

SeeDOS Product User Manual

Needle Cradle™

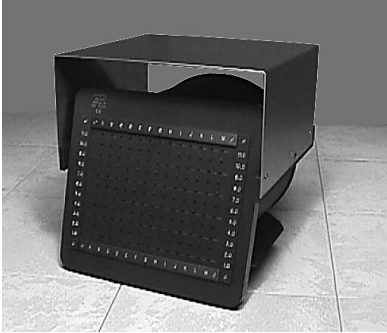





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General Precautions

Failure to observe these precautions may result in injury to personnel or damage to device.

-  **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

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 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.

Features and Specifications

Dimensions: Width: Length: Height: Weight:	30.0 cm (11.80 inches) 30.4 cm (11.96 inches) 26.8 cm (10.53 inches) 10 kg (22 lbs)
Needle Rows:	Vertical 13, Horizontal 11
Interchangeable Templates: Vertical: Horizontal:	A, a thru f, G A, B thru L, M 1.0, 2.0 thru 11.0 2.0, 2.5 thru 7.0 1.0, 1.5 thru 6.0
Material:	Aluminum: 3/4" front, 3/8" tube Stainless Steel: 1/16" cover

Specifications subject to change without notice.

Description

The Needle Cradle™, Part No. 90095, is designed for storage of loaded LDR prostate implant needles, prior to use in a patient. There are eleven horizontal rows for needle placement, an adequate number for difficult cases.

Interchangeable Templates allow an easy match to the ultrasound designations or treatment planning system. The two vertical options have the letter sequences of A a B b C...F f G, and A B C D E...K L M, while the three horizontal options have the number sequences of 1.0 2.0 3.0...10.0 11.0, 2.0 2.5 3.0...6.5 7.0, and 1.0 1.5 2.0...5.5 6.0.

A lightweight stainless steel needle cover slips easily over the needles to prevent accidental bumping of stylets. The cover can be removed and stored if not used.

The back plate is quickly removable without tools for access to the interior in case seeds are accidentally pushed through the needle while in the Needle Cradle™.

Operation

Preparation for use

Install the vertical and horizontal templates appropriate to the ultrasound machine or treatment planning system being used. One typical configuration is already installed at the factory. If this is unsuitable, remove the eight #4 Phillips head screws in the front face plate, and replace with the correct templates. Slide the stainless steel cover onto the front face plate and install the (2) pivot screws provided through the hole in each side of the cover. Tighten the pivot screws with the supplied hex driver.

Sterilize the unit following the sterilization equipment manufacturer's, or healthcare facility's recommendations. Users should validate the chosen sterilization procedures.

Loading needles into the Needle Cradle™

Load LDR brachytherapy seeds into prostate implant needles following healthcare facility recommendations for sterility and the patient's treatment plan. Standard Imaging also manufactures the Seed Sterilization Tray, Model 90085, and the Seed Slider, Model 90080, which greatly aid in this process.

Slide the cover up the front plate and pivot back over the Needle Cradle™. Slowly slide the loaded needles into the proper location in the Needle Cradle™. When finished, the cover can be lowered over the front plate for shielding and to protect the loaded needles.

Transporting the Needle Cradle™

When moving the Needle Cradle™, it is best to lower the cover and lift the unit while facing it using the handles mounted on either side of the tube. Due to the weight of the Needle Cradle™, care must be taken to always balance the entire unit during transport to prevent motion of the needles. Many institutions have found that transport on a dedicated cart greatly aids in this process.

Removal of Back Panel

The back round panel of the Needle Cradle™ can be removed quickly to check for loose seeds, without the need for tools. Simply unscrew the four captive screws mounted to the back panel and remove the cover.

Maintenance

As is standard practice, it is recommended that the Needle Cradle™ be examined after each use for deterioration.

Exterior cleaning of the device, if needed, can be done with a cloth slightly dampened with a solution of mild detergent and water.

Service

There are no serviceable parts on the device.

Parts and Accessories List

REF	Description
90095	Needle Cradle™
30193	Template Set (5 pairs)
80164	Instruction Manual
72007	Optional Template Pair, 0.0 - 10.0

Notice: We welcome your evaluation of this manual.

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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 of twenty-four (24) months for well chambers and twelve (12) months for all other Standard Imaging, Inc. products 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, Inc. not later than seven (7) days after the expiration date of the 12 or 24 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. This warranty extends to every part of the product except 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 for any warranty conditions unique to the product.

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