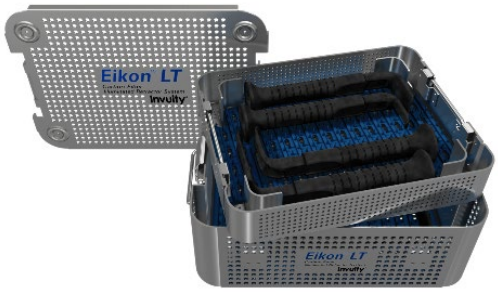
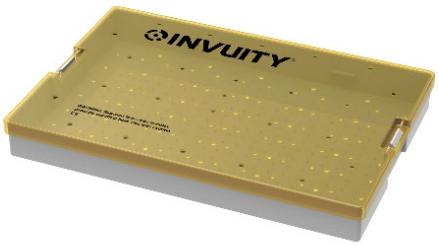
Sterilization Trays

REF ST2B / ST1C

Instructions for Use





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		NON STERILE	Rx Only		Consult Instructions for Use and Symbols Glossary on this website: www.invuity.com/documentlibrary

Sterilization Trays - Instructions for Use

Description

The Invuity Sterilization Tray is used during steam sterilization. The Sterilization Tray is available in plastic and metal material and available in multiple sizes.

Indications for Use

The Invuity Sterilization Tray is intended to allow transport and sterilization of enclosed medical device(s).

Contraindications

There are no known contraindications.

Warnings and Precautions

Cleaning and Sterilization:

- See “Warnings and Precautions” in the Decontamination and Sterilization section of this Instructions for Use.

Product Use:

- Prior to use, carefully inspect the Sterilization Tray for functionality, visible cracks, loose or bent components, or rough edges. Discard damaged devices according to hospital procedures and in accordance with local, state and federal laws and regulations.
- When loading instruments and accessories in the Sterilization Tray, adequately space instruments far enough apart to avoid contact with other metal instruments or object which may dent, ding, scrape or otherwise damage the surface of the instrument.
- Refer to the Instructions for Use for the Invuity devices for additional information.

Safety:

- Use of instruments for any purpose or in any manner other than described in this Instructions for Use may cause instrument damage or failure, which could result in patient or user injury.

Directions for Use

1. Prior to use, carefully inspect the Sterilization Tray for functionality, visible cracks, loose or bent components, or rough edges. Do not use damaged trays.
2. Carefully load Invuity Fiber Optic Cables, Retractors and/or Accessories in the Sterilization Tray.
3. Sterilize the Tray and contents according to the **Decontamination and Sterilization** section of this Instructions for Use.

Preparation for Cleaning

Equipment and Materials

WARNING: Use only Invuity-approved equipment unless otherwise specified. DO NOT modify any system component or accessory.

The following equipment is required to process devices per the instructions in this manual:

- Warm water (See the Water Quality section)
- Prepared, specially formulated cleaning agents (See the Cleaning Agents section)
- Absorbent wipes
- Soft, nonlinting cloth
- Syringe
- Non-abrasive, soft, flexible, synthetic bristle brushes
- Washer-disinfector (complies with ISO 15883 series)
- Cleaning agents as required by the washer-disinfector manufacturer
- Instrument air[1] < 140 kPa [< 20 psi]
- Oven

[1]Instrument air is medical gas that falls under the general requirements for medical gases as defined by the National Fire Protection Association (NFPA) Health Care Facilities Code, is not respired, is compliant with the American National Standards Institute (ANSI) / International Society of Automation (ISA) Quality Standard for Instrument Air, and is filtered to 0.01 microns, free of liquids and hydrocarbon vapors, and dry to a dew point of -40 °C [-40 °F].

Cleaning and Sterilization

Warnings/Precautions	• Clean the sterilization tray as indicated before first use. Use the cleaning methods as indicated in these instructions. Other cleaning methods may prevent proper sterilization of the equipment. • Do not use Sterrad® or other sterilization processes that contain chlorine (bleach) or enzymatic solutions. • It is recommended to use the appropriate Invuity Sterilization Tray to help protect any Invuity Fiber Optic Cable or Retractor from damage during transport, decontamination, sterilization, and storage. • Do not process instruments of different metals during sterilization, oxidation due to electrolytic effects may occur.
Cleaning	1. Use an enzymatic solution or a neutral pH detergent according to hospital protocol for pre-soak cleaning. Pay close attention to instructions for correct detergent dilution, temperature, and soak time. 2. Scrub the entire Invuity Sterilization Tray thoroughly using a soft brush and a neutral pH (7.0-8.5) detergent. An alkaline cleaning agent (neat, up to pH 11) is allowable, but not preferred. Alkaline cleaning agents may cause cosmetic damage or reduce the life of the product. The Invuity Sterilization Tray may be submerged when scrubbing. Take special care to thoroughly clean and remove all debris from the aeration holes. **Note: Do not use a stiff bristle brush or metal type brush to clean the tray. Avoid contact with other metal instruments or object which may dent, ding, scrape or otherwise damage the surface of the Sterilization Tray.** 3. Rinse the Sterilization Tray to remove residual debris and cleaning agents.

