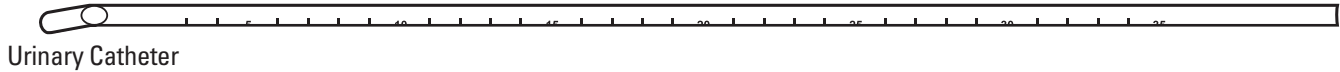


# INSTRUCTIONS FOR USE INLEXZO™ [inn-lex-zo] (gemcitabine intravesical system) For Intravesical Administration Only



Urinary Catheter



Green Stylet

Illustrations are not drawn to scale.


## Intended Use

INLEXZO releases gemcitabine into bladder urine during the indwelling period. See INLEXZO Prescribing Information (PI) for additional details.

**The contents of the Instructions for Use provide instructions for both the insertion and removal of INLEXZO. Ensure that the Instructions for Use are available and reviewed prior to insertion and removal of INLEXZO.**

## User

INLEXZO should be inserted and removed by a trained healthcare provider.

 MR Conditional	<b>MRI Safety Information</b> <b>INLEXZO is MR Conditional.</b> A patient with <b>INLEXZO</b> may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.
Parameter	Condition of Use/Information
<b>Nominal Values of Static Magnetic Field (T)</b>	1.5-Tesla and 3.0-Tesla
<b>Maximum Spatial Field Gradient (T/m and gauss/cm)</b>	50-T/m (5,000-gauss/cm)
<b>Type of RF Excitation</b>	Circularly Polarized (CP) (i.e., Quadrature Transmission)
<b>Transmit RF Coil</b>	Any transmit RF coil may be used.
<b>Receive RF Coil</b>	Any receive-only RF coil may be used
<b>Maximum Whole Body Averaged SAR (W/kg)</b>	2-W/kg (Normal Operating Mode)
<b>Limits on Scan Duration</b>	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks)
<b>MR Image Artifact</b>	The presence of INLEXZO produces an imaging artifact. Therefore, carefully select pulse sequence parameters if INLEXZO is located in the area of interest.

## ! Precautions

INLEXZO is a hazardous drug. Follow applicable special handling and disposal procedures while handling INLEXZO and during the insertion and removal procedure. Dispose of the used urinary catheter and stylet, INLEXZO, and its packaging per facility procedures and per applicable federal, state, and local regulations.

**Wear gloves, and take appropriate precautions, per local guidelines for handling hazardous drugs,** to prevent skin or mucus membrane exposure while handling INLEXZO and during the insertion and removal procedure.

If contact with INLEXZO is suspected, immediately wash the skin thoroughly or rinse the mucosa with copious amounts of water.

Advise patients and caregivers to **exercise caution when handling urine during indwelling period of approximately 3 weeks. See INLEXZO PI for details.**

INLEXZO contains one single-dose 225 mg strength gemcitabine intravesical system consisting of a flexible bi-oval shaped tube containing an almost white to light pink-brown colored component at the center surrounded by off white to light blue osmotic components.

## Important Information

**Use aseptic technique during insertion and removal of INLEXZO.**

Follow these instructions carefully, to avoid patient injury and ensure proper functioning.

## Insertion

To ensure proper insertion of INLEXZO and to avoid damage to INLEXZO, use only the following:

- Water-based lubricant
- Urinary catheter and stylet (supplied)

**Do not** use the urinary catheter and stylet for any other purpose. Do not re-sterilize/re-use the urinary catheter or stylet. Re-use of the urinary catheter and stylet can lead to its degradation, failure, and contamination, which can increase the risk of infection or transmission of blood borne pathogens to patients and users.

**Do not** use any components that are damaged or have damaged packaging.

Check the expiration ('EXP') date before use.

**Do not** use INLEXZO if expiration date has passed.

## Removal

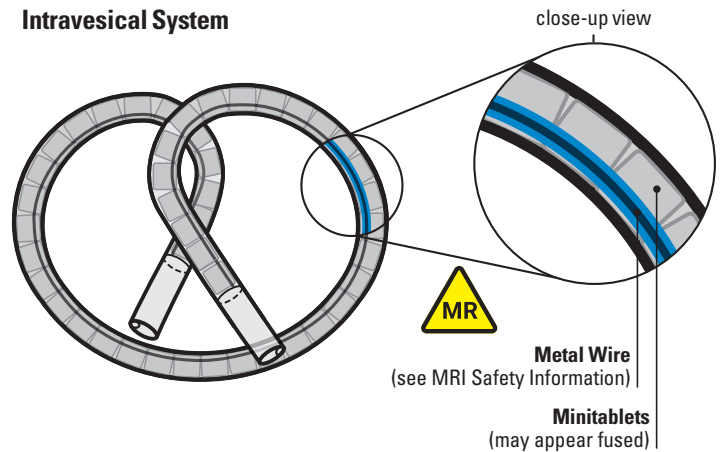
To ensure proper INLEXZO removal and to avoid damage to INLEXZO and/or cystoscope, use only the following:

