

AESCULAP® Aicon™ Container System

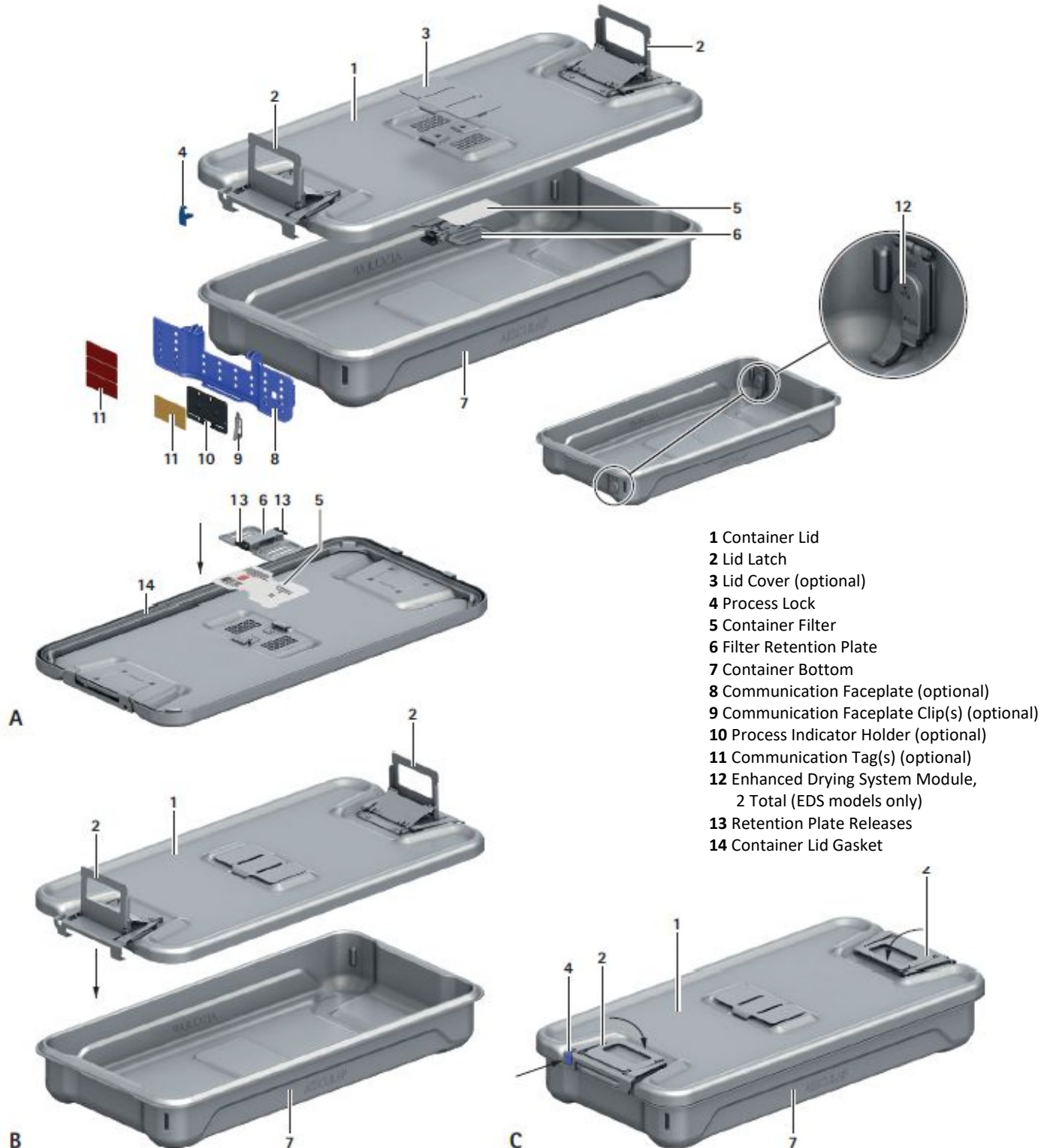
Instructions for Use



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AESCULAP® Aicon™ Container System Product Component Diagram



1.0 Purpose of Instructions for Use

The purpose of this document is to:

- Describe the components of the AESCULAP® Aicon™ Container System, how each should be used, and which components can be used together in each of the sterile processing modalities.
- Provide detailed instructions on how to use, decontaminate, clean and process the AESCULAP® Aicon™ Container System properly in different sterilization modalities.
- Give guidance for verifying the AESCULAP® Aicon™ Container System in your facility and application.

Instructions included in this document are based on validation testing by Aesculap® in a medical device testing laboratory using worst case scenario.

Personnel training and competency is required to perform all phases of processing. Sterilizing equipment, water supply and quality, and practices within a facility all contribute to providing an effective reprocessing system and should be monitored by each facility.

2.0 AESCULAP® Aicon™ Container System

The AESCULAP® Aicon™ Container System is a reusable rigid container system used for the packaging, transportation, and storage of instruments prior to, during, and after sterilization. It consists of the various sizes of container bottoms, container lid, and basket options, and should only be used with designated Aesculap® filters, locks and indicator cards identified in this IFU.

The AESCULAP® Aicon™ Container System can be identified by its JJ Series part number.

- The first digit of the model number designates the container length.
- The second digit designates the height.
- The last digit identifies the model and features.
 - o Standard solid bottom container, designated by the “0” at the end of the product number.
 - o Enhanced Drying System (EDS) solid bottom container, designated by the “1” at the end of the product number. The EDS container can also be identified by the Enhanced Drying Module, item 12 in the Product Component Diagram.
- The JJ Series use the same lids for the Standard and the EDS container bottoms.

