

MEDRAD® Imaging Bulk Package Transfer Spike

Instructions for Use



THIS IS A MULTI-DOSING PRODUCT.

Use the Transfer Spike to pull **multiple single doses** out of **one Imaging Bulk Package**.

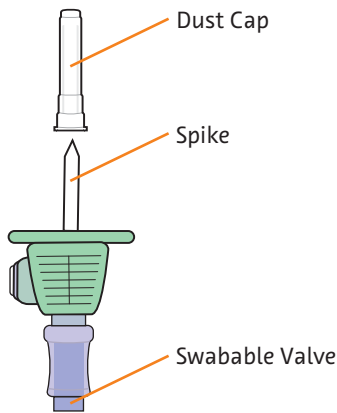
Training Information

Prior to using the device, Bayer recommends reading the information in these instructions and watching the training videos. Understanding this information will assist you in operating the device in a safe manner.

Training videos can be accessed at:
www.gadavist.com



Transfer Spike



Important Safety Notice: This device is intended to be used by individuals with 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 injection system operation manual for additional operating instructions and/or instructions for use for hand syringes.

Intended Use: The MEDRAD® Imaging Bulk Package Transfer Spike (Transfer Spike) is intended for the transfer of Gadavist® (gadobutrol) from bulk containers to sterile, empty hand syringes and/or sterile, empty syringes on syringe-based contrast delivery systems (injectors).

Indications for Use: The MEDRAD® Imaging Bulk Package Transfer Spike (Transfer Spike) is indicated for the transfer of Gadavist® (gadobutrol) contrast media as supplied in an approved **Imaging Bulk Package presentation (30 mL or 65 mL)** to empty, sterile hand syringes and/or empty, sterile syringes on single-use only syringe-based contrast power injection systems indicated for the controlled, automatic venous administration of contrast agents for MR procedures.

The Transfer Spike is to be discarded after one of the following conditions has occurred first: the contrast media container has been depleted, the Transfer Spike has been disconnected from the contrast media container, or after 24 hours has elapsed since the container was penetrated.

Contraindications: None known.

Restricted Sale: Rx Only

Operating temperature: +10°C to +40°C

MRI Safety Information: The MEDRAD® Imaging Bulk Package Transfer Spike (Transfer Spike) is MR Safe.

⚠ WARNING

Follow aseptic technique when using Transfer Spike. Contamination can result from improper aseptic technique. Discard Transfer Spike if there is any possibility that contamination may have occurred.

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.

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

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

Do not exceed 24 hours of use time. These disposables have been designed and validated for only 24 hours. Extended use of the Transfer Spike disposable poses risks to the patient including contamination and injury due to device malfunction.

| Symbol | Description |
|--------|---|
| | Attention: Refer to warnings and cautions on Instructions for Use packaged in each carton. (ISO 15223-1, 5.4.4) |
| | For use with one container of media only (Bayer-derived symbol) |
| | Do not exceed 24 hours of use time. (Bayer-derived symbol) |
| | Non-Pyrogenic (ISO 15223-1, 5.6.3) |
| | Do not use if package is opened or damaged (ISO 15223-1, 5.2.8) |
| | Date of Manufacture (ISO 15223-1, 5.1.3) |
| | Manufacturer (ISO 15223-1, 5.1.1) |
| | Temperature range (Transport) (ISO 15223-1, 5.3.7) |
| | Humidity range (Transport) (ISO 15223-1, 5.3.8) |

| Symbol | Description |
|--------|---|
| | Use By (ISO 15223-1, 5.1.4) |
| | Lot Number (ISO 15223-1, 5.1.5) |
| | Catalog Number (ISO 15223-1, 5.1.6) |
| | Sterilized using irradiation (ISO 15223-1, 5.2.4) |
| | Do Not Resterilize (ISO 15223-1, 5.2.6) |
| | Federal (USA) law restricts this device to sale by or on the order of a license healthcare practitioner. (FDA Final Rule - Use of Symbols in Labeling Docket No. FDA-2013-N-0125) |
| | Quantity (IEC TR 60878, 2794) |
| | Net Weight (ISO 7000, 1321B) |
| | This side up (ISO 7000-0623, ISO 780-No. 3) |

| Symbol | Description |
|--------|---|
| | Not made with natural rubber latex. (ISO 15223-1, 5.4.5 (Annex B, B.2)) |
| | Does not contain or include presence of phthalate. (BS EN 15986) |
| | Single Use Only (ISO 15223-1, 5.4.2) |
| | Consult instructions for use (ISO 15223-1, 5.4.3) |
| | Warning - Advises you of circumstances that could result in injury or death to the patient or operator. |
| | Caution - Advises you of circumstance that could result in damage to the device. |
| | Fragile, handle with care (ISO 15223-1, 5.3.1) |
| | Keep dry (ISO 15223-1, 5.3.4) |
| | MR Safe (ASTM F2503-13) |