- **Non-cutting**, grasping forceps
- Flexible or rigid cystoscope

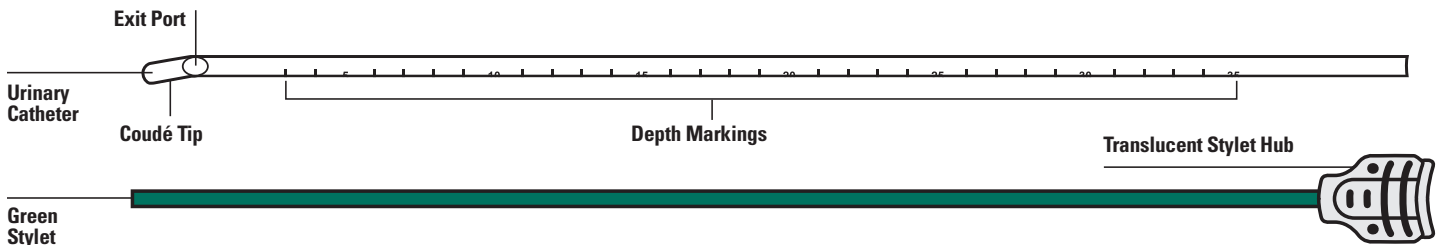
## Storage

Store in the original package at **20°C to 25°C** (68°F to 77°F); with excursions permitted between **15°C to 30°C** (59°F to 86°F) [see USP Controlled Room Temperature].

## INLEXZO™ Intravesical System



## Urinary Catheter and Stylet



## Prepare components for INLEXZO insertion

### 1. Gather supplies

#### Included in the product carton:

- One sterile INLEXZO
- One sterile urinary catheter and one sterile stylet

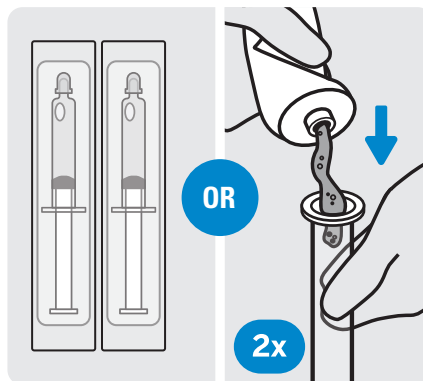
#### Not included in the product carton:

- Multiple pairs of gloves
- Two 10 mL prefilled water-based lubricant syringes

**OR**

- Two empty 10 mL syringes and water-based lubricant

### 2. Put on gloves

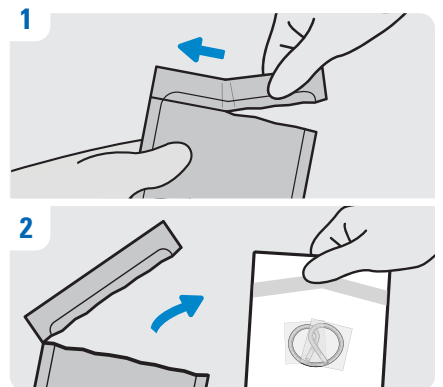


### 3. Prepare two syringes with sterile water-based lubricant

- Remove each sterile syringe prefilled with **water-based** lubricant from its packaging and place each syringe on the sterile work surface using aseptic technique.

**OR**

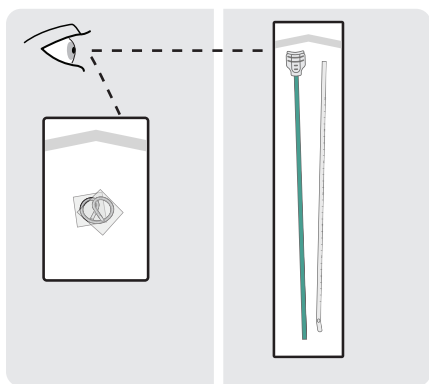
- Fill each of the two empty syringes with 2 mL to 3 mL of **water-based** lubricant plus additional lubricant for urinary catheter tip lubrication.
- Place each lubricant syringe on a sterile work surface using aseptic technique.
- The lubricant is to be used to lubricate the tip of the urinary catheter and to facilitate the insertion of INLEXZO.



