PRO-TEC™ SHIPPING SYSTEM

OPERATION MANUAL

001-754





Biodex Medical Systems, Inc.

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Important Safety Information



CAUTION: Federal Law restricts this device to sale by or on the order of a physician, sonographer or other licensed professional.



Follow the unpacking and assembly instructions document.



Before using this equipment, read the entire operation manual carefully. Failure to read the manual may result in user error or injury. Be sure to save all provided documents for future reference.



Make certain to understand all warning and caution labels as explained in the Before Proceeding section of this manual.



This product should be used only as specified in the operation manual.

Before Proceeding



The warnings, cautions and instructions provided in this manual must be read, followed and kept available for consultation at all times. Observing the information, instructions and procedures presented throughout this manual is essential for using this product both properly and safely.



SPECIFIC CAUTIONS:

- Allow only qualified, trained personnel to operate or service this product.
- If the equipment is used in a manner other than specified in this operation manual, the protection provided by the equipment may be impaired and results could be compromised.



CAUTION: Modifications to this product are only permitted by the manufacturer. Unauthorized modification of the product can result in hazards to the operator and patient, and will void the manufacturer's warranty. Do not modify this equipment without authorization from the manufacturer.

Biodex Warranty

Refer to the warranty card included with the product or contact Biodex Support Services.

Contact Information



Manufactured by:

Biodex Medical Systems, Inc.

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Introduction

Intended Use

The Pro-Tec Shipping System is designed to transport 3 cc and/or 6 cc Pro-Tec Pigs.

Indications for Use

The Pro-Tec Shipping System holds pigs securely in place. A heavy-duty zipper ensures the transport case remains securely closed until ready for use. Security tags or zip ties must be used as tamper evidence and to help keep the case closed. The top handles can Velcro together for easy lifting.

NOTE: In order to comply with DOT and IATA shipping regulations, the absorbent material supplied must be inserted into the vial pig of the Shipping System (see Directions for Use section). This material ensures that, in the event of a leak, all leaked material will be contained and absorbed. To purchase additional material for the Shipping System, contact Biodex's Sales Department at (631) 924-9000 or 1-800-224-6339.

Directions for Use

- 1. Wrap used syringe in a 3" absorbent square sheet.
- 2. Insert wrapped syringe into a 3 cc or 6 cc Pro-Tec Pig Bottom.





3. Screw the Pig Top Cover onto the Bottom Cover clockwise, securing the syringe.





- 4. Place syringe-filled pig into the bottom foam assembly of the shipping bag.
- 5. Continue inserting syringe-filled pigs until the shipping bag is full.

NOTE: If you are only partially filling the Pro-Tec Shipping Bag, evenly space out the syringe-filled pigs so that the weight of the unit is spread out.



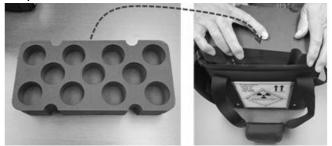
Filled Pro-Tec Shipping Bag



Pigs spaced evenly out

Partially Filled Pro-Tec Shipping Bag

6. Place the top foam assembly over the syringe-filled pigs securely.



- 7. Secure zippers of bag and have them meet in the center side.
- 8. Secure the zippers with a zip tie or lock.





- 9. Velcro the handles of the bag together.
- 10. Place the appropriate Radioactive Warning Placard into sleeves on both sides of the Shipping Bag.





Specifications

001-754 Shipping System, Pro-Tec

Dimensions:

Internal Container: 10.6" | x 5.5" w x 10.0" h (26.9 x

13.9 x 25.4 cm)

External Dimensions: 12" | x 7" w x 11" h (30.48cm x

17.8cm x 27.9cm)

Cubic Feet: ~0.33 ft (0.0009 cu meters)

Weight: 2.0 lb (0.90kg)

001-280 Pro-Tec Pig Red **001-281** Pro-Tec Pig White **001-282** Pro-Tec Pig Blue

Pro-Tec Dimensions:

Exterior: 8.5" x 1.94" (22cm x 4.9cm)

Interior: 0.70" dia x 7.4" | (1.77cm dia x 18.79cm |)

Pro-Tec Lead Shielding:

Body: 0.25" (0.63cm) Top: 0.25" (0.63cm) Bottom: 0.25" (0.63cm) Weight: 3lb (1.4kg)

Combined Lead Shielding:

Body: 0.25" (0.63cm) **Top**: 0.25" (0.63cm) **Bottom**: 0.25" (0.63cm)

Weight: Total system weight can vary depending on how

many pigs were purchased.

Regulations: Meets DOT Type A packaging

requirements when shipping up to 600

mCi (22.2 GBq) of I-131.

Meets IATA Dangerous Goods

Regulations,

60th Edition Sections 5.0.4.3, 10.5, and

10.6.1 thru 10.6.3.5.



Compliance reports for radioactive materials packaging are available by request or the Biodex website: www.biodex.com.

Replacement:

001-771 Sheets, Absorbent, 100/pkg 001-726 Tags, Wire Security, 25/pkg (Used to identify unauthorized access)

NOTE: System requires Absorbent Sheet to meet required DOT and IATA standards.

Maintenance and Disposal

Cleansing

As needed, cleanse the pig and container with a bleach solution. Rinse and dry each insert and the container before storing.

Disposal

An appropriate waste disposal company is to be contacted (i.e., the local collection point for waste separation). Properly dispose of the device at the end of its service life:

- The device packaging is disposed of through resource recycling.
- Plastic parts are disposed of as hazardous waste.



The disposal of equipment must be in accordance with the respective national regulations. Wear parts are considered hazardous waste. After being replaced, wear parts must be disposed of according to country-specific waste laws.

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The information in this document describes the product as accurately as possible, but is subject to change without notice.

Printed in the United States of America.

For technical assistance email info@biodex.com



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