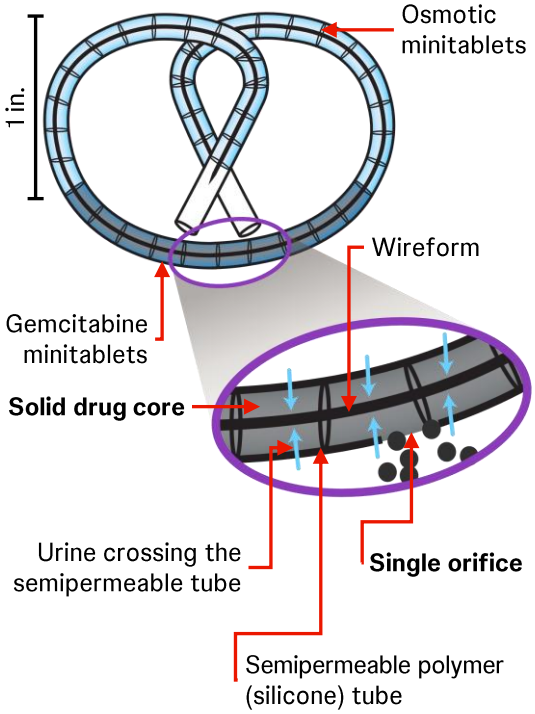
TAR-200: An Investigational Gemcitabine Intravesical System

Please **scan to watch** an animation on insertion of TAR-200

Drug Delivery Controlled via an Osmotic Engine[1,2]



Release rate is controlled by the osmotic gradient

Insertion and Removal Is an In-Office Procedure[3]

1. Insertion

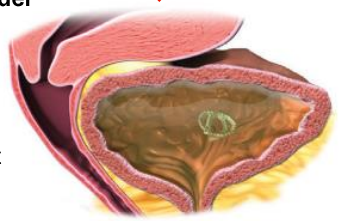
A. Gather supplies: **UPC** (catheter shaft and stylet), TAR-200, and two 1-mL slip tip syringes filled with lubricant

B. **Lubricate** tip of catheter shaft and introduce it into the urethra. Advance until urine return

C. Using the first syringe, inject lubricant into end of catheter shaft. Then, **load TAR-200 into the catheter**. Use the second syringe to inject lubricant into end of catheter shaft

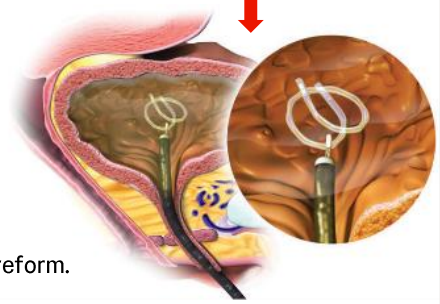
D. **Insert stylet into catheter shaft** until the stylet hub is flush with the proximal end of the catheter shaft. This ensures **TAR-200 exits the catheter shaft into the bladder**

E. **Remove** catheter shaft and stylet as a single unit



2. Indwelling

A. TAR-200 is **freely mobile** within the bladder over the indwelling period



3. Removal

A. Removal is performed 3 weeks after insertion

B. **Insert cystoscope** into bladder. Then, introduce **non-cutting grasping forceps** through cystoscope's working channel

C. **Grasp TAR-200** by silicone tubing and wireform. Do not grasp on or near ends of TAR-200

D. **Remove the cystoscope and forceps together to remove TAR-200** under direct vision. Do NOT remove TAR-200 through the cystoscope's working channel to avoid damaging TAR-200 and/or the cystoscope

Ongoing trials for TAR-200 in Bladder Cancer

Study name	SunRISe-1[4]	SunRISe-3[5]	SunRISe-5[6]	SunRISe-4[7]
Disease	BCG-unresponsive HR-NMIBC	BCG-naïve HR-NMIBC	Recurrent HR-NMIBC after BCG	MIBC, neoadjuvant to RC
Intervention (description)	TAR-200	TAR-200 + cetrelimab	TAR-200	TAR-200 + cetrelimab

Johnson & Johnson

TAR-200 is an investigational product, and the safety and efficacy of the product have not yet been determined. There is no guarantee that TAR-200 will be filed with/or approved for marketing by the FDA or other Health Authorities. For additional information, you may visit www.clinicaltrials.gov.

BCG, Bacillus Calmette-Guérin; CR, complete response; FDA, Food and Drug Administration; HR-NMIBC, high-risk non-muscle invasive bladder cancer; mAb, monoclonal antibody; MIBC, muscle-invasive bladder cancer; pCR, pathological complete response; PD-1, programmed death protein 1; RC, radical cystectomy; UPC, urinary placement catheter.

1. Grimberg DC, et al. *Eur Urol Focus.* 2020;6:620–22. **2.** Pons-Faudoa FP, et al. *Biomed Microdevices.* 2019;21:47. **3.** Data on File. Janssen Scientific Affairs, LLC. TAR-200 Instructions for Use. TV-ART-04992. **4.** ClinicalTrials.gov 2024. NCT04640623. Available at: https://clinicaltrials.gov/ct2/show/NCT04640623. Accessed October 22, 2024. **5.** ClinicalTrials.gov 2024. NCT05714202. Available at: https://clinicaltrials.gov/ct2/show/NCT05714202. Accessed October 22, 2024. **6.** ClinicalTrials.gov 2024. NCT06211764. Available at: https://clinicaltrials.gov/study/NCT06211764. Accessed October 22, 2024. **7.** ClinicalTrials.gov 2024. NCT04919512. Available at: https://clinicaltrials.gov/ct2/show/NCT04919512. Accessed October 22, 2024.