### 4. Open the INLEXZO foil pouch

1. Tear open the INLEXZO outer foil pouch at tear notch.
2. Remove the white INLEXZO inner pouch.

## Prepare components for INLEXZO insertion (continued)

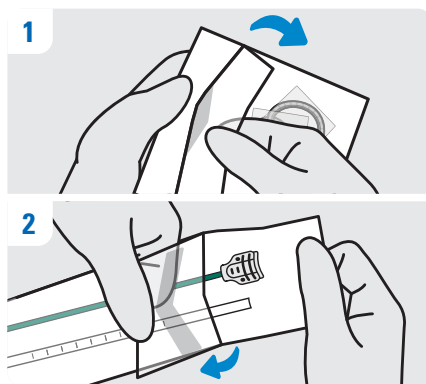


### 5. Examine the white component pouches for damage

Check the white INLEXZO pouch and white pouch containing the urinary catheter and stylet for damage (e.g., cuts, tears, punctures) that could compromise sterility of the components before opening.

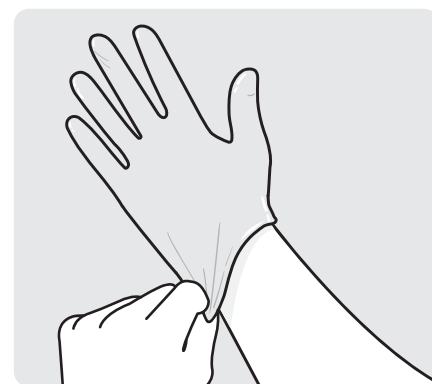
**⚠ Do not use if packaging is damaged.**

**⚠ Surfaces of the white INLEXZO pouch and the white component pouches are not sterile.**



### 6. Open the white component pouches and transfer the contents onto a sterile work surface

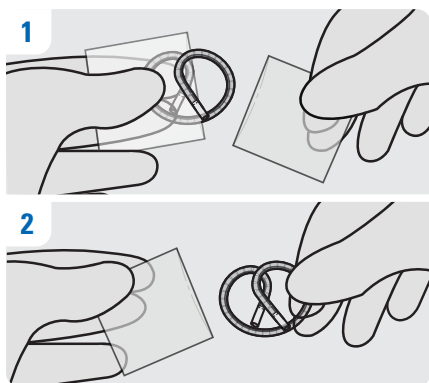
1. Open the white INLEXZO pouch and transfer INLEXZO onto a sterile work surface.
2. Do not remove plastic sleeves from INLEXZO.
3. Open the white pouch containing the urinary catheter and stylet and transfer the contents onto a sterile work surface.



### 7. Put on sterile gloves

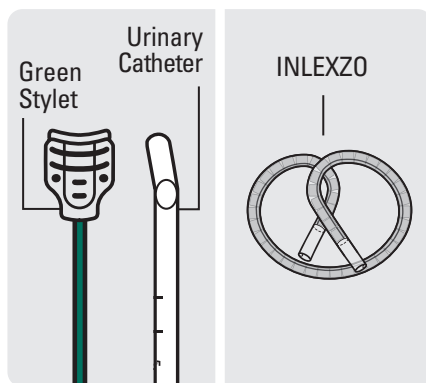
1. Ensure your patient is prepared for the procedure.
2. Put on sterile gloves.

## Prepare components for INLEXZO insertion (continued)



### 8. Remove plastic sleeves

Remove the plastic sleeves from INLEXZO.

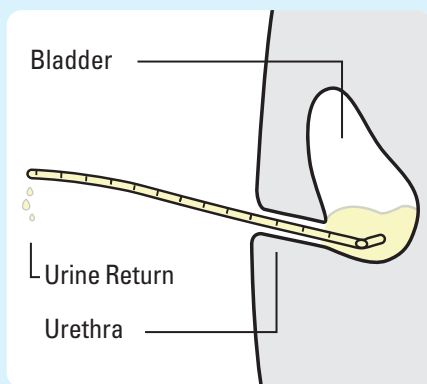


### 9. Inspect components

Inspect INLEXZO, the urinary catheter, and green stylet for damage.

