

SeedDOS Product User Manual

SeedVac™



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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.



CAUTION: Do not sterilize pump or power supply.



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.

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Overview

The SeedVac™ is a vacuum driven device designed to pull prostate implant seeds and spacers into a special needle fitted with a glass or plastic tip. These seeds and spacers are then placed into an implant needle. The prescribed sequence of seeds and spacers is visually verified in the glass tip before being placed into the needle.

The SeedVac™ is composed of the following parts: A vacuum pump, Fig.1, an aluminum hand piece, Fig. 2, which includes autoclaveable tubing to connect to the vacuum pump, a special needle, fitted with a glass or plastic tip to collect the seeds and spacers, Fig. 3, and an optional cartridge loading needle, used when inserting seeds into the cartridge of a Mick® TP Magazine (REF 7609, 7609-D), Fig. 4.

A brass shield near the end of the hand piece provides radiation protection during the loading procedure. In addition, a fine screen embedded inside the hand piece prevents seeds from being sucked into the flexible tubing or vacuum pump. If a seed is accidentally sucked into the hand piece, simply turn off the vacuum pump and point the tip of the hand piece downward.

The needles attach to the hand piece via a standard Luer lock. For the collection needles, a crimp at the junction of the glass tube and the stainless steel tube prevents any material from being sucked into the hand piece. Replacement tips should be sterilized and held in reserve in case one becomes non-sterile during loading. For the cartridge loading needle, a single seed is picked up at one time and manipulated as needed.

The tubing and aluminum hand piece must be sterilized between each use. All materials have been carefully selected to accommodate repeated sterilizations.


A UL® listed wall transformer (non-sterilizable) supplies the vacuum pump with power.

Needle Loading

To ease needle loading, the SeedVac needles can be rotated to point them in a direction suitable for collecting seeds. To do so, attach a needle, loosen the set screw holding the luer fitting, rotate the needle to the desired position, tighten the set screw. This should be done prior to sterilization. Sterilize the hand piece and several needles prior to use, following the sterilization equipment manufacturer's, or healthcare facility's recommendations. Users should validate the chosen sterilization procedures. **Do not** sterilize the vacuum pump or its wall transformer.

Connect the tubing of the hand piece to the vacuum pump, and one of the collection needles to the hand piece, following the accepted sterility procedures set up by your institution. Turn on the pump. The seeds and spacers should already be available and in sight near the loading area. To create a vacuum, place your finger over the hole near the front of the hand piece applying firm pressure to make a seal. As long as your finger remains over the hole there will be a continuous vacuum. Touch the glass tip to the seed or spacer to be picked up. Positioning the tip at a 30 - 40 degree angle will work well for sucking the seeds or spacers into the glass tube, Fig. 5. In addition, by working behind a Needle Loading Shield, such as SI Model No. 90070, one can reduce finger dose by angling the tip around the side of the Shield.

Draw the desired sequence of seeds and spacers into the glass tip. The sequence can be verified by visualizing the seeds and spacers through the glass. To load the needle, place the glass tip into the inner lumen of the implant needle, being certain to seat the tip near the bottom of the luminal funnel to insure a smooth flow of seeds into the needle. Lift your finger from the hole to break the vacuum and release the seeds into the needle.

 **WARNING:** Tilting the glass tip with respect to the lumen of the implant needle during this needle loading procedure could result in breakage of the glass tip. Use every precaution to prevent this and be certain that no glass shards fall into the needle under any circumstances. Glass needle tip breakage is an extremely unlikely event, but users should be aware of this possibility and avoid it.

Seed Counting

The SeedVac™ can also be useful for counting seeds as they are received from the manufacturer.

Simply verify the number of seeds that will fit into the glass tip at one time, and then count the number of full tips that can be filled, plus any remainder. This greatly reduces manual counting time and radiation exposure time.

Magazine Loading

Insert the optional Cartridge Loading Needle onto the Luer lock tip of the SeedVac™. Prepare the seeds and magazines to be loaded as usual, utilizing a stabilizing device for the cartridge, such as the Mick® V-Block (REF 7509). Enable the vacuum, and pick up a single seed as close to its center as possible, Fig. 6. If the seed is accidentally sucked into the needle tip, it will be able to proceed only a short distance (less than the seed length) before being stopped by a permanent block inside the needle tip. Simply lift your finger to disable the vacuum and drop the seed. Carefully insert the seed into the cartridge, and slide downward. **Maintain the vacuum during this entire time to ensure maximum seed holding power.** Release the vacuum only after the seed is in place. Repeat as needed to fill the cartridge.

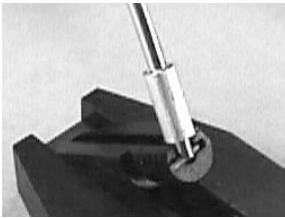


Figure 6: Inserting the seed into the magazine cartridge

Note: The tip is centered on the seed before insertion. Maintain the vacuum until the seed is fully in position within the cartridge.

