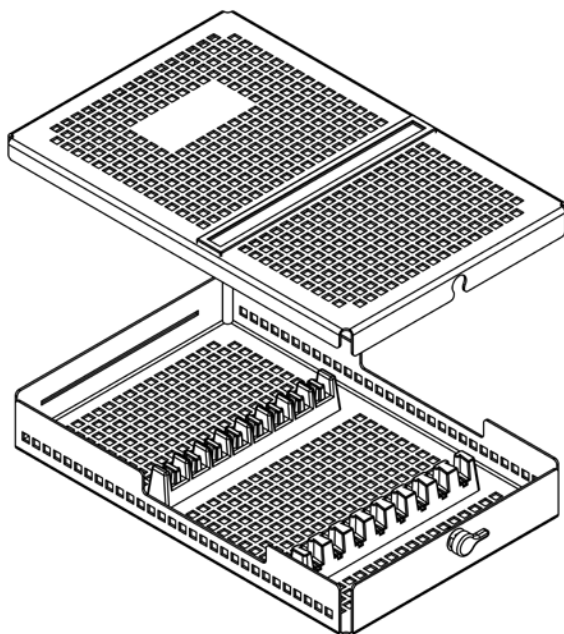
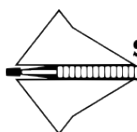


Instrument Sterilization Tray

Instructions for use



Manufactured exclusively for:



**STINGRAY SURGICAL
PRODUCTS**

Manufactured by:



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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

Indications for Use:

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

Sterilization Methods and Configurations

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

» Autoclave Sterilization Parameter:

Cycle : Pre-vacuum

Temperature : 270° F (132° C)

Exposure Time : 4 minutes

Minimum Dry Time : 30 minutes

Cassette / Tray Model	Aesculap® Container Model
IN-8823-AE	*JN444
IN-2880	*JK444
IN-6105	*JN742

Summit Cassette Model	Genesis™ Container Model
IN-2681	*CD2-10-CDL
IN-0000	*CD2-10-CDL
IN-8613	*CD2-10-CDL
IN-6105	*CD2-10-CDL

** Validated by Summit Medical for use in steam prevacuum 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 containers intended load claims.*

Limitation on Processing

- 1) The end of useful life on the Stingray Surgical Products Instrument Trays is determined by wear and damage due to use. Inspect the tray before use for wear and damage caused by use and discontinue use if visible signs of wear are present including corrosion, mechanical failures, cracking, peeling, flaking, broken welds, damaged feet, damaged latches, damaged Hold-It / Hold-Down, discoloration, etc.
- 2) See **Table 2.** for sterilization methods and configurations.
- 3) DO NOT OVERLOAD individual Hold-It slots. Load only one instrument per Hold-It slot.
- 4) For rigid container users, DO NOT WRAP Stingray Surgical Products Instrument Trays or components and place inside of container for sterilization.

- 5) Inside of sterilizers, DO NOT STACK individually wrapped or containerized Stingray Surgical Products Instrument Trays or components. Separate wrapped or containerized Stingray Surgical Products Instrument Trays or components from each other or any other items on separate shelves of the sterilizer to allow for maximum sterilant flow.
- 6) The use of non absorbent tray liners (i.e. silicone fingered organizing mat) can cause condensate to pool. If visible moisture is present, re-sterilize with a longer dry time.

WARNINGS

Use only neutral (6.0 – 7.5) pH detergents with the Stingray Surgical Products Instrument Trays and components to avoid damaging the finish. A detergent with a highly acidic or highly alkaline pH could permanently damage the anodized finish of the cassette and metal components.

DO NOT USE Detergents outside the neutral pH range (6.0-7.5).

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

UNIVERSAL PRECAUTIONS

Personnel should don all personal protective clothing and equipment as required by their employers / dept. operating procedures for the contamination level that they will be working at.

POINT OF USE

Remove soil with disposable cloth/paper wipe.

CLEANING

Equipment: Enzymatic detergent, brush and running water. Use only neutral (6.0 – 7.5) pH solutions, mildly alkaline and free of sodium carbonate to avoid damaging finish. DO NOT use scouring pads or abrasive cleaners. DO NOT store cassette in liquid.

Manual Gross Decontamination:

- 1) Remove all visible soil and contaminants using a soft bristle brush. The entire cassette should be immersed while cleaning to aid in the removal of contaminants and to reduce splashing of detergent on personnel for a minimum of 2 minutes.
- 2) Rinse thoroughly for a minimum of 1 minute with clean water to remove all detergent. See rinsing instruction on the detergent label.

