



# MEDRAD® Imaging Bulk Package Transfer Set (IBP TS) Instructions For Use



**UNITED STATES**  
Bayer Medical Care Inc.  
1 Bayer Drive  
Indianola, PA 15051-0780  
U.S.A.  
Phone: +1 (412) 767-2400  
+1 (800) 633-7231  
Fax: +1 (412) 767-4120

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## PRODUCT

Catalog Number	Description
IBP TS	MEDRAD® Imaging Bulk Package Transfer Set (IBP TS) Length: 23 inches; Tubing ID/OD: 0.120"/0.160"; Fluid Volume: 4mL

Bayer

NOT MADE WITH  
NATURAL RUBBER LATEX

Symbol	Description
	Attention: Refer to warnings and cautions on Instructions for Use packaged in each carton.
	For use with one container of media only
	Do not exceed 10 hours of use time.
	Non-Pyrogenic Fluid Path
	Do not use if package is opened or damaged
	Date of Manufacture

Symbol	Description
	Use By
	Lot Number
	Catalog Number
	Sterilized with Ethylene Oxide
	Do Not Resterilize
	Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Symbol	Description
	Manufacturer
	Not made with natural rubber latex.
	Warning - Advises you of circumstances that could result in injury or death to the patient or operator.
	Caution - Advises you of circumstances that could result in damage to the device.

**Introduction**

Read the information contained in this section. Understanding the information will assist you in operating the device in a safe manner.

**Important Safety Notice**

This device is intended to be used by individuals with adequate training and experience in diagnostic imaging studies.

REFER TO THE MEDIA MANUFACTURER'S "INSTRUCTIONS FOR USE" FOR ADDITIONAL INFORMATION.

PLEASE FOLLOW YOUR INSTITUTION'S POLICY FOR MEDIA ADMINISTRATION AND ASEPTIC TECHNIQUE.

**NOTE:** Refer to the injector system operation manual for additional operating instructions.

**Intended Use**

The MEDRAD® Imaging Bulk Package Transfer Set (IBP Transfer Set) is intended for the transfer of fluids from bulk containers to empty sterile syringes on syringe-based contrast delivery systems (injectors).

**Indications for Use**

The MEDRAD® Imaging Bulk Package Transfer Set (IBP Transfer Set) is indicated for the transfer of ULTRAVIST® (Iopromide), ISOVUE® (Iopamidol), and OMNIPAQUE™ (Iohexol) contrast media as supplied in an approved Imaging Bulk Package (IBP) presentation to empty sterile syringes on single-use only syringe-based contrast power injection systems indicated for the controlled, automatic venous administration of contrast agents for CT procedures.

The transfer set is to be discarded after one of the following conditions has occurred first: the contrast media container has been depleted, the contrast media use time has expired, or 10 hours has elapsed since the container was penetrated.

**Contraindications**

None known.

**Restricted Sale:** Rx Only

**Warning**

**Follow aseptic technique when setting up and using transfer set.** Contamination can result from improper aseptic technique. Properly discard transfer set if there is any possibility that contamination may have occurred during set up or use.

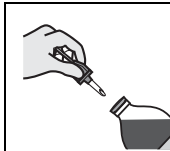
**Refer to the media manufacturer's "Instructions for Use" for use time.** Do not exceed the media manufacturer's recommended use time when using the transfer set.

**Wipe up spilled media immediately.** Patient or operator injury can result from spilled media.

**Visually inspect package and contents before each use.** Patient or operator injury can result if package is opened or damaged, or if damaged components are used. Do not use if sterile package is opened or damaged.

**Warning**

**Do not re-sterilize or reprocess.** Potential device failure includes significant component deterioration and system failure. Potential risks to the patient include injury due to device malfunction or infection as the device has not been validated to be reprocessed or re-sterilized.

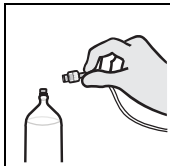


**Spike Contrast Media:**

1. Swab septum in accordance with media manufacturer's recommendation.
2. Remove cap from spike.
3. Insert spike into contrast media container in accordance with media manufacturer's recommendation, using aseptic technique.
4. Hang contrast media above injector head.

**Warning**

**Use care in handling and inserting spike into contrast media container.** The spike is sharp and may cause personal injury.



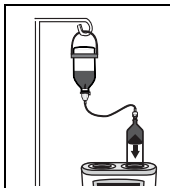
**Install Syringe and Connect Transfer Set:**

1. Install new sterile syringe.
2. Swab valve end with 70% isopropyl alcohol using aseptic technique.
3. Attach valve end to sterile syringe tip.

**Caution**

**Use 70% isopropyl alcohol (IPA) for disinfecting swabbable valve.** Exposure to other cleaning agents or disinfectant may lead to component damage or failure.

**Ensure all connections are secure; do not over-tighten.** This will help minimize leaks, disconnection, and component damage. Component damage or leaks can occur if not installed properly.

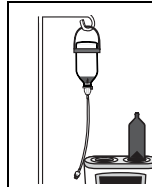


**Fill Syringes:**

1. Fill sterile syringe.
- NOTE:** Bubbles can be minimized through adjusting fill speed.

**Warning**

**Clear all air from the syringe and fluid path before connecting a patient to the injector.** Air embolization can result from failure to clear all air from the syringe and fluid path.



**Remove Valve End:**

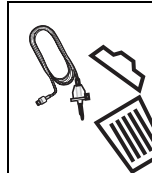
1. Disconnect valve end from syringe tip.
2. Let transfer set hang.
3. Use filled syringe.
4. Discard used syringe.



**Subsequent Syringe Fills:**

1. Install new sterile syringe.
2. Disinfect valve end with 70% isopropyl alcohol using aseptic technique.
3. Attach valve end to sterile syringe tip.
4. Fill new sterile syringe.
5. Disconnect valve end and let hang after each fill.
6. Use filled syringe.
7. Discard used syringe.

**NOTE:** Repeat until contrast media is depleted, the contrast media use time has expired, or 10 hours has elapsed since the container was penetrated.



**Discard Transfer Set:**

1. Discard transfer set and contrast media in accordance with facility policy when one of the following conditions has occurred first: contrast media container is depleted, contrast media use time is expired, or 10-hour has elapsed since the container was penetrated.

**Warning**

**Discard the transfer set after one of the following conditions has occurred first: the contrast media container has been depleted, the contrast media use time has expired, or 10 hours has elapsed since the container was penetrated.**

- Contamination or device malfunction can result from improper use of transfer set.
- Contamination can result from using the transfer set on more than one contrast media container.
- Use for more than 10 hours may lead to component damage or failure.