Container Size	Standard Container	EDS Container	Lid
Full Size 4 in.	JJ110	JJ111	JJ410
Full Size 6 in.	JJ120	JJ121	
Full Size 8 in.	JJ130	JJ131	
Full Size 10 in.	JJ140	JJ141	
Three-Quarter Size 4 in.	JJ310	JJ311	JJ430
Three-Quarter Size 6 in.	JJ320	JJ321	
Three-Quarter Size 8 in.	JJ330	JJ331	
Three-Quarter Size 10 in.	JJ340	JJ341	
Half Size 4 in.	JJ210	JJ211	JJ420
Half Size 6 in.	JJ220	JJ221	
Half Size 8 in.	JJ230	JJ231	
Half Size 10 in.	JJ240	JJ241	

The AESCULAP® Aicon™ Container System lid latches should remain in the closed position at all times except when installing on and removing the lid from the container bottom.

The JJ Series may be used with the perforated baskets and trays of both the AESCULAP® Aicon™ Container System and Aesculap® SterilContainer™ System. Non-Aesculap® pre-configured baskets that meet the clearance requirements, and can be properly aseptically presented may also be used. Medical device and container IFUs parameters (time and temperature) should be reconciled. Steam sterilization dry time performance may vary by facility based on water and steam quality and/or sterilization performance. Ensure you can achieve the same end result as identified in the instrument IFU. Follow facility's policies and procedures.

Notes:

- ❖ *Thoroughly clean all Aesculap® container products, baskets, accessories and replacement parts prior to first use and after container repair service has been performed.*
- ❖ *Aesculap® baskets and accessories can be cleaned and sterilized following accepted industry guidelines and by using the same processes as Aesculap® sterile container bottoms.*
- ❖ *AESCULAP® Aicon™ Container System has ONLY been validated with Aesculap® filters, locks and indicator cards.*
- ❖ *Aesculap® Instrument Organization System (IOS) pieces and mats are made of silicone and cutting them does not change the characteristics of the material and/or its function.*
- ❖ *Aesculap® only performed container testing with baskets and does not recommend using containers without baskets or with only mats.*
- ❖ *Silicone gasket in lid and filter retention plate are latex free.*
- ❖ *See AAMI ST79 for more details and recommendations.*
- ❖ *The ORganizer – Count Sheet Holder (MD333) is made from polypropylene. Per AAMI TIR17, this material is generally known to be compatible with Steam and EtO.*

3.0 AESCULAP® Aicon™ Container System Repairs

Like all reusable medical devices, the AESCULAP® Aicon™ Container System requires inspection prior to use (refer to Section [5.0 Inspection Prior to Use](#)), and proper care and handling.

The AESCULAP® Aicon™ Container System is a FDA Class II device that requires extensive testing and FDA 510(k) clearance. An Aesculap® trained technician can repair containers to the original equipment manufacturer dimensions and specifications of the original containers used in the validation and replace parts with the same Aesculap® components.

ONLY Aesculap® trained technicians are authorized to repair the AESCULAP® Aicon™ Container System. Using a non-Aesculap® repair technician to repair containers will void the Aesculap® Warranty on the container and may void any of the validation testing associated with Aesculap® containers.

Aesculap® offers a wide variety of container repair programs that can be performed by either our highly trained technicians at our central repair facility in St. Louis, or by our mobile van repair specialists. All of the repair specialists are Aesculap® employees who go through extensive training on Aesculap® products.

Contact an Aesculap® representative or call customer service (1-800-214-3392 or atcsr.us@aesculap.com) for more details.

Notes:

- ❖ *All products being returned for maintenance/repair must be thoroughly cleaned and decontaminated before service.*
- ❖ *Retention plates, EDS Modules, faceplates, lid cover and accessories should be replaced when they show wear, age and/or are damaged. These items may be ordered separately and replaced by users.*

4.0 Decontamination and Cleaning Process

Follow facility's policies, procedures, and ANSI/AAMI ST79 recommended guidelines for the transportation of soiled instruments and containers. Always wear appropriate personal protective equipment (PPE) per the healthcare facility's policy and procedures when transporting and cleaning the AESCULAP® Aicon™ Container System.

Container, lids and baskets that may not be used or needed right away should be decontaminated and cleaned prior to storage. The AESCULAP® Aicon™ Container System should be stacked neatly, either assembled or unassembled, in a dry, clean area.

Notes:

- ❖ *If container and/or lid are soiled, they must be fully cleaned. For containers and/or lids that are not soiled and have been removed from the operating room before the patient entered, the facility should determine best cleaning practice based on its established policy and procedures.*
- ❖ ***DO NOT USE*** abrasive cleaners, metal brushes or abrasive cleaning pads. Use of abrasive products can cause permanent damage to container surfaces. Use of abrasive cleaners or pads will result in warranty exclusion.
- ❖ ***DO NOT USE*** adhesive tape or permanent labels on the surface of the AESCULAP® Aicon™ Container System. Use container Communication Faceplate to identify sets and communicate the contents of the set.
- ❖ *Remove lid retention plate by pushing inward simultaneously on the two buttons on the center section of the retention plate. To replace lid retention plate, press down evenly on retention plate. Listen to audible "click" to confirm filter is locked in place.*
- ❖ *The AESCULAP® Aicon™ Container System lid latches should remain in the closed position at all times except when installing on and removing the lid from the container bottom. Aesculap® has validated the cleaning process with the lid latches in the closed position.*
- ❖ *Aesculap® baskets and accessories can be cleaned and sterilized following the same processes as Aesculap® sterile container bottoms, and accepted industry guidelines.*

4.1 Water Quality

Water quality is an important consideration in all stages of medical device reprocessing and can contribute to providing an effective reprocessing system and should be monitored by the facility. ANSI/AAMI ST108:2023 outlines the different types of water and the specific use of each.

