

PINSYNC® Vented Vial Adapter 13mm

For withdrawal of activated DEFINITY®, Vial for (Perflutren Lipid Microsphere) Injectable Suspension

Instructions for Use

The Vented Vial Adapter 13mm is intended for the transfer and mixing of drugs contained in vials.

Before handling the components, wash your hands with soap and hot water, and use appropriate aseptic technique.

Place the PINSYNC® package on a clean, flat and stable surface. Remove the white vial cap from the activated DEFINITY® vial and place it on the flat surface.

Step 1: Hold the sterile blister package as shown. Peel back Tyvek[®] cover from the blister package.

Precautions: Do not remove the vial adapter from the package.

Do not use the vial adapter if the package is damaged.

Do not use the vial adapter if it comes out of package.

Step 2: Place the vial on a flat surface and hold by the base. Using the blister package to hold the vial adapter, push the vial adapter straight down onto the vial top until it snaps securely into place.

Precautions: Do not place the vial adapter on at an angle.

Step 3: Remove the plastic blister package and discard it.

Precautions: Do not touch the exposed end of the vial adapter. This will result in contamination.

Step 4: Hold vial adapter by skirt to keep stationary. Attach a syringe to the vial adapter with a firm **clockwise twisting motion**.

Step 5: Turn the vial up-side down. Slowly pull plunger of the syringe to withdraw the desired amount of drug from the vial into the syringe.

Cautions: The potential to block the venting action exists if large amounts of air or drug are injected when the vial is inverted. If this occurs, turn the vial up right and pull the piston up the syringe barrel. When cleared proceed as directed in Step 5.

Step 6: Turn the vial up right and hold vial adapter by skirt to keep stationary. Remove the syringe from the vial adapter with a **counterclockwise twisting motion**. Discard both vial and vial adapter appropriately. The drug is now ready for administration. Follow normal safety practices to administer the drug.

DEFINITY® is now ready for administration.
Follow normal safety practices to administer DEFINITY®.



For withdrawal of activated DEFINITY®, Vial for (Perflutren Lipid Microsphere) Injectable Suspension

Instructions for Use

Cautions:

Federal (USA) law restricts sale of this device to physicians or on the order of a physician.

This device is intended to be used for one patient and one application only.

Single use only.

Reuse compromises safety and efficacy - It may cause contamination due to loss of sterility.

Contents are sterile and non-pyrogenic.

Resterilization may damage the device.

Precautions:

Do not remove the device from vials.

Dispose of used device in accordance with applicable regulations.

Do not use if package is damaged.



515968-0418

Manufactured for: Lantheus Medical Imaging, Inc. 331 Treble Cove Road North Billerica, MA 01862 USA For Ordering, Tel. Toll Free: 800-299-3431 All Other Business: 800-362-2668

Tyvek® is a registered trademark of E.I. DuPont de Nemours and Company.

 ${
m ROnly}\,$ Single Use Only

Manufacturer: West Pharma. Services IL, Ltd. 4 Hasheizaf St. Ra'anana 4366411 Israel

Issued on: May 3, 2018

Ref . No.: 8090243 Rev. No: 8.0