**Do not use** if the urinary catheter or green stylet are damaged or if the outer surface of INLEXZO is damaged.

## Insert INLEXZO



### 1. Lubricate the urinary catheter

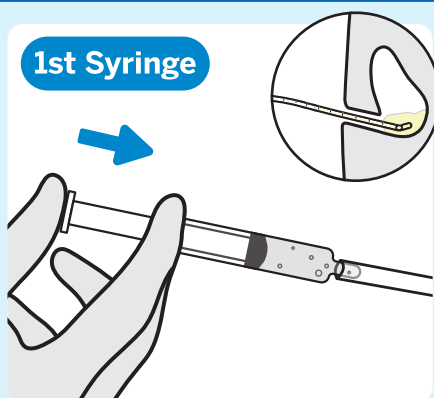
Lubricate tip of the urinary catheter.

The urinary catheter should be free of INLEXZO and the stylet.

### 2. Insert the urinary catheter (without stylet)

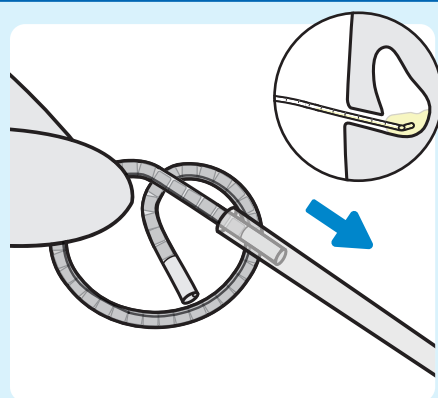
Introduce the urinary catheter into the urethra by hand and advance until urine return. Do not empty the bladder.

Use depth markings to maintain coude tip orientation and insertion depth position throughout the procedure.



### 3. Inject lubricant from the first syringe into the urinary catheter

Inject 2 mL to 3 mL of lubricant from the first syringe into the end of the urinary catheter with the urinary catheter placed in the bladder.

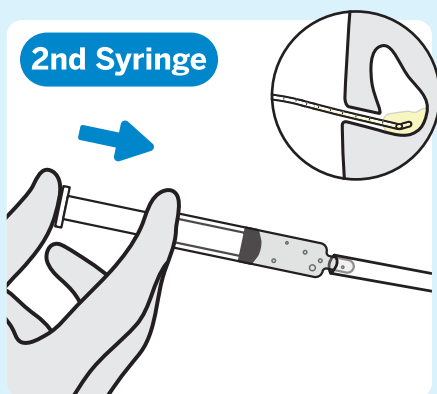


### 4. Insert INLEXZO into the urinary catheter

Insert either end of INLEXZO into the urinary catheter and advance until fully inserted.

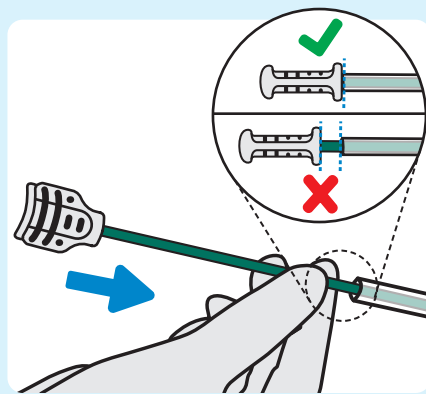
- ⚠ Do not excessively force the urinary catheter into the bladder.
- ⚠ In case of resistance, careful assessment and standard procedural techniques can be performed, as appropriate, in order to safely advance the urinary catheter into the bladder.
- ⚠ If advancement is obstructed or cause cannot be determined or resolved, withdraw the urinary catheter to avoid patient injury or urinary catheter damage.
- ⚠ Do not re-use urinary catheter.

## Insert INLEXZO (continued)



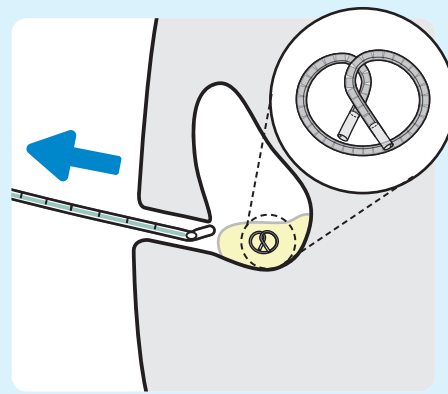
### 5. Inject lubricant from the second syringe into the urinary catheter

Inject 2 mL to 3 mL of lubricant from the second syringe into the urinary catheter to help advance INLEXZO further, with the urinary catheter placed in the bladder.



### 6. Insert stylet into the urinary catheter

Slowly insert the stylet into the urinary catheter until the stylet hub is flush with end of the urinary catheter. This ensures INLEXZO exits the urinary catheter and enters the bladder.