4.1.1 Utility Water

Utility water, per ANSI/AAMI ST108:2023, is water as it comes from the tap that might require further treatment to achieve the specifications. See ANSI/AAMI ST108:2023 for specifications table. This water is mainly used for flushing, washing, and rinsing.

4.1.2 Critical Water

Critical water, per ANSI/AAMI ST108:2023, is water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, DI, and RO 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. This water is recommended for the final rinse and steam generation to avoid discoloration or damage resulting from minerals found in utility water.

4.2 Detergent Solutions

Use detergent in a water solution where the detergent and water have a pH range of 6.5 to 8.5 to clean effectively and without causing damage to the AESCULAP® Aicon™ Container System.

Notes:

- ❖ *The use of utility water in mechanical washers may result in the water having a high alkaline level which could be harmful to the container surface. Critical water should be used for the final rinse.*
- ❖ *If white residue is observed on the container, this may have been caused by a high pH, alkaline, cleaning solution. Check pH level of water and detergent solution throughout the process—reduce to a pH of 6.5 to 8.5. The white residue does not impact form, fit or function.*

4.3 Transportation to Decontamination

Aesculap® suggests following ANSI/AAMI ST79 guidelines for the handling and transportation of contaminated instruments and containers in conjunction with facility policies and procedures.

The AESCULAP® Aicon™ Container System Standard Container has a solid bottom and can also be used to transport used and soiled instruments. When using it as a bio bin you must have a filter and the Lid Cover in place, and the container must be marked with an Aesculap® US991 bio hazard card.

If container and/or lid are soiled, they must be fully cleaned. For containers and/or lids that are not soiled and have been removed from the operating room before the patient entered, the facility should determine best cleaning practice based on its established policy and procedures. Only mechanical cleaning should be used to clean containers that were used as a bio bin.

Aesculap® also offers stainless steel bio bins that are only specifically designed for transport of soiled instruments. Aesculap® bio bins should be decontaminated following the same processes and practices as sterile containers.

See Aesculap® container catalog for more information on bio bins. Contact Aesculap® customer service to order.

4.4 Decontamination and Mechanical Cleaning

The AESCULAP® Aicon™ Container System lid latches should remain in the closed position at all times except when installing on and removing the lid from the container bottom. Aesculap® has validated the mechanical cleaning process with the lids in the closed position.

Mechanical Washer Validation Parameters (minimum)

Treatment	Time (mm:ss)	Temp
Wash Phase I	02:45	Cold tap water
Rinse	01:45	70°C
Dry	07:30	80°C

1. Remove all remaining external process indicators and disposable locks.
2. Remove lid from bottom of container.
3. Container Communication Faceplate may remain in place or removed and washed in an instrument basket.
4. Remove the basket and any instruments from the container.
5. Filter and retention plate
 - a. Remove retention plate.
 - b. Remove single use filter and discard (if present).
 - c. Rinse visible debris from retention plate(s).
 - d. The retention plate may be washed separately or installed during mechanical washing.
6. Rinse visible debris from all container components. For AESCULAP® Aicon™ Container System with EDS, the EDS module may be washed in place.
7. Place components on at an angle on the washer rack facing down to avoid water collection.
 - a. Lid handles should remain in the closed position to avoid damage.
 - b. Retention plates should face away from the direct force of pressurized washer jets to avoid damage during wash cycles.
 - c. Critical water is recommended for the final rinse and steam generation to avoid discoloration or damage resulting from minerals found in utility water.
 - d. The use of drying and/or rinse agents is not recommended.
8. After mechanical cleaning cycle
 - a. Thoroughly dry (either with a soft, dry cloth or air dry) all components, and retention before proceeding to preparation and packaging.
 - b. If retention plates were installed during mechanical washing, remove retention plate(s) and dry area between retention plate and container.

Notes:

- ❖ After cleaning visually inspect and repeat the cleaning process if a visually clean endpoint has not been achieved.
- ❖ Validation testing was performed using Prolystica® 2X Concentrate Enzymatic Cleaner (manufactured by Steris). Other medical device cleaning agents may provide similar results.

4.5 Decontamination and Manual Cleaning

Each facility should ensure their processing system provides similar results. Personnel training and competency is required to perform all phases of manual processing. Equipment, water supply, and practices all contribute to providing an effective reprocessing system and should be monitored by the facility.

Manual Cleaning Validation Parameters (minimum)

Cleaning Process Steps	Instructions
Cleaning Solution	Mild detergent solution ^{1, 2} .
Cleaning/Brushing	Submerged component and scrub with soft lint-free cloth clean container: 1 minute for bottom, 1 minute for lid.
Final Rinse	Thoroughly rinse with critical water to remove all detergent residues.
Dry	Dry using a lint-free cloth and compressed air.
Inspect	After cleaning visually inspect and repeat the cleaning process if a visually clean endpoint has not been achieved.
1. Validation testing was performed using Prolystica® 2X Concentrate Enzymatic Cleaner (manufactured by Steris). Other medical device cleaning agents may provide similar results 2. Use detergent in a water solution where the detergent and water have a pH range of 6.5 to 8.5 to clean effectively and without causing damage to the AESCULAP® Aicon™ Container System.	

