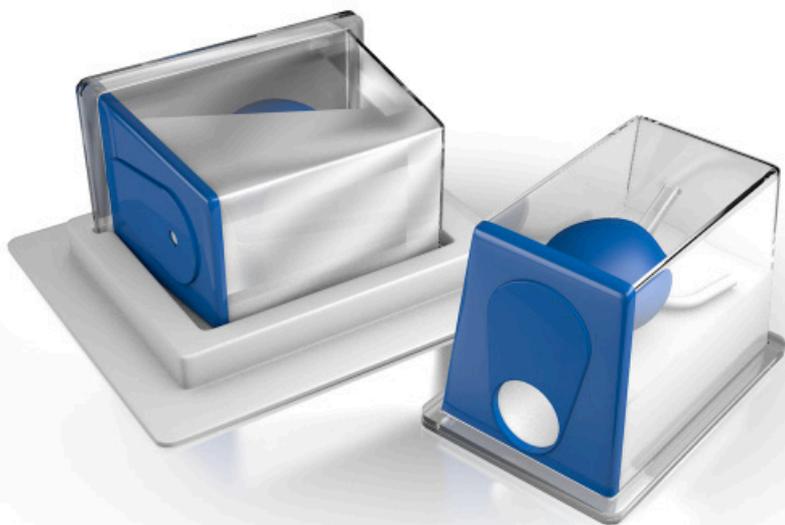


# Tissue-Equivalent Ultrasound Prostate Phantom

Model 053S, 053L & 053L-EF



ZERDINE<sup>®</sup> *Inside*  
A registered trademark of CIRS



## USER GUIDE

# CIRS

900 Asbury Ave • Norfolk, Virginia 23513 • USA • Tel: 757-855-2765 • [WWW.CIRSINC.COM](http://WWW.CIRSINC.COM)



## OVERVIEW

The CIRS Ultrasound Prostate Training Phantom is a multi-modality disposable phantom developed for practicing procedures which involve scanning the prostate with a rectal probe.

Gel formulations within the Model 053S & 053L are designed to minimize needle tracking and to provide imaging contrast under CT, MRI, ultrasound and elastography.

The prostate along with structures simulating the rectal wall, seminal vesicles and urethra is contained within an 11.5 x 7.0 x 9.5 cm clear acrylic container. A 3 mm simulated perineal membrane enables various probes and surgical tools to be inserted into the prostate.

This phantom is an ideal training device for ultrasound guided cryosurgery, radioactive seed implantation, and needle biopsy.

The phantom is available with (053L) and without lesions (053S) and can be ordered in either the standard side-fire configuration or an alternate geometry optimized for end-fire probes (053L-EF).

## PHANTOM SPECIFICATIONS

### Background

Ultrasound appearance: anechoic

CT appearance: dark

MRI appearance: dark (T1 weighted)

Elastography: soft

### Prostate

Dimensions: 5 cm x 4.5 cm x 4 cm

Ultrasound appearance: average echogenicity

CT appearance: dark, slight contrast with background

MRI appearance: bright (T1 weighted)

Elastography: soft, slight contrast with background

Volume: 53cc

### Seminal Vesicles

Dimensions: 7 mm Ø x 10 cm long

Imaging appearance is similar to prostate

### Urethra

Dimensions: 7 mm Ø

Ultrasound appearance: anechoic

CT appearance: dark, similar to prostate

MRI appearance: darker than prostate (T1 weighted)

Elastography: stiffer than prostate

### Rectal Wall

Dimensions: 6 cm x 11 cm x 0.5 cm

Imaging appearance is similar to urethra

### Lesions (053L and 053L-EF Only)

Qty: 3

Dimensions: Approximately 10 mm Ø

Ultrasound appearance: hypoechoic

CT appearance: bright

MRI appearance: dark (T1 weighted)

Elastography: stiff

### Perineal Membrane

3 mm thick Z-skin™ elastomer

(1) US Patent #5196343



## ***USE OF THE PHANTOM***

1. Remove phantom from sealed polyethylene bag.
2. Remove protective tape from openings in the phantom.
3. Scan the prostate in the usual manner using adequate coupling gel. Avoid excessive force on the rectal wall to avoid tearing.
4. Prostate can be biopsied through rectal wall or through the urethane perineal membrane.
5. The Prostate Phantom is also suitable for training in cryosurgical procedures, radioactive seed implantation, and thermal ablation and other minimally invasive procedures.

