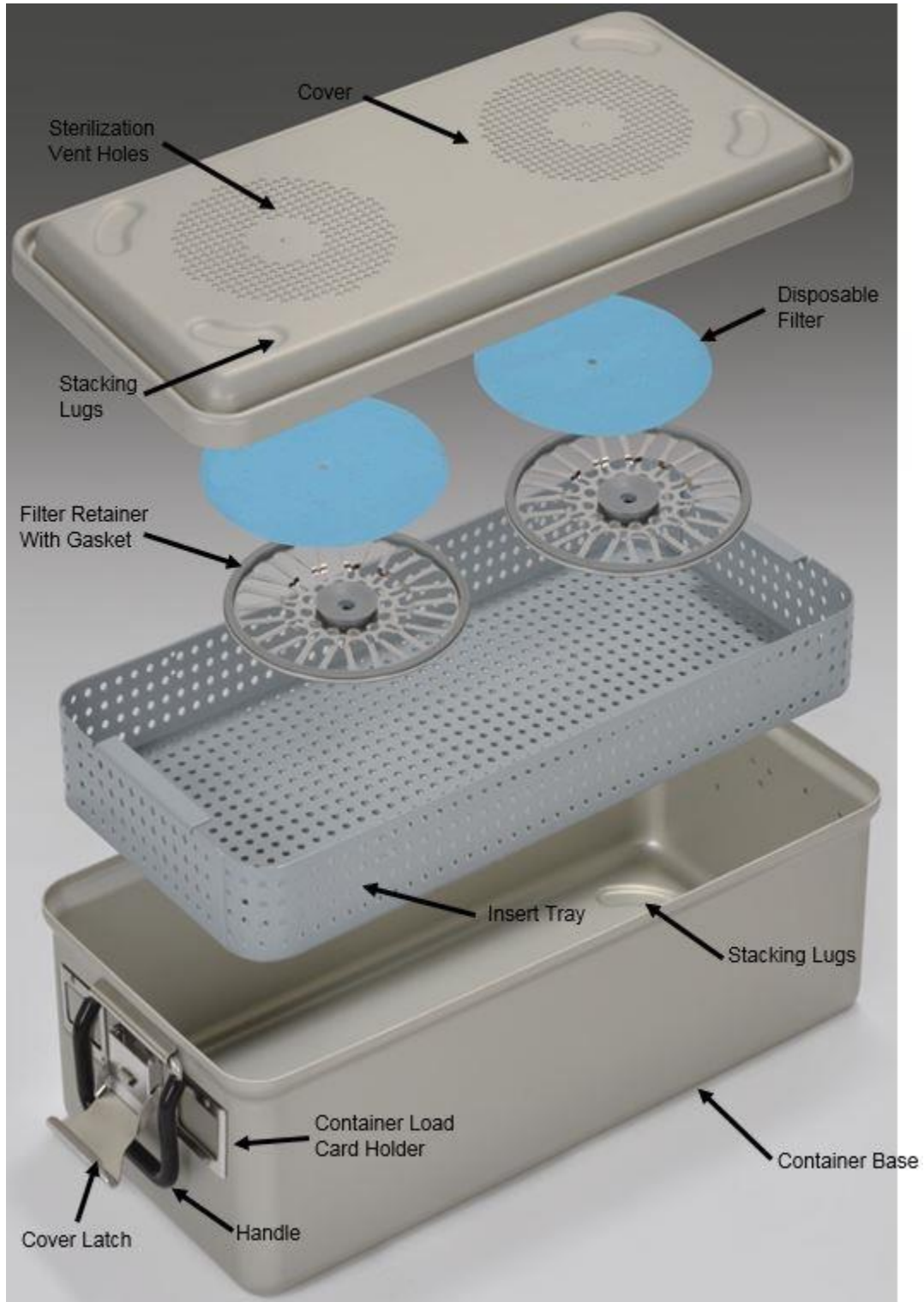




Reusable Rigid Sterilization Container System Instructions For Use



Exploded View of Basic Container Components



Jewel Precision Rigid Reusable Sterilization Container System			
Product Code	JP-24-6	JP-24-4	JP-29-6
Dynamic Air Removal Steam ⁽¹⁾	X	X	X
Gravity Steam			

Note ⁽¹⁾ The Jewel Precision Rigid Reusable Sterilization Container System has been validated for PreVacuum Steam Sterilization, and has been granted approval to market by FDA under K162600. Both AAMI ST8:2013 (Section 3.10) and ANSI/AAMI ST79:2017 (Section 2.19) define dynamic air removal cycles as "One of two types of sterilization cycles in which air is removed from the chamber and the load by a means of a series of pressure and vacuum excursions (prevacuum cycle) or by means of a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush pressure – pulse [SFPP] cycle)." Both conditioning methods provide effective air removal from the load.

Since both prevacuum and SFPP cycles are considered of the dynamic air removal type, if an instrument manufacturer's instructions for use state that a prevacuum cycle with sterilize time of 4 minutes 270F° (132°C) or 3 minutes 275°F (135°C) should be used for processing, the SFPP cycle with a sterilize time of 4 or 3 minutes, respectively, may be substituted for the prevacuum cycle.

The end user is responsible for developing validated processes which result in acceptable sterilization of container and contents.

Instructions for Use

These instructions provide information on how to use and maintain the Jewel Precision reusable rigid sterilization container system. For information that is not covered in the Instructions for Use, contact customer service at 1-973-857-5545. For

eIFU  visit www.jewelprecision.com

Indications for Use

The Jewel Precision Reusable Rigid Sterilization Container System is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It allows sterilization of the enclosed medical device and maintains sterility of the enclosed device until used, for a maximum of 1 year ⁽²⁾.

Jewel Precision Reusable Rigid Sterilization Containers are suitable for dynamic air removal (pre-vacuum) steam sterilization when used as described in the instructions for use.

Reusable containers, covers, filter holders, insert trays, and accessory items such as brackets of various configuration, dividers, caddies, and silicone nipple mats are intended to organize and secure the enclosed medical devices during sterilization and storage of the container.

Filter media allows ingress and egress of sterilant gas while providing a microbial barrier. Filter media is single use only and has a shelf life of 5 years ⁽³⁾.

