Seed Sterilization Tray
REF 90085
General Precautions

CAUTION:
Proper use of this device depends on careful reading of all instructions and labels.

CAUTION:
Steam Sterilize (autoclave) or ETO sterilize only. Do not gamma ray sterilize.

WARNING:
After steam sterilization, unit will be hot. Allow adequate cooling time before handling. Do not drop or mishandle unit.

Warnings and Cautions alert users to dangerous conditions that can occur if instructions in the manual are not obeyed. Warnings are conditions that can cause injury to the operator, while Cautions can cause damage to the equipment.

Typical Sterilization Procedures

CAUTION:
Do not use dry heat or chemical sterilization or damage to the parts may result.

WARNING:
These items are not sterile when shipped to the customer. Before use they must be sterilized using steam or ethylene oxide (EtO).

All parts are fabricated from the highest quality aluminum, stainless steel and plastic, and are designed to withstand high temperatures:

• Steam sterilization (autoclave):
  Use the normal cycle (250 degrees F or 121 degrees centigrade at 15 psi for 15 to 30 minutes) or the flash cycle (270 degrees F or 132 degrees centigrade at 30 psi for 3 to 12 minutes).

• Ethylene oxide (EtO) sterilization:
  Use cycle and aeration times recommended by the manufacturer of the Sterilizer or use those determined at the hospital.

Exterior cleaning should be done with a soft brush and a cloth. Gently brush all surfaces to remove dirt and dust. To remove any remaining dirt, use a cloth slightly dampened with a solution of mild detergent and water or a liquid disinfecting agent.
Sterilization of LDR brachytherapy seeds before implantation is desirable, and is a routine procedure at many medical centers. Instructions from seed manufacturers may include sterilization procedures. The Standard Imaging LDR Brachytherapy Seed Sterilization and Sorting Tray, REF 90085 shown in Figure 1, provides a convenient method of achieving this sterilization using a steam autoclave. The LDR Brachytherapy Seed Sterilization and Sorting Tray has ten wells for the placement of LDR seeds. Each well can easily hold up to 50 seeds, and is identified by a stamped number from one to ten.

Two interchangeable covers are provided.

1. The Loading Cover allows for access to one well at a time. It can also be used in conjunction with either the Seed Slider (REF 90090) or the Seed Alignment Tray (REF 90089) to load prostate implant needles.

2. The Sterilizing Cover has ten screened openings which align with the wells and insure proper sterilization of the seeds and tray without allowing seed egress.
Safety Lock Feature
As a safety feature, both covers can be locked in place to prevent accidental loss or spillage of seeds during transport within the health care facility. The cover is in the locking position when the arrow on the cover lines up with the arrow on the well. **To lock, screw the thumbscrew down until finger-tight.** In the lock position all wells are surrounded by 3/16 in. thick aluminum and exposure from LDR seeds in the wells is minimized.

Figure 2: The cover in the LOCK position.

Changing Covers
1. Unscrew and remove the top knob.
2. Lift off the cover.
3. Replace with the other cover and secure the top knob.

Loading the Seeds
The ten wells of the Sterilization Tray are useful for two main purposes. Seeds of different strengths can be placed in separate wells for sorting, calibration and identification. Also, when large quantities of seeds are used, 10% of the total can be placed in each well. The user is then shielded from 90% of the seeds during needle loading.

1. With the Loading Cover in place on the Sterilization Tray, position the opening over hole 1.
2. Load the wells with seeds.
3. Align the arrows and secure the thumb screw to lock the cover in place.

Sterilizing the Seeds
1. Remove the Loading Cover and attach the Sterilizing Cover to the Sterilization Tray.
2. Align the arrows and secure the thumb screw to lock the cover in place.
3. Just before the device is placed in the autoclave, release the thumb screw to unlock the Sterilizing Cover. Rotate the cover so the arrow lines up with the number 1. This aligns the screened areas with the wells and insures a good flow of steam during the sterilization process.

Figure 3: The cover in place for sterilization.

4. Sterilize the Loading Cover along with the loaded Sterilization Tray. Make sure the Sterilizing Cover is positioned as shown above. If either the Seed Slider or Seed Alignment Tray will be used, attach it to the Loading Cover and sterilize along with the Sterilization Tray. If the spatula will be used to remove the seeds from the well, it should also be sterilized at this time.

**WARNING:** The tray will be very hot after sterilization. Take adequate protection to prevent burns.

5. To be certain the seeds are dry, a drying cycle must be used. When the seeds are completely dry, handling is much easier. Drying cycle times will vary depending on the autoclave.