1. Remove all remaining external process indicators and disposable locks.
2. Remove lid from bottom of container.
3. Remove the basket and any instruments from the container.
4. Rinse visible debris from all container components.
 - a. Container Communication Faceplate should be inspected. If dirty, remove and clean or removed and washed with instrument basket.
 - b. Filter and retention plate
 - i. Remove retention plate.
 - ii. Remove single use filter and discard (if present).
 - iii. Rinse visible debris from retention plate(s).
5. Use a soft lint-free cloth and detergent to clean all the components.
6. Critical water is recommended for the final rinse and steam generation to avoid discoloration or damage resulting from minerals found in utility water.
7. After manually cleaning
 - a. Thoroughly dry (either with a soft, dry cloth or air dry) all components, and retention before proceeding to preparation and packaging.
 - b. Replace retention plate, EDS module (if equipped) and Faceplate if storing the containers with these items in place.

Notes:

- ❖ *Cleaning wipes with pH range of 6.5 to 8.5 that do not contain chlorides will not harm the aluminum surface but Aesculap® has no validation testing for the use of wipes in the decontamination and cleaning process. The use of wipes should be determined based on established facility policy and procedures. See cleaning wipe manufacturer Instructions for Use and ANSI/AAMI ST79.*
- ❖ *If components are too large to be immersed at the facility, then the components should be cleaned in a manner that will not produce aerosols. Please refer to ANSI/AAMI ST79 for recommended practices.*

5.0 Inspection Prior to Use

Inspection of the container and its components must be conducted **PRIOR TO EVERY USE**.

If any of the conditions described in this section are observed **DO NOT USE** the AESCULAP® Aicon™ Container System container bottom and/or lid. Contact Aesculap® for repair services. Using a non-Aesculap® repair technician to repair containers will void the Aesculap® warranty applicable to the container and may void any of the validation testing associated with Aesculap® containers. See Section [3.0 AESCULAP® Aicon™ Container System Repairs](#) for full details regarding repairs.

Please refer to Sections [7.0 AESCULAP® Aicon™ Container System Sterilizer Cycle Parameters — Steam](#) to determine appropriate container bottom, lid, filter, lock and indicator card for sterilization cycle being used.

Notes:

- ❖ *After cleaning, and before use, visually inspect and repeat the cleaning process if a visually clean endpoint has not been achieved.*
- ❖ *Remove lid retention plate by pushing inward simultaneously on the two buttons on the center section of the retention plate. To replace lid retention plate, press down evenly on retention plate. Listen to audible “click” to confirm filter is locked in place.*

5.1 Container System Inspection Criteria

1. All container components should be inspected and free from
 - a. Observable cracking in aluminum and/or plastic.
 - b. Any misalignment and/or dents in which the lid and bottoms do not adequately mate.
 - c. Any pitting in the aluminum.
2. Lid silicone gasket should be inspected and free from any sign of cracking or damage.
3. Inspect retention plate by pressing in on the two tabs and lifting.
 - a. Metal filter retention plate and silicone gasket should be inspected and free from:
 - i. Any sign of cracking or damage.
 - ii. Any misalignment or damage in which retention pin, filter, retention plate and/or gasket do not adequately mate.
 - b. Confirm retention plate is not bent. Note that when performing the inspection the retention plate has a raised gasket.
 - c. Confirm filter retention plate is secure and firm.
 - d. Remove retention plate from service if it does not meet criteria above, and replace with Aesculap® part number JJ600.
4. Inspect Enhanced Drying System in place (EDS bottom only).
 - a. Confirm EDS module is present, free from cracks and/or damage, and fully latched.

Notes:

- ❖ *If white residue is observed on the container, this may have been caused by a high pH, alkaline, cleaning solution. Check pH level of water and detergent solution throughout the process—reduce to a pH of 6.5 to 8.5. The white residue does not impact form, fit or function.*
- ❖ *Retention plates, Faceplates and Lid Cover should be replaced when they show wear, age and/or are damaged.*
- ❖ *Using inspection and test methods other than those outlined in this IFU are not recommended and have not been validated by Aesculap®.*

5.2 Basket, Tray and Accessory Inspection Criteria

Baskets, lifting platforms and trays should be inspected and free from:

1. Observable cracking and/or dents
2. Any misalignment of sides, bottom or handles
3. Any loose or worn handles, parts, accessories or instrument organization system components

6.0 Preparation and Assembly of Container System

Each container bottom must **ONLY** be used with the specific lid designed for that series of container, and it should not be combined with other Aesculap® or non-Aesculap® series of bottoms or lids.

6.1 Container System Lid Assembly

1. Inspection of the container and its components must be conducted prior to every use. Only use containers and components that have passed the inspection criteria outlined in [Section 5.0 Inspection Prior to Use](#).
2. Remove retention plate by pushing inward on the two buttons on the side of the center section of the retention plate.
 - a. Place one Aesculap® filter over perforated section on the inside of the container lid.
 - b. Confirm the filter lays flat and covers openings then align and secure each filter with the retention plate. Listen to audible “click” to confirm filter is locked in place.