Sterilization Parameters for the Jewel Precision Reusable Rigid Sterilization Container System

Sterilization Method	Cycle Parameters	Total System Weight	Applicable Containers / Accessories
Dynamic Air Removal Steam (Pre-Vacuum)	Exposure Temperature: 270°F (132°C) Pre-Conditioning Pulses: 3 Exposure Time: 4 Minutes	25 lbs.	Solid Bottom Containers with Covers and Filters; Stacking Trays, Lumen Devices, Instruments, Accessories: Bone Reamer, 19mm 0.130" x 13 1/8" Bone Reamer, 18.5mm 0.130" x 13 1/8" Bone Reamer, 18mm 0.130" x 13 1/8" Yankauer Suction Instrument 0.155" x 13 1/4" Frazier Suction Instrument, Thompson 0.150" x 12 1/4"

	<p>Dry Time Cycle: 30 Minutes</p> <p>Minimum Cooling Time: 60 Minutes (may vary according to load contents)</p> <p>Stack Height: Maximum 2</p>	<p>Frazier Suction Instrument, No. 5 Short 0.048" x 6"</p> <p>Frazier Suction Instrument, No. 7 Short 0.064" x 6"</p> <p>Frazier Suction Instrument, No. 6 Long 0.055" x 7 1/2"</p> <p>Frazier Suction Instrument, No. 7 Long 0.066" x 7 1/2"</p> <p>Frazier Suction Instrument, No. 8 Long 0.073" x 7 1/2"</p> <p>Frazier Suction Instrument, No. 9 Long 0.092" x 7 1/2"</p> <p>Frazier Suction Instrument, No. 10 Long 0.106" x 7 1/2"</p> <p>Frazier Suction Instrument, No. 11 Long 0.110" x 7 1/2"</p> <p>Frazier Suction Instrument, No. 12 Long 0.115" x 7 1/2"</p> <p>Poole Suction Instrument, Inner, 6 each 0.075" x 9 5/8"</p> <p>Poole Suction Instrument, Outer, 6 each 0.230" x 7 1/4"</p> <p>Lesion Reamer, 20mm 0.095" x 4"</p> <p>Lesion Reamer, 20mm 0.098" x 5 3/4"</p> <p>Forceps, Theken INST-21 980121-B</p> <p>Tiemann Hook Forceps (conjoined, touching surfaces*)</p> <p>Slap Hammer, Stainless Steel</p> <p>Caddy and Cover, Heat Stabilized Polypropylene (Tecapro) Bottom, Polyphenylsulfone (Radel) Cover</p> <p>Silicone Brackets, single slot through ten slot</p> <p>Stainless Steel screws and cap nuts</p> <p>Stainless Steel filter retainer assembly</p> <p>Filter media</p> <p>Silicone gaskets for cover and filter retainer</p> <p>Silicone nipple mat</p> <p>Materials**: Metals, Polymers</p>
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*Examples of instruments which are conjoined: scissors, forceps, clamps (including double action), hand held and self retaining retractors, needle holders, osteotomes / chisels, rongeurs, kerrison rongeurs, specula.

Note: Air tight occluded challenges are devices entailing surfaces which are completely obstructed. These types of devices have not been validated for use in the Jewel Precision Reusable Rigid Sterilization Container System.

**Materials: Intrinsically stable metals, composites, thermoplastic and thermosetting polymers designated for constant use at temperatures above 135°C.

Examples of intrinsically stable metals include stainless steel, titanium (commercially pure and alloys) and aluminum. Examples of thermoplastic polymers include Polyetheretherketone (PEEK), Polyetherketoneketone (PEKK), Polyetherimide (PEI), Acetal (Delrin), Polyphenylsulfone (PPSU), Polyamide (Nylon), Polytetrafluoroethane (PTFE), Polypropylene (PP), Acrylonitrile Butadiene Styrene (ABS), and Polyoxymethylene (POM).

Accessories and Device Challenges by Container Style and Sterilization Modality

Type of Container	Contents / Configuration	Pre-Vacuum Steam
Solid Bottom Container	Stacking Trays	Yes
	Lumen: 0.130" x 13 1/8"	Yes, maximum 3
	Lumen: 0.155" x 13 1/4"	Yes, maximum 1
	Lumen: 0.150" x 12 1/4"	Yes, maximum 1
	Lumen: 0.048" x 6"	Yes, maximum 1
	Lumen: 0.064" x 6"	Yes, maximum 1
	Lumen: 0.055" x 7 1/2"	Yes, maximum 1
	Lumen: 0.066" x 7 1/2"	Yes, maximum 1
	Lumen: 0.073" x 7 1/2"	Yes, maximum 1
	Lumen: 0.092" x 7 1/2"	Yes, maximum 1
	Lumen: 0.106" x 7 1/2"	Yes, maximum 1
	Lumen: 0.110" x 7 1/2"	Yes, maximum 1
	Lumen: 0.115" x 7 1/2"	Yes, maximum 1
	Lumen: 0.075" x 9 5/8"	Yes, maximum 6
	Lumen: 0.230" x 7 1/4"	Yes, maximum 6
	Lumen: 0.095" x 4"	Yes, maximum 1
	Lumen: 0.098" x 5 3/4"	Yes, maximum 1
	Occluded / Mated Challenge	Yes
	Silicone Bracket	Yes
	Silicone Mat	Yes
	Silicone Gaskets	Yes
	Caddy and Cover	Yes
	Filter	Catalog Number 100-0003
Stack Height	2	
Materials	Metals, Polymers	
Maximum Total Container System Weight	25 Pounds	


Solid Bottom Containers

Catalog Code Number	Description	Container Dimensions (with Cover), Inches	Container Weight (empty), Pounds
Master product JP-24-6	Full Length 6 Inch High Container with Cover	22.7 x 11.2 x 6.9	8.6

Container Accessories

Catalog Code Number	Accessory Description
100-0003	Filter, Single Use Only.
100-0004	Filter Retainer with USP Class VI Silicone gasket, replacement part.
100-0005	Cover with USP Class VI Silicone gasket, replacement part.
200-SI-01-01	One Slot Nylon Coated Bracket with Silicone Insert, 1mm
200-SI-01-02	One Slot Nylon Coated Bracket with Silicone Insert, 2mm
200-SI-01-03	One Slot Nylon Coated Bracket with Silicone Insert, 3mm
200-SI-01-04	One Slot Nylon Coated Bracket with Silicone Insert, 4mm
200-SI-01-05	One Slot Nylon Coated Bracket with Silicone Insert, 5mm
200-SI-01-06	One Slot Nylon Coated Bracket with Silicone Insert, 6mm
200-SI-01-07	One Slot Nylon Coated Bracket with Silicone Insert, 7mm
200-SI-01-08	One Slot Nylon Coated Bracket with Silicone Insert, 8mm
200-SI-01-09	One Slot Nylon Coated Bracket with Silicone Insert, 9mm