## ***CLEANING THE PHANTOM***

1. It is not essential to remove all coupling gel from the opening between uses. A small amount of residual gel will protect the phantom from desiccation.
2. If you wish to clean the residual coupling gel from the rectal wall, you may gently flush the rectal wall with water or a dilute bleach solution. Although the phantom has anti-microbial agents inside it, the bleach may inhibit mold growth inside the air-tight bag when the phantom is not in use.
3. Always store the phantom in an air-tight container when not in use. If using the provided polyethylene bag, squeeze out as much air as possible before sealing the bag.

## **HANDLING PRECAUTIONS AND END OF LIFE DISPOSAL**

This phantom is a disposable product and is not designed for extended use. It can be reused; however, as with any disposable training device, it will continue to deteriorate with each additional puncture.

For maximum product lifetime, store the phantom in an airtight bag or container. Standard room temperature and humidity is acceptable for storage. Sub-freezing temperatures should be avoided during shipping, as the freeze-thaw cycle may damage housing integrity and displace the targets. High temperatures may accelerate desiccation. If signs of weight loss are seen (such as a sunken scanning surface), contact CIRS for assistance.

**When not in use, the phantom must be stored in an air-tight container, such as a ziplock bag to minimize desiccation. Warranty will not cover dehydration.**

Technical questions should be referred to CIRS customer service at (800) 617-1177.



This product contains Zerdine, a non-flowing water-based, polyacrylamide material which is fully sealed within the phantom housing. Zerdine contains trace amounts of residual monomer acrylamide CAS#79-06-1. There are no known hazards when the phantom is used and stored as intended. Zerdine is fully cured and will not leak from the housing. Damage to the integrity of the housing may expose the user to Zerdine containing trace monomer acrylamide below levels necessary to cause adverse health effects. None the less, it is advised to wear protective gloves if handling exposed Zerdine gel. It is also advisable to wash hands and all surfaces with soap and water after handling exposed Zerdine gel.



Regulations regarding disposal of materials with trace acrylamide monomer vary by locality. Contact your local authority for instructions. If assistance is desired in the proper disposal of this product, including accessories and components, after its useful life, please return to CIRS.

## WARRANTY

All standard CIRS products and accessories are warranted by CIRS against defects in material and workmanship for a period as specified below. During the warranty period, the manufacturer will repair or, at its option, replace, at no charge, a product containing such defect provided it is returned, transportation prepaid, to the manufacturer. Products repaired in warranty will be returned transportation prepaid.

There are no warranties, expressed or implied, including without limitation any implied warranty of merchantability or fitness, which extend beyond the description on the face hereof. This expressed warranty excludes coverage of, and does not provide relief for, incidental or consequential damages of any kind or nature, including but not limited to loss of use, loss of sales or inconvenience. The exclusive remedy of the purchaser is limited to repair, recalibration, or replacement of the product at manufacturer's option.

This warranty does not apply if the product, as determined by the manufacturer, is defective because of normal wear, accident, misuse, or modification.

### NON-WARRANTY SERVICE

If repairs or replacement not covered by this warranty are required, a repair estimate will be submitted for approval before proceeding with said repair or replacement.

### RETURNS

If you are not satisfied with your purchase for any reason, please contact your local distributor prior to returning the product. Visit <https://www.cirsinc.com/distributors/> to find your local distributor. If you purchased your product direct through CIRS, call Customer Service at 800-617-1177, email [rma@cirsinc.com](mailto:rma@cirsinc.com), or fax an RMA request form to 757-857-0523. CIRS staff will attempt to remedy the issue via phone or email as soon as possible. If unable to correct the problem, a return material authorization (RMA) number will be issued. Non-standard or "customized" products may not be returned for refund or exchange unless such product is deemed by CIRS not to comply with documented order specifications. You must return the product to CIRS within 30 calendar days of the issuance of the RMA. All returns should be packed in the original cases and or packaging and must include any accessories, manuals and documentation that shipped with the product. The RMA number must be clearly indicated on the outside of each returned package. CIRS recommends that you use a carrier that offers shipment tracking for all returns and insure the full value of your package so that you are completely protected if the shipment is lost or damaged in transit. If you choose not to use a carrier that offers tracking or insure the product, you will be responsible for any loss or damage to the product during shipping. CIRS will not be responsible for lost or damaged return shipments. Return freight and insurance is to be pre-paid.

### WITH RMA NUMBER, ITEMS MAY BE RETURNED TO:

CIRS  
Receiving  
900 Asbury Ave,  
Norfolk, Virginia, 23513 USA

PRODUCT	WARRANTY PERIOD
Model 053S/ L/ L-EF - Tissue Equivalent Ultrasound Prostate Phantom	12 Months*

\*Please note: once any device has been inserted into the phantom (such as biopsy needles, localization wires, etc.) the 12 month warranty will not cover claims related to material desiccation or needle tracking.

# CIRS

**COMPUTERIZED IMAGING  
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