Notes:

- ❖ *The orientation of the paper filter can be placed in either orientation, label facing in or out of the retention plate. Facility should determine orientation based on its established policy and procedures.*
- ❖ *Aesculap® has only performed valuation testing with Aesculap® filters, locks and indicator cards identified in this IFU. Don't use non-Aesculap® processing supplies.*
- ❖ *Aesculap® JJ612 single use paper filter is not compatible with Low Temperature sterilizers.*
- ❖ *Aesculap® only used one filter under retention plate during our validation testing. If multiple filters are placed under retention plate accidentally we recommend that the set be rejected and be reprocessed.*

6.2 Assembly of Surgical Instrumentation

Instruments and all components of the AESCU LAP® Aicon™ Container System must be completely dry prior to sterilization processing to allow for adequate sterilant penetration. Sort and assemble thoroughly cleaned and dried instruments into the instrument basket(s), according to established hospital procedures. Follow instrument manufacturers' Instructions for Use.

6.3 Loading of Basket, Lifting Platform and Tray

Please refer to Sections [7.0 AESCULAP® Aicon™ Container System Sterilizer Cycle Parameters — Steam](#) to determine maximum weight of AESCULAP® Aicon™ Container System for sterilization modality selected.

1. Place assembled instrument basket(s), lifting platform or support racks into the prepared container bottom.
2. Select proper lid and insert filter under retention plate.
3. Open lid latches, place lid on assembled container bottom.
4. Confirm align of lid and latches on bottom, and simultaneously close both locking latches.

Notes:

- ❖ *All instruments should be arranged per the instrument manufacturers' Instructions for Use (IFU).*
- ❖ *Hospitals should refer to ANSI/AAMI and accepted industry guidelines, and sterilization manufacturers' Instructions for Use (IFU) regarding weights and weight limits.*
- ❖ *Medical device and container IFUs parameters (time and temperature) should be reconciled. Steam sterilization dry time performance for may vary by facility based on water and steam quality and/or sterilization performance. Ensure you can achieve the same end result as identified in the instrument IFU. Follow facilities policies and procedures.*
- ❖ *Trays and baskets may be stacked inside the AESCULAP® Aicon™ Container System if clearance requirements are met and the set follows proper acetic presentation guidelines.*

6.4 Internal Process Indicators

Per ANSI/AAMI ST79, internal process indicators are used to indicate that the container has been exposed to the sterilization process. If more than one basket/tray is used inside the container system, an indicator should be placed on each basket/tray.

The internal biological and/or chemical indicators may be placed in the center of each tray, unless the user feels a more challenging position exists elsewhere. In that case, place the chemical indicator where the user has determined the most challenging location. Use of internal indicators should be in accordance with the facility's policies and procedures.

Process indicators are designed to indicate that the device was exposed to the sterilization process while, integrating indicators are designed to react to all critical variables, with the stated values having been generated to be equivalent to, or exceed, the performance requirements given in the ISO 11138 series for BIs. See ANSI/AAMI ST79 for full description and use of each type of chemical indicator.

Notes:

- ❖ *Aesculap® has not validated placing paper count sheets inside the container. Users to process count sheets according to their facility's protocol.*

6.5 External Process Indicators and Tamper Evident Seals

Per ANSI/AAMI ST79, external process indicators are used to help visually distinguish between sets that have been exposed to sterilant and those that have not. The indicator dot on the lock is a secondary quick reference in comparison to the primary internal process indicator. Use of external indicators should be in accordance with the facility's policies and procedures.

1. Insert tamper evident lock on each end of the container in the container latch. Confirm lock is fully engaged before processing. Only the following Aesculap® locks have been validated for use with the AESCULAP® Aicon™ Container System.

AESCULAP® Aicon™ Container System Tamper Evident Locks					
Lock Color	Indicator	Part #	Quantity/Pack	PreVac Steam w/ Dry Time	PreVac Steam w/o Dry Time
Blue	No Indicator	JJ700	1,000	Yes	Yes
		JJ705	100		
Orange	Change ¹ Blue to Brown	JJ720	1,000	Yes	--
		JJ725	100		
Yellow	Change ¹ Blue to Brown	JJ721	1,000	--	Yes
		JJ726	100		
1. After sterilization, the external indicator should change from the original indicator color to indicate exposure to sterilant. <i>The post sterilization indicator color may vary and not be evenly shaded.</i>					

2. Use Aesculap® Faceplate with JJ582 Indicator Holder and MD346 Indicator Card for PreVac Steam with dry time and MD399 for PreVac Steam without dry time.

6.6 Container Storage

The AESCULAP® Aicon™ Container System is stackable. After sterilization, containers should be stored in a manner that reduces the potential for contamination, see ANSI/AAMI ST79 and ASHRAE guidelines for further details. **DO NOT** stack more than three, 25 lbs. each, containers high. Follow shelf manufacturer weight and height limit recommendations when stacking the containers during sterile storage.

Aesculap® has conducted 365 day shelf life validation testing on the AESCULAP® Aicon™ Container System after sterilization. The loss of sterility is normally event-related and not time-related. Loss of sterility is not so much connected to the storage periods as to outside influences and the effects of storage, transportation, and handling. Therefore, blanket statements cannot be made regarding appropriate storage periods, see EN ISO 11607-1, ANSI/AAMI ST79 and DIN 58953-8. Facilities should establish processes and procedures related to storage and shelf life.