200-SI-10-01	Ten Slot Nylon Coated Bracket with Silicone Insert, 1mm
200-SI-10-02	Ten Slot Nylon Coated Bracket with Silicone Insert, 2mm
200-SI-10-03	Ten Slot Nylon Coated Bracket with Silicone Insert, 3mm
200-SI-10-04	Ten Slot Nylon Coated Bracket with Silicone Insert, 4mm
200-SI-10-05	Ten Slot Nylon Coated Bracket with Silicone Insert, 5mm
200-SI-10-06	Ten Slot Nylon Coated Bracket with Silicone Insert, 6mm
200-SI-10-07	Ten Slot Nylon Coated Bracket with Silicone Insert, 7mm
200-SI-10-08	Ten Slot Nylon Coated Bracket with Silicone Insert, 8mm
200-SI-10-09	Ten Slot Nylon Coated Bracket with Silicone Insert, 9mm
200-SI-12-01	Twelve Slot Nylon Coated Bracket with Silicone Insert, 1mm
200-SI-12-02	Twelve Slot Nylon Coated Bracket with Silicone Insert, 2mm
200-SI-12-03	Twelve Slot Nylon Coated Bracket with Silicone Insert, 3mm
200-SI-12-04	Twelve Slot Nylon Coated Bracket with Silicone Insert, 4mm
200-SI-12-05	Twelve Slot Nylon Coated Bracket with Silicone Insert, 5mm
200-SI-12-06	Twelve Slot Nylon Coated Bracket with Silicone Insert, 6mm
200-SI-12-07	Twelve Slot Nylon Coated Bracket with Silicone Insert, 7mm
200-SI-12-08	Twelve Slot Nylon Coated Bracket with Silicone Insert, 8mm
200-SI-12-09	Twelve Slot Nylon Coated Bracket with Silicone Insert, 9mm
200-SI-09-01	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 1mm
200-SI-09-02	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 2mm
200-SI-09-03	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 3mm
200-SI-09-04	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 4mm
200-SI-09-05	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 5mm
200-SI-09-06	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 6mm
200-SI-09-07	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 7mm
200-SI-09-08	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 8mm
200-SI-09-09	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 9mm
200-SI-09-10	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 10mm
200-SI-09-11	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 11mm
200-SI-09-12	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 12 mm
200-SI-09-13	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 13mm
200-SI-09-14	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 14mm
200-SI-09-15	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 15mm
200-SI-09-16	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 16mm
200-SI-09-17	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 17mm
200-SI-09-18	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 18mm
200-SI-09-19	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 19 mm
200-SI-09-20	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 20mm
200-SI-09-21	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 21mm
200-SI-09-22	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 22mm
200-SI-09-23	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 23mm
200-SI-09-24	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 24mm
200-SI-09-25	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 25mm
200-SI-09-26	One Slot 45° Angle Nylon Coated Bracket with Silicone Insert, 26mm
200-0016	Phillips Pan Head Screw, 10-32 x 3/8", Stainless Steel
200-0017	Cap Nut, 10-32, Stainless Steel
400-0028	Pin Mat, USP Class VI Silicone
001-SI-055A	Full Tray, 10" x 20" x 2.25", Perforated, Anodized Aluminum
NV-36-9-CD	Caddy and Cover, Tecapro Bottom, Radel Cover, 3" x 3.25" x 0.75"

 **Caution**

- Do not use sterilization containers, covers, filter retainers, trays and brackets that are damaged or have signs of cracking, corrosion or pitting of aluminum surfaces, misalignment resulting in container and cover not mating properly, and damaged gaskets. Sterility and integrity of the contained devices could be compromised.
- Do not load containers into sterilizer on sides or upside down. Load containers so that the cover is always facing upward.

- Do not stack instruments within the sterilization container. Assemble instruments to allow uniform exposure to steam during the sterilization process.
- Do not stack more than 2 containers with 25 pound loads in each container in the sterilization chamber. Stacking of more than 2 containers and overloading of the sterilization chamber will adversely affect sterilization effectiveness.
- Do not use the contained devices if the inspection before use shows any issues with the physical integrity of the container, the integrity of the closures, the filter, and the external Biological Indicator (BI) or Chemical Indicator (CI). Sterile integrity of the contained devices could be compromised.

Precautions:

- Always follow the instrument manufacturer's instructions for safe handling of the instruments.
- Only use Jewel Precision parts and accessories as they are specifically designed to work properly with the Jewel Precision Containers and Trays.
- Locate brackets in the trays in a manner to ensure instruments such as hemostats and retractors are in open positions in order to facilitate effective sterilization. Instruments which have removable parts such as sleeves must be disassembled to facilitate effective sterilization.
- Small baskets, trays, other types of accessories, especially with cover or lids, should only be used with the sterilization container, if the sterilization container has been specifically designed and tested for that purpose.
- Use of nonabsorbent tray liners such as silicone pin mats may cause condensate to pool. Assure all container components are thoroughly dry prior to use.



Caution

Procedures detailed in the Instructions for Use should be carried out by trained, qualified personnel.

Assembly

Inspect, clean, and rinse Containers, Trays, and Accessories before use. Improper preparation of Containers, Trays, and Accessories may have adverse effects on nylon and anodized coatings.

Inspection Prior to Use

To ensure proper performance of Jewel Precision Rigid Sterilization Containers, Instrument Trays, and accessories, a thorough inspection of all components must be conducted prior to each use. Pay attention to the following:

Containers, covers, filter retainers, trays, and brackets must be free from:

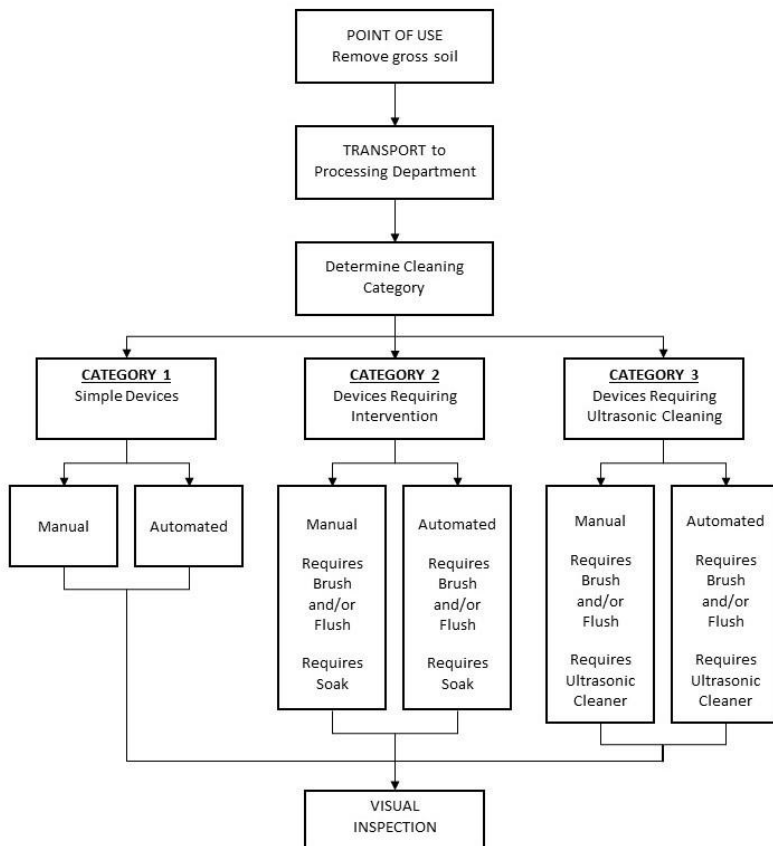
- Noticeable cracking.
- Any corrosion or pitting of aluminum surfaces.
- Misalignment resulting in container and cover not mating properly.
- Damaged gaskets.