REF GBP TS



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Bayer

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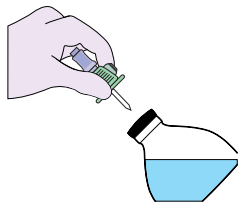
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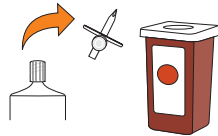
Turn over for instructions



1 Attach Disposables



1. Spike contrast media container (Gadavist IBP 30mL or 65mL) with Transfer Spike.



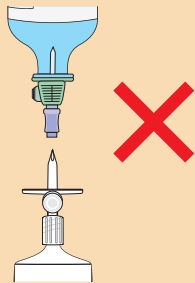
2. Remove contrast spike from injector syringe tip (if applicable).

⚠ WARNING

Do not spike the swabable valve of the Transfer Spike.

Contamination may result due to damage to the swabable valve.

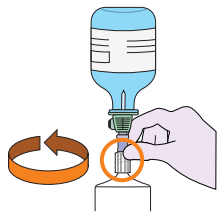
If penetrated, discard the Transfer Spike and contrast media container.



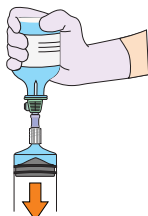
⚠ CAUTION

Ensure all connections are secure; do not over-tighten. Component damage or leaks can occur if not installed properly.

Use 70% isopropyl alcohol (IPA) for sanitizing swabable valve. Exposure to other cleaning agents or disinfectants may lead to component damage or failure.

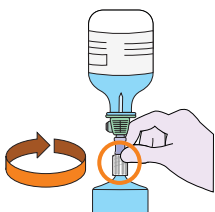


3. Attach assembly to syringe tip. Tighten counter-clockwise using swivel nut.

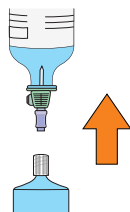


4. Fill syringe with individual, prescribed patient dose and hold assembly.

2 Detach Disposables



1. Detach assembly. Loosen clockwise using swivel nut.



2. Remove assembly from syringe. **Keep Transfer Spike attached to contrast media container.**

Training videos can be accessed at:
www.gadavist.com



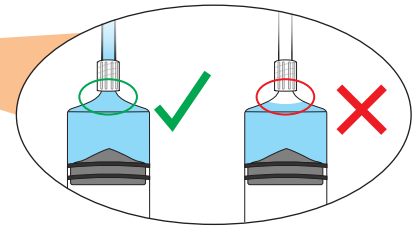
3 Purge Air

⚠ WARNING

Clear all air from the syringe and fluid path before connecting a patient to hand syringe or injector. Air embolization can occur.



1. Purge all air from the syringe and fluid path.



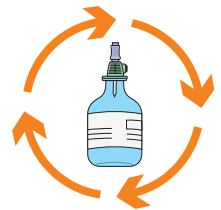
4 Subsequent Syringe Fills

⚠ WARNING

Do not use Transfer Spike with more than one media container. Contamination or device malfunction can result.

Do not re-spike the same contrast vial with the Transfer Spike. Re-spiking may result in contamination.

Keep the Transfer Spike attached to contrast media container. It can be used to fill individual, prescribed patient doses into new sterile syringes for multiple patients.



Sanitize the swabable valve of the Transfer Spike with 70% isopropyl alcohol using aseptic technique before each use.

5 Discard

⚠ WARNING

Discard the Transfer Spike per Indications for Use. Contamination or device malfunction can result from improper use of Transfer Spike.

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.

Discard the Transfer Spike and contrast media container in accordance with institution policy when one of the following conditions has occurred first:

- Contrast media container is empty,
- Transfer Spike has been disconnected from contrast media container, or
- 24 hours has elapsed since the container was penetrated.