The storage period of the AESCULAP® Aicon™ Container System has been investigated in various long-term studies. The preservation of sterility was demonstrated over this entire period. The storage conditions used in the tests met the requirements of ANSI/AAMI ST79 and ASHRAE.

7.0 AESCULAP® Aicon™ Container System Sterilizer Cycle Parameters — Steam

This section provides detailed charts that identify AESCULAP® Aicon™ Container System configurations, locks, indicator cards and filter(s), which should be used together for Steam modalities.

Aesculap® has performed validation testing that support the configurations shown. Configuring the container system in a manner not shown in the tables constitutes an off label use of the product.

Follow medical device manufacturers' IFU. Medical device and container IFUs parameters (time and temperature) should be reconciled. Steam sterilization dry time performance for may vary by facility based on water and steam quality and/or sterilization performance. Ensure you can achieve the same end result as identified in the instrument IFU. Follow facilities policies and procedures.

See Section [2.0 AESCULAP® Aicon™ Container System](#) for an explanation of the AESCULAP® Aicon™ Container System.

7.1 PreVac Steam without Dry Time - Standard and EDS Containers

- **Exposure Temperature & Time:** 270°F for 4 minutes
- **Dry Time:** 0 minutes minimum
- **Accessories:** Mats may be included

Container Size	Standard Container	EDS Container	Lid	Weight to Achieve Dry Time	Filter	Lock	Indicator Card ¹						
Full Size 4 in.	JJ110	JJ111	JJ410	25 lbs.	JJ612	JJ700 JJ705 JJ721 JJ726	MD346						
Full Size 6 in.	JJ120	JJ121		25 lbs.									
Full Size 8 in.	JJ130	JJ131		25 lbs.									
Full Size 10 in.	JJ140	JJ141		25 lbs.									
Three-Quarter Size 4 in.	JJ310	JJ311	JJ430	25 lbs.				JJ612	JJ700 JJ705 JJ721 JJ726	MD346			
Three-Quarter Size 6 in.	JJ320	JJ321		25 lbs.									
Three-Quarter Size 8 in.	JJ330	JJ331		25 lbs.									
Three-Quarter Size 10 in.	JJ340	JJ341		25 lbs.									
Half Size 4 in.	JJ210	JJ211	JJ420	25 lbs.							JJ612	JJ700 JJ705 JJ721 JJ726	MD346
Half Size 6 in.	JJ220	JJ221		25 lbs.									
Half Size 8 in.	JJ230	JJ231		25 lbs.									
Half Size 10 in.	JJ240	JJ241		25 lbs.									
1 Required Faceplate and JJ583 Indicator Holder													

7.2 PreVac Steam - EDS Containers, No Accessories

- **Exposure Temperature & Time:** 270°F for 4 minutes
- **Dry Time:** 8 minutes minimum
- **Accessories:** Mats and/or Lid Cover not included

Dry times may be longer in practice depending on sterilization performance and load density, quantity of instruments, instrument material, and water and steam quality.

Container Size	EDS Container	Lid	Weight to Achieve Dry Time	Filter	Lock	Indicator Card ¹			
Full Size 4 in.	JJ111	JJ410	22	JJ612	JJ700 JJ705 JJ720 JJ725	MD346			
Full Size 6 in.	JJ121		23						
Full Size 8 in.	JJ131		24						
Full Size 10 in.	JJ141		25						
Three-Quarter Size 4 in.	JJ311	JJ430	22						
Three-Quarter Size 6 in.	JJ321		23						
Three-Quarter Size 8 in.	JJ331		24						
Three-Quarter Size 10 in.	JJ341		25						
Half Size 4 in.	JJ211	JJ420	13						
Half Size 6 in.	JJ221		15						
Half Size 8 in.	JJ231		18						
Half Size 10 in.	JJ241		18						
1 Required Faceplate and JJ583 Indicator Holder									

7.3 PreVac Steam - Standard Containers, No Accessories

- **Exposure Temperature & Time:** 270°F for 4 minutes
- **Dry Time:** 15 minutes minimum
- **Accessories:** Mats and/or Lid Cover not included

Dry times may be longer in practice depending on sterilization performance and load density, quantity of instruments, instrument material, and water and steam quality.

Container Size	Standard Container	Lid	Weight to Achieve Dry Time	Filter	Lock	Indicator Card ¹
Full Size 4 in.	JJ110	JJ410	22	JJ612	JJ700 JJ705 JJ720 JJ725	MD346
Full Size 6 in.	JJ120		23			
Full Size 8 in.	JJ130		24			
Full Size 10 in.	JJ140		25			
Three-Quarter Size 4 in.	JJ310	JJ430	22			
Three-Quarter Size 6 in.	JJ320		23			
Three-Quarter Size 8 in.	JJ330		24			
Three-Quarter Size 10 in.	JJ340		25			
Half Size 4 in.	JJ210	JJ420	13			

Half Size 6 in.	JJ220		15			
Half Size 8 in.	JJ230		18			
Half Size 10 in.	JJ240		18			
<i>1 Required Faceplate and JJ583 Indicator Holder</i>						

7.4 PreVac Steam - Standard and EDS Containers, Accessories

- **Exposure Temperature & Time:** 270°F for 4 minutes
- **Dry Time:** 30 minutes minimum
- **Accessories:** Mats and/or Lid Cover included

Dry times may be longer in practice depending on sterilization performance and load density, quantity of instruments, instrument material, and water and steam quality.