Ultrasonic clean:

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

Automated washer:

Stingray Surgical Products Instrument Trays will complete the cleaning process in an automatic washer system. The validated cleaning process is reflected in **Table 1**.

Table 1.

CYCLE	WATER TEMP.	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 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 Stingray Surgical Products Instrument Trays for any remaining visible soil. **All visible soil must be removed by hand cleaning, brushing, ultrasonic and additional automatic cycles prior to sending to sterilization.**

DISINFECTION

Stingray Surgical Products Instrument Trays are intended to be terminally sterilized.

MAINTENANCE, INSPECTION AND TESTING

Stingray Surgical Products Instrument Trays may be reused until unacceptable deterioration such as corrosion, cracking, rust, peeling, flaking, discoloration, or mechanical failure occurs.

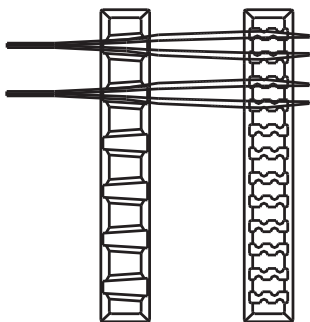
Signs of mechanical failure include:

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

ASSEMBLY

- 1) Place the instruments in the predetermined holders or area defined by the locating posts (see **Figure A**) so that all instrument surfaces will be exposed to sterilant. 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 trays.**

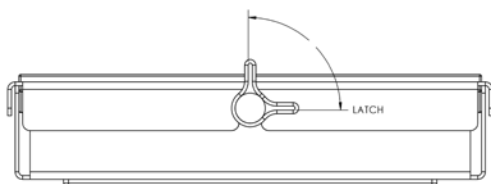
Figure A.



Note: Instruments should be prepared and sterilized according to the instrument manufacturer's instructions.

- 2) Place the tray cover on the tray base ensuring that the latches are properly positioned with the latch slot on the tray cover, then close the latches. See **Figure B**.

Figure B.



PACKAGING

Stingray Surgical Products Instrument Trays may be wrapped with a legally marketed wrap or placed in a legally marketed rigid container. Refer to sterilization methods on pages 2.

- 1) Wrap the cassette using the AAMI CSR double wrap method and per the wrap manufacturer's instructions.
- 2) Sterilize the pack using one of the sterilization cycles listed in **Table 2**.

Using with Rigid Container

Refer to sterilization methods and configurations table on page 2.

- 1) Before placing the tray in a rigid container ensure it has the proper foot style.
- 2) Place the tray(s) into the rigid container. Follow the container manufacturer's instructions for sealing the container.

Note: Do not wrap the trays before placing into the container for sterilization.

- 3) Sterilize the container and contents using one of the sterilization cycles listed in **Table 2**.

STERILIZATION

See **Table 2.** for sterilization methods and cycles that have been validated for the sterilization of Stingray Surgical Products Instrument Trays. These are only valid with sterilization equipment that is properly maintained and calibrated – AAMI TIR 12 p.37. Minimum dry times are required to prevent wet packs.

Table 2.

STERILIZATION METHOD	CYCLE (times)
Steam - PreVacuum	<u>Parameter :</u>
	Temperature 270° F (132° C)
	Expose Time 4 minutes
	Dry Time 30 minutes

Summit Medical has validated the following sterilization methods:

- The 4 minute autoclave sterilization cycle in legally marketed wrap, an Aesculap sterile container or a Genesis 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.

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.

WARRANTY

LIMITED WARRANTY FOR STINGRAY SURGICAL PRODUCTS INSTRUMENT TRAY.

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 STINGRAY SURGICAL PRODUCTS NOR ITS AFFILIATES SHALL BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL LOSSES OR DAMAGES, RESULTING FROM THE USE OR INABILITY TO USE THE STINGRAY SURGICAL PRODUCTS TRAY, 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. Stingray Surgical Products warrants the original purchaser that the Stingray Surgical Products Tray 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 purchase transfers the Stingray Surgical Products Tray 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 Stingray Surgical Products Tray prove defective during this period, you must notify Stingray Surgical Products, or an authorized distributor or dealer of Stingray Surgical Products. You must permit Stingray Surgical Products,

or its representatives to make such investigation, examination and tests as Stingray Surgical Products, deems appropriate and, if requested to do so, you will return the product to the factory at the address set forth below. Stingray Surgical Products' 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 Stingray Surgical Products Tray 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 Stingray Surgical Products or an authorized distributor or dealer of Stingray Surgical Products, or that have been modified without the express approval of Stingray Surgical Products. 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:

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