6. After drying cycle is complete, lock the Sterilization Cover with the thumbscrew (verify the arrows line up) and transport the seeds to the loading station.
General Operation Continued

Removing the Seeds

1. Remove the Sterilizing Cover and attach the Loading Cover.
2. Rotate the cover over each well and remove the seeds as needed to load into the treatment system.

Operation with Accessories

Using with the Seed Alignment Tray
The Seed Alignment Tray is used with a SeedVac™ to conveniently load needles and reduce radiation exposure.

1. Attach the Seed Alignment Tray to the Loading Cover by removing the two screws on top of the Loading Cover. Align the captive screws on the Alignment Tray to the nuts revealed in the Loading Cover. Secure finger-tight.

(The Seed Slider attaches in a similar fashion as the Seed Alignment Tray).

2. Sterilize the assembly with the loaded Sterilization Tray and spatula.
3. Remove the Sterilization Cover and attach the Loading Cover.
4. Use the sterilized spatula to scoop out the seeds from the wells.
5. Align the seeds in the slots on the Alignment Tray.
6. Use a SeedVac to pick up the seeds and spacers.
7. Proceed with loading the needles.

Using the Shielding Cover
The Shielding Cover is useful when the tray is loaded by one person and then sent out to be sterilized by another person or department.

Follow the instructions for Loading the Seeds on page 6.

1. Remove the Loading Cover and place the Sterilizing Cover on the Tray. Do not secure the top knob.
2. Align the arrow on the Sterilizing Cover with the number 1 on the Tray.
3. Place the Shielding Cover over the Sterilizing Cover.

Figure 4: The Seed Alignment Tray attached to the Loading Cover.

Figure 5: The cover in place for sterilization.
Operation with Accessories Continued

4. Verify the arrow is visible through the small hole as shown in Fig. 6.

5. Secure the assembly by tightening the top knob until the Shielding Cover is not movable.

6. Again, verify the arrow is visible through the small hole.

7. The device is now secure to transfer to another department or person for sterilization.

8. Once the device is sterilized, follow the instructions on page 8 for Removing the Seeds.

Maintenance

As is standard practice, it is recommended that the tray and covers be examined after each use for deterioration. The tray can be dismantled for cleaning when no seeds are present. Exterior cleaning should be done with a soft brush and a cloth. Gently brush all surfaces to remove dirt and dust. To remove any remaining dirt use a cloth slightly dampened with a solution of mild detergent and water or a liquid disinfecting agent.

There are no serviceable parts on the tray. Do not loosen or attempt to remove the flat head screw on the bottom of the device.

If assistance is desired in the proper disposal of this product (including accessories and components), after its useful life, please return to Standard Imaging.

Parts and Accessories

<table>
<thead>
<tr>
<th>REF</th>
<th>Description</th>
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<tbody>
<tr>
<td>90085</td>
<td>Seed Sterilization and Sorting Tray</td>
</tr>
<tr>
<td>80029</td>
<td>Instruction Manual</td>
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<tr>
<td>30178</td>
<td>Sterilizing Cover</td>
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<td>70080</td>
<td>Spatula</td>
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<td>72012</td>
<td>Shielding Cover</td>
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<td>90089</td>
<td>Seed Alignment Tray</td>
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<tr>
<td>90090</td>
<td>Seed Slider</td>
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</tbody>
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Features and Specifications

- **Number of seed wells**: 10
- **Dimensions**:
  - Height: 4.3 in. (11.0 cm)
  - Diameter: 6.3 in. (16.0 cm)
- **Weight**: 2.5 lbs. (1.1 kg)
- **Shielding thickness**: 3/16 in. Aluminum (min)

*Specifications are subject to change without notice.*
Service Policy

If service, including recalibration, is required, please contact Standard Imaging’s Customer Service department by phone or email prior to shipping the product. Standard Imaging’s Customer Service and Technical Service staff will attempt to address the product issue via phone or email. If unable to address the issue, a return material authorization (RMA) number will be issued. With the RMA number, the product can be returned to Standard Imaging. It is the responsibility of the customer to properly package, insure and ship the product, with the RMA number clearly identified on the outside of the package. The customer must immediately file a claim with their carrier for any shipping damage or lost shipments. Return shipping and insurance is to be pre-paid or billed to the customer, and the customer may request a specific shipper. Items found to be out of warranty are subject to a minimum service fee of 1 hour labor (excluding recalibrations) for diagnostic efforts and require a purchase order (PO) before service is performed. With concurrence from customer, the product may be replaced if it is unserviceable or if the required service is cost prohibitive. Products incurring service charges may be held for payment. Standard Imaging does not provide loaner products. See the Standard Imaging Warranty and Customer Responsibility for additional information.