If any of the above conditions occur, do not use the product. Return unusable products to Jewel Precision for repair or replacement.

Recommended Standardized Cleaning Process

The following flowchart provides an overview of three (3) categories of recommended AAMI standardized cleaning processes to be used prior to high-level disinfection and / or sterilization and identifies the minimum steps for each category.

The Jewel Precision JP-24-6 reusable sterilization container falls under the recommendations for **CATEGORY 2** - Devices Requiring Intervention. Follow the steps outlined in the flowchart and defined in the following processing instructions for AAMI Cleaning Process 2: Manual plus automated or manual only.



Processing instructions for Category 2

AAMI Cleaning Process 2: Manual plus automated

<p>WARNINGS</p>	<p>Use only properly diluted enzymatic or pH neutral (pH of approximately 7.0) cleaners which are recommended for use in cleaning sterilization containers manufactured from anodized aluminum. Use only mild, sodium carbonate free, enzymatic or pH neutral cleaners for effective cleaning without damaging the Container and Tray components. Contact the manufacturer of the cleaner to determine suitability for cleaning Container and Tray components and accessories. Use of a detergent with a highly acidic or highly alkaline pH could permanently damage the anodized finish of the container. A neutral pH is defined as 7.0. The post dilution pH level should be in the range of 5.5 to 8.5.</p> <p>Do not use high pH (highly alkaline) or low pH (highly acidic) cleaners, as they may damage the anodized finish of the container, or the nylon coated accessories. Do not use abrasive cleaners, or metal brushes. Use of abrasive products may cause permanent damage to surfaces. Use of high pH cleaners, abrasive cleaners, or metal brushes will void the product warranty.</p> <p>Users should inspect the container, trays and cover subsequent to cleaning, to verify a “Visually Clean” endpoint has been reached. If such an endpoint has not been reached, cleaning must be repeated.</p> <p>To ensure proper performance of Jewel Precision Rigid Sterilization Containers, Instrument Trays, and accessories, a thorough inspection of all components must be conducted <u>prior to each use</u>. Pay attention to the following:</p> <p>Containers, covers, filter retainers, trays, and brackets must be free from:</p> <ul style="list-style-type: none"> • Noticeable cracking. • Any corrosion or pitting of aluminum surfaces. • Misalignment resulting in container and cover not mating properly. • Damaged gaskets. <p>If any of the above conditions occur, do not use the product. Return unusable products to Jewel Precision for repair or replacement.</p>
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Limitations on processing	Do not clean anodized container components (container, cover, and anodized trays) which incorporate threaded components, in an ultrasonic washer. Cavitation which occurs during ultrasonic washing may loosen components which incorporate threads. Components that incorporate threads which are subject to loosening during washing should be inspected to determine if they require tightening.
Pre-treatment at the point of use	Remove excess soil by wiping and / or rinsing. Suction / flush internal channels with water. Keep moist to prevent soil from drying. Do not transport in standing liquid.
Transport to processing	Transport all soiled containers and accessories to the reprocessing area using procedures approved and validated by your institution. Soiled containers, accessories and instruments should be reprocessed as soon as possible after use.
Preparation before cleaning	All containers and trays must be open and disassembled as far as possible for reprocessing. Remove load identification cards and dispose or retain according to institutional policy. Do not reuse load identification cards. Remove cover from the container. Remove Filter Retainers and discard used sterilization filters. Remove trays from the container. Remove instruments from the trays and set aside for cleaning per the instructions provided by the instrument manufacturer. Remove processing indicators and any other accessories from the container and trays. Jewel Precision accessories are used in the containers and trays to organize medical devices for sterilization. Accessories must be inspected for security and soiling each time the container and trays are to be cleaned. Soiled accessories such as silicone finger mats and silicone bracket inserts may be cleaned with a soft bristle brush, paying attention to all difficult to access areas which may harbor soil or debris. All components and accessories of the Jewel Precision reusable rigid sterilization container system may be cleaned by manually or by automated mechanical processes. Rinse off gross debris with cool water (<45°C / 113°F). Do not allow organic soil to dry before rinsing, as it will be more difficult to remove. Many organic soils, including proteinaceous blood components such as albumin and hemoglobin, are water soluble and can be easily washed away with water alone. It is important to prevent the denaturing of these proteins by thermal or chemical means, by not using hot water, alcohol, or chemical sterilants, as denaturing can make their removal much more difficult. <u>The temperature of water used for pre cleaning should not exceed 45°C (113°F).</u>

Cleaning: <u>Manual</u>	<ol style="list-style-type: none"> 1. In an appropriate vessel, prepare a bath with a cleaning agent intended for cleaning surgical instruments (enzymatic / neutral pH detergent solution ((Endozime AW Plus, at 17 mL per 4L)), utilizing water with a temperature range of 81°F to 111°F (27°C to 44°C), and mixed according to the instructions for use of the detergent. 2. Fully immerse device in bath and flush/fill internal channels with cleaning solution. 3. Allow to soak for a minimum of 5 minutes. 4. Using a sponge or soft brush, clean the components under the detergent solution. Remove all visible soil from the container and components. Actuate all movable parts while brushing. Pay attention to difficult to clean areas such as hinges, small holes and openings. Change the detergent solution when it becomes grossly contaminated, bloody or turbid. 5. While still immersed, brush all surfaces (internal and external) of the device under the surface of the cleaning bath solution (to minimize chances for aerosolization). Brush until all visible soil is removed. 6. In a second vessel, rinse all surfaces of the device with copious amounts of water to remove any remaining debris that may have redeposited upon the device and all cleaning solution until water runs visually clear. 7. If applicable, flush internal channels with water to remove residual detergents and organics. Flush until water runs visually clear. 8. If using Manual cleaning process only, proceed to inspection. Otherwise, proceed to Automated section.
Cleaning: <u>Automated</u>	<ol style="list-style-type: none"> 1. Run in an instrument cleaning cycle using an automated washer. 2. Proceed to disinfection and final rinse section.

