# **Prostate Training Phantom**

Model 053-I





## 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.

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 waterbased, 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.

## **OBJECTIVE**

The CIRS Model 053I, Ultrasound Prostate Training Phantom was developed with Dr. Peter Grimm and his associates at the Seattle Prostate Institute for hands-on brachytherapy workshops. This version of our prostate training phantom has a smaller prostate gland than the Model 053 and the gland is opaque so seeds can be visualized with and without ultrasound. The included pubic arch provides users with the ability to practice placing seeds around bony structures.

**Note:** The prostate does not ultrasonically mimic the human prostate.

## SPECIFICATIONS OF PHANTOM

### Container

Material: Clear acrylic
Dimensions: 11.5 x 7.0 x 9.5 cm
Front probe opening: 3.2 cm Ø
Rear probe opening: 2.6 cm Ø

#### Perineal Membrane

3 mm thick Z-skin™ elastomer

#### **Background Gel**

Similar to water with very little backscatter or attenuation

#### Urethra

Dimensions: 0.7 cm Ø

Material: Zerdine® (1), low scatter

## **Seminal Vesicles**

Dimensions: 7 mm Ø x 10 cm long Material: Zerdine, high scatter

#### **Prostate**

Dimensions: 4 x 4.5 x 4 cm Material: Zerdine, low scatter

#### Rectal Wall

Dimensions: 6 x 11 x 0.2 cm Material: Zerdine, high scatter

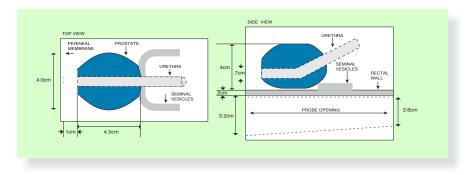
#### Other Features

Removable pubic arch





Model 053-I Ultrasound Images



## **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.

#### Note:

- 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.
- 2. For maximum product lifetime, store the phantom in an airtight bag or container. Standard room temperature and humidity is acceptable for storage. Subfreezing 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.
- 3. Technical questions should be referred to CIRS customer service at (800) 617-1177.
- 4. CIRS has evaluated the hazards of this fluid and does not believe it poses a hazard at the quantities and concentrations provided. Although this product has been evaluated and found to be safe if used as intended, it is always best to avoid repeated or prolonged skin contact with materials not intended for use on skin.

## 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, 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 053-I - Ultrasound Prostate Training Phantom	12 Months*

<sup>\*</sup>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.



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