Customer Responsibility

This product and its components will perform properly and reliably only when operated and maintained in accordance with the instructions contained in this manual and accompanying labels. A defective device should not be used. Parts which may be broken or missing or are clearly worn, distorted or contaminated should be replaced immediately with genuine replacement parts manufactured by or made available from Standard Imaging Inc.

⚠️ CAUTION: Federal law in the U.S.A. and Canadian law restrict the sale, distribution, or use of this product to, by, or on the order of a licensed medical practitioner. The use of this product should be restricted to the supervision of a qualified medical physicist. Measurement of high activity radioactive sources is potentially hazardous and should be performed by qualified personnel.

Should repair or replacement of this product become necessary after the warranty period, the customer should seek advice from Standard Imaging Inc. prior to such repair or replacement. If this product is in need of repair, it should not be used until all repairs have been made and the product is functioning properly and ready for use. After repair, the product may need to be calibrated. The owner of this product has sole responsibility for any malfunction resulting from abuse, improper use or maintenance, or repair by anyone other than Standard Imaging Inc.

The information in this manual is subject to change without notice. No part of this manual may be copied or reproduced in any form or by any means without prior written consent of Standard Imaging Inc.
Warranty

Standard Imaging, Inc. sells this product under the warranty herein set forth. The warranty is extended only to the buyer purchasing the product directly from Standard Imaging, Inc. or as a new product from an authorized dealer or distributor of Standard Imaging, Inc.

For a period provided in the table below from the date of original delivery to the purchaser or a distributor, this Standard Imaging, Inc. product, provided in the table is warranted against functional defects in design, materials and workmanship, provided it is properly operated under conditions of normal use, and that repairs and replacements are made in accordance herewith. The foregoing warranty shall not apply if the product has been altered, disassembled or repaired other than by Standard Imaging, Inc. or if the product has been subject to abuse, misuse, negligence or accident.

<table>
<thead>
<tr>
<th>Product</th>
<th>Warranty Period</th>
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<tbody>
<tr>
<td>Standard Imaging Ionization Chambers</td>
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<tr>
<td>Standard Imaging Well Chambers</td>
<td>2 years</td>
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<tr>
<td>Standard Imaging Electrometers</td>
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<tr>
<td>Standard Imaging Software Products</td>
<td>1 year</td>
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<tr>
<td>All Other Standard Imaging Products</td>
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<tr>
<td>Standard Imaging Custom Product</td>
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<td>Consumables</td>
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<td>Serviced Product</td>
<td>90 days</td>
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<tr>
<td>Resale Products</td>
<td>As defined by the Original Equipment Manufacturer</td>
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<td>ADCL Product Calibration</td>
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<tr>
<td>(Standard Imaging uses the UW-ADCL for recalibrations required under warranty)</td>
<td>0 - 90 days = 100% of ADCL Calibration Costs</td>
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<td>91 - 182 days = 75% of ADCL Calibration Costs</td>
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<td></td>
<td>183 – 365 days = 50% of ADCL Calibration Costs</td>
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<td>366 – 639 days = 25% of ADCL Calibration Costs</td>
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<tr>
<td>(days from date of shipment to customer)</td>
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Standard Imaging’s sole and exclusive obligation and the purchaser’s sole and exclusive remedy under the above warranties are, at Standard Imaging’s option, limited to repairing, replacing free of charge or revising labeling and manual content on, a product; (1) which contains a defect covered by the above warranties; (2) which are reported to Standard Imaging, Inc. not later than seven (7) days after the expiration date of the warranty period in the table; (3) which are returned to Standard Imaging, Inc. promptly after discovery of the defect; and (4) which are found to be defective upon examination by Standard Imaging Inc. Transportation related charges, (including, but not limited to shipping, customs, tariffs, taxes, and brokerage fees) to Standard Imaging are the buyer’s responsibility. This warranty extends to every part of the product except consumables (fuses, batteries, or glass breakage). Standard Imaging, Inc. shall not be otherwise liable for any damages, including but not limited to, incidental damages, consequential damages, or special damages. Repaired or replaced products are warranted for the balance of the original warranty period, or at least 90 days.

This warranty is in lieu of all other warranties, express or implied, whether statutory or otherwise, including any implied warranty of fitness for a particular purpose. In no event shall Standard Imaging, Inc. be liable for any incidental or consequential damages resulting from the use, misuse or abuse of the product or caused by any defect, failure or malfunction of the product, whether a claim of such damages is based upon the warranty, contract, negligence, or otherwise.

This warranty represents the current standard warranty of Standard Imaging, Inc. Please refer to the labeling or instruction manual of your Standard Imaging, Inc. product or the Standard Imaging, Inc. web page for any warranty conditions unique to the product.