

INTEGO™ VIAL SHIPPING CONTAINER FOR INTEGO™ TUNGSTEN VIAL SHIELD

OPERATION MANUAL

001-723
001-708



BIODEX

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This manual contains operation procedures for the following:

001-723 INTEGO™ Vial Shipping Container

001-708 INTEGO™ Tungsten Vial Shield



INTRODUCTION

The INTEGOTM Vial Shipping Container, for the INTEGOTM Vial Shield, is designed to transport a Hospira 30 ml vial containing high energy radionuclides. The system features a minimum of 0.375" up to 1.12" of lead shielding in the shipping container and 0.75 " of tungsten in the INTEGOTM Vial Shield to accommodate the concentrated volume and energy. It meets Yellow II DOT Type A packaging requirements when shipping up to 2.5 curies of FDG F-18. A unique design feature of the system allows the outer shipping container to remain on the floor. The technologist only has to lift the vial shield containing the vial. The Vial Shield weighs only 15.4 lb (7 kg), the entire system weighs 58.2 lb (26.5 kg).

DIRECTIONS FOR USE

(See Figure 1)

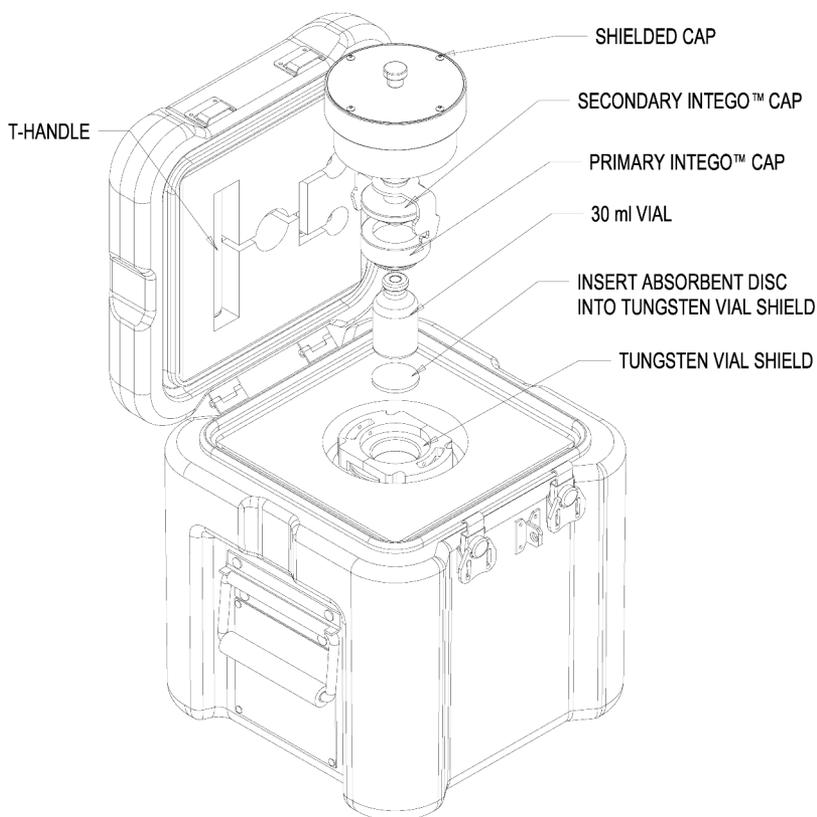


Figure 1

1. Open the shipping case by releasing the two hasps on the front of the case and lifting the lid.
2. In the lid is the INTEGO™ Vial Shield handle. Remove the handle from the lid and place it over the lid of the INTEGO™ Vial Shield cap. The cutout on each side of the handle goes over the cap support brace that is spring loaded to hold the cap on.
3. Lift up using the handle and remove the INTEGO™ Vial Shield from the shipping container. Move the Vial Shield behind an L-Block shield then press down on the handle and turn counterclockwise to turn the lock mechanism that is spring loaded on the Vial Shield. Once it is turned and unlocked, use the handle to lift up the secondary cap that is on the INTEGO™ Vial Shield.
4. Grab the primary cap and remove it from the Vial Shield. This cap is held on by two O-rings. It is a tight fit so that it stays in place.
5. Using a forceps, remove the vial from the Vial Shield.
6. You can clean the Vial Shield following the instructions provided later in the manual or that are supplied with the vial shield. Remember to remove the absorbent disc before cleaning.
7. Place a new absorbent disc into the bottom of the INTEGO™ Vial Shield.