<table>
<tr><td>Water Quality</td><td>WARNINGS:
Use appropriate water quality for each stage of the cleaning process. Mineral residues from hard water can stain the equipment and/or prevent effective cleaning and decontamination.
Use utility water for flushing, washing, and rinsing the equipment. Utility water is water that comes from the tap.
Use potable water for diluting cleaning agents. Potable water is water that is treated and delivered in a matter so that it meets United Sates (US) Environmental Protection Agency (EPA) or local guidelines as suitable for drinking.
Use critical water for final rinsing of the equipment prior to sterilization. Critical water is water that is extensively treated usually by a multistep treatment process that could include a carbon bed, softening, deionization, and reverse osmosis or distillation to ensure that the microorganisms and the inorganic and organic material are removed from the water. A final submicron filtration could also be part of the treatment process.
CAUTION: Poor water quality can adversely affect the life of medical devices. ALWAYS follow the water quality requirements per Association for the Advancement of Medical Instrumentation (AAMI) TIR 34.

Warm water with an optimum temperature range of 27 to 44 °C [80 to 110 °F] is recommended for manual cleaning. The water should not exceed 60 °C [140 °F] and should be warm to the touch.</td></tr>
<tr><td>Disinfection (Optional)</td><td>Disinfection processes do not ensure the margin of safety associated with sterilization processes. Therefore, disinfection is optional.</td></tr>
<tr><td>Sterilization</td><td>The following sterilization parameters have been validated for instruments in a tray, wrapped or unwrapped.

Note: Invuity endorses the following sterilization parameters per AAMI recommendations for wrapped instruments and container with combined weight of less than 25 lbs [11.3 kg].

<table>
<tr><td colspan="3">Steam Sterilization Parameters</td></tr>
<tr><td>Description</td><td>Gravity Displacement</td><td>Pre-Vacuum</td></tr>
<tr><td>Temperature</td><td>132°C[2] (270°F)</td><td>132-138°C (270-280°F)</td></tr>
<tr><td>Cycle Time</td><td>15 minutes[1]</td><td>3-8 minutes[1]</td></tr>
<tr><td>Dry Time</td><td>45 minutes</td><td>30 minutes</td></tr>
</table>
[1] Maximum exposure time may be extended to 18 minutes.
[2] Maximum sterilization temperature may be extended to 137 °C.

Note: Do not use Sterrad® or other sterilization processes that contain chlorine (bleach) or enzymatic solutions.

The final responsibility for verification of sterilization techniques lies directly with the hospital. To ensure the efficacy of hospital processing, all cycles and methods should be verified for different sterilization chambers, wrapping methods, and/or various loading configurations.

International sterilization parameters are per the following standards:
Australia/New Zealand per AS/NZS 4187
Netherlands per Field Standard for Loaner Instruments, Rev 03.02, April 2008
Europe and the United Kingdom per EN ISO 17664
Canada per CSA ISO 17664</td></tr>
<tr><td>Storage</td><td>Store Sterilization Trays in a clean, dry area.</td></tr>
</table>

Warranty

INVUITY warrants, for the earlier of (i) the expiration date, if applicable, or (ii) one (1) year from the date of purchase, that this medical device is free from defects in both material and workmanship when used normally for its intended purposes. Suitability of the medical device for any surgical procedure shall be determined by the user alone (in light of relevant instructions for use) and not by INVUITY, and such user shall be responsible for understanding how to use the device for its intended purpose. In the event that purchaser believes that any INVUITY medical device is defective, purchaser will promptly notify INVUITY. Any INVUITY brand named instrument delivered from INVUITY proving to be defective will, as purchaser's sole and exclusive remedy, be replaced at no charge or the amount paid refunded, at INVUITY's discretion, so long as the defect is discovered and reported to INVUITY within the earlier of thirty (30) days of discovery or one (1) year of purchase, and INVUITY determines that the product is defective and is covered by the warranty. Notwithstanding, INVUITY shall not be responsible for normal wear and tear, including minor cosmetic damage compromise or defect caused by re-sterilization. INVUITY does not repair, sharpen, recoat or otherwise refurbish any used product. The foregoing limited warranty and limited obligation of replacement is void and of no effect in the event that there is any modification made to the medical device or the medical device is used for any purpose other than its intended purpose.

LIMITATION OF LIABILITY. INVUITY DOES NOT ACCEPT LIABILITY TO CUSTOMER OR ANY THIRD PARTY BEYOND THE REMEDIES EXPRESSLY SET FORTH HEREIN, INCLUDING ANY LIABILITY FOR PRODUCTS NOT BEING AVAILABLE FOR USE. IN NO EVENT SHALL INVUITY BE LIABLE FOR LOST PROFITS, LOSS OF BUSINESS, LOSS OF USE, COSTS OF PROCUREMENT OF SUBSTITUTE GOODS, OR ANY OTHER CONSEQUENTIAL, EXEMPLARY, INCIDENTAL, SPECIAL, INDIRECT OR PUNITIVE DAMAGES, HOWEVER CAUSED AND UNDER ANY THEORY OF LIABILITY, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, OR FOR ANY CLAIM BY ANY THIRD PARTY, EXCEPT AS EXPRESSLY PROVIDED HEREIN.

Customer must obtain a Return Material Authorization to return product to Invuity. Returned product must be thoroughly cleaned and sterilized.

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Rev	CO #	Description	Approved Date	Effective Date	Originator
A	19-0168	Initial Release	06/24/2019	07/03/2019	J. Wentz

PRINTING INSTRUCTIONS

Print in house or at an approved supplier and route to receiving.

Do not print Revision History or Printing Instructions page (page 6 & 7).

Print in black ink on white paper.

Fold in booklet (folded size is 8.5in x 5.5in) with stapled spine.