

## Indications for Use

Intended for use in hospitals and healthcare facilities to contain other medical devices that are to be sterilized and to allow sterilization of the enclosed medical devices using steam sterilizers. Sterilized devices may be stored and transferred in the container.

**Contraindications:** None known.

## Precautions



Filters and filter retainers must show no visual deformations. These parts must be checked visually and for their functionality before usage.



Leave one inch of free space between the instruments and the inside of the container lid for effective processing.



Do not cover filter perforated section with paper wrapped instruments or any other objects that could obstruct the airway and steam flow. This obstruction may cause permanent damage to the container.



In order to avoid post-sterilization moisture caused by rapid cooling syndrome, cool drafts from air ducts or other air currents should be avoided. Do not place the container on cold surfaces or expose to a cold draft. To safeguard against accidents (burns, dropping, etc.), containers that are still hot should never be handled with bare hands. Containers need to remain on the container cart, in draft free area until cool enough to handle.

## Pre-Cleaning

Remove lid and basket with instruments from the container. Separate the safety lid from the container lid, if using safety lid. Remove filter retainer plate(s). If bottom perforated, also remove retainer plates. Remove indicators and disposable security seals and disposable paper filter.

## Cleaning and Disinfection

Users must specify by means of disinfection and cleaning plan, when and how the sterilization containers have to be cleaned and/or disinfected. Containers that are used for waste disposal have to be cleaned and disinfected each time after use. Do not use metal brushes or any abrasive cleaning material. Never use bleach or other corrosive chemicals to clean Integra containers. Abrasive products may cause chemical and physical corruptions that will void all manufacturer warranties. For more information concerning the inspection and cleaning of closed sterilization containers, please see Sections 5.2.3 and 7.5.9 of ANSI/AAMI ST79 Standard.

## Manual Cleaning

Use a soft sponge and neutral detergent (pH 7 phosphate-free). Use demineralized warm water.

Rinse all the parts without leaving any stain or residue on them. Thoroughly dry and store in clean and dry environment.

## Mechanical Cleaning

Mechanical cleaning of the containers is preferred to manual cleaning. Cleaning the containers with machines is only recommended if the washing machine has a special washing program for aluminum containers. Place the container bottom face down in the washing machine. (Washing Machine has to be designed for cleaning sterilization containers. This applies in particular to ensure secure replacement in the washing baskets and the arrangement of the spray jets or arms.) Do not use any cleaning solutions that contain soda or caustic acid. Do not use additional acidic neutralizers. Use neutral detergent (pH 7 phosphate-free). Use demineralized water for final rinsing as salt in the water may cause spotting during subsequent sterilizations. Lids and baskets have to be removed and washed individually. Thoroughly dry and store in clean and dry environment.

## Assembly For Use

Pre-Assembly Inspection and Preparation: Select surgical instrument set for sterilization.

Be sure all the components are completely dry. Select appropriate size baskets and containers.

Integra containers must be checked visually before each usage. Container bottoms, container lids and the surfaces where the seals sit must be free of dents, visible deformations, and anything else that might appear out of the ordinary. Do not use any spray oil or solvents on the lid seals. The seal in the inner lid must be completely inserted and undamaged. If there is any kind of damage, detected lids should not be used.

**Note:** Integra containers are designed to be used with single-use paper filters validated for use with the containers (Integra item number 775-250). The filters are 190mm (7.5 inches) in diameter.

Filter Assembly: Place one sheet of filter paper over each perforated section on the inside of Integra containers. Make sure it covers all the perforation holes properly.

Make sure that filters and filter retainers are placed properly. 'Click' sound should be heard while placing filter retainers by pressing on them which indicates locking is realized. For perforated bottoms; place one filter over the perforated section in the bottom of the container. Make sure you hear the click sound while pressing onto the protruding pin. There is no perforated section for the solid bottom model and it does not require a filter or retention plate.

**Caution:** Filters and filter retainers must show no visual deformations. These parts must be checked visually and for their functionality before usage.

## Instrument and Container Assembly

Place thoroughly cleaned and dried instruments into the instrument basket(s) according to established medical facility procedures. Complex instruments have to be prepared and sterilized according to the instrument manufacturer's instructions. Small baskets, trays and other types of accessories, especially with covers and lids, should only be used with the sterilization container which has been specifically designed for that purpose.

The wide body containers are validated for sterilization of instruments with lumens with a minimum diameter of 1mm and a maximum length of 300mm. Place instrument basket(s) into the prepared container bottom. Place assembled lid onto the container bottom, aligning handles on bottom with latches on lid. Simultaneously close both locking latches on the lid.

**Caution:** Leave one inch of free space between the instruments and the inside of the container lid for effective processing.

**Note:** Integra container systems are not validated for use with air-driven instruments or power systems.

## Processing Assembly

Select the appropriate indicator card and insert into the holding brackets on the outside of the container. Insert the security seals (775-400). Secure and Lock.

**Note:** 1) Integra containers are protected by disposable plastic security seals which, once attached, can be opened only by breaking which prevents inadvertent opening of the containers, and ensures that it is evident whether or not the sterility of the contents has been compromised. 2) Use of internal and external indicators should be in accordance with in-house protocol that is determined by the user.

**Loading the Sterilizer:** Integra containers should be placed horizontally in the sterilizer for effective sterilization and drying.

**Stacking:** No stacking is allowed during sterilization.

**Caution:** Do not cover filter perforated section with paper wrapped instruments or any other objects that could obstruct the airway and steam flow. This obstruction may cause permanent damage to the container.

Processing

The loading instructions of the sterilizer manufacturer should be observed.  
High vacuum (pre-vacuum, three pulse, standard) Temp: 132° C (270° F)  
Exposure Time: 4 minutes (minimum) Cycle Dry Time: 20 Minutes (minimum)  
Cool Time: Varies according to load contents.