	3. Cleaning cycle parameters:																												
	<table border="1"> <thead> <tr> <th>Phase</th> <th>Cycle Time in Minutes</th> <th>Water Temperature</th> <th>Cleaning agent</th> </tr> </thead> <tbody> <tr> <td>Pre Wash</td> <td>00:15</td> <td>Cool water (<45°C)</td> <td>Not Applicable</td> </tr> <tr> <td>Wash 1</td> <td>02:00</td> <td>Hot Water 65.5° C</td> <td>ENZOL pH neutral Enzymatic detergent 1oz/gallon</td> </tr> <tr> <td>Wash 2</td> <td>02:00</td> <td>Hot Water 65.5° C</td> <td>Prolystica 2X Neutral Detergent ¼ oz/gallon</td> </tr> <tr> <td>Rinse 1</td> <td>00:15</td> <td>Tap Water 82° C</td> <td>Not Applicable</td> </tr> <tr> <td>Critical Water Rinse (AAMI TIR34)</td> <td>00:10</td> <td>Non-Recirculating 82° C</td> <td>Not Applicable</td> </tr> <tr> <td>Drying</td> <td>07:00</td> <td>115.5 ° C</td> <td>Not Applicable</td> </tr> </tbody> </table>	Phase	Cycle Time in Minutes	Water Temperature	Cleaning agent	Pre Wash	00:15	Cool water (<45°C)	Not Applicable	Wash 1	02:00	Hot Water 65.5° C	ENZOL pH neutral Enzymatic detergent 1oz/gallon	Wash 2	02:00	Hot Water 65.5° C	Prolystica 2X Neutral Detergent ¼ oz/gallon	Rinse 1	00:15	Tap Water 82° C	Not Applicable	Critical Water Rinse (AAMI TIR34)	00:10	Non-Recirculating 82° C	Not Applicable	Drying	07:00	115.5 ° C	Not Applicable
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Drying	07:00	115.5 ° C	Not Applicable																										
Maintenance, Inspection and Testing	<ol style="list-style-type: none"> 1. Inspect for cleanliness, function and integrity. Use of lighted magnification and/or a digital borescope for visual inspection may be needed. 2. If visible soil remains, re-clean device. If the integrity of the device is in question, mark for repair and follow facility policies for repair/replacing damaged devices. 																												

Limits of Reuse and Acceptance Criteria for Reuse; Estimated Service Life

The Jewel Precision reusable rigid sterilization container has been validated for reuse through 100 sterilization and cleaning cycles, in both manual and automated cleaning processes, using the detergents and cycle parameters listed in the preceding table. Do not use sterilization containers, covers, filter retainers, trays and brackets that are damaged or have signs of cracking, corrosion or pitting of aluminum surfaces, misalignment resulting in container and cover not mating properly, and damaged gaskets. Sterility and integrity of the contained devices could be compromised.

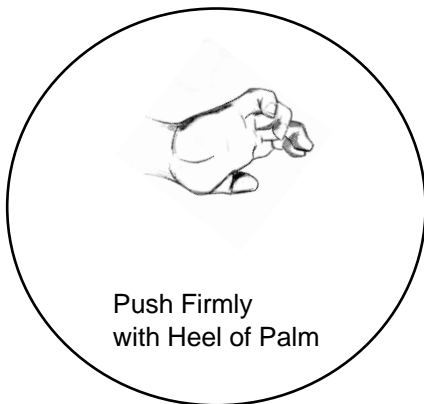
The estimated service life of the Jewel Precision Reusable Sterilization container is 10 to 12 years, based on competitors published data (Medline Industries Steriset, ©2021); or an average period of use of 13.25 years (Health Economics Review article: Analysis of processes and costs of alternative packaging options of sterile goods in hospitals – a case study in two German hospitals, January 17, 2019).

ASSEMBLY FOR USE:

Inspection and Preparation

- The Jewel Precision reusable rigid sterilization container system must be inspected prior to use for damage. Damage may result in improper function of container or trays. Failure due to damage includes the inability to close or to maintain a secure closure, which can result in sterility failure. Routine inspection of the gasket and lid will alert you to potential repair or replacement issues.
- Identify surgical instrument set to be sterilized.
- Identify the appropriate container, instrument trays and accessories.
- Assure all components are completely dry.

- Insure sterilization vent holes are unobstructed to permit proper dynamics during the sterilization process. Obstructed vent holes can hinder proper processing, and may result in failure to achieve sterilization, or damage to the container and / or its contents.
- Do not apply adhesive tape to the container, instrument trays, or accessories.
- Condensate may pool if tray liners such as finger mats are used.
- In mixed loads, place containers on the autoclave cart positioning them below wrapped absorbent goods, to prevent condensate from wetting the wrapped goods.
- Place appropriate internal and external FDA cleared steam biological and chemical sterilization indicators in accord with your institutional policy and procedures. The most challenging area of the rigid sterilization containers for the placement of internal BI's is the bottom instrument tray, when 2 trays are internally stacked, within lumens, within the pivot of an instrument such as forceps, or between an instrument and a supporting bracket.
- Use trays to separate instrument sets, allowing sufficient space to attain acceptable drying results.
- Place instrument sets securely in trays, taking care to keep instruments from obstructing placement of top tray and prevent cover from closing or damage filter retainers or instruments. Do not overload the trays. Separate instrument sets and place in multiple containers in order to prevent overloading and comply with ANSI/AAMI ST77: 2018 guidelines regarding weight limits for containers.
- Place instrument trays in container.
- Use only Jewel Precision single use filters, Part Number 100-0003 with the Jewel Precision reusable rigid sterilization container. Other filters have not been validated for use. Use one filter layer over each vent area, and secure each with a filter retainer. Do not use filters which are beyond the expiration date on the filter carton.
- Place filter retainers on the retaining pins protruding through the center of each filter.
- Using the heel of the palm of your hand, sharply depress the center cover of the filter retainer as shown in the graphic etched on the center cover and below. When properly engaged, there will be an audible "Click". Ensure proper engagement of filter retainers.



- Place cover on container and close both locking latches.
- Insert container locks, load identification cards, and any other items required by your institutional policies.

 **Caution**

- Each institution should validate sterilization cycles which are appropriate for the tray content, total load, stacking, and sterilizer being used. Consult the sterilizer manufacturer for specific recommendations.
- Review the sterilizer manufacturer's Instructions for Use to determine whether the utilities in your facility, such as equipment, steam quality, sterilization procedures, etc., satisfy the sterilizer manufacturer's requirements. Consult the sterilizer manufacturer to resolve issues with equipment and utilities.
- Institutions should refer to ANSI/AAMI ST77: 2018 guidelines regarding weight limits for containers. Utilize proper lifting and handling techniques for heavy containers. A Jewel Precision reusable rigid sterilization container weight of 25 pounds (11.34 kilograms) has been validated using a pre-vacuum steam sterilization process. The container was configured to represent a worst case sterilization vent to container volume ratio challenge using a 6" high container with internal trays stacked 2 high.
- Stack containers no more than two high in pre-vacuum steam sterilization cycles.