### 7. Remove the urinary catheter and stylet together as a single unit

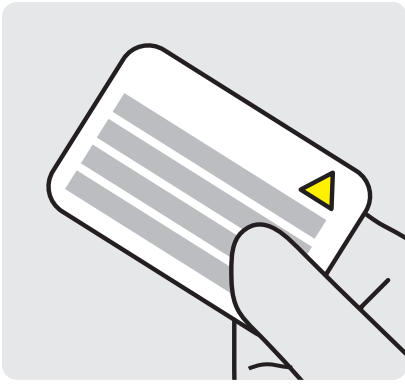
**Do not** remove the urinary catheter and stylet individually.

INLEXZO should remain inside the bladder.

- ⚠ If INLEXZO cannot be advanced, remove the urinary catheter and stylet together as a single unit. Ensure INLEXZO is also removed.
- Do not attempt to re-use the removed INLEXZO.
- Begin again by obtaining a new carton of INLEXZO including a new urinary catheter and stylet.

Retain Instructions for Use for the removal procedure.

## Post-Insertion Instructions



### 1. Provide the completed MRI Safety Information Card to the patient

Remove the MRI Safety Information Card from the carton.

Complete the details and give it to the patient.

Advise the patient to carry the card and to show their current and future healthcare providers in case of need for MRI scans.

- INLEXZO contains a metal wire. The patient can safely undergo an MR exam only under very specific conditions (see MRI Safety Information).

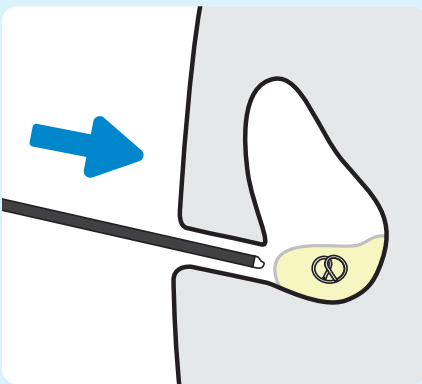
### 2. Inform the patient and caregivers about the indwelling period

The indwelling period is approximately 3 weeks. See INLEXZO PI for additional information.

Inform the patient and caregivers that INLEXZO will remain in the bladder for the indwelling dosing period.

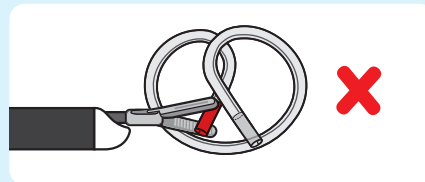
INLEXZO contains a hazardous drug. The patient and caregivers should be made aware of the need to **exercise caution when handling urine during the indwelling period**. See INLEXZO PI for additional information.

## Removal of INLEXZO after the indwelling period



**1. Lubricate the cystoscope**  
Use a water-based lubricant to lubricate the cystoscope.

**2. Insert the cystoscope**  
Insert the cystoscope into the bladder to locate INLEXZO.



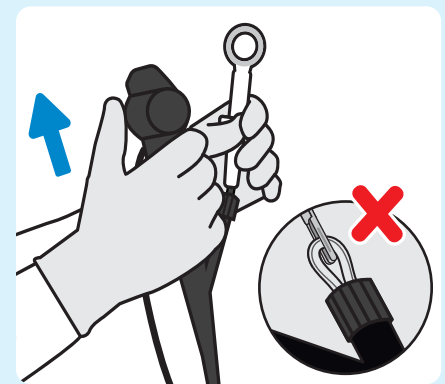
**3. Grasp INLEXZO**  
Introduce **non-cutting** grasping forceps through the working channel of the cystoscope.

**⚠ Do not use cutting forceps.**

Grasp INLEXZO over tubing and metal wire.

**⚠ Do not grasp on or near the ends of INLEXZO.**

Grasping near the ends of INLEXZO could result in exposing the metal wire, potentially causing damage to surrounding tissue.



**4. Remove INLEXZO**  
Remove the cystoscope and forceps out of the urethra **together** to remove INLEXZO under direct vision.

**Do not** remove INLEXZO through working channel of the cystoscope. Doing so may damage INLEXZO and/or the cystoscope.

### 5. Inspect INLEXZO

**⚠ After removal, inspect INLEXZO to confirm it is intact and unbroken.**

Manufactured for:  
Janssen Biotech, Inc.  
Horsham, PA 19044, USA.  
U.S. License Number 1864

This Instructions for Use has been approved by the U.S.  
Food and Drug Administration.  
Approved: 09/2025

For patent information:  
[www.janssenpatents.com](http://www.janssenpatents.com)  
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