Integra Jarit Containers IFU

Ethylene Oxide Sterilizer Processing

IFU-2017.01.05

MILLENNIUM SURGICAL
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Integra Jarit Containers are designed to provide a more efficient organization and utilization of surgical instruments for the operating room, surgi-center and central supply. The functional containers are manufactured from an anodized aircraft aluminum alloy to prevent corrosion. This aluminum alloy also has high thermal conductivity for faster drying and is lighter than other metals to make the container easier to transport.

PRE-CLEANING

- Remove lid and basket with instruments from the container.
- Remove the lid filter retention plate(s).
- Remove the bottom filter retention plate(s) if using perforated bottoms.
- Discard the disposable filter(s).
- Remove all indicators and disposable locks.

CLEANING

Do not use any abrasive products, material or stainless steel brushes to clean the containers. Abrasives can damage the aluminum surface of the container and will void all manufacturer warranties. Never expose to bleach or other corrosive chemicals. Exposure to bleach may result in pitting or damage to surface and will void all manufacturer warranties.

Manual Cleaning

- Use a soft sponge and a neutral pH (7) phosphate -free detergent such as Surgical Instrument Cleaner (5-3720, 5-3725 and 5-3726) to thoroughly clean the container. Use distilled (demineralized) water (room temperature) if possible.
- Rinse with water to remove the cleaning solution. Be sure to rinse thoroughly to remove all detergent residues.
- Thoroughly dry. Store in clean and dry environment.

Mechanical Cleaning

- Place the container bottom face down (open side down) in the washer.
- Handles should be folded down.
- Thoroughly dry. Store in clean and dry environment.

ASSEMBLY FOR USE

Pre-Assembly Inspection and Preparation

- All components must be thoroughly dry before assembling.
- Select surgical instrument set for sterilization.
- Select appropriate size container and basket(s).
- Inspect the inside channel of the lid to ensure the silicone gasket is in good condition. The gasket condition should be free from defects such as wear, cracks, cuts, tears, bubbling, loose fit in the channel, and anything else that might appear out of the ordinary. A defective gasket could indicate age and/or deterioration and should not be used. Contact the Integra Jarit service and repair department for further assistance.

Filter Assembly

- Place one sheet of filter paper over each perforated section on the inside of the container lid or bottom – making sure it is centered on the protruding pin. When using filter paper with indicator, be sure the indicator faces toward the inside of the container when the lid is in place and the indicator is visible through the retention plate.
- Secure each filter with the retention plate by pressing onto the protruding pin until you hear it click.
- Perforated bottoms: Place one sheet of the filter paper over the perforated section in the bottom of container – making sure it is centered on the protruding pin. Secure the filter with the retention plate by pressing onto the protruding pin until you hear it click.
- Solid bottoms: There is no perforated section and does not require a filter or retention plate.

NOTE : The filters validated for use with the container are Millennium item number 5-775200. The paper filters are 190-

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mm (7.5-inches) in diameter and intended for single-use only.

Instrument and Container Assembly

- Place cleaned and dried instruments into the instrument basket(s) according to established hospital procedures. Complex instruments (e.g. air-powered instruments, endoscopes, and instruments with lumens or channels) should be prepared and sterilized according to the instrument manufacturer's instructions. Within ethylene oxide sterilizers, the containers have been validated for sterilization of instruments with lumens up to 3 mm I.D. by 200 mm length. CAUTION: The containers are intended for use with non-porous materials such as stainless steel surgical instruments.
- Small baskets, trays, and other types of accessories, especially with covers and lids, should only be used with the sterilization container if the container has been specifically designed and tested for that purpose. CAUTION: Non-absorbent tray liners (e.g., plastic/silicone-fingered organizing mats) can cause condensate to pool. The use of these accessories within the container has not been tested.
- Place instrument basket(s) into the prepared container bottom.
- Place lid onto the container bottom, aligning handles on bottom with latches on lid.
- Simultaneously close both locking latches on the lid. Some downward pressure is needed to lock the lid in place.