- Use only genuine Jewel Precision filters, trays, accessories, and replacement parts. Genuine Jewel Precision branded items are validated for use with the Jewel Precision reusable rigid sterilization container. Use of parts other than those provided by Jewel Precision has not been validated.
- Assemble instruments to allow uniform exposure to steam during the sterilization process and to ensure instruments, such as hemostats and retractors, are in open positions in order to facilitate effective sterilization. Instruments which have removable parts, such as sleeves, must be disassembled to facilitate effective sterilization.
- Complex instruments, such as powered instruments, endoscopes, and instruments with multiple parts should be prepared and sterilized in accord with instructions provided by the instrument manufacturer.
- Device tracking must comply with your institutional policy and tracking system.
- Devices with surfaces which are complete, unbroken or obstructed represent air tight occluded challenges. Such devices have not been validated for use with the Jewel Precision reusable rigid sterilization container.
- Threaded connections that cannot be loosened prior to cleaning have not been validated for use with the Genesis reusable rigid sterilization container system.
- Devices with threaded connections which cannot be disconnected have not been validated for use with the Jewel Precision reusable rigid sterilization container.
- Materials which have been validated for use with the Jewel Precision reusable rigid sterilization container include metals, composites, and polymers. Other materials have not been validated for use.
- Jewel Precision Filters, Part Number 100-0003, are Single Use Only. Discard filters after each use. Use single filter layer thickness only. Place filters over each sterilization vent area. Be certain there are no folds, wrinkles or creases in the filter media. Do not use filters which are beyond the expiration date on the filter carton.
- Use the correct load identification card material for pre-vacuum steam sterilization. Cellulosic materials are compatible with steam processes.
- Note: Only Biological Indicators and Chemical Sterilization Process Indicators that are legally marketed and FDA cleared for use in Pulsed Pre-Vacuum Steam Sterilization at the specific cycle settings of temperature of 270°F / 132°C with exposure of 4 minutes may be used to monitor the sterilization process. In addition, these indicators must be used in accordance with your institutional policy and procedures.



Caution

- Do not use filter materials in the presence of flammable anesthesia. A safety hazard may occur.

Instrument and Container Assembly

Jewel Precision reusable rigid sterilization containers have been validated for sterilization of instruments and lumens with the following diameters and lengths, at a maximum container weight of 25 pounds, with 2 internally stacked trays, containers externally stacked 2 high in autoclave. Users must follow institutional guidelines and published standards for sterilization validation of their instrument sets. Each institution should validate sterilization cycles which are appropriate for the tray content, total load, internal and external stacking, and sterilizer being used.

<u>Instruments</u>	<u>Quantity</u>
Slap Hammer	1

<u>Occluded / Mated Instruments</u>	<u>Quantity</u>
Forceps	1
Hook Forceps	1

<u>Lumens</u>		<u>Inside Diameter x Length</u>
Bone Reamer, 19mm	1	0.130" x 13 1/8"
Bone Reamer, 18.5mm	1	0.130" x 13 1/8"

Bone Reamer, 18mm	1	0.130" x 13 1/8"
Yankauer Suction Instrument	1	0.155" x 13 1/4"
Frazier Suction Instrument	1	0.150" x 12 1/4"
Frazier Suction Instrument, No. 5 Short	1	0.048" x 6"
Frazier Suction Instrument, No. 7 Short	1	0.064" x 6"
Frazier Suction Instrument, No. 6 Long	1	0.055" x 7 1/2"
Frazier Suction Instrument, No. 7 Long	1	0.066" x 7 1/2"
Frazier Suction Instrument, No. 8 Long	1	0.073" x 7 1/2"
Frazier Suction Instrument, No. 9 Long	1	0.092" x 7 1/2"
Frazier Suction Instrument, No. 10 Long	1	0.106" x 7 1/2"
Frazier Suction Instrument, No. 11 Long	1	0.110" x 7 1/2"
Frazier Suction Instrument, No. 12 Long	1	0.115" x 7 1/2"
Poole Suction Instrument, Inner	6	0.075" x 9 5/8"
Poole Suction Instrument, Outer	6	0.230" x 7 1/4"
Lesion Reamer	1	0.095" x 4"
Lesion Reamer	1	0.098" x 5 3/4"

Definition of Lethality Challenge Type for Instruments Above

- Lumen:
A tube of listed Inside Diameter (ID) and Length (L). The Inner Diameter x Length Lumens listed above have been validated for use in pre-vacuum steam sterilization in the Jewel Precision reusable rigid sterilization container.
- Occluded / Mated:
Devices which have surfaces which are conjoined, meet, or touch. Examples used in this challenge: single action forceps and hook forceps have **conjoined** surfaces which are normally held in the open position during sterilization. Similar instruments are scissors, clamps, retractors, needle holders, Kerrison rongeurs, and specula. Instruments secured to silicone brackets have surfaces which **meet or touch**. Examples used in this challenge: hammers and lumens. Similar instruments are chisels and osteotomes. Airtight occluded challenges are devices with surfaces that are completely obstructed. Such devices have not been validated for use with the Jewel Precision reusable rigid sterilization container.

Tray Liners

Using absorbent tray liners has not been validated in Jewel Precision reusable rigid sterilization containers. Jewel Precision reusable rigid sterilization containers have been validated for pre-vacuum sterilization and drying with the use of non-absorbent tray liners (silicone pin mats). The use of tray liners is not required to achieve proper drying when processed using the suggested sterilization cycle parameters.

Stacking of Trays

Jewel Precision trays are designed to stack by supporting upper trays on the integral handles of the tray. The trays are designed to provide approximately 1 1/8" (2.85 cm) clearance between the tray and the top of the container. Keep instruments below the upper edge of the tray, to facilitate proper closing and seating of the upper sealing surface of the container against the cover gasket.

Materials

All materials must meet the requirement for constant use above 135°C. Such materials include:

- Inherently stable metals. Examples are stainless steel, aluminum, and titanium.
- Composite materials. An example is Carbon Fiber Reinforced Epoxy.
- Thermoplastic polymers. Examples are Polyetheretherketone (PEEK), Polyetherketoneketone (PEKK), Polyetherimide (PEI, Ultem), Polyoxymethylene (Acetal, Delrin), Polyphenylsulfone (Radel), Polyamide (Nylon), Polytetrafluoroethylene (PTFE, Teflon), Polypropylene (PP), and Acrylonitrile / Butadiene / Styrene (ABS).
- Thermosetting polymers. Examples of thermosetting polymers are Phenol Formaldehyde (Phenolic resin) and Organopolysiloxane (Silicone resin).

PROCESSING:

Loading the Sterilizer

- Containers should be flat in order to achieve effective sterilization and drying. Do not place containers on their side. Do not invert containers.
- When sterilizing mixed loads, place containers on shelves below absorbent wrapped goods. Make certain sterilization vent holes are unobstructed by wrapped goods, internal items, and other containers. Place containers on unlined autoclave shelves in order to achieve acceptable drying.
- Containers have been validated stacked two high with a 25 pound load in each, including lumens previously listed.
- Utilize safe lifting and handling practices, as containers may be heavy.
- Each institution should validate sterilization cycles which are appropriate for the tray content, total load, stacking, and sterilizer being used.

