

LDR Brachytherapy Seed Sterilization and Sorting Tray

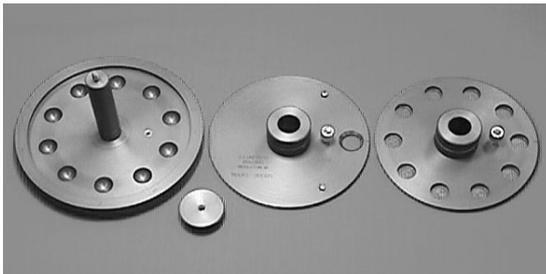


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General Precautions

 **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.

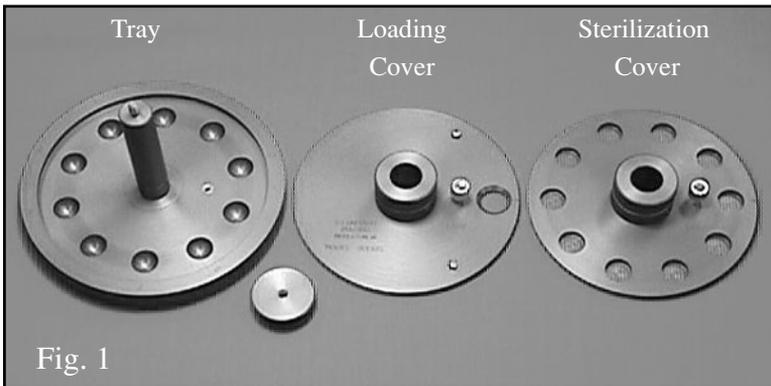
Customer Responsibility

 Federal law in the U.S.A. and Canada restricts the sale, distribution or use of this device to, by or on the order of a licensed medical practitioner. The use of this device should be restricted to the supervision of a qualified medical physicist. Handling of radioactive sources is potentially hazardous and should be performed by qualified personnel. Should repair or replacement of this device become necessary after the warranty period, the customer should seek advice from Standard Imaging Inc. prior to such repair or replacement. If this device 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. The owner of this device 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.

Description

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.

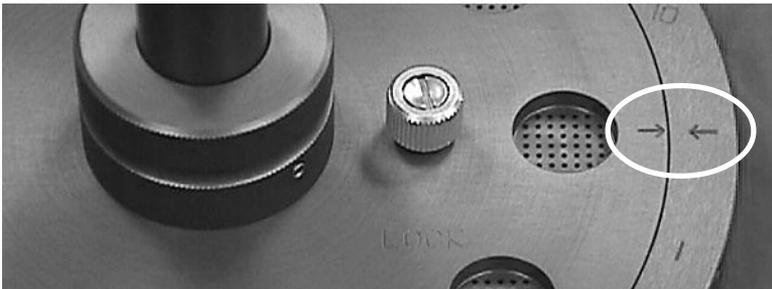


Fig. 2: The cover in the LOCK position.

Features and Specifications

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

Specifications subject to change without notice.

Operation

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.

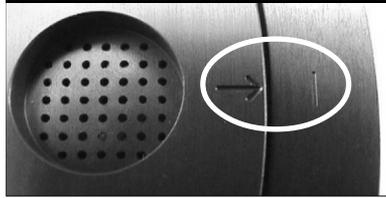


Fig. 3: The cover in place for sterilization.

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.
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.

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

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.

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.

Accessories

Using 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.

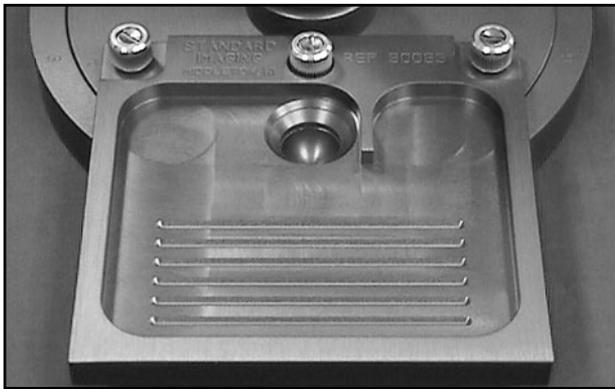


Fig. 4: The Seed Alignment Tray attached to the Loading Cover.

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

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.

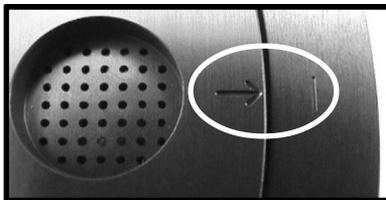


Fig. 5: The cover in place for sterilization.

3. Place the Shielding Cover over the Sterilizing Cover.

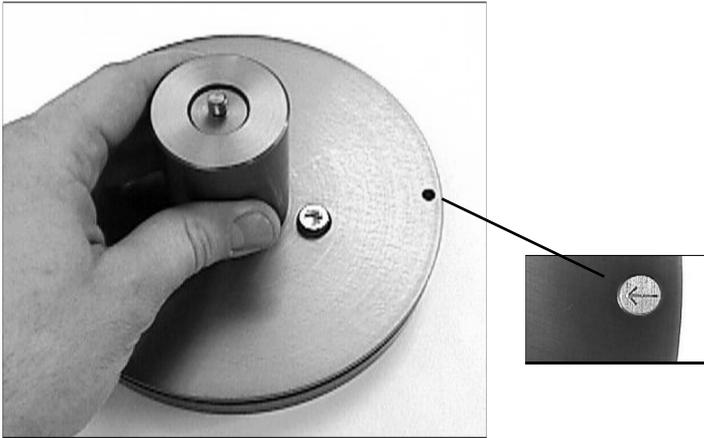


Fig. 6:

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.

Service

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.

Parts and Accessories List

REF	Description
90085	Seed Sterilization and Sorting Tray
80029	Instruction Manual
30178	Sterilizing Cover
70080	Spatula
72012	Shielding Cover
90089	Seed Alignment Tray
90090	Seed Slider

Warranty

This product is sold by Standard Imaging Inc. 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 of twelve (12) months from the date of original delivery to the purchaser or a distributor, this product is warranted against functional defects in 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 disassembled, altered or repaired other than by Standard Imaging Inc. or if the product has been subject to abuse, misuse, negligence or accident.

Standard Imaging's sole and exclusive obligation and the purchaser's sole and exclusive remedy under the above warranties are limited to repairing or replacing free of charge, at Standard Imaging's option, a product: (1) which contains a defect covered by the above warranties; (2) which are reported to Standard Imaging not later than seven (7) days after the expiration date of the 12-month warranty period; (3) which are returned to Standard Imaging promptly after discovery of the defect; and (4) which are found to be defective upon Standard Imaging's examination. Transportation charges are the buyer's responsibility. STANDARD IMAGING INC. SHALL NOT BE OTHERWISE LIABLE FOR ANY DAMAGES, INCLUDING BUT NOT LIMITED TO, INCIDENTAL DAMAGES, CONSEQUENTIAL DAMAGES, OR SPECIAL DAMAGES.

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