NOTE: For effective sterilization and drying, the weight of the basket and basket contents should not exceed the following:

- 16 lbs for 1/2 (small) size containers
- 20 lbs for 3/4 (medium) size containers
- 25 lbs for Full (large) size containers
- All instruments should be assembled to allow for uniform exposure to sterilization agents.

CAUTION: Leave minimum of one inch clearance for effective processing.

Processing Assembly

- Insert set indicator card(s) into the holding bracket(s) on the outside of the container. A tab at one end of the indicator card will facilitate insertion and removal.
- Insert the plastic tamper-proof seals into the locking channel on each end.
- Secure and lock.

NOTE : Use of internal and external indicators should be in accordance with inhouse protocol, determined by the user.

NOTE: The process indicators validated for use with containers are Millennium item number 5-775300. These indicators are for use in ethylene oxide or steam sterilizers.

Loading the Sterilizer

- The container should be placed flat/level for effective sterilization and drying.

CAUTION: Containers should not be stacked when used within ethylene oxide sterilizers.
CAUTION: Do not cover filter perforated section with paper wrapped instruments or any other objects that could obstruct the way to air flow and sterilant flow. Permanent damage may occur to the container as a result of this obstruction.

- The container needs to remain on the container cart, in a draft free area, until cool enough to handle.

NOTE: A container with a solid bottom may require additional cooling time; the additional required cooling time to be determined by the user.

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PROCESSING - Ethylene Oxide (EO)
Run loaded sterilizer according to the manufacturer's instructions at:

- Concentration: 725 mg/L
- Temperature: 131°F (55°C)
- Exposure Time: 60 minutes [minimum]
- Humidity: 70 percent
- Aeration Time: 8 hours [minimum]

CAUTION: If aeration requirements for a device being sterilized within the container exceed the aeration requirements of the container, the device manufacturer's aeration recommendations must be followed.

SHELF LIFE
A real-time event-related shelf life study has been performed on the containers. The conclusion of the study is that the container is capable of storing sterilized medical devices for a maximum of 360 days as long as the container integrity has not been compromised.

THE CONTAINER SYSTEM WARRANTY
Integra Jarit hereby warrants all Integra Jarit Containers purchased directly from Integra Jarit or an Authorized Dealer in accordance with the following terms and conditions:

The Integra Jarit Container is guaranteed to be free from defects in material and workmanship when used for its intended purpose. Any Integra Jarit Container that proves defective in workmanship or material will either be repaired or replaced, at Integra Jarit discretion, without charge.

Containers not purchased from an authorized source may not be authentic or meet Integra Jarit quality standards.

Container Gaskets Warranty
The warranty period for Integra Jarit container gaskets is three years from the date of purchase.

Periodic Maintenance
Periodic Maintenance is suggested to ensure all parts are in good working order.

Repair or Replacement
Under this Warranty, and at its discretion, Integra Jarit will repair or replace any parts of the product found to be defective in workmanship or material. Integra Jarit will determine, at its discretion, the cause and nature of any defect, the necessity and manner of repair or replacement, and all other matters pertaining to the conditions of the Integra Jarit Container System. Integra Jarit, Inc. Returned Goods Policy applies to all returned items (refer to details in current Surgical price list).

Exclusions
This Warranty shall not apply to any conditions(s) or damage resulting from negligence, misuse, improper handling, improper cleaning, improper opening techniques, or unauthorized repair work including but not limited to:

- Incidents of abuse such as denting of the Integra Jarit 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 Jarit at the request of the customer.
- Damage from fire, flood and other occurrences not under the control of Integra Jarit, Inc.

Integra Jarit Containers IFU
Gravity Steam Sterilizer Processing

IFU-2017.01.05

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The Integra Jarit Rigid Sterilization Container System is intended for use in hospitals and health care facilities to contain other medical devices that are to be sterilized and to allow sterilization of the enclosed medical devices, including surfaces and lumens, using gravity steam sterilizers. The recommended gravity steam sterilization cycle parameters are 45 minutes exposure at 121 deg C and a 20 minute dry time. 2 metal lumens 3-mm in diameter and up to 200-mm in length were validated. The container is intended for use with nonporous materials such as stainless steel surgical instruments.