Suggested Sterilization Cycle Parameters

The following parameters are based upon ANSI/AAMI ST77: 2018, ANSI/AAMI ST79: 2017 with amendments A1:2020, A2:2020, A3:2020, A4:2020, and AAMI TIR 12:2020 guidelines for Pulsed Pre Vacuum Steam Sterilization and Gravity Displacement Steam Sterilization processes.

Each institution should validate sterilization cycles which are appropriate for the tray content, total load, stacking, and sterilizer being used. Consult with the sterilizer manufacturer for specific recommendations. Complex instruments, such as powered instruments, endoscopes, instruments with lumens or channels, and instruments with multiple parts should be prepared and sterilized in accord with instructions provided by the instrument manufacturer.

The following recommendations may include sterilization temperatures, cycle parameters, and total weight which differ from those used in your institution. Sterilizers can differ in performance characteristics. Therefore, it is necessary to perform testing of containers and trays with instruments and accessories, using biological and chemical process indicators to determine effective sterilization parameters for the load placed in your sterilizer.

The following recommendations are validated sterilization process parameters. These are not inclusive of all combinations of process parameters which may yield acceptable sterilization results. The following recommendations were validated for a Jewel Precision reusable rigid sterilization container with typical content, under worst case load conditions. Adjustment of sterilization cycle and drying parameters may be necessary to yield acceptable sterilization results. The end user is responsible for developing validated processes which result in acceptable sterilization of container and contents.

Pulsed Pre Vacuum Steam Sterilization:

Temperature:	270°F / 132.°C
Number of Preconditioning Pulses:	4
Exposure Time:	4 Minutes.
Drying Time with Total Weight of 25 lb.:	30 Minutes, required to prevent wet packs.
Stack Height:	Maximum of 2 containers.

Total System Weight:	25 pounds load in each container.
Cooling Time:	Will vary based upon content and total load.
Shelf Life:	Up to One-Year ⁽¹⁾ has been validated post sterilization.

Steam Flush Pressure Pulse (SFPP) Steam Sterilization:

AAMI recognizes both the Prevacuum and SFPP cycle as a "dynamic-air-removal type". Both AAMI ST8:2013 (Section 3.10) and ANSI/AAMI ST9:2017 (Section 2.19) define dynamic air removal cycles as "One of two types of sterilization cycles in which air is removed from the chamber and the load by a means of a series of pressure and vacuum excursions (prevacuum cycle) or by means of a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush pressure – pulse [SFPP] cycle)." Both conditioning methods provide effective air removal from the load.

Following load conditioning, the sterilization phase of SFPP and Prevacuum cycles is the same, with exposure times of 4 and 3 minutes for temperatures of 270F° (132°C) and 275°F (135°C) respectively. After sterilization, both cycles use a vacuum to remove steam from the load and dry it.

Since both prevacuum and SFPP cycles are considered of the dynamic air removal type, if an instrument manufacturer's instructions for use state that a prevacuum cycle with sterilize time of 4 minutes 270F° (132°C) or 3 minutes 275°F (135°C) should be used for processing, the SFPP cycle with a sterilize time of 4 or 3 minutes, respectively, may be substituted. However, the end user is responsible for developing validated processes which result in acceptable sterilization of container and contents.



CAUTION: Avoid cool drafts from air vents or other air current sources during the cool down period. Such exposure may cause the formation of post sterilization moisture within the tray. Allow containers to cool for 30 minutes, or to 118° F prior to handling to prevent burns. Cooling time will be affected by ambient environmental temperature and drafts.

Note: Total weight is that of the assembled container, including instruments, trays and accessories.

Sterility Maintenance

The Jewel Precision Reusable Rigid Sterilization Container System is intended to allow sterilization of the enclosed medical devices, and has been validated to maintain sterility of the enclosed medical devices until used, for a maximum of **One-Year ⁽¹⁾**. Jewel Precision reusable rigid sterilization container contents should be considered to be non-sterile under any of the following conditions:

- A filter is not present and fully covering all sterilization vent holes.
- A filter retainer is loose or not fully secured to its mating pin on the container cover.
- A filter is wet, damaged, creased, or folded.
- Multiple filters have been placed under one or more filter retainers.
- A filter has been reused.
- There is no internal chemical indicator found in the basket when opened, when use is required by institutional policy.
- The internal chemical indicator does not indicate the item has been processed.
- The gasket is damaged or separated from the cover.
- The container flange which mates with the cover gasket is damaged or dented causing a gap in the compression indentation in the gasket.
- There is residual condensate noted within the container upon opening for use.

Aseptic Presentation

Institutional procedures and AAMI guidelines should always be followed when using and presenting the Jewel Precision reusable rigid sterilization container. Following are suggested steps for aseptic presentation.

- Non-Scrubbed individual positions the Jewel Precision reusable rigid sterilization container at the level of the sterile field on a dry flat surface.
- Non-Scrubbed individual inspects physical integrity of the container, ensuring the integrity of the closures and any locks which have been used, inspects the load identification card for correct instrument identification and has valid expiration date, inspects the filters which are visible through the sterilization vent holes have not been damaged, and inspects any external Biological Indicator (BI) or Chemical Indicator (CI) which may be present.
- Non-Scrubbed individual breaks and removes any container locks, and releases the container cover latches by placing thumbs on the hasps and fingers under the lock levers, then gently pulls levers upward to release to disengage the hasps from the cover.
- Non-Scrubbed individual removes the cover from the container by placing fingers under the cover and raising it vertically to separate from the container, and inspects the cover gasket for damage and security within the gasket channel of the cover. Gasket should exhibit a consistent impression caused by intimate contact with the upper rim of the container.
- Scrubbed individual should inspect any internal CI for proper endpoint response.
- Inspect the container and note any missing or damaged component such as the filters, filter retainers, cover, gaskets; process indicators which have not reached their visible end point or are missing; or missing or broken container locks. Anything noted is reason to consider the container contents not sterile. It is important to conduct this inspection prior to placing any content on the sterile field.
- The scrubbed individual should avoid all contact with the outer surfaces of the container and cover, upper rim of the container, and the surface on which the container rests. When removing an inner instrument tray, use aseptic technique to grasp both handles in order to lift the tray straight up to clear the container, and subsequently place instrument tray on the sterile field. If a container contains more than one instrument tray, each should be moved separately to the sterile field.

Transport of Soiled Instrument Sets for Cleaning

Follow your institutional policy regarding transport of soiled instruments for cleaning. Instrument sets may be transported in the Jewel Precision reusable rigid sterilization container system. Transport and clean as soon as practical, to keep soil wet. Dried soil may be difficult to remove.