Container Size	Standard Container	EDS Container	Lid	Weight to Achieve Dry Time	Filter	Lock	Indicator Card ¹			
Full Size 4 in.	JJ110	JJ111	JJ410	22	JJ612	JJ700 JJ705 JJ720 JJ725	MD346			
Full Size 6 in.	JJ120	JJ121		23						
Full Size 8 in.	JJ130	JJ131		24						
Full Size 10 in.	JJ140	JJ141		25						
Three-Quarter Size 4 in.	JJ310	JJ311	JJ430	22						
Three-Quarter Size 6 in.	JJ320	JJ321		23						
Three-Quarter Size 8 in.	JJ330	JJ331		24						
Three-Quarter Size 10 in.	JJ340	JJ341		25						
Half Size 4 in.	JJ210	JJ211	JJ420	13						
Half Size 6 in.	JJ220	JJ221		15						
Half Size 8 in.	JJ230	JJ231		18						
Half Size 10 in.	JJ240	JJ241		18						
1 Required Faceplate and JJ583 Indicator Holder										

Notes:

- ❖ *Max Total Weight = AESCULAP® Aicon™ Container System (bottom and lid) + Baskets (including mats) + Instruments + Container Accessories.*
- ❖ *For steam cycles, running a longer exposure time and/or drying time than those stated will not harm the AESCULAP® Aicon™ Container System. See instrument IFU regarding the effect on instruments.*
- ❖ *For steam cycles, if different cycle times or temperatures are used, they must be equivalent or greater than the minimum parameters noted.*
- ❖ *Position containers on the autoclave cart below wrapped sets. Heavier container sets should be placed below lighter container sets.*
- ❖ *For PreVac Steam cycles without dry time, Aesculap® recommends that each facility establish its own guidelines and policies for processing, documenting, holding/transporting and using sets.*
- ❖ *For PreVac Steam, stacking should not exceed 18 inches in height for effective air removal and adequate steam penetration. Both standard and EDS bottoms can be stacked during sterilization and in storage.*
- ❖ *See Section [9.0 Indications for Use](#) for additional information on the AESCULAP® Aicon™ Container System and accessories.*

8.0 Aseptic Presentation

Hospital procedures and AORN guidelines should always be followed when using and presenting the AESCULAP® Aicon™ Container System. The following are a set of suggested steps for an aseptic presentation of a processed sterile container.

1. Non-scrubbed person positions container on a separate dry flat surface at or slightly above the level of the sterile field.
2. Non-scrubbed person inspects physical integrity of the closed container system and assures locks are in place. For AESCULAP® Aicon™ Container System with EDS, confirm the blue indicators are visible from the outside.
3. Non-scrubbed person inspects the exterior chemical indicator(s).
 - a. After sterilization, the external indicator should change from the original indicator color to the recommended post sterilization indicator color. The recommended post sterilization indicator color may not be evenly shaded but should be shades of the proper processed color to indicate exposure to sterilant.
4. Non-scrubbed person breaks locks by simultaneously moving the latches into the open position. Before removing the lid, discard all broken pieces of the locks.
5. Non-scrubbed person opens the latches the rest of the way and removes the lid in one single step. Close lid latches after removing it from the container.
6. Non-scrubbed person checks the integrity of the filter with the naked eye by removing the filter retention plate and examining.
7. Non-scrubbed person and/or scrubbed person assures internal indicator(s) changed.
8. Scrubbed person removes the sterile contents inside by grasping both handles using appropriate aseptic technique, lifting basket and contents out.
9. Scrubbed person may move the sterile contents into the sterile field once inspection has been completed successfully.

Notes:

- ❖ *Using inspection and test methods other than those outlined in this IFU are not recommended and have not been validated by Aesculap®.*
- ❖ *Retention plates should be replaced when they show wear, age and/or are damaged.*
- ❖ *Through the sterilization process the filter may become wavy from moisture but should remain held in place by the retention plate and cover the filter openings.*
- ❖ *Hospital procedures and AORN guidelines for aseptic presentation should always be followed. Employees should be trained to the facility's procedures before performing aseptic presentation or participating in the Operation Room.*

9.0 Indications for Use

The following are FDA 510(k) cleared Indications for Use for the AESCULAP® Aicon™ Container System. The AESCULAP® Aicon™ Container System can be identified by its JJ Series part number. See Section [6.6 Container Storage](#) for details related to storage, stacking and shelf life.

9.1 AESCULAP® Aicon™ Container System — Steam Sterilization

The AESCULAP® Aicon™ Container System is a reusable rigid sterilization container system intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device during transport and until used. This container system is compatible for use in steam sterilization according to the configurations listed in the tables below.

The AESCULAP® Aicon™ Container System consists of two different container styles: a solid bottom container and enhanced drying system (EDS) container.

The AESCULAP® Aicon™ Container System includes accessories such as baskets, trays, silicone mats, instrument organizational accessories, holders, indicator cards, tamper evident locks, lid covers, faceplate holders, count sheet holders and tags.

The attached tables identifies the load configurations.

