

Prostate Training Phantom

Model 070L



ZERDINE® Inside
A registered trademark of CIRS



USER GUIDE

CIRS

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OVERVIEW

The Model 070L is a realistic and durable prostate training phantom for both diagnostic and interventional procedures.

Enhanced realism has been achieved with a Zerdine® gel formulation that simulates the ultrasound contrast between the prostate and background tissue. The gel formulations provide CT, MR and elastography contrast for multi-modality imaging.

Z-Skin™ provides perineal access for interventional procedures, and closes up on itself after it is punctured so that the Zerdine® gel inside the phantom is not exposed to air during scanning. Minimal air exposure better protects the gel from drying out, thus increasing the phantom's useful life. In addition, Z-Skin is extremely stretchable and will protect the gel inside the phantom from tearing when the rectal probe is manipulated at severe angles. The phantom accommodates both end-fire and side-fire ultrasound transducers. Zerdine® is specially formulated to minimize tearing when punctured, providing a self-healing capability that dramatically extends the life of the phantom during interventional procedures.

The phantom contains embedded lesions.

PHANTOM SPECIFICATIONS

CONTAINER

Dimensions: 12.7 x 12.7 x 12.7 cm
Weight: 2 lbs
Probe opening: 12 mm

PERINEAL MEMBRANE

Material: Z-Skin

BACKGROUND GEL

Standard Ultrasound background
0dB with respect to liver reference

URETHRA

Dimensions: 0.7 cm Ø
Material: Zerdine®(1), anechoic

SEMINAL VESICLES

Dimensions: 7 mm Ø x 10 cm long
Material: Zerdine, hypoechoic with respect to background

PROSTATE

Hypoechoic with respect to background
45 cc Digitally Modeled with seminal vesicles and bladder
Model 070L: Embedded lesions

LESIONS

Qty: 2
One slightly hypoechoic, one hypoechoic
Brighter than prostate under MRI
Darker than prostate under CT

RECTAL WALL

Material: Z-Skin

MODEL 070 INCLUDES

Tissue-Equivalent Prostate Phantom
User Guide
12-Month Warranty*

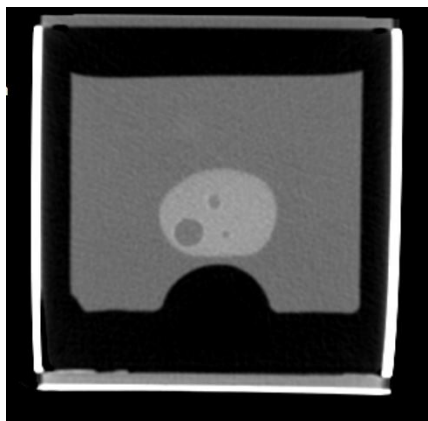
*Please note: once any device has been inserted into the phantom (such as biopsy needles, localization wires, etc.) the 12 month warranty will not cover claims related to material desiccation or needle tracking.

MODEL 070 KIT OPTIONS

070L-035: includes all parts from standard Model 070, CT DICOM Data Set⁽²⁾ (Serial number specific, 1.5 mm slice) thickness @ 120 kvp

(1) US Patent # 5196343

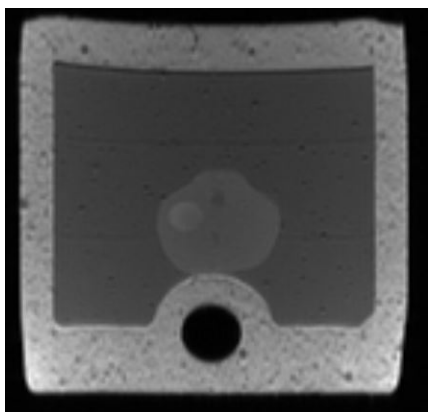
(2) DICOM Images are provided with a free DICOM reader (Onis 2.6). If using alternate software to read the images, please notify CIRS of any special requirements for making the data compatible with your software. For instance, some programs include special checks of the DICOM header file or the DICOM directory when loading the image data set.



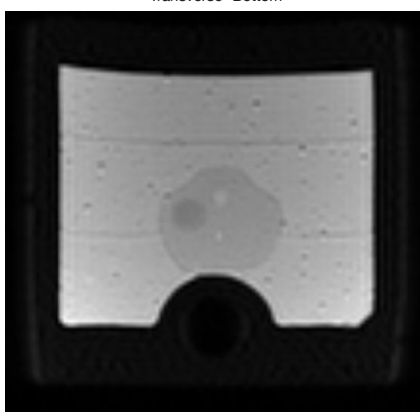
Model 070L CT Image



Model 070L US Images:
Anterior Posterior- Top
Transverse- Bottom



Model 070L MR T1 Image



Model 070L MR T2 Image

USE OF THE PHANTOM

1. Scan the prostate in the usual manner using adequate coupling gel.
2. Prostate can be biopsied through rectal wall or through the Z-Skin perineal membrane.
3. The Prostate Training Phantom is also suitable for training in cryosurgical procedures, radioactive seed implantation, and thermal ablation and other minimally invasive procedures.

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 standard room temperature and humidity. 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 Customer Service or your local distributor prior to returning the product. Visit <https://www.cirsinc.com/distributors/> to find your local distributor. Call 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 070L - Prostate Training Phantom	12 Months*

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