Maintenance


Jewel Precision reusable rigid sterilization containers are manufactured of deep drawn anodized aluminum with stainless steel hardware and medical grade silicone gaskets. Jewel Precision Instrument Trays are manufactured in anodized aluminum alloy, or aluminum alloy coated with medical grade nylon polymer. Brackets are manufactured of stainless steel and coated with medical grade nylon polymer, and have medical grade silicone inserts. When properly cared for, Jewel Precision containers, trays, covers, brackets and accessories can provide many years of instrument protection.

Do not use the Jewel Precision reusable rigid sterilization container system when evident wear or damage to the container, components or accessories may compromise attaining a sterile state of the contents, or maintenance of a sterile barrier. Beware of: broken or worn gaskets in the cover and filter retainers; cracks or dents in the upper surface of the container which mates with the cover gasket which may prevent closure or result in an incomplete seal; oxidation of the aluminum surface inside the container and cover which is indicative of failure of the anodized protective surface.

When releasing the latches to remove the cover, a typical upward rebound will be noted as the cover gasket decompresses. The gasket should bear a contiguous indentation from the container surface against which it is held in compression. A noted lack of rebound when releasing the latches requires inspection of both the gasket and the latches to determine the cause, which may be corrected by replacing the cover, or correcting engagement of the latches with the cover.

Cover and filter retainer gaskets must be free of cuts and tears.

Components may be cleaned using automatic washing equipment or processed by hand.

 Filters are single use only. Discard filters after use.

The following items must be inspected prior to use to insure acceptable working performance of the Jewel Precision reusable rigid sterilization container and accessories:

Container Base

- Upper surface of the container which mates with the cover gasket must be free of dents or cracks, which may prevent closure or result in an incomplete seal.
- Damaged latch components, which may prevent closure or result in an incomplete seal.
- Missing rivets or load identification card holders.
- Damaged handle components.
- Damaged stacking lugs, which may present unsafe stacking conditions.
- Dents with holes or fissures which may penetrate the container.
- Oxidation of aluminum surfaces, indicating failure of the anodized surface.

Container Cover

- Gasket is broken, cut, visibly worn, or separating from the cover, which may result in an incomplete seal.
- Dents in the cover in the area of the gasket, which may result in an incomplete seal.
- Dents in the cover in the area of the filter retainers, which may result in an incomplete seal.
- Missing or worn filter retainer mounting pins.
- Obstructed sterilization vent holes.
- Damaged stacking lugs, which may present unsafe stacking conditions.
- Dents with holes or fissures which may penetrate the container.
- Oxidation of aluminum surfaces, indicating failure of the anodized surface.

Filter Retainers

- Gasket is broken, cut, visibly worn, or separating from the retainer, which may result in an incomplete seal.
- Deformity of the retainer which results in the gasket not sitting flat on the inner surface of the cover.
- Missing or broken retainer latch parts.
- Retainer does not properly compress against filter upon installation.

Process Specific Recommendations for Accessories and Containers

Jewel Precision Reusable Rigid Sterilization Container and Accessories		Sterilization Process			
Solid Bottom Container	Contents / Configuration	Pre-Vacuum Steam	100% Ethylene Oxide	STERRAD® 50	STERRAD® 100S
JP-24-6, 6" Height	Trays	Yes	NO	NO	NO
	Stacking Trays	Yes	NO	NO	NO

Lumens:	YES	NO	NO	NO
	<u>Quantity</u>			
0.130" x 13 1/8"	1			
0.130" x 13 1/8"	1			
0.130" x 13 1/8"	1			
0.155" x 13 1/4"	1			
0.150" x 12 1/4"	1			
0.048" x 6"	1			
0.064" x 6"	1			
0.055" x 7 1/2"	1			
0.066" x 7 1/2"	1			
0.073" x 7 1/2"	1			
0.092" x 7 1/2"	1			
0.106" x 7 1/2"	1			
0.110" x 7 1/2"	1			
0.115" x 7 1/2"	1			
0.075" x 9 5/8"	6			
0.230" x 7 1/4"	6			
0.095" x 4"	1			
0.098" x 5 3/4"	1			
Occluded / Mated Challenge:	Yes	NO	NO	NO
<u>Forceps, Hook Forceps</u>				
Silicone Brackets	Yes	NO	NO	NO
Silicone Finger Mat	Yes	NO	NO	NO
Filter	Yes, 100-0003	NO	NO	NO
Stack Height, Internal	2 trays			
Stack Height, External	2 containers	NO	NO	NO
Materials	Metals, Polymers Composites	NO	NO	NO
Maximum total Container system weight	25 pounds (11.34 kg)	NO	NO	NO

PRODUCT WARRANTY

The Jewel Precision reusable rigid sterilization container product line is guaranteed to be free of functional defects due to workmanship or materials when used as directed for the intended purpose. Jewel Precision will repair or replace, at our discretion, any product found to have a manufacturing defect within one (1) year from the date of delivery, at no charge to the customer.

Jewel Precision does not warrant that anodizing in colors other than clear (no color) will remain fast. Colored anodizing is subject to fading with repeated sterilization and cleaning processes.

The following exclusions apply to the Jewel Precision Reusable Rigid Sterilization Container product line replacement warranty:

- Damage resulting from the use of high pH or abrasive cleaning agents, or metal brushes. Refer to Instructions for Use for proper care. Use only enzymatic or pH neutral cleaners.
- Damage caused by improper handling, misuse or abuse.
- Damage from fire or Acts of God.

Modification or repair of the Jewel Precision reusable rigid sterilization container, components, or accessories is unauthorized, and may affect product performance and the ability to achieve the required sterility assurance level.

RETURNED GOODS REPAIR POLICY

Jewel Precision endeavors to provide customer satisfaction with our products and customer service. If you encounter a situation requiring the return of a Jewel Precision product, please contact us at 973-857-5545 to obtain return authorization. All returns require a Returned Goods Authorization number, assigned by Jewel Precision. **A label must be affixed to the outside of each returned package indicating that the product being returned has been CLEANED AND DECONTAMINATED.** Items returned without such labeling will be returned to the sender at their expense. Jewel Precision will evaluate the returned product prior to determining whether to repair product, or issuing any credit to the customer.

The following items cannot be returned, unless due to manufacturing defect or product complaint:

- Product held over 60 days from date of delivery.
- Used products.
- Modified or customized product.
- Products which have been discontinued.
- Improperly packaged products.

Products received by Jewel Precision which are determined to be ineligible for repair or credit issuance shall be returned to the customer with an explanation of the determination.


Product must be returned within 60 days of the date of original delivery, unless being returned due to manufacturing defect or product complaint.


Product which falls outside the above criteria may be returned, and a credit will be issued as follows:


- Product returned in original packaging and in as new condition.
- Product returned after 60 days will be issued partial credit.


Notes:

- (2) One-year shelf life based on independent laboratory testing. Test results on file at www.jewelprecision.com
- (3) Five-year shelf life based on independent laboratory testing. Test results on file at www.jewelprecision.com


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The Artists of the Industry