Table 1. AESCULAP® Aicon™ Container System Lumen Configurations

Sterilization Cycle	Size	Lumens
PreVac Steam with dry time (270°F, 4 min. Exposure)	Full Size	4 stainless steel lumens with > 1 mm ID x <500 mm L
	Three-Quarter Size	4 stainless steel lumens with > 1 mm ID x <400 mm L
	Half Size	4 stainless steel lumens with > 1 mm ID x <200 mm L
PreVac Steam without dry time (270°F, 3 min. Exposure) Non-Porous	Full Size	Non lumened instruments
	Three-Quarter Size	Non lumened instruments
	Half Size	Non lumened instruments
PreVac Steam without dry time (270°F, 4 min. Exposure) Porous	Full Size	4 stainless steel lumens with > 1 mm ID x <500 mm L
	Three-Quarter Size	4 stainless steel lumens with > 1 mm ID x <500 mm L
	Half Size	4 stainless steel lumens with > 1 mm ID x <125 mm L

Table 2. AESCULAP® Aicon™ Container System Configurations, Without Silicone Mat and Lid cover*

Container Type	Sterilization Method	Container Bottom Part #	Container Lid Part #	Total Loaded Container Weight (lbs.)*
Solid Bottom Container	PreVac Steam 270°F 4 min. Exposure 15 minute* dry time	JJ140	JJ410	25
		JJ130		24
		JJ120		23
		JJ110		22
		JJ340	JJ430	23
		JJ330		22
		JJ320		20
		JJ310		18
		JJ240	JJ420	18
		JJ230		18
		JJ220		15
		JJ210		13
EDS Container	PreVac Steam 270°F 4 min. Exposure 8 minute* dry time	JJ141	JJ410	25
		JJ131		24
		JJ121		23
		JJ111		22
		JJ341	JJ410	23
		JJ331		22
		JJ321		20
		JJ311		18
		JJ241	JJ420	18
		JJ231		18
		JJ221		15
		JJ211		13
Solid Bottom Container	PreVac Steam Without dry time 270°F 3 min. Exposure (Non-porous)	JJ140	JJ410	25
		JJ130		
		JJ120		
		JJ110		
	AND	JJ340	JJ430	25
		JJ330		
		JJ320		
		JJ310		
	PreVac Steam Without dry time 270°F 4 min. Exposure (Porous)	JJ240	JJ420	25
		JJ230		
		JJ220		
		JJ210		

Container Type	Sterilization Method	Container Bottom Part #	Container Lid Part #	Total Loaded Container Weight (lbs.)*
EDS Container	PreVac Steam Without dry time 270°F 3 min. Exposure (Non-porous)	JJ141	JJ410	25
		JJ131		
		JJ121		
		JJ111		
	AND	JJ341	JJ410	25
		JJ331		
		JJ321		
		JJ311		
	PreVac Steam Without dry time 270°F 4 min. Exposure (Porous)	JJ241	JJ420	25
		JJ231		
		JJ221		
		JJ211		

Table 3. AESULAP® Aicon™ Container System Configurations, with Silicone Mat and Lid Cover*

Container Type	Sterilization Method	Container Bottom Part #	Container Lid Part #	Total Loaded Container Weight (lbs.)*
Solid Bottom Container	PreVac Steam 270°F 4 min. Exposure 30 minute* dry time	JJ140	JJ410	25
		JJ130		24
		JJ120		23
		JJ110		22
		JJ340	JJ430	23
		JJ330		22
		JJ320		20
		JJ310		18
		JJ240	JJ420	18
		JJ230		18
		JJ220		15
		JJ210		13
EDS Container	PreVac Steam 270°F 4 min. Exposure 30 minute* dry time	JJ141	JJ410	25
		JJ131		24
		JJ121		23
		JJ111		22
		JJ341	JJ410	23
		JJ331		22
		JJ321		20
		JJ311		18
		JJ241	JJ420	18
		JJ231		18
		JJ221		15
		JJ211		13

Container Type	Sterilization Method	Container Bottom Part #	Container Lid Part #	Total Loaded Container Weight (lbs.)*
Solid Bottom Container	PreVac Steam Without dry time 270°F 3 min. Exposure (Non-porous)	JJ140	JJ410	25
		JJ130		
		JJ120		
		JJ110		
	AND	JJ340	JJ430	25
		JJ330		
		JJ320		
		JJ310		
	PreVac Steam Without dry time 270°F 4 min. Exposure (Porous)	JJ240	JJ420	25
		JJ230		
		JJ220		
		JJ210		
EDS Container	PreVac Steam Without dry time 270°F 3 min. Exposure (Non-porous)	JJ141	JJ410	25
		JJ131		
		JJ121		
		JJ111		
	AND	JJ341	JJ410	25
		JJ331		
		JJ321		
		JJ311		
	PreVac Steam Without dry time 270°F 4 min. Exposure (Porous)	JJ241	JJ420	25
		JJ231		
		JJ221		
		JJ211		

*Dry times and load weights are based on container with silicone mats and/or lid cover.

Table 4: AESCULAP® Aicon™ Container System Sterilization Cycle Compatible Accessories - PreVac Steam

Accessories	PreVac Steam with dry time	PreVac Steam Without dry time
Baskets, trays, indicator cards, tamper evident locks, faceplate holders, and tags.	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes
Silicone mats	Yes ¹	Yes
Lid Covers	Yes ¹	Yes

¹ Using silicone mats and/or lid covers may require a longer drying time.

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Reference to AAMI (Association for the Advancement of Medical Instrumentation) and AORN (Association of periOperative Registered Nurses) recommended practices are based on the guidelines that were available at the time of this publication. Since these standards are regularly updated, it is recommended to review the most current document and standards from these organizations.

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