For effective sterilization and drying, the weight of the single container, basket and basket contents should not exceed the following: 16 lbs for the one-half size container, 20 lbs for the three-quarter size container, and 25 lbs for the full size container.

Sterilized devices may be stored and transported within the container. The container is intended to maintain sterility for a maximum of 60 days as long as the integrity of the container has not been compromised.

Containers should not be stacked when used within gravity steam sterilizers.

The functional containers are manufactured from an anodized aircraft aluminum alloy to prevent corrosion. This aluminum alloy also has high thermal conductivity for faster drying and is lighter than other metals to make the container easier to transport.

PRE-CLEANING

- Remove lid and basket with instruments from the container.
- Remove the lid filter retention plate(s).
- Remove the bottom filter retention plate(s)
- Discard the disposable filter(s).
- Remove all indicators and disposable locks.

CLEANING

Do not use any abrasive products, material or stainless steel brushes to clean the Integra Jarit Containers. Abrasives can damage the aluminum surface of the container and will void all manufacturer warranties. Never expose to bleach or other corrosive chemicals. Exposure to bleach may result in pitting or damage to surface and will void all manufacturer warranties.

Manual Cleaning

- Use a soft sponge and a neutral pH (7) phosphate -free detergent such as Surgical Instrument Cleaner (5-3720, 5-3725 and 5-3726) to thoroughly clean the container. Use distilled (demineralized) water (room temperature) if possible. Verify that all visible contamination is removed.
- Rinse with water to remove the cleaning solution. Be sure to rinse thoroughly to remove all detergent residues.
- Thoroughly dry. Store in clean and dry environment.

Mechanical Cleaning

- Place the container bottom face down (open side down) in the washer.
- Handles should be folded down.
- Follow manufacturers instructions for proper use
- Thoroughly dry. Store in clean and dry environment.

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ASSEMBLY FOR USE

Pre-Assembly Inspection and Preparation

- All components must be thoroughly dry before assembling
- Select appropriate size container and basket.
- Inspect the inside channel of the lid to ensure the silicone gasket is in good condition. The gasket condition should be free from defects such as wear, cracks, cuts, tears, or bubbles, loose fit in the channel, and anything else that might appear out of the ordinary. A defective gasket could indicate age and/or deterioration and should not be used.
- Inspect the container top and bottom for any dents or marks. Check the handles and latches for proper operation. Finally, when placing the filters, verify that the retaining ring “clicks” into place.
- Please refer to AMSI/AAMI ST 79 Standard for additional recommendations for inspections and cleaning of sterilization containers (Sections 5.2.3 and 7.5.9).
- The container systems have been validated to withstand 50 sterilization cycles with no evidence of deterioration.
- The following container lids can be used for each container base:

Lid Size	**Perforated Base to be used with Lid**
½ size Lid (11 ¼ in x 11 in)	
PN 3-6100-00	PN 3-5110-10 (4 in height)
	PN 3-5110-13 (5 1/3 in height)
	PN 3-5110-15 (6 in height)
¾ size Lid (18 ¼ in x 11 in)	
PN 3-6300-00	PN 3-5310-10 (4 in height)
	PN 3-5310-13 (5 1/3 in height)
	PN 3-5310-15 (6 in height)
Full size Lid (23 in x 11 in)	
PN 3-6500-00	PN 3-5510-10 (4 in height)
	PN 3-5510-13 (5 1/3 in height)
	PN 3-5510-15 (6 in height)

If there is any evidence of damage or deformation of the device, or if any of the moving parts fail to operate as intended, then remove the container from service and contact your representative for further assistance.

Filter Assembly

- Place one sheet of filter paper over each perforated section on the inside of the container lid or bottom – making sure it is centered on the protruding pin. When using filter paper with indicator, be sure the indicator faces toward the inside of the container when the lid is in place and the indicator is visible through the retention plate.
- Secure each filter with the retention plate by pressing onto the protruding pin until you hear it click.
- Perforated bottoms: Place one sheet of the filter paper over the perforated section in the bottom of container – making sure it is centered on the protruding pin. Secure the filter with the retention plate by pressing onto the protruding pin until you hear it click.

