No. (K190260)	Summit Medical Validation Load Description	Total Load Weight (excludes the 25-lbs. loading rack)
4	**Load 4a:** Consisted of the load limit for rigid and semi-rigid channeled instruments: • **Three (3) double channel semi-rigid endoscopes** (ureteroscope – 0.7 mm × 500 mm and 1.1 mm × 500 mm) were packaged, one (1) per cassette, in **three (3)** IN 7323-R **cassettes**. • Additional rigid channel instruments were added to reach a **total of 15 channels**. Each cassette included appropriate silicone instrument holders and was wrapped. **Load 4b:** Consisted of the load limit for rigid and semi-rigid channeled instruments: • **Three (3) double channel semi-rigid endoscopes** (ureteroscope – 0.7 mm × 400 mm and 1.1 mm × 400 mm) were packaged, one (1) per cassette, in **three (3)** IN-0007-TF **cassettes**. • Additional rigid channeled instruments were added to reach a **total of 15 channels**. Each cassette included appropriate silicone instrument holders and was placed in an Aesculap JM440 rigid container.	Load 4a = 5 lbs/cassette, 15 lbs total Load 4b = 11 lbs/cassette, 33 lbs total
7	**Summit Medical Validation Load 7a:** Consisted of the load weight limit for general medical instruments representing the following geometries: • Box-lock hinge • Pivot hinge • Luer-lock General medical instruments were spread across **three (3)** IN-7323-R **cassettes** with appropriate silicone holders, each weighing 25 lbs. The cassettes were wrapped. **Summit Medical Validation Load 7b:** Consisted of the load weight limit for general medical instruments representing the following geometries: • Box-lock hinge • Pivot hinge • Luer-lock General medical instruments were spread across **three (3)** IN-0006-TF **cassettes** with appropriate silicone holders. Cassettes were placed in Aesculap JM440 containers, each weighing 25 lbs.	Load 7a = 25 lbs/cassette 75 lbs total Load 7b = 25 lbs/cassette 75 lbs total
8	**Summit Medical Validation Load 8a:** Consisted of the load limit of **five (5) total flexible endoscope channels** in wrapped cassettes: • **Two (2) double-channel flexible endoscopes** (ureteroscopes – 1 mm x 850 mm and 1 mm x 989 mm) were packaged, one (1) per cassette, in IN-0003-R cassettes. • **One (1) single-channel flexible endoscope** (ureteroscope – 1 mm x 850 mm) was packaged in an IN-0004-R cassette. Cassettes included appropriate silicone holders and were wrapped. **Summit Medical Validation Load 8b:** Consisted of the load limit of **four (4) total flexible endoscope channels** in cassettes packaged in rigid containers: • **Two (2) double channel flexible endoscopes** (ureteroscope – 1 mm x 850 mm and 1 mm x 989 mm) were packaged, one (1) per cassette, in IN-0003-TF cassettes with appropriate silicone holders. Each cassette was placed inside an Aesculap JM442 container.	Load 8a = 4.3 lbs/cassette, 13 lbs total Load 8b = 8.3 lbs/cassette, 25 lbs total

STORAGE
Store terminally sterile cassettes that are wrapped or containerized on storage shelf in a horizontal position. Consult wrap or container manufacturer for shelf life information.

DISPOSAL
In the event the Instrument Protection Systems do not pass inspection prior to use or have otherwise been deemed no longer fit for purpose, the devices shall be disposed of in line with local protocol. The method of disposal shall depend on the potential risks of cross-contamination and infection when the need for disposal is identified.

SERIOUS INCIDENT REPORTING
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the FDA/competent authority of the Member State in which the user and/or patient is established.

WARRANTY

LIMITED WARRANTY FOR SUMMIT MEDICAL INSTRUMENT PROTECTION SYSTEM.

THIS LIMITED WARRANTY AND THE REMEDY PROVIDED HEREIN ARE EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS WARRANTIES AND, UNLESS STATED HERE-IN, 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 SYSTEM, 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 system 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 System 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 System 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 repair or replace the defective product or products, without charge for parts or labor. Postage, insurance or shipping costs incurred in presenting your System product 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, or 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

Symbol Reference Key	
	Consult instructions for use
	Quantity
	Non-sterile
REF	Catalogue number
LOT	Batch Code
	Date of Manufacture
	Caution
	Manufacturer
	Country of Manufacture (Made in the US)
	Do not use if package is damaged
UDI	Unique Device Identifier
	Distributor
	Importer
Not made with natural rubber latex.	

Chase Medical
800 E. Campbell Rd. Suite 252
Richardson, TX 75081 USA

P: 972.783.7005
www.chasemedical.com

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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