**Caution:** In order to avoid post-sterilization moisture caused by rapid cooling syndrome, cool drafts from air ducts or other air currents should be avoided. Do not place the container on cold surfaces or expose to a cold draft. To safeguard against accidents (burns, dropping, etc.), containers that are still hot should never be handled with bare hands. Containers need to remain on the container cart, in draft free area until cool enough to handle.

**Note:** Maximum load weight of the basket and its contents should not exceed the following chart for effective sterilization and drying:

Integra containers with filter system			
Model	Perforations	Dimensions	Load Limit LBS
1/1 size container models	Perforated lid and non-perforated bottom	580 x 280 x 100 mm	24.75
		580 x 280 x 135 mm	24.75
		580 x 280 x 150 mm	24.75
		580 x 280 x 200 mm	24.75
		600 x 400 x 120 mm	24.75
		600 x 400 x 180 mm	24.75
	Perforated lid and perforated bottom	580 x 280 x 100 mm	24.75
		580 x 280 x 135 mm	24.75
		580 x 280 x 150 mm	24.75
		580 x 280 x 200 mm	24.75
		580 x 280 x 260 mm	24.75
		600 x 400 x 120 mm	24.75
		600 x 400 x 180 mm	24.75
	Full size wire and perforated baskets	540 x 255 x 30 mm	N/A
		540 x 255 x 50 mm	N/A
		540 x 255 x 70 mm	N/A
		540 x 255 x 100 mm	N/A
3/4 size container models	Perforated lid and non-perforated bottom	465 x 280 x 100 mm	12.5
		465 x 280 x 135 mm	12.5
		465 x 280 x 150 mm	12.5
	Perforated lid and perforated bottom	465 x 280 x 100 mm	12.5
		465 x 280 x 135 mm	12.5
		465 x 280 x 150 mm	12.5
	Mid size wire and perforated baskets	405 x 255 x 30 mm	N/A
		405 x 255 x 50 mm	N/A
		405 x 255 x 70 mm	N/A
		405 x 255 x 100 mm	N/A
1/2 size container models	Perforated lid and perforated bottom	285 x 280 x 100 mm	9.25
		285 x 280 x 135 mm	9.25
		285 x 280 x 150 mm	9.25
		285 x 280 x 200 mm	9.25
		285 x 280 x 260 mm	9.25
	Perforated lid and non-perforated bottom	285 x 280 x 100 mm	9.25
		285 x 280 x 135 mm	9.25
		285 x 280 x 150 mm	9.25
		285 x 280 x 200 mm	9.25
	Half size wire and perforated baskets	255 x 245 x 30 mm	N/A
		255 x 245 x 50 mm	N/A
		255 x 245 x 70 mm	N/A
		255 x 245 x 100 mm	N/A

Shelf Life

In protected storage (temperature, humidity, air filtration etc. controlled medical facility storage room conditions) containers can store high-vacuum (pre-vacuum) sterilized medical devices for up to 6 months, provided the integrity of the container is not compromised. (Tamper-evident security seal 775-400 remains intact.) **Note:** Integra containers can be stacked during storage, one on top of another. Make sure that heavier container is placed at the bottom.

Periodic Maintenance

Integra suggests periodic maintenance to ensure all parts are in good working order.

Integra Container Systems Warranty

Integra hereby warrants all products carrying the registered trademark and logo of Integra purchased directly from Integra or an authorized dealer in accordance with the following terms and conditions: The warranty period of Integra containers is two years from the date of purchase. Integra containers are guaranteed to be free from defects in material and workmanship when used for its intended purpose. Containers that prove defective in material or workmanship will either be repaired or replaced free of charge during the warranty period. Containers that are not purchased from Integra or an authorized source may not meet Integra quality standards.

Repair or Replacement

Under this warranty, Integra will repair or replace any parts and determine the nature of any defect, the necessity and manner of repair or replacement, and all other matters pertaining to the conditions of the Integra container systems.

Exclusions

This warranty shall not apply to any condition(s) or damage resulting from misuse, improper cleaning, improper handling, negligence, improper opening or unauthorized repair work including but not limited to: Incidents of abuse such as denting of Integra container due to dropping or other instances of mechanically applied pressure. Damage determined to be related to caustic or abrasive cleaning agents, items modified by the customer, items modified or customized by Integra at the request of the customer, damage from fire, flood and other occurrences not under the control of Integra.

Returned Goods Policy

Products must be returned in unopened packages with manufacturer's seals intact to be accepted for replacement or credit unless returned due to a complaint of defect.


Repairs And Maintenance

Should your containers require repair or maintenance, contact Integra for return authorization and address. Containers returned to Integra for repair must have a statement testifying that each container has been thoroughly cleaned and sterilized. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your container repair.


PRODUCT INFORMATION DISCLOSURE

INTEGRA AND ITS SUBSIDIARIES ("INTEGRA") AND MANUFACTURER EXCLUDE ALL WARRANTIES, EXCEPT INTEGRA'S APPLICABLE STANDARD WARRANTY WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NEITHER INTEGRA NOR MANUFACTURER SHALL BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. NEITHER INTEGRA NOR MANUFACTURER ASSUME NOR AUTHORIZE ANY PERSON TO ASSUME FOR THEM ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.


Symbols used on labeling




Manufacturer <sup>1</sup>




Consult Instruction for Use




European Authorized Representative




CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician




Catalog number



Product complies with the requirements of directive 93/42/EEC (Class I Devices Only)




Lot Number




Caution! See Warnings and Precautions

<sup>1</sup> Company responsible for a device marketed under its own name regardless of whether "manufactured for" or "manufactured by" the company.



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