NOTE : The filters validated for use with the container are Millennium item number 5-775200. The paper filters are 190-mm (7.5-inches) in diameter and intended for single-use only.

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Instrument and Container Assembly

- Place cleaned and dried non-porous materials such as stainless steel surgical instruments into the instrument basket according to established hospital procedures. Within gravity steam sterilizers, the containers have been validated for sterilization of instruments with two (2) stainless steel lumens 3 mm I.D. by up to 200 mm length.
- All instruments should be assembled to allow for uniform exposure to sterilization agents.
  CAUTION: Leave minimum of one inch clearance for effective processing.
- For effective sterilization and drying, the weight of the single container, basket and basket contents should not exceed the following:

  - 16 lbs for 1/2 (small) size containers
  - 20 lbs for 3/4 (medium) size containers
  - 25 lbs for Full (large) size containers

CAUTION: Complex instruments (e.g. air-powered instruments, endoscopes, and instruments with lumens or channels) should be prepared and sterilized according to the instrument manufacturer's instructions.

CAUTION: Small baskets, trays, and other types of accessories, especially with covers and lids, should only be used with the sterilization container if the container has been specifically designed and tested for that purpose.

CAUTION: Non-absorbent tray liners (e.g., plastic/silicone- fingered organizing mats) can cause condensate to pool. The use of these accessories within the container has not been tested.

- Place instrument basket(s) into the prepared container bottom.
- Place lid onto the container bottom, aligning handles on bottom with latches on lid.
- Simultaneously close both locking latches on the lid. Some downward pressure is needed to lock the lid in place.

Processing Assembly

- Insert set indicator card(s) into the holding bracket(s) on the outside of the container. A tab at one end of the indicator card will facilitate insertion and removal.
- Insert the plastic tamper-proof seals into the locking channel on each end.
- Secure and lock.

NOTE : Use of internal and external indicators should be in accordance with inhouse protocol, determined by the user.

NOTE: The process indicators validated for use with containers are Millennium item number 5-775300. These indicators are for use in ethylene oxide or steam sterilizers.

Loading the Sterilizer

- The container should be placed flat/level for effective sterilization and drying.

  CAUTION: Containers should not be stacked when used within gravity steam sterilizers. The containers were validated using 3 containers placed side by side in the sterilizer.

  CAUTION: Do not cover filter perforated section with paper wrapped instruments or any other objects that could obstruct the way to air flow and sterilant flow. Permanent damage may occur to the container as a result of this obstruction.

- The container needs to remain on the container cart, in a draft free area, until cool enough to handle.

Integra Jarit Containers IFU
Gravity Steam Sterilizer Processing

IFU-2017.01.05

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PROCESSING:
Gravity Steam Warning: The sterilization containers should ONLY be used at the specified conditions described below:

Run loaded sterilizer according to the manufacturer's instructions at:

- Temperature: 250°F (121°C)
- Exposure Time: 45 minutes
- Dry Time: 20 minutes

SHELF LIFE
A real-time event-related shelf life study has been performed on the containers. The conclusion of the study is that the container is capable of storing sterilized medical devices for a maximum of 360 days as long as the container integrity has not been compromised. If the container is not opened or the filters perforated or contaminated, the container can be subjected to routine storage and handling activities and sterility will be maintained.

WARRANTY
Integra Jarit hereby warrants all Integra Jarit Containers purchased directly from Integra Jarit or an Authorized Dealer in accordance with the following terms and conditions: The Integra Jarit Container is guaranteed to be free from defects in material and workmanship when used for its intended purpose. Any Integra Jarit Container that proves defective in workmanship or material will either be repaired or replaced, at Integra Jarit discretion, without charge. Containers not purchased from an authorized source may not be authentic or meet Integra Jarit quality standards.

Container Gaskets Warranty
The warranty period for Integra Jarit container gaskets is three years from the date of purchase.

Periodic Maintenance
Periodic Maintenance is suggested to ensure all parts are in good working order.

Repair or Replacement
Under this Warranty, and at its discretion, Integra Jarit will repair or replace any parts of the product found to be defective in workmanship or material. Integra Jarit will determine, at its discretion, the cause and nature of any defect, the necessity and manner of repair or replacement, and all other matters pertaining to the conditions of the Integra Jarit Container System. Integra Jarit, Inc. Returned Goods Policy applies to all returned items (refer to details in current Surgical price list).

