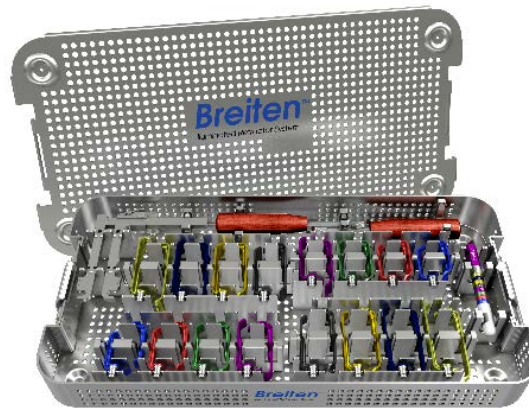




## Breiten® Sterilization Tray





### Instructions for Use



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			<b>R<sub>x</sub> Only</b>		Consult Instructions for Use and Symbols Glossary on this website: <a href="http://www.invuity.com/documentlibrary">www.invuity.com/documentlibrary</a>
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# Breiten Sterilization Tray - Instructions for Use

## Description

The Breiten Sterilization Tray is used during steam sterilization. The Breiten Sterilization Tray is available in metal material and in two sizes (Narrow and Standard).

## Indications for Use

The Breiten 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 Breiten 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 Breiten 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 Breiten Sterilization Tray for functionality, visible cracks, loose or bent components, or rough edges. Do not use damaged trays.
2. Carefully load the Breiten Retractors and Accessories in the Breiten Sterilization Tray.
3. Sterilize the Tray and contents according to the **Decontamination and Sterilization** section of this Instructions for Use.

# Decontamination and Sterilization

## Decontamination and Sterilization Instructions for Reusable Instruments

Warnings/Precautions	<ul style="list-style-type: none"> <li>• The Breiten Sterilization Tray is provided non-sterile and must be thoroughly cleaned and sterilized prior to use.</li> <li>• Do not use Sterrad® or other sterilization processes that contain chlorine (bleach) or enzymatic solutions.</li> <li>• It is recommended to use the appropriate Breiten Sterilization Tray to help protect any Retractors and Accessories from damage during transport, decontamination, sterilization, and storage.</li> <li>• Do not process instruments of different metals during sterilization, oxidation due to electrolytic effects may occur.</li> </ul>															
Cleaning	<p><b>Sterilization Trays:</b></p> <ol style="list-style-type: none"> <li>1. Clean and decontaminate tray after each use. Use hospital approved detergents and techniques for pre-soak cleaning. Use manual or mechanical cleaning to remove visible tissue or waste on instruments and accessories before loading in the Breiten Sterilization Tray.</li> <li>2. Scrub the entire Breiten Sterilization Tray thoroughly using a soft brush and a neutral pH (7.0-8.5) detergent. The Breiten Sterilization Tray may be submerged when scrubbing. Take special care to thoroughly clean and remove all debris from the aeration holes. <b>Note: Do not use a stiff bristle brush or metal type brush to clean the instruments. Avoid contact with other metal instruments or object which may dent, ding, scrape or otherwise damage the surface of the Breiten Sterilization Tray.</b></li> <li>3. Rinse the Breiten Sterilization Tray with distilled water to remove residual debris and cleaning agents.</li> </ol>															
Sterilization	<p>The following sterilization parameters have been validated for instruments in a tray, wrapped or unwrapped. <b>Invuity endorses the following sterilization parameters per AAMI recommendations for wrapped instruments and container with combined weight of less than 25 lbs.</b></p> <table border="1" data-bbox="667 1423 1284 1667"> <thead> <tr> <th colspan="3">Steam Sterilization Parameters</th> </tr> <tr> <th>Description</th> <th>Gravity Displacement</th> <th>Pre-Vacuum</th> </tr> </thead> <tbody> <tr> <td>Temperature</td> <td>132°C (270°F)</td> <td>132°C (270°F)</td> </tr> <tr> <td>Cycle Time</td> <td>15 minutes</td> <td>4-6 minutes</td> </tr> <tr> <td>Dry Time</td> <td>45 minutes</td> <td>30 minutes</td> </tr> </tbody> </table> <p><b>Note: Do not use Sterrad® or other sterilization processes that contain chlorine (bleach) or enzymatic solutions.</b></p>	Steam Sterilization Parameters			Description	Gravity Displacement	Pre-Vacuum	Temperature	132°C (270°F)	132°C (270°F)	Cycle Time	15 minutes	4-6 minutes	Dry Time	45 minutes	30 minutes
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Temperature	132°C (270°F)	132°C (270°F)														
Cycle Time	15 minutes	4-6 minutes														
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Storage	Store Sterilization Trays in a clean, dry area.															

# 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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INSTRUCTIONS FOR USE

Breiten Sterilization Trays

Rev	CO #	Description	Approved Date	Effective Date	Originator
A	18-0415	Initial Release	7/11/18	8/3/18	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 5 & 6).

Print in black ink on white paper.

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