NOTE: *In order to comply with DOT and IATA shipping regulations, the absorbent material must be inserted into the INTEGO™ Vial Shield portion of your INTEGO™ shipping system as shown in Figure 1. This material ensures that, in the event of a leak, all leaked material will be contained and absorbed. The model number for the absorbent pad is 14176-11.*

8. Using a forceps, lift the filled Hospira 30 ml vial and place it into the INTEGO™ Vial Shield.
9. Press the primary INTEGO™ cap into the lower portion of the shield.
10. Using the T-handle, lift the secondary cap and place it onto the INTEGO™ Vial Shield. Press down on the T-handle and turn clockwise to engage the locking mechanism of the secondary cap.
11. Remove the pressure from the T-handle and lift up using the T-handle to lift the INTEGO™ Vial Shield. Place the vial shield into the shipping container.

12. Remove the T-handle from the vial shield and place the T-handle into the lid of the shipping container. Lift the cap using the knob and place the plastic/stainless/lead cap over the INTEGO™ Vial Shield.
13. Close the lid of the shipping container. To lock, place each of the two hasps onto the respective bracket and turn the twist cams until tight.
14. You must place a wire seal or zip tie through the hasps and standoff to secure the container. If you receive a container with the seal broken, you will know it has been opened or tampered with.
15. If you have a PET transport cart, you can secure the shipping container to the cart for transport in the facility. Place the container so the hasps face the side of the cart. This will allow the container to be opened without removing it from the cart, if desired. Place the bungee cord over the plastic container and secure. The Velcro Hook and Loop Fastener® can now be strapped around the container. You can stack more than one container on the cart by adjusting the straps to fit the number of containers.

CLEANING INSTRUCTIONS

As needed, cleanse the vial shield and container with a bleach solution. Rinse and dry each part and container before storing.

SPECIFICATIONS

001-708 Shield, Vial, Tungsten, INTEGO™

Dimensions:

Exterior: 3" outside dia x 5.83" height overall (8 cm dia x 15 cm)

Interior: 1.5" inside dia x 2.75" h (3.8 cm dia x 7 cm)

Tungsten Shielding:

Sides: 0.75" (2 cm)

Bottom: 0.75" (2 cm)

Vial Shield Cap: 1.4" (3.5 cm) over septum; 1.19" (3 cm) minimum over rest of vial shield opening

Weight: 15.4 lb (7 kg)

001-723 Container, PET Vial Shipping, INTEGO™

Dimensions:

Container: 11.75" l x 11.75" w x 12.5" h (29.8 x 29.8 x 31.8 cm)

Cubic Feet: ~1 cu ft (.03 cu meters)

Lead Shielding:

Top: 0.25" (0.63 cm)

Bottom: 1.0" (2.54 cm)

Sides: Varies depending on location from 0.375" to 1.12" (0.95 cm to 2.8 cm)

Weight: 42.8 lb (19.5 kg)

Combined Weight: 58.2 lb (26.5 kg)

REGULATIONS



- Meets DOT II Type A packaging requirements when shipping up to 2.5 Ci (92.5 GBq) of FDG F-18



- Meets IATA Dangerous Goods Regulations, 50th 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 visit our website: www.biodex.com.

REPLACEMENT

14176-11 Disc, Absorbent

001-726 Tags, Wire Security, 25/pkg

(Used to identify unauthorized access)

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



Certified Quality Management System

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