Exclusions
This Warranty shall not apply to any conditions(s) or damage resulting from negligence, misuse, improper handling, improper cleaning, improper opening techniques, or unauthorized repair work including but not limited to:

- Incidents of abuse such as denting of the Integra Jarit 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 Jarit at the request of the customer.
- Damage from fire, flood and other occurrences not under the control of the manufacturer.

Integra Jarit Containers IFU

Pre-Vacuum Sterilizer Processing

IFU-2017.01.05

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PRE-CLEANING

- Remove lid and basket with instruments from the Container.
- Remove the lid filter retention plate(s).
- Remove the bottom filter retention plate(s) if using perforated bottoms.
- Discard the disposable filter(s).
- Remove all indicators and disposable locks.

CLEANING

Do not use any abrasive products, material or stainless steel brushes to clean the Integra Jarit Containers. Abrasives can damage the aluminum surface of the container and will void all manufacturer warranties. Never expose to bleach or other corrosive chemicals. Exposure to bleach may result in pitting or damage to surface and will void all manufacturer warranties.

Manual Cleaning

- Use a soft sponge and a neutral pH (7) phosphate -free detergent such as Surgical Instrument Cleaner (5-3720, 5-3725 and 5-3726) to thoroughly clean the container. Use distilled (demineralized) water (room temperature) if possible.
- Rinse with water to remove the cleaning solution. Be sure to rinse thoroughly to remove all detergent residues.
- Thoroughly dry. Store in clean and dry environment.

Mechanical Cleaning

- Place the container bottom face down (open side down) in the washer.
- Handles should be folded down.
- Thoroughly dry. Store in clean and dry environment.

ASSEMBLY FOR USE

Pre-Assembly Inspection and Preparation

- All components must be thoroughly dry before assembling.
- Select surgical instrument set for sterilization.
- Select appropriate size container and basket(s).
- Inspect the inside channel of the lid to ensure the silicone gasket is in good condition. The gasket condition should be free from defects such as wear, cracks, cuts, tears, bubbling, loose fit in the channel, and anything else that might appear out of the ordinary. A defective gasket could indicate age and/or deterioration and should not be used. Contact the Integra Jarit service and repair department for further assistance.

Filter Assembly

- Place one sheet of filter paper over each perforated section on the inside of the container lid or bottom – making sure it is centered on the protruding pin. When using filter paper with indicator, be sure the indicator faces toward the inside of the container when the lid is in place and the indicator is visible through the retention plate.
- Secure each filter with the retention plate by pressing onto the protruding pin until you hear it click.
- Perforated bottoms: Place one sheet of the filter paper over the perforated section in the bottom of container – making sure it is centered on the protruding pin. Secure the filter with the retention plate by pressing onto the protruding pin until you hear it click.
- Solid bottoms: There is no perforated section and does not require a filter or retention plate.

NOTE : The filters validated for use with the container are Millennium item number 5-775200. The paper filters are 190-mm (7.5-inches) in diameter and intended for single-use only.

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Instrument and Container Assembly

- Place cleaned and dried instruments into the instrument basket(s) according to established hospital procedures. Complex instruments (e.g. air-powered instruments, endoscopes, and instruments with lumens or channels) should be prepared and sterilized according to the instrument manufacturer's instructions. The containers have been validated for sterilization of instruments with lumens up to 3 mm I.D. by 400 mm length, for the Full (large) size container and up to 3mm I.D. by 200mm length for the ½ (small) and ¾ (medium) size containers.
  CAUTION: The containers are intended for use with non-porous materials such as stainless steel surgical instruments.
- Small baskets, trays, and other types of accessories, especially with covers and lids, should only be used with the sterilization container if the container has been specifically designed and tested for that purpose.
  CAUTION: Non-absorbent tray liners (e.g., plastic/silicone-fingered organizing mats) can cause condensate to pool. The use of these accessories within the container has not been tested.
- Place instrument basket(s) into the prepared container bottom.
- Place lid onto the container bottom, aligning handles on bottom with latches on lid.
- Simultaneously close both locking latches on the lid. Some downward pressure is needed to lock the lid in place.