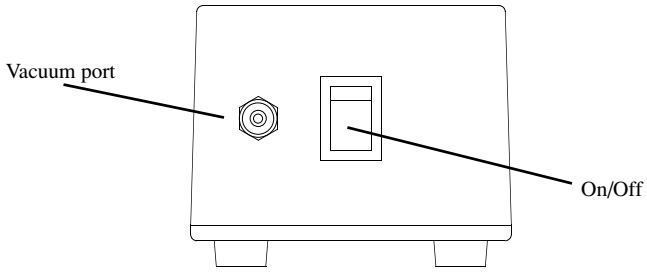
Maintenance

Exterior cleaning of the vacuum pump can be done with a soft brush and a cloth. Gently brush all surfaces to remove dirt and dust. Remove any remaining dirt with a cloth slightly dampened with a solution of mild detergent and water or a liquid disinfecting agent. Be especially careful that this is an external cleaning only and do not permit any liquid to seep into the vacuum pump in any manner during cleaning.

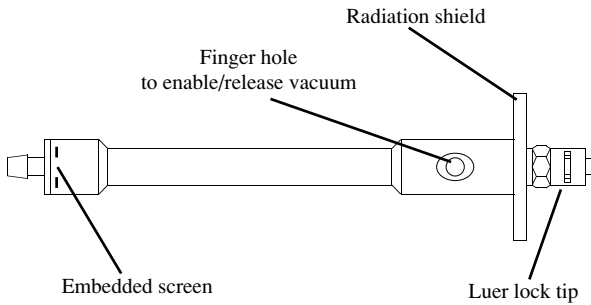
Check each glass tip before sterilization and use to make certain that no cracks or chips are visible. Discard any damaged tips. Replacement needle sets are available from Standard Imaging, REF 72009 or 72010.

Service

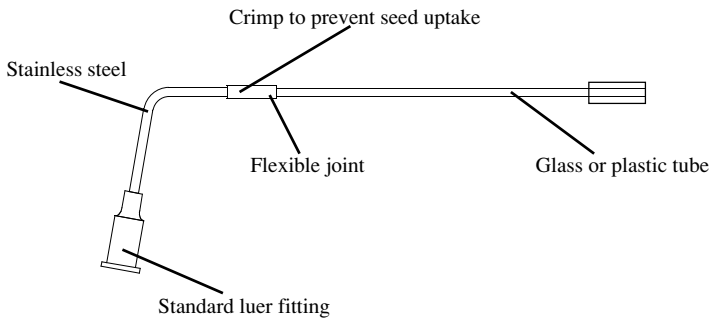
There are no serviceable parts on the SeedVac™.



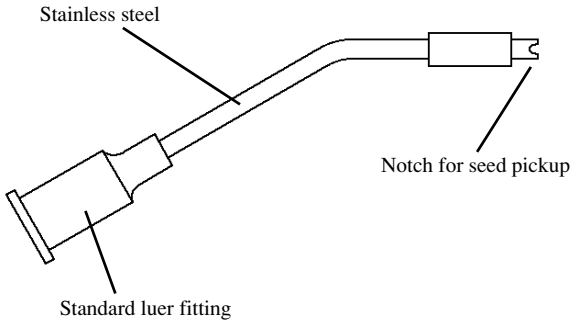
Vacuum Pump
Figure 1



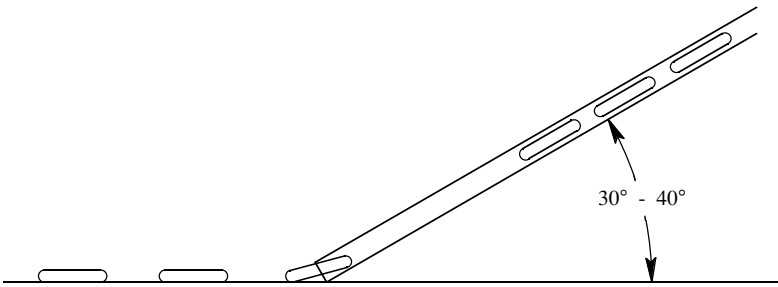
Hand Piece
Figure 2



Special Needle for Seed/Spacer Collection
Figure 3



Optional Cartridge Loading Needle
Figure 4



Typical Seed Loading Method.
Figure 5

Parts and Accessories List

REF	Description
90091	SeedVac™
72009	Replacement Glass Tip Set (10 glass tips without needles)
72010	Replacement Needle Assembly Set (3 needle assemblies and 6 spare glass tips)
72011	Wall Mount Power Supply
80191	Instruction Manual
30378	Optional Cartridge Needle
11095	.035" Hex Wrench

***Notice:** We welcome your evaluation of this manual.*

Your comments and suggestions help us improve our publications.

Doc No. 80191-03, 8/00, 9 pgs.

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, glass components excluded, 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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For further information or a quotation
please contact Colin Walters at
cwalters@seedos.com