NOTE: For effective sterilization and drying, the weight of the basket and basket contents should not exceed the following:

- 16 lbs for 1/2 (small) size containers
- 20 lbs for 3/4 (medium) size containers
- 25 lbs for Full (large) size containers
- All instruments should be assembled to allow for uniform exposure to sterilization agents.

CAUTION: Leave minimum of one inch clearance for effective processing

Processing Assembly

- Insert set indicator card(s) into the holding bracket(s) on the outside of the container. A tab at one end of the indicator card will facilitate insertion and removal.
- Insert the plastic tamper-proof seals into the locking channel on each end.
- Secure and lock.

NOTE: Use of internal and external indicators should be in accordance with inhouse protocol, determined by the user.

NOTE: The process indicators validated for use with containers are Millennium item number 5-775300. These indicators are for use in ethylene oxide or steam sterilizers.

Loading the Sterilizer

- The container should be placed flat/level for effective sterilization and drying.
- The container should be positioned on the autoclave cart below wrapped items for optimum sterilization and drying conditions.
- Stacking: Only containers with perforated bottoms should be stacked in High Vacuum (pre-vacuum) sterilizers; do not stack containers with solid bottoms! Stacking should not exceed 18" in height for effective air removal and adequate steam penetration.
  CAUTION: Do not cover filter perforated section with paper wrapped instruments or any other objects that could obstruct the way to air flow and steam flow. Permanent damage may occur to the container as a result of this obstruction.

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PROCESSING - high vacuum (pre-vacuum)
Run loaded sterilizer according to the manufacturer's instructions at:

- High Vacuum (pre-vacuum, three pulse, standard)
- Temp: 270° F
- Exposure Time: 4 Minutes (minimum)
- Cycle Dry Time: 20 Minutes (minimum)
- Cool Time: Varies according to load contents
  CAUTION: Cool drafts from air ducts or other air currents should be avoided during the cooling phase to avoid post-sterilization moisture caused by rapid cooling syndrome.
- The container needs to remain on the container cart, in a draft free area until cool enough to handle.

NOTE : A Container with a solid bottom may require additional cooling time; the additional required cooling time to be determined by the user.

SHELF LIFE
A real-time event-related shelf life study had been performed on the containers. The conclusion of the study is that the container is capable of storing high vacuum (pre-vacuum) sterilized medical devices for a maximum of 360 days for the Solid Bottom Containers and 360 days for the Perforated Bottom Containers as long as the container integrity has not been compromised.

CONTAINER SYSTEM WARRANTY
Integra Jarit hereby warrants all Integra Jarit Containers purchased directly from Integra Jarit or an Authorized Dealer in accordance with the following terms and conditions:

The Integra Jarit Container is guaranteed to be free from defects in material and workmanship when used for its intended purpose. Any Integra Jarit Container that proves defective in workmanship or material will either be repaired or replaced, at Integra Jarit discretion, without charge. Containers not purchased from an authorized source may not be authentic or meet Integra Jarit quality standards.

Container Gaskets Warranty
The warranty period for Integra Jarit container gaskets is three years from the date of purchase.

Periodic Maintenance
Periodic Maintenance is suggested to ensure all parts are in good working order.

Repair or Replacement
Under this Warranty, and at its discretion, Integra Jarit will repair or replace any parts of the product found to be defective in workmanship or material. Integra Jarit will determine, at its discretion, the cause and nature of any defect, the necessity and manner of repair or replacement, and all other matters pertaining to the conditions of the Integra Jarit Container System. Integra Jarit, Inc. Returned Goods Policy applies to all returned items (refer to details in current Surgical price list).

Exclusions
This Warranty shall not apply to any conditions(s) or damage resulting from negligence, misuse, improper handling, improper cleaning, improper opening techniques, or unauthorized repair work including but not limited to:

- Incidents of abuse such as denting of the Integra Jarit 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 Jarit at the request of the customer.
- Damage from fire, flood and other occurrences not under the control of the manufacturer.